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REVIEW

Update of Research Progress on Small Incision Lenticule Extraction (SMILE) Lenticule Reuse

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Abstract: The SMILE lenticule is a complete corneal stroma that is removed from SMILE surgery. Since the increasing number of SMILE surgeries, a large number of SMILE lenticules have been produced, so the reuse and preservation of the stromal lens has become a research hotspot. Due to the rapid development of the preservation and clinical reuse of SMILE lenticules, there have been many related studies in recent years, so we updated it on this basis. We searched PubMed, Web of Science, Embase, Elsevier Science, CNKI, WANFANG Data and other databases for all articles published on the preservation and clinical reuse of SMILE lenticules, screened useful articles, selected relevant articles published in the last five years as the main body for summary, and then reached a conclusion. The existing preservation methods of SMILE lenticule include Moist chamber storage at low temperature, cryopreservation technique dehydrating agent and corneal storage medium, which have their own advantages and disadvantages. Presently, smile lenticules can be used for the treatment of corneal ulcers and perforations, corneal tissue defects, hyperopia, presbyopia and keratectasia, which have been proven to be relatively effective and safe. More research on smile lenticule reuse needs to be carried out to confirm its long-term efficacy.

Keywords: SMILE lenticule, refractive surgery, preservation, clinical reuse

Background

SMILE is one of the mainstream refractive surgery methods that uses a femtosecond laser to scan the corneal stroma from different angles, forms a lens, and then removes it from a small incision at the edge. SMILE lenticule is a complete corneal stroma that is removed from patients during SMILE surgery. Since SMILE lenticules can be completely removed in all operations, the reuse of the stromal lens has gradually become a research hotspot. Current studies related to SMILE lenticules are mainly divided into two aspects; one is about the biological characteristics of the cornea itself, and the other is related to the study of clinical use.[1] This manuscript summarizes the clinical reuse of SMILE lenticules.

The premise of reuse is the effective preservation of SMILE lenticule, which mainly includes reducing its immunogenicity and maintaining its transparency and the integrity of the original structure.

It was reported that human corneal stromal lenticules from SMILE have low pathogenicity but high immunogenicity,[2] and gamma irradiation can further reduce the pathogenicity of the lens without affecting its optical properties.[3,4] The existing storage methods are as follows.

Moist Chamber Storage at Low Temperature

Moist chamber storage is a method of corneal preservation with a long history. It involves placing the enucleated eyes in a sealed jar with a temperature of 0–4 degrees C that contains a pad of gauze soaked in saline to provide a humid environment. This storage method is limited to 24–48 hours.[5]

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Cryopreservation Technique

The cryopreservation technique seems to be a safe method of long-term SMILE lenticule storage,[6–9] but it can be damaged in the process of freezing and thawing.[10–12] Moreover, the technical complexity and costs of the cryopreservation technique limit its clinical application, especially in developing countries.

Dehydrating Agent

Certain dehydrants can also be used to preserve SMILE lenticules. Studies have proven that human corneal stroma can be biobanked for up to 2 weeks under dehydrated conditions without losing its molecular or biomechanical properties after rehydration.[13] Currently, commonly used dehydrating agents mainly include silica gel, glycerol and silicone oil. Silica gel is a common dehydrating agent for cornea preservation. Glycerol has excellent dehydrating and antimicrobial properties,[14] and its usage for preserving donor lamellar tissue has been widely confirmed.[15,16] However, glycerol is more likely to cause lenticule edema and reduce the density of collagen fibers.[17] It was reported that storage in anhydrous glycerol at −78 °C is an ideal method for reducing antigens without damaging the lenticule's structure and function.[2] Silicone oil might prove to be a novel agent for corneal tissue storage owing to its stability, low toxicity and high hydrophobicity. Glycerol, silicone oil and silica gel could be used for lenticule preservation. Silica gel is more conducive to maintaining optical transmittance than the other two agents.[18] The toxicity of dehydrating agents on SMILE lenticules and whether there are other effects on them during dehydration and rehydration remain to be further studied.

Corneal Storage Medium

CSM is a kind of medium that can effectively maintain normal corneal endothelial activity and normal corneal thickness.

Corneal Potassium TES (CPTES)

CPTES is a cryogenic corneal preservation medium with high potassium content that can prevent the loss of intracellular potassium and thus maintain osmotic pressure balance to maintain corneal integrity. The advantage of CPTES is that the preservation method is simple, eliminating the possibility of other uncertain components in the preservation medium, and the low temperature is not conducive to the growth of pathogenic microorganisms. However, the rewarming time is slightly longer, taking 2 hours to restore the normal corneal thickness at 34 °C lavage, so it is difficult to apply in clinical practice.[19,20]

Chondroitin Sulfate Medium (CSM)

CSM has a better effect on corneal preservation for a long time and causes less damage to endothelial cells after preservation for up to 14 days than other preservation media. The disadvantage is that the corneal thickness increases significantly during the storage period. Adding dextrose can reduce the degree of corneal thickening, which can usually resolve within 1 week after surgery.[21]

Optisol GS

Ex vivo studies found that the damage of the Optisol-GS medium stored at 4 °C increased significantly after 7 to 10 days.[22,23] It was reported that SMILE lenticules stored in Optisol GS have more biological activity and integrity than those stored in glycerol.[17]

Cornea Cold (GenBio, San Diego, CA)

Cornea Cold is a storage medium recently approved by the FDA for storage for up to 21 days in Europe.[24]

Life4 °C

Life4 °C is also FDA approved but for only 14 days of storage.[25]

Chen Medium (Chen Laboratories, Phoenix, MD)

Chen medium also received FDA approval for corneal storage, and storage of corneal tissue in it can result in minimal injury for up to 14 days.[26]

It is a feasible approach for the storage of stromal lenticules after refractive surgery to build long-term lenticule banking based on these methods,[27] and some countries have already established relatively mature lenticule banking. In addition, it has been reported that short-term storage of SMILE lenticules in phosphate buffer saline (PBS) has no significant effect, at least for the first 48 hours at 4 °C or room temperature before transportation to technical facilities for long-term storage,[28] making emergency preservation of lenticules possible under nonprofessional conditions.

We will introduce the clinical reuse of SMILE lenticules in the following aspects.

Repair of Tissue Defects

SMILE Lenticule Transplantation for Corneal Ulcer and Perforation

At present, the main treatment methods for intractable corneal ulcers, melting and perforation include soft corneal contact lenses, conjunctival autograft transplantation, amniotic membrane transplantation and corneal transplantation. Among these treatments, corneal transplantation is the most important and effective,[29] but due to the shortage of corneal donors, especially in developing countries, many patients cannot undergo surgery.[30]

Tectonic keratoplasty using SMILE-extracted lenticules is a comparatively safe, effective, and reliable alternative approach for the treatment of corneal lesions[31] and alleviates the problem of insufficient corneal grafts to a certain extent. It was reported that the advantage of SMILE lenticules is that they can effectively repair corneal defects and improve local inflammatory reactions, and the operation has good repeatability.[32] The single-piece SMILE lenticule has a thick middle and a thin edge. OCT can be used to evaluate the depth and range of corneal lesions before surgery and then change the shape of the implant according to the needs of the patient to improve the surgical treatment effect.[32,33] In addition to using single-piece SMILE lenticules,[34–36] fibrin glue combined with multiple SMILE lenticules can be used to treat corneal ulcers and perforations. However, it is currently believed that multilayer SMILE lenticules with uneven thickness cannot be kept transparent and are generally only used for the therapeutic repair of large perforated corneal ulcers in emergency situations.[37–39] The amniotic membrane contains a large number of growth factors and cytokines, which are very effective in the treatment of corneal infection and inhibition of neovascularization. However, the amniotic membrane is soft and soluble, and when combined with SMILE, lenticules can compensate for the shortcomings of using the amniotic membrane alone and are more consistent with the corneal hierarchy, which can reduce posttransplantation complications.[40] He et al[41] reported the first case of Mooren's ulcer complicated with pterygium treated with a lenticule obtained by myopic SMILE. They used the corneal lenticule obtained by SMILE for lamellar keratoplasty, followed by pterygium excision and conjunctival autografting. The patient recovered well one year after the operation without complications or recurrence.

Treatment for Corneal Dermoid Tumor

Wan[42] and Pant[43] et al both reported the use of SMILE lenticule transplantation in corneal dermoid tumor patients as an alternative to traditional corneal transplantation. Follow-up showed improvement in postoperative vision and astigmatism, and all patients had no immune rejection at the end of follow-up. These results suggest that SMILE lenticule transplantation can restore corneal integrity and may be a safe and effective treatment for corneal dermoid tumors. Furthermore, traditional sutures can lead to irregular astigmatism and increased operation time. More literature has reported that it seems to be a safe, feasible and inexpensive surgical option to use lenticules obtained from SMILE with fibrin glue for transplantation, which is used to manage microperforations and complex corneal tears.[37,39,44]

Application of Refraction

With the aging of the population and changes in people's living habits, the occurrence of hyperopia and presbyopia is increasing. In addition, people's living standards have improved, so traditional glasses have been unable to meet people's

needs for convenience in life, so finding new treatment methods has been an urgent need. The appearance of SMILE lenticules provides a new clinical idea for the treatment of presbyopia and hyperopia.

Treatment for Hyperopia

Hyperopia is a type of ametropia in which parallel light enters the eye while the eye is relaxed and focused behind the retina instead of forming a clear image on the retina. The treatment methods include wearing glasses and surgical treatment. The existing surgical methods include laser-assisted in situ keratomileusis (LASIK) and laser-assisted subepithelial keratomileusis (LASEK).

The treatment of hyperopia by SMILE lenticule is to implant the corneal matrix removed by SMILE surgery into the cornea of the corrected object and change the central curvature of the cornea. Although in vitro studies showed that the biomechanics of SMILE lenticule in the correction of hyperopia decreased compared with that before surgery, it had no significant effect on the surgical results.[45] Pradhan et al[46] reported for the first time a case of hyperopia due to aphakia after congenital cataract surgery using fresh allogeneic SMILE lenticule transplantation. Ganesh et al[7] treated hyperopia with cryopreserved allogeneic SMILE lenticules and followed up for up to six months. The postoperative visual acuity of the patient was significantly improved, and no rejection occurred during follow-up. They believe that SMILE lenticule transplantation has good predictability in the treatment of moderate hyperopia but poor predictability in the treatment of high hyperopia without lens.

Zhang et al[47] showed that SMILE lenticule implantation was safe, effective, and predictive 1 year after correction for hyperopia. Moshirfar et al[48] reported the first case of allogeneic SMILE lenticule for hyperopia correction in the United States, and the postoperative visual result suggested that it is an effective method for hyperopia correction. A study by Wu et al[49] had shown that SMILE lenticule is an effective way to correct moderate to high hyperopia, and its result is similar to transepithelial phototherapeutic keratectomy (PTK-EP). Liu et al[50] described the first use of toric lenticule implantation with the triple marking method to correct hyperopia and hyperopic astigmatism following small incision lenticule intrastromal keratoplasty, which is safe and stable in the short term. It provides more possibilities for lens transplantation to treat hyperopia. Zhou et al[51] performed autologous SMILE lenticule implantation in the left eye of a woman with myopia in the right eye and hyperopia in the left eye, and her postoperative vision was significantly improved without corresponding complications. Another study conducted by Sun et al[52] evaluated the safety, effectiveness, stability, and predictability of fresh autologous RL implantation for the treatment of hyperopia. The CDVA improved in all cases, and the refractive result remained stable throughout the follow-up period without any complications. Li et al[53] also performed autologous SMILE lenticule implantation in 10 patients, all of whom were successful without complications. They also developed a refractive correction formula for predicting autologous SMILE lenticule implantation in hyperopic patients, but this formula needs further validation and adjustment. According to the research of Li et al,[54] when using SMILE lenticules to treat hyperopia, nerve fibers will regenerate into the implanted lenticule after autologous lenticule implantation, and keratocytes in lenticules demonstrate a gradual return to a normal morphology. Moshirfar et al[55] proposed an improved surgical technique, called small-incision lenticule intrastromal keratoplasty (sLIKE). This technique implants the lenticule into an intrastromal pocket, thus reducing injury to the subbasal nerve plexus injury, reducing dry eye symptoms, biomechanical strength, and the chance of epithelial cells to grow. The study of Zhang et al[56] showed that SMILE lenticules can be used to correct highly hyperopic astigmatism with good safety, effectiveness and repeatability.

In addition, Lazaridis et al designed a SMILE lenticule with specific refractive power to treat rare hyperopia and high astigmatism after LASIK while also increasing the thickness of the patient's original cornea. Hyperopia and astigmatism were completely corrected after the operation, with stable diopter and no rejection during the 1-year follow-up.[57]

Treatment for Presbyopia

Presbyopia is the most common visual problem in people over the age of 40, and SMILE lenticule is a relatively new treatment for presbyopia. Animal experiments conducted by Liu,[58] Lim[59] and Angunawela[6] et al have shown that SMILE lenticules are currently feasible and safe for the treatment of presbyopia. However, due to the lack of human experiments and because most of the results are obtained from experiments on nonprimates, further clinical research is needed to draw

more accurate conclusions. Jacob et al[60] used an allogenic corneal inlay prepared from a SMILE lenticule, and all patients were operated on successfully without postoperative complications. This preliminary study proved the safety and efficacy of a PEARL corneal inlay in the correction of presbyopia. However, further studies are recommended to determine long-term results.

Application of Keratectasia

Keratectasia is a common refractive instability disease associated with progressive destruction of the corneal structure, mainly including keratoconus, iatrogenic keratectasia, pellucid marginal degeneration (PMD), Terrien's marginal degeneration (TMD) and keratoglobus.

Smile Lenticule in the Treatment of PMD

Kalinnikov et al[61] reported a case of using a SMILE lenticule in lamellar keratoplasty for the treatment of marginal corneal degeneration. This new surgical method combines intrastromal lamellar keratoplasty and a 359° intracorneal ring segment implantation to achieve the correction of ametropia and corneal thinning. Despite the lack of long-term observation, the new surgical method described in this case report was successful for this particular patient, so it may be effective and safe in the severe stage of the disease.

Smile Lenticule in the Treatment of Iatrogenic Keratectasia

Li et al[62] reported a case of iatrogenic keratectasia after LASIK using an allogenic smile lenticule. Then, they included 7 similar patients treated with the same surgical method and followed up for three years, and all patients had satisfactory outcomes and no significant complications during the follow-up.[63]

Smile Lenticule in the Treatment of Keratoconus

Keratoconus is an uncommon autosomal recessive inheritance characteristic of corneal ectasia that results in corneal central anterior bulging, conus formation and high irregular astigmatism. Treatment methods include frame glasses, corneal contact lenses, corneal collagen crosslinking, intrastromal corneal ring implantation and keratoplasty, among which corneal collagen crosslinking is the most important treatment for keratoconus at present. However, in some patients with severe disease, corneal thickness is insufficient to support corneal collagen crosslinking therapy.

The study of Sachdev et al[64] provided a new way to solve this dilemma by thickening the patients' thin corneal stroma with a Smile lenticule, followed by routine corneal collagen crosslinking. The technique was found to be safe and effective in a few cases, but long-term studies are required to further establish the efficacy and feasibility of this procedure. They also evaluated intracorneal ring segment (ICRS) implantation combined with corneal collagen crosslinking (CXL) using a small incision SMILE lenticule for intraoperative stromal augmentation in thin corneas and found that the procedure was safe and effective.[65] Similar studies were carried out by Ganesh[66] and Cagini[67] et al, and their study suggested that the combination of SMILE lenticule and CXL may be a feasible option for keratoconus and delay or avoid the need for a corneal transplant. However, Wang[68] study showed that although CXL combined with SMILE lenticule implantation can effectively improve corneal thickness and prevent conus progression, it is not superior to single collagen crosslinking and will further aggravate ametropia. Mastropasqua et al[69,70] designed a modified femtosecond laser flap cutting operation to produce an intrastromal pocket and implant lenticules into recipient corneas. Their research shows that the addition of stromal lenticules to keratoplasty can effectively improve the corneal shape and vision of patients with keratoconus in clinical practice. The addition of a negative meniscus shape can cause the cone to flatten and increase the corneal thickness. They observed the cornea in vivo after femtosecond laser-assisted stromal lenticule addition keratoplasty in keratoconus under in vivo confocal microscopy and found that the patient had a temporary decrease in the density of the nerve plexus and a slight inflammatory reaction. In addition, the donor-recipient interface reflectivity was equivalent to that of femtosecond laser refractive surgery, and there was no sign of stromal opacification or stromal rejection in one year of follow-up.[71] The in vitro study of Pedrotti et al further proved that femtosecond laser-assisted stromal lenticule addition is feasible in the recovery of corneal thickness and adjustment of posterior corneal elevation in the corneal ectatic area.[72] An in vivo study by Nubile et al[73] found that stromal lenticule addition

keratoplasty (SLAK) reshapes the cornea through central flattening, stromal thickening and epithelial thickness recovery. The research of Doroodgar[74] and Jadidi[75] et al showed that it is feasible to use femtosecond laser customized SMILE lenticule implantation to treat advanced keratoconus, which can improve the vision, topography and refraction of the implanted eyes. Excimer laser ablation may be feasible for thinning and reshaping SMILE-derived lenticules before reimplantation or allogenic transplantation,[76] and Jafarinasab et al[77] invented a new type of surgery, femtosecond laser-assisted allogenic stromal keratoplasty with excimer laser-assisted donor keratomileusis, in which both eyes underwent corneal crosslinking at the same time to further improve the surgical effect. The study of Wei et al[78] also proved that small-incision femtosecond laser-assisted intracorneal concave lenticule implantation (SFII) is an effective procedure to prevent the progression of keratoconus due to its minimal invasiveness and capability of maintaining a steady biometry of the cornea.

Conclusions

In conclusion, smile lenticules allow for a new method for the treatment of corneal ulcers and perforation, corneal tissue defects, hyperopia, presbyopia and keratectasia. Although many studies have proven that the application of SMILE lenticule in these aspects is relatively effective and safe, studies with longer follow-up and larger sample sizes are required to confirm its long-term efficacy compared to current treatments, as well as its role as alternative management.

Author Contributions

All authors contributed to data analysis, drafting or revising the article, have agreed on the journal to which the article will be submitted, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests in this work.

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