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Risks and Complications Associated with Refractive Surgery

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ABSTRACT

Myopia, hyperopia, and astigmatism (together called ametropia) are the top causes of vision impairement worldwide. Refractive surgery, surgical modification of refractive surfaces in the eye, are prominent solutions for treating ametropia. This study made a summary of the risks (poor refractive outcomes of either high residual ametropia after surgery or the postoperative development of refractive errors) and complications associated with seven refractive surgery procedures for ametropia. Risks and complications were summarized and discussed in categorized form, the incidence of each undesirable outcome in percent, rather than in quantified form, the severity of occurrence on average, help readers to identify the chances of undesirable results directly. The incidence of risks and complications were also stratified based on related factors, depending on the availability of data. Brief descriptions and analyses of the results of data summaries were included at the beginning of the discussion of the risks and complications of each refractive surgery procedure; specific data was also included to allow for comparison. In general, laser-assisted in situ keratomileusis (LASIK), laser-assisted sub-epithelium keratomileusis (LASEK), and small incision lenticule extraction (SMILE) procedure were found to yield few undesirable outcomes, while all seven procedures were crucial for the system of solutions for refractive errors.

Introduction

Ametropia, abnormalities of the refractive states of the eye including myopia, hyperopia, and astigmatism, is the most common type of refractive errors, the most common vision problems [1]. Research data from 1990 to 2016 suggested that the pooled prevalence of myopia increased from 10.4% to 34.2% between 1993 and 2016, while that of hyperopia and astigmatism stabled around 30.6% and 40%, respectively [2]. Similar results were also found in Europe from 1990 to 2013: 30.9% of adults of age 25-99 were affected by myopia (25.2% affected by hyperopia and 23.9% affected by astigmatism), whereas 47.2% of adults of age 25-29 were affected [3]. Uncorrected refractive errors caused worldwide 20.9% of all blindness and 50.9% of all vision impairment in 2010 [4].

Refractive surgery, a surgical correction of refractive errors in the eyes, was first formulated in 1885 and then operated and extensively investigated since the 1960s [5]. Unlike eyeglasses (spectacles), which produce inconvenience to patients' life and have limited clear vision-field, or contact lenses, which produce complications like corneal neovascularization and bacterial keratitis; refractive surgery is a prominent solution for many ophthalmic problems such as myopia, hyperopia, presbyopia, and astigmatism [6]. With increased precision of machinery involved in refractive surgery and new high-techniques being implemented, surgical outcomes were improved with fewer incidence of technical mistakes in the recent years [7,8]. Considering the advantages of refractive surgery and expected future breakthroughs in artificial intelligence which further assists the surgical procedure, refractive surgery may become the primary solution to refractive errors in near future [7,9].

However, the sequelae of refractive surgery like scleral perforation and corneal ectasia cannot be ignored [10-12]. Myopic or hyperopic regression can also occur after refractive surgery [13]. These problems result naturally from the operations even without technical errors; the risks are inevitable for patients to consider if refractive surgery should be conducted. This article provided a summary of the known risks and complications of seven refractive surgery procedures for ametropia in a categorical fashion with associated factors, including age, myopic or hyperopic condition of the eye, *etc*. The information collected and discussed in this paper will serve as a reference for patients' and clinicians' decisions on refractive surgery.

Causes of Ametropia and Principles of Refractive Surgery

A human eyeball has three major layers. The outer layer consists of a transparent layer at the front of eyeball called cornea and a dense and opaque protective sheath extending from cornea to the back of eyeball called sclera. Cornea has an 8-mm radius of curvature and a thickness of 0.55 mm and is transparent, enabling the passage of light; whereas sclera has a 12-mm radius of curvature and a thickness varying from 0.4 to 1 mm and is opaque, blocking light out [14]. Cornea is consisted of epithelium, Bowman's layer, stroma (makes up 90% of the corneal thickness), Descemet's membrane, and endothelium ordering from surface to deep [14]. The middle layer of eyeball contains three parts: 1) the iris, which controls the size of the pupil in response to light intensity and in turn controls the amount of light entering the eye; 2) the ciliary body, which produces aqueous humor filling the space between cornea and iris named anterior chamber and contains muscles controlling the shape of transparent lens with a finer focus on the image (a mechanism known as accommodation); and 3) the choroid, which lines the inner side of the sclera and is responsible for 85% of blood flow in the eye [14]. The inner layer of eyeball is the retina, which is a thin layer filled with light-sensitive nerve cells and is responsible for the sensation and transduction of light signals [14].

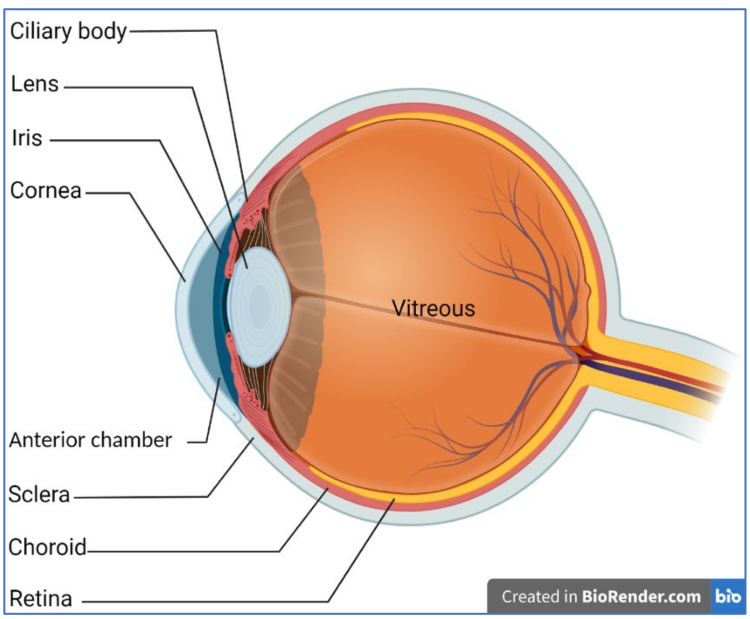

Figure 1. The structure of eye.

For a clear image to be perceived, light from every point entering the eye must be refracted and projected precisely onto the retina; otherwise, refractive errors will occur [14]. Light entering the eye can be parallel (for light from far objects) or diverging (for light from close objects). Refraction of light in the eyeball is accomplished by the cornea, anterior chamber, lens, and vitreous in the posterior part of the eye (as shown in Figure 1), each helping in converging the light [16]. When the eyeball is too long (horizontally) or the refractive components are too strong in refractive power, the image is projected anterior to the retina, leading to weakened vision for far objects known as myopia. On the other hand, weakened vision for close objects is called hyperopia; it occurs when the eyeball is too short or when the refractive components are too weak in refractive power, causing the image to be projected posterior to the retina. Astigmatism occurs when refractive surfaces of the eye are rotationally asymmetrical in thickness and curvature, leading to weakened vision at any distance [14, 16].

In spectacle correction, glasses or contact lenses alter the direction of incoming light through refraction and thus make up for refractive deficiency, excess, or abnormalities in the eye, guaranteeing successful focus of the image. In refractive surgeries, curvature and thickness of the cornea can be tailored by ablation of the epithelium or stroma. Alternatively, the lens can be replaced or complemented by inserting an additional artificial lens [16]. Compared to correction by spectacles, correction by refractive surgery would enable patients to become independent of vision aids, making patients' life more convenient.

Types of Refractive Surgery Procedures

This paper included 7 refractive surgery procedures due to the abundance of clinical data as well as their popularity and effectiveness. First, corneal flap procedures, which involve the creation of a corneal flap (anterior tissues of the cornea including the epithelium, the Bowman's membrane, and partial stromal tissue of the cornea) using a femtosecond laser or microkeratome and the ablation of the corneal stroma, include automated lamellar keratoplasty (ALK) and laser-assisted *in situ* keratomileusis (LASIK) [17,18]. Second, surface corneal procedures, involving the ablation of anterior part only of the cornea, include photorefractive keratectomy (PRK) and laser-assisted sub-epithelium keratomileusis (LASEK) [19]. Third, lens procedures including implantable collamer lens (ICL) and refractive lens exchange (RLE) require an addition of artificial lens or replacement of the original lens [20,21]. And the last type of procedure is small incision lenticule extraction (SMILE) [16,22].

Risks and Complications

The summary of each refractive surgery procedure contained two components: poor refractive outcomes and complications. The poor refractive outcomes were further discussed as residual and development of ametropia. Although data on mean postoperative ratings were more abundant, categorized data (incidence of undesirable results) serve as a better estimator in discussions of risks, so only categorized data were used in this study.

Automated Lamellar Keratoplasty (ALK)

ALK involves the creation of a corneal flap and the ablation of underlying corneal stromal tissue using microkeratome. ALK is often used in the correction of mild myopia and hyperopia, and was believed to cause more refractive problems and complications when treating more severe refractive errors.

Poor Refractive Outcomes

For myopic ALK (M-ALK), the correlation coefficient of predicted correction and actual correction stabled around 0.75 diopters (D) after the operation, suggesting little postoperative development of refractive errors [23]. However, a loss of 0.25-0.75 diopters of visual acuity was found in 12.94% of the patients after M-ALK [24]. Another study pointed out that the washboard effect could cause irregular cuts, leading to severe refractive errors such as astigmatism [23,25].

Refractive errors after hyperopic ALK (H-ALK) was found to be more significant. One study suggested that eyes with relatively mild hyperopia, defined by 1-3 D of spherical equivalent (SE), had 6.35% and 9.38% chance, respectively, of having significant postoperative myopia (-1.12 D or less) or hyperopia (1 D or more); eyes with relatively severe hyperopia, defined by 3-5 D of SE, had 7.69% and 38.46% chance of having significant postoperative myopia and hyperopia, respectively [26]. Over-correction or induction of astigmatism in H-ALK was not mentioned in previous studies.

Other Complications

Other complications include visual opacity, corneal dystrophy, corneal infection, tumor growth, and keratectasia. The combined risk and complications mentioned above for adults reached 38%. Children (less than or equal to 16 years old) were not found to experience visual opacity or keratectasia, but they had corneal dystrophy and infection up to 58% [27]. Less common complications, Descemet membrane (DM) perforation and corneal perforation without explained causes were found in 46 patients to have an incidence of 6.52% and 2.35%, respectively [25,28,29]. There were also rare cases of complications caused by operational errors, including iris ablation leading to severe vision impairment and cataracts [30,31].

Laser-assisted *in situ* Keratomileusis (LASIK)

LASIK involves the creation of a corneal flap and the ablation of underlying corneal stromal tissue using a femtosecond laser. LASIK has a greater range of applicability in treating myopia and hyperopia. LASIK was popular because it is nearly painless and leads to very few complications.

Poor Refractive Outcomes

In a 3-months follow-up study including 19,753 individuals with an average of -5.9 D of myopia undergoing LASIK procedure, 10% experienced postoperative SE of less than -1 D, and 7.3% experienced the loss of 1-2 lines of visual acuity (on the Snellen chart), suggesting overall optimistic results from LASIK [32]. Furthermore, there was a steady trend of improvement in outcomes of LASIK (measured by postoperative SE) and a trend of decrement in loss of visual acuity after LASIK from 1998 to 2007. In 2007, only 2 % individuals experienced postoperative SE of less than -1 D, and only 2.5 % individuals experienced a loss of visual acuity of 1-2 lines [32]. The efficacy index of treatment, modeled by preoperative uncorrected visual acuity (UDVA, based on 20/X criteria of the Snellen chart) divided by preoperative best-corrected visual acuity (BCVA), was significantly lower for patients with more severe myopia: in 2007, patients with -10 D or less SE had average efficacy index of 0.86, while patients with -5 D or more SE had 0.97 for the same measurement [32].

However, the predictability of LASIK for treating hyperopia was lower: in two studies with mean preoperative SE of 5.28 D and 5.13 D, each had 32% and 33% of patients having postoperative SE of 1 D or more, respectively; other studies have suggested that patients with less than 5 D hyperopia had less than 10% chance of having postoperative SE of 1 D or more [33,34,35,36].

Other Complications

Dry eye symptoms persisting for more than six months were common in LASIK, with an incidence of 20%. For the age group of 20-49, significantly higher risks of dry eye were found in older people, women, people with greater preoperative SE, and people experiencing greater ablation depth (details on the influence of these factors were not discussed in the original study) [37]. Other complications had a much lower incidence. One meta-analysis including 53,731 LASIK surgeries conducted between 1998 to 2015 suggested an overall complication rate of 0.98%, and the overall annual complication rate since 2010 was less than 0.8% [38,39]. More importantly, among these risks, flap complications, including eccentric, dislodged, folded flaps, loose epithelium were the most common types (64% of all complications); and flap complications were expected to reduce significantly in the future as with clinicians' increasing experience in flap creation [36,38,39].

Photorefractive Keratectomy (PRK) and Laser-assisted Sub-epithelium Keratomileusis (LASEK)

PRK involves the removal of corneal epithelium and the use of an excimer laser to alter the shape of the outer layers of the cornea. Because of the large removal of corneal epithelium, which was highly linked with a series of complications, RPK was recently replaced by LASIK or LASEK procedures. However, PRK remains crucial for some patients, such as those with corneal topography that suit for corneal surface procedures but cannot perform LASEK due to contact allergy to alcohol [40].

LASEK procedure was similar to PRK, except that the corneal epithelium in LASEK was reattached after the ablation of underlying tissues. LASEK avoids the damage to corneal epithelium, while other procedures such as LASIK and PRK often do so. The clinical data on complications of LASEK were reported mostly as special cases, suggesting the low incidence of complications in the LASEK procedure.

Poor Refractive Outcomes

In the study of Alió *et al*., under-correction (more than 1 D) after PRK in patients with high myopia (-10.25 to -14.00 D of SE) had an incidence of 6.3%, while that in patients with moderate or low myopia (≥-10 D) had 3.3%; regression also occurred more commonly in patients with high myopia (6.3%, compared with 1.1% for patients with moderate or low myopia) [41]. Postoperative UDVA worse than 20/40 (corresponding to ≤-1 D or ≥1 D of SE) was not found to be statistically significant among patients undergoing PRK and LASEK [42]. However, an 8-year follow-up study demonstrated much worse refractive outcomes of PRK: 45.56% of patients with high myopia (-6 D or less) bore postoperative SE of more than 1 D, suggesting much less precision of PRK and potential significant recurrence of myopia after PRK treatments [43].

The loss of visual acuity of more than 0.5 D in 1% of the 200 eyes was found in PRK treatment for hyperopia [44]. In another 2-year follow-up study, 19% of eyes experienced a loss of visual acuity of 1-2 lines after PRK for hyperopia, and no eyes experienced the loss of more than 0.5 D [45]. In the same study, only 9 % of eyes experienced a loss of visual acuity of 0.25-0.5 D after LASEK for hyperopia, and LASEK also had a higher efficacy index than does PRK, suggesting a better refractive outcome by surgery than by spectacles adjustment [45].

Other Complications

Corneal haze, which can lead to significant loss of visual acuity, is the most common complication of PRK. In the 8-year follow-up study, 11.34% of PRK-treated patients experienced corneal haze, particularly in myopic eyes [43]. In patients with corneal haze after PRK, 28.57% (6/21) had trace haze after treatment, and 4.76% had significant haze residual (diagnosed as level 1 corneal haze severity) [43]. In addition, the incidence of another serious complication called corneal ectasia was 0.5% among eyes treated with PRK [46,47]. However, a 5-year follow-up study found corneal ectasia continued to develop for more than 1 year in 65% patients 27.2 months after PRK procedure even with retreatment after reduced visual acuity experienced by patients, suggesting a significant risk of corneal ectasia in PRK procedures in the long term [48]. Corneal haze was found to have an incidence of 8% in patients undergoing LASEK, but the haze was much milder than that in PRK, and all haze was cured completely after retreatment [44]. LASEK was found to cause no long-term dry eye symptoms, myopic, or hyperopic regression [45]. Discomfort during and after the operation was also less prominent in LASEK than in PRK [45].

Small Incision Lenticule Extraction (SMILE)

SMILE involves the creation of corneal lenticules using a femtosecond laser and the suction of the tissue through a small incision site. SMILE, known as a painless procedure, avoids damage to the corneal epithelium. Even though it had desirable refractive outcomes with fewer complications compared with PRK and LASIK, its unique complications resulting from the suction procedure were difficult to avoid.

Poor Refractive Outcomes

7 studies suggested an overall risk of 14.59% of greater than 0.5 D postoperative SE of 0.5 D for SMILE procedure for myopia, and this risk in patients with higher myopic levels (around -7 D) was greater (up to 23%); it was also found that studies with longer follow-up period had less of this risk, suggesting a continuing improvement of refractive states after SMILE procedure.[49-55] The overall risk of losing more than 2 lines of visual acuity in the 7 studies was 1.7%, and was similarly more pronounced in people with more severe myopia [49-55]. The data above suggested good visual outcomes of the SMILE procedure for treatment of myopia.

A 3-month follow-up study suggested an 11% risk of having postoperative SE of 0.5 D or more, and only 1 case of loss of 2 lines of visual acuity in 36 eyes occurred after SMILE retreatment [57]. Another 1-year follow-up study suggested no loss of more than 0.5 D of visual acuity after SMILE for 93 cases of hyperopia [57].

Other Complications

A study examining 1,800 eyes that underwent SMILE procedures showed an 8% incidence of mild corneal haze (all of which were recovered with retreatment), 1% irregular corneal topography, 0.3% interface infection, and 0.3% interface leakage [58]. This study also elicited some complications during the operation, including epithelial abrasions, tears at the incision site, and difficult lenticule extraction; but these complications were not believed to affect the visual outcomes of the procedure [58]. More serious complications were corneal cap perforation (0.7%), central epithelial defect (0.3%, all recovered spontaneously in the study but required retreatment), posterior plane dissection (0.33%), presence of bubble layer (0.73%), and incisional bleeding (0.93%) [59-61].

Implantable Collamer Lens (ICL)

ICL involves the implantation of a contact lens into the eye between the iris and the natural lens. Patients undergoing ICL upon review had on average high myopia or hyperopia. It is effective for a great range of ametropia (especially for myopia, where -20 D of SE could even be addressed). Since ICL involves operations in deep inner structures compared with other procedures and causes different types of complications, the risks of ICL were discussed separately below.

Poor Refractive Outcomes

A 12-year follow-up study including 112 myopia cases suggested an incidence of 25.5% for having a SE of more than 1 D one year after the ICL surgery, and 65.7% for 12 years after the surgery [62]. After 12 years, 8.9% of eyes lost more than 2 lines of visual acuity [62]. This outcome was attributed to greater severity of myopia, because the patients with less severe myopia (-3 D to -7.88 D) experienced a dramatic reduction on chance of having loss of more than 1 line of visual acuity (from 15% in the first week after operation to 5% six months later) [62,63]. Another study with a shorter follow-up length (median 14.0 months) and patients with average preoperative myopia of -16.23 D suggested even worse results: 58% patients had postoperative SE greater than 1 D. It ascertained the role of severe myopia in poorer refractive outcomes [64].

One study suggested that 0 out of 10 hyperopic patients with a mean preoperative SE of 7.14 D experienced postoperative SE of more than 1 D, while another study suggested much less optimistic results: 38% incidence of loss of 1 or more lines of visual acuity in a 6-year follow-up study for hyperopic patients undergoing ICL (mean preoperative SE =6.3) [65,66]. The study by Birgit et al suggested a slightly less incidence of 27% (mean preoperative SE =7.88 D) [64]. No other relevant data were found, and the exact risk of poor refractive outcomes after ICL is not confirmed.

Other Complications

Previous investigations suggested a slow but noticeable development of lens opacity after ICL: the one-year follow-up study suggested no lens opacity, the 12-year follow-up study suggested 13.88% incidence, and another 7.5-year follow-up study found the composite incidence of cataract, a severe form of lens opacity, to be 2.7% [62,65,67,68]. Yet the development of lens opacity was associated with older age and higher myopic levels, meaning that careful patient selection would reduce this risk [68]. Pupillary block has been identified in 3.2% of the patients undergoing ICL [67]. An annual loss of about 1.8% of endothelial cell density (ECD) was found in ICL procedure, with the first year having the most significant loss of 6.46% on average [62]. However, another study suggested much better outcomes: an average of 1.75% increase in ECD was found in the first year, while ECD decreased by only 1.42% five years after ICL compared with preoperative ECD [69]. Retinal detachment (RD) was also found after the ICL procedure, particularly in patients with high myopia (0.57%: 3-year follow-up, mean preoperative SE of -10 D; 1.64%: 1-year follow-up, mean preoperative SE of -14.54 D and all Chinese; 1.75%: 4-years follow-up, mean preoperative SE of -14.8 D) [70-72].

Refractive Lens Exchange (RLE)

RLE involves the replacement of the natural lens with an artificial contact lens. Compared with ICL, RLE is also mainly for patients with more severe refractive errors but causes worse refractive outcomes. However, because the original lens is removed in RLE, its complications and patient groups are different from those of ICL.

Poor Refractive Outcomes

One study found an incidence of 59% for postoperative SE greater than 1 D and an incidence of 21% for postoperative SE greater than 2 D after RLE procedures [73]. Another study found similar results of an incidence of 48.39% of postoperative SE greater than 1 D in myopic patients [74]. However, Gabrić *et al.* found much better outcomes of an incidence of 12% of postoperative SE greater than 1 D and an incidence of 4.2% of postoperative SE greater than 2 D [75]. Patients in all studies were highly myopic, and the follow-up length of the studies was not obviously different. In addition, 13.2% of myopic patients undergoing RLE experienced loss of 1 or more lines of BCVA [76]. Data on undesirable refractive outcomes after RLE for hyperopia was not found.

Other Complications

One study integrating the results of five studies on RLE for myopia suggested a RD rate of 2.2% for RLE after myopia, and longer time after surgery (implicated from follow-up time) and a higher degree of myopia was associated with higher incidence [77]. Data on RD after RLE for hyperopia was few, but one study compared the occurrence of RD and incidence of myopia and hyperopia and concluded that RD rate would be much less likely to occur in hyperopia [78]. Other complications of RLE are less serious and could be retreated with a high probability of success. These complications included posterior capsule opacification (occurring in 30.8% of patients undergoing RLE), lens rotation (9.23 % of patients), and cystoid macular edema (0.77% of patients) [79-81].

Conclusion

This study provided a review of the risks and complications of seven refractive surgeries primarily used today to treat ametropia. LASIK, LASEK, and SMILE were shown to have the least risks and complications among the 5 corneal procedures, while the difference of risks and complications between ICL and RLE was not evident. The difference in risks and complications between corneal and lens procedures cannot be discussed, as they adopt completely different mechanisms and target different patient groups. Although the information merely about the undesirable outcomes is insufficient for readers to evaluate the desirability of a procedure, the results of this study still provided a reference for choosing to perform refractive surgeries. Even with seemingly obvious advantages of some procedures over others, each procedure still has its use for some types of patients, before becoming obsolete and replaced by other procedures (as for the case of PRK and LASEK mentioned previously). Some procedures including corneal inlay implantation and intrastromal corneal ring segment were also used today, but clinical data regarding their effectiveness and complications were very few, and many were in the form of special case reports, so these procedures were not included in this paper. Even for the procedures that were included, the data size was too small for a high confidence level of the data statistics. Data on the treatment of astigmatism was even rarer, and many belong to the category of myopic or hyperopic astigmatism, which are grouped and presented as a part of myopia or hyperopia, so outcomes of the treatment of astigmatism were minimally presented and discussed in this paper. However, data forms on the development and residual of refractive errors after treatment in most studies were encouragingly congruent, being presented as both preoperative, postoperative, and change in average SE, and as incidence (rate) of undesirable SE residual and development. It enabled this paper to summarize data in a categorical form as to help the most readers to understand and utilize the results, to present a significant number of data from past studies. It is worthy to mention, however, that considerable amounts of data were not categorized and that the research method of this paper may have led to variability in data collection.

Although the limited number of current data did not enable the anticipated results of "risks and complications uniformly stratified based on age, level of refractive errors, gender, ethnicity, and other associated factors", some basic trends of factors underlying the incidence of complications and poor outcomes were identified in this paper, including older age and higher degrees of ametropia. The data review would nevertheless provide insights to readers in evaluating one's risks in undergoing refractive surgeries.

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