• Meta-Analysis •

Small-incision lenticule extraction versus femtosecond lenticule extraction for myopic: a systematic review and Meta-analysis

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Abstract

• AIM: To examine differences in efficacy, accuracy, safety, aberrations and corneal biomechanical between small incision lenticule extraction (SMILE) and femtosecond lenticule extraction (FLEx) for myopia.

• METHODS: Comprehensive studies were conducted on the PubMed, MEDLINE, EMBASE, and Cochrane Controlled Trials Register before 31 July, 2015. Meta-analyses were performed on the primary outcomes [loss of ≥2 lines of corrected distance visual acuity (CDVA), uncorrected distance visual acuity (UDVA) ≥20/20, spherical equivalent (SE) within ±0.50 diopters (D), final refractive SE], secondary outcomes were high-order aberrations (HOAs) and corneal biomechanical [central corneal thickness (CCT), corneal hysteresis (CH) and corneal resistance factor (CRF)].

• RESULTS: Seven trials describing a total of 322 eyes with myopia were included in this Meta-analysis. No significant differences were found in the efficacy [UDVA weighted mean difference (WMD) -0.01; 95%CI: -0.04 to 0.01; *P*=0.37, UDVA ≥20/20, OR 1.49; 95%CI: 0.78 to 2.86; *P*=0.23], accuracy (SE WMD -0.03; 95%CI: -0.12 to 0.07; *P*=0.58 , SE within ±0.5 D OR 1.25; 95%CI: 0.34 to 4.65; *P*=0.74), HOAs (WMD -0.04; 95%CI: -0.09 to 0.01; *P*=0.14) and CCT WMD 1.83; 95%CI: -7.07 to 10.72; *P*=0.69, CH WMD -0.01; 95%CI: -0.42 to 0.40; *P*=0.97, CRF WMD 0.17; 95%CI: -0.33 to 0.67; *P*=0.50) in the last fellow-up. But for safety, FLEx may achieve fewer CDVA lost two or more two lines (OR 11.11; 95%CI: 1.27 to 96.86; *P*=0.03) than SMILE, however CDVA (WMD 0.00; 95%CI: -0.03 to 0.02; *P*=0.77) is similar.

• CONCLUSION: SMILE and FLEx are comparable in terms of both efficacy, accuracy, aberrations and corneal biomechanical measures in the follow-up，but FLEx seems to be better in safety measures. The results should be interpreted cautiously since relevant evidence is still limited, although it is accumulating. Further large-scale, well-designed randomized controlled trials are urgently needed.

• **KEYWORDS:** myopia; small-incision lenticule extraction; femtosecond lenticule extraction; Meta-analysis

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INTRODUCTION

Myopia is the first most common eye disorder, which seriously affecting to more than 80% Asian people[1-2]. Refractive surgery is the most popular and effective treatment, especially in China. In recent years, refractive lenticule extraction (ReLEx) is a relatively new refractive procedure using the femtosecond laser for the correction of refractive errors[3-11]. The ReLEx technique has been used for femtosecond lenticule extraction (FLEx) by lifting a hinged flap as well as for small-incision lenticule extraction (SMILE) without the flap, which has been developed as the basis of femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK) and proposed as an alternative to conventional LASIK. Using ReLEx technique, only a few side effects were found in 1000 successful operations, approximately. Numbers of eyes treated is currently being expanded that is good for further standardize of this technique. FLEx demands an about 20-mm side cut, whereas SMILE just need to cut 3 to 4 mm for corneal flap making. Visual function, corneal subbasal nerve density, corneal biomechanical, ocular surface parameters and subjective symptoms may be affected by the difference in side-cut length after these new procedures. There are a limited number of articles comparing the outcomes between the 2 surgical procedures[12-23], however the results are not completely consistent. As we all known FLEx procedure is only rarely performed today. Maybe one of the reasons is that there is no a Meta-analysis to compare the 2 surgical procedures, which many surgeons thought SMILE is better than FLEx. But this Meta-analysis may change our mind.

Therefore, we aim to compare differences in efficacy, accuracy, safety, changes in aberrations and corneal biomechanical properties between SMILE and FLEx for myopic in this Meta-analysis.

MATERIALS AND METHODS

Search Strategy In the following databases, data source articles from January 2000 to 31 July, 2015 were searched: PubMed, MEDLINE, EMBASE, and Cochrane Library. Key words included the following terms: "small incision lenticule extraction" or "femtosecond lenticule extraction" and "SMILE" or "FLEx". All of the selected comprehensive studies' titles and abstracts were independently browsed by two authors (Wang JS and Jia Y). Then the two (Wand JS and Jia Y) carefully read the full texts of the remaining studies and their bibliographies to decide whether they met all of the inclusion criteria or not. No language restriction was used on the publications.

Inclusion and Exclusion Criteria Inclusion criteria as follows were used to identify studies: 1) case-control study, cohort, cross-sectional, retrospective study and randomized controlled trials (RCTs); compared SMILE and FLEx for myopic correction; 2) any degree of myopia patients without history of ocular surgery and systemic disease; and 3) reported at least one of the outcome measures: logMAR corrected distance visual acuity (CDVA), logMAR uncorrected distance visual acuity (UDVA), loss of ≥2 lines of CDVA, UDVA20/20 or better, spherical equivalent (SE), SE within ±0.50 D, high-order aberrations (HOAs), central corneal thickness (CCT), corneal hysteresis (CH) and corneal resistance factor (CRF). Duplicate studies and studies that data can't be used were excluded.

Data Extraction Data were carefully collected into a standardized form from the included studies by two independent authors (Wang JS and Xie HT) according to the inclusion criteria. First author, publication time, country, mean age, gender, number of eyes and quality scores were extracted from the eligible articles. Numbers of eyes were not restriction defined. The disagreements between the reviewers were resolved after discussion with another author (Zhang MC).

Quality Assessment Jadad *et al*[24] scale was used to evaluate the methodologic quality of each study according to 3 dimensions: randomization, masking, and participant withdrawals/dropouts. And one additional point was added for each if randomization or blinding were appropriate. The maximum score is 5 when all of the 3 aspects get the highest score. The two reviewers (Wang JS and Xie HT) assessed the scores independently using this method and discussed each other to resolve the disagreements. Studies scored higher than 3 were regarded as high quality.

Statistical Analysis Not all trials reported original outcomes of interest. If necessarily data couldn't be obtained from the texts, they would be calculated. RevMan software (version 5.2; Cochrane Collaboration, Oxford, United Kingdom) was adopted for statistical analysis. The 95% confidence interval (CI), a pooled odds ratio (OR) with 95%CI and weighted mean difference (WMD) was calculated for summary estimates, dichotomous outcomes and continuous outcome, respectively. Meanwhile, statistical heterogeneity was assessed by the use of Chi-square test, tau^2 and Higgins I^2[25]. If I^2 is lower than 50% that would indicate a minor heterogeneity existed and fixed-effects model would be used for analysis, otherwise, it's a significant heterogeneity and random-effects model would be applied[26]. If P<0.05, it was considered to be statistically significant[27]. If there was a correlation between summary estimates and sample size obviously, it suggested the presence of publication bias that would be checked out by the funnel plot[28].

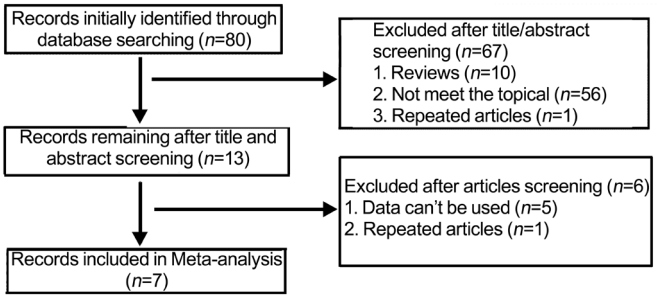

Figure 1 The flow chart of selection of trails.

RESULTS

Results of Search The flow chart of selection of studies is showed in Figure 1. Among 80 relevant studies yielded by searches terms, 8 articles[12-19] satisfied our inclusion criteria. Of these, one[19] was from the same patient group that had already been included[14,16]. Eventually, a total of 7[12-18] published between 2013 to 2015 were adopted for final Meta-analysis. There were no statistically significant differences in baseline measurements between the two groups of each article.

Study Characteristics and Quality Three RCTs[12,14,16] and 4 nonrandomized controlled trials[13,15,17-18] totally contained 322 eyes (201 in SMILE group and 189 in FLEx group). Actually, 2 trials[14,16] assigned the same eyes of each group, which contained different outcomes. So we just included 35 eyes of each group for one time. Finally, 166 in SMILE group, 154 in FLEx group and 320 eyes totally were included. The characteristics and Jadad score of the seven trials were listed in Table 1. Sample scale ranged from 20 to 35. Four[12,14-16] trials were paired-eye studies and the other 3 studies [13,17-18] used two different populations. Five of the seven articles[12-14,16,18] had follow-up ≥6mo. Four trials[12-13,15,17] had 100% completeness of follow-up and 3 trials[14,16,18] reported participant withdrawals or dropouts. Finally, Jadad score of the 7 trials higher than 3 that showed all of them with high quality.

Efficacy Measures LogMAR UDVA was available in four publications[12-14,17], and no statistically significant difference was discovered between the two groups (WMD -0.01; 95%CI:

Table 1 Basic characteristics and Jadad score of the seven studies

First author, year	Country	No. of eyes		Mean preop. SE(D)		Fu (mo)	Jadad score
		SMILE	FLEx	SMILE	FLEx		
Kamiya, 2014 [12]	Japan	26	26	-4.21±1.63	-4.18±1.72	6	5
Agca, 2014[13]	Turkey	20	20	-4.03 ±1.61	-4.46±1.61	12	4
Vestergaard, 2014[14]	Denmark	35	35	-7.56±1.11	-7.59±0.97	6	5
Kamiya, 2014[15]	Japan	24	24	-4.1±1.7	-4.1±1.7	3	4
Vestergaard, 2014[16]	Denmark	35	35	-7.56±1.11	-7.59±0.97	6	5
Kobashi, 2015[17]	Japan	26	26	-4.87±1.67	-4.47±1.43	3	4
Ang, 2014[18]	Singapore	35	23	-5.84±2.12	-5.9±2.01	12	3

SE: Spherical equivalent; Fu: Follow up.

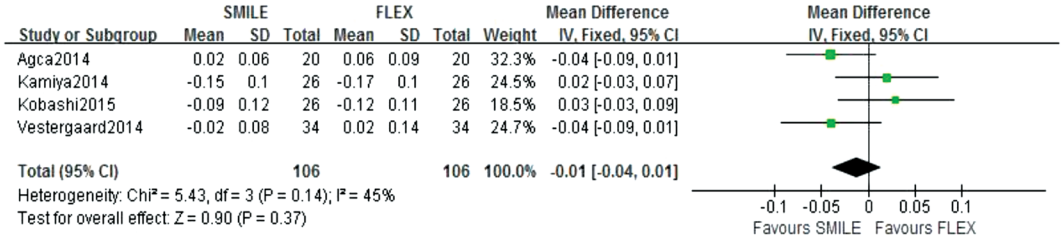

Figure 2 Forest plot of logMAR UDVA after SMILE *vs* FLEx UDVA: Uncorrected distance visual acuity; SMILE: Small incision lenticule extraction; FLEx: Femtosecond lenticule extraction; df: Degrees of freedom; Chi^2: Chi-square test; I^2: Extent of inconsistency; Z: Overall effect.

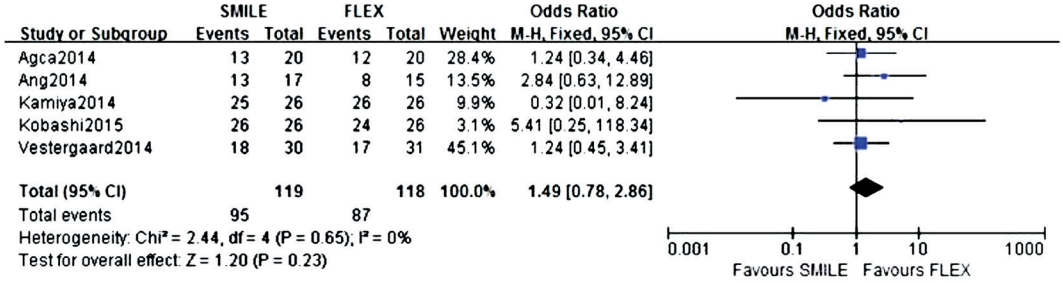

Figure 3 Forest plot of proportion of eyes with UDVA ≥20/20 after SMILE *vs* FLEx UDVA: Uncorrected distance visual acuity; SMILE: Small incision lenticule extraction; FLEx: Femtosecond lenticule extraction; df: Degrees of freedom; Chi^2: Chi-square test; I^2: Extent of inconsistency; Z: Overall effect.

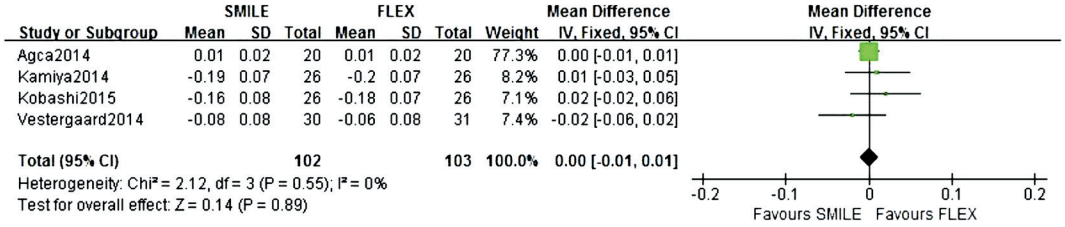

Figure 4 Forest plot of logMAR CDVA after SMILE *vs* FLEx UDVA: Uncorrected distance visual acuity; SMILE: Small incision lenticule extraction; FLEx: Femtosecond lenticule extraction; df: Degrees of freedom; Chi^2: Chi-square test; I^2: Extent of inconsistency; Z: Overall effect.

-0.04 to 0.01; *P*=0.37) (Figure 2). The results didn't be changed after sensitivity analysis of excluding the two nonrandomized controlled trials[13,17] (WMD -0.01; 95%CI: -0.05 to 0.03; *P*=0.61).

UDVA of 20/20 or better was available in five publications[12-14,17-18]. No statistically significant difference in comparing the two groups was discovered (OR 1.49; 95%CI: 0.78 to 2.86; *P*=0.23) (Figure 3). The results didn't be changed after sensitivity analysis of excluding the three nonrandomized controlled trials[13,17-18] (OR 1.07; 95%CI: 0.41 to 2.78; *P*=0.89).

Safety Measures LogMAR CDVA was available in four trials[12-14,17] that included 205 eyes. No statistically significant difference was found in this outcome between SMILE group and FLEx group (WMD 0.00; 95%CI: -0.01 to 0.01; *P*=0.89) (Figure 4). The results didn't be changed after sensitivity analysis of excluding the two nonrandomized controlled trials[13,17] (WMD 0.00; 95%CI: -0.03 to 0.02; *P*=0.77).

The data of patients losing ≥2 was available in four trials[12-14,17]. Among them 8 eyes with SMILE and 1 eye with FLEx had lost ≥2 lines of CDVA after surgery in 1 trial[17] and the other

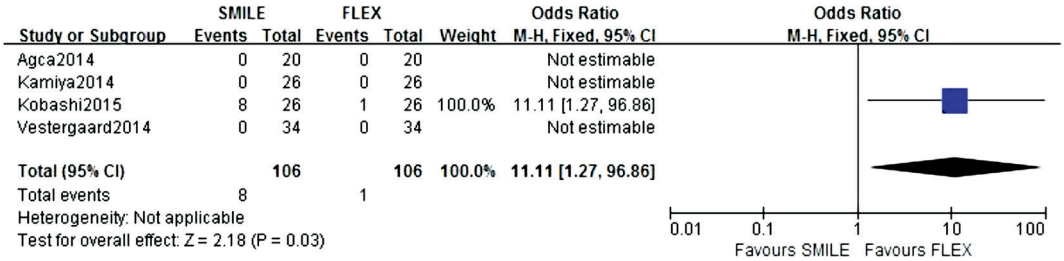

Figure 5 Forest plot of proportion of eyes with CDVA lost two or more lines after SMILE *vs* FLEx CDVA: Corrected distance visual acuity; SMILE: Small incision lenticule extraction; FLEx: Femtosecond lenticule extraction; Z: Overall effect.

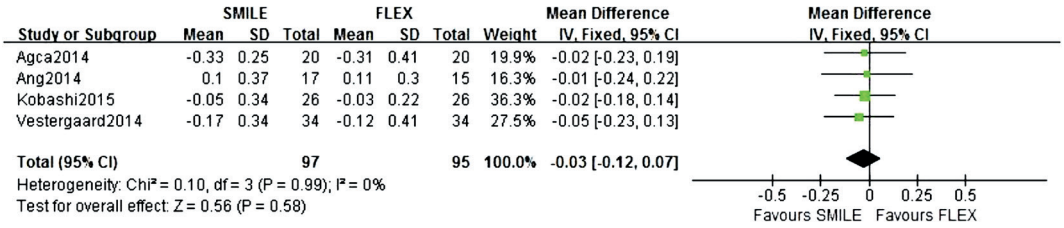

Figure 6 Forest plot of SE after SMILE *vs* FLEx SE: Spherical equivalent refraction; SMILE: Small incision lenticule extraction; FLEx: Femtosecond lenticule extraction; df: Degrees of freedom; Chi^2: Chi-square test; I^2: Extent of inconsistency; Z: Overall effect.

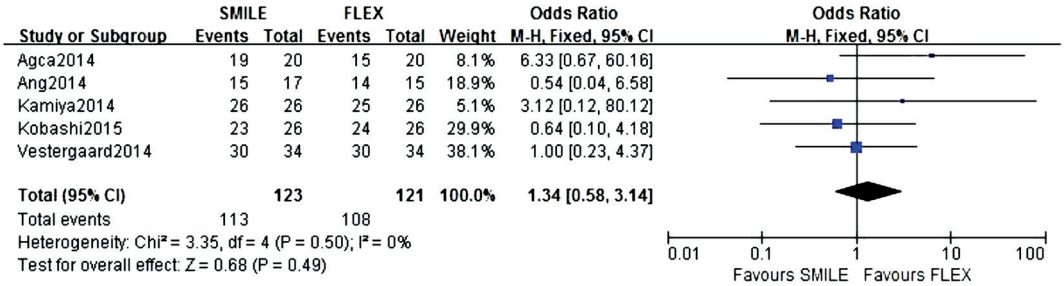

Figure 7 Forest plot of proportion of eyes SE within±0.50 D after SMILE *vs* FLEx SE: Spherical equivalent refraction; SMILE: Small incision lenticule extraction; FLEx: Femtosecond lenticule extraction; df: Degrees of freedom; Chi^2: Chi-square test; I^2: Extent of inconsistency; Z: Overall effect.

three trials[12-14] without eyes lost more than 2 lines of CDVA. A statistically significant in this outcome was discovered (OR 11.11; 95%CI: 1.27 to 96.86; *P*=0.03) (Figure 5).

Accuracy Measure Meta-analysis was achieved on account of 5[13-14,16-18] studies reported data of SE. But there were two studies[14,16] come from the same patients and materials, so we just included Vestergaard *et al*[14] in this part. No significant difference was discovered in SE (WMD -0.03; 95%CI: -0.12 to 0.07; *P*=0.58) (Figure 6).

Refractive within ±0.5 D was available in five trials [12-14,17-18], and no significant difference was appeared in forest plot (OR 1.34; 95%CI: 0.58 to 3.14; *P*=0.49) (Figure 7). The results didn't be changed after sensitivity analysis of excluding the three nonrandomized controlled trials [13,17-18] (OR 1.25; 95%CI: 0.34 to 4.65; *P*=0.74).

Higher-oder Aberrations Two trials[13-14] including 108 eyes reported anterior corneal aberration values in optical zone diameters ≥5 mm.The forest plot showed that no significant difference was existed between the groups (WMD -0.04; 95%CI: -0.09 to 0.01; *P*=0.14) (Figure 8). The results didn't be changed after sensitivity analysis of excluding the nonrandomized controlled trial[13] (WMD -0.03; 95%CI: -0.09 to 0.03; *P*=0.33).

Corneal Biomechanical CCT were available in four trials[13-16] that included 224 eyes. CH were available in two trials[15-16] that included 116 eyes. And CRF were available in two trials[15-16] that included 116 eyes. No statistically significant difference was discovered in comparing the 2 groups in corneal biomechanical parameters, respectively CCT (WMD 1.83; 95%CI: -7.07 to 10.72; *P*=0.69) (Figure 9A), CH (WMD -0.01; 95%CI: -0.42 to 0.40; *P*=0.97) (Figure 9B) and CRF (WMD 0.17; 95%CI: -0.33 to 0.67; *P*=0.50) (Figure 9C). The results didn't be changed after sensitivity analysis of excluding the nonrandomized controlled trials of each subgroup.

Heterogeneity Heterogeneity test is trying to find whether there are genuine differences between the results (heterogeneity) or whether the variation is just an accident event (homogeneity). Excitingly, all studies passed the test of heterogeneity (*P*≥0.1).

Publication Bias There was no obviously correlation between study sample and any other evidence of publication bias for the comparison from the funnel plot.

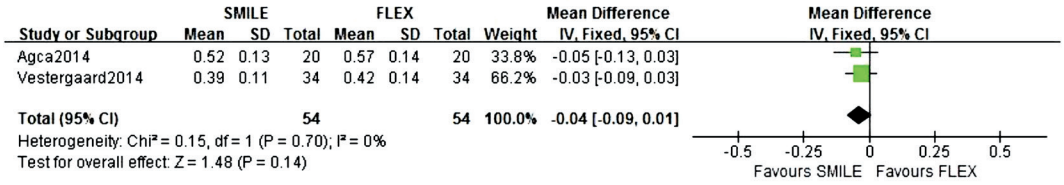

Figure 8 Forest plot of total HOAs derived from the anterior corneal surface after SMILE *vs* FLEx HOAs: Higher-order aberrations; SMILE: Small incision lenticule extraction; FLEx: Femtosecond lenticule extraction; df: Degrees of freedom; Chi^2: Chi-square test; I^2: Extent of inconsistency; Z: Overall effect.

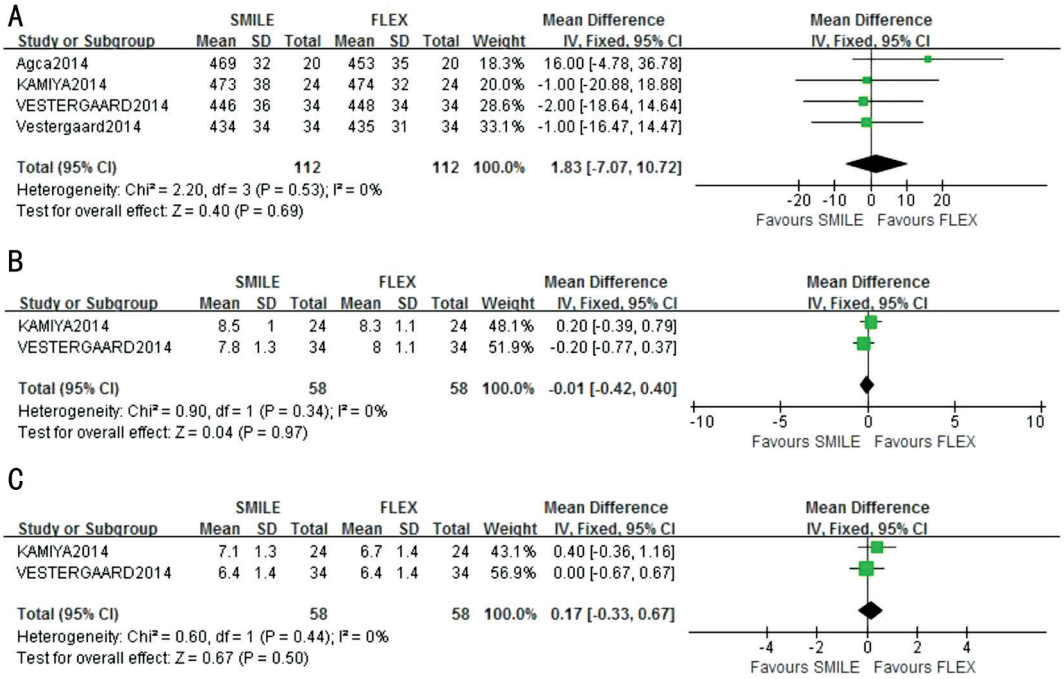

Figure 9 Center corneal biomechanical [CCT (A), CH (B), CRF (C)] after SMILE *vs* FLEx CCT: Central corneal thickness; CH: Corneal hysteresis; CRF: Corneal resistance factor; SMILE: Small incision lenticule extraction; FLEx: Femtosecond lenticule extraction; df: Degrees of freedom; Chi^2: Chi-square test; I^2: Extent of inconsistency; Z: Overall effect.

DISCUSSION

Our study compared the outcomes of SMILE and FLEx based on the published comparative articles for myopia and myopic astigmatism. The pooled results showed that no significant difference was discovered in the proportion of eyes with UDVA, CDVA, UDVA ≥20/20, within ±0.50 D of target refraction, HOAs, CCT, CH, CRF. A significant difference was existed in CDVA lost 2 or more lines postoperatively between the 2 groups. But the result for safety measure (loss of ≥2 lines of CDVA) was less conclusive because only 1 trial was estimated and no sensitivity analysis could be performed. As far as we know, it will be the first study to compare SMILE and FLEx using Meta-analysis and will provide a new reference for clinical work.

"All femto" method was initially introduced for FLEx by lifting a hinged flap above and further developed as SMILE without lifting a flap and the latter had been developed as the basis of FS-LASIK and proposed to replace LASIK for myopia all over the word. Relatively, SMILE appeared fewer dry eye and corneal sensitivity than FS-LASIK that shown different length of side-cut may affect visual quality, corneal biomechanical properties and so on after refractive operation. FLEx is a fairly new technique which was introduced in Germany since 2008[29]. Whereas, the most recently rapidly gaining popularity technique is SMILE, which was described by Sekundo *et al*[6] and became clinically available in 2011. There are limited studies comparing SMILE and FLEx maybe because of both of them are still very new techniques. Meanwhile, the eyes of the comparative studies are usually small samples that have been published. Four articles[20-23] compared SMILE and FLEx about the outcomes of corneal sensation , corneal subbasal nerve density, Schirmer's test and tear film break-up time, but the number of studies is too little to accomplishing a Meta-analysis. Given the low frequency of poor outcomes, large sample size and well-designed RCT is required in the future to detect potential differences.

Although the results are positively, but the limitations also should be pointed out. Firstly, the follow-up was finitude and disunion. Most of the available data was observed within 1y which would limit the value of conclusions. Unfortunately,

subgroup analysis according to follow-up could be running. Secondly, limited number of included trails and small sample of each trial make the analyses with low power. Similarly, subgroup analysis according to the degree of myopia could be running. Thirdly, only published data was included and the publication bias may be existed. Although, funnel plots of safety, efficacy, accuracy, HOAs and corneal biomechanical show that the bias may be ruled out. The last but not least, the species of devices of femtosecond laser and instruments of eye examination didn't be considered in our research. Nevertheless, this Meta-analysis provides more powerful evidence for our clinically work than the individual reports alone.

To sum up, our results suggest that SMILE and FLEx have comparable in terms of efficacy, accuracy, aberrations and corneal biomechanical measures. In addition, FLEx may achieve fewer CDVA lost two or more lines than SMILE, although CDVA is similarity. Long-term follow-up RCTs with large sample and well-designed are needed to determine the relative merits in both SMILE and FLEx.

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Conflicts of Interest: **Wang JS,** None; **Xie HT,** None; **Jia Y,** None; **Zhang MC,** None.

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