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Foldable Capsular Vitreous Body Implantation for Complicated Retinal Detachment Caused by Severe Ocular Trauma

Abbreviated Title: FCVB Implantation for Complicated RD

Meili Li^{1*}, YuTang^{2*}, Suyan Li¹, Zhengpei Zhang¹, Lina Guan¹, Jie Li¹, Jing Xu¹, Sujuan Ji¹

¹Department of Ophthalmology, The Affiliated Xuzhou Municipal Hospital of Xuzhou Medical University, Xuzhou First People's Hospital, Eye Institute of Xuzhou. Xuzhou Daxue Road, No.269, Jiangsu, China.

²Xuzhou Medical University. Xuzhou Tongshan Road, No.209, Jiangsu, China.

*These authors contributed equally in this work

Meili Li master's degree limeili0319@163.com ORCID: 0000-0003-1959-7161

YuTang bachelor degree ty110401@163.com ORCID: None

Suyan Li Ph. D. lisuyan1226@126.com ORCID: 0000-0003-3860-1381

Zhengpei Zhang master's degree jsxzyszzp@126.com ORCID: None

Lina Guan master's degree glnqlngd715@163.com ORCID: None

Jie Li master's degree lijie850819@163.com ORCID: None

Jing Xu bachelor degree 317038936@qq.com ORCID: None

Sujuan Ji master's degree doctorjsj@163.com ORCID: 0000-0002-7299-5671

Corresponding Author:

Sujuan Ji. Department of Ophthalmology, The Affiliated Xuzhou Municipal Hospital of Xuzhou Medical University, Xuzhou First People's Hospital, Eye Institute of Xuzhou. Xuzhou Daxue Road , No.269, Jiangsu, China. Fax number: +860516-68383308. Email: doctorjsj@163.com. Tel: +8613952180417. ORCID: 0000-0002-7299-5671

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Keywords foldable capsular vitreous body, complicated retinal detachment, ocular trauma, vitrectomy

Summary Statement

The study was conducted to explore the effects of foldable capsular vitreous body implantation for complicated retinal detachment caused by severe ocular trauma. The results show that foldable capsular vitreous body implantation is effective and safe, and it allows patients to face life positively and optimistically.

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Abstract

Purpose: To explore the effectiveness, safety and psychological impact of foldable capsular vitreous body (FCVB) implantation for complicated retinal detachment caused by severe ocular trauma.

Methods: This was a prospective, single-arm, surgical interventional case series study. A standard 3-port 23-gauge pars plana vitrectomy was performed, and the FCVB was implanted into the vitreous cavity. Observed indicators, including the best corrected visual acuity (BCVA), intraocular pressure (IOP), retinal reattachment, complications and patient satisfaction, were analyzed to evaluate the study.

Results: A total of 28 cases (eyes) were enrolled, with a mean follow-up of 16.93 ± 9.67 months and an average age of 51.11 ± 10.14 years, including 22 men (78.57%). The FCVB was successfully implanted, and the retina was reattached in all cases. The postoperative BCVA improved in 7 cases, and remained unchanged in 21 cases ($p > 0.05$). The average IOP was 7.01 ± 2.43 mmHg before surgery and 8.54 ± 2.93 mmHg after surgery ($p < 0.05$). Complications such as FCVB displacement, endophthalmitis, secondary glaucoma, silicone oil emulsification and escape did not occur during the follow-up period. Patients with FCVB implantation are highly satisfied. Most patients

feel hope, positive and optimistic about life.

Conclusion: FCVB implantation for complicated retinal detachment caused by severe ocular trauma is effective and safe, and it allows patients to face life positively and optimistically.

1. Introduction

Severe ocular trauma is one of the causes of monocular blindness, which can not only cause a serious decline in the quality of life but also affect appearance and thus affect the mental health of patients¹. The etiologies and complications of ocular injuries vary². Severe ocular trauma includes penetrating eye injury, rupture of the eyeball, complicated retinal detachment, retinal defect, choroidal detachment, suprachoroidal and vitreous hemorrhage³. The first-line treatment was to perform eye repair surgery, and the second-line traditional treatment was to choose pars plana vitrectomy (PPV) combined with silicone oil filling or to give up surgery. In the former patient, this may eventually cause silicone oil dependence and produce various complications, such as intraocular hypertension, corneal degeneration, retinal redetachment and silicone oil emulsification⁴. Patients who are not suitable for PPV or give up surgery will eventually experience atrophy of the eyeball, which affects appearance. Further negative psychological problems, such as low self-esteem, pessimism and depression, will occur.

For patients with severe visual impairment or complicated conditions that are not

suitable for posterior approach PPV combined with silicone oil filling surgery, if we can find a way to support the shape of the eyeball and keep the appearance basically normal or even preserve part of the vision, the psychological problems caused by appearance can be avoided. Foldable capsular vitreous body (FCVB) uses a modified polysiloxane elastomer as the basic material for preparing film pouches; the material becomes elastically deformed; has good tensile, physical and mechanical properties; and low hardness⁵. Compared with the direct injection of silicone oil into the vitreous cavity, FCVB avoids the direct contact of silicone oil with the intraocular tissues⁶, which prolongs the retention time in the eye, reduces related complications caused by silicone oil, and does not require a second oil extraction operation. As a result, FCVB can be placed in the eye for a long time. We implanted FCVB into the vitreous cavity after PPV to study the effectiveness, safety and psychological impact in the treatment of complicated retinal detachment caused by severe ocular trauma.

2. Methods

2.1 Ethical standards

The study was approved by the Ethics Committee of Xuzhou First People's Hospital. The research process followed the Declaration of Helsinki.

2.2 Patients

From October 2018 to August 2021, patients treated with FCVB in Xuzhou First People's Hospital were enrolled in this prospective, single-arm, surgical interventional case series study. We first selected patients with complicated retinal detachment caused by severe eye trauma (Figure 1). Second, the best corrected visual

acuity (BCVA) of these patients must be so poor that they can only recognize hand move (HM), light perception (LP) or no light perception (NLP). Third, the axial length (AL) of the injured eye was between 16 and 28 mm. In addition, patients with severe systemic diseases that could not tolerate surgery, patients who were allergic to silicone, patients with serious eye inflammation or endophthalmitis and patients whose fundus could not be observed due to corneal opacity were excluded. Patients found to be treatable with silicone oil during surgery were also excluded. All patients approved the surgery in written form after being explained the risks and complications in detail.

2.3 Surgical procedure

The operations were performed by the same surgeon, who had more than 10 years of experience in PPV. Before the surgery, A-scan ultrasound or orbital computed tomography was performed to estimate the AL, which helped us choose the size of the FCVB. The right eye was taken as an example. The patients were placed in the supine position. After retrobulbar anesthesia, the surgical area was disinfected with iodophor and 75% alcohol and then placed on sterile towels. Lenses with or without cataracts were removed with phacoemulsification. Then, a standard three-port PPV via 23G trocars was performed. The vitreous hemorrhage and proliferation membrane were peeled off and cut clean. If necessary, heavy water was injected to flatten the retina, and a laser was used to conglutinate the retina and choroid. The lens capsule was removed and an iris hole was made in the subnasal position. Gas–liquid exchange was performed, and the air pressure was increased to 50-60 mmHg to reduce bleeding.

After cutting and detaching the supratemporal bulbar conjunctiva, a scleral incision was made and expanded to 4 mm parallel to the limbus at a location 5 mm behind the limbus. The FCVB was checked for leaks by injecting with air and then putting it into the water (Figure 2). After folding by an assistant, the FCVB was placed in the injector and sent into the vitreous cavity perpendicular to the sclera from the expanded puncture. The scleral incision was sutured with an 8-0 absorbable suture to stabilize the intraocular pressure (IOP). According to the FCVB size, a suitable volume of silicone oil (viscosity was 5000 mpa.s) was slowly injected into the capsule. It should be noted that, as the capsule was unfolded, the trocars were gradually removed to avoid puncturing it. Viscoelastics were injected into the anterior and posterior chambers to maintain intraocular pressure and eyeball shape. A simple applanation tonometer can be used to measure intraocular pressure during the operation. After adjusting the position of the FCVB, the tube was ligated with 5-0 nonabsorbable sutures, and the valve was fixed to the scleral surface. The fascia, bulbar conjunctiva and punctures were sutured separately with 8-0 absorbable sutures. (Figure 3, Supplemental Digital Content 1, <http://links.lww.com/IAE/B701>).

2.4 Follow-up strategy and observed indicators

Close observation and follow-up are necessary within the first month after surgery, especially the first week. Regular follow-up was conducted at 1, 3, and 6 months postoperatively and then every 6 months until loss. A minimum of 1 year of follow-up was required for the patients.

The postoperative effectiveness of FCVB implantation was evaluated by

observed indicators at the last follow-up, including BCVA, IOP (with Goldmann applanation tonometry, GAT), retinal reattachment and FCVB position (with B-scan ultrasound and fundus photography), shape of the eyeball (with slit lamp biomicroscopy) and facial appearance (with facial photography). Complications during and after surgery were recorded to assess the safety of FCVB implantation.

Patient satisfaction with treatment outcomes and feelings was graded according to the following system: feel dissatisfied as 0, feel satisfied sometime as 1, feel satisfied most of the time as 2, feel satisfied all the time as 3.

2.5 Statistical analysis

Statistical analysis was performed by SAS v9.02 software (SAS Institute Inc., Cary, NC, USA). Continuous data was described as the Mean \pm SD, and categorical data was described as percentages. Continuous data were compared using Student's t test. Categorical data were compared by the chi-square test (Cochran-Mantel-Hanenszel, CMH). $p < 0.05$ was considered significant.

3. Results

3.1 Baseline data

A total of 28 cases (eyes) were enrolled, with a mean follow-up of 16.93 ± 9.67 months (range from 6 to 36 months). There were 22 men (78.57%) and 6 women (21.43%), with an average age of 51.11 ± 10.14 years. The age range was between 31 and 71 years old. There were 14 cases in the right eye (50%) and 14 cases in the left eye (50%). Metal accounted for 35.71% of the causes of ocular trauma, as shown in Table 1, followed by fist, wood and traffic accidents. In addition, 2 cases with eyeball

atrophy were waiting for surgery for 1 year after ocular trauma, 3 cases for two months, and 23 cases within one month after primary suture.

3.2 Evaluation of the effectiveness

Most patients maintained their preoperative vision after surgery. Postoperative BCVA improved in 7 cases compared with preoperative, BCVA remained unchanged in 21 cases (we found that there was no difference between BCVA and naked vision). The results are shown in Table 2. There was no statistically significant difference between postoperative and preoperative BCVA ($p > 0.05$). The average IOP was 7.01 ± 2.43 mmHg before surgery and 8.54 ± 2.93 mmHg after surgery, and the difference was statistically significant ($p < 0.05$). During the follow-up period of all cases, the FCVB was intact and well positioned, the retina was reattached, the shape of the eyeball in all cases was maintained well, and the appearance did not seem to be significantly different from the contralateral eye (Figure 1).

3.3 Evaluation of safety

The retina was reattached in all cases during the operation, and the FCVB was also successfully implanted in the vitreous cavity in all cases. There was no massive bleeding or FCVB rupture during the operation. In one case, the position of the FCVB was found to be slightly shifted after implantation and returned to normal after adjustment with the iris restorer. Mild inflammation in the anterior chamber was found in 6 cases, which usually disappeared with anti-inflammatory treatment approximately 1 month after surgery. In the early postoperative period, 9 patients developed hemorrhage in the anterior chamber, and the bleeding gradually stopped

within 3 days after the intravenous infusion of hemostatic drugs. The hemorrhage was absorbed, in 8 cases, one week after the operation and, in 1 case, 3 weeks after the operation. In one case, the IOP temporarily increased to 28 mmHg on the 7th day after surgery and returned to normal after the application of carteolol hydrochloride and brinzolamide eye drops for one week. One case had a shallow anterior chamber, and after performing anterior chamber-plasty on the third day after FCVB surgery, the depth of the anterior chamber returned to normal. One case had valve exposure 3 weeks after surgery, and we placed simple sutures to avoid further complications. Complications such as rejection, corneal degeneration, FCVB displacement, endophthalmitis, secondary glaucoma, strabismus, silicone oil emulsification and escape did not occur during the follow-up period.

3.4 Satisfaction evaluation

Conjunctival or scleral hyperemia in all patients disappeared between 1 and 2 months after surgery and did not affect appearance eventually. Some patients had a mild foreign body sensation within 1 month after surgery. No atrophy of the eyeballs occurred. As shown in Table 3, postoperative satisfaction was significantly better than preoperative satisfaction ($p < 0.05$). None of the patients regretted the decision. Most patients felt that life was full of hope, felt positive and optimistic about life, did not worry about others looking at the injured eye, and even took the initiative to introduce the implanted FCVB to their friends.

4. Discussion

For complicated retinal detachment caused by severe ocular trauma, the

traditional treatment is to perform PPV, inject silicone oil to fill the vitreous cavity after flattening the retina^{7, 8}, and maintain a prone position for more than 3 months after surgery to achieve good pressure on the retina⁹. The intraocular pressure will remain low, and even retinal redetachment will occur after removal of intraocular silicone oil tamponade in some patients. In these cases, another silicone oil filling operation must be performed, which we call silicone oil-dependent eyes^{6, 10}. Patients who have undergone one or more surgeries for complicated retinal detachment, especially those who have used silicone oil, are more likely to develop epiretinal proliferation (ERP), which will lead to the final failure of the operation¹¹. Silicone oil will cause a toxic effect on ganglion cells and lead to visual deterioration¹². Moreover, silicone oil will emulsify due to direct contact with eye tissue, and the emulsified silicone oil droplets will shift, run into the anterior chamber, cause corneal endothelial damage, block the angle of the chamber (causing secondary glaucoma), and even shift into the brain tissue to cause more serious complications^{9, 13}. In addition, if the time is too long from injury or the intraocular structure is severely damaged, patients who are not suitable for PPV will eventually experience atrophy of the eyeball and collapse of the eye socket, affecting facial appearance.

Fortunately, in recent years, a capsular artificial vitreous called FCVB, initially developed independently in China, has been used to replace silicone oil to support the retina¹⁴. It is a transparent macromolecule cross-linking polymer of polyvinylsiloxane and polyhydrosiloxane with good mechanical properties and biocompatibility and has been proven to be nontoxic to mouse fibroblast cell lines¹⁴. The optical properties of

FCVB indicate that transmittances are 92%, hazes are 5.74%, and spectral transmittance is 97%, which reveal that FCVB is a highly transparent material and can meet the requirement of an artificial vitreous body to be transparent. In addition, FCVB can endure a 1500 mW, 0.2 s, 532 nm green laser¹⁵. The FCVB has been approved by the Chinese Food and Drug Administration and obtained CE certification for distribution and use in the European Economic Area¹⁶. In 2012, FCVB was rated one of four advances in retinal detachment surgery worldwide¹⁷. In recent years, FCVB has been increasingly used in clinical treatment. Similar to the results of previous clinical studies^{18, 19}, during the follow-up period, all cases in our study achieved retinal reattachment. Although postoperative visual acuity is not significantly improved compared with preoperative visual acuity, intraocular pressure is maintained in a balanced state, which not only preserves preoperative visual acuity but also maintains the shape of the eyeball, which shows that implantation of the FCVB is an effective treatment in eyes with complicated retinal detachment caused by severe ocular trauma²⁰. According to Lin et al., IOP and visual acuity did not show a significant difference in FCVB eyes compared with preoperative measurements²¹. The visual acuity and intraocular pressure after FCVB implantation showed a slight elevation compared with those of preoperative eyes in another study²². Although the FCVB has good retinal supporting function, it has a higher incidence of cataracts²³. As a result, the lens needs to be removed during the operation.

An experimental study showed that FCVB tamponade in rabbit eyes did not cause retinal vascular pathologic changes or retinal hypoxia²⁴. The FCVB had

sufficient porosity to allow cytokines to pass through and favorable permeability of proteins in the human eye²⁵. The change in the density of corneal endothelial cells was not statistically significant in the 12 months after FCVB implantation, and ultrasound biomicroscopy showed that the FCVB smoothly contacted but did not crush the ciliary body²². Compared with directly filling the vitreous cavity with silicone oil, the FCVB avoids direct contact between silicone oil and intraocular tissues and reduces related complications caused by silicone oil. The FCVB was implanted successfully in all cases in our study, and there was no massive bleeding or FCVB rupture during the operation.

The most common postoperative complications are anterior chamber hemorrhage and inflammation, which can be completely cured after drug treatment. The average intraocular pressure after FCVB implantation was low, but the finger-measured intraocular pressure was Tn in this study, which may be caused by the use of different measuring instruments. According to the study of Bäurle et al., the IOP measured by GAT after PPV is on average 2.5-6 mm Hg lower than the dynamic contour tonometer PASCAL (DCT) and even underestimated the IOP by 12 mm Hg compared to DCT in one extreme case with gas endotamponade²⁶. In our study, there was a case of a shallow anterior chamber after surgery, which may have been related to the insufficient amount of viscoelastic substance injected into the anterior chamber during the operation. Although filtered clean air can also be used to fill the anterior chamber to maintain the intraocular pressure and depth of the anterior chamber, the study by Zhang et al. showed that viscoelastic substances are better²⁷. Valve leakage and

foreign body sensation can be avoided if the valve is made smaller in the future. Complications such as rejection, corneal degeneration, FCVB displacement, endophthalmitis, secondary glaucoma, silicone oil emulsification and strabismus did not occur during the follow-up period in this study, which indicates that it is safe for FCVB implantation and is similar to previous research results⁶.

Our research found that patients with FCVB implantation were highly satisfied. According to patient experience and recent research²⁸, the first and most important reason is due to a good or acceptable eyeball and facial appearance, which will improve people's self-confidence and maintain healthy social emotions. Second, conventional complex retinal detachment repair with silicone oil may result in recurrent retinal detachment or silicone oil dependence, which ultimately leads to multiple surgeries, and the patient will suffer from physical, mental and financial burdens. The FCVB can help patients avoid these burdens. In addition, because there is no need for a long-term prone position, patients can have good rest and return to work earlier, and their families do not need to take care of them all the time, which will bring more positive and optimistic attitudes in daily life and work. Interestingly, the FCVB can be used not only as a vitreous substitute but also as a drug delivery system to treat or prevent diseases, such as endophthalmitis and proliferative vitreoretinopathy (PVR)^{29,30}. If the price drops to the level of intraocular lenses, the FCVB may become popular.

In summary, FCVB implantation for complicated retinal detachment caused by severe ocular trauma is effective and safe, and it can also eliminate psychological

barriers, improve patient satisfaction and allow patients to face life positively and optimistically.

A list of abbreviations

PPV: pars plana vitrectomy

FCVB: foldable capsular vitreous body

BCVA: best corrected visual acuity

HM: hand motion

LP: light perception

NLP: no light perception

AL: axial length

IOP: intraocular pressure

GAT: Goldmann applanation tonometer

CMH: Cochran-Mantel-Hanenszel

ERP: epiretinal proliferation

DCT: dynamic contour tonometer PASCAL

PVR: proliferative vitreoretinopathy

Declarations

Ethics approval

The research was ethically approved by the Xuzhou First People's Hospital Ethics Committee.

Availability of data and material

The datasets used and/or analysed during the current study are available from the

corresponding author on reasonable request.

Authors' contributions

Meili Li: Drafting of the manuscript and funding support

Yu Tang: Acquisition of data

Suyan Li: Technical Support

Zhengpei Zhang: Conception and design of the research

Lina Guan: Analysis and interpretation of data, funding support

Jie Li: Review and synthesis of the literature

Jing Xu: Participated in research implementation and follow-up arrangements

Sujuan Ji: Critical review and revision of the manuscript, funding support

Conflict of interest statement

None of the authors has any financial/conflicting interests to disclose.

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Figure legends

Fig. 1. Preoperative and postoperative imaging of the injured right eye. Preoperative B-scan ultrasound showed retinal detachment, choroidal detachment, suprachoroidal hemorrhage and vitreous hemorrhage (A). Preoperative anterior segment photography showed bulbar conjunctival hyperemia, corneal edema and hyphema (B). During the follow-up period of all cases, the FCVB was intact and well positioned (C, D, E), and the retina was reattached (C, E). The shape of the eyeball in all cases was maintained

well (D), and the appearance did not seem to be significantly different from the contralateral eye (F).

Fig. 2. Composition and leak check of FCVB. The FCVB consists of a valve, tube and capsule (A). The FCVB was checked for leaks by injecting with air and then putting it into the water (B).

Fig. 3. The surgical procedure (the case of right eye as example). A scleral incision was made and expanded to 4 mm parallel to the limbus at the supratemporal location of 5 mm behind the limbus (A). After folding by an assistant, the FCVB was placed in the injector and sent into the vitreous cavity perpendicular to the sclera from the expanded puncture (B). The scleral incision was sutured with 8-0 absorbable sutures to stabilize the IOP (C). A suitable volume of silicone oil (viscosity was 5000 mpa.s) was slowly injected into the capsule (D). The tube was ligated with 5-0 nonabsorbable sutures, and the valve was fixed to the scleral surface (E). The fascia and bulbar conjunctiva were sutured separately with 8-0 absorbable sutures (F).

Table 1. Patient Characteristics

Items	Description	n	Mean±SD/ Percent
Age	total	28	51.11 ± 10.14
Gender	male	22	78.57%
	female	6	21.43%
Eye	right	14	50%
	left	14	50%
Cause of trauma	metal	10	35.71%
	fist	5	17.86%
	wood	4	14.29%
	traffic accident	4	14.29%
	plastic	2	7.14%
	stone	1	3.57%
	grass	1	3.57%
	firecracker	1	3.57%

Table 2. Postoperative BCVA and IOP Compared to Preoperative Data

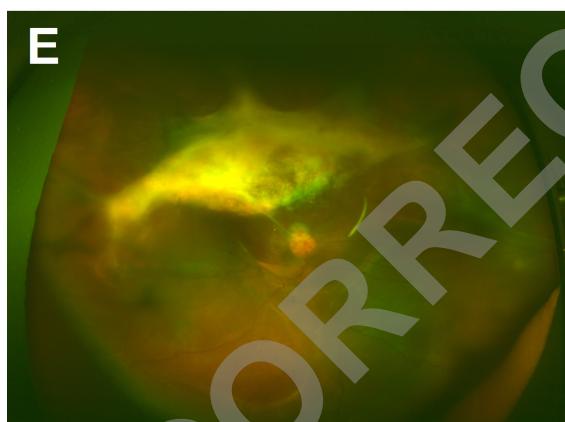
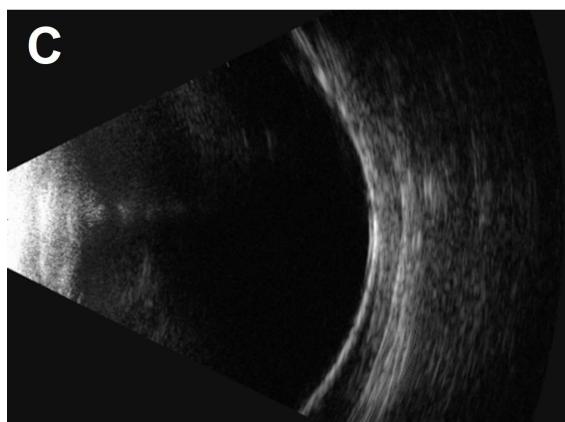
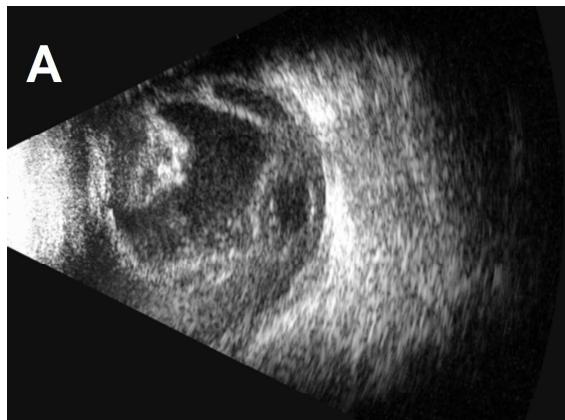
Items	Total n	BCVA			IOP (mmHg)			
		NLP	LP	HM	χ^2 value	p value	Mean±SD t value	p value
preoperative	28	14	11	3	1.55	0.21	7.01±2.43	
postoperative	28	11	10	7			8.54±2.93	3.03 0.0054

NLP, no light perception; LP, light perception; HM, hand motion; FC, finger counting;
IOP, intraocular pressure.

Table 3. Postoperative Patient Satisfaction Compared to Preoperative Data

Items	Total n	scores*				χ^2 value	<i>p</i> value
		0	1	2	3		
preoperative	28	9	17	2	0		
postoperative	28	1	11	14	2	17.56	<.0001

* Feel dissatisfied as 0, feel satisfied sometime as 1, feel satisfied most of the time as 2, feel satisfied all the time as 3.



A



B



