A Pilot Clinical Study of Complex Rhegmatogenous Retinal Detachment Treatment Via Foldable Capsular Buckle Scleral Buckling

Cheng Li
Sun Yat-sen University
Baike Zhang
The 988th Hospital of People's Liberation Army Joint Logistic Force
Yong Jia
The 988th Hospital of People's Liberation Army Joint Logistic Force
Lisha Guo
The 988th Hospital of People's Liberation Army Joint Logistic Force
Chunlei Wang
The 988th Hospital of People's Liberation Army Joint Logistic Force
Yaofan Xing
The 988th Hospital of People's Liberation Army Joint Logistic Force
Qiaoyun Li
The 988th Hospital of People's Liberation Army Joint Logistic Force
Xuemin Tian (13949005500@163.com)
The 988th Hospital of People's Liberation Army Joint Logistic Force https://orcid.org/0000-0001-6328-7318

Research Article

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Abstract

Purpose: To evaluate the feasibility of and identify problems in treating complex rhegmatogenous retinal detachment using foldable capsular buckle scleral buckling.

Methods: This prospective clinical study enrolled five patients with complex rhegmatogenous retinal detachment who were treated with foldable capsular buckle scleral buckling at the 988th Hospital of People's Liberation Army Joint Logistic Force, China. During the 24-week follow-up period, the patients underwent measurements of their best-corrected visual acuity, slit-lamp examination, indirect ophthalmoscopy, and visual field testing. Additionally, B-ultrasound and fundus photography of the patients' retinal reattachments helped evaluate the treatment's post-surgery efficacy. We determined the safety of foldable capsular buckle scleral buckling based on the occurrence of infection, eye pain, diplopia, elevated intraocular pressure, and other serious postoperative complications.

Results: The complex rhegmatogenous retinal detachments of all five patients were successfully treated and evaluated via B-ultrasound and fundus photography after surgery. Visual acuity was enhanced in four patients 24 weeks after surgery, while the remaining patients developed diplopia after surgery. No other complications were observed.

Conclusion: This pilot study preliminarily determined that foldable capsular buckle scleral buckling is a feasible treatment for the efficient and safe treatment of complex rhegmatogenous retinal detachment. These results support this surgery as a potential and novel alternative to current extraocular procedures for the treatment of complex rhegmatogenous retinal detachment.

Introduction

Rhegmatogenous retinal detachment (RRD) is the most common form of retinal detachment. It is caused by a retinal 'break' that allows the ingress of fluid from the vitreous cavity to the subretinal space, resulting in retinal separation [1, 2]. RRD is clinically classified as simple or complex detachment. In simple RRD, retinal detachment is localized to a single, small retinal tear or hole at the retinal periphery, accompanied by good visibility of the fundus [3, 4]. However, in complex RRD, the detachment is partial, subtotal, or total, with a large retinal tear, multiple retinal breaks, posterior breaks, potential associations with vitreous hemorrhage, proliferative vitreoretinopathy (PVR), or other fundus diseases [3–5]. Currently, pars plana vitrectomy (PPV) is the most suitable surgery for complex RRD [3, 6–10]. However, PPV has several disadvantages, including acceleration of the development of cataracts in phakic eyes, increased risk of PVR and epiretinal membranes, low oxygen distribution in the vitreous, and higher cost [11–17]. Therefore, surgery can that effectively treat complex RRD is still under investigation.

In a previous preliminary study, we tentatively used foldable capsular buckle (FCB) external buckling to treat simple RRD in five patients and all retinas were reattached with few complications [18]. Compared with traditional external surgery, from the perspective of surgical principles, this surgery is less invasive, easier to perform, has fewer postoperative complications, and is less painful for patients. FCB is a commercially available product that is modified from foldable capsular vitreous bodies (FCVB) and is designed for scleral buckling to treat simple RRD [19]. The FCVB is made of silicone rubber and consists of a thin capsule with a tube-valve system, wherein the medium can be injected into the capsule [20]. Currently, a multi-center clinical study investigating RRD treatment via FCB scleral buckling is in progress. However, RRD treatment with FCB scleral buckling has only been used for simple RRD [18], and this technique has not previously been used to treat complex RRD.

We suggest that FCB scleral buckling combined with other adjuvant therapies, such as retinal photocoagulation, transscleral cryotherapy, and vitreous gas injection, may be suitable for the treatment of partial complex RRD for several reasons. First, because FCB scleral buckling can generate a larger buckling area on the sclera, it may be better to treat RRD with extensive retinal detachment or adjacent multiple retinal breaks. Second, compared with traditional scleral buckling, FCB may be easier to implant and place relatively posteriorly, making this surgery more suitable for patients with RRD with retinal breaks in the posterior region of the eye. Third, because the FCB generates spherical pressure, the pressure ridge is relatively smooth, which can reduce the effect of retinal surface tension and enhance retinal reattachment. Although our previous experiments aimed at treating simple RRD, successful retinal attachment and fewer postoperative complications led us to speculate that FCB scleral buckling could be a less invasive and simpler approach to treating some cases of complex RRD [18].

In this study, we tentatively used FCB to treat complex RRD patients who refused PPV surgery for various reasons. Through this pilot clinical study, we aimed to evaluate the feasibility of using FCB scleral buckling to treat complex RRD, identify problems that may arise during treatment, and lay the foundation for further research on FCB scleral buckling.

Methods

Ethics approval

The prospective observational clinical study protocol was reviewed and approved by the Institutional Review Board and Ethics Committee of the 988th Hospital of People's Liberation Army Joint Logistic Force, China (9882019000), and adhered strictly to the principles of the World Medical Association's (WMA) Declaration of Helsinki of the World Medical Association. All patients were provided with an explanation of the purpose and design of the study, and they were informed that FCB scleral buckling is still an off-label treatment for RRD. The patients provided written informed consent prior to participating in the study.

Subjects

This was a prospective study, and the patient inclusion criteria were as follows: to start, the patients had to have retinal detachments caused by one giant retinal tear or multiple retinal breaks that subtended less than 6 mm in their longest dimension, or had RRD associated with pseudophakia, high myopia, vitreous hemorrhage, PVR, or other fundus diseases. Some patients were not candidates for PPV surgery for various reasons. The exclusion criteria were patients who were allergic to silica, had severe systemic disease, were intolerant of surgery, or had previously received other surgical treatments, including PPV, scleral buckling, or pneumatic retinopexy.

FCB scleral buckling and surgical procedure

We followed a previously published surgical method without implementing significant changes [18].

Post-operative observation

To evaluate the efficacy of FCB scleral buckling on retinal reattachment, we performed B-ultrasound, optical coherence tomography, and fundus photography 1 week postoperatively (P1W). The main postoperative outcome was anatomical restoration of the retina at 24 weeks postoperatively (P24W). Additionally, the postoperative observation included best-corrected visual acuity (BCVA) (LogMAR) and recording of complications at 1 week, 2 weeks, 3 weeks, 4 weeks, 12 weeks, and 24 weeks post-surgery. The safety of the treatment was evaluated based on infection, eye pain, diplopia, elevated intraocular pressure (IOP), and other serious postoperative complications at 24 weeks after surgery.

Results

All the clinical characteristics and surgical outcomes are summarized in Table 1.

Table 1
Clinical characteristics and surgical outcomes of the study subjects

Variables	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Gender	Male	Female	Male	Male	Female
Age (years)	48	41	54	42	21
Onset of symptoms to the time of surgery (days)	10	2	3	4	30
Initial IOP (mmHg)	9	12	17	13	12
Eye axis (mm)	27.12	26.21	25.84	23.49	25.78
Other oculopathy	High myopia and posterior staphyloma	None	None	Pseudophakic eye	Proliferative vitreoretinopathy
Reason for refusing PPV	Surgery effect concern	Pregnant	Discomfort	Discomfort	Surgery effect concern
Initial BCVA	20/40	HM*	20/100	20/200	20/50
Hole location	Superotemporal	Superotemporal	Superotemporal	Temporal	Lower
Retinal involvement scope	2 quadrants	2 quadrants	2 quadrants	2 quadrants	2 quadrants
Macula affected	No	Yes	Yes	Yes	Yes
Intraoperative treatment	Condensation	None	Condensation	Condensation	Condensation
Post-operative treatment	Photocoagulation	Photocoagulation	Photocoagulation	Photocoagulation	Photocoagulation
BCVA at 1 week post-operation	20/40	20/80	20/80	20/50	20/50
BCVA at 24 weeks post-operation	20/25	20/40	20/32	20/32	20/40
Other adjuvant treatments	Daily injections of 250 ml 20% mannitol and 40 mg methylprednisolone sodium succinate	Intravitreal gas injection on tenth post-operative day	Released a small amount of fluid from the FCB	None	None
Discomfort and complications after surgery	Foreign body sensation and eye pain until the day after surgery	Subretinal fluid	Diplopia	None	None

*HM: Hand motion

In total, five patients were included in the study (three men and two women) with a mean age of 41.2 years (range: 21–52 years). The mean time from when the patients experienced a symptom of RRD to when they received surgery was 9.8 days (range: 2–30 days). The mean initial IOP was 12.6 mmHg (range: 9–17 mmHg) and the mean eye axis was 25.688 mm (range: 23.49–27.12 mm). The main reasons for refusing PPV included surgery effect concerns, meaning the patients were not satisfied with the effect of PPV on their contralateral eye, previous surgery, or they were encouraged by the better surgical outcomes of other subjects (2/5), pregnancy (1/5), or discomfort with PPV surgery (2/5).

Evaluating the efficacy of FCB scleral buckling for complex RRD treatment

Three patients' retinal holes were located in the superotemporal region, one was in the temporal retina, and one was in the lower retina. The retinal detachment of all five patients involved two quadrants, and only one patient's macula was not affected. Four patients underwent intraoperative condensation, and all patients received postoperative photocoagulation. At 24 weeks post-operation (P24W), all patients had good retinal anatomical restoration. At 1 week post-operation (P1W), three patients had enhanced BCVA, and at P24W, all patients had enhanced BCVA. The retinal detachments and anatomical restorations of all five patients are shown in Figures 1–5.

Safety evaluation of FCB scleral buckling

In terms of safety, none of the five patients experienced adverse events, such as endophthalmitis, cardiovascular events, or other systemic reactions. There were no acute high IOP events caused by the FCB scleral buckling, nor were there episodes of severe postoperative bleeding or unbearable discomfort, as observed in the safety evaluation of a previous study [18]. However, it should be noted that Patient 3 developed diplopia after the operation and her eye movement was limited, which could have been a complication of FCB implantation affecting the lateral rectus. However, when the retina was reattached and the FCB was removed, her diplopia resolved, and the limitations of her eye movement were corrected. Additionally, Patient 1 had a foreign body sensation and eye pain, but on the second day post-surgery, it spontaneously remitted. Therefore, this study proved that FCB scleral buckling is safe.

Discussion

This pilot clinical study preliminarily demonstrated that FCB scleral buckling is a feasible treatment alternative for retinal reattachment in some complex RRD cases when patients refuse PPV surgery. Considering a previous exploratory clinical study that used this technique to treat simple RRD, we suggest that FCB scleral buckling may represent an innovative surgical method to improve general RRD management [18].

From the postoperative examination results of five patients, it is clear that external FCB exerted pressure on the sclera and retina, and that its location was not easily changed by ocular movement during the postoperative observation period. Combined with subretinal fluid release, transscleral cryotherapy, and retinal photocoagulation, FCB scleral buckling surgery greatly improved the BCVA of the five patients compared to before surgery, indicating that this innovative surgical method supports retinal reattachment and restores function. The retina was successfully reattached after surgery in all the patients.

For Patient 2, postoperative examination showed a small amount of subretinal fluid in the upper peripheral fundus; therefore, we conducted intravitreal gas injection on the tenth postoperative day to promote close attachment of the retina. The second day after intravitreal gas injection, the retina was fully reattached. Postoperative OCT of Patient 5 showed that the neuroepithelial retina was still slightly detached, which may be due to the patient's long period of retinal detachment, viscous subretinal fluid, and severe PVR proliferation cord. However, a relatively common scenario in patients who undergo retinal reattachment is the slow absorption of viscous subretinal fluid and full reattachment. Considering the severe retinal detachment in all five patients, combined with the special case of high myopia, intraocular lens, or PVR, we show that FCB scleral buckling is effective in the treatment of complex RRD.

None of the five patients experienced severe adverse events, such as endophthalmitis, cardiovascular events, or other systemic reactions. Moreover, there were no acute high IOP events caused by FCB scleral buckling, nor were there episodes of severe postoperative bleeding or extreme discomfort. However, it should be noted that Patient 3 developed diplopia after the operation, which did not resolve after fluid was released from the FCB, but continued until the FCB was removed. This may have occurred because the FCVB influenced the extraocular muscles, especially since it was located under the rectus in accordance with the patient's retinal detachment and hole location. However, the complication was resolved by removing the FCVB, indicating that its influence on the extraocular muscles is reversible. Because the FCB balloon is not continuously implanted under the conjunctiva, diplopia may occur in some patients, but with the removal of the balloon, this issue will resolve. Therefore, with these few complications and using the 3/n rule, we are confident that the true complication rate of FCB scleral buckling is no more than 60% [21].

FCB scleral buckling is an improvement of traditional external scleral surgery, compared to which it might possess advantages and avoid some shortcomings. In external scleral surgery, the fundus image is inverted through an indirect ophthalmoscope and the magnification is small, making it difficult to perform and master. In addition, post-eyeball anesthesia is needed to increase the risk of puncturing the eyeball. Moreover, the sclera needs to be exposed by repeatedly pulling the muscle, thus inducing pain in the patient and introducing a high risk of the occurrence of the oculocardiac reflex. In contrast, in FCB scleral buckling, all these procedures are conducted under a microscope and involve fewer muscles, making it less invasive and easier to perform. Only Patient 2 in this study received local surface infiltration anesthesia, which may indicate that this surgery is especially suitable for the elderly, young children, nervous patients, patients in poor health, and even pregnant women.

This type of surgery also has a larger pressure range, usually covering the hole and surrounding the detached retina. Although the spherical pressure generated by the FCVB and its indwelling time can be controlled, we tentatively used FCB scleral buckling to treat some complex RRD patients, although these patients should have received PPV surgery but refused. As a type of external scleral surgery, FCB scleral buckling has the common advantages of external scleral surgery and could avoid some disadvantages of PPV surgery, such as increased risk of PVR and epiretinal membranes as well as low oxygen distribution in the vitreous, which could further accelerate cataracts in phakic eyes and damage trabecular meshwork cells [11–16]. FCB scleral buckling could also avoid optic nerve atrophy, disruption of ciliary body secretion induced by silicone oil injection, and other complications caused by PPV surgery [13, 22–29].

This study showed that FCB scleral buckling can be a feasible, effective, and safe alternative to retinal reattachment in some complex RRD cases when patients refuse PPV surgery. However, certain shortcomings of this surgery should not be neglected: it is relatively difficult to fix if the FCVB is located under the muscle, and patients with an FCVB are at risk of developing temporary diplopia, although this can be relieved by releasing some water from the balloon. Additionally, the current study design has some limitations, notably a small number of subjects, lack of a control group, and no comparison with conventional treatment strategies. Accordingly, a large-scale randomized study controlled with PPV should be conducted to further confirm the efficacy and safety of FCB scleral buckling.

In summary, this study showed that FCB scleral buckling is a simple, easy to learn, less invasive, and less complicated alternative for treating some complex RRD cases when patients refuse PPV surgery. These promising results grant us the confidence to conduct large-scale multicenter clinical trials to further verify the efficacy and safety of FCB sclera buckling.

Declarations

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Author Contributions: All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by [Cheng Li] and [Baike Zhang]. The first draft of the manuscript was written by [Cheng Li] and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Conflicts of interest

The authors have no relevant financial or non-financial interests to disclose.

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Figures

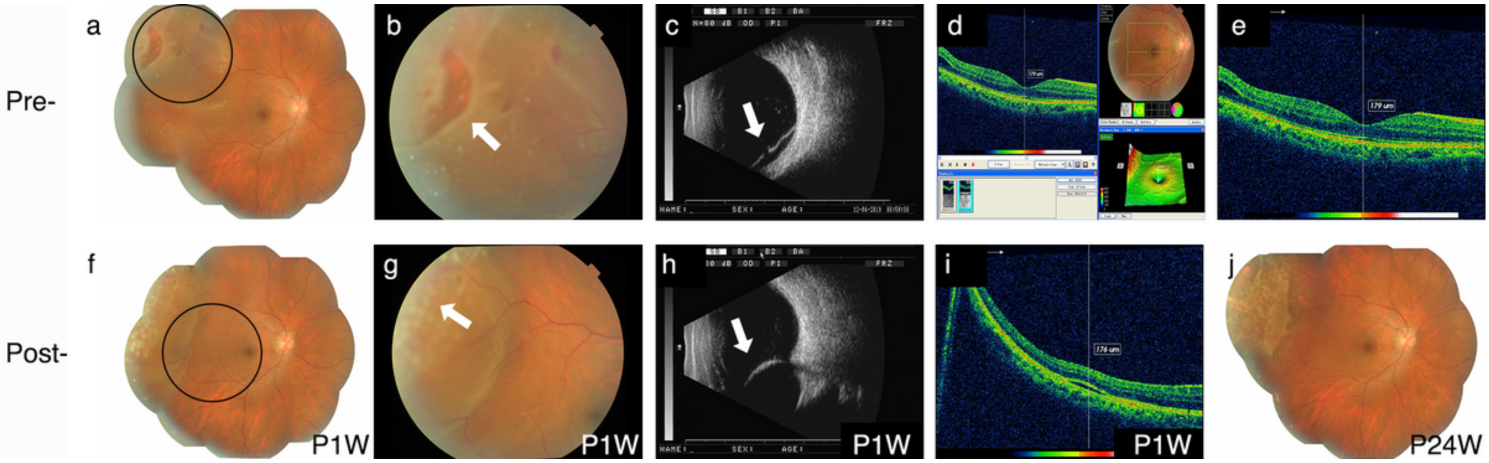

Figure 1

FCB scleral buckling efficacy on Patient 1, who had RRD for 10 days caused by a large retina tear and several small retina breaks

a. Fundus image showing retinal detachment pre-surgery. **b.** The amplified circle area from **A** showing the retinal tear (white arrow). **c.** B-ultrasound scan showing retinal detachment pre-surgery (white arrow). **d–e.** OCT showing an unaffected macula. **f.** Fundus image of FCB scleral buckling at 1-week post-surgery (P1W). **g.** Fundus image showing clear and distinct photocoagulation spots (white arrow). **h.** Post-operative B-ultrasound scan showing FCB's clear pressure on the sclera (white arrow). **i.** OCT showing a small amount of remaining subretinal fluid and the mostly reattached retina. **j.** Fundus image at 24 weeks post-operation (P24W) showing the well-reattached retina.

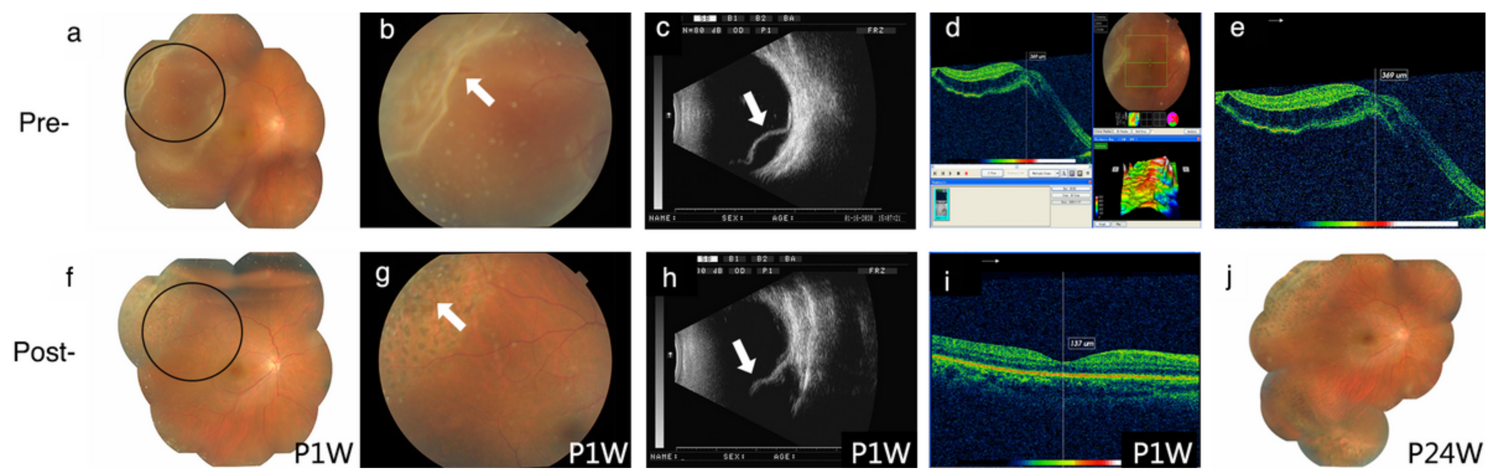

Figure 2

FCB scleral buckling efficacy on Patient 2

a. Fundus image showing retinal detachment pre-surgery. **b.** The amplified circle area from **A** showing the retinal tear (white arrow). **c.** Pre-operative B-ultrasound scan showing retinal detachment (white arrow). **d–e.** OCT showing an affected and detached macula. **f.** Fundus image of FCB scleral buckling at 1-week post-surgery (P1W). **g.** Fundus image showing clear and distinct photocoagulation spots (white arrow). **h.** Post-operative B-ultrasound scan results showing the FCB's clear pressure on the sclera (white arrow). **i.** OCT showing the reattached macular. **j.** Fundus image at 24 weeks post-operation (P24W) showing the well-reattached retina.

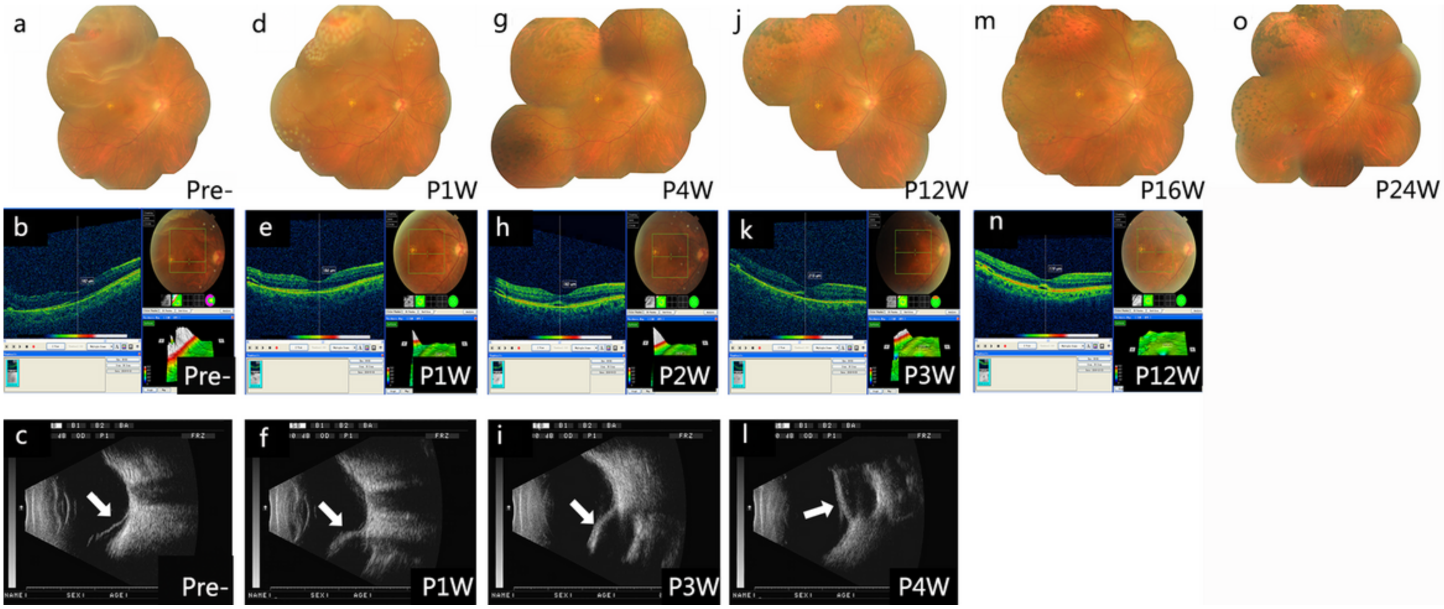

Figure 3

FCB scleral buckling efficacy with a giant retina tear in Patient 3

a. Fundus image showing retinal detachment pre-surgery. **b.** OCT showing the affected macula and its unaffected central fovea. **c.** Pre-surgery B-ultrasound scan showing retinal detachment (white arrow). **d.** Fundus image of FCB scleral buckling 1 week post-surgery (P1W). **e.** OCT showing no lesion present on the central fovea of the macula P1W. **f.** B-ultrasound scan results P1W showing the FCB's clear pressure on the sclera (white arrow). **g.** Fundus image showing the retina attached at 4 weeks post-operation (P4W). **h.** OCT showing a small lesion present on the central fovea of the macula 2 weeks post-operation (P2W). **i.** B-ultrasound showing better retinal restoration 3 weeks post-operation (P3W). **j.** Fundus image showing the retina attached at 12 weeks post-operation (P12W). **k.** OCT showing a small lesion on the central fovea of the macula P3W. **l.** B-ultrasound scan showing the attached retina P4W. **m.** Fundus image showing the attached retina 16 weeks post-operation (P16W). **n.** OCT showing a small lesion present on the central fovea of the macula at P12W. **o.** Fundus image showing attached retina 24 weeks post-operation (P24W).

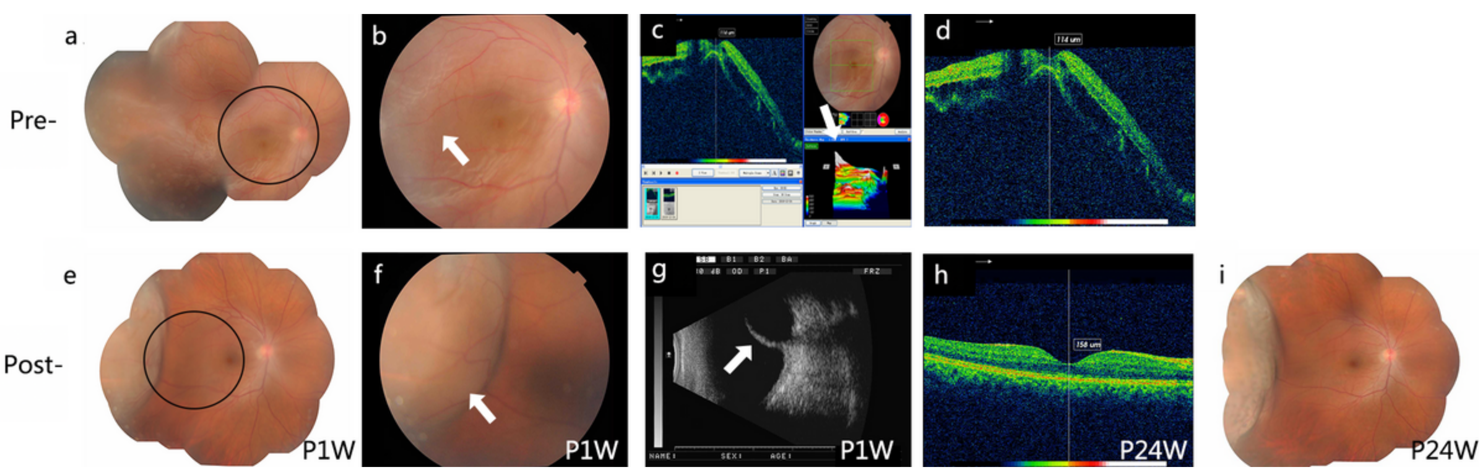

Figure 4

FCB scleral buckling efficacy in the pseudophakic eye of Patient 4

a. Fundus image showing retinal detachment pre-surgery. **b.** The amplified circle area from **A** showing the detached retina (white arrow). **c**–**d.** OCT showing an affected and detached macula. **e.** Fundus image of FCB scleral buckling at 1-week post-surgery (P1W). **f.** Fundus image showing clear and distinct photocoagulation spots (white arrow). **g.** Post-operative B-ultrasound scan results showing the FCB's clear pressure on the sclera (white arrow). **h.** OCT showing the reattached macular. **i.** Fundus image at 24 weeks post-operation (P24W) showing the well-reattached retina.

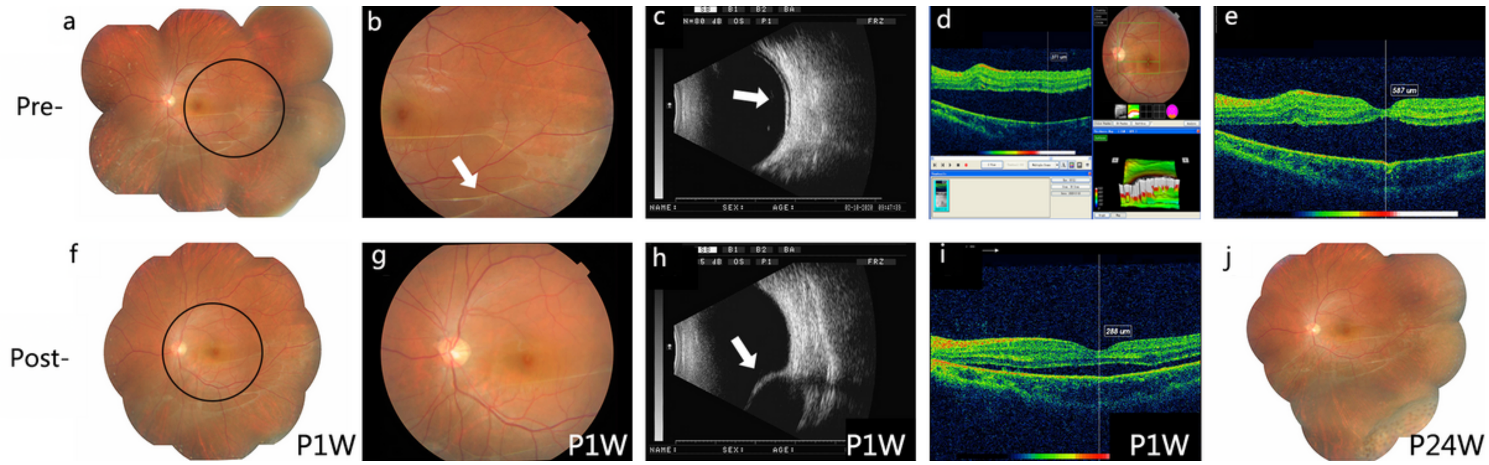

Figure 5

FCB scleral buckling efficacy in Patient 5 after a long period of retinal detachment and PVR proliferation cord

a. Fundus image showing retinal detachment pre-surgery. **b.** The amplified circle area from **A** showing the proliferation cord (white arrow). **c.** Pre-surgery B-ultrasound scan showing retinal detachment (white arrow). **d–e.** OCT showing an affected and detached macula. **f.** Fundus image of FCB scleral buckling at 1 week post-operation (P1W). **g.** Fundus image showing indistinct photocoagulation spots. **h.** Post-operative B-ultrasound scan results showing the FCB's clear pressure on the sclera (white arrow). **i.** OCT showing the much improved macular but also a small amount of retained subretinal fluid. **j.** Fundus image at 24 weeks post-operation (P24W) showing the well-reattached retina.