

A PILOT CLINICAL STUDY OF TREATING RHEGMATOGENOUS RETINAL DETACHMENT BY SILICONE RUBBER BALLOON SCLERAL BUCKLING

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Purpose: To evaluate the efficacy and primary safety of treating rhegmatogenous retinal detachment (RRD) using foldable capsular vitreous body scleral buckling.

Methods: Five patients with simple RRD were treated with foldable capsular vitreous body scleral buckling. B-ultrasound and fundus photography examining of retina reattachment were used to evaluate the postsurgery efficacy. The safety of the treatment was evaluated based on the occurrence of infection, eye pain, diplopia, elevated intraocular pressure, and other serious postoperative complications after surgery. The observation time after the operation was at least 12 weeks.

Results: The simple RRD of all five patients was successfully reattached before being evaluating by B-ultrasound and fundus photography after surgery. Visual acuity was enhanced in two patients who were macularly affected. One patient had temporary diplopia and eye movement limitation after surgery. No other complications were recorded.

Conclusion: This pilot study determined that foldable capsular vitreous body scleral buckling can be efficacious and safe for simple RRD. The results indicate that this surgery may be a novel alternative to the current extraocular procedures for simple RRD.

RETINA 40:1918–1928, 2020

With a high incidence range of 6.3 to 17.9 per 100,000, rhegmatogenous retinal detachment (RRD) is a potentially blinding disease that is characterized by the separation of the inner neurosensory retina from the outer retinal pigment epithelium.^{1,2} Primary RRD occurs because of the formation of a retinal break, vitreoretinal traction, and entry of the lique-

fied vitreous through the break.³ Currently, repairing RRD is the quintessential procedure of vitreoretinal surgeons worldwide and includes three main techniques—scleral buckling, pars plana vitrectomy (PPV), and pneumatic retinopexy, all of which are used successfully for the treatment of RRD and that have primary success rates of up to 90%.^{4–7}

Scleral buckling, which requires the surgeon to sew a silicone strip or sponge to the outside of the eye, was first introduced in the 1950s and had been the standard method used for treating RRD for several decades.^{8,9} Although the application of PPV has significantly increased and become the most commonly used procedure, even with the evolution of vitrectomy machines and related instruments,^{9–16} pars plana vitrectomy surgery still has disadvantages, such as the acceleration of cataracts in phakic eyes, a lower initial rate of anatomical success, increased risk of proliferative vitreoretinopathy and an epiretinal membrane, and a higher cost.^{8,17–21} However, scleral buckling is an extraocular procedure, does not require that a posterior vitreous detachment be present, and does not promote

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

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cataract formation; so, it still has some merits and continues to play an important role in retinal reattachment surgery.^{22–30} Indeed, PPV surgery will remain an ideal treatment option in selected cases, especially in patients who are younger, in phakic eyes, and in limited retinal detachment, particularly with a hole in the lattice or an inferior location, even in subjects with high myopia.^{31–33} However, we cannot ignore the fact that some of the shortcomings of scleral buckling—such as it requiring more anesthesia and higher surgical skills, hence meaning it is difficult to teach—may still induce change of refractive errors or diplopia postoperatively.⁸ For these reasons, PPV surgery is still undergoing modifications and has evolved along with advances in the materials, instrumentation, and surgical techniques.

One of the innovations for improving scleral buckling is the Lincoff temporary balloon buckle.³⁴ With this technique, the surgeon uses an inflatable silicone explant that is inserted through the conjunctiva at the ora serrata and that then expands beneath the retinal break to achieve a buckling effect that closes the break and allows subretinal fluid to be absorbed. Adhesion is obtained by transconjunctival cryopexy before inserting the balloon or by laser coagulation postoperatively after the break has flattened against the retinal pigment epithelium. After several days, the balloon is removed at the bedside under topical anesthesia.^{34,35} This type of surgery is simple in that no foreign body is permanently buried in the orbital tissues, no postoperative positioning of the patient is necessary, and no intraocular manipulations are needed.³⁶ Compared with conventional scleral buckling, this surgery does not need scleral suturing, eliminating the risk of scleral perforation, requiring a shorter operating time, and causing less surgical trauma to the periocular tissues.^{36,37} However, this balloon is currently not commercially available; in addition, another drawback is that leaving a long pipe for an extended time outside the eye can be uncomfortable and inconvenient for the patients, resulting in its limited use.³⁸

With the aim of overcoming the above drawbacks of scleral buckling and of the Lincoff temporary balloon buckle, we tentatively used a foldable capsular vitreous body (FCVB) for the external buckling to treat simple RRD. An FCVB is a substitution of the vitreous body that can be used to treat severe retinal detachment.³⁹ In the current study, the FCVB was made of silicone rubber and consisted of a thin vitreous cavity-shaped capsule with a tube-valve system. The balanced salt solution (BSS) or silicone oil can be injected into the capsule through the tube-valve system.⁴⁰ The FCVB has been approved by the China

Food and Drug Administration, obtained CE certification for distribution and use in the European Economic Area, and has been clinically used in these countries. By using the FCVB as the material for scleral buckling to treat RRD, we attempted making the operation easier, more convenient, and painless for the patients compared with the conventional scleral buckling surgery. Moreover, the special shorter tube-valve system—which can be placed under the conjunctiva to make this surgery safer than the Lincoff temporary balloon buckle and to reduce the chance of orbital infection at the same time—maintains the extraocular procedure's safety and ease of operation compared with PPV treatment.

Accordingly, the current pilot clinical study was designed primarily to evaluate the efficacy and safety of using FCVB external buckling to treat simple RRD and to prepare for further randomized controlled clinical trials using an FCVB to treat this kind of disease.

Methods

The study protocol was reviewed and approved by the Ethics Committee of the People's Liberation Army 153rd Hospital (No. 2017011), and it adhered strictly to the principles of the World Medical Association and Declaration of Helsinki. All patients were provided with an explanation of the purpose and design of the study, and they were informed that the product is not currently labeled for scleral buckling use. They provided written informed consent before participating in the study.

Subjects

We selected patients whose retinal detachments were caused by only one retinal break, where the retinal detachment did not exceed two quadrants, and where there were no cases of accompanying proliferative vitreoretinopathy. The exclusion criteria were patients known to be allergic to silica, who had a severe system disease or were intolerant of surgery, or who had once received other surgical treatment, such as PPV, scleral buckling, pneumatic retinopexy, and the Lincoff temporary balloon buckle. We also excluded complicated RRDs accompanied by pseudophakia, other fundus diseases, and media opacity. Five patients were recruited from May to June 2018. Their basic information is summarized in Table 1.

Foldable Capsular Vitreous Body

The FCVB we selected was the AV-10P (Vesber, Guangzhou, China), which is made of silicone rubber and consists of a thin vitreous cavity-shaped capsule

Table 1. Basic Information of the Study Subjects

Variables	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Sex	Female	Female	Female	Male	Female
Age (years)	49	26	62	56	45
Initial BCVA	Hand motion	Hand motion	20/200	20/200	20/25
Postoperation visual acuity	20/100	20/32	20/40	20/50	20/25
Initial IOP (mmHg)	12	12	12	14	12
Retinal involvement scope	1 quadrant	1 quadrant	1 quadrant	2 quadrants	2 quadrants
Macula affected	Yes	Yes	No	No	No
Hole location	Superotemporal	Temporal	Inferotemporal	Superotemporal	Superonasal
Intraoperative treatment	Transscleral cryotherapy	Transscleral cryotherapy	Transscleral cryotherapy	Transscleral cryotherapy	Transscleral cryotherapy
Postoperative treatment	Photocoagulation	Photocoagulation	Photocoagulation	Photocoagulation	Photocoagulation

with a tube–valve system, as shown in Figure 1. The BSS can be injected into the capsule through the tube–valve system, which exerts pressure on the sclera.

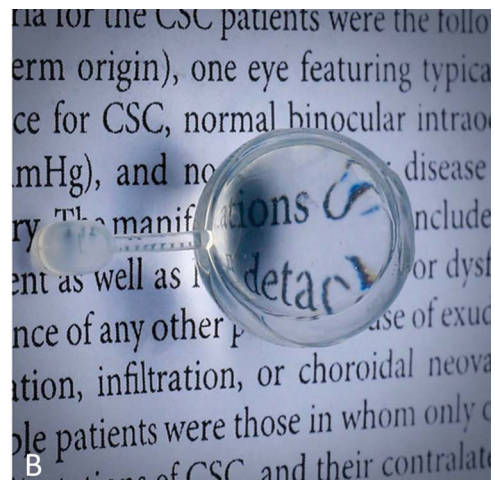
Surgical Procedure

Before the operation, we conducted a routine ophthalmologic examination that included best-corrected visual acuity (BCVA), intraocular pressure (IOP), anterior segment examination with a slit-lamp, three-mirror contact lens examination and binocular indirect ophthalmoscope, fundus photography, B-ultrasound examination, optical coherence tomography (OCT), eye axis measurement, and a general medical examination. A detailed fundus examination was also performed on the contralateral eye of the patients. Through the detailed fundus examination, we determined the scope of retinal detachment, either with or without involvement of the macula, found the location of retinal tears, and

determined the proliferative vitreoretinopathy grading.

The surgery was conducted as follows: After subconjunctival infiltration anesthesia, the conjunctival sac was repeatedly washed with diluted iodophor and saline. The bulbar conjunctiva was cut 5 mm behind the limbus and parallel to the limbus along the direction of the retina tear. The incision was about 4 mm in length, and the subconjunctival tissue was separated from the sclera (Figure 2A). Along the scleral, backward separating the subconjunctival tissue to forming a tunnel of about 10 to 12 mm in length and a radial incision of about 1 mm was made at the high point of the retinal detachment in the direction of the hole. A 25-G syringe needle was obliquely inserted into the subretinal space to release the subretinal fluid (about 1 mL), and then, the drainage hole was sutured (Figure 2B). Under microscope, the retinal holes were repositioned. The FCVB was vacuumed and folded, and the

Fig. 1. Foldable capsular vitreous body structure. The FCVB was made of silicone rubber and consisted of a thin vitreous chamber–shaped capsule with a tube–valve system. A. The size and shape of the FCVB. B. FCVB is transparent after being filled with media.



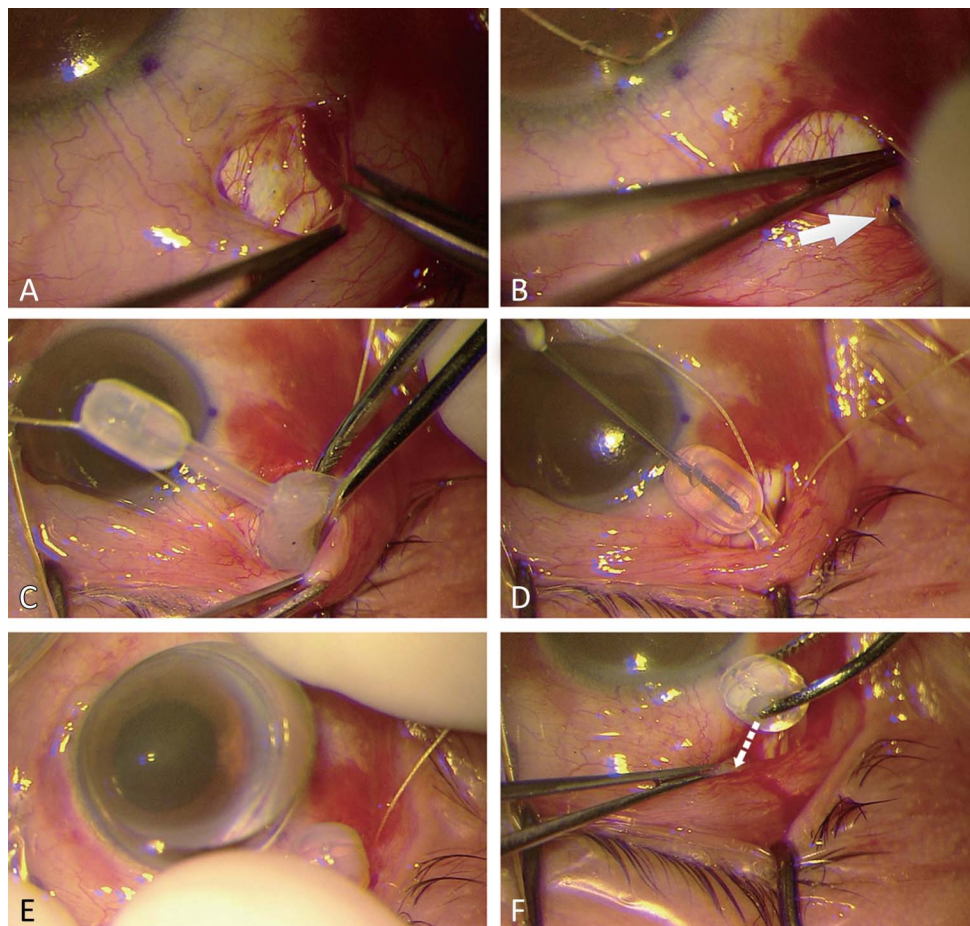


Fig. 2. Surgical operation. The bulbar conjunctiva was cut 5 mm behind the limbus along the direction of the hiatus, parallel to the limbus. The incision was about 4 mm in length, and the subconjunctival tissue was separated from the sclera (A). A 25-G syringe needle is obliquely inserted into the subretinal space to release the subretinal fluid (about 1 mL) (B). A vacuumed and folded FCVB; the surgeon placed the FCVB along the pre-made tunnel with the spherical surface-facing sclera (C). Injected 1 mL of normal saline through the drainage valve device (D). Checked the scleral pressure from the FCVB (E). The balloon drainage valve was folded under the conjunctiva in a transverse direction (F).

surgeon placed the FCVB along the pre-made tunnel with the spherical surface-facing sclera (Figure 2C). The scleral incision was closed with a suture, and a 5.0 nonobservable suture was used to fixate the balloon drainage tube to 8 to 10 mm behind the limbus; then, 1 mL of normal saline was injected through the drainage valve device (Figure 2D). We then checked the scleral pressure by the FCVB (Figure 2E) and further fixed all the drainage tubes. The balloon drainage valve was folded under the conjunctiva in a transverse direction (Figure 2F), and the conjunctival incision was performed using two needles. Tobramycin dexamethasone eye ointment was applied, and the affected eye was bandaged. During the operation, transscleral cryotherapy was applied conventionally, and conventional retinal photocoagulation was used postoperatively to close the hole and promote retinal reattachment. Observation was performed at least 12 weeks after surgery, and the balloon was removed after the laser treatment and when transscleral cryotherapy and photocoagulation spots appeared with obvious pigmentation. For the procedure for taking out the FCVB, this was per-

formed in the operating room with subconjunctival infiltration anesthesia. However, some patients felt that their postoperative recovery was going well and that there were no obvious complications, so they were more willing to keep the FCVB for more few weeks. All surgical procedures were performed by the same surgeon in the surgery room.

Postoperative Observation

Postoperative observation included anatomical restoration of the retina, visual acuity, fundus photography, B-ultrasound, and recording the postoperative complications until at least 12 weeks after surgery. To evaluate the efficacy of the treatment, the FCVB pressing retinal reattachment degree was assessed using B-ultrasound, and fundus photography was recorded after the surgery. The safety of the treatment was evaluated based on the occurrence of infection, eye pain, diplopia, elevated IOP, and other serious postoperative complications for 12 weeks after the surgery. Three of the patients came back for a 1-year follow-up.

Results

Efficacy Evaluating of Foldable Capsular Vitreous Body Scleral Buckling

When she came to our hospital, Patient 1 complained of a sudden vision loss in her right eye for 2 days, the BCVA of her right eye was only hand motion, and the IOP was 12 mmHg. Fundus examination, B-ultrasound scan, and fundus photography all showed extensive retinal detachment in superotemporal location involving one quadrant and an elliptical hole in it, as shown in Figure 3, A–D (the red area shows the field of detachment). This patient had

a history of high myopia. Foldable capsular vitreous body scleral buckling was performed on the second day. Postoperative B-ultrasound examination and fundus photography showed that the FCVB had placed obvious pressure on the retina, and the photocoagulation spots were clear and distinct (Figure 3, E–H). To further confirm the effect and location of FCVB scleral buckling, we also conducted magnetic resonance imaging examination; the results are shown in Figure 3, I–K. It was obvious that the FCVB could press the sclera, as the arrows indicate in the figure. At 4 weeks after the operation, the BCVA of her right eye was enhanced to 20/100, and the IOP was 16 mmHg. During the 12 weeks after the operation, the retina

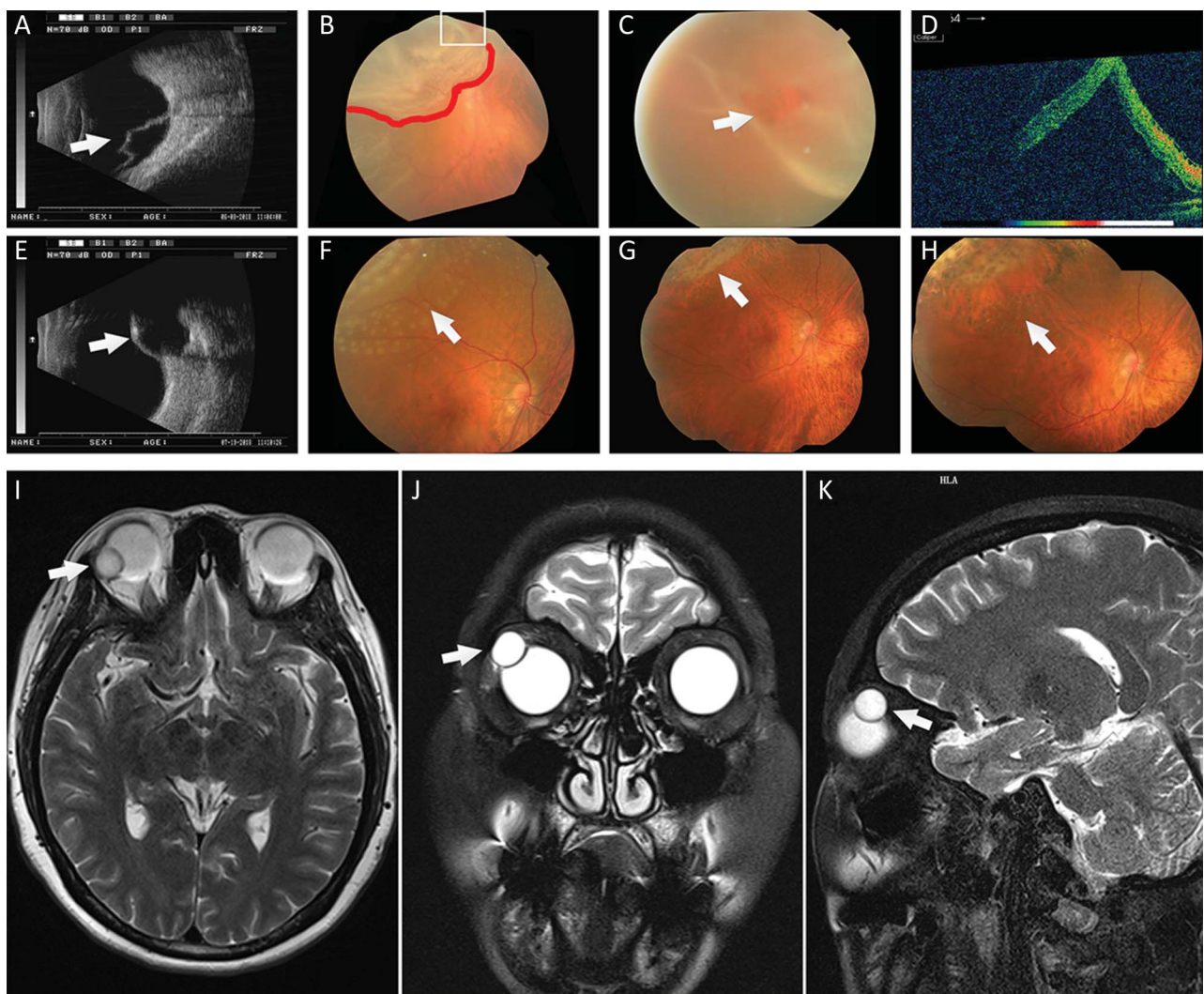


Fig. 3. Fundus photography, B-ultrasound, and magnetic resonance imaging showing FCVB sclera buckling before and after operation. The B-ultrasound shows retinal detachment before surgery (white arrow) (A). The fundus image shows retinal detachment before surgery (white arrow) (B). The square frame in (B) is amplified to show the retinal hole (white arrow), and the red area shows the field of detachment. C. The OCT shows retinal detachment before surgery (D). The B-ultrasound shows FCVB sclera buckling after surgery (white arrow) (E). The fundus image of photocoagulation spots at 2 weeks after surgery (white arrow) (F). The fundus image of FCVB sclera buckling at 4 weeks after surgery (white arrow) (G). The fundus image of FCVB sclera buckling at 1 year after surgery (white arrow) (H). The magnetic resonance imaging results after operation show the FCVB clearly placed pressure on the sclera (white arrows) (I–K).

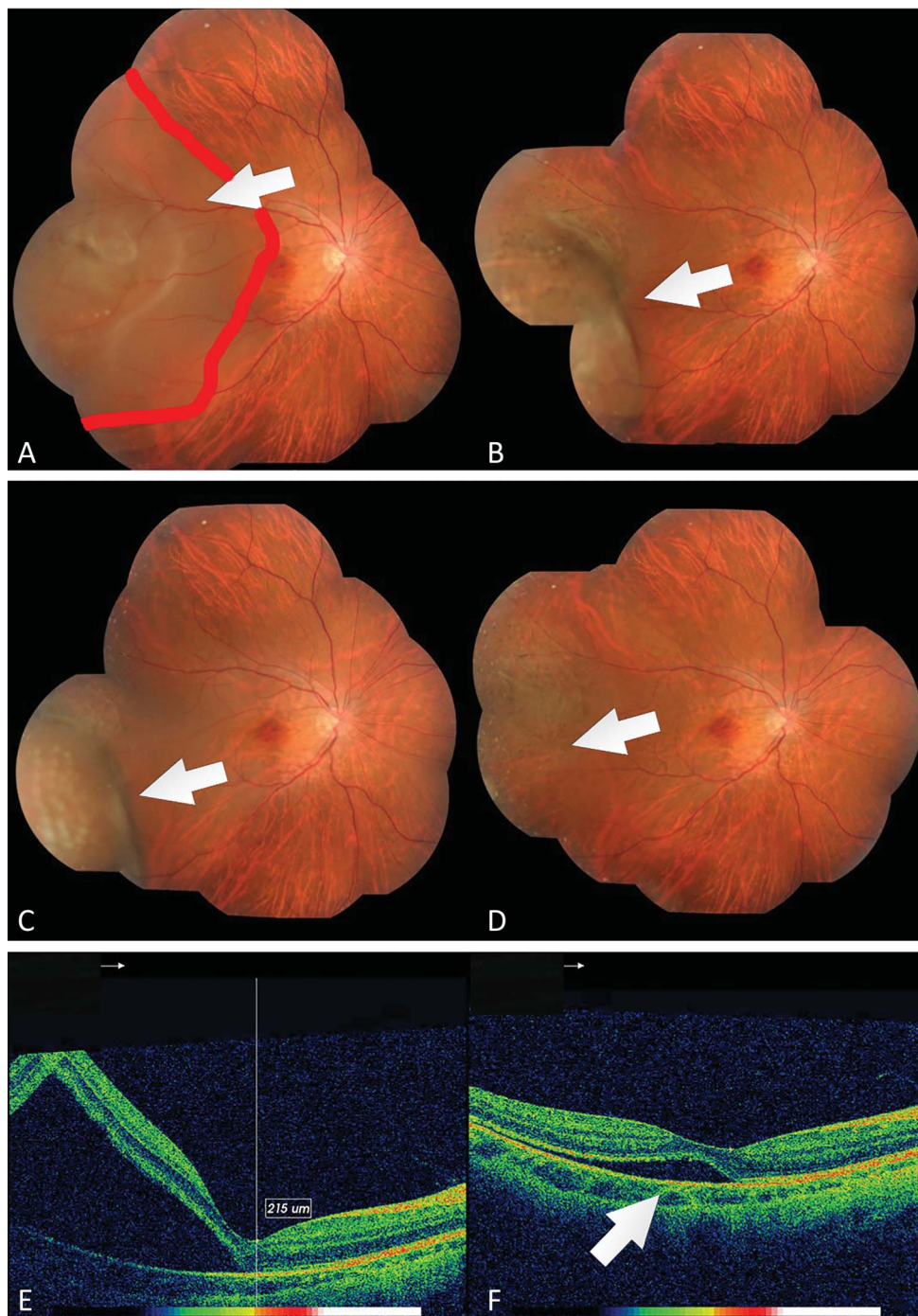


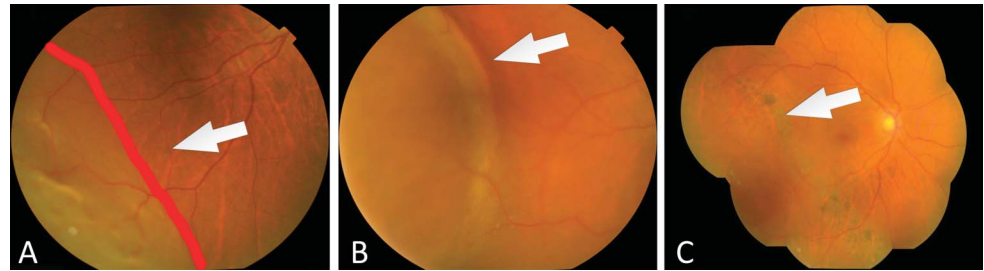
Fig. 4. Fundus photography showing FCVB sclera buckling before and after operation. The fundus image shows retinal detachment before surgery (white arrow), and the red area shows the field of detachment. **A.** The fundus image of FCVB sclera buckling after surgery (white arrow) (**B**). The fundus image of FCVB sclera buckling after photocoagulation (white arrow) (**C**). The fundus image of FCVB sclera buckling 1 year after surgery (white arrow) (**D**). The OCT examination before surgery (**E**). The OCT shows the retina reattachment condition after removing the FCVB (white arrow) (**F**).

reattached, and the patient did not complain of any discomfort.

The retinal detachment of Patient 2 was located on the peripheral temporal side of the fundus, the BCVA of her right eye was hand motion, and the IOP was 12 mmHg. The B-ultrasound scan and fundus photography both showed an extensive retinal detachment in the peripheral temporal location involving two quadrants and an elliptical hole in it, as shown in Figure 4,

A and E. Postoperative fundus photography showed that the FCVB had placed clear pressure on the retina, and the photocoagulation spots were clear and distinct (Figure 4, B and C). After removing the FCVB, we could also see that retinal reattachment was continuing (Figure 4D). The OCT showed that, after removing the FCVB, some hydrops still existed under the retina (Figure 4F). At 4 weeks after the operation, the BCVA of the patient's right eye was 20/32, and the IOP was

Fig. 5. Fundus photography showing FCVB sclera buckling before and after the operation. The fundus image shows retinal detachment before surgery (white arrow), and the red area shows the field of detachment. **A.** The fundus image of FCVB sclera buckling after surgery (white arrow) (**B**). The fundus image of FCVB sclera buckling 1 year after surgery shows that retinal reattachment can last a long time (white arrow) (**C**).



15 mmHg. In the 12 weeks after the operation, the retina reattached, and the patient did not complain of any discomfort. So far, the surgery has been completed for 1 year, and the patient has not complained of any discomfort.

When she came to our hospital, Patient 3 complained of vision loss in her right eye for 1 month, the BCVA of her right eye was 20/200, and the IOP was 12 mmHg. A fundus examination showed extensive retinal detachment in the inferotemporal location involving one quadrant and an elliptical hole, as shown in Figure 5A. After the FCVB scleral buckling, the FCVB could not be fixed well because it was affected by the lateral rectus, and the position was somewhat skewed. Thus, we conducted another minor surgery to adjust the FCVB. After these operations, fundus photography showed that the FCVB had placed clear pressure on the retina (Figure 5B). However, because this patient complained that she suffered from diplopia after the surgery, we checked her eye movements and found her right eye movement to the nasal side was weakened. This complication improved after the FCVB was removed. At 4 weeks after the operation, the BCVA of her right eye was 20/40, and the IOP was 15 mmHg. In the 12 weeks after the operation, the retina had reattached and was continuing to do so. So far, the surgery has been completed for 1 year, and the patient has not complained of any discomfort.

Patient 4 complained of sudden vision loss in his right eye for 3 days, his initial BCVA was 20/200, and the IOP was 14 mmHg. A fundus examination showed extensive retinal detachment in the nasal and superior side involving two quadrants, as shown in Figure 6A. However, the macula was not affected. After FCVB scleral buckling, the postoperative B-ultrasound examination and fundus photography showed that the FCVB had placed clear pressure on the retina, and the photocoagulation spots were clear and distinct (Figure 6B). At 4 weeks after operation, the BCVA of the patient's right eye was 20/50, and the IOP was 16 mmHg. During the 12 weeks after the operation, the

retina reattached and was continuing to do, and the patient did not complain about any discomfort. One year after surgery, it can be seen that the retina is still reattached (Figure 6B).

Patient 5 complained that the vision in her left eye had been unclear for 1 month; her initial BCVA was 20/25, and the IOP was 12 mmHg. A fundus examination showed a retinal detachment on the superonasal side involving two quadrants, as shown in Figure 7A. After FCVB scleral buckling, the postoperative fundus photography showed that the FCVB had placed clear pressure on the retina (Figure 7B). At 4 weeks after the operation, the BCVA of her right eye was 20/25, and the IOP was 16 mmHg. During the 12 weeks after the operation, the retina was continuing to reattach, and the patient did not complain of any discomfort.

Through the results of B-ultrasound examination, fundus photography, and BCVA at 4 weeks after the operation, it could be seen that FCVB scleral buckling had placed pressure on the sclera and retina, and this surgery could promote retina reattachment as well as enhance BCVA in RRD-affected macular patients.

Safety Evaluation of Foldable Capsular Vitreous Body Sclera Buckling

In terms of safety, none of the five patients experienced adverse events, such as endophthalmitis, cardiovascular events, or any other systemic reactions. Also, there were no acute high IOP events caused by FCVB scleral buckling; there were no episodes of severe postoperative bleeding or unbearable discomfort. However, it should be noted that Patient 3 had diplopia after the operation, and her eye movement was limited, which could have been a complication of the FCVB implantation affecting the lateral rectus. However, when her retina was reattached and the FCVB was removed, her diplopia resolved, and the limitation of her eye movement was corrected. Therefore, FCVB scleral buckling was essentially proven to be safe.

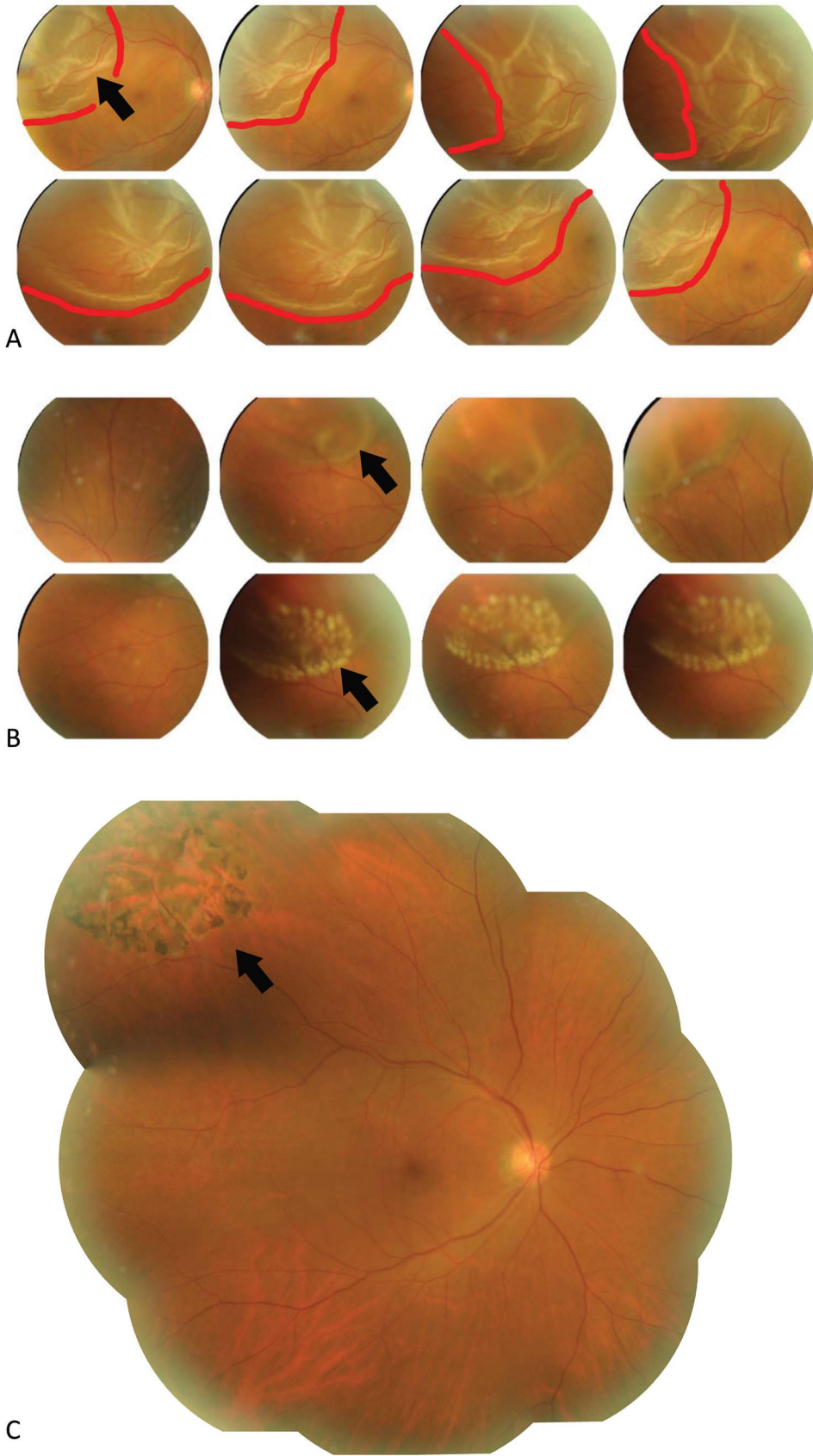
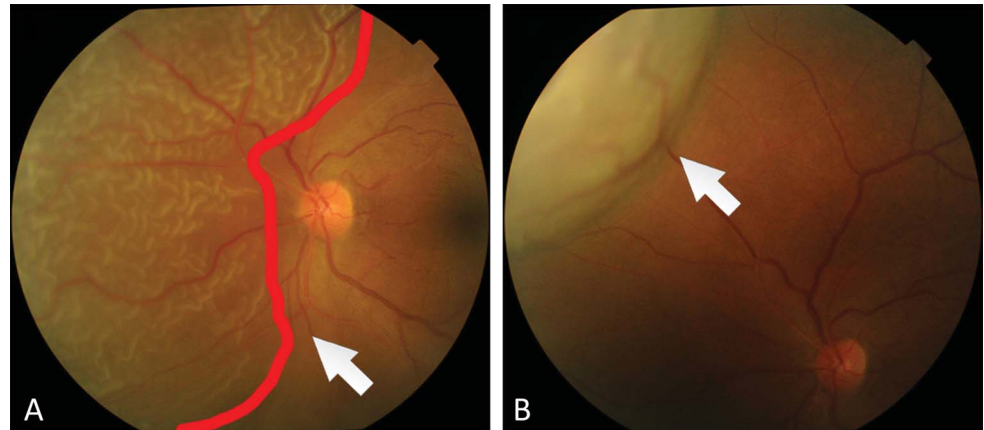


Fig. 6. Fundus photography showing FCVB sclera buckling before and after the operation. The fundus image shows retinal detachment before surgery (black arrow), and the red area shows the field of detachment. **A.** The fundus image of FCVB sclera buckling after surgery (black arrow) (**B**). The fundus image of FCVB sclera buckling 1 year after surgery shows that retinal reattachment can last a long time (white arrow) (**C**).

Fig. 7. Fundus photography showing FCVB sclera buckling before and after the operation. The fundus image shows retinal detachment before surgery (white arrow), and the red area shows the field of detachment. **A.** The fundus image of FCVB sclera buckling after surgery (white arrow) (**B**).



Discussion

This is the first pilot clinical study showing preliminary results that FCVB scleral buckling is an effective and safe operation for reattaching the retina in RRD cases. The goal of retinal detachment surgery is to find and close all breaks³⁵; accordingly, this may provide an innovative surgical method to improve the management of RRD.

In terms of its efficacy, from the five studied patients, the postoperative B-ultrasound, fundus photography, and magnetic resonance imaging showed that the external FCVB placed pressure on the sclera and retina, and its location was not easily altered by ocular movement during the postoperative observation period. Combined with subretinal fluid release, transscleral cryotherapy, and retinal photocoagulation, this innovative surgical method could promote retina reattachment and restoration of function, which, in turn, can enhance the postoperative BCVA of the patients whose maculae were affected.

In terms of safety, none of the five patients experienced endophthalmitis, severe systemic reactions, or acutely high IOP. Only Patient 3 complained of diplopia, and this may have been the result of FCVB implantation under the lateral rectus. Diplopia could be a complication of FCVB scleral buckling, especially considering the FCVB was located under the rectus according to the retina detachment and hole location. However, this complication could be resolved after the FCVB is removed, and compared with other intraocular surgery or traditional sclera buckling which may operate all the extraocular muscles, this kind of surgery is still safer.

In addition to its positive efficacy and safety, it is noteworthy that compared with traditional external scleral surgery, this kind of surgery possesses obvious advantages as a surgical procedure. In traditional external scleral surgery, the fundus image is inverted

through an indirect ophthalmoscope, and the magnification is small, making it difficult to master and apply. At the same time, posteyeball anesthesia is needed, increasing the risk of puncturing the eyeball. Moreover, during traditional external scleral surgery, the sclera needs to be exposed by repeatedly pulling the muscle, inducing pain in the patient and introducing a high risk of oculocardiac reflex. However, because all these procedures are conducted under a microscope, the FCVB scleral buckling technique is less invasive and easy to perform, and postoperative laser treatment is easier. Indeed, the FCVB presents fewer postoperative complications and less pain and is especially suitable for the elderly and young children. However, in effect, this kind of surgery has a larger pressure range, usually covering the hole and surrounding detached retina, and the indwelling time of the FCVB can be controlled. It is also important to note that there is no need to pull the muscle tissue during this operation. Compared with Lincoff temporary balloon buckling, the FCVB has been commercialized in the European Union and China, and it has a short drainage tube that can be buried under the conjunctiva, thus reducing much of the discomfort, inconvenience, and risk of orbital infection. Being made of high-purity silicone rubber also means that the FCVB has excellent biocompatibility.

Because of the limited number of patients in the current study, it is not yet possible to draw a more comprehensive conclusion. However, looking at these five patients, the current study shows that FCVB scleral buckling may achieve good results for simple RRD, even for those with macular detachment, and can also avoid some of the complications associated with vitrectomy. In our study, all the eyes had improved visual acuity as a result of the surgery. However, this surgical method also has certain shortcomings: For example, if the FCVB is located under the muscle, it is relatively difficult to fix. There is also

the risk of displacing the FCVB and developing temporary diplopia. Also, the current study has some limitations, including a small number of subjects, a lack of a control group, and a lack of a comparison with conventional treatment strategies. Accordingly, further studies need to include adjusting and improving the FCVB according to the external scleral buckling operation and performing a large-scale randomized controlled trial to further confirm its efficacy and safety.

Selecting the appropriate cases and the correct operation are important to both the RRD patient and the ophthalmologist. In summary, FCVB scleral buckling is a simple, easy-to-learn, less-invasive, less-complicated, efficacious, and safe surgery for treating simple, one-hole, and no proliferative vitreoretinopathy-accompanying RRDs.

Key words: foldable capsular vitreous body, rhegmatogenous retinal detachment, sclera buckling.

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