

# SILICONE OIL-FILLED FOLDABLE CAPSULAR VITREOUS BODY VERSUS SILICONE OIL ENDOTAMPONADE FOR TREATMENT OF NO LIGHT PERCEPTION AFTER SEVERE OCULAR TRAUMA

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**Purpose:** To compare the anatomical and functional outcomes of silicone oil (SO)-filled foldable capsular vitreous body (FCVB) and SO endotamponade in vitrectomy for patients with no light perception after ocular trauma.

**Methods:** A total of 64 patients (64 eyes) with no light perception caused by severe ocular trauma were divided into FCVB and SO groups based on the surgical treatment. The main outcome measurements were retinal reattachment rate, intraocular pressure, best-corrected visual acuity, and number of operations.

**Results:** Both the FCVB group (29 eyes) and the SO group (35 eyes) showed significant improvement in postoperative best-corrected visual acuity and intraocular pressure. The two groups showed no significant differences in final intraocular pressure and the retinal reattachment rate. The postoperative vision ( $\geq$ LP) in the FCVB group was significantly worse than in the SO group (FCVB [4/29] vs. SO [18/35],  $P = 0.003$ ). However, the number of surgeries in the FCVB group was significantly lower than in the SO group (FCVB [1.10] vs. SO [2.23],  $P < 0.001$ ).

**Conclusion:** Vitrectomy combined with SO endotamponade shows better short-term improvement in the treatment of no light perception caused by severe ocular trauma. However, SO-filled FCVB can effectively prevent many complications caused by direct SO endotamponade, such as secondary surgeries or SO dependence.

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There is a great likelihood of injury because of the contact and position of the eye. Eye trauma can cause globe wound, cataract, intraocular hemorrhage, ciliary body damage, choroidal damage, retinal detachment, retinal prolapse, and ocular nerve damage,<sup>1,2</sup> leading to loss of vision including no light perception (NLP).<sup>3</sup> Injury to the posterior segment of the eye easily causes NLP,<sup>2</sup> which carries a dismal prognosis, thereby increasing the economic burden of patients and their families.

It is difficult to restore light perception (LP) even with active surgical intervention in ocular trauma with NLP. In the past, to avoid complications such as sympathetic ophthalmia and phthisis bulbi caused by severe ocular trauma, primary enucleation for traumatized eyes with NLP was often used.<sup>4</sup> Nowadays, with the development and application of vitrectomy with endotamponade, severely traumatized eyes with NLP

can recover LP or better vision<sup>5</sup> or at least preserve the globe.

At present, common vitreous tamponade materials in clinical practice can be broadly categorized into gaseous vitreous, liquid vitreous, and gellike vitreous substitutes. Silicone oil (SO) or expansile gas is the most widely used vitreous tamponade materials.<sup>6</sup> Currently, in cases with severe ocular trauma with NLP, vitrectomy combined with SO endotamponade is commonly implemented. However, SO could emulsify resulting in several complications, such as the development of keratopathy and ocular hypertension.<sup>7</sup> These patients need to undergo a second surgery including the SO removal. Some patients face problems of SO dependence, thereby, warranting SO displacement. Therefore, researchers have been seeking suitable vitreous substitutes. Based on recent reports, some doctors have used a new type of foldable

capsular vitreous body (FCVB) to tamponade the vitreous cavity.<sup>8,9</sup> Silicone oil could be injected into the capsule of the FCVB, thereby, avoiding SO emulsification owing to the barrier provided by the FCVB capsule.<sup>10</sup> Vitrectomy combined with SO-filled FCVB has been used effectively and safely for treating severe retinal detachment.<sup>10,11</sup> However, the preferred surgical method for treating severe ocular trauma is still unclear.

Therefore, we retrospectively compared the anatomical and functional outcomes of SO-filled FCVB and SO endotamponade for treating NLP in a vitrectomy study for eye injury.

## Methods

In this retrospective and comparative clinical study, patients with NLP as the initial visual acuity (VA) after the ocular trauma were reviewed. All the patients were treated at the Eye Hospital of Wenzhou Medical University from January 2017 to October 2020. The study was approved by the Ethics Committee of the Eye Hospital of Wenzhou Medical University and was conducted in accordance with the tenets of the Declaration of Helsinki.

In this study, the inclusion criteria were patients with NLP and severe retinal injuries after ocular trauma. The exclusion criteria were patients with a history of retinal or optic nerve diseases (8 cases), endophthalmitis (5 cases), and missing records (6 cases). Based on the surgical treatment methods received, the recruited 64 patients (64 eyes) were

divided into two groups: vitrectomy combined with SO-filled FCVB endotamponade (FCVB group) and vitrectomy combined with SO endotamponade (SO group).

The LP inspection was conducted in a dark room. The examiner covered the healthy eyes of the patient and used an indirect ophthalmoscope light source with the highest intensity for projecting light into the injured eye from all angles and distances. Inspection was conducted by at least two senior ophthalmologists and was confirmed by the chief surgeon.

All the patient records were analyzed in detail, including demographics, patient age, sex, involved eye, type and zone of injury, orbital and ocular comorbidities, time to vitrectomy, and number of operations. All the patients after ocular trauma received proper treatment at admission. Cases with open globe injuries underwent debridement and timely suturing surgery. Local antibiotic and corticosteroid were administered in all cases. Subsequently, the vitreoretinal surgical intervention was performed in all cases. The vision before vitrectomy could have increased from NLP and was recorded.

Patients were positioned in the supine position and underwent surgeries under retrobulbar or general anesthesia. Surgeons preferred general anesthesia in patients who underwent vitrectomy combined with FCVB implantation and preferred local anesthesia in those combined with SO endotamponade procedures. A routine 3-port 23-gauge transconjunctival pars plana vitrectomy was performed for resecting the intraocular opacification, lens, and vitreous body. Intraocular electrocoagulation and peeling of the subretinal and epiretinal membranes were conducted if necessary. Perfluorocarbon liquids or gas–liquid exchange was applied to flatten the retina. Besides, endolaser photocoagulation or cryotherapy was conducted for retinal breaks and damage zones. After gas–liquid exchange, patients were injected with SO into the vitreous cavity in the SO group and implanted with SO-filled FCVB in the FCVB group subsequently.

Based on the axial length, a suitable type of FCVB was prepared and the integrity of the capsule was checked. The specific procedure of FCVB implantation was subsequently conducted as follows: 1) A limbus conjunctival flap 4.5 mm away from the corneal limbus was created and the scleral incision was expanded to 4 mm in the superior temporal quadrant. 2) The FCVB was triple folded and directed into the vitreous cavity using an injector. 3) 8-0 interrupted sutures were used to suture the large sclera incision. 4) Silicone oil was injected into the capsular inner space until the intraocular pressure (IOP) recorded was approximately 15 mmHg using

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the drainage valve. The injected SO volume was less than the maximum injection volume of each model. 5) The lens surface of the capsule of the FCVB was adjusted to be placed facing the lens. If tilted, the position of the FCVB capsule could be properly adjusted using an iris reposer or viscoelastic tip. An appropriate volume of viscoelastic tip was injected into the anterior chamber. 6) The drainage valve was ligated using 5-0 suture, the valve was affixed to the scleral wall, the drainage valve was pushed beneath the posterior fascial layer in the superior temporal quadrant, and the fascia and bulbar conjunctiva were sutured (Figure 1).

In all the cases, 8-0 interrupted sutures for the scleral and conjunctival incisions were used and the incision was checked for leakage and IOP. 0.5 mL/2.5 mg dexamethasone was injected into the subconjunctiva, and the conjunctival sac was covered with tobramycin dexamethasone ointment, and the eye was bandaged. The patients of the SO group maintained a prone position postoperatively, and local antibiotics and glucocorticoids were administered in all the cases; additional systemic antibiotics and glucocorticoid treatment were prescribed in cases of the FCVB group. Follow-up details, including the follow-up period, best-corrected VA (BCVA) and IOP, and anatomic outcome, were recorded.

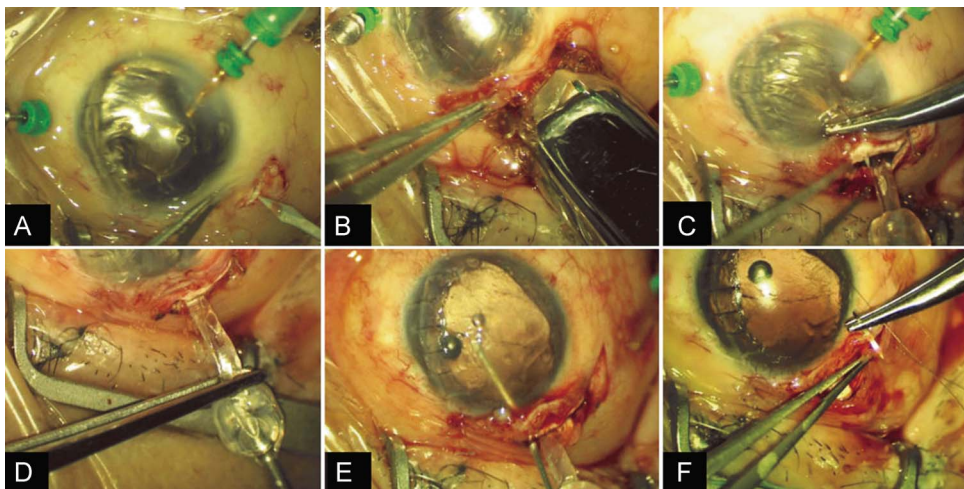
Statistical analyses were performed using the SPSS version 23.0 software (SPSS Inc, Chicago, IL). Continuous variables are expressed as mean  $\pm$  SD or median {25th–75th percentile, (M [P25–P75])} when applicable; categorical data are reported as counts and percentages. Measurements obtained before and after the injection were compared using both paired *t*-tests and nonparametric test for continuous variables and

chi-square test for nominal variables. *P* values  $<$  0.05 were considered statistically significant.

## Results

The research included 64 eyes (26 left eyes) of 64 patients (55 men) with a mean age of  $48.34 \pm 12.68$  years (range: 21–80 years). All the patients had NLP after injury. The patients comprised 4 cases of closed-globe injuries and 60 cases of open-globe injuries (rupture: 43/60, 71.7%; penetrating: 5/60, 8.3%; perforating: 3/60, 5.0%; and intraocular foreign body: 9/60, 15.0%). The injury zone contained zone I (4/64, 6.3%), zone II (6/64, 9.4%), and zone III (54/64, 84.4%). All eyes had additional severe trauma complications such as orbital involvement (13/64, 20.3%), hyphema (60/64, 93.8%), ciliary body injury (44/64, 68.8%), lens injury (62/64, 96.9%), vitreous hemorrhage (64/64, 100.0%), proliferative vitreoretinopathy (10/64, 15.6%), retinal detachment (64/64, 100.0%), choroidal injury (48/64, 75.0%), or nerve injury (11/64, 17.2%). All the aforementioned preoperative data showed no statistically differences between the two groups (Table 1).

The time to vitrectomy in the FCVB group was longer than the SO group, with significant differences (17 [10–22] vs. 10.5 [8–11], *P* = 0.007). The median ocular trauma score was 31.53 (P25–P75: 26.00–44.00). Before vitrectomy, the BCVA of two patients in the FCVB group and seven patients in the SO group showed an improvement from NLP to LP or hand motion. The median preoperative IOP was 6.84 mmHg (P25–P75: 4.75–7.90 mmHg). Although the preoperative values including the ocular trauma score, VA, and IOP in the SO group were better than in the FCVB



**Fig. 1.** Procedures of FCVB implantation: (A) 4-mm incision was created as an FCVB implantation site on the sclera. (B) Foldable FCVB was directed into the vitreous cavity with the injector. (C) Large scleral incisions were sutured using 8-0 absorbable interrupted sutures. (D) Silicone oil was slowly injected into the capsule through the drainage valve with a syringe until the IOP was approximately 15 mmHg. (E) Lens surface of the capsule of the FCVB was adjusted to be placed facing the lens, and the viscoelastic tip was injected into the anterior chamber. (F) The drain tube was ligated with a 5-0 suture and affixed to the sclera and the

fascia, and bulbar conjunctiva was sutured subsequently.

Table 1. General and Clinical Information of Patients With Severe Ocular Trauma With NLP\*

	FCVB Group	SO Group	<i>P</i>
No. of eyes	29	35	
Age (in years)	47.03 ± 13.95	49.43 ± 11.62	0.456
Gender			
Male/female	24/5	31/4	0.720
Eye			0.447
Left/right	10/19	16/19	
OTS	29.34 (26.00–35.00)	33.34 (26.00–49.00)	0.156
Injury type			
Rupture	22/29 (75.9%)	21/35 (60.0%)	0.401
Penetrating	2/29 (6.9%)	3/35 (8.6%)	
Perforating	1/29 (3.4%)	2/35 (5.7%)	
IOFB	4/29 (13.8%)	5/35 (14.3%)	
Contusion	0/29	4/35 (11.4%)	
Injury zone			
Zone I	1/29 (3.4%)	3/35 (8.6%)	0.770
Zone II	3/29 (10.3%)	3/35 (8.6%)	
Zone III	25/29 (86.2%)	29/35 (82.9%)	
Timing to vitrectomy (in days)	17 (10–22)	10.5 (8–11)	0.007
BCVA before vitrectomy			
NLP	27/29 (93.1%)	28/35 (80.0%)	0.166
≥LP	2/29 (6.9%)	7/35 (20.0%)	
Preoperative IOP (mmHg)	6.16 (5.00–7.40)	7.39 (4.50–9.00)	0.103
Orbital involvement	9/29 (31.0%)	4/35 (11.4%)	0.052
Hyphema	28/29 (96.6%)	32/35 (91.4%)	0.620
Ciliary body injury	22/29 (75.9%)	22/35 (62.9%)	0.264
Lens injury	29/29 (100.0%)	33/35 (94.3%)	0.497
Vitreous hemorrhage	29/29 (100.0%)	35/35 (100.0%)	
Choroidal injury	23/29 (79.3%)	25/35 (71.4%)	0.333
PVR	5/29 (17.2%)	5/35 (14.3%)	1.000
Retinal detachment	29/29 (100.0%)	35/35 (100.0%)	
Nerve injury	5/29 (17.2%)	6/35 (17.1%)	1.000

\*Continuous variables are expressed as mean ± SD ( $\bar{x} \pm s$ ) or median (25th percentile–75th percentile) (M [P25–P75]). IOFB, intraocular foreign body; OTS, ocular trauma score; PVR, proliferative vitreoretinopathy.

group, there were no statistically significant differences between the two groups (Table 1).

After surgery, the median follow-up period was 13.64 months (P25–P75: 12.38–14.90). In the FCVB group, four patients (4/29, 13.8%) reverted to LP, whereas in the SO group, 18 patients (18/35, 51.4%) recovered LP or better vision (Table 2). The final postoperative BCVA and IOP values in both the groups were significantly improved compared with that of the preoperative values, with all  $P < 0.05$  (Tables 2 and 3).

Although the postoperative retinal reattachment rate and IOP were higher in the SO group, there was no statistically significant difference between the two groups (Table 4). Figure 2 illustrates representative cases of both the groups. The final postoperative BCVA significantly differed between the two groups ( $P = 0.003$ ). The mean values of IOP during the follow-up period are showed in Figure 3. A total of 23 cases (23/35, 65.7%) with SO endotamponade underwent SO removal, 8 cases (8/35, 22.9%) under-

went repeated replacement and removal of SO, 3 cases (3/35, 8.6%) underwent enucleation, and 1 case (1/35, 2.9%) underwent removal of SO and implantation of FCVB postoperatively. Only three patients (3/29, 10.3%) in the FCVB group underwent enucleation,

Table 2. Comparison of Preoperative and Postoperative BCVA in Two Groups

	BCVA	Preoperative	Postoperative	<i>P</i>
FCVB group	NLP	27/29 (93.1%)	25/29 (86.2%)	0.015
	LP	2/29 (6.9%)	4/29 (13.8%)	
	HM	0/29	0/29	
	FC	0/29	0/29	
SO group	NLP	28/35 (80.0%)	17/35 (48.6%)	0.001
	LP	5/35 (14.3%)	12/35 (34.3%)	
	HM	2/35 (5.7%)	4/35 (11.4%)	
	FC	0/35	2/35 (5.7%)	

FC, finger count; HM, hand motion.

Table 3. Comparison of Preoperative and Postoperative IOP in Two Groups

IOP (mmHg)	Preoperative	Postoperative	<i>P</i>
FCVB group	6.16 (5.00–7.40)	9.13 (6.50–10.80)	0.000
SO group	7.39 (4.50–9.00)	10.61 (8.90–12.50)	0.001

and none of the others had secondary surgery (Table 5). The number of operations in the SO group was significantly higher than in the FCVB group (1.10 vs. 2.23,  $P < 0.001$ ) (Table 4).

### Discussion

This study compared SO-filled FCVB implantation and SO endotamponade as treatment options for cases with severe ocular trauma causing NLP.

Considering the risk of sympathetic ophthalmia, many ophthalmologists commonly consider primary enucleation for treating eyes with NLP after severe ocular trauma.<sup>4</sup> However, with the development of microvitreoretinal surgery, eyes with NLP could possess improved vision or a salvageable globe using vitrectomy combined with SO endotamponade.<sup>12,13</sup> Yang et al<sup>14</sup> reported 19 patients with severely traumatized eyes with a VA of NLP, in whom vitrectomy combined with SO endotamponade was performed with good results. Ebaddollah et al<sup>13</sup> reported 10 patients with severely traumatized eyes with NLP treated by vitrectomy combined with SO endotamponade. The advent of FCVB implantation provides a new method for the treatment of severe ocular trauma causing NLP. Lin et al<sup>8,10,11</sup> reported a total of 12 patients with severe retinal detachments or choroidal detachment effectively and safely treated with vitrectomy and FCVB implantation. Zhang et al<sup>15</sup> reported nine patients with ocular trauma treated by vitrectomy and FCVB implantation, among these nine eyes, five had penetrating injuries, whereas four had contusions of the eyeball involving large defects of the retina or choroids. Zhang et al<sup>16</sup> also reported 20 patients with ocular trauma and SO-dependent eyes treated with FCVB implantation, revealing that the patients' VA

did not significantly change; however, the IOP increased significantly. The difference in efficacy between these two methods is not clear at present. Therefore, this study was conducted to compare the efficacy of vitrectomy combined with SO-filled FCVB implantation and vitrectomy combined with SO endotamponade.

This study showed that the preoperative data including ocular trauma score, IOP, and BCVA before vitrectomy in the FCVB group was lower than in the SO group; cases with orbital involvement in the FCVB group were greater. These preoperative data may reveal that the conditions of the cases in the FCVB group were worse; however, there were no statistically significant differences between the two groups except in the timing to vitrectomy. Therefore, we believe that the compared therapeutic effect of the two different treatment groups is reliable, although this serial case study was not randomized.

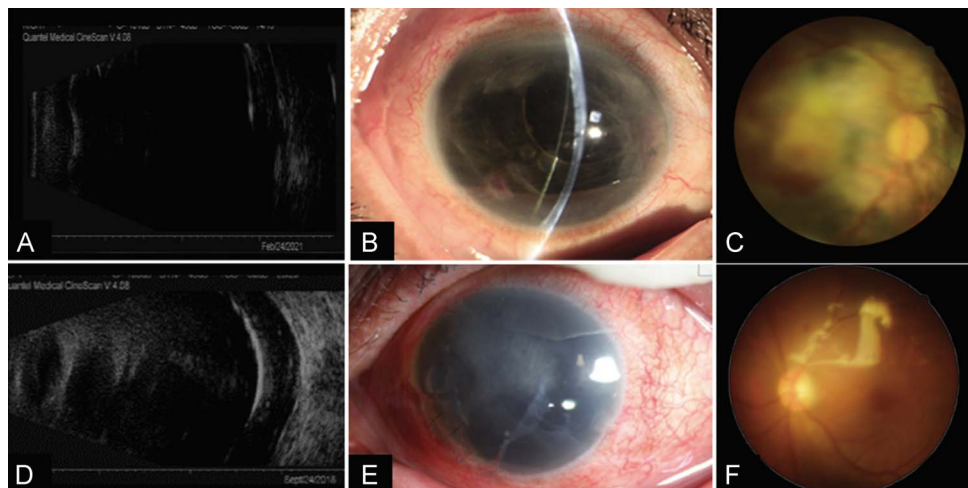
As for the timing to vitrectomy, the timing in the FCVB group was significantly longer than in the SO group; we consider various reasons for this. For patients, SO-filled FCVB implantation is more expensive than direct SO endotamponade; several patients consider this issue for some time. Foldable capsular vitreous body is a new vitreous substitute<sup>17</sup>; doctors are still relatively conservative in its use and apprehensive regarding the effectiveness<sup>16</sup> and occurrence of infection. Besides, FCVB only can be used in few top hospitals of the big city nowadays; hence, some patients spend time on hospital transfer. However, this delay did not affect the selection of the surgical method because the doctors chose SO-filled FCVB implantation based on the severity of ocular trauma and the willingness of the patients. We also believe that this delay may not affect the prognosis. A review study reported that the anatomical success was not significantly related to the timing of intervention; however, there are insufficient data to conclude whether early or delayed surgery leads to improved outcomes at long-term follow-up.<sup>18</sup>

Both the methods have a specific effect on vision improvement; postoperative BCVA of the SO group was significantly better than that of the FCVB group.

Table 4. Comparison of Postoperative Values Between the Two Groups

	FCVB Group	SO Group	<i>P</i>
Retinal reattachment ratio	15/29 (51.7%)	26/35 (74.3%)	0.061
Postoperative IOP (mmHg)	9.13 (6.50–10.80)	10.61 (8.90–12.50)	0.115
Postoperative visual acuity			
NLP	25/29 (86.2%)	17/35 (48.6%)	0.003
≥LP	4/29 (13.8%)	18/35 (51.4%)	
No. of operations	1.10	2.23	0.000

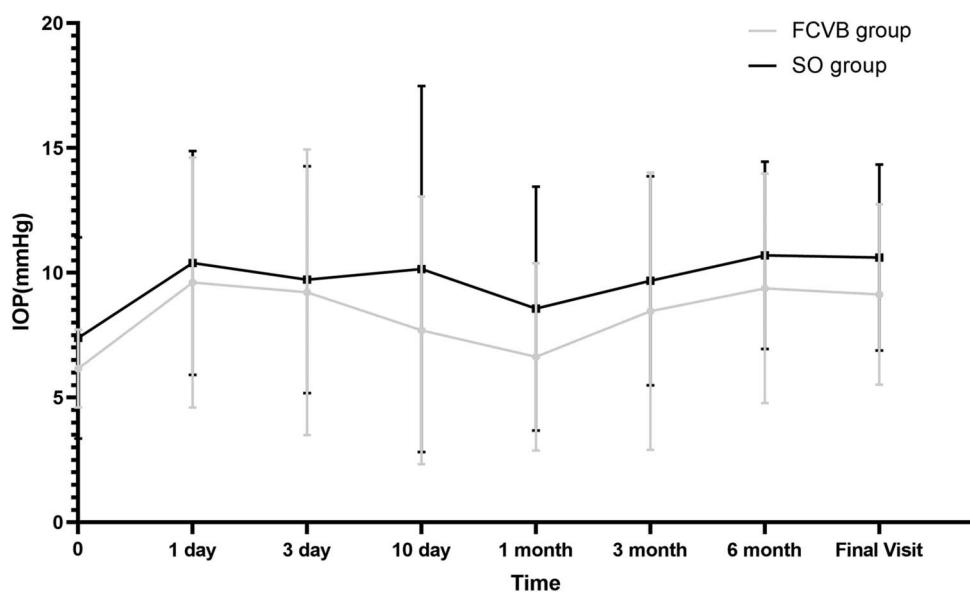
**Fig. 2.** Postoperative results of representative cases in FCVB and silicone oil endotamponade (SO) group; (A) B-ultrasound of the FCVB group three months after surgery. B. Slit-lamp biomicroscopy of the FCVB group 3 months after surgery. C. Fundus photography of the FCVB group 3 months after surgery. D. B-ultrasound of the SO group 3 months after surgery. E. Slit-lamp biomicroscopy of the SO group 3 months after surgery. F. Fundus photography of the SO group 3 months after surgery.



Retinal reattachment is a prerequisite for vision recovery. The retinal reattachment rate of the SO group (74.3%) was higher than that of the FCVB group (51.7%). After vitrectomy, because of its high interfacial tension (35 mN/m against water), SO covers the retinal breaks effectively closing the break and maintaining retinal attachment to allow peribreak adhesion forms.<sup>19</sup> Moreover, SO limits free spread of proliferative cells and biochemical mediators through the vitreous cavity, acting as a space filler, promoting retinal reattachment eventually.<sup>20</sup> Foldable capsular vitreous body supports the retina through a solid arc, and there exists a thin gap between it and the retina,<sup>8</sup> which may cause insufficient reattachment of the retina. Therefore, SO supports the retina more adequately than the FCVB and, thus, could prevent the transition of vitreous fluid into the subretinal space

resulting in a higher rate of retinal reattachment. However, SO endotamponade cannot guarantee that all patients achieve retinal reattachment in severe ocular trauma. The retinal reattachment rate of the SO group is 74.3%, which is consistent with the literature report.<sup>21,22</sup> Therefore, some patients still require additional surgery.

The IOP depends on the dynamic balance pressure of the aqueous humor, and the lower IOP in the FCVB group may be related to the unattached retina. Aqueous humor flows out through the subretinal pathway resulting in decreased IOP.<sup>23</sup> However, with an increase in the ciliary body compensatory function, the IOP gradually restores. Hence, the appropriate size of the FCVB and proper amount of SO are necessary to reduce the possibility of low IOP. During the follow-up period, there was no significant difference



**Fig. 3.** Postoperative IOP profile after vitrectomy combined with FCVB and silicone oil endotamponade (SO) group.

Table 5. Comparison of Postoperative Additional Surgeries in Two Groups

	FCVB Group	SO Group
Without additional surgery	26	0
Secondary surgery	3	27
Enucleation	3	3
Removal of SO	0	23
Removal of SO and implantation of FCVB	0	1
Third surgery	0	8
Repeated replacement and removal of SO	0	8

in the IOP between the two groups indicating that the two methods were equally efficacious in restoring the IOP.

Silicone oil directly contacts the intraocular tissue. Silicone oil emulsification is inevitable; hence, patients require secondary surgery for its removal or displacement.<sup>24</sup> Multiple surgeries have resulted in physical and mental trauma and economic burden to patients. In addition, there have been reports regarding SO toxicity and the loss of secretory function of the ciliary body after long-term contact with SO.<sup>25,26</sup> The use of FCVB is able to resolve these hazardous complications completely.

Foldable capsular vitreous body plays a key role in separating SO from the intraocular tissue, avoiding a series of complications caused by SO directly contacting the intraocular tissues. Foldable capsular vitreous body is composed of tailor-made modified liquid silicone rubber.<sup>9</sup> In vitro experiments showed that FCVB has almost no stimulation after direct contact with the eye tissue and no obvious complications after implantation.<sup>27–30</sup> Besides, SO-filled FCVB is proven to be safe in a 3-year clinical study and no emulsification was observed.<sup>10</sup> In our study, patients who underwent SO-filled FCVB implantation over three years also did not have obvious side effects. Silicone oil-filled FCVB implantation greatly reduces the psychological and physical trauma of patients caused by multiple surgeries, and improves the patients' quality of life, especially in cases of severe ocular trauma with the possibility of SO-dependence in the future.

The study has several limitations. It was a retrospective study and lacked randomization. Despite these limitations, to the best of our knowledge, this is the first clinical study to compare vitrectomy combined with SO-filled FCVB implantation and vitrectomy combined with SO endotamponade for the treatment of NLP after severe ocular trauma.

In conclusion, our study showed that both surgical approaches have effective influence in treating NLP caused by severe ocular trauma. Although vitrectomy

combined with SO endotamponade is more effective during short term in the treatment of NLP caused by severe ocular trauma, SO direct endotamponade may lead to many complications requiring secondary or multiple surgeries. Therefore, for patients who believe to improve their vision, vitrectomy combined with SO endotamponade is recommended; however, to avoid SO dependence or in patients with severe ocular trauma, in whom anatomical reduction cannot be achieved, vitrectomy combined with SO-filled FCVB implantation is recommended. The findings of this study are helpful for surgeons to select appropriate treatment methods and reduce intraoperative complications. The long-term efficacy between the two groups warrants further research with a longer follow-up observation.

**Key words:** foldable capsular vitreous body, no light perception, ocular trauma, silicone oil, vitrectomy.

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