



Foldable capsular vitreous body indications, complications, and outcomes: a systematic review

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Abstract

Purpose Foldable capsular vitreous body (FCVB) is an emerging vitreous substitute that has been recently introduced to treat various advanced vitreoretinal conditions including severe ocular trauma, complicated retinal detachment (RD), and proliferative vitreoretinopathy.

Methods Review protocol was prospectively registered at PROSPERO (CRD42022342310). A systematic literature search using PubMed, Ovid MEDLINE, and Google Scholar for articles published until May 2022 was performed. The search included the following keywords: foldable capsular vitreous body, FCVB, artificial vitreous substitutes, and artificial vitreous implants. Outcomes included indications of FCVB, anatomical success rates, postoperative intraocular pressure (IOP), best-corrected visual acuity (BCVA), and complications.

Results A total of 17 studies that utilized FCVB up to May 2022 were included. FCVB was used intraocularly as a tamponade or extraocularly as a macular/scleral buckle for various retinal conditions including severe ocular trauma, simple and complex RD, silicone oil-dependent eyes, and highly myopic eyes with foveoschisis. FCVB was reported to be successfully implanted in the vitreous cavity of all patients. Final retinal reattachment rate ranged from 30 to 100%. Postoperative IOP improved or was maintained in most eyes, with low postoperative complication rates. Improvement in BCVA ranged from 0 to 100% of subjects.

Conclusion Indications of FCVB implantation have recently widened to include multiple advanced ocular conditions such as complex RD, but also include simpler conditions as uncomplicated RD. FCVB implantation showed good visual and anatomical outcomes, few IOP fluctuations, and a good safety profile. Larger comparative studies are required to further evaluate FCVB implantation.

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Key messages**What is known**

- Foldable capsular vitreous body (FCVB) is a novel vitreous substitute that has been recently introduced to treat various advanced vitreoretinal conditions including severe ocular trauma, complicated retinal detachment (RD), and proliferative vitreoretinopathy.

What this study adds

- This systematic review showed that FCVB may be used intraocularly as a tamponade or extraocularly as a macular/scleral buckle for various retinal conditions including severe ocular trauma, simple and complex RD, silicone oil (SO) dependent eyes, and highly myopic eyes with foveoschisis.
- FCVB showed good visual outcomes, few IOP fluctuations, and a good safety profile.

Keywords Foldable capsular vitreous body · Artificial vitreous · Vitreous implants · Retinal detachment · Ocular Trauma · Macular hole · Retina

Abbreviations

AC	Anterior chamber
AL	Axial length
BCVA	Best-corrected visual acuity
DDS	Drug delivery system
FCVB	Foldable capsular vitreous body
F/U	Follow-up
IRB	Institutional review board
IOP	Intraocular pressure
MH	Macular hole
NIH	National Institutes of Health
PDR	Proliferative retinopathy
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PVR	Proliferative vitreoretinopathy
RCT	Randomized controlled trial
RD	Retinal detachment
RRD	Rhegmatogenous retinal detachment
SO	Silicone oil
VC	Vitreous cavity

Introduction

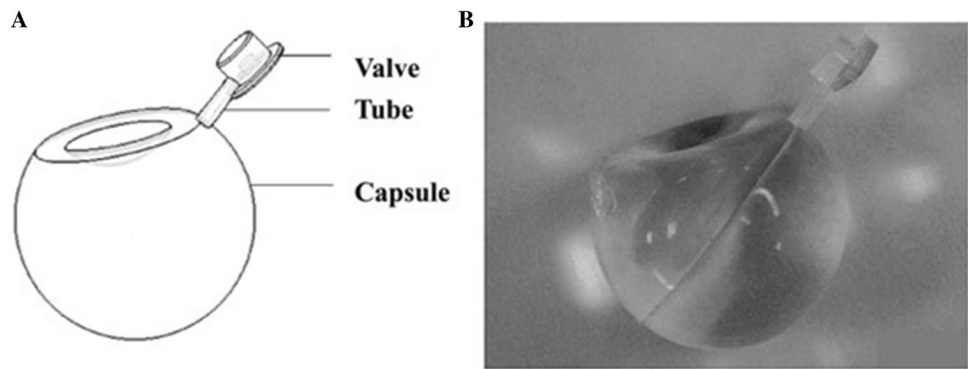
The vitreous body is a transparent, gel-like structure that occupies more than 80% of the eye's volume. It contains approximately 99% water and only about 1% proteins, organic lipids, inorganic salts, and hyaluronan, and functions to support the ocular structures, provide nutrition, transport metabolites such as oxygen, and act as a refractive medium [1]. However, the vitreous body is unable to regenerate, which creates the need for alternatives in cases of ocular pathology that require the removal of the vitreous. The ideal vitreous substitute should mimic the natural vitreous body characteristics including its transparency, volume

retention, biocompatibility, and elasticity [2]. Several artificial vitreous substitutes are currently available such as inert gases, silicone oil (SO), heavy SO, and hydrogels [3]. Many complications are reported secondary to the use of current vitreous substitutes, including cataract development, high intraocular pressure (IOP), corneal degeneration, SO emulsification, and even complete blindness [2]. Therefore, an ideal and safe artificial vitreous body is yet to be found.

Foldable capsular vitreous body (FCVB) is a novel vitreous substitute that was first developed by the State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Center, Sun Yat-sen University, and jointly produced by Guangzhou Vesber Biotechnology Co., Ltd, China. The FCVB is composed of a thin (30 μ m) vitreous-shaped capsule, a drain tube, and a valve (Fig. 1). It is made of tailor-made modified liquid silicone rubber [4]. After foldable implantation into the vitreous cavity, balanced salt solution (BSS), physiological balanced solution, or SO may then be injected into the FCVB, and the capsule is inflated in order to support the retina and regulate the IOP via the tube–valve system [4, 5]. Several animal studies were conducted to evaluate the efficacy and safety of FCVB [5–7]. Wang et al. [5] showed that inflation with either saline or SO showed good biocompatibility and retinal support in rabbit eyes; in addition, FCVB inflated with SO can decrease complications associated with SO, such as migration into the AC and emulsification. Chen et al. [6] demonstrated that FCVB only caused minor refractive changes in the rabbits' model compared with SO. Feng and colleagues [7] developed a new approach of using FCVB inflated with polyvinylalcohol (PVA) hydrogel as a vitreous substitute to prolong the implantation function of the capsule.

When compared with SO and heavy SO, FCVB was found to have a smaller effect on refraction depending on the Gullstrand-Emsley and Liou-Brennan schematic eyes [8]. Furthermore, FCVB can provide sustained release of dexamethasone sodium phosphate (DexP, Baiyunshan Tianxin Pharmaceutical Co., Ltd.,

Fig. 1 Foldable capsular vitreous body (FCVB) consists of a thin vitreous-shaped capsule, a drain tube, and a valve. **A** Graphical Illustration of FCVB. **B** Real illustration of FCVB (adapted from (26) distributed under the terms of the Creative Commons Attribution 3.0 License)



Guangzhou, China) and serve as an intravitreal drug delivery system (DDS) [9]. In addition, overall post-surgical complications of FCVB could be lower, compared to SO tamponade, with no need for patients to keep a prone position after surgery. [10]

Recently, several studies have been performed by various investigators to evaluate the utility, safety, and efficacy of FCVB in the treatment of various ocular conditions including complicated retinal detachments (RD), severe ocular trauma, and endophthalmitis [11–13]. We aimed to provide a systematic review of these studies and to report on the indications and complications, as well anatomical and functional success rates of FCVB.

Methods

Registration, search strategy, and database search

This systematic review was conducted as per the recommendation of the PRISMA checklist for systematic reviews and meta-analyses [14]. Our protocol was prospectively registered at PROSPERO on June 25, 2022 (Registration number: CRD42022342310). The study adhered to the tenets of the Declaration of Helsinki, and the necessity for an institutional review board (IRB) approval was not required since it did not involve human subjects. A systematic literature search using PubMed, Ovid MEDLINE, and Google Scholar for all articles published until May 2022 was performed. The search included the following keywords: foldable capsular vitreous body, FCVB, artificial vitreous substitutes, and artificial vitreous implants. For example, the search strategy in PubMed was as follows: “foldable capsular vitreous body” OR “FCVB” OR “artificial vitreous”.

Selection of studies

Following the exclusion of duplicates, the identified titles and abstracts were reviewed independently by two investigators (H.A.S. and S.I.), and all relevant studies were included in the review. Any disagreement between both investigators was

resolved by an open discussion. Further adjudication was also provided by the senior investigator (A.G.E.). Backward and forward reference list checking was also performed to find additional relevant papers.

Inclusion and exclusion criteria

All studies that used FCVB for any indication were included. Exclusion criteria included the following: single case reports, case series with less than 3 eyes, and articles with follow-up of less than 3 months. Only articles that were published in the English language were included, and no restrictions were applied to the study type other than those previously mentioned.

Data extraction and assessment of methodological quality and risk of bias

All included studies were read in full by two investigators independently (H.A.S and S.I.), and the following data was extracted using Microsoft Excel: name of authors, title, year of publication, the design of the studies, the number of included eyes, the inclusion and exclusion criteria of patients, their demographic characteristics, the indications of FCVB implantation, the anatomical success rate of FCVB represented by the success rate of its implantation and the final retinal reattachment rate, types of complications and their rate, the IOP post-FCVB implantation, the final BCVA, and the follow-up period. Data extracted by both investigators were compared by a third investigator (L.A.S.), discrepancies were discussed, and a consensus was reached. Methodological quality and risk of bias were assessed using the NIH quality assessment tool for the specific study type (<https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools>).

Results

A detailed description of the design and baseline characteristics of included studies is provided in Table 1. A total of 17 studies that evaluated the indications, safety, and efficacy

Table 1 Design and characteristics of included studies (N = 17)

Study	No. of eyes	Design of study	Age range in years (average)	Male gender (N/T)	Inclusion criteria	Exclusion criteria	Ref
Xu X et al	18	Retrospective case series study	34–70 (50.61 ± 11.63)	17/18	(1) Severe ocular rupture with retinal and choroid injury, VA < 0.05; (2) ocular trauma with mild ocular atrophy, ocular axis of 16.00–28.00 mm; (3) SO-dependent eye	(1) Severe liver or kidney dysfunction, cardiovascular disease, nervous system disease, and inability to tolerate FCVB implantation; (2) single eye (3) severe intraocular infections, uveitis, or intraorbital infections; (4) diseases affecting the development of the orbit in the contralateral eye; (5) allergies to silicone materials or scars	[11]
Chen S et al	27	Retrospective case series study	20–69 (39.70 ± 13.02)	26/27	(1) Age 18 to 65 years; (2) VA < 0.05; (3) without a lens; (4) ocular AL between 16 and 28 mm; (5) severe RD that could not be treated by vitreous substitutes	(1) Allergies to silicone rubber or scar diathesis; (2) enophthalmia; (3) uveitis; (4) other uncontrollable eye diseases; (5) PDR; (6) the lens of the target eye was transparent; (7) serious heart, lung, liver, or kidney dysfunction; (8) pregnancy or breast-feeding females; (9) drug abuse or alcoholism	[12]
Zhang X et al	20	Retrospective case series study	2–65 (40.05)	17/20	(1) Severe RD that could not be cured with SO tamponade; (2) rigid retinal re-detachments or inferior holes that occurred after > 3 months of SO tamponade; (3) AL ≤ 26 mm	(1) Scar physique; (2) glaucoma; (3) eye inflammation; (4) macular diseases	[13]
Deng J et al	26	Retrospective case series study	20–60 (36)	23/26	(1) All open ocular trauma wounds are located in zone III; (2) preoperative VA grade ≥ IV	Not fulfilling inclusion criteria	[20]
Hao Jiang et al	7	Retrospective case series study	17–54 (38.57 ± 11.70)	6/7	(1) History of severe ocular trauma; (2) had undergone several operations; (3) had an IOP which could not be maintained with SO tamponade; (4) satisfied the requirements of FCVB implantation	The exclusion criteria were contraindications approved by the China Food and Drug Administration (FDA)	[25]
Liu N et al	5	Retrospective case series study	18–46 (32 ± 14)	3/5	Patients with severe SO-dependent eyes	(1) Allergic to silica gel, scar diathesis; (2) endophthalmitis; (3) uveitis; (4) transparent lens in the operated eye; (5) PDR; (6) contralateral BCVA ≤ 0.4; (7) history of intraocular surgery in contralateral eyes; (8) other uncontrollable ocular comorbidities; (9) severe renal and liver function damage or severe systemic diseases; (10) pregnant, preparing for pregnancy, or lactating women; (11) history of drug use or alcoholism	[27]

Table 1 (continued)

Study	No. of eyes	Design of study	Age range in years (average)	Male gender (N/T)	Inclusion criteria	Exclusion criteria	Ref
Shao Z et al	52	Retrospective cohort study	<21: 6 (11.5%) 21–30: 3 (5.8%) 31–40: 14 (27%) 41–50: 13 (25%) 51–60: 11 (1.1%) 61–70: 5 (9.6%)	45/52	(1) Age 18 to 70 years; (2) VA in the treated eye < 0.05; (3) ocular AL between 16 and 28 mm; (4) severe RD not amenable to treatment by vitreous substitutes	(1) Mental illness; (2) severe systemic disease; (3) other uncontrollable eye diseases; (4) allergy to silicone rubber or scar diathesis; (5) pregnancy or breast-feeding female	[24]
Zhang C et al	64: 29 in FCVB group and 35 in SO group	Retrospective cohort study	21–80 (48.34 ± 12.68)	FCVB: 24/29 SO: 31/35	Patients with NLP and severe retinal injuries after ocular trauma	(1) History of retinal or optic nerve diseases; (2) endophthalmitis; (3) missing records	[18]
Li M et al	28	Prospective case series study	31–71 (51.11 ± 10.14)	22/28	(1) Complicated RD caused by severe eye trauma; (2) BCVA ≤ HM, LP, or NLP; (3) AL of the injured eye between 16 and 28 mm	(1) Severe systemic diseases that could not tolerate surgery; (2) allergic to silicone; (3) serious eye inflammation or endophthalmitis; (4) treatable with SO during surgery; (5) patients whose fundus could not be observed due to corneal opacity	[16]
Lin X et al	3	Prospective case series study	19–53 (N/A)	2/3	Severe RD that could not be reattached easily with SO tamponade	(1) Serious ocular inflammation; (2) single eye; (3) dysfunction of any important organ	[17]
Zhang B et al	5	Prospective case series study	26–62 (N/A)	4/5	(1) RDs were caused by only one retinal break; (2) the RD did not exceed two quadrants; (3) no accompanying PVR	(1) Allergic to silica; (2) severe systemic disease; (3) who had once received other surgical treatment, such as PPV; (4) complicated RRDs accompanied by pseudophakia; (5) other fundus diseases; (6) media opacity	[23]
Liu B et al	8	Prospective case series study	44–60 (N/A)	3/8	(1) Age 18 years to 75 years; (2) high myopia with AL > 26.5 mm; (3) BCVA ≤ 20/50; (4) the presence of extensive macular schisis or foveoschisis associated with foveal RD; (5) evidence of a posterior staphyloma on clinical examination	(1) Monocular patients; (2) full thickness MH; (3) isolated slight foveoschisis; (4) severe macular scar; (5) macular detachment which extended beyond the posterior pole to the peripheral retina; (6) prominent vitreomacular traction; (7) history of vitrectomy or macular buckle; (8) history of glaucoma; (9) active hemorrhage or inflammation; (10) any media opacity which precluded imaging or clinical evaluation of the macula	[26]
Lin X et al	3	RCT	19–53 (31.3)	2/3	(1) Severe RD that could not be easily reattached with SO tamponade; (2) rigid retinal redetachments (3) inferior holes that occurred after silicone or heavy oil tamponade had been attempted	(1) Serious heart, lung, liver, or kidney dysfunction; (2) serious eye inflammation; (3) single eye; (4) suitable SO-filled eyes	[10]

Table 1 (continued)

Study	No. of eyes	Design of study	Age range in years (average)	Male gender (N/T)	Inclusion criteria	Exclusion criteria	Ref
Zhang Z et al	27; 13 in air group, 14 in viscoelastic group	RCT	Mean \pm SD: air group: 41.8 \pm 13.5, viscoelastic group: 42.4 \pm 14.2	Air group: 10/13 Viscoelastic group: 11/14	(1) Able to attend F/U; (2) AL \leq 28 mm eyes; (3) severe RD; (4) severe posterior trauma; (5) BCVA: HM, LP, or NLP	(1) Only one eye; (2) serious eye inflammation; (3) suitably SO-filled eyes; (4) glaucoma; (5) unoperated eye (uveitis; sympathetic ophthalmia); (6) scar physisique; (7) serious heart, lung, liver, or kidney dysfunction	[15]
Zhang R et al	9	RCT	13–53 (29.3)	9/9	(1) Severe RDs that were not easily re-attached by SO; (2) rigid retinal re-detachments; (3) inferior holes after SO or heavy oil tamponade	(1) Serious heart, lung, liver, or kidney dysfunction; (2) serious eye inflammation; (3) single eye; (4) suitable SO-filled eyes	[19]
Lin X et al	11	RCT	13–53 (27.5)	10/11	(1) Severe RD that could not be easily reattached with SO tamponade; (2) rigid retinal redetachments; (3) inferior holes that occurred after SO or heavy oil tamponade	(1) Serious heart, lung, liver, or kidney dysfunction; (2) serious eye inflammation; (3) only one eye; (4) suitably SO-filled eyes	[21]
Wang P et al	23; 8 in FCVB group, 15 in control group	RCT	FCVB: 13–43, controls: 28–76	FCVB: 7/8 Controls: 4/15	(1) Severe posterior scleral ruptures with large retinal absence; (2) severe scleral ruptures with RDs and choroidal detachments; (3) rigid retinal redetachments; (4) inferior holes after SO or heavy SO tamponade	(1) Serious heart, lung, liver, or kidney dysfunction; (2) ocular diseases including autoimmune uveitis, PDR, pathological myopia; (3) single eye; (4) stable SO-filled	[22]

AC, anterior chamber; AL, axial length; BCVA, best-corrected visual acuity; FCVB, foldable capsular vitreous body; F/U, follow-up; HM, hand motion; IOP, intraocular pressure; LP, light perception; MH, macular hole; N, number of males; N/A, not applicable; NLP, no light perception; PDR, proliferative diabetic retinopathy; PPV, pars plana vitrectomy; PVR, proliferative vitreoretinopathy; RD, retinal detachment; RCT, randomized clinical trial; RPE, retinal pigment epithelium; RRD, rhegmatogenous retinal detachment; RRR, retinal reattachment rate; SO, silicone oil; T, total number of participants; VA, visual acuity; VC, vitreous cavity

of FCVB in the period between January 2011 and May 2022 were included [10–13, 15–27]. Figure 2 shows the PRISMA flowchart summarizing the results of the search strategy and reasons for exclusion. Identified studies were six retrospective case series, two retrospective cohort studies, four prospective case series, and five randomized controlled trials (Table 1). Results of the assessment of the main outcome measures of these studies including indications of FCVB implantation, anatomical success rate, postoperative IOP, final best-corrected visual acuity (BCVA), and rates and types of complications are summarized in Table 2. The results of the quality assessment of included studies using the NIH quality assessment tool are illustrated in supplementary tables. Overall, seven studies showed fair quality assessment [10, 15, 18, 19, 21, 22, 24], and 10 studies had a good quality assessment [11–13, 16, 17, 20, 23, 25–27].

Indications of FCVB implantation

FCVB may be used intra-ocularly as tamponades or extra-ocularly as a macular or scleral buckle [10–13, 15–27]. Indications of FCVB implantation included severe ocular trauma such as perforating and penetrating injuries, severe blunt trauma, and those leading to atrophica bulbi, retinal and choroidal detachments, as well as endophthalmitis, silicone oil

(SO)-dependent eyes, severe proliferative vitreoretinopathy (PVR), recurrent RD after SO removal, primary failure of RD surgery using SO, C3F8, or heavy SO tamponade, severe PVR that could not be managed using heavy SO, simple and complex rhegmatogenous RD, and in highly myopic eyes with foveoschisis and posterior staphyloma.

Implantation and anatomical success rates

FCVB was reported to be successfully implanted in the vitreous cavity (VC) of all patients in all studies. Final retinal reattachment rate (RRR) was found to be 100% of all included patients in all studies except for Zhang et al. [15], Zhang et al. [18], Lin et al. [10], and Chen et al. [12] where it was 30%, 51.7%, 73%, and 92.59%, respectively. No results regarding anatomical success rate, however, were reported by Shao et al. [24]. In the study by Zhang et al. [18], the RRR of the SO group (74.3%) was higher than that of the FCVB group (51.7%).

Postoperative IOP

Xu et al. [11], Zhang et al. [18], Hao Jiang et al. [25], Li Cheng et al. [23], and Liu et al. [27] all showed that there was no significant change in IOP values from baseline following

Fig. 2 Flow diagram showing search results and reasons for exclusion of studies

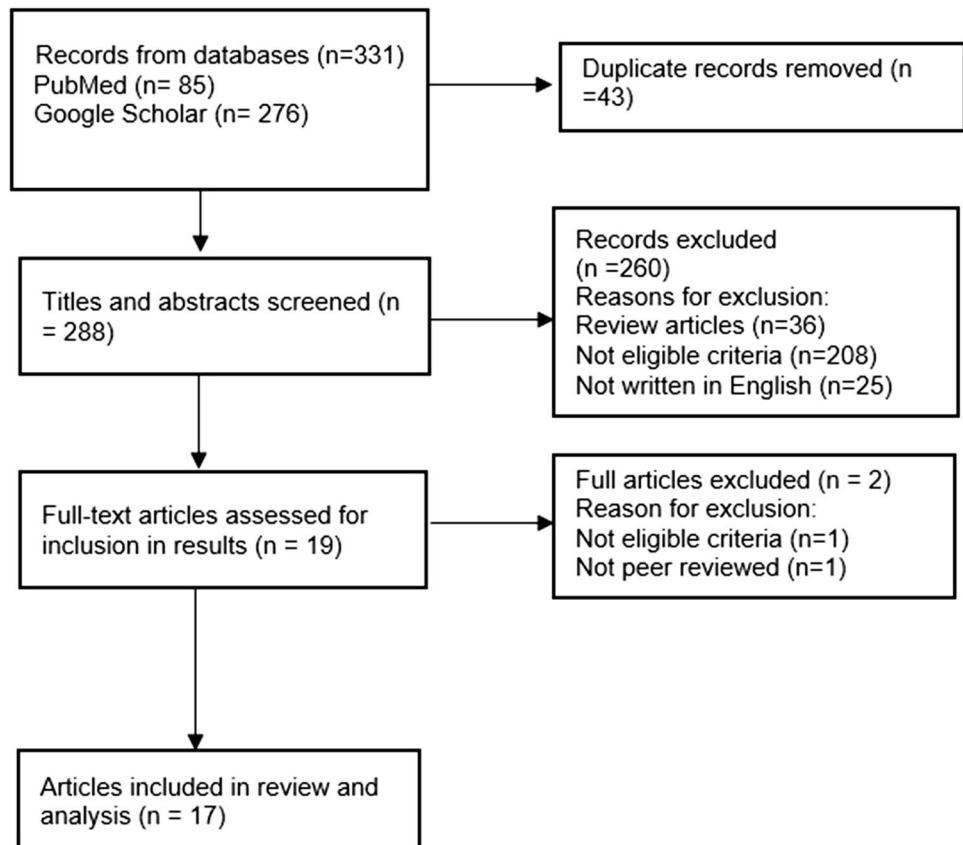


Table 2 The main outcomes retrieved from included studies

Study	Indications/uses	Anatomical success	Postoperative IOP	BCVA	Complications (%)	F/U (months)	Ref
Lin X et al	(1) Severe ocular rupture with retinal or choroidal detachments (2) RD failed to respond to SO or C3F8 tamponade	73% RRR 100% FCVB SI	Significant IOP elevation in 2 eyes and a steady value in one eye	Two cases showed improved BCVA	Three eyes (100%) with slight conjunctival hyperemia, 3 eyes (100%) with hyphema	12	[10]
Xu X et al	(1) Severe ocular trauma (2) SO-dependent eyes	100% RRR 100% FCVB SI	IOP values did not change from baseline	BCVA improved in 7 (38.89%) eyes. In contrast, 10 (55.56%) eyes showed no improvement, and one (5.56%) eye had decreased vision	Four eyes (22.2%) with localized opacity, and 2 eyes (11.1%) with obvious gray-white opacity	12	[11]
Chen S et al	(1) Severe ocular trauma (2) Recurrent RD	92.59% RRR 100% FCVB SI	The postoperative IOP (9.85 ± 6.48 mmHg) was lower than the preoperative IOP (14.85 ± 12.17 mmHg)	The postoperative IOP (0.75 ± 0.91) BCVA grading was less than the preoperative grading (1.20 ± 0.95)	Fourteen eyes (51.8%) with corneal opacity, 13 eyes (48.1%) with shallow AC, one eye (3.7%) with balloon break during surgery, and a drainage tube exposure after surgery	10.44 ± 2.68	[12]
Zhang X et al	(1) Severe ocular trauma (2) SO-dependent eyes	100% RRR 100% FCVB SI	The postoperative IOP elevated from the preoperative IOP of 12.90 ± 7.06 mmHg to 15.15 ± 3.36 mmHg	BCVA did not improve postoperatively	Two eyes (10%) with keratopathy and ocular inflammation, 3 eyes (15%) with hematocele in the AC, one eye (5%) with eyeball atrophy	12	[13]
Zhang Z et al	(1) Severe posterior trauma (2) Severe RD failed to respond to SO (3) Severe PVR failed to respond to heavy SO	30% RRR 100% FCVB SI	Postoperative IOP dropped by 1.42 ± 2.19 mmHg in the viscoelastic group and 1.88 ± 2.17 mmHg in the air group at the 24th weeks	N/A	Air group vs. viscoelastic group: Corneal blood staining (1 eye vs. 0 eyes), transient postoperative diffuse hemorrhage (5 eyes vs. 1 eye), inflammation reaction (9 eyes vs. 4 eyes), and postoperative fibrin exudation (4 eyes vs. 1 eye), and 3 eyes (11.1%) with post-vitreotomy hypotony	24	[15]
Li M et al	(1) Severe ocular trauma (2) Eyeball atrophy	100% RRR 100% FCVB SI	The postoperative IOP elevated from the preoperative IOP of 7.01 ± 2.43 mmHg to 8.54 ± 2.93 36 mmHg	The postoperative BCVA improved in 7 cases and remained unchanged in 21 cases	Six eyes (21.4%) with mild inflammation in the AC, 9 eyes (32.1%) with hemorrhage in the AC, one eye (3.7%) with shallow AC, one eye (3.7%) with valve exposure	16.93 ± 9.67	[16]

Table 2 (continued)

Study	Indications/uses	Anatomical success	Postoperative IOP	BCVA	Complications (%)	F/U (months)	Ref
Lin X et al	(1) Severe ocular trauma (2) Severe RD	100% RRR 100% FCVB SI	At the end of the 3 years, there were no differences in the IOP between the treated and control eyes in cases 1 and 2, whereas the IOP of the treated eye was 5 mm Hg lower than that of the control eye in case 3	The postoperative BCVA improved in all cases	N/A	36	[17]
Zhang C et al	(1) Severe ocular trauma	RRR%: FCVB: 51.7% SO: 74.3%	The postoperative IOP values did not change from baseline	The postoperative BCVA improved in both groups	N/A	14	[18]
Zhang R et al	(1) Severe ocular trauma (2) Severe choroidal or RD	100% RRR 100% FCVB SI	N/A	N/A	Nine eyes (100%) with slight conjunctival hyperemia	3	[19]
Deng J et al	(1) Severe ocular rupture	100% RRR 100% FCVB SI	The mean postoperative IOP was 11 ± 5 mm Hg (no comparison to the preoperative IOP values was observed)	BCVA was LP in 10 cases, NLP in 13 cases, and HM in 3 cases (no comparison to the preoperative VA values was observed)	Three (11.5%) eyes with corneal degeneration, 7 eyes (26.9%) with corneal endothelial dystrophy, 8 eyes (30.7%) with shallow AC, 8 eyes (30.7%) with hyphema, 14 eyes (53.8%) with organized membrane in the pupil, 3 eyes (11.5%) with epiphora, and 3 eyes (11.5%) with FCVB drainage tube exposed	10–14	[20]
Lin X et al	(1) Severe ocular trauma (2) Severe choroidal or RD (3) RD failed to respond to SO or C3F8, or heavy SO tamponade	100% RRR 100% FCVB SI	IOP at the 3-month implantation time was slightly lower than at baseline	BCVA did not improve postoperatively	Eleven eyes (100%) with slight conjunctival hyperemia, 2 eyes (18.1%) with hyphema	3	[21]
Wang P et al	FCVB: (1) Penetrating ocular injury (2) Ocular contusion Control: (1) Idiopathic MH (2) RRD	100% RRR 100% FCVB SI	N/A	N/A	Eight eyes (100%) with slight conjunctival chemosis, 2 eyes with point-like opacities in the intra-FCVB fluid (25%)	3	[22]
Zhang B et al	(1) Simple RRD	100% RRR 100% FCVB SI	The postoperative IOP improved in all patients (case 1: 12 to 16, case 2: 12 to 15, case 3: 12 to 15, case 4: 14 to 16, case 5: 12 to 16)	Postoperative BCVA improved in all cases	One eye with diplopia (20%)	12	[23]
Shao Z et al	(1) Severe ocular trauma (2) RD	N/A	N/A	N/A	N/A	N/A	[24]

Table 2 (continued)

Study	Indications/uses	Anatomical success	Postoperative IOP	BCVA	Complications (%)	F/U (months)	Ref
Hao Jiang et al	(1) Severe ocular trauma (2) SO-dependent eyes	100% RRR 100% FCVB SI	The postoperative IOP values did not change from baseline	BCVA did not improve postoperatively, except in one case from LP to HM	Five eyes (71.4%) with corneal opacity and keratopathy	6	[25]
Liu B et al	(1) highly myopic eyes with foveoschisis, posterior staphyloma, and AL > 26.5 mm	Gradual anatomic improvement of macula	N/A	BCVA improved in 7 (87.5%) eyes, but slightly decreased in 1 eye (12.5%)	Five eyes (62.5%) with IOP elevation, 2 eyes (25%) with suprachoroidal hemorrhage, 8 eyes (100%) with persistent abduction limitation, one eye (12.5%) with binocular diplopia, persistent 4 eyes (50%) with undulation of RPE layer	11.6	[26]
Liu N et al	(1) Severe SO-dependent eyes	100% RRR 100% FCVB SI	The postoperative IOP values did not change from baseline	BCVA did not improve postoperatively	One eye (20%) with hyphema	13.5 ± 1.5	[27]

AC, anterior chamber; AL, axial length; BCVA, best-corrected visual acuity; FCVB, foldable capsular vitreous body; F/U, follow-up; HM, hand motion; IOP, intraocular pressure; LP, light perception; MH, macular hole; N/A, not applicable; NLP, no light perception; PDR, proliferative diabetic retinopathy; PPV, pars plana vitrectomy; PVR, proliferative vitreoretinopathy; RD, retinal detachment; RCT, randomized clinical trial; RPE, retinal pigment epithelium; RRD, rhegmatogenous retinal detachment; RRR, retinal reattachment rate; SI, successful implantation; SO, silicone oil; VA, visual acuity; VC, vitreous cavity

FCVB implantation. Chen et al. [12] showed a significant reduction in postoperative IOP (IOP of 14.85 ± 12.17 mm Hg to 9.85 ± 6.48 mm Hg, $p < 0.01$) following implantation. Zhang et al. [15] compared FCVB with viscoelastic versus FCVB with air and showed that postoperative IOP in both groups varied at different time points. On the 1st postoperative day, the IOP increased by 1.61 ± 1.53 mmHg in the viscoelastic group, while it decreased by 4.06 ± 4.02 mmHg in the air group compared to baseline values. Similarly, IOP increased by 1.33 ± 2.39 mmHg in the viscoelastic group and decreased by 1.75 ± 2.92 mmHg in the air group on the 3rd postoperative day. However, at the 24th week postoperatively, IOP dropped by 1.42 ± 2.19 mmHg in the viscoelastic group ($p = 0.0231$) and by 1.88 ± 2.17 mmHg in the air group ($p = 0.0051$) compared to baseline values. Lin et al. [17] showed that at the end of 3 years of follow-up, there were no differences in the IOP between the treated and control eye in two subjects, whereas the IOP of the treated eye was 5 mm Hg lower than that of the control eye in a third subject. Furthermore, in another study, Lin et al. [21] showed that the IOP at 3-month post-FCVB implantation was slightly lower than at baseline. However, the IOP at each time point in the FCVB-implanted eyes did not show a significant difference, except at 4 weeks post-implantation, and at 3 months after capsule removal. On the other hand, Zhang et al. [13] showed significant elevation in postoperative IOP levels (an increase from 12.90 ± 7.06 mmHg to 15.15 ± 3.36 mmHg, $p < 0.0001$) following FCVB implantation, which was also shown by Li et al. [16] (increase from 7.01 ± 2.43 mmHg to 8.54 ± 2.93 mmHg, $p < 0.05$). Lin et al. [10] showed that the IOP at each time point after FCVB implantation was significantly elevated compared with those at baseline in 2 eyes, with a stable value in one eye. Furthermore, Zhang et al. [23] reported improved IOP values postoperatively in all subjects. Deng et al. [20] showed that the mean postoperative IOP was 11 ± 5 mm Hg but did not compare it with the preoperative IOP. Notably, no results regarding postoperative IOP were reported by Zhang et al. [19], Wang et al. [22], Shao et al. [24], and Liu et al. [26].

Postoperative BCVA

Xu et al. [11] showed that BCVA significantly improved in seven (38.89%) eyes. In contrast, 10 (55.56%) eyes showed no obvious improvement, and one (5.56%) eye had decreased VA postoperatively. Chen et al. [12] showed that the final VA scores were either maintained or slightly lower than the initial VA scores. However, in some cases in which the retinal tissue was not damaged, the VA significantly improved after FCVB implantation. Zhang et al. [18] showed that the final postoperative BCVA values were significantly improved compared with that of the preoperative values. Hao Jiang et al. [25] results revealed that BCVA did not

improve postoperatively except in one subject (14.3%), where BCVA improved from LP to HM. Li et al. [16] showed that postoperative BCVA significantly improved in 7 subjects while remaining unchanged in 21 subjects. Lin et al. [10] reported improved BCVA in 2 subjects, remaining unchanged in one subject. Meanwhile, Liu et al. [26] showed that BCVA improved in 7/8 subjects (87.5%) gaining 21.5 Early Treatment Diabetic Retinopathy Study letters on average but slightly decreased in one subject (12.5%). Deng et al. [20] reported improved BCVA in 4 subjects (15.4%), remaining stable in the rest of the subjects. Moreover, Lin X et al. [17] and Zhang et al. [23] reported improved postoperative BCVA in all subjects. However, Zhang et al. [13], Lin et al. [21], and Liu et al. [27] showed no significant changes in BCVA postoperatively, while Zhang et al. [15], Zhang et al. [19], Wang et al. [22], and Shao et al. [24] did not report on BCVA results.

Complications

The summary of complications is provided in Table 2. Lin X et al. [10] reported that all 3 eyes included in their study developed slight conjunctival hyperemia and hyphema. Xu et al. [11] reported 4 eyes (22.2%) with a localized corneal opacity and 2 eyes (11.1%) with an obvious grayish white corneal opacity. Chen et al. [12] reported 14 eyes (51.8%) with corneal opacity, 13 eyes (48.1%) with a shallow anterior chamber (AC), one eye (3.7%) with balloon break during surgery, and a one with drainage tube exposure after surgery. Zhang et al. [13] reported 2 eyes (10%) with keratopathy and ocular inflammation, 3 eyes (15%) with hyphema, and one eye (5%) with atrophía. Zhang et al. [15] compared an air-filled capsule versus a viscoelastic-filled capsule and found increased complication rates in the viscoelastic group as follows: corneal blood staining (1 eye vs. 0 eyes), transient postoperative diffuse hemorrhage (5 eyes vs. 1 eye), inflammatory reaction (9 eyes vs. 4 eyes), postoperative fibrin exudation (4 eyes vs. 1 eye), and 3 eyes (11.1%) with post-vitreotomy hypotony (one eye in the viscoelastic group vs two eyes in the air group).

Li et al. [16] reported 6 eyes (21.4%) with mild AC inflammation, 9 eyes (32.1%) with hyphema, one eye (3.7%) with a shallow AC, and one eye (3.7%) with valve exposure. Furthermore, Deng et al. [20] reported 3 (11.5%) eyes with corneal degeneration, 7 eyes (26.9%) with corneal endothelial injury, 8 eyes (30.7%) with shallow AC, 8 eyes (30.7%) with hyphema, 14 eyes (53.8%) with an organized pupillary membrane, 3 eyes (11.5%) with epiphora, and 3 eyes (11.5%) with FCVB drainage tube exposure. Lin et al. [21] reported 11 eyes (100%) with slight conjunctival hyperemia and 2 eyes (18.1%) with hyphema. Wang et al. [22] reported 8 eyes (100%) with slight conjunctival chemosis and 2 eyes with point-like opacities in the intra-FCVB fluid (25%).

Moreover, Zhang et al. [23] reported one eye with diplopia (20%), one eye (20%) with FB sensation and pain, and one eye (20%) with subretinal fluid in patients with RRD treated with FCVB scleral buckling. Hao Jiang et al. [25] reported 5 eyes (71.4%) with corneal opacity and keratopathy. Liu et al. [27] reported one eye (20%) with hyphema. Liu et al. [26] reported 5 eyes (62.5%) with IOP elevation, 2 eyes (25%) with suprachoroidal hemorrhage, 8 eyes (100%) with persistent abduction limitation, one eye (12.5%) with binocular diplopia, and 4 eyes (50%) with retinal pigment epithelium undulation. However, no results regarding postoperative complications were reported by Lin et al. [17], Zhang et al. [18], Zhang et al. [19], or Shao et al. [24].

Discussion

Currently, vitreous substitutes have main drawbacks, including short periods of intraocular stability, suboptimal biocompatibility, and multiple complications. Indeed, there is no perfect material that can completely resemble the functions of the natural vitreous body [2, 3]. FCVB was designed to change the traditional retinal supporting mode using a 360° arc pressure effect and to isolate the intraocular tamponade (such as SO) from the retina by a capsule, which is a new therapeutic strategy. Since then, FCVB implantation has been reported to significantly decrease the odds of intraocular tamponade-related complications. Moreover, patients were not obligated to keep a prone position postoperatively. For optimal IOP outcomes, SO can also be extracted through the FCVB's drainage valve or injected with normal saline and/or SO [4, 8]. FCVB may also function to prevent SO emulsification by decreasing its interaction with blood components and surrounding structures [7]. By remaining inside the FCVB, migration of SO into the surrounding structures was also prevented leading to a reduction of SO-related complications. For example, in the study by Lin et al. [17], which had the longest follow-up period of 3 years following FCVB implantation for severe RD, no SO-related complications were reported in 3 eyes with SO-filled FCVB.

The postoperative IOP was elevated or maintained after FCVB implantation in most of the studies [10, 15–17]. However, Zhang Z et al. [15] reported 3 eyes (11.1%) with transient hypotony post-FCVB implantation. The mechanism of transient hypotony after FCVB implantation is not fully understood yet. There are some proposed mechanisms for transient hypotony after FCVB implantation. The inflammatory response resulting from the surgical scleral incision and ciliary body local injury might contribute to hypotony [28]. Hypotony in inflammation is thought to occur as a result of a prostaglandin-mediated aqueous shutdown combined with an increase in uveoscleral outflow [29]. Furthermore, reoperations and longer procedures are more vulnerable to

transient hypotony because reoperations and longer procedures have significantly more fluid leakage [30]. It is postulated that previous surgeries may change the elasticity and regenerative capacity of scleral tissue, therefore rendering wound tissues more prone to leakage.

FCVB was reported to be successfully implanted in the VC with 100% RRR of all eyes in most of the studies. However, failure to reach 100% RRR post-FCVB implantation was also reported [10, 12, 15, 18]. This may relate to the initial severity of the RD or ocular trauma, or due to BSS leakage secondary to tiny openings existing in the capsule of the FCVB. In the study by Zhang et al. [18], the RRR of the SO group (74.3%) was higher than that of the FCVB group (51.7%). This may be explained by the high interfacial tension of SO which allows a better apposition against the retina compared to the FCVB that only provides a solid arc pressure resulting in inadequate retinal support [18].

Despite that the postoperative BCVA depends on the preoperative VA of the patient and the degree of the injury, FCVB showed promising results by improving the BCVA in most of the involved eyes. Some studies, however, reported loss of BCVA in a few patients. For example, Xu et al. [11] showed that BCVA was reduced in one (5.56%) eye postoperatively which was thought to be associated with severe RD and scarring caused by acute retinal necrosis. Other studies, however, showed no improvement in BCVA in any subject following FCVB implantation, possibly due to the advanced vitreoretinal pathologies included in these studies [27].

FCVB implantation results in minor refractive changes. On the contrary, Stefansson et al. [31] reported a 9.30 D hyperopic shift in human eyes with SO substitution, while in the Gullstrand-Emsley schematic eye, SO tamponade resulted in higher refractive shifts (+8.71 D) compared to BSS-filled FCVB (−0.338 D) [8]. Furthermore, Shao et al. [24] showed that mental health significantly improved in patients following FCVB implantation. In their study, 44.23% of patients with ocular trauma and retinal detachment were depressed, 48.08% were anxious, and 19.23% were sensitive to interpersonal communication prior to FCVB implantation. However, after FCVB implantation, only 17.31% remained depressed, 15.38% were anxious, and 9.62% were sensitive to interpersonal communication.

FCVB could be loaded with BSS or SO [4, 5]. Some studies recommended using BSS rather than SO for several reasons [5, 6, 8]; particularly, BSS-filled FCVB seemed to closely resemble the normal vitreous morphology and is suggested to restore its physiological functions such as support, refraction, and cellular barriers without silicone oil complications. Furthermore, BSS-filled capsules affected refraction less than SO or heavy SO tamponade. Finally,

Zhang et al. [15] compared viscoelastic-filled AC versus air-filled AC during FCVB implantation and concluded that a viscoelastic-filled AC was associated with better IOP control and a less serious complication rate.

Limitations of the current review include the small number of included studies, the relatively short duration of the included studies, the heterogeneity of the studies and their design, and the inclusion of results from non-comparative retrospective case series which are inherently limited by their design. However, studies on FCVB are limited, even though it has been available for more than 10 years, indicating a slow uptake of the technology especially outside China. This could be due to insufficient information on this relatively new technology, different regulatory agencies policies, patents, insufficient marketing of the technology, and logistical issues. Prospective controlled trials utilizing FCVB are also rare. Finally, some included studies had missing data, and so we could not report on some of their outcomes which may have affected our conclusions. More prospective studies, preferably multicenter, are thus needed to shed further light on the value of this technique.

Conclusion

FCVB implantation has been used in the management of various complicated ocular conditions including severe ocular trauma, complicated RD, SO-dependent eyes, and myopic foveoschisis but has also been used in simpler conditions including uncomplicated RD. When compared to SO, FCVB showed good visual outcomes, fewer IOP fluctuations, and a good safety profile. We provided the first systematic review of studies reporting on FCVB implantation. Larger multicenter randomized comparative studies with a longer follow-up period are needed to further characterize the indications, complications, and long-term outcomes of FCVB implantation.

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Author contribution HAS and SI have made considerable contributions in the conception and design of the study, in the acquisition, analysis, and interpretation of the data, and in the drafting of the manuscript. LAS and AGE have made a substantial contribution in the conception and design of the work and in the revision of the manuscript. All authors read and approved the final manuscript.

Data availability All the data used in this study are available within the article.

Declarations

Ethical approval Ethical approval for this study was waived by the institutional review board of Cairo University since it was a systematic review that did not involve conducting research on humans or animals. No informed consent form was required. The study adhered to the tenets of the Declaration of Helsinki.

Conflict of interest The authors declare no competing interests.

Competing interests All authors declare no conflicts of interest associated with the conduct of this work.

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