

# Postoperative efficacy, safety, predictability, and visual quality of implantable collamer lens implantation versus small incision lenticule extraction in myopic eyes: a Meta-analysis

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## Abstract

• **AIM:** To compare the postoperative efficacy, safety, predictability, and visual quality of implantable collamer lens (ICL) implantation versus small incision lenticule extraction (SMILE) in myopia eyes.

• **METHODS:** PubMed, EMBASE, Web of Science, Cochrane Library and several Chinese databases were searched at May 2021 to select relevant studies in comparison of clinical outcomes between ICL implantation and SMILE for myopia. The primary outcomes were efficacy, safety, and predictability. And the secondary outcomes were postoperative higher-order ocular aberrations (HOAs), modulation transfer function cutoff frequency (MTF), objective scatter index (OSI), contrast sensitivity and a quality of vision (QoV) questionnaire.

• **RESULTS:** A total of 1036 eyes from 10 studies, of which 503 eyes underwent ICL implantation and 533 eyes underwent SMILE, were enrolled in this Meta-analysis. Pooled results revealed that ICL group had a better safety index and post-corrected distance visual acuity (CDVA) ( $P=0.007$ ,  $<0.00001$ , respectively), and a lower percentage of eyes with a postoperative CDVA lost 1 line ( $P=0.007$ ) than the SMILE group. No significant differences were found in comparison of the other primary outcomes. In the long-term follow-up ( $>6$ mo), ICL group had a lower total HOA, coma, and spherical aberration than SMILE group ( $P=0.003$ ,  $<0.00001$ ,  $0.04$ ). Yet higher trefoil was found in ICL group at 6mo after surgery ( $P=0.003$ ). Additionally, ICL group also had a higher MTF value ( $P=0.02$ ), and a higher contrast

sensitivity score for spatial frequencies of 1.5, 6, and 12 cpds ( $P=0.02$ ,  $0.005$ ,  $0.02$ , respectively). And it also had a lower score of bothersome in QoV questionnaire than SMILE group ( $P=0.003$ ).

• **CONCLUSION:** ICL implantation and SMILE have similar and comparable outcomes in term of the efficacy and predictability for correcting high myopia. However, ICL group is relatively safer and also has better visual quality in comparison of SMILE group.

• **KEYWORDS:** implantable collamer lens; small incision lenticule extraction; myopia; refractive surgery; Meta-analysis

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## INTRODUCTION

With the increasing prevalence of refractive errors, myopia becomes one of the ocular diseases with the highest incidence. It is estimated that the number of high myopic patients over the world will reach to 163 million in 2020, and by 2050, it will reach to 938 million<sup>[1]</sup>. Over the past decades, several refractive surgeries have been proposed to address refractive errors<sup>[2-3]</sup>. It is generally divided into two categories, one is laser correction surgery, and the other is intraocular lens implantation surgery.

Since the introduction of femtosecond laser small incision lenticule extraction (SMILE) in 2011<sup>[4]</sup>, its efficacy, safety and predictability have been reported widely<sup>[5-7]</sup>. SMILE removes intrastromal lenticule through a small incision without a corneal flap. Therefore, it has a lower risk of flap-related complications and surgery-associated dry eye, as well as better postoperative stability of corneal biomechanics compared with traditional surgical techniques<sup>[8-9]</sup>. Although corneal refractive correction is a fairly safe surgery that provides superior visual

outcomes for low-to-moderate myopic patients, postoperative corneal ectasia may occur in eyes with high myopia or thin cornea<sup>[10-11]</sup>.

Posterior chamber phakic intraocular lens implantation is the most popular refractive surgery for moderate-to-high myopia correction, especially in eyes that are not suitable for corneal surgery. Implantable collamer lens (ICL) implantation is removable and not restricted by corneal thickness. The design of the center hole in ICL V4c allows the free circulation of aqueous humor, which reduces the loss of corneal endothelial cell and the incidence of cataract<sup>[12-13]</sup>. Several studies have demonstrated the postoperative benefits of SMILE and ICL for myopia correction, yet the conclusion is controversial<sup>[14-17]</sup>. Moreover, no study comprehensively reported the clinical outcome in comparison of ICL implantation and SMILE for myopic eyes. The purpose of this Meta-analysis is to systematically summarize the outcomes of postoperative efficacy, safety, predictability, and visual quality of ICL implantation versus SMILE in myopia eyes.

## MATERIALS AND METHODS

**Search Strategy** Two independent reviewers (Li HY and Ye Z) searched the following databases: PubMed, EMBASE, Web of Science, Cochrane Library and four Chinese databases (CNKI, WANFANG, CMJD and SinoMed). To gather as much data as possible, and to identify all trials comparing SMILE and ICL, the following items were used for PubMed: (“posterior chamber phakic intraocular lens”[Title/Abstract] OR “posterior chamber phakic intraocular lenses”[Title/Abstract] OR “posterior chamber phakic IOLs”[Title/Abstract] OR “posterior chamber phakic IOL”[Title/Abstract] OR “pIOL”[Title/Abstract] OR “pIOLs”[Title/Abstract] OR “implantable collamer lens”[Title/Abstract] OR “ICL”[Title/Abstract] OR “implantable collamer lenses”[Title/Abstract] OR “ICLs”[Title/Abstract]) AND (“small incision lenticule extraction”[Title/Abstract] OR “SMILE”[Title/Abstract] OR “lenticule extraction”[Title/Abstract] OR “femtosecond lenticule extraction”[Title/Abstract] OR “FLEx”[Title/Abstract]) AND (“Myopia”[MeSH Terms] OR “myopi\*”[Title/Abstract]). After removing the duplicate, all possible articles were reviewed without any date or language restriction. Additionally, reference lists of all eligible studies were also searched to identify related articles. Any disagreement between the two reviewers was resolved by a third reviewer (Li ZH).

**Eligibility Criteria** The selection criteria were: 1) controlled clinical trials, including prospective/retrospective randomized/nonrandomized controlled studies; 2) age more than 18y; 3) eyes had either SMILE or ICL implantation for myopia and/or astigmatism correction; 4) at least one primary or secondary outcome compared; 5) a follow-up period of least 3mo. Trials if they contained only one or none of the refractive surgeries,

or retreatments, or if eyes were hyperopia, or if participants were followed up for less than three months after surgery, were excluded.

**Outcome Measures** The primary outcomes were efficacy, safety, and predictability. Efficacy measures included the efficacy index [postoperative uncorrected distance visual acuity (UDVA)/preoperative corrected distance visual acuity (CDVA)], the final postoperative UDVA, the percentages of eyes achieving a postoperative UDVA of 20/20 or better and gaining one or more lines of postoperative UDVA comparing to preoperative CDVA. Safety measures included the safety index (postoperative CDVA/preoperative CDVA), the final postoperative CDVA, the percentages of eyes losing one or two lines of postoperative CDVA comparing to preoperative CDVA. Predictability measure was the mean refractive spherical equivalent and the percentage of eyes with a postoperative refractive spherical equivalent in  $\pm 0.5$  diopter (D) and  $\pm 1.00$  D of the target spherical equivalent.

The secondary outcomes were postoperative higher-order ocular aberrations (HOAs), and visual quality including modulation transfer function cutoff frequency (MTF), objective scatter index (OSI), contrast sensitivity and a quality of vision (QoV) questionnaire. QoV is a validated and standardized questionnaire for measuring visual quality in eyes after refractive surgery<sup>[18-19]</sup>. Ten symptoms were evaluated with each item reported by the patient on the following subscales: frequency, severity, and bothersome. Each subscale has a score ranging from 0 (never) to 3 (very often or severe). Due to the variation of the follow-up period (1wk to 27mo) and the restriction of studies, data reported at the end of each follow-up were pooled.

**Data Extraction and Quality Assessment** The data extraction and quality assessment were independently performed by 2 authors. The following trial characteristics were extracted from all eligible articles: the first author, publication year, trial design, country, sample size, preoperative refractive spherical equivalent, follow-up period and assessment scores. Any discrepancies would be resolved by the third author. The Newcastle-Ottawa Scale (NOS) was used for quality assessment of non-randomized comparative trials<sup>[20]</sup>. The maximum NOS score is 9, assessing the following 3 parts: selection (0–4 points), comparability (0–2 points), and outcome (0–3 points). Researches that score less than 6 points were considered to be of low quality.

**Statistical Analysis** All results were described in forest plots, with lines representing the estimated values of different studies and their confidence intervals, and the boxes graphically representing the weight assigned to each study in calculating the combined estimator of a given outcome. For continuous variables, means and standard deviations were used to calculate

**Table 1 Characteristics of the enrolled studies**

Study	Design	Country	SMILE		ICL		Follow-up (mo)	Quality assessment
			Eyes (n)	Pre-SE (D)	Eyes (n)	Pre-SE (D)		
Ganesh 2017 <sup>[21]</sup>	Prospective	India	10	-4.58±1.59	10	-5.98±1.15	12	6
Li 2018 <sup>[22]</sup>	Retrospective	China	70	-4.35±0.78	70	-4.58±0.55	6	6
Piao 2018 <sup>[25]</sup>	Retrospective	China	80	-8.85±0.32	72	-9.16±0.31	12	6
Qin 2019 <sup>[24]</sup>	Prospective	China	48	-8.00±1.65	48	-8.15±1.71	3	8
Yang 2019 <sup>[26]</sup>	Prospective	China	34	-9.45±3.41	34	-9.99±3.16	3	7
Chen 2020 <sup>[17]</sup>	Prospective	China	76	-7.59±1.36	64	-7.59±1.18	6	6
Niu 2020 <sup>[23]</sup>	Prospective	China	37	-7.03±1.00	39	-7.14±1.11	12	7
Wei 2020 <sup>[16]</sup>	Prospective	China	103	-7.39±0.79	94	-7.60±1.01	6	7
Siedlecki 2020 <sup>[15]</sup>	Cross-section	Germany	40	-7.34±0.92	40	-7.28±1.25	26	5
Aruma 2021 <sup>[14]</sup>	Retrospective	China	35	-5.07±0.67	32	-5.21±0.73	12	6

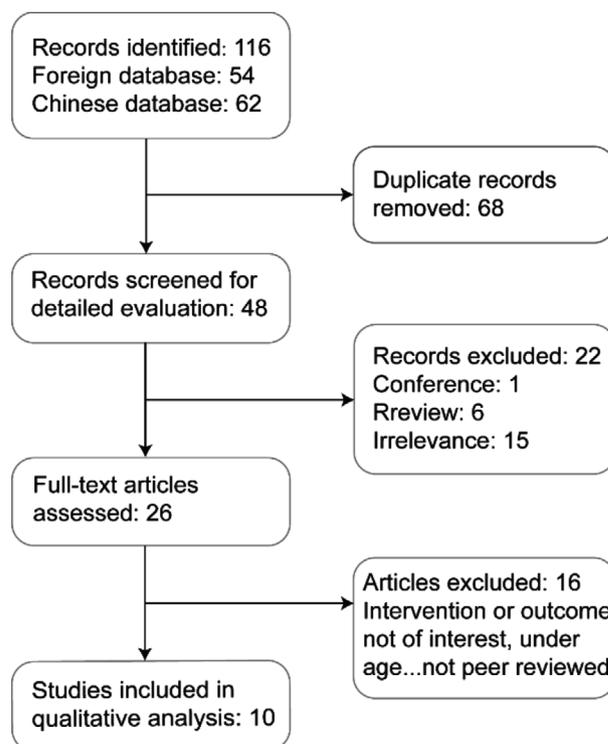
SMILE: Femtosecond laser small incision lenticule extraction; ICL: Implantable collamer lens; Pre-SE: Preoperative mean refractive spherical equivalent; D: Diopter.

mean difference. For dichotomous variables, pooled estimates of the odds ratio was calculated. Substantial heterogeneity was evaluated using  $I^2$  statistics. If  $I^2$  value greater than 50% or the  $P$  value was less than 0.10, the random-effect model was a substitute for fixed-effect model. Then, subgroup analysis was performed to evaluate the possible source of heterogeneity. All data of the primary and secondary outcome was analyzed using Review Manager (version 5.3, Cochrane Collaboration, Oxford, UK). A possibility less than 0.05 was considered statistically significant.

**RESULTS**

**Search Results** The detailed step of the literature search is shown in Figure 1. Initially, there were initially 116 studies were identified. And 48 studies remained after removing the duplicate, of which 22 studies were excluded because of irrelevance. Therefore, 26 records were identified for full-text assessment. Among these, 16 studies were removed due to the following reasons: not controlled trial, intervention or outcomes not of interest, under age, not peer reviewed. Finally, 10 articles were extracted for qualitative analysis<sup>[14-17,21-26]</sup>.

**Study Characteristics and Quality** A total of 552 patients (1036 eyes) were enrolled in the final analysis, with 271 patients (503 eyes) in the ICL group, and 281 patients (533 eyes) in the SMILE group. Due to the difficulty to achieve completely randomized, controlled and double-blind design in comparing the clinical outcomes of ICL and SMILE in correcting myopia, this Meta-analysis identified 6 prospective nonrandomized, 3 retrospective nonrandomized and 1 cross-section comparative studies. Table 1 shows the main characteristics and quality assessment of the including 10 studies. Overall, all of the enrolled studies had good quality (average NOS score: 6.4). For patient selection, all studies have scored 2 points with single-center cohort design. For comparability, only one study controls did not match the

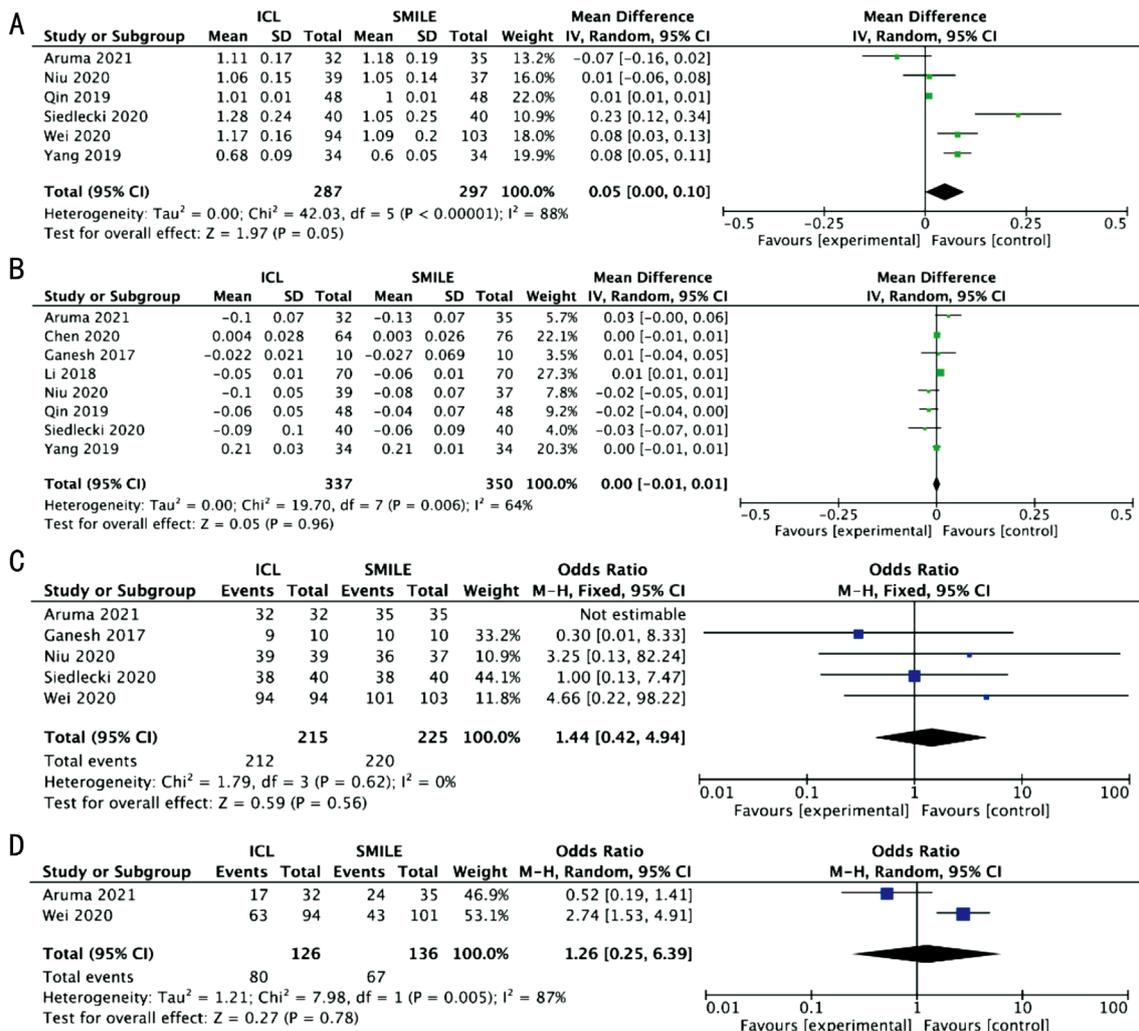


**Figure 1 Flowchart for the study screening.**

additional factor. For outcome measures, all subjects of the enrolled studies completed follow up and had a follow-up for at least 3mo.

**Primary Outcomes**

**Efficacy** Figure 2 shows the results of efficacy between ICL and SMILE surgery. There were no significant differences of the efficacy index and postoperative UDVA of the two groups ( $P=0.05, 0.96$ , respectively). The overall percentages of eyes with a postoperative UDVA of 20/20 or better were 98.60% in ICL group, and 97.78% in SMILE group ( $P=0.56$ ). After ICL implantation, the postoperative UDVA of 63.49% eyes had gained 1 line in comparison of preoperative CDVA, and the corresponding value after SMILE was 49.26%. No significant



**Figure 2** Forest plots showing the results of efficacy comparing SMILE with ICL implantation A: Efficacy index; B: Postoperative UDVA; C: Postoperative UDVA of 20/20 or better; D: Gaining one or more lines of postoperative UDVA comparing to preoperative corrected distance visual acuity. SMILE: Small incision lenticule extraction; ICL: Implantable collamer lens; UDVA: Uncorrected distance visual acuity.

difference was found in comparison of these percentages ( $P=0.78$ ).

**Safety** Figure 3 shows the results of safety between ICL implantation and SMILE surgery. Statistically significant differences were found in the comparison of safety index ( $P=0.007$ ) and postoperative CDVA ( $P<0.00001$ ) and the proportion of eyes with lost 1 line in CDVA ( $P=0.007$ ) between ICL and SMILE, which demonstrated a higher safety for ICL than SMILE. After ICL implantation, 1.14% eyes had lost 1 line in CDVA; and the corresponding value after SMILE was 8.00%. No one had a postoperative CDVA lost 2 lines in both groups.

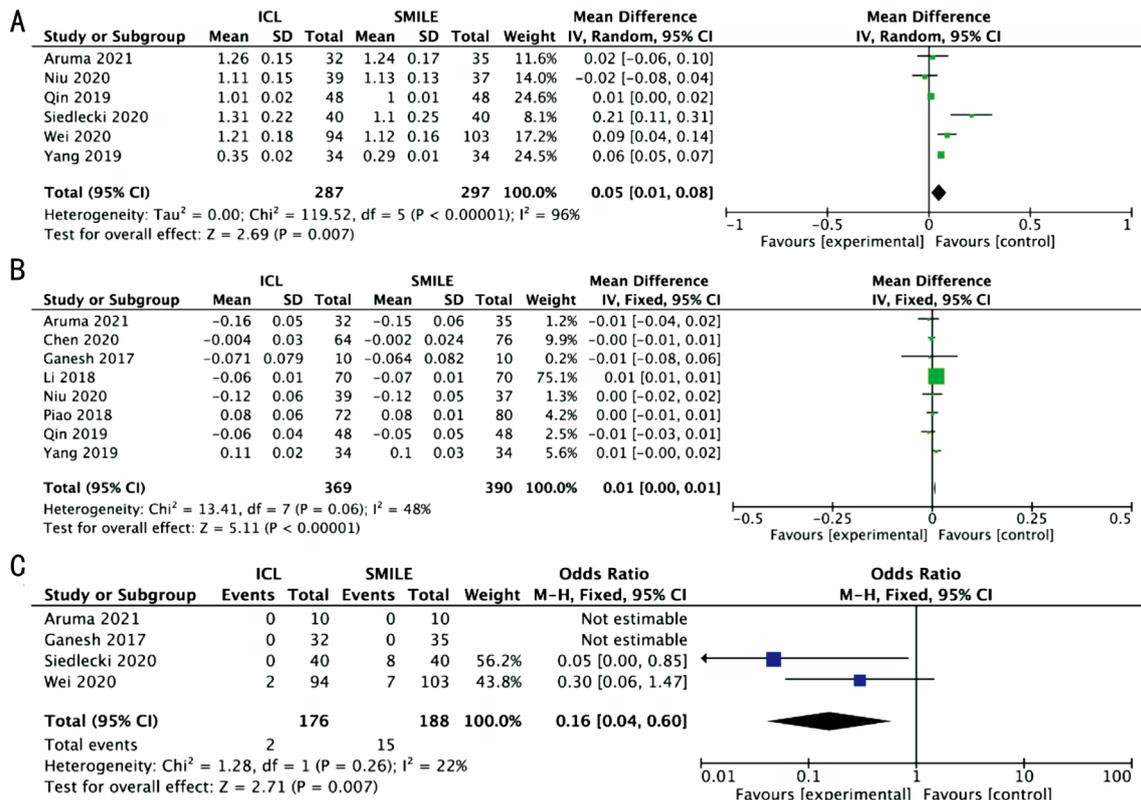
**Predictability** The results of predictability between ICL and SMILE is shown in Figure 4. The overall proportion of eyes with a postoperative refractive spherical equivalent in  $\pm 0.5$  D ( $\pm 1.00$  D) of the target spherical equivalent was 91.43% (100.00%) in ICL group, and 93.51% (100.00%) in SMILE group. The postoperative mean refractive spherical equivalent and the proportion of eyes within  $\pm 0.5$  D of the

target spherical equivalent, did not differ between the two groups ( $P=0.85, 0.46$ , respectively).

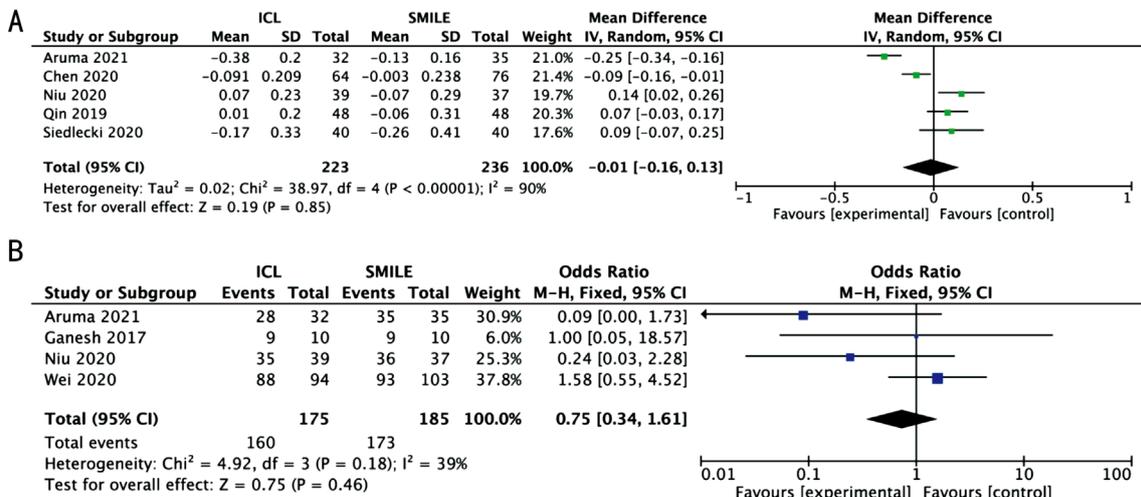
**Second Outcomes**

**Higher-order ocular aberrations** The comparison of total HOA, coma, trefoil and spherical aberration at 1wk and 1, 3, 6, and 12 or longer months after surgery is shown in Figure 5. The total HOA of the ICL group was significantly lower than that of the SMILE group at 1wk and 6mo after surgery ( $P<0.00001$  and  $P=0.003$ , respectively). ICL group also had a lower coma at 1wk to 12mo after surgery (all  $P<0.01$ ). However, higher trefoil was found in ICL group at 6mo after surgery ( $P=0.003$ ) and higher spherical aberration at 1wk after surgery in comparison of SMILE group ( $P=0.009$ ). At 6 and 12 or longer months after surgery, spherical aberration in ICL group was lower than SMILE group ( $P=0.04, 0.02$ , respectively).

**Visual quality** Figure 6 shows the results of MTF, OSI at 1wk and 1, 3, 6, and 12 or longer months after surgery and contrast sensitivity for spatial frequencies of 1.5, 3, 6, 12, and 18 cpds. The ICL group had a higher MTF value at 1y or longer



**Figure 3** Forest plots showing the results of safety comparing SMILE with ICL implantation A: Safety index; B: Postoperative CDVA; C: Losing one line of postoperative CDVA comparing to preoperative CDVA. SMILE: Small incision lenticule extraction; ICL: Implantable collamer lens; CDVA: Corrected distance visual acuity.



**Figure 4** Forest plots showing the results of predictability comparing SMILE with ICL implantation A: Mean refractive spherical equivalent; B: The proportion of eyes within ±0.5 D of the target spherical equivalent. SMILE: Small incision lenticule extraction; ICL: Implantable collamer lens.

after surgery ( $P=0.02$ ), and a higher OSI value at 1mo after surgery ( $P<0.00001$ ), and a higher contrast sensitivity score for spatial frequencies of 1.5, 6, and 12 cpds ( $P=0.02$ , 0.005, 0.02, respectively). The comparison of the 3 linear-scaled QoV scores between ICL and SMILE are shown in Figure 7. No significant difference was found in visual symptom frequency ( $P=0.33$ ) and severity ( $P=0.78$ ). Yet the score of bothersome in ICL group was significantly lower than that of SMILE group ( $P=0.003$ ), which indicated that the former group had less overall stimulation because of visual disturbances.

**Subgroup Analysis** The heterogeneity has decreased to a certain extent when the eyes were sub-grouped according to the preoperative mean refractive spherical equivalent ( $<6$  D or  $>6$  D). Figure 8 shows the results of subgroup analysis. Significant difference was only found in safety index between ICL implantation and SMILE in subgroup comparison ( $P=0.007$ ). Additionally, the higher efficacy index and safety index were found in ICL group when the preoperative mean refractive spherical equivalent was more than 6 D ( $P=0.01$ , 0.007, respectively). And the postoperative UDVA

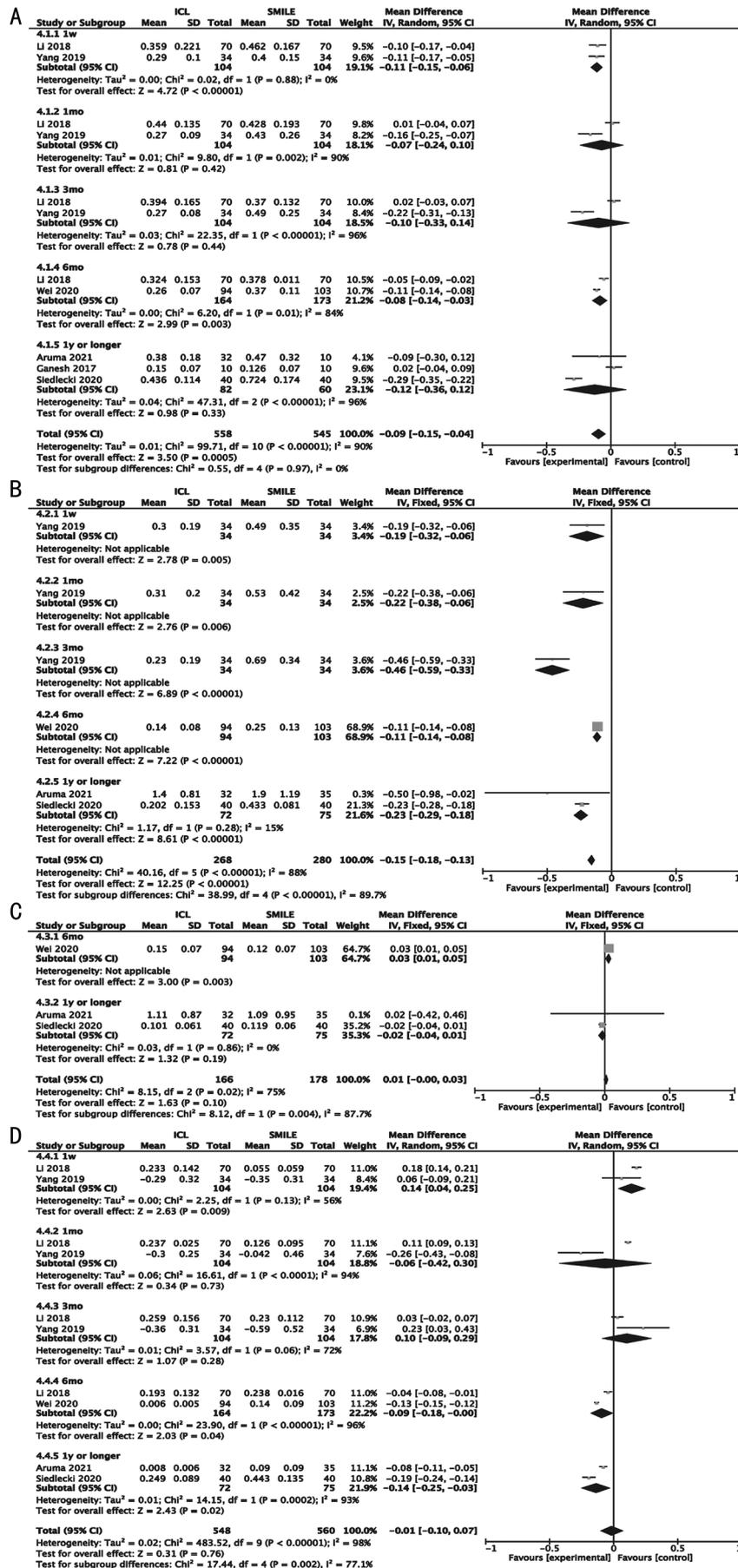


Figure 5 Forest plots showing the results of higher-order ocular aberrations comparing SMILE with ICL implantation at 1wk and 1, 3, 6, and 12 or longer months after surgery A: Total higher-order ocular aberrations; B: Coma; C: Trefoil; D: Spherical aberration. SMILE: Small incision lenticule extraction; ICL: Implantable collamer lens.

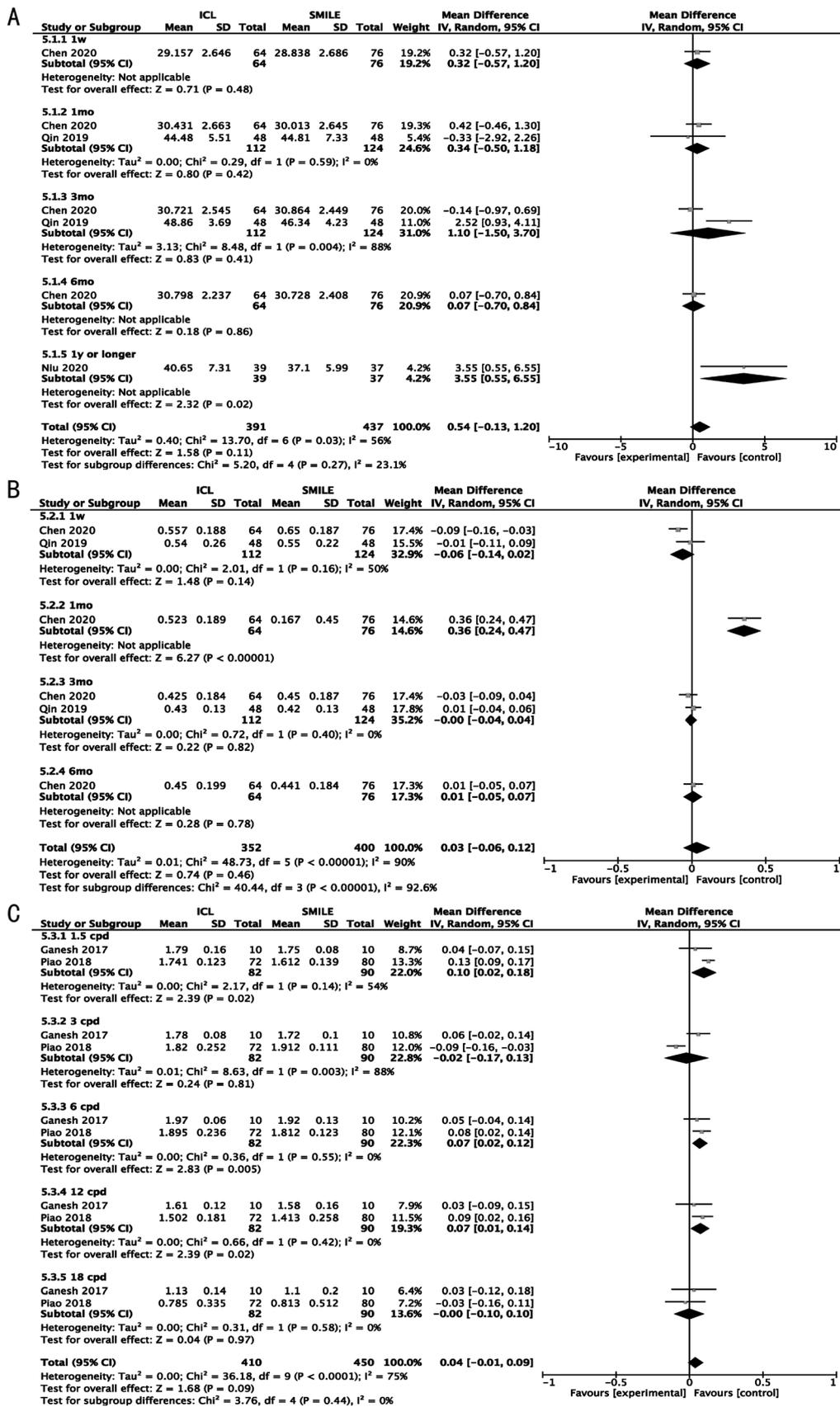
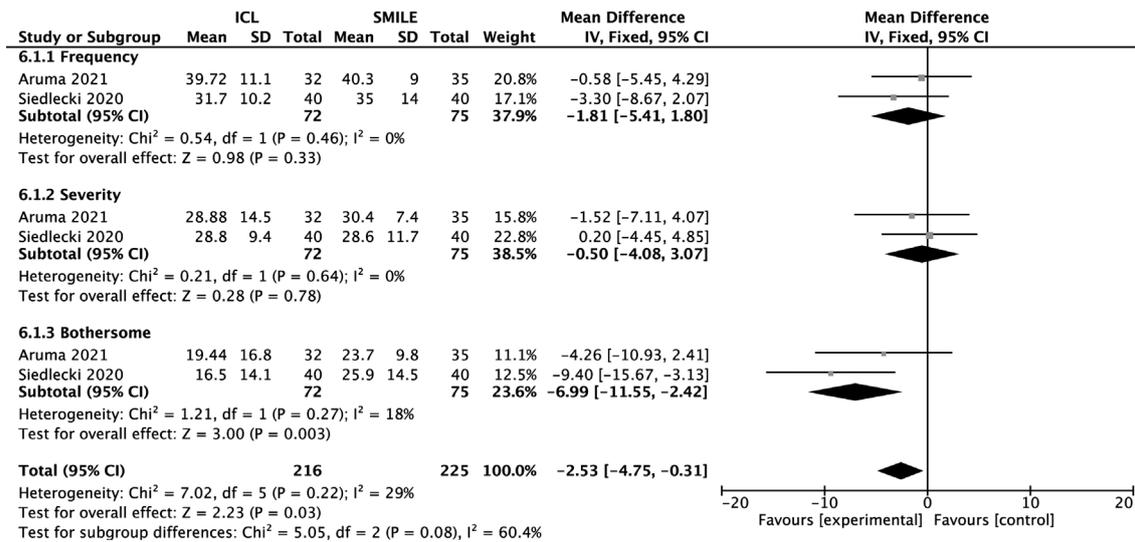


Figure 6 Forest plots showing the results of visual quality comparing SMILE with ICL implantation A: Modulation transfer function cutoff frequency; B: Objective scatter index; C: Contrast sensitivity. SMILE: Small incision lenticule extraction; ICL: Implantable collamer lens.

after ICL implantation was better than SMILE in eyes with preoperative mean refractive spherical equivalent less than 6 D (P<0.00001).

**DISCUSSION**

With the advancement of refractive correction surgery, postoperative visual quality has become the most important



**Figure 7 Forest plots showing the results of 3 linear-scaled QoV scores comparing SMILE with ICL implantation** SMILE: Small incision lenticule extraction; ICL: Implantable collamer lens.

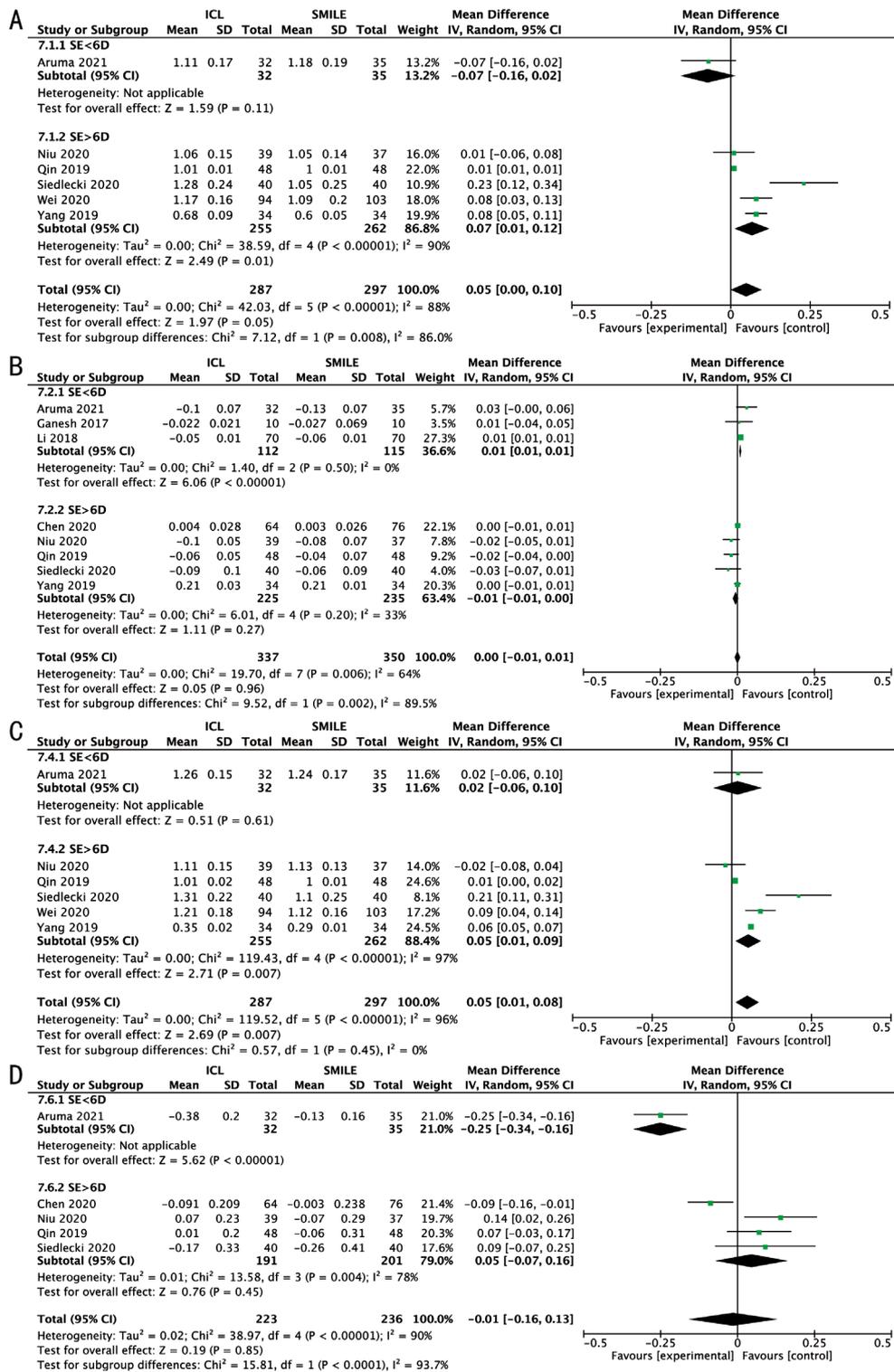
research topic. The visual quality of the newest refractive procedures needed to be evaluated, especially in comparison of ICL implantation and SMILE for myopia eyes. A previous Meta-analysis by Cao *et al*<sup>[27]</sup> compared the outcomes between ICL and SMILE for high myopia correction in adults. However, they only included five studies and only compared the efficacy index, safety index, changes in Snellen lines of CDVA, predictability, incidence of halos, and change in HOAs. The differences in MTF, OSI, contrast sensitivity and QoV questionnaire between the two groups were lacking. This study was the first Meta-analysis that assessed the postoperative efficacy, safety, predictability, subjective and objective visual quality of ICL implantation versus SMILE in correcting myopic eyes.

When assessing the full-text, the author found that Kamiya *et al*<sup>[28]</sup> and Moshirfar *et al*<sup>[29]</sup> also met inclusion criteria. However, this study eventually did not analyze the data of the two articles because of the mismatched baseline data, especially the preoperative refractive spherical equivalent. This Meta-analysis showed that ICL implantation and SMILE had comparable results in terms of efficacy and predictability for correcting myopia. Only one study reported the post-UDVA in both groups was inferior to preoperative CDVA<sup>[26]</sup>. And more than 90% eyes had a postoperative refractive spherical equivalent within  $\pm 0.5$  D of target spherical equivalent in both groups. These results were consistent with previous long-term studies at postoperative five years or longer<sup>[30-32]</sup>. In addition, this study indicated that ICL implantation had a higher safe index and better postoperative CDVA than SMILE surgery. And postoperative CDVA loss was seen at 1.14% eyes in ICL group and 8.00% eyes in SMILE group.

Moreover, this Meta-analysis also compared the subjective and objective visual quality after ICL implantation and SMILE

for myopia correction. The subjective parameters included the postoperative HOAs, MTF, OSI, and contrast sensitivity for spatial frequencies of 1.5, 3, 6, 12, and 18 cpds. The QoV questionnaire was used to evaluate the objective visual quality after surgery. In this Meta-analysis, only 5 studies compared the HOAs between ICL implantation and SMILE in myopic eyes, with only 2 studies showing the results from 1wk to 12mo after surgery. The fewer induced aberration indicated the better postoperative visual quality. Current study showed that the total HOA and trefoil were higher in SMILE group at 6mo after surgery, yet no significant differences were found at 1y or longer. However, a higher coma at 1wk to 12mo after surgery and a higher spherical aberration at 6mo or longer were found in SMILE group. These results could be based on the fact that ICL was designed with a negative spherical aberration, and its implantation was an intraocular surgery without changing corneal shape<sup>[33]</sup>.

The MTF value at 1y or longer after surgery and contrast sensitivity scores for spatial frequencies of 1.5, 6 and 12 cpds in ICL group, were higher than that of SMILE, which indicated a better postoperative objective quality of visual after ICL implantation. Yet the higher OSI value at 1mo after ICL implantation showed the more scattering. The possible reason to explain these results is that the integrity of the central cornea after ICL implantation avoids the effect of wound healing on postoperative visual quality<sup>[34]</sup>. Additionally, our Meta-analysis showed comparable QoV scores of frequency, severity after ICL implantation and SMILE. However, less bothersome was found in ICL group. The most frequent postoperative complaint after ICL implantation was halos, which may be associated with differences between pupil diameter and ICL optic zone diameter<sup>[35]</sup>. Although Eppig *et al*<sup>[36]</sup> considered the inner wall of the ICL central hole potentially resulting



**Figure 8 Forest plots showing the results of subgroup analysis** A: Efficacy index; B: Gaining one or more lines of postoperative UDVA comparing to preoperative corrected distance visual acuity; C: Safety index; D: Postoperative UDVA. SMILE: Small incision lenticule extraction; ICL: Implantable collamer lens; UDVA: Uncorrected distance visual acuity.

in postoperative night vision disturbances, the other study<sup>[37]</sup> suggested the design of central hole would not cause more halos than that of the traditional ICL. After SMILE surgery, the most frequent complaint was blurred vision, which might result from the delayed corneal healing and dry eye<sup>[16,38]</sup>. These findings demonstrated that the objective visual quality of ICL implantation was slightly better than SMILE in correcting

high myopia. It is worth noting that no evidence could show the correlation between subjective visual quality and objective clinical measurements, which indicated that objective measurements may not provide insight into the visual quality of patients with normal or near-normal vision. Therefore, more attention should be paid to measure the subjective QoV after ICL implantation or SMILE. Due to the limited number of

studies or eyes comparing the visual quality in both groups of this study, these results may be worthy of scrutiny. More long-term studies are needed to explore the difference in subjective and objective visual quality of ICL implantation and SMILE for myopic correction.

In order to investigate the source of heterogeneity, subgroup analysis according to different preoperative refractive spherical equivalent and sensitivity analysis were performed in this Meta-analysis. For subgroup analysis, a significant higher efficacy and safety index was found in eyes with a preoperative refractive spherical equivalent more than 6 D after ICL implantation. Therefore, ICL implantation was more suitable for correcting high myopia in comparison of SMILE. These results were consistent with previous studies in eyes with high myopia<sup>[16,24]</sup>. Due to the more laser ablation for correcting high myopia, the cornea was oblate with the increasing HOAs, resulting in the lower accuracy of SMILE surgery<sup>[15]</sup>. Moreover, for eyes with a preoperative refractive spherical equivalent less than 6 D, a better postoperative UDVA was obtained after ICL implantation than SMILE surgery. The possible reason is the less induced scattering and HOAs after ICL implantation<sup>[21]</sup>. Sensitivity analysis was not performed for pairs with high heterogeneity after subgroup analysis because of the limited number of study.

This study has several limitations. First, most articles enrolled in this Meta-analysis were nonrandomized controlled trials, of which 3 articles were retrospective design. We choose to accept this limitation due to the lack of randomized controlled trials in comparison of the clinical outcomes between ICL implantation and SMILE in myopia eyes. Second, the variability of patient characteristics, preoperative refractive spherical equivalent and single-center trial with a limited sample size also caused a publication bias, resulting in a high heterogeneity. However, subgroup analysis was performed to identify the publication bias of this Meta-analysis. Finally, some studies included the both eyes of the same patient undergoing refractive surgery. Yet this limitation was acceptable in comparison of the clinical outcome on different refractive surgery in most published studies<sup>[8,30]</sup>.

In conclusion, ICL implantation and SMILE had similar and comparable outcomes in term of the efficacy and predictability for correcting myopia. However, ICL group is relatively safer and also had better postoperative visual quality in comparison of SMILE group. Since the relatively wide range of correctable refractive errors, we considered that ICL implantation was superior to SMILE in correcting myopia.

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