

Comparison of rigid versus foldable iris-fixed phakic intraocular lens implantation for high myopia

A systematic review and meta-analysis

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Abstract

Background: This study aimed to assess the efficacy of rigid versus foldable iris-fixed phakic intraocular lens (PIOL) implantation in the treatment of high myopia.

Methods: A systematic search based on electronic databases such as Pubmed, Embase, and Cochrane Library was conducted to identify relevant studies published up to January 11, 2019. The pooled odds ratios and weighted mean differences (WMDs) with corresponding 95% confidence intervals were calculated.

Results: Eight comparative studies with 835 participants were included in this meta-analysis. The overall WMD showed statistical significance in terms of postoperative uncorrected distance visual acuity (UDVA), mean postoperative spherical equivalence (SE), and mean postoperative intraocular higher-order aberrations (HOA) (μm) for a 6-mm pupil, suggesting that foldable PIOL group showed significant improvement of high myopia, compared to rigid PIOL group. Besides, compared with rigid PIOL group, foldable PIOL group had beneficial effect on the proportion of eyes with central endothelial cell density (ECD) loss in patients with high myopia.

Conclusion: This meta-analysis provided the up-to-date evidence and found that foldable PIOL group had significant beneficial effect on UDVA, SE, HOA, contrast sensitivity, and ECD, except best spectacle-corrected visual acuity, and safety in the treatment of high myopia over rigid PIOL group.

Abbreviations: BSCVA = best spectacle-corrected visual acuity, CIs = confidence intervals, CLE = clear lens extraction, CS = contrast sensitivity, ECD = endothelial cell density, HOA = higher-order aberrations, MRSE = mean refractive spherical equivalent, ORs = odds ratios, PIOL = phakic intraocular lens, SE = spherical equivalence, UDVA = uncorrected distance visual acuity, WMDs = weighted mean differences.

Keywords: foldable phakic intraocular lens, high myopia, implantation, meta-analysis, rigid phakic intraocular lens

1. Introduction

High myopia usually defined as ametropia (refractive error) with >6.00 diopters.^[1,2] It is characterized by persistent deepening of diopter, obvious prolongation of axial length (ocular axis), early onset of fundus lesions, progressive aggravation, and obvious impairment of visual function, obvious genetic tendency

(autosomal recessive inheritance), and most of them are accompanied by intraocular complications.^[3,4] In 2018, 112 million persons were affected by high myopia, accounting for the second most common cause of blindness globally.^[5-7] There are three main organic lesions in high myopia:

- (1) prolongation of ocular axis;
- (2) abnormal sclera;
- (3) retinal, choroidal, and vitreous degeneration.^[5]

Also, high myopia is complicated with a variety of fundus lesions, such as choroidal and retinal pigment epithelial atrophy, retinal detachment, retinal splitting, macular hemorrhage, macular, and other complications.^[8,9] However, there is still a lack of effective treatment for high myopia. The use of frame glasses is a convenient and safe method to correct high myopia, but the spherical aberration by thick lenses and high concave lenses presented great inconvenience to the life and vision of patients with high myopia. While refractive surgery eliminates the need to wear glasses or contact lenses, achieving satisfactory vision sight.^[10]

Refractive surgeries such as laser corneal refractive surgery, phakic intraocular lens (PIOL) implantation, and clear lens extraction (CLE) have been developed for the treatment of high myopia.^[11,12] PIOL implantation is a safer method for correcting myopia in the range of -6.00D to -20.00D , showing

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significantly less effect on the loss of best spectacle-corrected visual acuity (BSCVA) and better contrast sensitivity (CS) than corneal refractive surgery.^[9,13] Rigid PIOL versus foldable PIOL are considered to have good safety and efficacy.^[14,15] Both of them are implanted in the same location with the same fixative mechanism, but they have different material properties and require different incision sizes.^[15]

Since the role of rigid PIOL and foldable PIOL in the treatment of high myopia is still less evaluated, a number of studies with larger sample size and most up-to-date trials was conducted to obtain a more extensive and clearer evidence. However, no conclusive agreement was acquired due to the following limitations: insufficient number of comparative studies and lack of conformity in the duration of follow-up among observational studies due to bias. Therefore, a comprehensive meta-analysis was conducted to clarify the efficacy and complications of rigid PIOL versus foldable PIOL implantation in the treatment of high myopia based on the evidences from previous comparative studies.

2. Material and methods

The present meta-analysis was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines to evaluate the efficacy of rigid versus foldable iris-fixed PIOL implantation in the treatment of high myopia.

2.1. Literature search

A systematic search was performed to identify relevant studies using electronic databases such as PubMed, Embase, and Cochrane Library published till January 11, 2019. The following key words were used for retrieving the articles: “ciliary sulcus-fixed” OR “ciliary-fixed” OR “staar” OR “Artisan” OR “Verisyse” OR “Artiflex” OR “Veriflex” OR “irisfixed” OR “iris-fixated” OR “iris-claw”) AND (“myopia” OR “shortsightedness” OR “nearsightedness”. In addition, we also manually searched the references of the original articles to retrieve any eligible articles for this meta-analysis. Moreover, if studies had partly overlapping or familiar subjects, only the latest or more comprehensive study was selected in this meta-analysis.

2.2. Study selection

The inclusion criteria were as follows:

- (1) study design: comparative study;
- (2) population: patients with high myopia;
- (3) intervention: rigid versus foldable iris-fixated PIOL; and
- (4) follow-up: more than 6 months.

The exclusion criteria were as follows:

- (1) patients younger than 18 years of age or had unstable refraction;
- (2) patients who had preoperative ophthalmic diseases or contraindications or had undergone ophthalmic surgeries, especially refractive surgeries;
- (3) letters, comments, editorials, case reports, proceedings, personal communications; and
- (4) studies that reported no quantitative outcomes reported.

All included patients were diagnosed with high myopia and were randomized to those who receive rigid PIOL and foldable

PIOL. In addition, the primary endpoints were the mean changes of the efficacy, predictability, safety and visual quality as measured by using the uncorrected distance visual acuity (UDVA); spherical equivalence (SE); BSCVA, endothelial cell density (ECD), complications (including additional surgery due to inadequate PIOL position; pupil irregularities; anterior capsule opacities; decentration of PIOL; local iris atrophy; glare; cataract formation; decentration of the PIOL); higher-order aberrations (HOA), and CS.

2.3. Data extraction and quality assessment

Studies were identified by two independent reviewers to determine their eligibility for inclusion. In case of uncertainty regarding the eligibility of the article, a third reviewer was consulted to resolve the disagreements and make the final decision. The screening included two stages. Firstly, all titles and abstracts of the retrieved articles were reviewed against the inclusion and exclusion criteria. If in case the information was inadequate to make a decision, then the full texts were retrieved to further examine the eligibility of the study. Systematic reviews that shared a similar scope to this review were also identified during screening, and their reference lists were scanned and added to the screening data set.

For all included studies, the following information on study characteristics and outcomes were extracted: name of the first author, year of publication, country, study design, number of participants, intervention type, age, and major outcomes.

2.4. Quality assessment

The methodological quality of included studies was rated by using a modified version of the Downs and Black checklist.^[16] The modified version had 26 criteria that evaluated reporting, external validity, biases, and confounding of the studies and the total score indicated the methodological quality: excellent if the scores ranged from 21 to 23, good if 15 to 20, fair if 10 to 14, and poor if ≤ 9 .^[17]

2.5. Statistical analysis

The mean changes of parameters, including the efficacy, predictability, safety, and visual quality measured were compared between participants in rigid PIOL and foldable PIOL. The odds ratio (OR) with 95% confidence intervals (CIs) was used to evaluate the binary data. The weighted mean differences (WMDs) with 95% CIs were used to evaluate the continuous data for each individual study. A χ^2 -based test of homogeneity was performed using Cochran Q statistic and I^2 . Random effects models of analysis were used if heterogeneity was detected ($I^2 > 50\%$); and otherwise, a fixed effects model was used. Sensitivity analysis was carried out by using the “leave-one-out procedure” for each trial. Publication bias analysis was performed to detect an asymmetric funnel, and funnel plots were used to evaluate the results between small and large studies. A two-sided P value of $< .05$ was considered as statistical significance for one comparison group over the other. All analyses were performed using Net Meta XL (version 5.1).

3. Results

3.1. Study characteristics

Figure 1 presents a flowchart of the studies screened and reviewed. A total of 403 studies were identified according to the

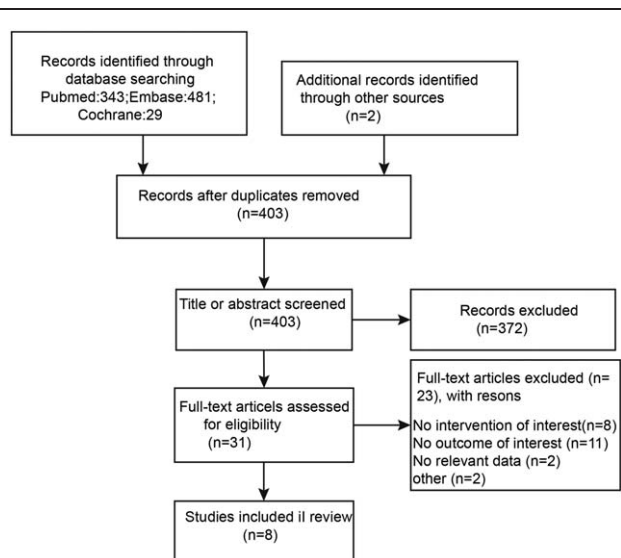


Figure 1. Flowchart of study selection and inclusion process.

inclusion and exclusion criteria. Of these, 372 articles were discarded after screening the titles and abstracts. The full texts of the remaining 31 articles were reviewed, and 23 articles were excluded. Finally, eight studies that met the eligibility criteria were included in this meta-analysis.^[14,15,18–23]

The reasons for the exclusion is that the study objective was not consistent with the intervention of interest (n=8), the outcome of interest (n=11), relevant data (n=2), and others (n=2). The

most common reason for exclusion was a non-comparative study design.

The detailed characteristics of the patients included in those eight studies are summarized in Table 1. Overall, the sample sizes ranged from 31 to 410. The total number of patients with high myopia was 835 (401 participants received rigid PIOL, and 434 participants received foldable PIOL). The quality of the included studies (Modified Downs and Black Scale) is shown in Table 2. The total scores of the methodological quality of the eight studies ranged from 14 to 23, indicating that the quality of those eight studies was high.

3.2. Clinical outcomes

3.2.1. Efficacy. Six studies provided enough data on UDVA and were included in the meta-analysis.^[21–26] Figure 2A shows the forest plot for the proportion of eyes with postoperative UDVA of 20/20 or better. The pooled OR of postoperative UDVA of 20/20 was not significantly different between the rigid and foldable PIOL groups (pooled OR=0.37, 95% CI=0.07–1.84, P=.24). The proportion of eyes with postoperative UDVA of 20/40 or better was higher in the foldable PIOL than in the rigid PIOL group (pooled OR=0.40, 95% CI=0.21–0.79, P=.55, Fig. 2B). Finally, we evaluated the mean postoperative UDVA (log MAR) in patients with high myopia. Random effects analysis had to be used due to a significant heterogeneity among four studies (Q=12.98, I²=77.00%, P<.01). The longest length of follow-up from each trial was included in the meta-analysis. The overall WMD was statistically significant (pooled WMD=0.10, 95% CI=0.04–0.11, Fig. 2C), revealing that foldable PIOL was superior to rigid PIOL in terms of postoperative UDVA.

Table 1
Characteristics of the included studies.

Studies (author year)	Design	Follow-up	Age (rigid)	Age (foldable)	No. of eyes (rigid)	No. of eyes (foldable)	Pre-SE (rigid)	Pre-SE (foldable)
Alio 2003	Retrospective	NR	32.0	36.8	16	15	-13.38±4.33	-11.32±3.10
Bohac 2016	Retrospective	36 months	33.1	35.2	198	212	-13.27±5.1	-10.12±2.96
Couillet 2006	RCT	12 months	37.8*	37.8*	31	31	-10.3±3.2	-9.5±2.2
Karimian 2014	Retrospective	12–56 months	27.0	30.0	40	36	-11.6±3.7	-9.59±1.97
Parsipour 2016	Prospective cohort	12 months	NR	NR	24	33	-10.39±8.43	-10.39±2.29
Tahzib 2008	Retrospective	12 months	40.0	41.0	22	27	-9.90±2.74	-9.95±1.43
Torii 2013	Retrospective	6 months	39.2	37.6	23	30	-11.84±4.90	-9.78±3.20
Yasa 2018	Retrospective	60 months	31.0	30.0	47	50	-12.50±3.51	-11.50±3.46

NR=not reported, PIOL=phakic intraocular lens, RCT=randomized controlled trail, SE=spherical equivalence.

All studies compared Artisan vs Artiflex, except Bohac 2006 and Yasa 2018, in which Verisyse and Veriflex were compared.

* No distinction between the two groups.

Table 2
Quality of the included studies (Modified Downs and Black Scale).

Studies (author year)	Reporting	External validity	Bias	Confounding	Total scores
Alio 2003	8	3	3	1	15
Bohac 2016	9	2	3	2	16
Couillet 2006	9	3	7	4	23
Karimian 2014	9	3	3	1	16
Parsipour 2016	6	2	4	2	14
Tahzib 2008	8	3	4	2	17
Torii 2013	9	3	4	2	18
Yasa 2018	9	3	4	2	18

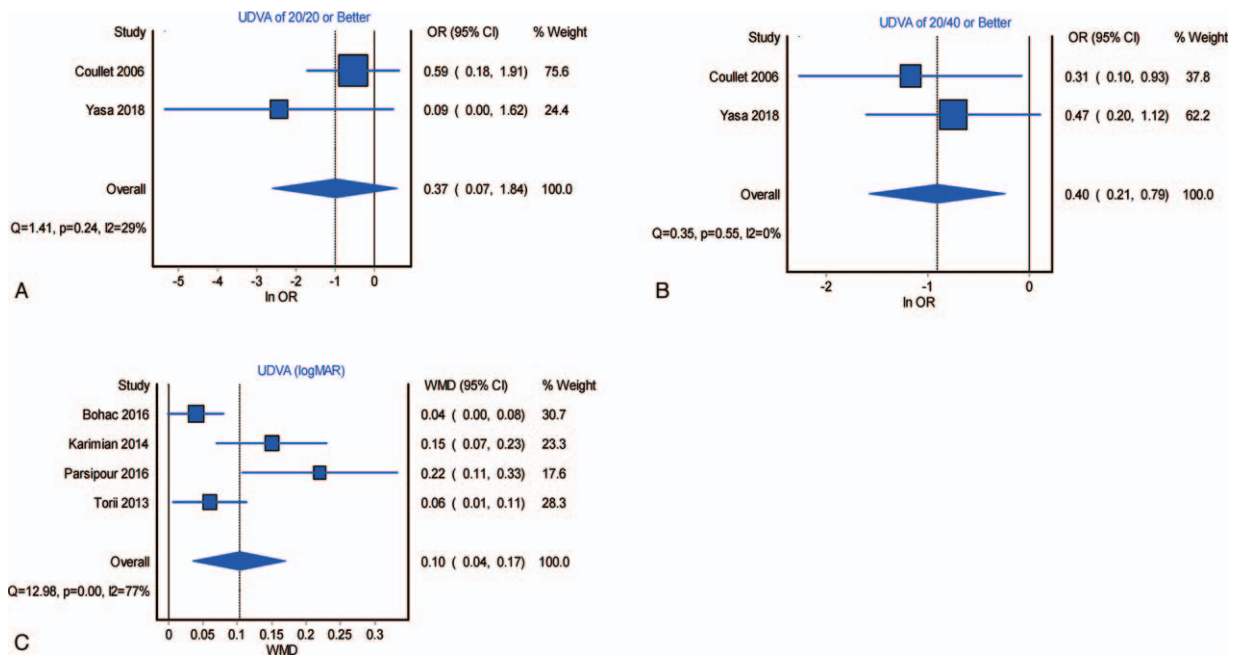


Figure 2. Forest plot showing the odds ratios and weighted mean difference estimates efficacy by phakic intraocular lens implantation in the treatment of high myopia. (A) Proportion of eyes with postoperative UDVA of 20/20 or better; (B) proportion of eyes with UDVA of 20/40 or better; (C) mean postoperative UDVA (logMAR). UDVA=uncorrected distance visual acuity

3.2.2. Predictability. Seven studies included postoperative SE and were included in this meta-analysis.^[14,15,18–20,22,23] The patients were divided into two subgroups according to their postoperative SE. Figure 3A shows the forest plot for the proportion of eyes with postoperative SE within ± 0.50 D of the target. The pooled OR revealed no significant differences between rigid and foldable PIOL (pooled OR=0.59, 95% CI=

0.34–1.02, $P=.93$). In addition, the proportion of eyes with postoperative SE within ± 1.00 D was better with foldable than with rigid PIOL (pooled OR=0.39, 95% CI=0.20–0.76, $P=.55$, Fig. 3B). The WMD of change from baseline in mean postoperative SE was favorable to foldable PIOL over rigid PIOL (pooled WMD=–0.21, 95% CI=–0.37 to –0.05, Fig. 3C).

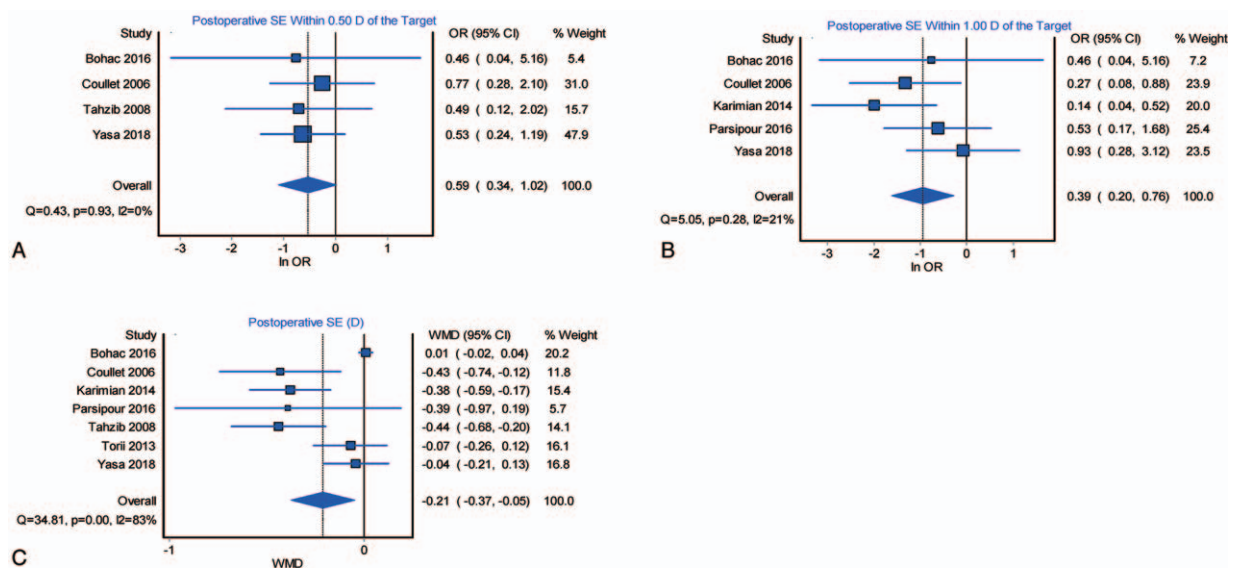


Figure 3. Forest plot showing the odds ratios and weighted mean difference estimates predictability by phakic intraocular lens implantation in the treatment of high myopia. (A) Proportion of eyes with postoperative SE within ± 0.50 D of the target; (B) proportion of eyes with postoperative SE within ± 1.00 D of the target; (C) Mean postoperative SE.

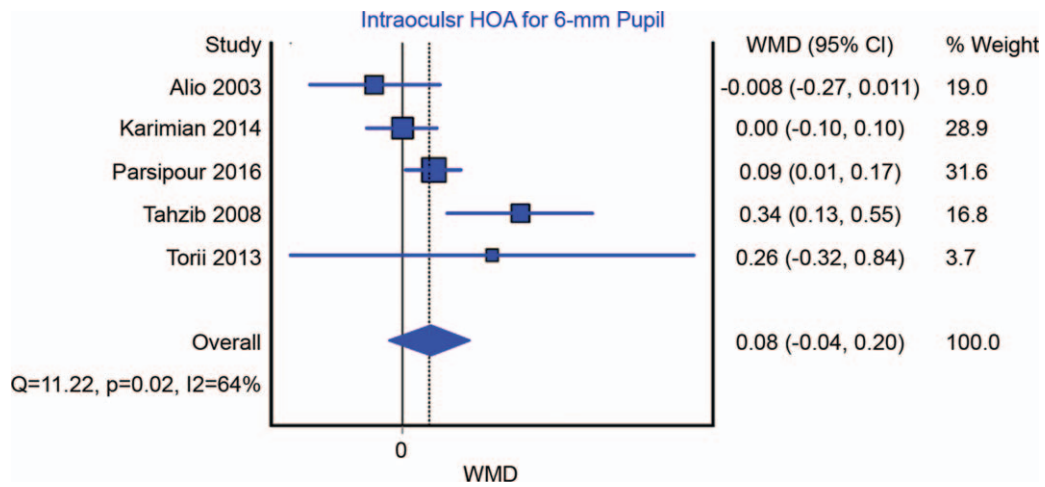


Figure 4. Forest plot showing the odds ratios and weighted mean difference estimates of mean postoperative intraocular HOA (μm) for a 6-mm pupil by phakic intraocular lens implantation in the treatment of high myopia. HOA=higher-order aberrations.

3.2.3. Visual quality. Five trials measured the mean postoperative intraocular HOA (μm) for a 6-mm pupil, and all showed a statistically significant effect in the Foldable PIOL group. This meta-analysis estimated a significant WMD of 0.08 (95% CI = -0.04 to 0.20, $P = .02$, Fig. 4), suggesting that foldable PIOL led to better visual quality compared with rigid PIOL.

Two trials measured the mean postoperative CS after treatment for high myopia. A significant difference was found in the mean postoperative CS at 3cpd (pooled WMD = -0.10, 95% CI = -0.23 to 0.02, $P = .48$, Fig. 5A), 6cpd (pooled WMD = -0.23, 95% CI = -0.35 to -0.11, $P = .32$, Fig. 5B), 12cpd (pooled WMD = -0.17, 95% CI = -0.28 to -0.06, $P = .70$, Fig. 5C), and 18cpd (pooled WMD = -0.21, 95% CI = -0.32 to -0.10, $P = .75$, Fig. 5D).

3.3. Safety and complications

Five studies^[14,15,18-20] measured the proportion of eyes that lost two or more lines of BSCVA. Five trials^[15,18-20,22] investigated the mean change in central ECD loss (cells/ mm^2). Three studies^[18-20] showed the proportion of eyes with postoperative complications. The results suggested that no significant difference in the proportion of eyes that lost two or more lines of BSCVA in the rigid PIOL group (OR = 2.44, 95% CI = 0.64-9.26, $P = .28$, Fig. 6A). Regarding the mean change in central ECD loss (cells/ mm^2), the results supported that compared with rigid PIOL, foldable PIOL had a beneficial effect on central ECD loss in patients with high myopia (pooled WMD = -24.76, 95% CI = -45.80 to -3.73, Fig. 6B).

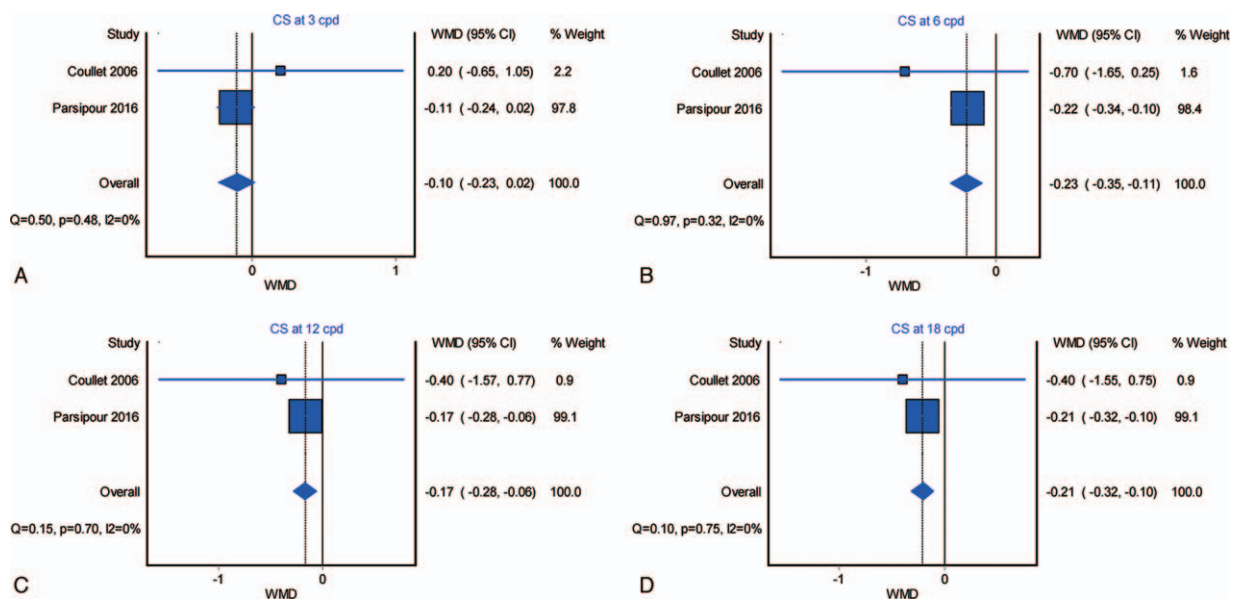


Figure 5. Forest plot showing the odds ratios and weighted mean difference estimates of visual quality by phakic intraocular lens implantation in the treatment of high myopia. (A) Mean postoperative CS at 3cpd; (B) mean postoperative CS at 6cpd; (C) mean postoperative CS at 12cpd; (D) mean postoperative CS at 18cpd. CS=contrast sensitivity.

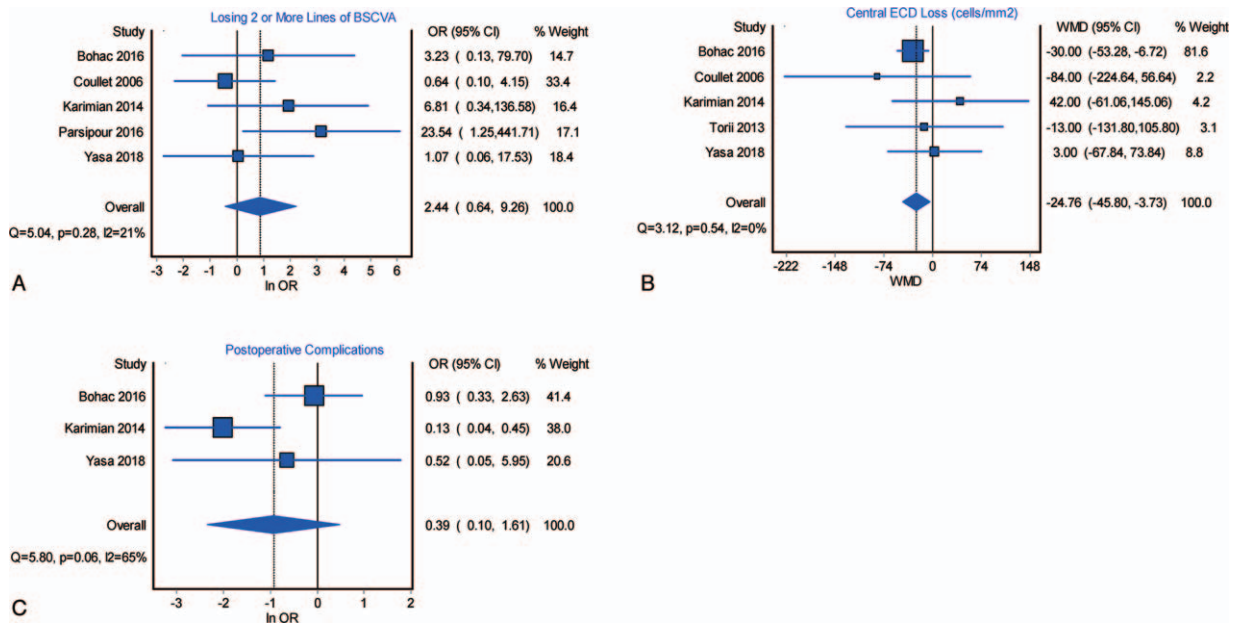


Figure 6. Forest plot showing the odds ratios and weighted mean difference estimates safety by phakic intraocular lens implantation in the treatment of high myopia. (A) Proportion of eyes with postoperative SE within ± 0.50 D of the target; (B) proportion of eyes with postoperative SE within ± 1.00 D of the target; (C) mean postoperative SE. SE=spherical equivalence.

The complications in the included studies are shown in Table 3. Three of the eight studies measured the proportion of eyes with postoperative complications in the treatment of high myopia. The overall WMD showed no significant difference (pooled WMD=0.39, 95% CI=0.10–1.61, $P=.06$, Fig. 6C).

3.4. Sensitivity analysis

Sensitivity analyses were performed using the leave-one-out approach (Table 4). The direction of the combined estimates presented above showed no significant variations with the removal of the studies, indicating that the meta-analysis was robust, and the data was not overly influenced by any specific study.

3.5. Publication bias

The review of the funnel plots could not rule out the potential publication bias for UDVA; SE; best BSCVA, ECD, complications; and HOA, respectively. This indicated that the results of the Egger and Begg tests showed no evidence of publication bias.

4. Discussion

This meta-analysis demonstrated no between-group differences for BSCVA, ECD, and complications in all patients with high myopia. Compared to rigid PIOL group, foldable PIOL group had beneficial effect on UDVA, SE, HOA, and CS in the treatment of high myopia. This updated systematic review and meta-analysis focused on examining the efficacy, predictability, safety, and visual quality of PIOL implantation in high myopia based on evidences from comparative studies and specifically stratified based on the duration of follow-up.

Previous meta-analyses studies that included observational studies of varied and insufficient quality have drawn conflicting and ambiguous conclusions.^[24,27] These results indicated no differences in the effects between the two approaches, but heterogeneity among individual studies pointed out the need for the conduction of more clinical studies and inclusion in the meta-analysis. Recently, Secretariat et al^[24] reported the comparison of PIOLs with LASIK, PRK, and CLE for patients with moderate to high myopia. Besides, myopic astigmatism showed that PIOLs

Table 3
Descriptions of complications in the included studies.

Studies (author year)	Rigid iris-fixed PIOL	Foldable iris-fixed PIOL
Alio 2003	NR	NR
Bohac 2016	4 additional surgery due to inadequate PIOL position. 1 pupil irregularities 1 anterior capsule opacities 1 decentration of PIOL	6 additional surgery due to inadequate PIOL position 1 pupil irregularities 1 anterior capsule opacities
Coulet 2006	None	None
Karimian 2014	2 local iris atrophy 2 glare	4 local iris atrophy 12 glare
Parsipour 2016	NR	NR
Tahzib 2008	NR	NR
Torii 2013	None	None
Yasa 2018	1 cataract formation	1 cataract formation 1 decentration of the PIOL

NR=not reported, PIOL=phakic intraocular lens.

Table 4**Sensitivity analyses using a leave-one-out procedure.**

Excluded study	Pooled effects	LCI 95%	HCI 95%	Cochran Q	P	I ²
UDVA (logMAR)						
Bohac 2016	0.13	0.04	0.22	7.93	.02	74.78
Karimian 2014	0.09	0.01	0.16	8.74	.01	77.11
Parsipour 2016	0.07	0.02	0.13	5.85	.05	65.84
Torii 2013	0.13	0.02	0.24	12.70	.00	84.26
Postoperative SE within 0.50D of the target						
Bohac 2016	0.59	0.33	1.05	0.39	.82	0.00
Couillet 2006	0.52	0.26	1.02	0.02	.99	0.00
Tahzib 2008	0.61	0.33	1.11	0.36	.83	0.00
Yasa 2018	0.64	0.29	1.39	0.33	.85	0.00
Postoperative SE within 1.00D of the target						
Bohac 2016	0.38	0.17	0.84	5.03	.17	40.39
Couillet 2006	0.43	0.18	1.02	4.52	.21	33.67
Karimian 2014	0.50	0.26	0.97	2.10	.55	0.00
Parsipour 2016	0.35	0.14	0.84	4.67	.20	35.82
Yasa 2018	0.30	0.15	0.59	2.46	.48	0.00
Postoperative SE (D)						
Bohac 2016	-0.26	-0.43	-0.09	14.46	.01	65.43
Couillet 2006	-0.18	-0.34	-0.01	27.94	.00	82.11
Karimian 2014	-0.17	-0.33	-0.01	22.71	.00	77.99
Parsipour 2016	-0.20	-0.37	-0.03	33.23	.00	84.96
Tahzib 2008	-0.16	-0.32	-0.01	22.77	.00	78.04
Torii 2013	-0.24	-0.44	-0.04	34.49	.00	85.50
Yasa 2018	-0.25	-0.46	-0.05	34.73	.00	85.60
Losing 2 or more lines of BSCVA						
Bohac 2016	2.54	0.48	13.42	4.97	.17	39.69
Couillet 2006	4.73	1.07	20.93	2.35	.50	0.00
Karimian 2014	2.09	0.43	10.15	4.39	.22	31.60
Parsipour 2016	1.40	0.39	4.95	2.04	.57	0.00
Yasa 2018	3.24	0.60	17.33	4.74	.19	36.69
Central ECD loss (cells/mm ²)						
Bohac 2016	-1.48	-50.58	47.61	2.06	.56	0.00
Couillet 2006	-23.41	-44.69	-2.13	2.42	.49	0.00
Karimian 2014	-27.67	-49.16	-6.18	1.43	.70	0.00
Torii 2013	-24.33	-47.68	-0.99	3.08	.38	2.49
Yasa 2018	-27.45	-49.48	-5.42	2.47	.48	0.00
Postoperative complications						
Bohac 2016	0.17	0.06	0.52	0.98	.32	0.00
Karimian 2014	0.85	0.33	2.21	0.19	.67	0.00
Yasa 2018	0.36	0.05	2.46	5.76	.02	82.65
Intraocular HOA for a 6-mm pupil						
Alio 2003	0.12	-0.01	0.25	8.68	.03	65.42
Karimian 2014	0.12	-0.05	0.29	8.84	.03	66.05
Parsipour 2016	0.09	-0.10	0.28	10.50	.01	71.42
Tahzib 2008	0.04	-0.04	0.12	4.22	.24	28.87
Torii 2013	0.07	-0.05	0.20	10.78	.01	72.18

BSCVA = best spectacle-corrected visual acuity, ECD = endothelial cell density, HOA = higher-order aberrations, HCI = higher confidence interval, LCI = lower confidence interval, SE = spherical equivalence, UDVA = uncorrected distance visual acuity.

showed better results than these alternative surgical options for the outcomes of UCVA, predictability and stability of mean refractive spherical equivalent (MRSE), postoperative MRSE, safety (measured as clinically significant loss of BSCVA), and gains in BSCVA. Correction of refractive cylinder (astigmatism) is the only outcome that favored refractive surgery over PIOLs. This was observed for both toric and non-toric PIOLs (toric PIOLs correct for astigmatism, while non-toric PIOLs do not). Common adverse events in the LASIK groups included diffuse lamellar keratitis and striae in the corneal flap. In the PIOL groups, lens repositioning and lens opacities (both asymptomatic and visually significant cataracts) were the most commonly observed adverse

events.^[24] In addition, Kamiya et al^[27] focused at one year post surgery, and the results showed that PIOLs are safer than excimer laser surgical corrections for moderate to high myopia in the range of -6.0 to -20.0D and PIOLs are mostly preferred by patients. Hence, the objective of this meta-analysis is to determine whether PIOL have beneficial effects on efficacy, predictability, safety and visual quality about PIOL among high myopia.

The present meta-analysis study aimed to fill the evidence gap by focusing on comparative studies and including the trials that are published recently. The results showed that compared with rigid PIOL group, foldable PIOL group had significant beneficial effect on UDVA, SE, HOA, and CS, except BSCVA, ECD, and

complications in the treatment of high myopia. With the restriction of sources of evidences to comparative studies of moderate to high quality, the measured and unmeasured confounding factors that are commonly observed in observational studies are minimized. Thus, the results were more consistent among trials, and the data used in this meta-analysis with the duration of follow-up was well controlled in the comparative studies.^[25] The study also found that foldable PIOL showed a statistically significant beneficial effect on UDVA, SE, HOA, and CS in the treatment of high myopia. The underlying mechanism for this difference was that the rigid PIOL group had increased level of efficacy, predictability and visual quality in the treatment of high myopia, except safety when compared to foldable PIOL group. Both rigid and foldable PIOLs are effective in correcting high myopia. The foldable lens demonstrated better refractive outcome; however, subclinical inflammation was observed in the foldable PIOL group and potential influence of inflammation on endothelial cell count loss required further investigation.^[9,18]

Meta-analysis is a powerful tool and can provide more efficient results compared to a single study, especially in analyzing the unexplained studies.^[25,28] On one hand, in order to effectively minimize the influence of heterogeneity, a systematic analysis based on evidence from comparative studies was conducted to further explore the scope of application for PIOL implantation as one of the therapeutic methods in patients with high myopia.^[26,29] Same as previous meta-analyses, this review strictly adhered to the PRISMA guidelines and the methodology increased the robustness and validity of the results. Only comparative studies were included in this systematic review and all were objectively judged to be of high quality.^[30] On the other hand, we strictly followed the literature inclusion criteria and the quality of enrolled literatures was satisfactory to assess the efficacy and complications of PIOL implantation in the treatment of high myopia in a separate analysis. All these advantages have increased the statistical power of meta-analysis. The present meta-analysis deemed that foldable PIOL group had significant beneficial effect on UDVA, SE, HOA, CS, and ECD, except BSCVA, and safety in the treatment of high myopia over rigid PIOL group.

The strengths of this systematic review and meta-analysis were the inclusion of relatively homogenous studies due to comparative study designs, ability to conduct a meta-analysis on multiple follow-up durations, and focus on clinically relevant outcome measures. However, some details need to be further refined. Firstly, the protocol of PIOL implantation in the included studies was different, and the duration of intervention varied in the meta-analysis, which might confound the pooled results. Secondly, iris claws might be misplaced more often than others, the position of the lens also should be paid close attention in the treatment of high myopia by rigid or foldable PIOL implantation. In addition, due to lack of uniform cut-off values in the optimal therapeutic modalities of PIOL implantation, it remained difficult for us to set up a baseline, which might cause the pooled outcome higher or lower than the actual value, causing a bias in the results of the effect of PIOL implantation. Therefore, the optimal strains, dosage and duration of probiotics intervention required further investigation. Large-scale clinical trials are warranted to determine the ideal dose composition of probiotics product.

5. Conclusion

In summary, this systematic review and meta-analysis provided the most up-to-date evidence and demonstrated that compared to

rigid PIOL group, foldable PIOL group had significant beneficial effect on UDVA, SE, HOA, CS, and ECD, except BSCVA, and complications in the treatment of high myopia. However, more data is still needed from comparative studies to validate these findings. More high-quality multicenter studies should be conducted and published to provide long-term follow-up results, and should be switched from systematic reviews of observational studies to examine a detailed list of outcome measures.

Author contributions

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