Case Series

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Ten-year evaluation on efficacy, safety, and predictability of femtosecond laser corneal small incision lenticule extraction for correction of myopia and myopic astigmatism: a case series

Guo-Hong Zhao, PhD[a], Li-Jun Zhang, BSc[b], Yan Sun, BSc[b], Jin-Da Wang, PhD[a,*], Chang-Xi Chen, BSc[c,*], Kai Cao, PhD[c,*]

Objective: The objective was to evaluate the 10-year long-term outcomes of patients undergoing small incision lenticule extraction (SMILE).

Methods: In this continuous case series, the authors enrolled a total of 113 patients (208 eyes) who underwent SMILE 10 years prior. Measured parameters included uncorrected visual acuity (UCVA), corrected distance visual acuity (CDVA), and cycloplegia spherical equivalent error (SER).

Results: One hundred thirteen patients were enrolled in this study. Patients' age ranged from 18 to 44 years (mean: 30.2 years). One hundred ninety-three eyes (92.8%) and 176 eyes (84.6%) had an UCVA ≥ 20/20 at 3 months and 10 years postoperatively. The mean efficacy index, measured at 3 months and 10 years postoperatively, were 1.041 and 1.023, respectively; the difference was not statistically significant. Three months after the operation, best-corrected visual acuity (BCVA) decreased by 1 line in 19 eyes (9.1%), remained unchanged in 158 eyes (76.0%), and increased by ≥ 1 line in 31 eyes (14.9%). Ten years after operation, BCVA decreased by 2 lines in 15 eyes (7.2%) and by 1 line in 35 eyes (16.8%); remained unchanged in 142 eyes (68.3%); increased ≥ 1 line in 16 eyes (7.7%). The mean safety index, measured at 3 months and 10 years postoperatively, were 1.147 and 1.331, respectively; the difference was not statistically significant. The mean SER at 3 months and 10 years postoperatively was −0.112 and −0.276, respectively; the difference was statistically significant.

Conclusion: There was a decrease in SER 10 years after SMILE surgery compared with 3 months postoperatively, there was no significant decrease in the efficacy index or safety index.

Keywords: long-term follow-up, myopia, refractive surgery, small incision lenticule extraction

Introduction

With the extensive application of femtosecond laser technology in the field of ophthalmic refractive surgery in recent years, corneal refractive surgery has gradually developed in the direction of being minimally invasive or noninvasive, with small incision lenticule extraction (SMILE) being the most representative surgical method[1–11]. SMILE does not require the preparation of an open corneal flap, which greatly decreases the risk for related complications. In addition, SMILE preserves the corneal subcutaneous basal plexus, maintains good preservation of corneal biomechanics[12,13], and reduces the influence of surgery on the peripheral nerves of the cornea. Patients who undergo SMILE tend to recover rapidly and comfortably. However, despite the use of SMILE in clinical practice for 20 years, most clinical studies investigating SMILE have a follow-up duration of ≤ 2 years[1–11], while evidence based on long-term follow-up (≥ 5 years) has rarely been reported. As such, this study aimed to assess the 10-year long-term efficacy, safety, predictability, and stability of SMILE in patients with myopia and myopic astigmatism.

HIGHLIGHTS

- The highlight of this study is that the follow-up time is as long as 10 years, and the evidence evaluating the postoperative effect of femtosecond laser corneal small incision lenticule extraction for correction of myopia and myopic astigmatism for such a long time is rarely reported before.

Materials and methods

This was a retrospective case series study, the preparation for this work began in August 2023, the patients who underwent SMILE

[a]Beijing Tongren Eye Center, Beijing Tongren Hospital, Capital Medical University, Beijing, People's Republic of China, [b]Linyi Hospital of Traditional Chinese Medicine, Shandong, People's Republic of China and [c]Beijing Institute of Ophthalmology, Beijing Tongren Hospital, Capital Medical University, Beijing, People's Republic of China

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*Corresponding authors. Address: Beijing Institute of Ophthalmology, No. 17 Hougou Alley Dongcheng District Beijing People's Republic of China. Tel.: +10 582 659 00. E-mail: anzhen602@163.com (K. Cao), and E-mail: wjinda@163.com (J.D. Wang); E-mail: chenchangxi@163.com (C.X. Chen).

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surgery before 31 July 2013 were retrospectively reviewed. A total of 237 patients were identified, of which 178 were contacted, 113 were willing to participate and satisfied the inclusion and exclusion of our study. The work has been reported in line with the Preferred Reporting Of Case Series in Surgery (PROCESS) Criteria[14].

Inclusion criteria

1) Patients undergone SMILE surgery for correction of myopia and myopic astigmatism 10 years ago. 2) The patient had a complete record of examinations at 3 months after surgery, including uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), cycloplegia spherical equivalent error (SER), and intraocular pressure.

Exclusion criteria

1) Patients with eye diseases (glaucoma, diabetic retinopathy, cataract, age-related macular degeneration, uveitis, and optic neuropathy). 2) Ocular trauma. 3) History of ocular surgery. 4) With systemic immune disease. 5) Those who are unwilling to participate in the 10-year follow-up or could not achieve to participate in the follow-up.

Examinations

Ophthalmic examinations were done for all enrolled patients. Examinations included UCVA and BCVA using Snellen chart. The children's pupils were dilated using tropicamide eye drops, and the refractive error was subsequently measured using an autorefractor (ARK-510A; Nidek Co Ltd). A slit lamp microscope was used for anterior segment observation and an automatic noncontact tonometer (Canon TX-20; Canon Inc.) was used for intraocular pressure measurement. Fundus photography was performed with a Canon retinal fundus camera (CR-DGI; Canon, Inc.).

Outcomes

The outcomes included efficacy index, safety index, and surgical predictability. Efficacy index = postoperative UCVA/ preoperative BCVA.

Safety index = postoperative BCVA/preoperative BCVA[15–17].

The difference between attempted SER and achieved SER (DIF) was calculated, and the percentage of DIF within ±0.5 diopter (D) and ±1.0 D to assess the predictability[18–20].

Statistical analysis

For continuous outcomes, we calculated the mean values and SD. To evaluate the 10-year long-term efficacy and safety, the changes in safety index and efficacy index measured three months after surgery and 10 years after surgery were compared by paired *t*-test. Logistic regression was performed to explore the influence factors of UCVA decline. The significance level was 0.05, two-tailed. All statistical analysis was done using the open-source R program (https://www.r-project.org/, version 4.2.0).

Quality control

In order to ensure the continuity of data, each examination was completed by an inspector using the same equipment. Two ophthalmologists with more than 2 years of experience were responsible for the interpretation of fundus images. If there was disagreement, the final diagnosis was made by another senior ophthalmologist. Missing data was handled using a Markov chain Monte Carlo method.

Results

Characteristics of the participants and operated eyes

Two hundred thirty-seven patients undergoing SMILE surgery were retrospectively reviewed, 178 got in touch, 65 were excluded, finally, 113 cases (208 eyes), including 58 males and 55 females, were enrolled in this study (flow chart of participants selection see Fig. 1). The patients' age ranged from 18 to 44 years, with an average of 30.2 ± 5.1 years. The preoperative SER ranged from –3.5 to –7.5 D, with an average of –5.5 ± 1.1 D. The central corneal thickness ranged from 510 to 605 μm, with an average of 551.3 ± 29.4 μm. Corneal curvature ranged from 40.06 to 46.25 D. The intraocular pressure ranged from 13 to 21 mmHg.

All the operations were successfully completed, and the thickness of the lenticule ranged from 55 to 118 μm, with an average of 92.2 ± 17.2 μm. The residual bed thickness ranged from 281 to 398 μm, with an average of 335.3 ± 40.2 μm. Postoperative intraocular pressure ranged from 11 to 20 mmHg, with an average of 15.2 ± 1.3 mmHg.

Changes in visual acuity and the efficacy index

Before surgery

The BCVA was ≥ 20/25 in all eyes; ≥ 20/20 in 182 eyes (87.5%); ≥ 20/16 in 61 eyes (29.3%); and ≥ 20/12.5 in 22 eyes (10.6%).

Three months postoperatively

The UCVA was ≥ 20/25 in all eyes; ≥ 20/20 in 193 eyes (92.8%); ≥ 20/16 in 85 eyes (40.9%); and ≥ 20/12.5 in 32 eyes (15.4%) (Fig. 2).

Ten years postoperatively

The UCVA was ≥ 20/25 in all eyes; ≥ 20/20 in 176 eyes (84.6%); ≥ 20/16 in 72 eyes (34.6%); and ≥ 20/12.5 in 25 eyes (12.0%).

The mean (± SD) efficacy index, measured at 3 months and 10 years postoperatively, were 1.041 ± 0.179 and 1.023 ± 0.186, respectively; the difference was not statistically significant ($t = 0.614$; $P > 0.05$).

Influence factors of UCVA decline

Results of logistic regression showed that age (OR = 2.356) and time of near work (OR = 1.166) were the risk factors of UCVA (Table 1). The risk of decline in UCVA after 10 years increases by 2.356 times for every 1-year increase in age at the time of surgery. The risk of decline in UCVA after 10 years increases by 1.166 times for every 1 h increase in near work every day.

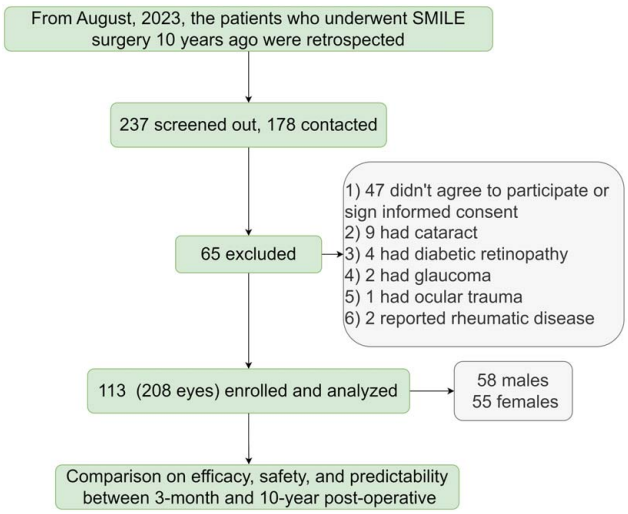

Figure 1. Flow chart of participants selection.

Changes in the safety index

Three months postoperatively

BCVA decreased by 1 line in 19 eyes (9.1%); remained unchanged in 158 eyes (76.0%); increased by 1 line in 25 eyes (12%); and increased by ≥2 lines in six eyes (2.9%). No BCVA decreased by ≥2 lines (Fig. 3).

Ten years after surgery

BCVA decreased by 2 lines in 15 eyes (7.2%) and by 1 line in 35 eyes (16.8%); remained unchanged in 142 eyes (68.3%); increased by 1 line in 13 eyes (6.3%); and increased by 2 lines in three eyes (1.4%).

The mean safety index, measured at 3 months and 10 years postoperatively, were 1.147±0.184 and 1.331±0.235, respectively; the difference was not statistically significant ($t=0.315$; $P>0.05$).

As to complications, 56 patients reported dry eye symptoms, and one reported ceratitis.

Table 1

Influence factors of uncorrected visual acuity decline.

Variables	β	P	OR	95% CI
Sex	−0.333	0.283	0.717	0.390 (1.316)
Age	0.857	0.002	2.356	1.365 (4.067)
SER	0.001	0.935	1.001	0.970 (1.034)
IOP	−0.098	0.841	0.907	0.350 (2.350)
Dry eye symptom	−0.004	0.459	0.996	0.985 (1.007)
Postoperative corneal edema	0.082	0.574	1.085	0.816 (1.444)
Time of near work	0.154	0.013	1.166	1.074 (1.267)

IOP, intraocular pressure; OR, odds ratio; SER, spherical equivalent error.

Predictability and stability of surgery

In this study, 177 (85.1%) and 151 (72.6%) eyes exhibited a DIF of within ±0.5 D 3 months and 10 years postoperatively, respectively, while 205 (98.6%) and 182 (87.5%) eyes exhibited a DIF of within ±1.0 D, respectively.

The mean SER at 3 months and 10 years postoperatively was −0.112±0.385 and −0.276±0.389, respectively; the difference was statistically significant ($t=4.125$; $P<0.05$).

Discussion

The short-term effects of SMILE for myopia correction have been reported in several studies, but there is a lack of evidence evaluating its long-term effects as well as safety, stability and predictability. In this study, patients who underwent SMILE for 10 years or longer were enrolled, the efficacy index, safety index, as well as the SER at 3 months and 10 years postoperatively were compared to assess the long-term effect.

In this study, the percentage of patients with UCVA ≥20/20 reached 92.8% at 3 months postoperatively and decreased to

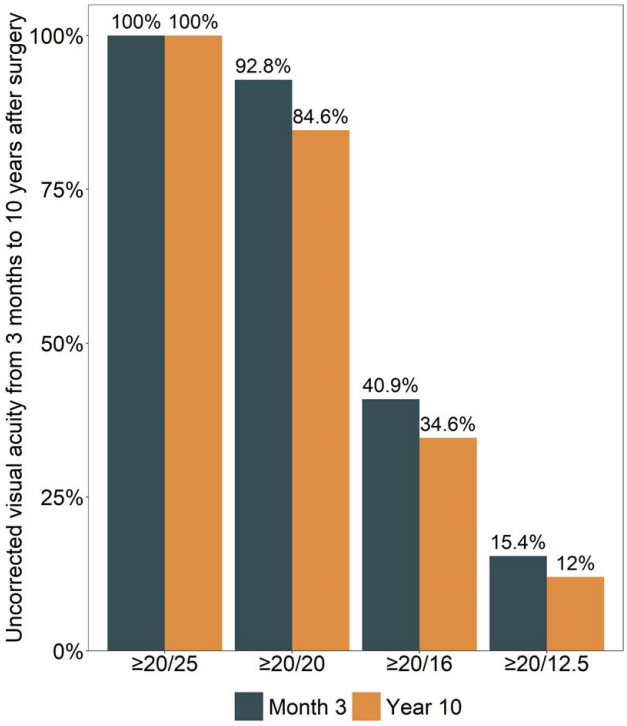

Figure 2. Distribution of uncorrected visual acuity three months and 10 years after surgery.

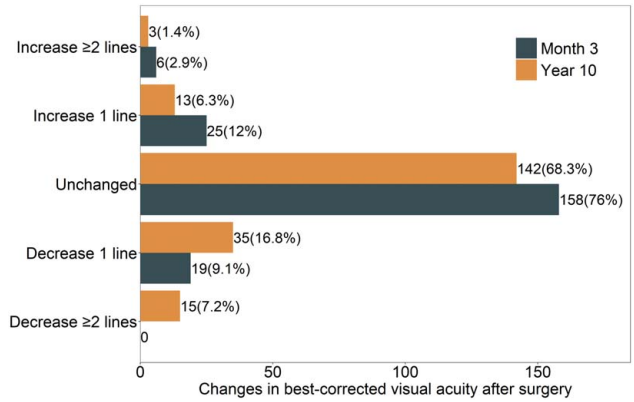

Figure 3. Changes of the best-corrected visual acuity 3 months and 10 years after surgery.

84.6% 10 years later. Xia *et al*.[9] reported that 100% of their patients achieved a UCVA of ≥20/20, which was better than our results due to two reasons. First, the follow-up period in the study by Xia *et al*.[9] was shorter than ours; and second, the mean age of the patients was 28.3 years, whereas the mean age in our study was 30.2 years.

Another important finding of our study is that age is a risk of UCVA, every 1-year increase in age at surgery increases the risk of UCVA decline 10 years later by 2.356 times. This is of great significance for the surgical guidance of patients undergoing SMILE. Doctors and patients must consider patient age before conducting SMILE. Considering that humans develop presbyopia with age, it is necessary to thoroughly consider the benefits of SMILE before conducting the operation; however, the older the patient, the shorter the benefit. Additionally, near-work time is also a risk factor for the postoperative decline in visual acuity. The risk for UCVA declines after 10 years is increased by 1.166 times for every 1 h increase in near-daily work. This risk factor is difficult to eliminate or alter because, with the development of the social economy, individuals have become increasingly inseparable from computers and mobile phones, which are all used with proximity to the eyes. In the future, there maybe a large market for the development of electronic screens that can cast near images into the distance. That is, the screen is still used nearby, but the image of the object in the screen is 3 m or 5 m away.

Interestingly, although theoretically dry eye symptoms may lead to unstable tear film and irregular corneal surface, thus causing vision loss, we did not find dry eye symptoms to be a risk factor of vision loss in the present study. There may be many reasons for this. On the one hand, the influence of dry eye symptoms on vision may not be as large as age and near work. Therefore, dry eye symptoms was not statistically significant in multivariate analysis after adjusting age and near work time. On the other hand, patients with dry eyes symptom may have received treatment during the 10 years follow-up, or the status of the tear film might be changed by other reasons.

In this study, the mean efficacy index at 3 months and 10 years postoperatively was 1.041±0.179 and 1.023±0.186, respectively, with no statistical difference. There were no differences in safety indicators between 3 months and 10 years postoperatively, indicating that the effect of SMILE could be maintained for ≥10 years.

In the present study, the difference between attempted SER and achieved SER was calculated, and the percentage of difference of within ±0.5 D, and ±1.0 D was used to assess predictability. The percentage difference of within ±0.5 D decreased from 85.1% 3 months postoperatively to 72.6% 10 years postoperatively. Furthermore, the percentage difference of within ±1 D decreased from 98.6 to 87.5%. The mean SER decreased from –0.112 to –0.276 D. The decrease in SER indicates a trend of refractive regression with time. However, this change may be caused by various factors, such as attenuation of the surgical effect or it may be linked with patient eye-use habits. For instance, excessive use of electronic screens may lead to myopia progression, even among adults[21,22].

In conclusion, 10 years after SMILE surgery, more eyes showed a decrease in visual acuity compared with 3 months after surgery, but there was no significant decrease in the efficacy index or safety index. SER decreased significantly.

Strength and limitation

The highlight of this study is that the follow-up time is as long as 10 years, and the evidence evaluating the postoperative effect of SMILE for such a long time is rarely reported before. The limitation is that considering that 237 patients were initially screened in this study, 178 patients were contacted, and only 113 patients finally responded, so the representativeness of the sample might be affected. Besides, we did not find retinal hemorrhage, active myopic choroidal neovascularization, or other severe fundus lesions in the participants. However, tessellation, tilted optic disc, beta peripapillary atrophy, and staphyloma were observed. But unfortunately, we are not sure when these fundus lesions occurred and how much impact they will have on vision, so we did not exclude these patients, which may cause bias to the results.

Ethical approval

This study was approved by the Ethics Committee of Beijing Tongren Hospital affiliated to Capital Medical University, and all patients voluntarily signed informed consent. The reference number is trec2023-ky082.

Consent

Written informed consent was obtained from the patient for publication and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

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None.

Author contribution

G.-H.Z.: data collection, data analysis, interpretation, and writing the paper; L.-J.Z. and Y.S.: data collection and reviewing the paper; C.-X.C.: interpretation and reviewing the paper; J.-D.W.; writing the paper; K.C.: study concept and design and writing the paper.

Conflicts of interest disclosure

The authors declares no conflict of interest.

Research registration unique identifying number (UIN)

Not registered.

Guarantor

Not applicable.

Data availability statement

Data will be available on reasonable request, please contact the corresponding author.

Provenance and peer review

Not invited.

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