

Clinical outcomes after small incision lenticule extraction versus femtosecond laser-assisted LASIK for high myopia: a Meta-analysis.

Yanyan Fu

Xiangya Hospital Central South University

Yewei Yin

Xiangya Hospital Central South University

Yang Zhao

Xiangya Hospital Central South University

Aiqun Xiang

Xiangya Hospital Central South University

Ying Lu

Xiangya Hospital Central South University

Tu Hu

Xiangya Hospital Central South University

Yuanjun Li

Xiangya Hospital Central South University

Kaixuan Du

Xiangya Hospital Central South University

Xiaoying Wu

Xiangya Hospital Central South University

Dan Wen (✉ wendan@csu.edu.cn)

Xiangya Hospital Central South University <https://orcid.org/0000-0001-7813-949X>

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Abstract

Background To compare postoperative clinical outcomes of high myopia after being treated by Small incision lenticule extraction (SMILE) and femtosecond laser in situ keratomileusis (FS-LASIK).

Methods Comprehensive studies were conducted on the PubMed, MEDLINE, EMBASE, the Cochrane Library, and Chinese databases. Trials meeting the selection criteria were quality appraised, and the data were extracted by 2 independent authors, and the RevMan 5.3 version software were used in analyzing.

Result Ten studies involving 637 patients (1093 eyes; 575 eyes in the SMILE group and 518 eyes in the FS-LASIK group) were included in this meta-analysis. Pooled result revealed no significant differences in the following outcomes: the logMAR values of postoperative UDVA (WMD = -0.01, 95% CI: -0.02, 0.00, $I^2=0\%$, $P = 0.10$ at postoperative 1mo; WMD = -0.01, 95% CI: -0.00 to 0.01, $I^2=0\%$, $P = 0.35$ at postoperative 3mo; WMD = -0.01, 95% CI: -0.02 to 0.01, $I^2=17\%$, $P = 0.26$ at long term), the logMAR values of postoperative CDVA (WMD = -0.02, 95% CI: -0.04 to 0.00, $I^2=0\%$, $P = 0.11$), and the postoperative mean refractive SE (WMD = 0.02, 95% CI: 0.04 to 0.08, $I^2=29\%$, $P=0.60$). In the long-term observation, postoperative tHOA (WMD = -0.10, 95% CI: -0.13 to -0.07, $I^2=15\%$, $P<0.00001$) and postoperative spherical aberration (WMD = -0.13, 95% CI: -0.17 to -0.09, $I^2=38\%$, $P<0.00001$) were found to be less in the SMILE group compared with the FS-LASIK group, but no significant difference was found in postoperative coma (WMD = -0.02, 95% CI: -0.04 to 0.00, $I^2=98\%$, $P=0.40$). We also found greater PCE change post FS-LASIK than SMILE at long term follow-ups (WMD = -0.69, 95% CI: -1.36 to -0.01, $I^2=0\%$, $P<0.05$, however, there was no significant difference between the two groups at 3- or 6- months. (WMD = -0.19, 95% CI: -0.41 to 0.03, $I^2=31\%$, $P=0.09$; WMD = -0.20, 95% CI: -0.50 to 0.10, $I^2=17\%$, $P=0.20$)

Conclusion For patients with high myopia, both SMILE and FS-LASIK are safe and efficacious. However, SMILE induced less tHOA and spherical aberration compared with FS-LASIK. Besides, FS-LASIK showed a greater increase in PCE than SMILE only at long term follow-ups. It remains to be seen whether the patients can get a better visual quality after SMILE and more comparative studies focused on high myopia is necessary.

Background

With the increasing proportion of high myopia, high requirements for the predictability and the visual quality of a refractive surgery are put forward [1]. Compared with low to moderate myopia, patients with high myopia cause more postoperative wound healing increasing the risk of stromal haze formation and refractive regression, reduced long-term stability of the obtained refractive correction [2, 3]. In addition, for high myopia, postoperative clinical outcome and visual quality are generally difficult to reach the expected condition [4]. Consequently, which kind of corneal refractive surgery is more suitable for high myopia is not only a concern for patients, but also an issue for ophthalmologists to research on.

Recently, SMILE and FS-LASIK have become the most popular options in corneal refractive surgery. FS-LASIK has proved to be effective, safe and predictable for treating myopia [5]. However, the creation of the corneal flap and the ablation of the stroma limit the application of FS-LASIK, which may increase the risk of treatment regression, corneal biomechanics changes and flap complications. Small incision lenticule extraction (SMILE) becomes a new option for patients and the corneal flap production is replaced by the removal of the corneal stroma lenticule from a minimized incision to reduce the complications of corneal flap and dry eye [6].

Many scholars have focused on the clinical efficacy of these two kinds of refractive surgery. However, most studies on comparison after SMILE and FS-LASIK consider correction of low to moderate myopia [7, 23, 34, 36], only a few comparative studies [2, 4] targeted population of high myopia. Hence, the aim of this meta-analysis is to review on the existing comparative studies in greater depth for understanding the differences between SMILE and FS-LASIK in terms of the safety, efficacy, predictability, and visual quality when correcting high myopia. And the changes of corneal biomechanical were also discussed in this meta-analysis.

Methods

A meta-analysis was performed in accordance with Meta-analysis of Observational Studies in Epidemiology (MOOSE) guideline [8], following the generally accepted recommendations [9].

Search strategy

In order to gather records that compare SMILE and LASIK for treating high myopia as many as possible, two reviewers independently searched the electronic database as follows, PubMed, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL) and a Chinese database (CNKI, WANFANG and Weip) from March 2018 to April 2019. The following keywords were used in the search: high myopia (e.g. high myopia, high short-sight, high nearsighted or high correction), LASIK (e.g. LASIK or Keratomileusis, femtosecond laser in situ keratomileusis) and SMILE (e.g. SMILE, lenticule extraction, small incision lenticule extraction). The search process of PubMed was showed in Fig. 1. No date or language restrictions in the electronic search were used, and the last search was on November 24, 2019. Two reviewers firstly screened the titles and abstracts independently, and then, the potentially relevant reports were assessed as complete manuscripts, and finally they selected the articles in accordance with our inclusion criteria. Any disagreements between the reviewers were eliminated through discussion, and two reviewers reached a consensus about the result and interpretation eventually.

Inclusion criteria

This meta-analysis adopted the following criteria to assess whether those articles were included: (1) study design: randomized or non-randomized clinical trials; (2) population: patients with high myopia (preoperative spherical equivalent up to -6.00 diopters, or Sphere more than- 5.00 diopters and Cylinder

more than- 1.00 at the same time); (3) intervention: SMILE versus FS-LASIK; (4) outcome variables: visual acuity or aberration or other parameters that represent clinical outcomes; (5) data: original clinical articles with independent data.

Exclusion criteria

1) Repeated publications, 2) or unpublished literature, 3) abstracts, case-reports, reviews, letters, comments non-comparative studies and non-human investigations, 4) or reports with incorrect or incomplete data were excluded.

Data extraction

Two independent reviewers extracted data from the included studies using a customized form. Some outcomes were presented with subgroups according to the follow-up time (e.g. within 1 month or long term after surgery). The reason for this method was that 1-month data can demonstrate the short-term effect after the operation, while the latter can reflect the long-term effect. In addition, heterogeneity will be significant if the data at different follow-up times are analyzed together. The following parameters were extracted:

1. The primary outcomes measures represent postoperative safety, efficacy and predictability, for instance, the logMAR values of uncorrected distance visual acuity (UDVA) and the logMAR values of corrected distance visual acuity (CDVA), and Postoperative mean refractive spherical equivalent (SE)

2. The secondary outcomes measures were objective parameters of aberration, in some respects, suggesting postoperative visual quality Including total higher-order aberration (tHOA), spherical aberration, coma. And corneal biomechanical parameters including posterior corneal elevation (PCE) changes, CH and CRF values.

Although there were multiple reports for a particular study, data from the most recent and representative publication were almost extracted.

Quality assessment

Because the clinical study of FS-LASIK and SMILE for correction of myopia is difficult to achieve completely random control and double-blind method, only one [13] was a randomized controlled study, most of the included studies are non-randomized comparative trial. The quality of included studies was assessed by Newcastle-Ottawa scale (NOS) [10] which was adopted to evaluate the cohorts. The scores of these 10 included studies were revealed in Table 1, along with judgement about each risk of bias item for each included study (Fig. 2). The Average score of these 10 studies is 5.8 (NOS: ranged from minimum of 0 (low quality) and maximum of 9 (high quality)).

Statistical analysis

Meta-analysis was conducted by RevMan 5.3 statistical software, using weight mean difference (WMD) and the corresponding 95% confidence interval (CI) to calculate the continuous outcomes. Firstly, we used I^2 to test the heterogeneity of the included literature, and the fixed-effect modeling was carried out when there was no statistical heterogeneity between the literature ($P \geq 0.1, I^2 < 50\%$). Conversely, the random-effect modeling was used for analysis when the included literature bore significant evidence of statistical heterogeneity ($P < 0.1, I^2 > 50\%$). The results were presented by Z value, and each Z value corresponded to a P value, which was considered to be significant statistical difference when less than 0.05.

Sensitivity analysis and publication bias

In order to evaluate the robustness of statistical model, a sensitivity analysis was carried out by “leave-one-out” analysis, which was used to exclude each included study in turn and quantize the influence of the individual studies on the pooled estimates. The results showed that when study of Li-kun Xia et al was excluded [11], the I^2 value of UDVA in LogMAR within 1 mo had reduced sharply, and the P value showed a stable statistical difference. The funnel plots (Fig. 3B) also showed qualitatively symmetrical when we excluded the study by Li-kun Xia et al, statistically with the Egger’s test [12] ($P = 0.207$ to 1.000) and Begg’s tests [13] ($P = 0.246$ to 1.000) for the studies indicated no obvious publication bias.

Results

Search Results

Figure 1 was a flow-process diagram of the selection of publications in this study. Initially, A total of 79 potentially eligible publications were selected through the electronic database. Then except for 12 duplicate reports, 67 papers underwent title and abstract screening. 33 studies were excluded as a result of following reasons: 11 studies did not have control group, and just made a separate description of SMILE or FS-LASIK; and 7 studies’ control groups were not SMILE and FS-LASIK; meanwhile there were 15 Studies whose subjects were not high myopia. Finally, there remained 10 studies [2,3,11,14-20] that met our inclusion criteria and they were included in this meta-analysis.

Study Characteristics and Quality

Table 1 summarized the main characteristics and the quality assessment of these 10 included studies, which were published from 2014 to 2019. A total of 637 patients (1093 eyes) were evaluated, with 575 eyes in the SMILE group (53%) and 518 eyes in the FS-LASIK group (47%). All of these 10 included studies were retrospective non-random control trials. Therefore, studies were assessed by Newcastle-Ottawa scale (NOS)

(**Table 1**), we also revealed judgements about each risk of bias item for each included study (**Figure 1**). Overall, these included studies showed a good quality (Average score of NOS:6.0).

Primary Outcomes

The logMAR values of postoperative UDVA. Of these 10 articles, 4^[11,14-16] reported the the logMAR values of postoperative UDVA. And we excluded the study by Likun Xia et al^[11] in the first subgroup because its high sensitivity. An examination of the forest plot showed that, for high myopia, there was no significant statistical difference between the SMILE group and FS-LASIK group in UDVA after 1- and 3-month follow-ups(WMD=-0.01; 95% CI:-0.02,0.00;I²=0%; P=0.10,WMD=-0.00; 95% CI:-0.00 to 0.01;I²=0%; P=0.35;**Figure 3A**).And 3^[11,14,16]studies were followed up for a longer period of time, and the same results were obtained at long term after surgery(WMD=-0.01; 95% CI:-0.02 to 0.01,I²=17%;P=0.26,**Figure 3A**).And the same is true for the total results(WMD = -0.00, 95% CI, -0.01 to 0.00, I²=3%,P = 0.38,**Figure 3A**). And the Funnel plots (**Figure 3B**) suggested a slim possibility of publication bias.

Postoperative Mean Refractive SE. There are 4 studies^[14-17] compared the postoperative mean refractive SE outcomes between the SMILE and FS-LASIK groups. The forest plot showed no significant differences in postoperative mean refractive SE between both groups for patients with high myopia(WMD =0.02, 95% CI:-0.04 to 0.08, I²=29%, P=0.60,**Figure 5**).

Secondary Outcomes

Aberration

3 studies^[11,14,17] presented the data of postoperative aberration at long term follow-ups. We extracted data at 3 years after operation from 2 studies by Likun Xia^[11] and Tian Han^[14], and data at 6 months after operation from Xiaojing li's^[17] study. Due to the measurement bias, there was heterogeneity among these 3 studies, **Table 3** shows the differences in the measurement of aberrations in 3 included studies.

Postoperative tHOA. The tHOA forest plots indicated significant differences between the two groups. For high myopia, both SMILE group and FS-LASIK group would lead to a higher tHOA, but the postoperative tHOA in SMILE group was significantly lower than that in FS-LASIK group at a long period of observation(WMD =-0.10, 95% CI:-0.13 to -0.07, I²=15%, P<0.00001,**Figure 6**).

Postoperative Spherical aberration. SMILE group also introduced less Spherical aberration than FS-LASIK group after long term follow-up(MD =-0.13, 95% CI:-0.17 to -0.09, I²=63%, P<0.00001,**Figure 7**).

Postoperative Coma. For high myopia ,no significant difference was found in the postoperative coma between SMILE group and FS-LASIK group with long term observation after surgery(WMD =-0.02, 95% CI:-0.04 to 0.00, I²=98%, P=0.40,**Figure 8**)

Biomechanical effects

PCE change. There are 2 include studies^[2,19] described the change in PCE, and the change in PCE at 3, 6 and long term post operation for high myopia are shown in **Figure 9A**. At 3 and 6 months post operation, no significantly difference was found in the PCE change between the two groups(WMD =-0.19, 95% CI:-0.41 to 0.03, I²=31%, P=0.09;WMD =-0.20, 95% CI:-0.50 to 0.10, I²=17%, P=0.20,**Figure 9A**). By long term

observation(Bingjie Wang^[2]:1 year; Xueyi Zhou^[19]:2 years), PCE change was significantly greater in the FS-LASIK group than the SMILE group (WMD =-0.69, 95% CI:-1.36 to -0.01, I²=0%, P≤0.05 ,Figure 9A).And the same result was found the total outcomes(WMD = -0.22, 95% CI:-0.40 to -0.05, I²=0%,P = 0.01,Figure 9A). And the Funnel plots (Figure 9B) presented a symmetrical distribution suggesting a slim possibility of publication bias.

CH and CRF values. There are only 2 include studies^[2,20] provided biomechanical parameters :CH and CRF of the cornea. Although both articles are measured with the ORA (Ocular Response Analyzer) device, there is a lack of comparability between the data. We tabulated the data about CH and CRF of the cornea(Table 2).For patients with high myopia ,post-operative CH values for both procedures were statistically significantly lower than preoperative values(P≤0.001), however between the two groups, there was no statistically significant difference (Bingjie Wang et al^[2];Iben Bach Pedersen^[20]).Similarly, postoperative CRF values were significantly lower than preoperative values for both groups, however between the two groups, The reduction in CRF at 6 and 12 months was significantly greater in the FS-LASIK group than the SMILE group(Bingjie Wang et al^[2]).But Iben Bach Pedersen^[20] reported no significantly difference between SMILE group and FS-LASIK group.

Discussion

This Meta-analysis focused on the patients with high myopia from the view of postoperative clinical outcomes and visual quality after SMILE or FS-LASIK and made systematic comparative analysis.

The Primary Outcomes illustrated both SMILE group and FS-LASIK group had good efficacy, safety, predictability for treating high myopia. In terms of efficacy, the result of the logMAR values of UDVA in the SMILE group had no significant difference compared with that of the FS-LASIK group, suggested that both SMILE and FS-LASIK could bring a good visual acuity for high myopia. Besides, Likun Xia^[11] reported the proportions of eyes achieving UDVA of 20/20 or better (92.3% in the SMILE group and 90.8% in FS-LASIK group) with 3 years follow-up. In refractive surgery, the overall safety may be assessed by the induced change in CDVA, the logMAR values of CDVA showed no significant difference between the two groups. In general, loss or gain of two or more lines on the Snellen visual acuity card is considered to be significant and noticeable for the patient. 1 study^[11] revealed that the proportion of eyes losing one or more lines of BCVA showed no significant difference between the SMILE group(0%) and FS-LASIK group(0%).When it comes to predictability, no significant difference was found in the postoperative mean refractive SE between the two groups at long term follow-ups. Guofu Chen^[16] also reported the proportion of eyes with postoperative refractions within ± 0.50 D of the targets(90.1% in the SMILE group and 76.6% in FS-LASIK group) with 6 months follow-up.

Related studies^[21–22] had mentioned that many patients suffered glare with halo or decrease of contrast sensitivity in dark environment during the early stage of postoperative recovery, which may be caused by the increase of postoperative aberrations after operation. When patients had higher requirements for

visual quality, we should focus more on visual quality involved not only visual acuity, but also aberration, contrast sensitivity and other objective parameters.

The Secondary Outcomes suggested that, both in the SMILE group and FS-LASIK group, the value of postoperative aberrations had significantly increased with long term observation. FS-LASIK, moreover, introduced a larger tHOA and spherical aberration than SMILE, but no difference was found in Coma between the two groups. There were complex reasons, for example, SMILE had less traumatism to the cornea, hence the postoperative aberration caused by corneal epithelial cell proliferation was less than FS-LASIK [23]. Besides, the corneal flap had more obvious effect on higher order aberrations, an unbalanced healing and a deviation or displacement of corneal flap, especially in high myopia, both of these situations can lead to a sharp increase in aberration [24].

Primarily, the increasing of postoperative tHOA occurred more in the FS-LASIK group at long term follow-up. Possible reasons accountable for the results are as follows, firstly, the different ways to remove corneal tissue. Because the increase of high order aberration induced by corneal refractive surgery mainly comes from corneal flap and stroma bed. The effect of corneal flap is more obvious, and the deviation or displacement of corneal flap can lead to the increase of high order aberration [27]. Secondly, the different ways of wound healing [17], the design of small incision and the non-lifted flap lenticule extraction technique in SMILE caused less disruption of the peripheral nerve and collagen fibers and maximally persisted more structural integrity of the cornea than FS-LASIK. Moreover, Riau's study^[25] suggested that, in vivo, excimer laser in LASIK released more cytokines and chemokines which recruited the inflammatory cells to the injury site. On the contrary, SMILE with small size of incision and the femtosecond laser treatment may result in less wound healing time and less corneal inflammation, which played an important role in aberration.

Spherical aberration of cornea is one of the most important factors that limit the optical quality of the retinal image and the spatial resolution capabilities of the visual system. The occurrence of spherical aberration was influenced by the biomechanical factors. Li's research [17] discussed the aberration compensation between anterior and posterior corneal surfaces after SMILE and FS-LASIK, it pointed out that the posterior corneal surface plays a compensatory role in the balance of spherical aberrations. The increase of the spherical aberration on the anterior cornea surface was much more remarkable than that on the posterior surface because the ablation of the laser was performed on the anterior surface of the cornea. So that, the weak aberration of the posterior surface cannot compensate enough for the much stronger aberration of the anterior surface. This may explain why FS-LASIK introduces more spherical aberrations in high myopia. Besides during the process of corneal remodeling, the corneal flap was more likely to bring a non-spherical change of cornea which also contribute to the increase of spherical aberration [26].

There seems to be no difference in the coma introduced by the two procedures. Wu [27] also indicated that the changes of coma after SMILE had its own characteristics. For instance, small incision (2 ~ 4 mm) and separation of lenticule made the wound healing mode different from that for FS-LASIK, and the coma

along the incision direction (vertical direction) changed greatly with only a little effect on the horizontal direction. Other scholars believed that the increase in vertical coma after smile was related to the imbalanced optical changes along the axis [17], and a certain amount of vertical coma may be beneficial to the visual quality for high myopia, however, this view needed to be further discussed. In FS-LASIK, the pedicle of corneal flap was located on the horizontal plane of cornea, which may accordingly produce the coma in the horizontal direction. Palikaris [28] had also proved that the increase of horizontal coma can be associated with the amblopia after FS-LASIK.

Contrast sensitivity was another important index reflecting the subjective quality of vision from the patient's perspective. In this analysis, we only found one comparative study [11] that reported about the changes of CS after refractive surgery in patients with high myopia. With 3 years follow-up, no significant differences in CS values for all spatial frequencies (1.5, 3, 6, 12 and 18cqd) were found between SMILE group and FS-LASIK group. The change of CS was associated with spatial frequency, light condition, pupil diameter size and many other factors. Although some scholars suggested that FS-LASIK guided by wave-front aberration can significantly improve the postoperative contrast sensitivity [29], we still needed more direct evidence and more comprehensive comparative studies for high myopia to explain the differences in CS between these two groups.

We also discussed corneal biomechanical changes post SMILE and FS-LASIK. Anterior corneal stroma become thinner after refractive surgery, the morphology and curvature of corneal surface are changed at the same time, especially the morphology of posterior surface. Some patients with high myopia faced the risk of refractive regression, which can directly affect the long-term stability of refractive, and even leads to iatrogenic corneal dilatation, keratoconus and other complications. The precursors of these diseases are shown as corneal ectasia of posterior surface

We found Change in PCE has statistical significance only at long term follow-ups, there was no significant difference between the two groups at 3- or 6- months post operation. Many studies [2, 14, 19] have reported similar results and provide complementary evidence for high myopia. Although the FS-LASIK procedure has been optimized by the femtosecond laser in past 10 years, complications relating to the corneal flap still occur in an otherwise perfect FS-LASIK [25]. Because a flap is necessary before laser ablation, that could fracture the corneal biomechanical stability. SMILE, with flapless procedure, not only have fewer complications, but also leaves the anterior-most stromal lamellae intact after the procedure [2]. Besides Dawson [30] found that the Bowman's layer to be the strongest part of the cornea. Obviously, SMILE has less microdistortions in the Bowman's layer compared with FS-LASIK. This stability may be advantageous long term, as seen in our study. It is reasonable to presume that posterior surface was more stable after SMILE compared with LASIK. However, change in PCE was related to many factors, such as high myopia, low-residual stromal bed [31, 32], curvature and remaining thickness of Cornea. More comparative research needs to be done with eliminating these interference factors, to make this point more valid.

CH represents corneal resistance to deformation, in other words, the viscoelasticity of the corneal tissue, while CRF indicates the resistance of the whole cornea^[33]. Several studies suggested lower CH and CRF values may indicate a biomechanically weaker cornea^[34, 35], like in keratoconus eyes. Wang^[2] found that SMILE biomechanical parameters demonstrated a slight recovery at 12 months, while FS-LASIK biomechanical parameters continued a downward trend. Biomechanically, SMILE removes the corneal tissue in the deeper and relatively weaker stroma, thus, SMILE could leave the cornea with greater biomechanical strength than LASIK. It is known that CH and CRF values are correlated with corneal thickness. It may be reasonable to speculate that for high refractive correction, and thus in thinner residual stromal bed, the advantages of SMILE on corneal biomechanical may be more obvious and stable. Some scholars also reported that CH and CRF were reduced post SMILE and FS-LASIK, with less change in biomechanical parameters in SMILE^[36]. And in the middle and low myopia, there was no significant difference between the two procedures^[37].

In the statistical process of this meta-analysis, several important limitations may lead to bias. First was the measurement bias, caused by extracting data of aberration from different wave-front analyzers (Table 3). Sensitivity analysis was performed by excluding one study at a time, and the heterogeneity of these results were stable. Secondly, bias of follow-up time. We reduced this bias by dividing the outcomes into subgroups. Thirdly, selection bias. Most subjects of included studies were from Asia.

Conclusions

In conclusion, both SMILE and FS-LASIK had comparable safety and efficacy when used for correcting high myopia. However, this analysis indicated that SMILE procedure may had advantages in some respect, especially for high myopia, SMILE introduced less tHOA and Spherical aberration than FS-LASIK and maximally protects the structural integrity of the cornea. Ultimately, further randomized, double-blinded, prospective studies with longer period of follow-up focusing on high myopia were necessary to provide a better evidence for this conclusion, meanwhile such studies would provide useful guidelines and better choice of refractive surgery for patients with high myopia.

Abbreviations

SMILE: Small incision lenticule extraction; FS-LASIK: Femtosecond laserassisted laser in situ keratomileusis; FS: Femtosecond laser; WMD: Weighted mean difference; UDVA:Uncorrected distance visual acuity; CDVA:corrected distance visual acuity;SE:Spherical equivalent; tHOA: Total higher-order aberration; PCE:Posterior corneal elevation; NOS:Newcastle-Ottawa scale; PRISM: Preferred reporting items for systematic reviews and meta-analyses;

Declarations

Ethics approval and consent to participate

This study followed the tenets of the Declaration of Helsinki and was approved by the ethics committee of XiangYa Hospital, Central South University. Informed written consent was obtained from all participants.

Consent for publication

Not applicable.

Availability of data and materials

Available upon request from the first author; Dr. Yanyan Fu.

Competing interests

All authors declare that they have no competing interests.

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Authors' contributions

Yanyan Fu :drafted the manuscript and data collection and statistics. Yewei Yin:data collection.Yang Zhao and Aiqun Xiang participated in the statistical analysis.Tu Hu and Yuanjun Li helped to draft the manuscript. Dan Wen and Xiaoying Wu participated in the design of the study and project funding.Kaixuan Du>Data collection and material preparation.All authors read and approved the final manuscript.

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Tables

Table 1 Characteristics of the 10 Included Studies

Table 2. Summary of comparison in parameter CH and CRF

Table 3. Measurement bias of 3 included studies.

Included studies	Types of refractive surgery			Different measurements of aberrations
	SMILE	VS	Wavefront-guided FS-LASIK	
Likun Xia et al [3]				HOAs, WASCA wavefront analyzer; Carl Zeiss Meditec AG, Jena, Germany
Tian Han et al [15]			SMILE VS FS-LASIK	Pentacam HR, Type 70900, Wetzlar, Germany
Xiaojing Li [17]			SMILE VS FS-LASIK	Pentacam; Oculus GmbH, Wetzlar, Germany

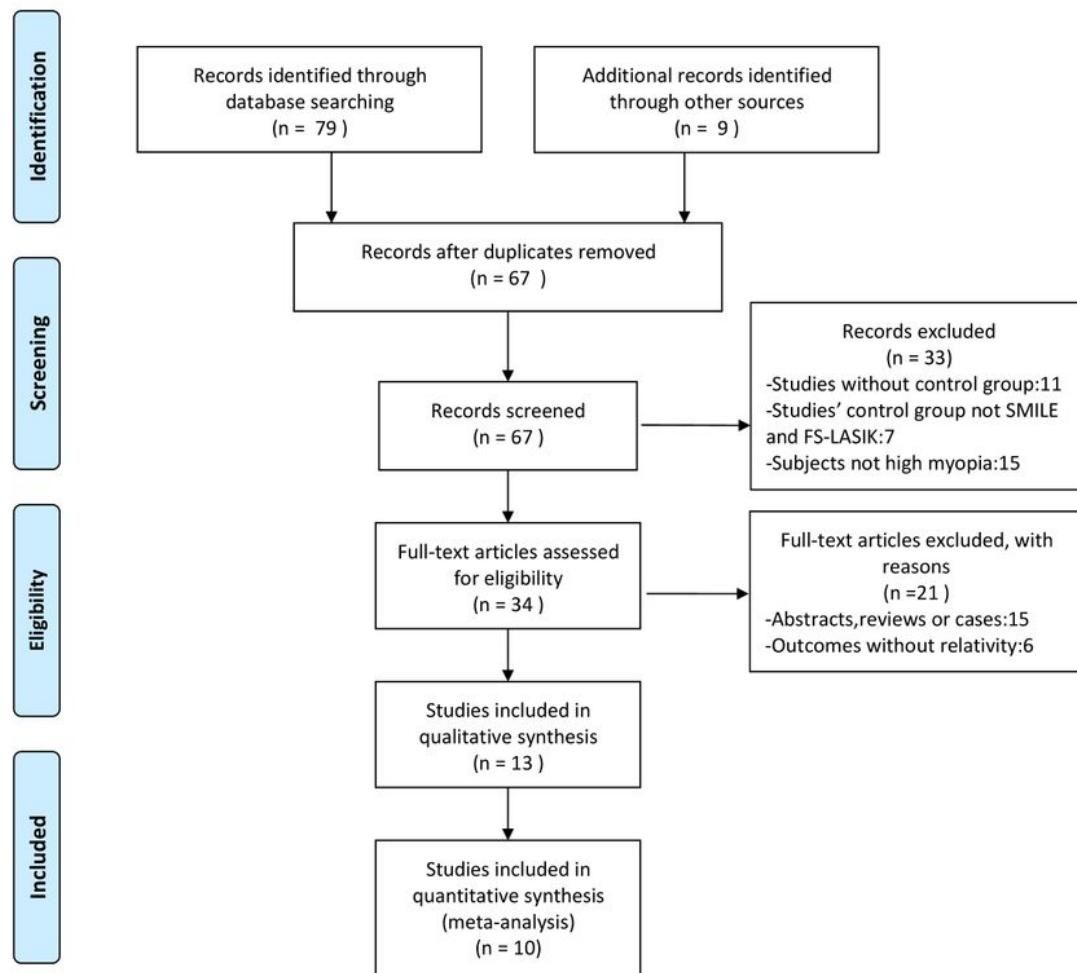
Figures

Study or subgroup	Year	Design	Language	SMILE group		FS-LASIK group		Follow-up (mo)	NOS
				Eyes (n)	SE (D)	Eyes (n)	SE (D)		
Bingjie Wang [2]	2016	CT	English	50	-7.60±1.12 (≤-6.00)	56	-7.68±1.19 (≤-6.00)	12mo	6
Bingjie Wang [3]	2015	CT	English	47	-7.46±1.11 (≥-6.00)	43	-7.44±1.13 (≥-6.00)	12 mo	6
Likun Xia [11]	2018	CT	English	78	-8.11±1.09 [-6.00~-12.00]	65	-8.05±1.12 [-6.00~-12.00]	36mo	6
Tian Han [14]	2018	CT	English	60	-6.54±1.69 (≥-6.00)	41	-7.15±1.92 (≥-6.00)	36mo	7
Congrong Jing [15]	2018	CT	Chinese	134	-6.00~-10.00	106	-6.00~-10.00	3mo	5
Guofu Chen [16]	2017	RCT	Chinese	64	-9.59±0.57 (≤-9.00)	64	-9.77±0.56 [≤-9.00]	6mo	6
Xiaojing Li [17]	2015	CT	English	55	Sphere :-5.74±1.39 Cylinder :-0.66±0.70 (≥-6.00)	51	Sphere :-6.18±1.61 Cylinder :-0.83±0.66 (≥-6.00)	6 mo	5
Yueming Zhou [18]	2016	CT	Chinese	66	≤7.58±2.14 (-6.125 ~ -9.75)	66	-7.62±1.83 (-6.00~9.875)	6mo	5
Xueyi Zhou [19]	2019	CT	English	39	-10.79±0.81 (-10.00~-13.00)	34	-11.06±0.99 (-10.00~-14.50)	24mo	6
Iben Bach Pedersen [20]	2014	CT	English	29	-5.50~-10.5	35	-5.5 to -10.5	12mo	6

Included studies	Measurement	Difference	Time	SMILE	FS-LASIK	P value or Significant difference
Bingjie Wang [2] Iben Bach Pedersen [20]	The Ocular Response Analyzer(ORA) (Reichert, Inc, Depew, NY)	Difference in CH	Month 6 - Preoperative CH □(P < 0.001)	□ -2.67±1.29	-2.42±1.38	P=0.327
			Month12 - Preoperative CH □(P < 0.001)	-2.55±1.44	-2.53±1.38	P=0.942
		Difference in CRF	Month 6 - Preoperative CH □(P < 0.001)	□ -2.53±1.22	-3.09±1.46	P=0.037
	Ocular Response Analyzer (ORA) (Reichert Inc. Depew, NY)		Month12 - Preoperative CH □(P < 0.001)	-2.24±1.29	-3.33±1.34	P≤0.001
		Difference in CH	Postoperative CH (more than one year)	8.56±0.19	8.58±0.15	No Significant difference
		Difference in CRF	Postoperative CRF (more than one year)	7.12±0.23	7.12±0.18	No Significant difference



PRISMA 2009 Flow Diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed.1000097

For more information, visit www.prisma-statement.org.

Figure 1

Flow Diagram of the literature search.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bingjie Wang 2015	?	+	?	+	+	+	+
Bingjie Wang 2016	-	+	?	+	+	+	+
Congrong Jing 2018	-	+	-	+	+	+	?
Guofu Chen 2017	+	+	-	+	+	+	+
Iben Bach Pedersen 2014	-	+	-	+	+	+	+
Likun Xia 2018	?	+	?	+	+	+	+
Tian Han 2018	-	+	-	?	+	+	+
Xiaojing Li 2015	-	?	+	+	+	+	?
Xueyi Zhou 2019	-	?	?	+	+	+	+
Yueming Zhou 2016	-	-	+	+	+	+	+

Figure 2

Judgements about each risk of bias item for each included study.

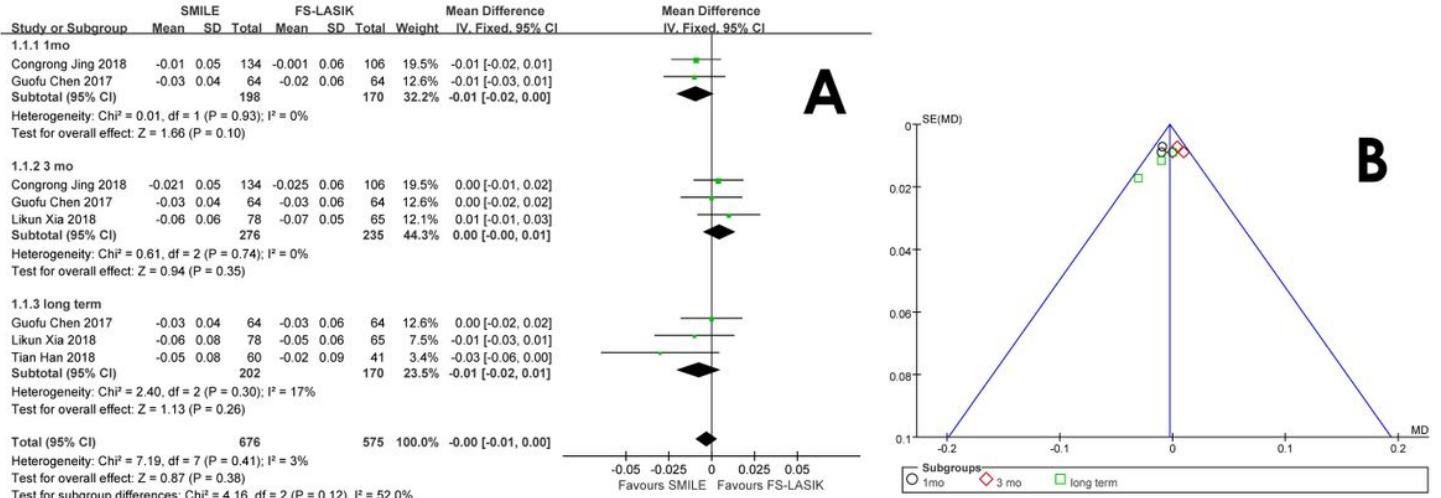


Figure 3

The logMAR values of UDVA after SMILE versus FS-LASIK.

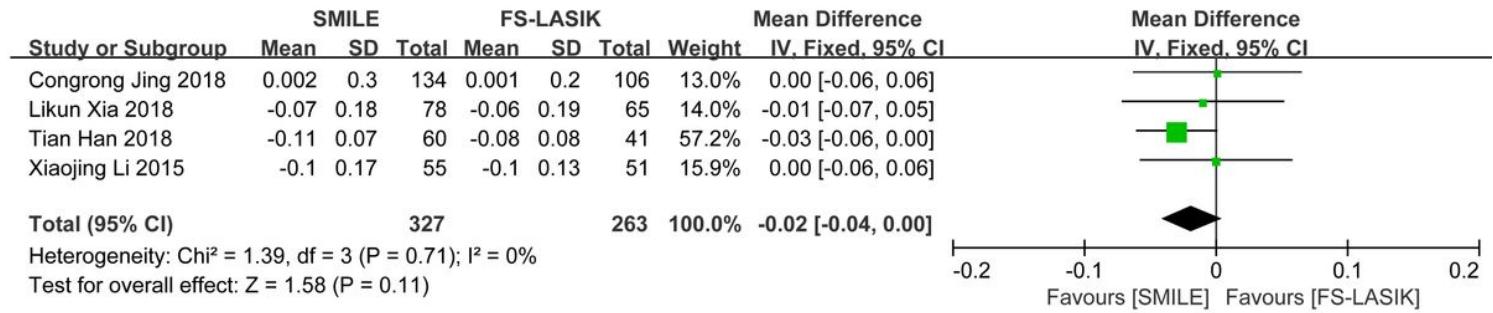


Figure 4

The logMAR values of CDVA after SMILE versus FS-LASIK.

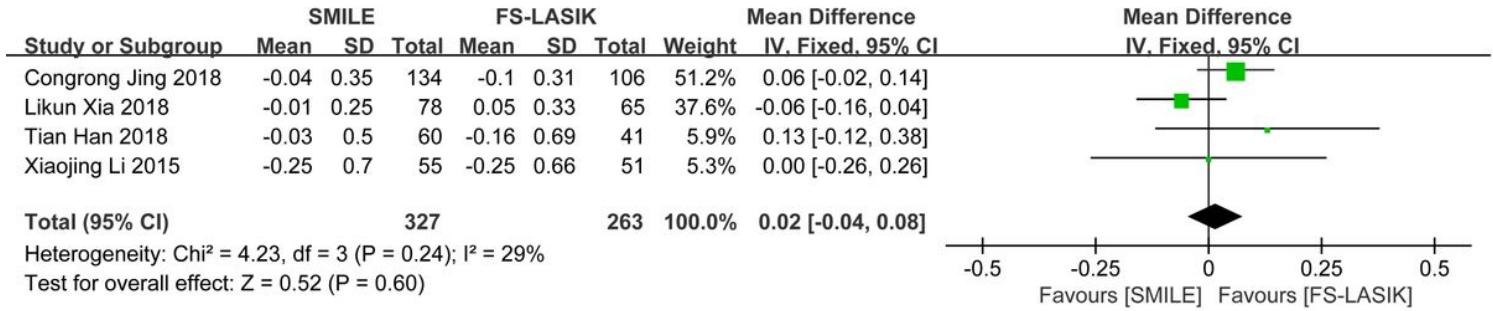


Figure 5

Postoperative mean refractive SE after SMILE versus FS-LASIK.

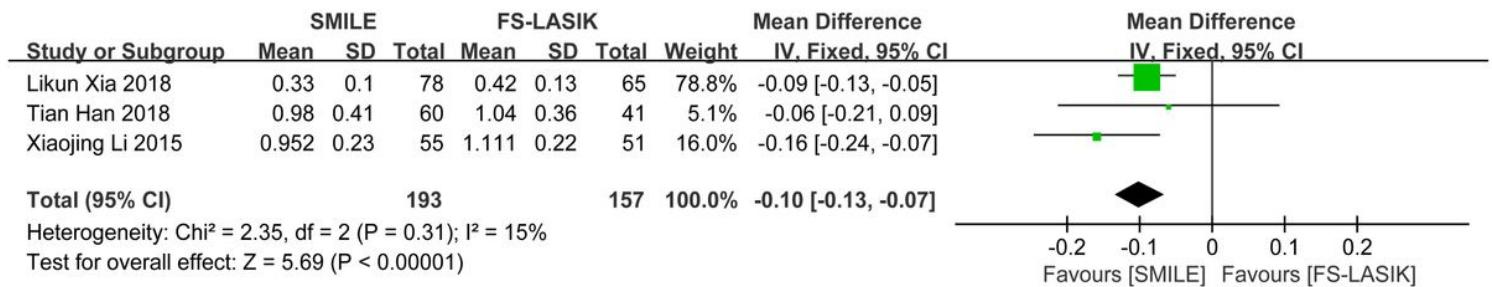


Figure 6

Postoperative tHOA after long term follow-up.

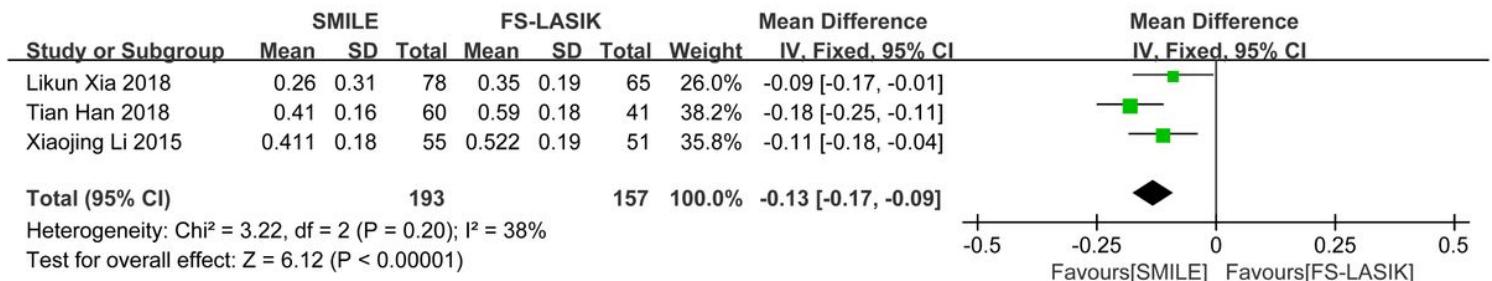


Figure 7

Postoperative Spherical aberration after long term follow-up.

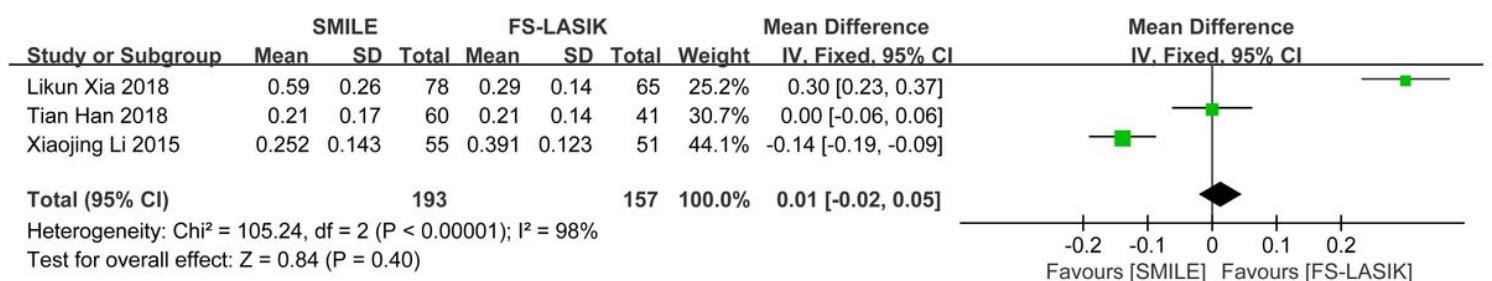


Figure 8

Postoperative Coma after long term follow-up.

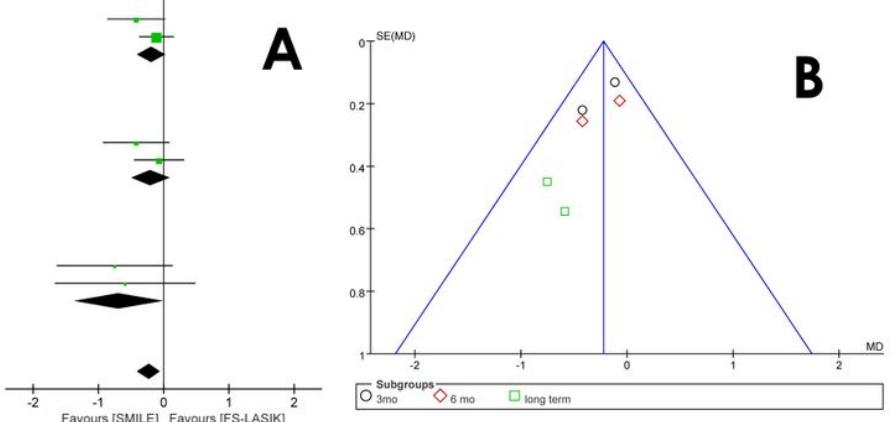
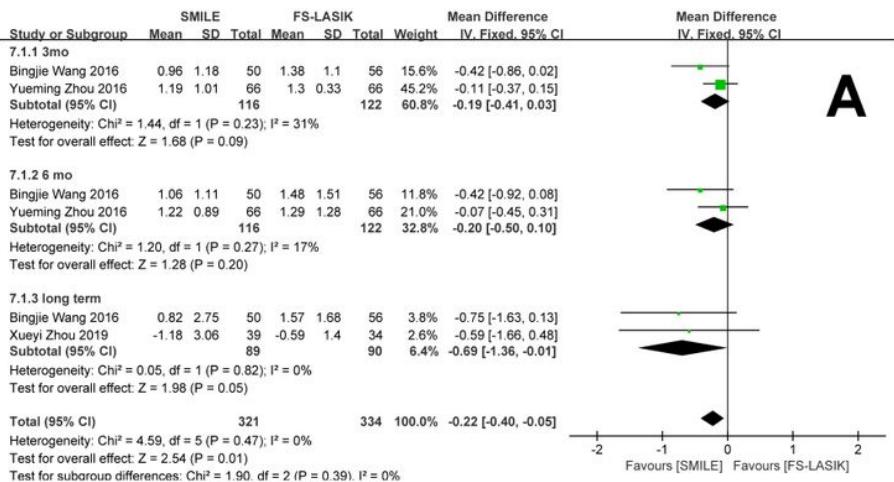


Figure 9

Change in PCE after after SMILE versus FS-LASIK.

Supplementary Files

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- [REFERENCE16.pdf](#)
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