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Systematic review of the efficacy and safety of stage I or II IOL implantation in patients with diabetic retinopathy

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Abstract

Background: Intraocular lens (IOL) implantation is required after vitrectomy combined with cataract surgery in diabetic retinopathy patients. However, the question of whether an IOL should be implanted in stage I after vitrectomy or stage II during silicone oil filling has been controversial, and there has been no systematic review of this clinical issue.

Methods: WanFang, SinoMed CNKI, VIP, PubMed, Embase, and Cochrane Library databases were systematically searched for relevant studies. The deadline was May 8, 2021. All studies of stage I or II IOL implantation in patients with diabetes who underwent vitrectomy were included. Revman 5.3 software was used for the meta-analysis.

Results: Four studies, involving 253 eyes, were included. This study analyzed the literature with a common outcome index by meta-analysis and systematically evaluated the literature without a common outcome index. Four studies compared the efficacy and safety of the 2 sequential surgical methods in patients with diabetic retinopathy. The results of the meta-analysis showed that there was no significant difference in the efficacy and safety of stage II IOL implantation when compared with stage I IOL implantation ($P > .05$). One study showed that stage II cataract surgery with oil extraction resulted in better postoperative visual acuity and fewer complications than stage I cataract surgery with vitrectomy. One study showed that stage II IOL implantation during oil extraction had better postoperative visual acuity than stage I IOL implantation during vitrectomy without increasing surgical complications.

Conclusion: Vitrectomy combined with stage II IOL implantation is safer and more effective than stage I in patients with diabetic retinopathy; however, more clinical studies are needed to verify this.

Abbreviations: CI = confidence interval, IOL = intraocular lens, OR = odds ratio.

Keywords: diabetic retinopathy, effectiveness, IOL implantation, safety, systematic review

1. Introduction

Diabetic retinopathy and cataracts are common complications of diabetes.[1–5] With the improvements in ophthalmic microsurgery technology, vitrectomy combined with cataract surgery for diabetic retinopathy has become the main surgical method,[6,7] and most patients need to be filled with silicone oil after vitrectomy.[8–10] However, whether an intraocular lens (IOL) should be implanted in stage I after vitrectomy in patients with diabetic retinopathy or stage II implantation during silicone oil filling has been controversial, and there has been no systematic review of this clinical issue. Therefore, to guide clinicians in this surgical approach, we systematically reviewed the efficacy and safety of stage I and II IOL implantation for vitrectomy in patients with diabetic retinopathy. The remainder of this paper is organized as follows.

2. Materials and Methods

2.1. Ethics

No ethical approval or informed consent was required for this study, because it only analyzed the published data and no individual participant data were involved.

2.2. Literature search

We conducted a comprehensive literature review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols.[11–13] PubMed, Embase, Cochrane, CBM, Wanfang, CNKI and VIP databases were searched from inception to May 8, 2021. The search terms included "diabetic retinopathy," "silicone oil removal," and "cataract surgery."

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The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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The detailed search strategy is shown in File S1, Supplemental Digital Content, http://links.lww.com/MD/I187. No language restrictions were applied. The search terms used were free, truncated and thematic. We manually searched the reference list of all the retrieved articles to identify those articles that met the criteria.

2.3. The inclusion and exclusion criteria

Two researchers screened all articles according to the predetermined selection criteria. Any differences were discussed and resolved by 2 participants. The inclusion criteria were as follows: clinical trial studies (including multicenter studies, randomized controlled trials, cohort studies, and case-control studies); subjects included patients with diabetic retinopathy; intervention measures: stage I refers to the first operation for vitrectomy, phacoemulsification, and silicone oil injection, and stage II refers to the second operation for silicone oil removal. Two sequential surgical methods were used: 1) Stage I: vitrectomy + phaco + silicone oil injection; stage II: silicone oil removal + IOL implantation (Stage II IOL Implantation Group). 2) Stage I: vitrectomy + phaco + silicone oil injection + IOL implantation; stage II: silicone oil removal (Stage I IOL Implantation Group) articles with records of postoperative effectiveness and complications, complete 4-table data and odds ratios (ORs) were included. The exclusion criteria were as follows: patients requiring vitrectomy for non-diabetic retinopathy; duplicate publications and literature provide incomplete or unknown messages; and other experimental studies other than clinical studies, case reports, conference abstracts, and basic experiments.

2.4. Data extraction

Two researchers independently screened the literature, extracted the data, and conducted cross-checking according to the inclusion and exclusion criteria of this study. Any disagreements were resolved through further discussion or judgment by a third researcher. The extracted information included: the first author, year of publication, place of study, type of diabetes, time of follow-up, number of eyes studied, age of the patients and duration of diabetes. Outcome indicators included the visual acuity improvement rate and positive ocular complications.

2.5. Assessment of study quality

According to the type of literature, the Methodological Index for Non-Randomized Studies score was used to evaluate the methodological quality of non-randomized clinical trials.[6] Two researchers independently completed the evaluation steps. Differences in evaluation results were resolved through further discussion or determined by a third researcher.

2.6. Statistical analysis

Statistical data analysis was performed using RevMan 5.3 provided by The Cochrane Collaboration. Count data were calculated using the relative OR and its 95% confidence interval (CI). Heterogeneity between the studies was analyzed using the Q test and I^2. When the heterogeneity test result was $P > .05$ ($I^2 \leq 50\%$), the fixed effect model was used to calculate the combined statistic. Heterogeneity was observed among the results of multiple studies when the heterogeneity test result was $P < .05$ ($I^2 > 50\%$). Therefore, it is necessary to analyze the reasons for heterogeneity in detail, and use a random-effects model for combined processing. Funnel plots were used to assess the risk for publication bias.

3. Results

3.1. Identification of eligible studies

A total of 103 relevant papers were obtained, including 11 from CNKI, 11 from SinoMed, 13 from Wanfang, 2 from VIP, 5 from PubMed, 45 from Embase, and 16 from The Cochrane Library. After excluding duplicate literature, 66 studies were obtained, and 16 literature remained after preliminary screening by reading the research titles and abstracts of the relevant literature. Studies that did not meet the inclusion criteria were excluded after reading the full literature. Finally, 4 literature were included in this systematic review[14–17] (Fig. 1).

3.2. Characteristics of included studies

The characteristics of these studies are summarized in Table 1. Two studies included in this systematic review were prospective studies, and 2 were retrospective studies. Among the 4 papers, 1 is a published master's thesis and 3 are journal papers. The total sample size of this systematic review was 253.

3.3. Evaluation of clinical indicators

Konovalova et al[16] conducted a prospective study of 67 patients (67 eyes) with diabetic retinopathy who underwent combined surgery of the anterior and posterior segments, including 35 patients in the Stage II IOL Implantation Group and 32 in the Stage I IOL Implantation Group. The patients were followed up for 6 months. There was a statistically significant difference in visual acuity improvement between the 2 groups ($P < .05$). The incidence of secondary neovascular glaucoma and cystoid macular edema in the Stage II IOL Implantation Group was lower than that in the Stage I IOL Implantation Group. The difference between the 2 groups was statistically significant ($P < .05$).

Guo et al[17] conducted a prospective study of 91 patients (91 eyes) with diabetic retinopathy complicated by cataract, including 49 patients in the Stage II IOL Implantation Group and 42 patients in the Stage I IOL Implantation Group. The patients were followed up for 3 months. Su et al[14] studied 73 eyes of patients with diabetic retinopathy who underwent combined surgery of the anterior and posterior segments, of which 41 eyes were in the Stage II IOL Implantation Group and 29 were in the Stage I IOL Implantation Group. The patients were followed up for 6 months after the operation. In the meta-analysis of these 2 studies, the rate of postoperative visual acuity improvement was not significantly different between the 2 groups (OR = 1.28, 95% CI: 0.65–2.50; $P > .05$) (Fig. 2).

There were no significant differences in the rates of retinal holes (OR = 1.31, 95% CI: 0.41–4.19; $P > .05$), retinal detachment (OR = 0.31, 95% CI: 0.06–1.63; $P > .05$), choroidal hemorrhage (OR = 2.45, 95) % CI: 0.25–24.03; $P > .05$), and vitreous hemorrhage (OR = 2.06, 95% CI: 0.39–10.92; $P > .05$) (Fig. 3).

In a study by Xu et al,[15] 25 eyes of 25 patients with proliferative diabetic retinopathy who underwent vitrectomy + phacoemulsification + silicone oil filling were analyzed, of which 9 eyes were implanted with IOL while silicone oil was removed, and IOL was implanted in 16 eyes during vitrectomy. The patients were followed up for an average of 10 months after surgery. No recurrent retinal detachment was found in either group after surgery.

4. Discussion

IOL implantation is required after vitrectomy in combination with cataract surgery in patients with diabetic retinopathy. Some scholars believe that the inflammatory reaction in the anterior chamber may be exacerbated after surgery due to the increased operation steps and operation time during

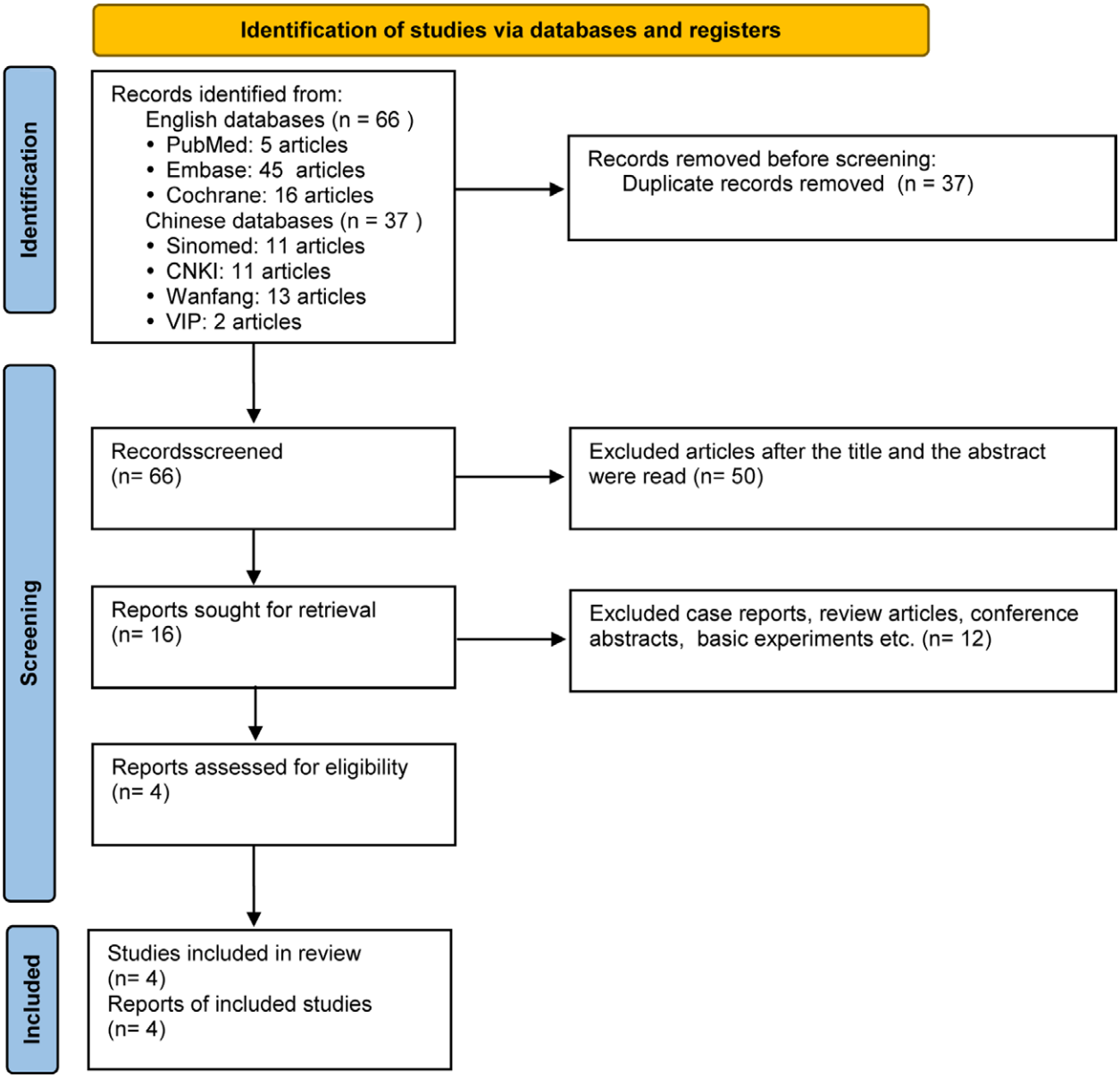

Figure 1. Flow chart of literature screening.

Table 1

Characteristics of studies included in the systematic review.

					Stage II IOL Implantation Group			Stage I IOL Implantation Group			
Author	Year	Study location	Type of diabetes	Follow-up time (min)	Eyes	Age (yr)	Course of diabetes (yr)	Eyes	Age (yr)	Course of diabetes (yr)	MINORS score
Xu et al	2017	China	NR	6–27	9	62 ± 7.69	1–12	16	61 ± 9.63	0–24	18
Su et al	2019	China	I and II	6	41	61.2 ± 6.4	12.1 ± 3.1	29	61.2 ± 6.4	12.1 ± 3.1	18
Guo et al	2020	China	I and II	3	49	63.4 ± 9.2	12.4 ± 3.3	42	61.3 ± 9.7	10.5 ± 2.9	18
Konovalova et al	2021	Russia	NR	6	35	60.8 ± 10.1	15.7 ± 8.4	32	61.4 ± 10.3	17.6 ± 6.9	18

IOL = intraocular lens, MINORS = Methodological Index for Non-Randomized Studies, NR = not reported.

vitrectomy.[6,18–20] At the same time, the small diameter of the optical part of the implanted IOL may affect fundus observation and supplemental fundus laser treatment after surgery. Therefore, in clinical medicine, some surgeons prefer silicone oil for intraocular filling after vitrectomy to reduce the risk of intraocular proliferation and postoperative retinal detachment.[21–25] When the intraocular microenvironment of the patient stabilized, silicone oil was removed and the IOL was implanted in stage II.[26–29] However, there may also be silicone oil emulsification and adhesion and opacity of the anterior and/or posterior lens capsules after vitrectomy, which can cause difficulty in implanting IOL in stage II.[15,30] At this

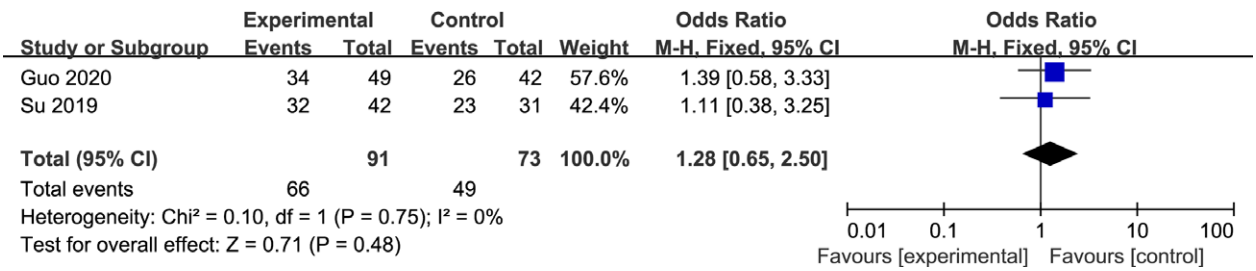

Figure 2. Forest plot of visual acuity improvement rate in Stage II and Stage I IOL Implantation Group. IOL = intraocular lens.

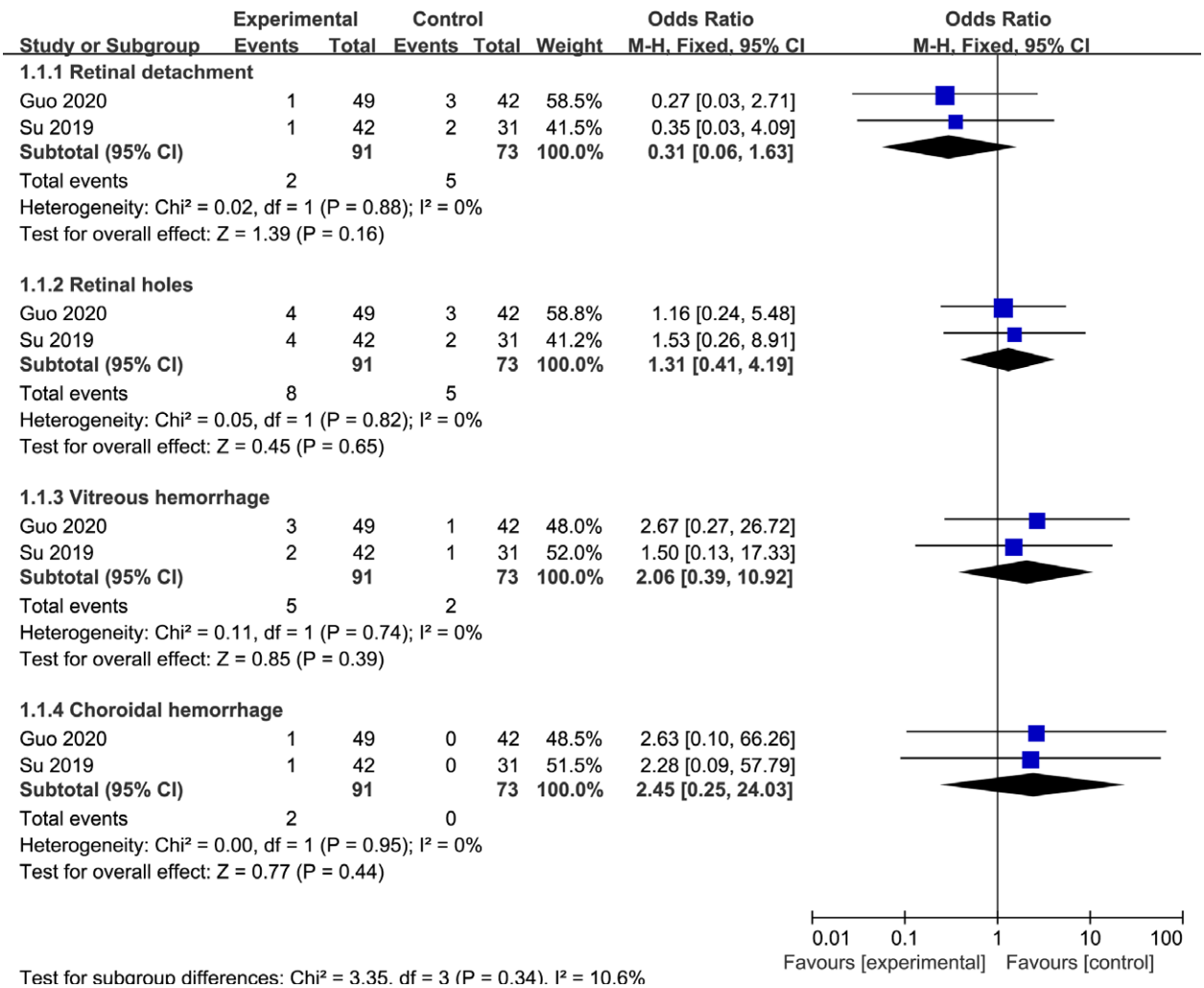

Figure 3. Forest plot of positive ocular complications incidence in Stage II and Stage I IOL Implantation Group. IOL = intraocular lens.

time, an IOL is usually implanted into the ciliary sulcus, which increases the incidence of pigment dissemination, secondary glaucoma and IOL eccentricity.[31–33] Therefore, the timing of IOL implantation is controversial in clinical practice.

In this study, we searched 7 databases including Cochrane Library, PubMed, Embase, CNKI, Wanfang, Sinomed and VIP. Three retrieval methods were adopted: free, extended, and subject words. These measures ensure the comprehensiveness of the included literature, and it is beneficial to objectively evaluate the efficacy and safety of IOL implantation in stage I or II in patients with diabetic retinopathy for vitrectomy. The 4 studies included in this review used different indicators to evaluate the efficacy and safety of surgery. We conducted a meta-analysis of some of the literature and only conducted a descriptive systematic descriptive review of the remaining studies. The meta-analysis results of 2 studies suggest no significant difference in the visual prognosis and incidence of retinal holes, retinal detachment, choroidal hemorrhage and vitreous hemorrhage between the Stage II IOL Implantation Group and Stage I IOL Implantation Group.[14,17] Xu et al[15] found that stage II IOL implantation resulted in better postoperative visual acuity than stage I IOL implantation, which may be related to better recovery of the primary disease and stabilization of the eye's refractive state during stage II IOL implantation. Konovalova et al[16] found that stage II IOL implantation had better postoperative visual acuity and fewer postoperative complications than stage I. Therefore, stage II IOL implantation is advocated.

The main limitations of this systematic review are as follows: the number of studies included in the research analysis was

small, and the research objects of Xu et al[15] not only included patients with diabetic retinopathy, but also patients with rhegmatogenous retinal detachment, macular hole, penetrating eye injury, etc, which have a certain selection bias; the sources of the included literature are relatively concentrated, and there are currently few relevant studies in Europe and the US, which have a certain publication bias; and the results of the included literature studies may have been affected by differences in surgeons' technical experience and outcome evaluation methods, which may have affected the results of this meta-analysis and systematic review to a certain extent. These limitations limit the strength of the systematic review results, and high-quality prospective clinical studies are required.

In summary, based on the results of this systematic review, it can be concluded that vitrectomy combined with stage II IOL implantation in patients with diabetic retinopathy is safer and more effective than stage I. However, further clinical studies are required to verify this finding.

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Supervision: Yanling Wang.
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