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EARLY AND LATE COMPLICATIONS FOLLOWING VISION CORRECTION WITH SMILE AND LASIK METHODS. ANALYSIS OF DIFFERENCES

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ABSTRACT

Vision correction through refractive surgical procedures has become increasingly precise and patient-specific, with SMILE (Small Incision Lenticule Extraction) and LASIK (Laser-Assisted in Situ Keratomileusis) emerging as two of the most commonly performed techniques for the treatment of myopia and astigmatism. Both methods offer excellent visual outcomes and rapid postoperative recovery; however, they differ significantly in terms of surgical approach, which in turn influences the profile and frequency of complications. This review explores and compares the complications associated with each procedure, highlighting key differences in both early and late postoperative outcomes.

Early complications such as dry eye syndrome, transient visual disturbances, and epithelial healing irregularities tend to occur more frequently after LASIK. This is likely due to the creation of a corneal flap in LASIK, which can disrupt more corneal nerves and tissues. In contrast, SMILE, which involves only a small peripheral incision without a flap, preserves more of the corneal architecture, leading to a reduced incidence of postoperative dryness and inflammation.

Furthermore, long-term complications, including corneal ectasia, appear to be less prevalent following SMILE, likely owing to the better biomechanical stability maintained in the cornea. A nuanced understanding of these complication patterns is essential for clinicians to select the most appropriate technique based on individual patient characteristics, ocular anatomy, and lifestyle demands. Tailoring the surgical approach not only improves clinical outcomes but also helps in minimizing procedural risks and enhancing patient satisfaction.

KEYWORDS

SMILE, LASIK, Early Complications, Late Complications, Laser Vision Correction, Dry Eye

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Introduction

Development of Laser Vision Correction Techniques

The evolution of laser vision correction methods has undergone remarkable advancements since their inception. A pivotal milestone in this field was the introduction of femtosecond lasers, which revolutionized refractive surgery by enabling precise intrastromal corneal interventions. The concept of creating a lenticule—a lens-shaped structure within the corneal stroma—that could be manually extracted as a whole was designed to eliminate the need for excimer laser ablation. Early experimental techniques, described in the mid-1990s, utilized picosecond lasers to cut the lenticule, which was then manually extracted following the creation of a corneal flap. However, these methods faced significant challenges, including surface irregularities caused by limited precision during manual preparation. (1, 7) (3, 9, 11)

The introduction of femtosecond lasers markedly improved procedural accuracy, paving the way for further advancements in lenticule extraction techniques. Initial studies on femtosecond laser-based methods were conducted on animal models and visually impaired patients in the late 1990s and early 2000s. Despite promising outcomes, clinical trials were sparse. The landscape shifted in 2007 with the launch of the VisuMax femtosecond laser by Carl Zeiss Meditec. This device reintroduced lenticule extraction techniques through a procedure known as Femtosecond Lenticule Extraction (FLEx). (3, 9, 11)

Preliminary results of FLEx demonstrated refractive outcomes comparable to those achieved with LASIK. However, the visual recovery period was longer due to suboptimal energy parameters and scanning modes. Subsequent refinements to the procedure reduced recovery times and enhanced precision, establishing FLEx as a viable alternative to traditional excimer laser-based methods.

Building on the success of FLEx, a new procedure known as Small Incision Lenticule Extraction (SMILE) was developed. Unlike FLEx, SMILE eliminates the need to create a corneal flap by allowing the lenticule to be extracted through a small incision measuring only 2–3 mm. This minimally invasive approach preserves greater structural integrity of the cornea, reducing the risk of flap-related complications and the potential for corneal ectasia. (6, 10, 17)

SMILE gained widespread popularity following initial clinical trials, which demonstrated its safety and efficacy. The technique's ability to minimize tissue disruption and promote faster recovery has made it a preferred choice among refractive surgeons. The growing body of scientific literature continues to affirm SMILE as a groundbreaking advancement in refractive surgery, highlighting its transformative impact on the field.

Description of the SMILE Procedure

The Small Incision Lenticule Extraction (SMILE) procedure begins with positioning the patient so that the cornea rests against a custom-fitted glass contact element of the femtosecond laser. When the cornea contacts the glass, a meniscus layer of tear film forms, enabling the patient to clearly see the fixation target, as the light beam is precisely adjusted to their refractive error. The surgeon instructs the patient to focus on a green light. Once the eye is aligned, suction ports are activated to stabilize the eye. This ensures automatic alignment of the visual axis and corneal apex with the center of the contact glass, integrated into the laser system and the area where the lenticule will be created. (3, 9, 11)

The surgeon verifies the alignment by comparing the corneal reflex and pupil center using topographic imaging obtained through the Atlas system (Carl Zeiss Meditec, Jena, Germany). If the alignment is suboptimal, the suction is released, and the docking process is repeated. Utilizing suction and curved contact glass, the intraocular pressure increases to 70–80 mmHg, maintaining intraocular circulation and allowing the patient to retain vision throughout the procedure.

In the first phase, the femtosecond laser creates the lenticule's posterior surface, proceeding from the external corneal layers inward to minimize interference with the patient's central vision. Next, the anterior lenticule surface, termed the"cap, " is formed, along with a small, 2–3 mm incision connecting the cap's interface to the corneal surface. The entire suction process takes approximately 35 seconds, remaining constant regardless of the refractive error, as cutting parameters are fixed, and only the distance between cuts increases with higher refractive corrections. (3, 9, 11)

The second phase involves moving the patient under a surgical microscope for lenticule separation and removal. The incision is opened, and the lenticule's upper and lower edges are carefully identified, facilitating precise separation of tissue layers. Typically, the upper lenticule surface is separated first using standard lamellar techniques with gentle back-and-forth tool movements. The lower lenticule layer is then separated similarly. Some surgeons prefer immobilizing the eye during separation to better control the force used. After both layers are separated, the lenticule is removed using microforceps or other tools designed specifically for the procedure.

At the end of the surgery, any excess tissue in the cap area is evenly redistributed along the corneal periphery to prevent microfolds or wrinkles on the cap surface. This process can be performed using either the built-in slit lamp of the VisuMax system or a standard slit lamp with fluorescein dye and cobalt light to better assess surface tension in residual areas.

During procedure planning, the surgeon can customize parameters such as cap thickness, cap diameter, side-cut angle, refractive correction, lenticule diameter (optical zone), and minimum lenticule thickness. These adjustments allow for precise differentiation between the lenticule's posterior and anterior surfaces.

Description of the LASIK Procedure

The Laser-Assisted in Situ Keratomileusis (LASIK) procedure begins with precise preparation of the patient's cornea, which involves creating a thin corneal flap using either a mechanical microkeratome or a femtosecond laser. The patient is positioned lying down, and the surgeon adjusts the patient's head to ensure optimal access to the operative eye. A suction ring is then applied to the cornea to stabilize the eyeball and prevent movement during the procedure. (3, 9, 11)

In the first phase, the surgeon uses a microkeratome or femtosecond laser to create a corneal flap, typically measuring between 100 and 130 micrometers in thickness. The femtosecond laser generates thousands of microscopic air bubbles within the corneal stroma, creating a smooth cutting plane. Once the flap is created, the surgeon gently lifts it to expose the deeper corneal layers that will undergo excimer laser ablation. (3, 9, 11)

During the second phase, the excimer laser precisely reshapes the stromal layer of the cornea. The laser emits high-energy ultraviolet light pulses that remove microscopic amounts of corneal tissue to correct the refractive error. This ablation process is computer-controlled and based on accurate measurements of the patient's refractive error, ensuring the desired optical outcome. The reshaping typically takes a few to several seconds, depending on the level of correction required. During this phase, the patient is instructed to focus on a fixation light, which helps direct the laser pulses accurately.

After ablation, the surgeon carefully repositions the corneal flap to its original position, where it naturally adheres due to the adhesive properties of the corneal layers. Sutures are not required, as the cornea heals on its own. The flap is aligned to ensure maximum stability and to avoid microfolds or surface wrinkles. The surgeon verifies the flap's correct positioning under an operating microscope and makes any necessary minor adjustments.

The entire LASIK procedure typically takes 10–15 minutes per eye and is associated with a short recovery time. Patients may experience mild discomfort or dryness in the initial hours post-surgery, but most regain full visual acuity by the following day. Due to its precision and speed, LASIK has become one of the most widely performed vision correction procedures globally.

Early Complications Following SMILE and LASIK Procedures

Early complications after laser vision correction, including dry eye, healing disturbances, and optical phenomena (halo and glare), are influenced by both the characteristics of the procedure and the patient's individual anatomical features. Corneal properties, pupil size, and the degree of refractive error are critical factors that can affect the frequency and severity of these complications. (1, 7) (3, 8) (3, 5, 12)

Dry Eye

Dry eye is a particularly common early complication, especially in patients with a thin Bowman's layer or overall reduced corneal thickness. Both LASIK and SMILE can cause significant damage to corneal innervation, which plays a vital role in tear film regulation. Damage to branches of the trigeminal nerve, responsible for corneal innervation, leads to impaired tear reflexes and decreased tear production. Patients with pre-existing ocular conditions, such as dry eye syndrome, are especially susceptible to this complication. Women in menopause face an increased risk due to hormonal changes, including decreased estrogen and androgen levels, which regulate the function of lacrimal and meibomian glands. Reduced secretion of the aqueous and lipid layers of the tear film exacerbates dry eye symptoms in this group. (3, 5, 12)

In LASIK patients, the risk of dry eye is higher due to the need to sever more nerve fibers during the creation of the corneal flap. Individuals with shallow orbital cavities, which limit corneal accessibility, may require deeper cuts, further increasing the risk of dry eye. In contrast, SMILE avoids flap creation, significantly reducing this risk. However, patients with extremely thin corneas or high refractive errors may experience similar symptoms due to prolonged peripheral nerve regeneration. (3, 5, 12)

Healing Complications

The healing process after LASIK and SMILE procedures is particularly crucial for patients with irregular corneal topography, such as keratometry indicating mild asymmetry or significant variations in stromal thickness. In LASIK, patients with thin corneas or large optical zone diameters are at greater risk of flap displacement or deformation during healing. Additionally, individuals with a history of corneal infections or injuries may face a higher likelihood of complications related to the flap incision site. (4, 11, 15)

In SMILE, the absence of a corneal flap results in a more stable healing process. However, patients with steeply curved corneas (e.g., subclinical keratoconus) may encounter difficulties in lenticule separation during the procedure, potentially affecting the final refractive outcome. Moreover, individuals with limited stromal elasticity may experience small microcracks at the incision site, necessitating a longer recovery period. (4, 11, 15)

Optical Phenomena (Halo and Glare)

Optical phenomena such as halo and glare are particularly bothersome for patients with large pupil diameters, especially under low-light conditions. Halo, appearing as bright rings around light sources, and glare, characterized by light bursts, result from the interaction of light with the corneal surface and higher-order aberrations that may develop after surgery. (8, 13, 16)

In LASIK, patients with large pupil diameters (greater than 6 mm under scotopic conditions) are more susceptible to these phenomena. The ablation zone on the cornea may be smaller than the dilated pupil, leading to light diffraction at the edge of the treatment area. In SMILE, this issue is less pronounced because the procedure does not involve excimer laser ablation, preserving a more natural corneal shape. However, patients with highly steep corneas or significant surface asymmetry may still experience higher-order aberrations regardless of the chosen method. (8, 13, 16)

Late Complications Following SMILE and LASIK Procedures

Although late complications after laser vision correction are less common, they can have significant implications for long-term treatment outcomes and patients' quality of life. Complications such as corneal ectasia, persistent visual quality issues, and chronic dry eye are influenced by both the surgical technique and the anatomical and biomechanical characteristics of the patient's cornea. (1, 7) (4, 9) (8, 14, 18)

Corneal Ectasia

Corneal ectasia is one of the most severe complications following LASIK and, less frequently, SMILE. This condition occurs as a result of progressive corneal thinning and bulging, leading to irregular astigmatism and reduced visual acuity. The mechanism of ectasia involves weakened biomechanical strength of the cornea, which may result from excessive tissue removal during the procedure or from corneal topography abnormalities, such as subclinical keratoconus. (6, 10, 17)

In LASIK, the creation of a corneal flap disrupts the continuity of Bowman's layer and weakens the stromal structure. Additionally, the flap, although repositioned after the procedure, does not contribute to restoring the cornea's structural strength, increasing the risk of deformation. Patients with thin corneas, large ablation zones, or irregular topography are particularly prone to developing ectasia. The risk is also elevated in individuals with a history of corneal injuries or congenital structural abnormalities.

The SMILE technique, by avoiding flap creation, preserves greater biomechanical integrity of the cornea, significantly reducing the risk of ectasia. This method primarily targets the deeper stromal layers, leaving Bowman's layer and the superficial corneal layers largely intact. However, patients with corneal topography irregularities, such as subclinical keratoconus, may still face a risk of ectasia, especially if they undergo excessive refractive correction.

Persistent Visual Quality Disturbances

Persistent visual quality disturbances, including halo, glare, reduced night vision acuity, and diminished contrast sensitivity, pose a significant challenge for some patients after LASIK and SMILE procedures. These phenomena often result from the development of higher-order aberrations in the cornea, which disrupt the optical properties of the eye. (8, 13, 16)

In LASIK, excimer laser ablation can create irregularities in the central corneal region, especially in patients with high refractive errors, leading to optical issues such as halo and glare. Patients with large pupil diameters (greater than 6 mm under scotopic conditions) are more susceptible to these problems, as the edge of the ablation zone may fall within the field of vision in low light, causing light diffraction.

In SMILE, higher-order aberrations are generally less pronounced because the procedure involves lenticule removal rather than excimer laser ablation, preserving a more natural corneal shape. However, patients with extremely steep corneas or significant asymmetry in corneal topography may still experience visual disturbances after SMILE. Additionally, some effects, such as halo, may arise from uneven pressure distribution during lenticule separation, although these are typically less severe compared to LASIK. (8, 13, 16)

Chronic Dry Eye

Chronic dry eye is a complication that can persist for months or even years after surgery, particularly in patients with pre-existing dry eye syndrome. In LASIK, the regeneration of corneal nerve fibers takes longer due to the severing of numerous nerves during flap creation. Damage to corneal innervation leads to impaired tear reflexes, resulting in reduced tear production and accelerated tear evaporation. (3, 5, 12)

In SMILE, nerve regeneration occurs more rapidly as the procedure causes less disruption to corneal innervation. However, patients with thin corneas, high refractive errors, or hormonal imbalances, such as those occurring during menopause, may still experience chronic dry eye symptoms. In such cases, supportive therapies such as lubricating eye drops, omega-3 fatty acid supplementation, or hormonal treatment may be necessary to alleviate symptoms and improve tear film stability. (3, 5, 12)

Importance of Patient Qualification

A thorough assessment of corneal anatomical characteristics and the patient's overall health is critical in minimizing the risk of late complications following laser vision correction. Patients with thin corneas, large pupil diameters, irregular corneal topography, or pre-existing dry eye syndrome must be carefully evaluated. When necessary, such patients may be referred to alternative vision correction methods, such as phakic intraocular lenses, to ensure optimal safety and outcomes. (1, 7) (4, 9) (3, 5, 12)

Recovery After SMILE and LASIK Procedures

The recovery process following laser vision correction plays a critical role in preventing both early and late complications. Proper postoperative care, adherence to the surgeon's recommendations, and adjusting activities to the healing phase significantly impact the final treatment outcomes and minimize the risk of complications. (1, 7) (4, 9)

SMILE

Recovery after SMILE is relatively short due to the minimally invasive nature of the procedure. The small 2–3 mm incision reduces corneal tissue damage, lowering the risk of infection, healing disturbances, and chronic dry eye. Proper postoperative care, such as using lubricating eye drops and avoiding eye rubbing, allows patients to quickly return to normal activities. (3, 5, 12)

However, resuming intense activities, such as contact sports, too soon can lead to microdamage at the incision site, increasing the risk of infection or healing complications. Additionally, insufficient eye hygiene in the first days after the procedure may result in corneal inflammation. Following recommendations for eye protection during the first month post-surgery is essential to minimize the risk of complications.

LASIK

Recovery after LASIK involves a higher risk of flap-related complications. Creating a corneal flap temporarily weakens the structural integrity of the cornea, making it more susceptible to displacement or damage during the first days after the procedure. Even minor mechanical trauma, such as eye rubbing, can cause flap displacement, resulting in corneal irregularities and reduced visual acuity.

Failure to adhere to recommendations for avoiding strenuous physical activities during the first month post-surgery increases the likelihood of complications such as infections or microdamage to the flap. Contact sports, such as soccer or boxing, should be postponed for at least 6–8 weeks to ensure stable flap reattachment and minimize the risk of displacement. Additionally, dry air in airplane cabins can exacerbate dry eye symptoms, so patients are advised to use lubricating eye drops during flights in the postoperative period. (3, 5, 12)

Importance of Recovery in Preventing Complications

The recovery period is critical, as it presents the highest risk for complications in both LASIK and SMILE procedures. Non-adherence to postoperative guidelines can lead to infections, flap displacement (in the case of LASIK), or improper corneal healing (in the case of SMILE). Resuming physical activities too early can damage the cornea, potentially delaying healing and adversely affecting the final refractive outcomes.

Properly managed recovery not only reduces the risk of complications but also accelerates the stabilization of refractive results. Patients who follow recommendations for eye protection, medication use, and activity limitations are less likely to experience chronic dry eye, higher-order aberrations, or persistent visual disturbances. (3, 5, 12) (8, 13, 16)

Summary and Future Perspectives

Laser vision correction using SMILE and LASIK plays a vital role in the treatment of refractive errors, offering patients effective and safe solutions. While both methods exhibit high safety and efficacy profiles, their use is associated with early and late complications that differ in nature and frequency. SMILE, with its minimally invasive approach, provides significant advantages in reducing the risk of dry eye and preserving corneal biomechanical integrity. Meanwhile, LASIK, as a more versatile technique, remains the gold standard for addressing a wide range of refractive errors. (1, 7) (4, 9) (3, 5, 12)

Despite extensive research on the efficacy and safety of both methods, further analysis is needed in this field. Long-term studies are particularly crucial to assess the durability of refractive outcomes and the risk of late complications, such as corneal ectasia and chronic dry eye, over a period of five years or more. Advanced imaging techniques, such as optical coherence tomography (OCT) and confocal microscopy, could provide valuable insights into structural changes in the cornea following SMILE and LASIK procedures. (4, 9) (3, 5, 12) (6, 10, 17)

Future research could also focus on developing advanced predictive algorithms to improve patient selection for specific procedures based on their individual anatomical and biological characteristics. Comparative studies of both methods in patient groups with varying refractive errors, pupil sizes, or corneal structures could offer valuable guidance for a more personalized approach to refractive surgery.

The ongoing development of surgical technologies and patient monitoring techniques, combined with long-term clinical outcome analysis, could pave the way for enhanced safety and efficacy in laser vision correction. In particular, conducting prospective controlled studies involving diverse patient groups and considering factors such as age, sex, hormonal status, and prior ocular conditions may provide a more comprehensive understanding of the impact of these procedures on ocular health. (1, 7)

Conclusions

The analysis of early and late complications following SMILE and LASIK demonstrates that both laser vision correction methods have unique advantages and limitations that must be considered when selecting patients for the procedure. SMILE, with its minimally invasive technique, is associated with a lower risk of flap-related complications, reduced incidence of dry eye, and better preservation of corneal biomechanical integrity. In contrast, LASIK, as a more versatile method, allows for the treatment of a broader range of refractive errors but carries a higher risk of flap-related complications and higher-order aberrations. (1, 7) (4, 9) (3, 5, 12) (8, 13, 16)

The choice of the appropriate vision correction method should be based on the individual anatomical characteristics of the patient, such as corneal thickness and topography, pupil diameter, and existing conditions, such as dry eye syndrome. In women undergoing menopause, special attention should be paid to the potential impact of hormonal changes on tear film stability and corneal healing after surgery. (3, 5, 12)

Despite differences in techniques and complications, both methods provide high efficacy and improved quality of life for patients. However, further long-term studies are necessary to fully evaluate their impact on ocular health and to develop even more precise diagnostic and qualification tools. The use of advanced imaging techniques, such as OCT and confocal corneal microscopy, could provide new data to support the continued refinement of surgical technologies and enhance the safety of refractive procedures. (8, 14, 18)

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