·Meta-Analysis·

Efficacy, safety, predictability, aberrations and corneal biomechnical parameters after SMILE and FLEx: Meta-analysis

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Abstract

• AIM: To identify possible differences of efficacy, safety, predictability, higher-order aberrations and corneal biomechnical parameters after small-incision lenticule extraction (SMILE) and femtosecond lenticule extraction (FLEx).

• METHODS: A systematic literature retrieval was conducted in Medline, Embase and the Cochrane Library, up to October, 2015. The included studies were subject to a Meta-analysis. Comparison between SMILE and FLEx was measured as pooled odds ratio (OR) or weighted mean differences (WMD). Of 95% confidence intervals (CI) were used to analyze data.

• RESULTS: A total of seven studies were included. Firstly, there were no differences in uncorrected distance visual acuity (UDVA) 20/20 or better (OR, 1.37; 95% CI, 0.69 to 2.69; P=0.37) and logMAR UDVA (WMD, -0.02; 95% CI, -0.05 to 0.01; P=0.17) after SMILE versus FLEx. We found no differences in corrected distance visual acuity (CDVA) unchanged (OR, 0.98; 95% CI, 0.46 to 2.11; P=0.97) and logMAR CDVA (WMD, -0.00; 95% CI, -0.01 to 0.01; P=0.90) either. Secondly, we found no differences in refraction within ±1.00 D (OR, 0.98; 95% CI, 0.13 to 7.28; P=0.99) and ±0.50 D (OR, 1.62; 95% CI, 0.62 to 4.28; P=0.33) of target postoperatively. Thirdly, for higher-order aberrations, we found no differences in the total higher-order aberrations (WMD, -0.04; 95% CI, -0.09 to 0.01; P=0.14), coma (WMD, -0.04; 95% CI, -0.09 to 0.01; P=0.11), spherical (WMD, 0.01; 95% CI, -0.02 to 0.03; P=0.60) and trefoil (WMD, -0.00; 95% CI, -0.04 to 0.03; P=0.76). Furthermore, for corneal biomechanical parameters, we also found no differences (WMD, 0.08; 95% CI, -0.17 to 0.33; P=0.54) after SMILE versus FLEx.

• CONCLUSION: There are no statistically differences in efficacy, safety, predictability, higher-order aberrations and corneal biomechnical parameters postoperative between SMILE and FLEx.

• **KEYWORDS:** visual quality; aberrations; corneal biomechnical parameters; small-incision lenticule extraction; femtosecond lenticule extraction

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INTRODUCTION

Femtosecond laser has been introduced into the refractive surgery market for laser *in situ* keratomileusis (LASIK) flaps for decades [1]. The femtosecond laser has offered some advantages over manual microkeratomes, including increased accuracy, fewer flap correlated complications, and the ability to cut thinner flaps without the risk of forming a button hole [2-3]. In 2006, a new breakthrough called refractive lenticule extraction (ReLEx) for correcting myopia and myopic astigmatism was introduced [4]. In this procedure, neither a microkeratome nor an excimer laser was required. It used only the femtosecond laser system for flap creating and lenticule processing [5]. It was first conducted as femtosecond lenticule extraction (FLEx). Clinical studies[6-8] have evaluated FLEx as a potential alternative to femtosecond laser-assisted LASIK. In other words, FLEx has been proved advanced[9-11]. Since then, the method developed and turned into a flapless surgery named small-incision lenticule extraction (SMILE), which allowed lenticule removal through a small incision [12]. Once it was first published in 2011, SMILE has gained great interest among refractive surgeons for its flapless feature and all-in-one femtosecond laser procedure [13]. Clinical studies [14-15] have shown that SMILE is a large success in the refractive surgery field. Early refractive results have shown that ReLEx (SMILE and FLEx) is promising and encouraging, but comparisons of the relative benefits between the two techniques are still controversial. In the current study, a Meta-analysis was performed of comparative studies of SMILE versus FLEx.

MATERIALS AND METHODS

Search Strategy We conducted a systematic literature search (up to October, 2015) of Medline, Embase and the Cochrane Library for studies describing the comparative outcomes of SMILE and FLEx. The search terms were "small-incision lenticule extraction", "femtosecond lenticule extraction", "SMILE" and "FLEx". The search was limited to English-published paper. The titles and abstracts were first selected according to the objective of this study. The full-text articles were retrived to determine whether they met our inclusion criteria.

Inclusion and Exclusion Criteria To start with, the studies had to be randomized controlled trials (RCTs) or non-randomized comparative studies. Second, the studies should compare the postoperative visual outcomes, high-order aberrations or corneal biomechanical parameters postoperative. Third, patients aged 18-60y with myopia and myopia astigmatism, no significant co-pathology, no history of other ocular disease or previous ocular surgery, no keratoconus or suspected keratoconus, no severe dry eyes, and no systemic disease associated with impaired or abnormal wound healing. Patients were also excluded with the calculated postoperative corneal residual bed thickness less than 250 μm.

The search was not restricted to RCTs, because of the paucity of the relevant studies. Controlled clinical trials, including prospective and retrospective cohort studies, were also included. Letters, review articles, animal or laboratory studies and conference abstracts were not included. Studies irrelevent to our analysis were not included.

Data Extraction Two independent investigators (Ma J and Cao NJ) evaluated the quality of each study using the Jadad Scale (5-point) or the Newcastle-Ottawa Scale (NOS). We used the Jadad Scale for RCTs, the NOS for non-randomized cohort studies. The third investigator (Xia LK) examined the results and a consensus was reached. Using the Jadad Scale, high scores indicated high quality with questions regarding randomization, double blinding and withdrawal and dropouts. Studies scoring >3 points were considered to be of high quality. Using the NOS, we analyzed the selection, comparability and outcomes. The maximum score was 9 points. Studies scoring >6 points were considered to be of high quality.

Statistical Analysis All statistical analysis was performed with Review Manager 5.3 (The Cochrane Collaboration, Oxford, England). For continuous outcome data, we calculate the weighed mean differences (WMD) in the Meta-analysis. For dichotomous outcome data, odds ratios (ORs) were calculated. Of 95% confidence intervals (CIs) were calculated for summary estimates. A P value less than 0.05 was considered to be statistically significant different. A fixed-effects model was used to pool the data. When substantial heterogerneity was present, a random-effect model was used.

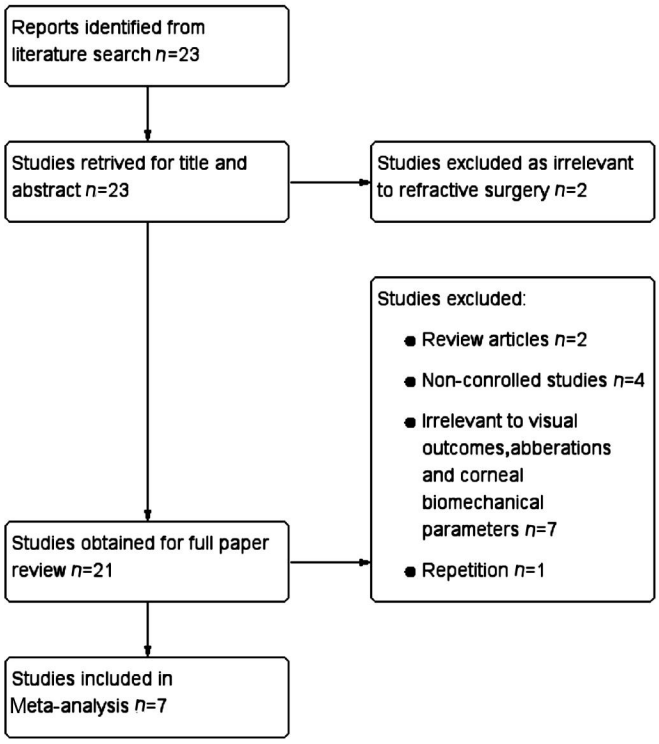

Figure 1 Study selection process of RCTs and non – randomizied cohort studies.

RESULTS

Literature Search A total of 23 studies were retrived and only 7 studies [16-22] were included in our analysis. The trial selection process is shown in Figure 1 and Table 1. Four studies [17,19-20,22] are RCTs, and the other 3 studies [16,18,21] are non-randomized cohort studies (Tables 2, 3).

Quality Assessment The quality assessments of the included studies are shown in Tables 2, 3. In the 4 RCTs[17,19-20,22], randomization, double blinding, withdrawal and dropouts were taken into consideration. One study[17] gained high score of 5 points, indicating high quality. Though the score of the other 3 RCTs was not high, considering their clinical value and lacking in high quality trials, we still included them in our analysis. In the NOS, we regarded the selection, comparability and outcomes. All of the 3 studies gained high score, indicating high quality.

Efficacy We calculated the proportion of eyes with postoperative uncorrected distance visual acuity (UDVA) of 20/20 or better. Four studies[16-19] reported data for this outcome. Analysis of these data showed no difference between the two groups (OR, 1.37; 95% CI, 0.69 to 2.69; P= 0.37) (Figure 2).

We also compared the mean logMAR UDVA between the two groups. Examination of the forest plot showed no difference in the mean logMAR UDVA (WMD, -0.02; 95% CI, -0.05 to 0.01; P=0.17) (Figure 3).

Safety We counted the proportion of eyes with postoperative corrected distance visual acuity (CDVA) unchanged postoperatively, 3 studies[17-19] reported the results, showing no significant differences between the two groups (OR, 0.98; 95% CI, 0.46 to 2.11; P=0.97) (Figure 4).

Table 1 Characteristics of clinical studies comparing SMILE and FLEx

Study	Design	Year	Country	SMILE group		FLEx group		Follow-up (mo)
				Eyes (*n*)	Preoperative	Eyes (*n*)	Preoperative	
Ang *et al*[16]	CT	2014	Singapore	17	-5.84±2.12	15	-5.90±2.01	12
Kamiya *et al*[17]	RCT	2014	Japan	26	-4.21±1.63	26	-4.18±1.72	6
Vestergaard *et al*[18]	CT	2014	Denmark	30	-7.56±1.11	31	-7.59±0.97	6
Agca *et al*[19]	RCT	2014	Turkey	20	-4.03±1.61	20	-4.46±1.61	12
Kamiya *et al*[20]	RCT	2014	Japan	24	-4.10±1.70	24	-4.10±1.70	3
Pedersen *et al*[21]	CT	2014	Denmark	29	-7.10±0.29	31	-7.43±0.20	-
Vestergaard *et al*[22]	RCT	2014	Denmark	34	-7.56±1.11	34	-7.59±0.97	6

RCT: Randomized controlled trials; CT: Comparetive trial; SE: Spherical equivalent; -: Not available.

Table 2 Jadad Scale (5-point) for RCTs

Study	Randomization	Double blinding	Withdrawals and dropouts	Sum of score
Kamiya *et al*[17] 2014	2	2	1	5
Agca *et al*[19] 2014	1	0	1	2
Kamiya *et al*[20] 2014	1	0	1	2
Vestergaard *et al*[22] 2014	1	0	1	2

Jadad Scale allocates 1 to 2 points for the following items: Randomization, double blinding and withdrawal and dropouts. The total score ranged from 0 to 5 (0-2 points means low quality and 3-5 points means high quality).

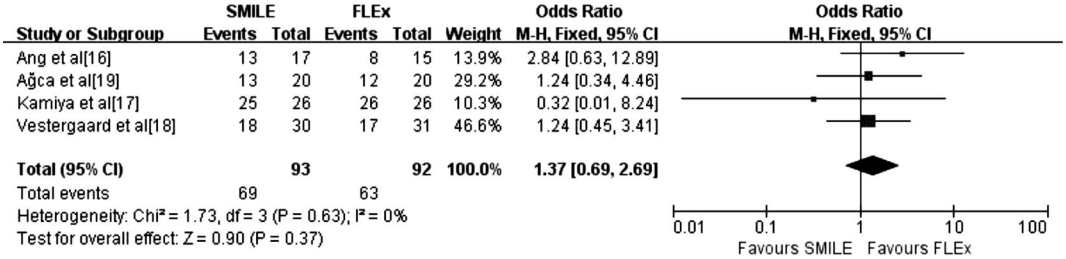

Figure 2 Proportion of eyes with UDVA 20/20 or better after SMILE versus FLEx postoperatively.

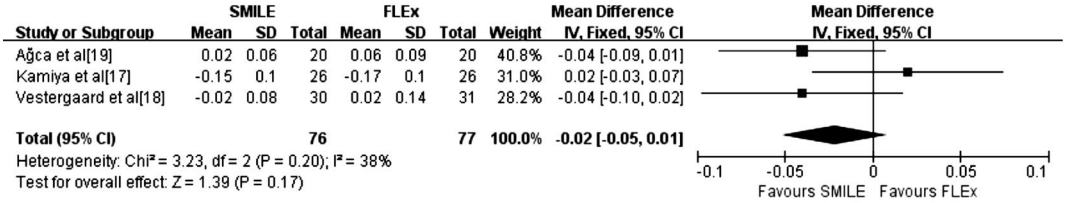

Figure 3 LogMAR UDVA after SMILE versus FLEx postoperatively.

Table 3 Newcastle-Ottawa Scale for non-randomized cohort studies

Study	Selection	Comparability	Outcomes	Sum of score
Ang *et al*[16] 2014	3	2	2	7
Vestergaard *et al*[18] 2014	2	2	2	6
Pedersen *et al*[21] 2014	3	2	2	7

NOS generates a quality score, maximum of 9 points, based on assessment of three study characteristics: selection (maximum of 4 points), comparability (maximum of 2 points) and outcomes (maximum of 3 points).

Mean postoperative logMAR CDVA were also analyzed. Three studies[17-19] reported the mean logMAR CDVA and the results showed no significant differences between the two groups (WMD, -0.00; 95% CI, -0.01 to 0.01; P=0.90) (Figure 5).

Predictability We analyzed the proportion of eyes with postoperative refraction within ±1.00 D and within ±0.50 D of target. Data were available for analysis in 4 studies[16-19]. There were no statistically significant differences between the two groups within ±1.00 D of target (OR, 0.98; 95% CI, 0.13 to 7.28; P=0.99) (Figure 6) and within ±0.50 D of target (OR, 1.62; 95% CI, 0.62 to 4.28; P=0.33) (Figure 7).

Corneal Higher-order Aberrations For higher-order aberrations (HOAs), we analyzed total HOAs, coma, spherical and trefoil. Two studies[18-19] were taken into account. The results showed no statistically significant differences between the two groups in total HOAs (WMD, -0.04; 95% CI, -0.09 to 0.01; P=0.14), coma (WMD, -0.04; 95% CI, -0.09 to 0.01; P=0.11), spherical (WMD, 0.01; 95% CI, -0.02 to 0.03; P=0.60) and trefoil (WMD, -0.00; 95% CI, -0.04 to 0.03; P=0.76) (Figure 8).

Corneal Biomechanical Parameters We analyzed corneal hysteresis (CH) and corneal resistance factor (CRF) postoperative. Three studies[20-22] were included for this objective. In terms of CH, there were no significant differences between the 2 groups (WMD, 0.03; 95% CI, -0.29 to 0.35; P=0.87). For CRF, SMILE presented a better outcome (WMD, 0.15; 95% CI, -0.24 to 0.54; P=0.45). For the total result, SMILE presented a better result as well (WMD, 0.08; 95% CI, -0.17 to 0.33; P=0.54) (Figure 9).

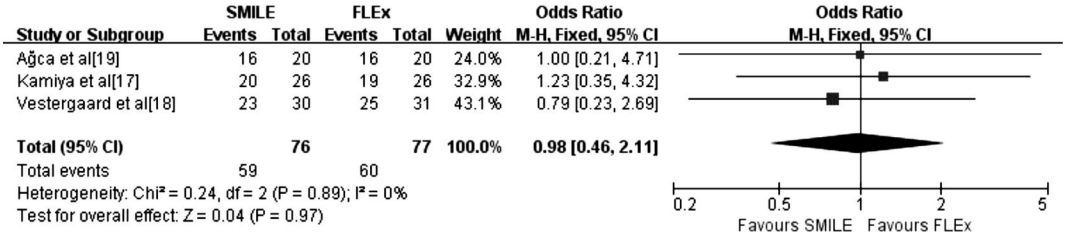

Figure 4 Proportion of eyes with CDVA unchanged after SMILE versus FLEx postoperatively.

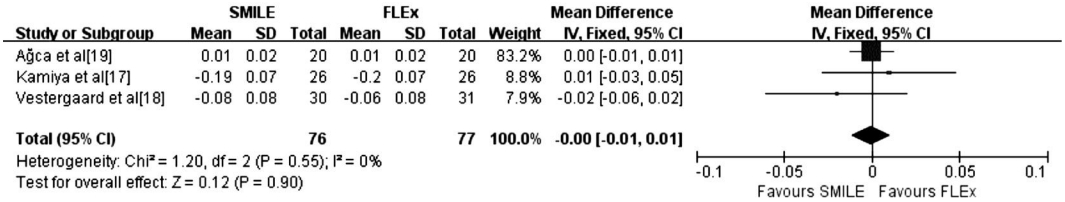

Figure 5 LogMAR CDVA after SMILE versus FLEx postoperatively.

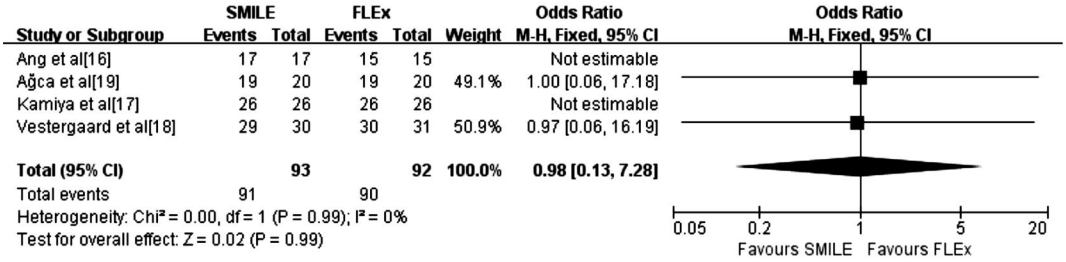

Figure 6 Proportion of eyes with postoperative refraction within ±1.00 D of target after SMILE versus FLEx postoperatively.

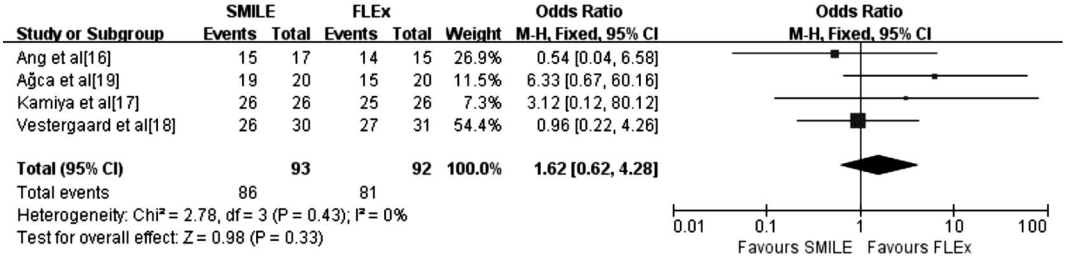

Figure 7 Proportion of eyes with postoperative refraction within ±0.50 D of target after SMILE versus FLEx postoperatively.

DISCUSSION

The results of efficacy, safety, and predictability were identical between SMILE and FLEx in our study. All of the relative data [16-19] showed no statistical differences. That is to say, either SMILE or FLEx can best correct myopia and myopic astigmatism. We are also looking forward to the good consequence, because the techniques are similar during the 2 procedures except for the difference in the cap (SMILE) and flap (FLEx). It is of clinical value to compare SMILE with FLEx for the visual quality. SMILE is flapless, but smaller incision, harder operation. The lenticule may be incomplete during the extraction. On the contrary, a hinged-flap is created and lifted before extracting the lenticule in FLEx, so the space is wide enough to operate. Unfortunately, more corneal nerves are cut off and more patients are concerning about dry eyes after FLEx. To sum up, considering the identical refraction result postoperative, we can select either of the 2 methods under different circumstances to correct myopia and myopic astigmatism.

In teams of HOAs, as is known to all, corneal refractive surgeries will change HOAs of the cornea [23-25], and that is why some patients always concern about the flare and the decreased quality of night vision. Firstly, the pupil diameter will affect HOAs [26]. Under dim light, the pupil will widen and HOAs will increase. In our study, we only included the data collected under the pupil diameter equal to 5.0 mm or even larger [18-19] to make the result credible and homogeneous. Secondly, the smaller optical zone, the higher HOAs [27] .We set the same diameter in the 2 procedures to avoid the diversity. Last but not least, the flap will induce HOAs. Tran *et al* [28] noted that the creation of the LASIK flap alone can induce aberrations. Unlike LASIK, the femtosecond laser was used to create the flap in FLEx, and no flap was created in SMILE. In the reported studies, the increase of HOAs was equal to or less after SMILE or FLEx than other surgeries [23-25]. The common conclusion may be reached due to the lenticule processing instead of corneal stroma ablating. But SMILE and FLEx are similar in surgical techniques other than the cap (SMILE) and flap (FLEx). So we are wondering if SMILE will have lower HOAs than SMILE postoperative. The results in our study showed no statistically significant differences between the two groups in

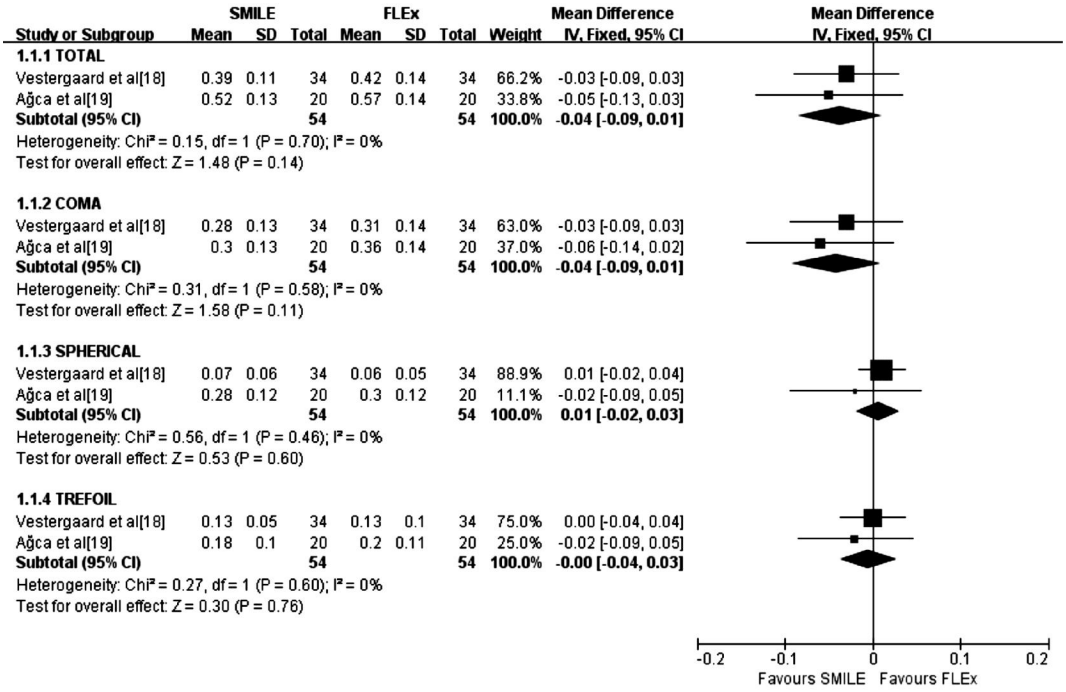

Figure 8 Higher-order aberrations of eyes after SMILE versus FLEx postoperatively.

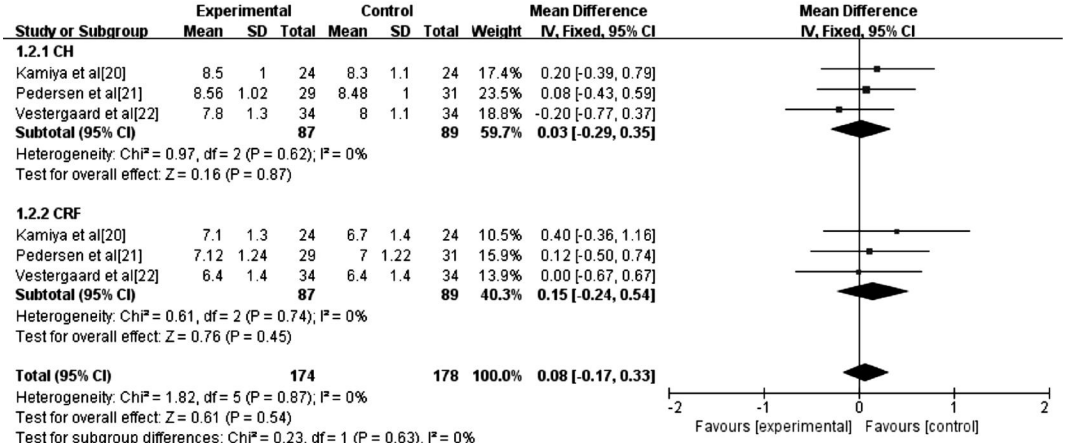

Figure 9 Corneal biomechnical parameters of eyes after SMILE versus FLEx postoperatively.

total HOAs (P=0.14), coma (P=0.11), spherical (P=0.60) and trefoil (P=0.76) (Figure 8). Therefore, we infer that either a femtosecond flap or a subsequent surface incision does increase HOAs, but the increase does not differ. Considering that only 2 studies [18-19] were taken into consideration, the result may be limited, and further more data are still required.

For corneal biomechnical parameters, we analyzed CH and CRF postoperative. To our knowledge, removal of corneal tissue can induce a biomechanical weakness of the cornea[21]. Therefore, it is important to characterize such corneal biomechanical changes. On the one hand, we can predict the outcomes preoperatively. On the other hand, we can avoid adverse events postoperatively. In FLEx, a flap is created to access the stromal lenticule, and the anterior stromal tissue is destroyed. In SMILE, a subsequent surface incision allows the surgeon to dissect and remove the lenticule, so less anterior stromal tissue is destroyed. We believe the anterior stromal tissue is stronger than the posterior, and will have benificial biomechanic effects [29]. So SMILE may have biomechanical advantages over FLEx in the early times. But we found no differences since we searched the data for a long time postoperatively (Figure 9). We have to admit that CH and CRF only reflect parts of corneal biomechanical structure. Furthermore, although the visual outcomes may be the same, ocular biomechanics may be different between the two methods. This may be attributed to the lack of studies with long-term follow-ups. We would like to accept the fact that the results are limited and more researches comparing parameters other than CH and CRF should be explored.

A limitation of our review was the diversity of follow-up time ranging from 3mo to 1y. We even cannot find the exactly follow-up time of 1 study [21]. So the follow-up time shorter than 1y may be inadequate to determine the final visual outcomes. Another limitation was the inclusion of RCTs and non-randomized observational studies, resulting in potential bias. Furthermore, only 7 studies [16-22] met our analysis, more studies were required to verify our conclusion.

In conclusion, our present study found no significant differences in efficacy, safety, predictability HOAs and corneal biomechanical parameters after SMILE versus FLEx. Considering the result was limited and inconclusive, further more randomized, prospective studies with a large sample size, identical intervention parameters and complete outcome measurements are needed to increase our understanding of the benefits of SMILE and FLEx.

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Conflicts of Interest: Ma J, None; **Cao NJ,** None; **Xia LK,** None.

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