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COMPARISON BETWEEN RELEASABLE SCLERAL BUCKLING AND VITRECTOMY IN PATIENTS WITH PHAKIC PRIMARY RHEGMATOGENOUS RETINAL DETACHMENT

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Purpose: To compare the efficiency of releasable scleral buckling (RSB) and pars plana vitrectomy (PPV) in the treatment of phakic patients with primary rhegmatogenous retinal detachment.

Methods: The current study was a prospective randomized clinical trial. One hundred and ten eyes from 110 patients with primary rhegmatogenous retinal detachment and proliferative vitreoretinopathy of Grade B or less were included in this study. The patients were randomly allocated into an RSB group and a PPV group. The functional and anatomical success was compared between groups.

Results: The primary anatomical success rate (PPV 41/43 [95.35%] and RSB 38/41 [92.68%]) and final anatomical success rate (PPV and RSB 100%) showed a nonsignificant difference. The best-corrected visual acuity, intraocular pressure, and complications were not different between the groups. However, the incidence of cataract progression was higher in the PPV group (26 of 43 [60.47%]) than in the RSB group (4 of 41 [9.76%]) at the 12-month follow-up. The subfoveal choroidal thickness increased significantly in the RSB group 3 months after surgery, but no longer differed at the postoperative 6-month and 12-month follow-ups. The axial length had increased significantly 1 month after surgery, but the difference was no longer significant at 3 months, 6 months, and 12 months.

Conclusion: The RSB and PPV procedures have the same effects on the functional and anatomical success for patients with phakic primary rhegmatogenous retinal detachment. Nevertheless, based on the few cases of intraocular complications and cataract progression, we believe that the RSB technique should be preferentially recommended.

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Rhegmatogenous retinal detachment (RRD) occurs when the fluid from the vitreous cavity passes through a break and separates the outer segments of the photoreceptors from the retinal pigment epithelium (RPE)[1] with an estimated prevalence of 1/10,000 individuals.[2] The general treatments for an RRD are pars plana vitrectomy (PPV) and scleral buckling (SB).[3,4] The PPV technique directly relieves the vitreous traction by using internal drainage of the subretinal fluid (SRF), gas–fluid exchange, and laser photocoagulation or cryotherapy of the reattached retina combined with or without gas or silicone oil tamponade.[4] The SB technique is known to relieve the vitreous traction indirectly by using a segmental scleral silicone implant in the area corresponding to the retinal break and the encircling silicone band, combined with drainage of the SRF and transscleral cryotherapy.[3]

Although SB can be applied to a large variety of retinal detachments (RDs), it does have some predictable complications, such as axial elongation with secondary myopization, anterior-segment ischemia with the compression of the long posterior arteries, choroidal detachment and lens displacement with anterior chamber shallowing, and motility disturbances.[5–9] To reduce the incidence of such complications, we modified the conventional SB procedure and designed a releasable SB (RSB) technique.[10] Instead of the silicone sleeves, we used 6-0 absorbable sutures to tie up both the ends of the encircling band. In our previous study, we compared a releasable encircling band with a conventional encircling scleral band for treating primary RRD and found that the surgery-associated axial elongation and myopization and flattening of the anterior chamber were dramatically reduced, with no change in the surgical anatomical success with the releasable encircling band.[10]

There is still no consensus on the optimal approach for the management of uncomplicated RRD cases. A previous comparison of the SB and PPV procedures for treating primary RRD showed that there were no significant differences in the single-operation success rates and visual acuities.[11] In addition, Heimann et al[7] compared the SB and PPV techniques in phakic RRD cases and showed that better postoperative best-corrected visual acuity (BCVA) was achieved in the SB group, with the same anatomical outcome. Sun et al[12] conducted a meta-analysis determining that SB was superior in terms of the final visual acuity and the occurrence of postoperative cataracts in uncomplicated phakic RRD cases, and that PPV was more likely to achieve a favorable final reattachment in pseudophakic RRD cases.

The aim of this study was to determine whether the RSB procedure for phakic patients with RRD is an effective approach, and whether it reduces the risk of developing cataracts and reduces the disadvantages associated with a conventional SB.

Methods

Trial Design

This study was conducted as a randomized controlled clinical trial in which two interventions (RSB and PPV) were compared in patients with primary RRD. The eligible patients were randomized in a 1:1 ratio to receive either the RSB or PPV. This study adhered to the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of the Zhongshan Ophthalmic Center (2017KYPJ058), registered at the International Standard Randomized Controlled Trial registry (ISRCTN95808249). Written informed consent was obtained from all of the participants before surgery.

Participants

The study participants were recruited at the Zhongshan Ophthalmic Center from January 2015 until May 2016. The inclusion criteria were as follows: primary RRD without any complicating factors,[13] aged 18 years and older, and Grade A or B proliferative vitreoretinopathy. Those patients with any kind of previous ocular surgery, trauma, RD resulting from a macular hole, RD with choroidal detachment as detected by ultrasound biomicroscopy,[14] severe cataracts, and previous posterior uveitis were excluded from this study. The patients meeting the inclusion criteria were randomized into RSB and PPV groups according to the random number table method. Six scheduled follow-up visits were assigned for 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months after surgery.

Interventions

The surgeries were performed by one experienced surgeon (L.L.). In the RSB group, the episcleral encircling band (2.5 × 120 mm) was fixed by 5-0 nonabsorbable sutures in the equatorial region of each quadrant. The ends of the encircling band were joined and preliminarily fixed by a silicone sleeve to adjust the strain of the encircling band. Then, we tied up both ends using 6-0 absorbable sutures and removed the silicone sleeve. The retinal breaks were coagulated by retinal transscleral cryopexy. At the surgeon's discretion, an additional segmental silicone buckle, if needed, was placed under the encircling band at the location of the retinal breaks. These additional segmental buckles were orientated parallel to the encircling band and were fixed

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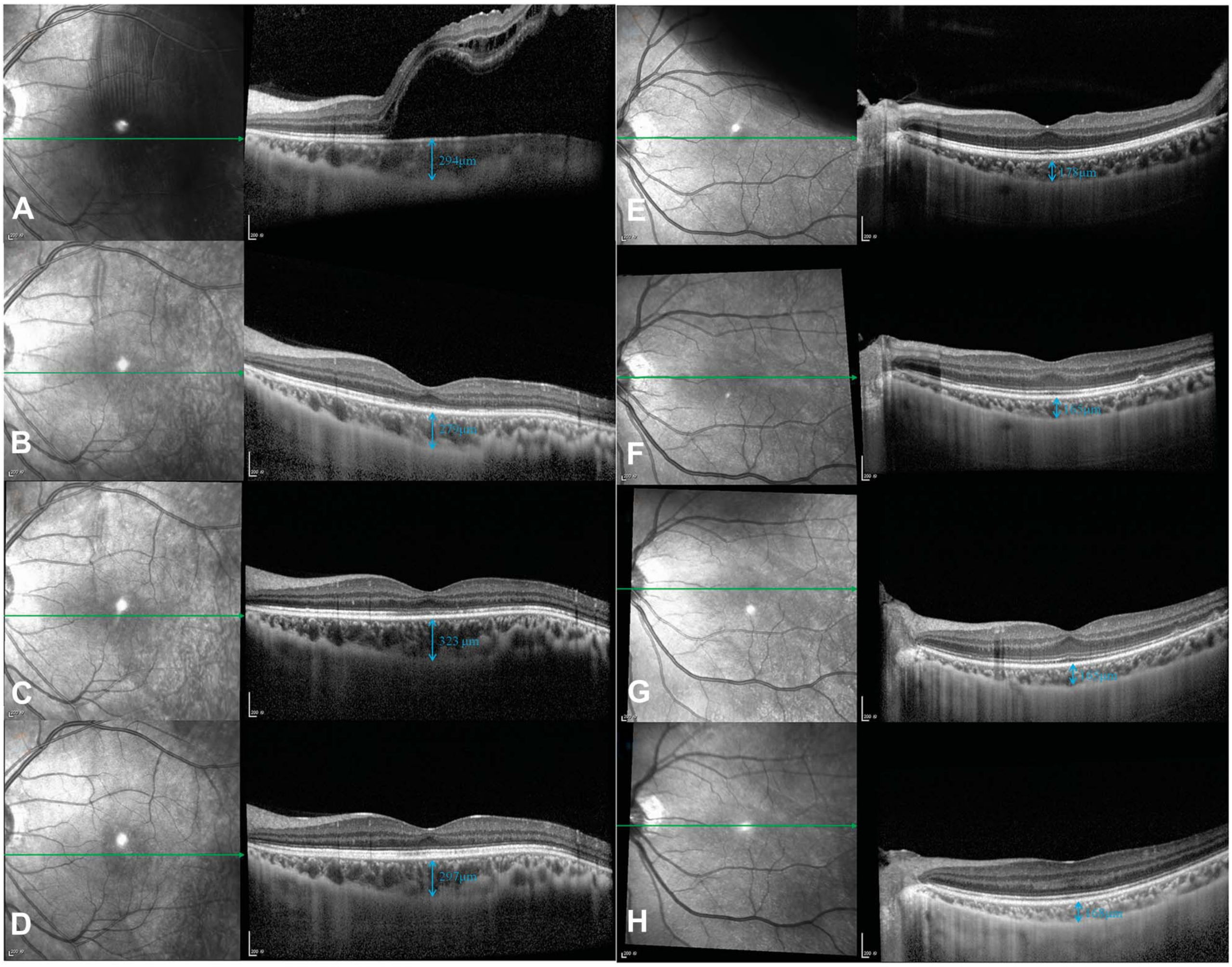

Fig. 1. Optical coherence tomography images of patients who underwent RSB (**A**–**D**) and PPV (**E**–**H**) for primary RRD. The preoperative (**A** and **E**), 1-month postoperative (**B** and **F**), 3-month postoperative (**C** and **G**), and 6-month postoperative (**D** and **H**) optical coherence tomography images are shown respectively.

on the sclera with additional sutures, independent of the encircling band. The other optional surgical steps included the transscleral exodrainage of the SRF and anterior chamber paracentesis. In the PPV group, the patients underwent a standard 23-gauge (23-G) vitrectomy, and the vitreous was removed to relieve all the traction surrounding the retinal break. The SRF drainage was achieved through a preexisting break, with or without perfluoro-N-octane assistance. An endolaser was used to surround all the retinal breaks, and all the surgeries used a 10% C_3F_8 intraocular tamponade agent. The 23-G sclerotomy was sutured only if it leaked at the end of the surgery.

Clinical Data

The baseline data collected included the age, sex, lens status, extension of RD, macula-off/-on, BCVA, intraocular pressure (IOP), and symptom duration. Macula-off was defined as the complete detachment of the macula. The carefully recorded postoperative data included the BCVA, IOP, choroidal thickness (CT), axial length (AL), anterior chamber fibrin, anterior chamber inflammation,[15] cataract progression, choroidal/subretinal hemorrhage, and any other associated complications. Primary success was defined as the retina remaining reattached for 12 months after one operation. The final anatomical success was defined as the retina remaining reattached for 12 months after one or more operations. Small incidences of localized SRF without an increase during the follow-up visits were not considered to be surgical failures. All the recurrent cases underwent PPVs for the second surgery.

The IOP and BCVA were recorded at the following postoperative intervals: 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months. The BCVA was determined using the Early Treatment Diabetic Retinopathy Study chart converted to the logarithm of the

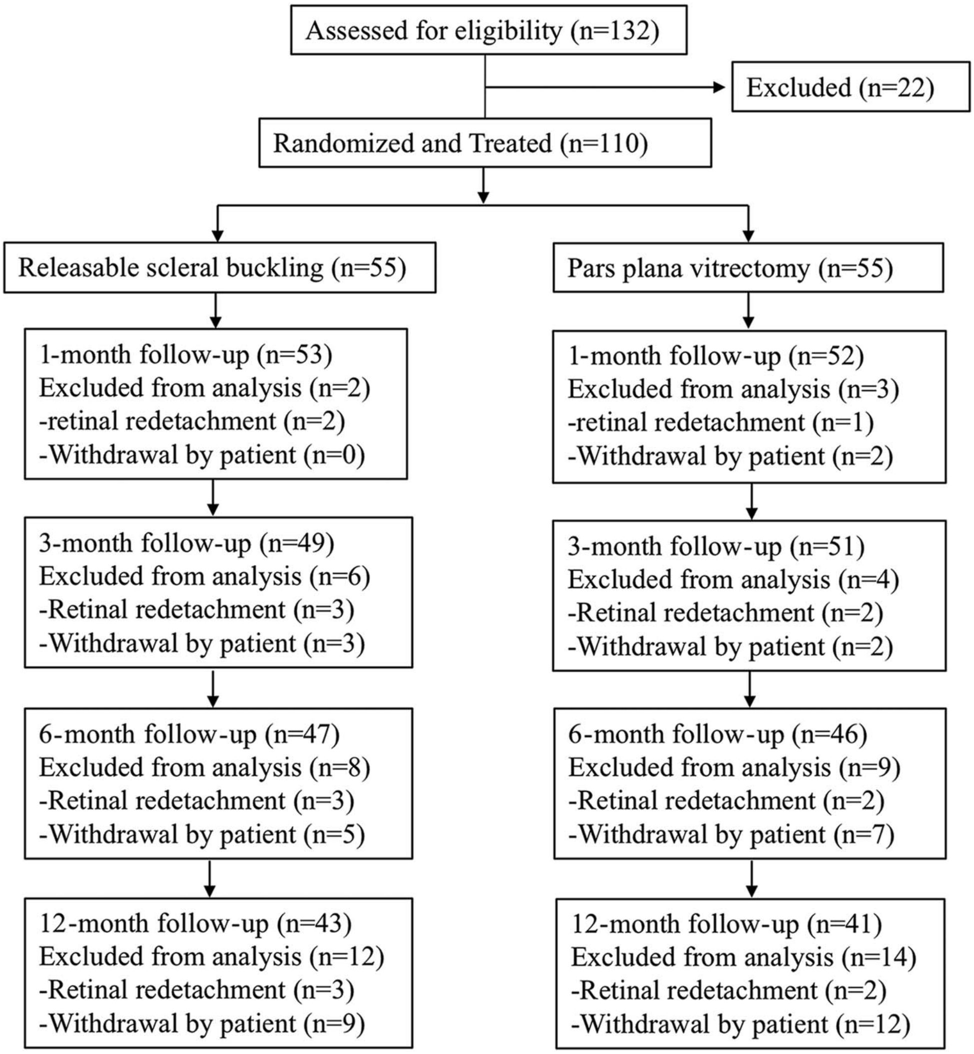

Fig. 2. Participant disposition.

minimum angle of resolution (logMAR)[16] for statistical analysis. Grading of inflammation was based on the Standardization of Uveitis Nomenclature criteria.[15] The postoperative cataract formation or progression was determined at 1 year by one doctor (C.L.), if it was considered to be visually significant. The CT was measured using enhanced depth imaging through spectral domain optical coherence tomography at the fovea (Spectralis; Heidelberg Engineering, Heidelberg, Germany). The CT was measured as the distance from the outer edge of the hyperreflective RPE to the chorioscleral interface (Figure 1). The CT was recorded according to the average parameters measured by two doctors (X.Z. and L.H.), and the AL was measured by using the IOL Master (Carl Zeiss Meditec AG, Jena, Germany).

Statistics

The statistical analysis was performed using SPSS 12 software (SPSS Inc, Chicago, IL). The continuous data were presented as the mean values ± SDs. The chi-square test, Fisher's exact test, and independent-samples *t*-test were used as appropriate, with a P value <0.05 considered to be statistically significant.

Results

Participant Characteristics

Figure 2 displays the consort flow diagram. A total of 110 patients were included in this study and were randomly assigned into a PPV group (55 patients: 25 men and 30 women) and an RSB group (55 patients: 32 men and 23 women) ($P = 0.182$). The demographic and clinical characteristics of the patients are shown in Table 1. The statistical comparison between the PPV and RSB groups showed that there was no significant difference in the baseline data.

Table 1. Demographic and Preoperative Examination Findings for PPV Group Versus RSB Group

	PPV (n = 55)	RSB (n = 55)	*P*
Age (years), mean	48.54 ± 11.77	42.18 ± 15.50	0.066
Sex			
Men, n (%)	25 (45.45%)	32 (58.18%)	0.182
Women, n (%)	30 (54.55%)	23 (41.82%)	
Lens			
Clear, n (%)	42 (76.36%)	45 (81.82%)	0.482
Cataract, n (%)	13 (23.64%)	10 (18.18%)	
Duration of symptoms (weeks, mean ± SD)	3.45 ± 2.62	3.86 ± 2.30	0.520
Macula			
Off, n (%)	37 (67.27%)	33 (60.00%)	0.428
On, n (%)	18 (32.73%)	22 (40.00%)	
PVR			
Grade A	34 (61.82%)	32 (58.18%)	0.697
Grade B	21 (38.18%)	23 (41.82%)	
Retinal break localization, n (%)			
Superior	39 (70.91%)	37 (67.27%)	0.680
Inferior	16 (29.09%)	18 (32.73%)	
No. of breaks	1.3 ± 0.8	1.3 ± 0.9	0.914
Myopia (>6 diopters), n	12	14	0.654
Extension of RD (quadrant), n	2.88 ± 0.77	2.76 ± 0.72	0.782
Follow-up (month, mean ± SD; range)	8.7 ± 2.5; 5.2–11.3	8.9 ± 3.1; 5.7–13.2	0.816

PVR, proliferative vitreoretinopathy.

Anatomical Outcomes

Initial surgery anatomical success was achieved in 41 of 43 patients (95.35%) in the PPV group and in 38 of 41 (92.68%) patients in the RSB group (*P* = 0.606). Two eyes (4.65%) in the PPV group developed retinal redetachment because of the development of new retinal breaks. Three eyes (7.32%) in the RSB group developed retinal redetachment because of a new retinal break (1 eye), missed retinal breaks at the initial surgery (1 eye), and macular hole formation (1 eye). For the 5 eyes with retinal redetachment, PPV combined with a silicone oil tamponade was performed in 2 eyes, PPV combined with C_3F_8 gas injection was performed in 1 eye, and PPV combined with silicone oil tamponade and SB was performed in 2 eyes. Final anatomical success was achieved in 100.00% of both groups.

Best-Corrected Visual Acuity

There was no difference of the baseline BCVA between the groups. The mean preoperative BCVA was 1.41 logMAR (20/510) and 1.26 logMAR (20/360) in the PPV and RSB groups, respectively (*P* = 0.141, Table 2). Overall, the mean BCVA improved in both groups, with a final BCVA of 0.68 logMAR (20/95) in the PPV group and 0.63 logMAR (20/87) in the RSB group (*P* = 0.731).

Intraocular Pressure

There was no difference in the baseline IOP between the groups. The mean preoperative IOPs were 12.54 mmHg and 11.26 mmHg in the PPV and RSB groups, respectively (*P* = 0.766, Table 2). Although the IOP

Table 2. Comparison of BCVA and IOP Between PPV and RSB Group

	LogMAR BCVA (Snellen)			IOP (mmHg)		
	PPV	RSB	*P*	PPV	RSB	*P*
Preoperative	1.41 ± 0.96 (~20/510)	1.26 ± 0.78 (~20/360)	0.141	12.54 ± 2.52	11.26 ± 2.75	0.766
Day 1	2.09 ± 0.37 (~20/2,500)	1.03 ± 0.31 (~20/210)	0.691	16.96 ± 4.00	19.38 ± 7.03	0.051
Week 1	1.82 ± 0.45 (~20/1,330)	1.43 ± 0.37 (~20/540)	0.718	14.38 ± 2.31	14.95 ± 2.54	0.873
Month 1	1.29 ± 0.65 (~20/390)	0.88 ± 0.43 (~20/150)	0.299	13.25 ± 1.36	12.43 ± 1.74	0.845
Month 3	0.74 ± 0.41 (~20/110)	0.66 ± 0.38 (~20/90)	0.846	13.46 ± 1.48	13.29 ± 1.52	0.836
Month 6	0.89 ± 0.42 (~20/150)	0.61 ± 0.46 (~20/80)	0.214	12.89 ± 1.54	13.42 ± 2.35	0.637
Month 12	0.68 ± 0.53 (~20/95)	0.63 ± 0.41 (~20/87)	0.731	13.15 ± 1.42	13.35 ± 1.74	0.824

Table 3. Comparison of CT and AL Between PPV Group and RSB Group

	Subfoveal CT (μm)			AL (mm)		
	PPV	RSB	*P*	PPV	RSB	*P*
Month 1	226.44 ± 46.38	249.03 ± 47.28	0.068	24.40 ± 1.68	25.44 ± 2.20	0.038
Month 3	225.88 ± 47.33	260.43 ± 50.30	0.009	24.41 ± 1.67	25.12 ± 1.72	0.087
Month 6	232.28 ± 51.15	234.78 ± 46.69	0.843	24.43 ± 1.66	24.74 ± 1.74	0.481
Month 12	233.28 ± 49.57	236.68 ± 46.70	0.635	24.39 ± 1.76	24.75 ± 1.72	0.767
P	0.926	0.043		0.967	0.589	

increased to 16.96 mmHg in the PPV group and 19.38 mmHg in the RSB group on the first postoperative day, there was no significant difference (P = 0.051). Overall, the mean IOP decreased in both groups, with a final IOP of 13.15 mmHg in the PPV group and 13.35 mmHg in the RSB group (P = 0.824).

Choroidal Thickness

The subfoveal CT was measured by enhanced depth imaging optical coherence tomography (Table 3). In the PPV group, there was no difference between the 1-, 3-, 6-, and 12-month postoperative follow-ups (P = 0.926). However, the subfoveal CT at 3 months (260.43 ± 50.30 μm) was significantly higher than that at 1 month (249.03 ± 47.28 μm), 6 months (234.78 ± 46.69 μm), and 12 months (236.68 ± 46.70 μm) after surgery in the RSB group (P = 0.043). At the 1-month postsurgical follow-up, there was no statistically significant difference between the PPV (226.44 ± 46.38 μm) and RSB (249.03 ± 47.28 μm) groups (P = 0.068). However, the subfoveal CT was significantly higher in the RSB group (260.43 ± 50.30 μm) when compared with the PPV group (225.88 ± 47.33 μm) at the 3-month postsurgical follow-up (P = 0.009). There was no difference between the groups at the 6-month (P = 0.843) or 12-month (P = 0.635) follow-up.

Axial Length

No significant differences were seen within the PPV group (P = 0.967) or RSB group (P = 0.589) at the different postsurgical periods. Although the AL was significantly higher in the RSB group (25.44 ± 2.20 mm) when compared with the PPV group (24.40 ± 1.68 mm) 1 month after surgery (P = 0.038), there were no statistically significant differences between the groups at 3 months (P = 0.087), 6 months (P = 0.481), and 12 months (P = 0.767).

Complications

All the complications recorded during the procedures and follow-ups are shown in Table 4. Elevated IOP requiring pharmacotherapy (IOP over 25 mmHg) was observed in 5 of the 55 (9.09%) patients in the PPV group and in 3 of the 55 (5.45%) patients in the RSB group (P = 0.463). Anterior chamber inflammation was observed in three patients (5.45%) in the PPV group, but none in the RSB group (P = 0.243). In addition, anterior chamber fibrin was observed in one patient in the PPV group and none in the RSB group (P = 1.000). None of the eyes had globe perforations during the RSB procedures, and no eye in either group had complications, such as endophthalmitis, choroidal hemorrhage, or subretinal hemorrhage. A primary anatomical failure was obtained in 2 of 43 patients (4.65%) in the PPV group and in 3 of 41 patients (7.32%) in the RSB group (P = 0.606). There was cataract development and progression in 26 of 43 patients (60.47%) in the PPV group and in 4 of 41 patients (9.76%) in the RSB group (P = 0.000) at 12 months, which included 9 eyes that underwent cataract surgery in the PPV group. Residual SRF was observed in 0 of 43 patients in the PPV group and 2 of 41

Table 4. Analysis of Postoperative Complications for PPV Versus RSB

	PPV	RSB	*P*
IOP over 25 mmHg, n (%)	5/55 (9.09%)	3/55 (5.45%)	0.463
A/C inflammation $>$2+, n (%)	3/55 (5.45%)	0	0.243
A/C fibrin, n (%)	1/55 (1.82%)	0	1.000
Endophthalmitis	0	0	1.000
Choroidal/subretinal hemorrhage	0	0	1.000
Failed primary surgery, n (%)	2/43 (4.65%)	3/41 (7.32%)	0.606
Postoperative cataract, n (%)	26/43 (60.47%)	4/41 (9.76%)	$<$0.001
SRF	0/43	2/41 (4.88%)	0.235
ERM	3/43 (6.98%)	1/41 (2.44%)	0.616

A/C, anterior chamber; ERM, epiretinal membrane.

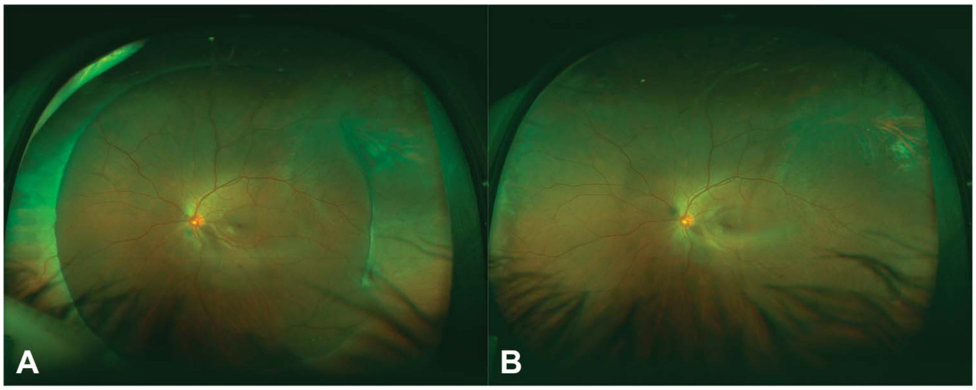

Fig. 3. Peripheral indentation at 1 month after surgery (**A**). The indentation disappeared at 3 months after surgery (**B**).

patients in the RSB group (P = 0.235). Epiretinal membranes were observed on optical coherence tomography in three eyes in the PPV group and one eye in the RSB group (P = 0.616).

Discussion

Our study indicated that both the RSB and PPV can achieve similar final BCVAs and single surgery anatomical successes in patients with primary RRD; however, the incidence and progression of cataracts in the RSB group was significantly lower than that in the PPV group. At the 12-month postsurgical follow-up, there was no difference in the IOP, CT, AL, or complications between the RSB and PPV groups.

In a conventional SB, the sutured encircling band is a permanent procedure.[17] The undesirable postoperative side effects, such as a shallow anterior chamber, increased AL, and myopia, are caused by the encircling band tension. The RSB is a modified procedure based on the conventional SB in which we used 6-0 absorbable sutures to tie up both ends of the encircling band, instead of silicone sleeves and nonabsorbable sutures. After the sutures were absorbed around 3 months postoperatively (Figure 3), the biometric parameters stabilized. In a previous study, the comparison of the RSB and conventional SB concluded that they had the same effects on the reattachment rates, but the RSB reduced the surgery-associated axial elongation and persistent high IOP caused by the conventional SB.[10]

Schwartz and Flynn[18] summarized the comparison of SB with PPV. Scleral buckling relieved the vitreous traction indirectly with equal effectiveness for superior and inferior breaks, whereas PPV relieved the vitreous traction directly, with higher effectiveness in the superior breaks. The advantages of SB included no prone positioning required after surgery and a lower equipment cost, while the advantage of PPV was less pain after surgery. The potential complications for SB were refractive changes, motility disturbances, vitreous or retinal incarceration, suprachoroidal or subretinal hemorrhage, and migration of the buckling elements. The potential complications for PPV were induced cataracts, elevated IOP, new breaks, retinal trauma, and optic nerve trauma.

The RSB is a modified SB procedure, and in this study, we compared the RSB and PPV in patients with primary RRD. The cataract progression was much greater in the PPV group than in the RSB group ($P < 0.001$). Our results showed postoperative cataract progression in 60.47% of the patients in the PPV group and 9.76% in the RSB group ($P < 0.001$). Up until the 1-year follow-up, most of the patients with cataracts had nuclear opacities. Among them, 9 eyes underwent cataract surgery in the PPV group and none did in the RSB group. The cataract progression in this study was comparable with the outcomes from other series after PPV surgery (from 58% to 85%).[7,19,20]

Our study also indicated that the RSB had no effect on the AL at the 3-month postsurgical follow-up. A number of studies have implied that the SB used to treat RRD induces axial elongation, causing secondary myopization.[8,21] In this study, the AL in the RSB group was significantly longer than that in the PPV group (P = 0.038) at 1 month postoperatively. However, from 3 months to 12 months postoperatively, there was no statistically significant difference between groups, presumably due to the absorbable suture dissolving and releasing the band tension and the height of the buckle diminishing. In our study, we found a statistically significant increase in the subfoveal CT in the RSB group at 3 months, but no significant difference at 1 month, 6 months, and 12 months, which could be explained by venous engorgement caused by the encircling band.[22]

This study does have several limitations. First, the CT measurements were performed manually using a built-in caliper. Second, the sample size in our study was small, and it was difficult to draw definitive conclusions due to the low statistical power. Third, there was a lack of AL and CT before surgery due to RD involving the macula.

In summary, we compared the RSB and PPV in primary RRD patients. When compared with PPV, the rates of single surgery anatomical success and the final BCVA were similar, but the incidence of cataract progression was much lower in the RSB group. Based on these results, we believe that the RSB technique should be preferred and recommended.

Key words: releasable scleral buckling, vitrectomy, rhegmatogenous retinal detachment.

Acknowledgments

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