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PATCHING RETINAL BREAKS WITH HEALAFLOW IN 27-GAUGE VITRECTOMY FOR THE TREATMENT OF RHEGMATOGENOUS RETINAL DETACHMENT

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Purpose: To report the surgical outcomes of primary rhegmatogenous retinal detachment (RRD) repaired by 27-gauge pars plana vitrectomy combined with Healaflow patch and air tamponade.

Methods: In an initial vitro experiment, we observed and compared the dissolution and displacement of the dispersion spots of 0.05-mL Healaflow and sodium hyaluronate. We then performed a prospective, interventional cohort study on 38 eyes in 37 consecutive patients with primary rhegmatogenous retinal detachment. All eyes underwent pars plana vitrectomy combined with Healaflow patch and air tamponade; the postoperative period did not involve prone positioning. The primary and final anatomical attachment rate, best-corrected visual acuity, and intraoperative and postoperative complications were evaluated.

Results: In the in vitro experiment, the viscoelastic Healaflow remained adherent with no change in the size of the area; however, the control dissolved completely in the balance solution. The patient study included 16 women (43.2%) and 21 men (56.8%) (mean age, 59.5 ± 9.5 years; mean follow-up period, 8.9 ± 3.8 months). A single break was present in 21 (55.3%) and 2 to 5 breaks in 17 cases (44.8%). The macula was involved in 25 (65.8%) and attached in 13 cases (34.2%) intraoperatively. Initial reattachment was achieved in 37 (97.4%) and final reattachment in 38 cases (100%). In one case (2.6%), the macula redetached because of failure of the chorioretinal scar to develop around the treated break. Mean preoperative and postoperative best-corrected visual acuities were 1.02 ± 0.82 logarithm of the minimum angle of resolution (median Snellen acuity: 20/125, range: 20/20,000–20/20) and 0.23 ± 0.17 logarithm of the minimum angle of resolution (median Snellen acuity: 20/32, range: 20/100–20/20), respectively ($P < 0.001$). Intraocular pressure was elevated transiently in 28 eyes (73.7%). There were no other intraoperative complications or postoperative scleral incision leakage.

Conclusion: A 27-gauge pars plana vitrectomy combined with Healaflow patch, and air tamponade results in a high reattachment rate in the treatment of rhegmatogenous retinal detachment. Thus, patients can benefit from early visual recovery and less complications.

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With recent technological advances and improved techniques, pars plana vitrectomy (PPV) has become the most common surgical procedure for the treatment of primary rhegmatogenous retinal detachment (RRD) in most developed countries and some developing countries. Although RRD is a common condition, the therapeutic outcomes are not satisfac-

tory. The reported primary reattachment rate in RRD with PPV technique varies from 72% to 88%.^{1–3} To improve the success rates of PPV, various techniques have been proposed, such as combining PPV with an encircling band; use of long-acting inert gases, perfluoroalkane,⁴ silicone oil,^{5,6} and heavy silicone oil⁷; as well as strict positioning of the patient during the

postoperative period.^{8,9} One of the downside of using intraocular gas is the transient visual impairment when a large amount of gas remains in the vitreous cavity, which may discourage patients from choosing the sutureless vitrectomy. In addition, the intraocular gas tamponade could result in a series of complications, such as cataract formation, secondary glaucoma, as well as retinal artery occlusion.^{10,11} The use of silicone oil tamponade can change the refractive state of the eye.¹² Moreover, the intraocular silicone oil usually needs additional surgery to be removed to prevent complications.¹³

Healaflow (Anteis S.A., Plan-Les-Ouates, Switzerland) consists of over 97% water, sodium hyaluronic acid (22.5 mg/mL) of nonanimal origin cross-linked with 1,4-butanediol diglycidyl ether, and phosphate and NaCl salts to maintain a physiological pH (7.0) and osmolarity (305 mOsm/kg). The estimated specific gravity is approximately 1.03 and the refractive index $i = 1.341$. It is a commercially available translucent hydrogel and has been used in glaucoma filtering surgery as a space filler and to prevent postoperative scarring.¹⁴ Healaflow is a slow resorbable and self-degrading viscoelastic agent. The ordinary viscoelastic agent can stay for 24 hours to 48 hours, but Healaflow can stay for more than 6 months to 9 months.

This study aimed to determine the role of Healaflow patch in sealing retinal breaks and as an adjunct to 27-G vitrectomy for the treatment of primary RRD without prone positioning.

Methods

This study was approved by the Ethics Committee of the Tianjin Medical University Eye Hospital

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(2016KY-18) and adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all patients, and the study was registered with Clinical Trials (ID NCT03542162). This prospective, clinical study was performed on consecutive patients with primary RRD undergoing PPV in a tertiary ophthalmic hospital between March 2017 and May 2018. We included the patients with primary RRD within 4 weeks.

Exclusion criteria were as follows: proliferative vitreoretinopathy (PVR) Grade C or higher, retinal dialysis, retinoschisis, secondary RRD, significant corneal opacity preventing optimal visualization, giant retinal tears, less than 3 months of follow-up and visual loss due to other unrelated ocular morbidities. One of the authors (Chuanzhen, Zheng) entered the patient data into the electronic patient record. We documented preoperative, intraoperative, and postoperative findings and a detailed surgical procedure for every case.

In vitro experiments: A culture flask was filled with air, and 0.05-mL Healaflow (Anteis S.A.) (experimental group) and 0.05-mL sodium hyaluronate (Alcon Laboratories, Fort Worth, TX) (control group) were placed in three different positions, namely, the interior surface of the lid, the side wall, and the bottom of a culture flask. Dispersed circular spots of 5 mm × 5 mm were formed in 3 different positions. The culture flask was then filled with balance solution and placed in two different temperatures (37°C and room temperature). We observed and compared the dissolution and displacement of the dispersion spots with the 2 different viscoelastic agents on Day 3, Day 7, and Day 14 (Figures 1–3).

Surgical Procedure

We performed a 27-gauge (G) PPV with the Constellation Vision System (Alcon Laboratories, Inc). After retrobulbar anesthesia, standard 3-port transconjunctival sclerostomy was made by oblique sclerotome. A contact wide-angle viewing lens (Volk MiniQuad XL; Volk Optical, Inc, Mentor, OH) was used for all cases. We performed cataract phacoemulsification and intraocular lens implantation if cataract was present. Vitrectomy was performed with the aim of releasing the vitreoretinal traction in the vicinity of the retinal break. In cases of large breaks or vitreous incarceration around the break, we used 20% diluted triamcinolone acetonide (40 mg/mL; Kenalog [Bristol-Myers Squibb, Princeton, NJ]) to enhance visualization. Fluid–air exchange was performed in all cases through the existing retinal tears; no additional drainage retinotomy was performed. After the retina was

Interior surface of the lid

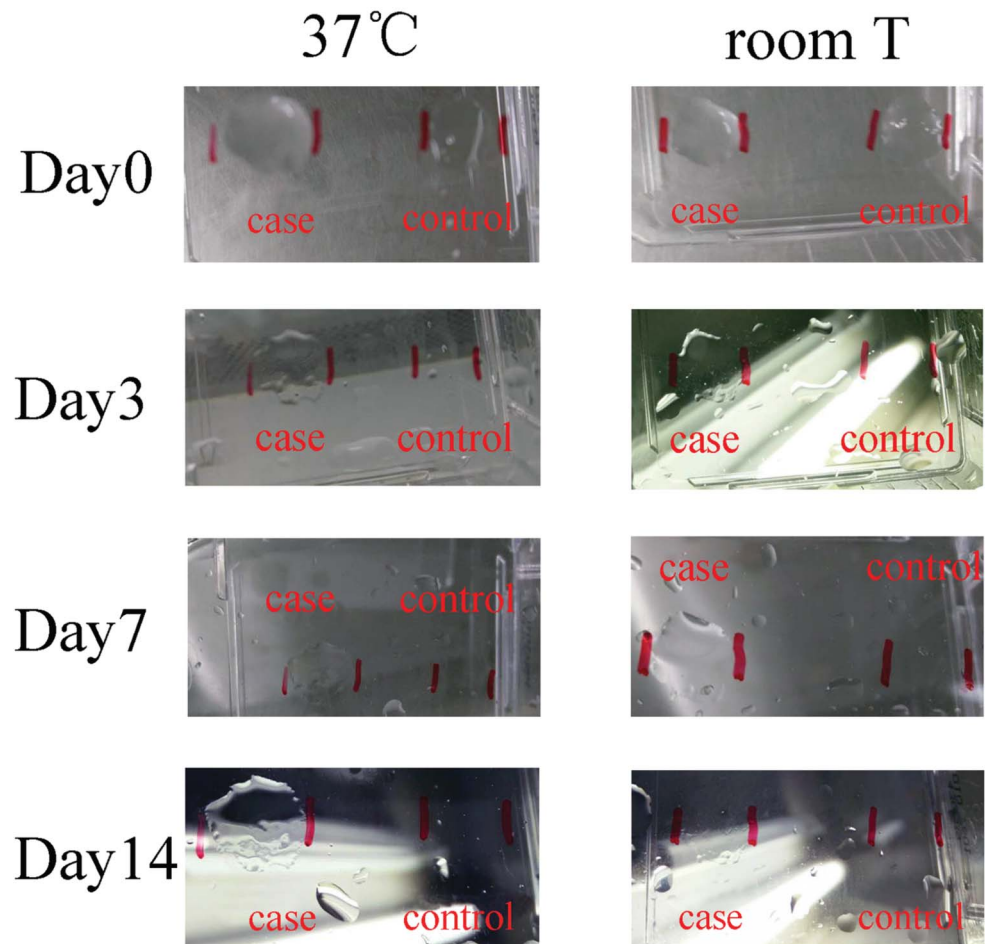


Fig. 1. Healaflo and sodium hyaluronate placed in the interior surface of the lid.

completely reattached, we applied 532-nm green diode pumped Nd:YAG laser photocoagulation (EYELITE Photocoagulator; Alcon Laboratories, Inc) around the flattened retinal breaks, following which the vitreous cavity was filled with air.

We covered the surface of all retinal tears completely with Healaflo using a 27-G needle. The amount of Healaflo injection was determined according to the size of the tears. The detailed procedure is shown in Figure 4 and **Supplement Digital Content 1** (see **Video**, <http://links.lww.com/IAE/B146>). We left the scleral incisions unsutured. Cotton-tipped buds were used to massage the wounds, and there were no restrictions on patient positioning after the surgery.

Follow-up of Patients

Postoperative examination was performed on Day 1; after 1 week; at 1 and 3 months; and at the last follow-up visit. We prescribed local application of a broad-

spectrum antibiotic eye drop, nonsteroidal anti-inflammatory drug eye drops, and glucocorticoid eye drops for each patient after the surgery for 1 month. We evaluated each patient by slit-lamp biomicroscopy with the QuadrAspheric fundus lens (Volk Optical, Inc) at follow-up. The outcome measures included best-corrected visual acuity (BCVA), primary reattachment rate, final reattachment rate after additional procedures, and postoperative complications. We provided the necessary treatment in case of complications, such as high intraocular pressure. The main outcome measure was the primary retinal reattachment rate after at least the 3-month follow-up. The secondary outcome measures were the final BCVA and postoperative complications. Primary retinal reattachment was defined as complete reattachment of the entire retina without any additional procedures during the follow-up period. The patients were not asked to be in prone position or any other position during the postoperative period.

Side wall

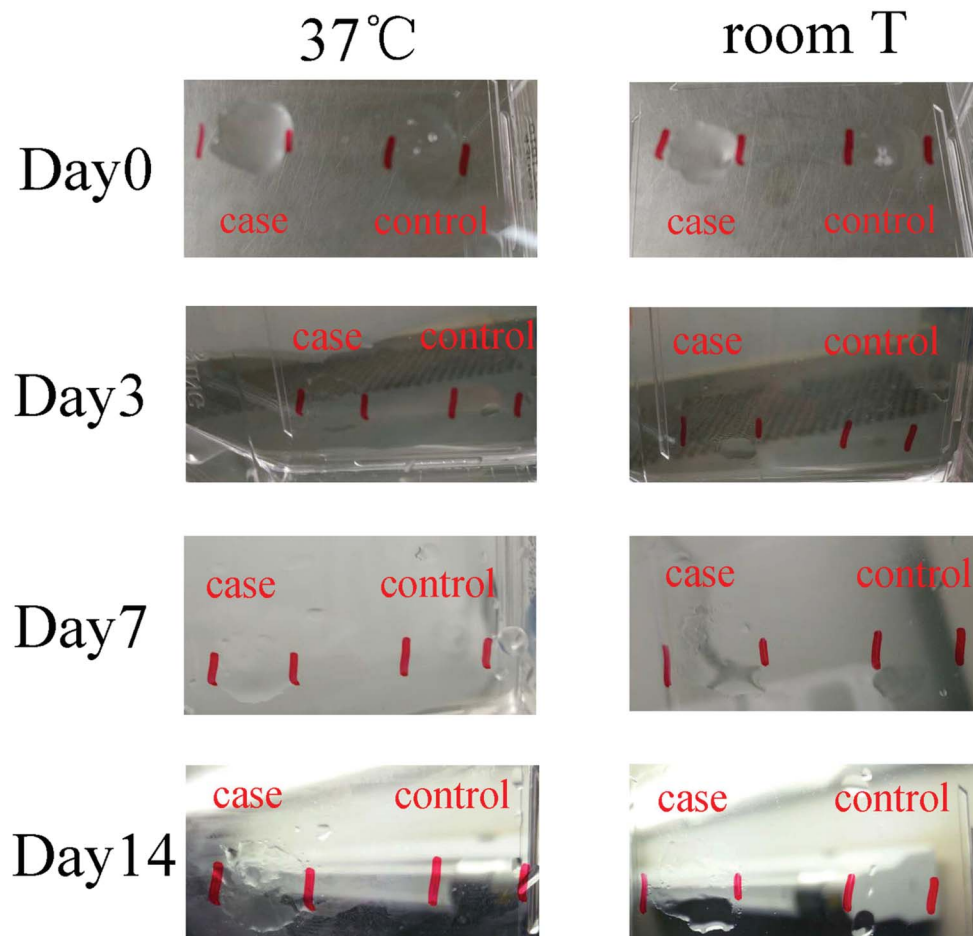


Fig. 2. Healaflow and vitreous sodium placed in the side wall of the culture flask.

Statistical Analysis

We performed a descriptive analysis. We calculated the frequencies and percentages for qualitative values, and mean values and SDs for quantitative values. We performed the chi-square test for the comparison using SPSS version 19.0. A Type I error of 5% was considered significant.

Results

The *in vitro* experiment showed that the Healaflow remained adherent, and the size of the area did not change at the end of the observation period. However, the control viscoelastic agent was dissolved completely in the balance solution 3 days later (Figures 1–3).

For our clinical study, a total of 37 consecutive patients (38 eyes) with primary RRD were enrolled. The patients were composed of 16 women (43.2%) and 21 men (56.8%) with a mean age of 59.5 ± 9.5

years (range 44–71). Six patients (15.8%) presented with high myopia. There were 33 (86.8%) phakic eyes and 5 (13.2%) pseudophakic eyes. Half of the phakic eyes (50%) had uneventful phacoemulsification and a posterior chamber intraocular lens. The mean follow-up period was 8.9 ± 3.8 months (range 3–14). The turn-up rate at the follow-up visits was 100% (37 patients) for the first week, first month and the 3-month visit, and 91.9% (34 patients) for the 6-month visit. The baseline clinical characteristics of the patients are shown in Table 1.

The mean number of quadrants affected was 2.2 ± 0.6 (range 1–4). A single break was present in 21 cases (55.3%), and 2 to 5 breaks (including 5) were present in 17 cases (44.8%). There were 66 total retinal breaks, of which 12 breaks were located in the inferior retina (between 4 and 8 o'clock, including the 4 and 8 o'clock positions), and the other 54 breaks were located in the superior retina (between 8 and 4 o'clock). Forty (60.6%) retinal breaks were horseshoe tears, and 26

Bottom

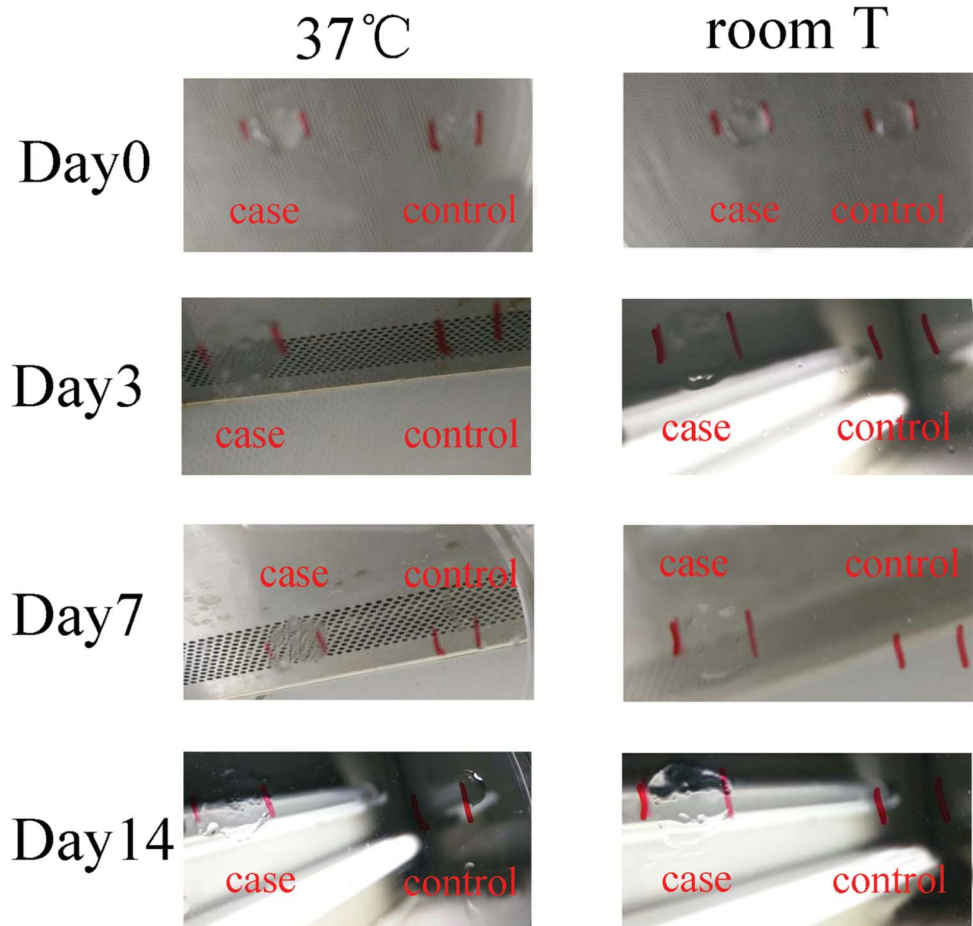


Fig. 3. Healaflo and vitreous sodium placed in the bottom of the culture flask.

(39.4%) were atrophic holes. Table 2 illustrates the characteristics of the retinal breaks. Intraoperatively, we found the macula to be involved in 25 eyes (65.8%) and attached in 13 cases (34.2%). The mean duration of macular detachment was 12.6 ± 9.5 days (range, 3–30 days). Iatrogenic retinal tears occurred in 2 cases (5.3%), one in the superior retina, and one in the inferior retina. The mean duration of the surgical procedure was 39.3 ± 6.4 minutes (range, 28–55 minutes). Healaflo patch combined with air tamponade was used in all cases. On the first postoperative day, 34 cases (89.5%) had more than 90% air in the vitreous cavity. The air was completely absorbed 5 days to 10 days after the surgery. Initial reattachment was achieved in 37 cases (97.4%). Final reattachment was achieved in all cases (100%). There was one case (2.6%) of re-detachment because of failure of the chorioretinal scar to develop around the treated break; this was confirmed during the reoperation. There were no signs of PVR in any patient. Postoperatively, 28 patients experienced

temporary high intraocular pressure (IOP) (>21.0 mmHg) that returned to normal after 1 week to 3 weeks (average 13 days) with local and symptomatic treatment. The incidence of cataract was 12.5% (2 cases) in 16 phakic eyes. Cataract phacoemulsification and intraocular lens implantation were performed in these patients after the 6-month follow-up. Mean preoperative BCVA was 1.02 ± 0.82 logarithm of minimum angle of resolution (median Snellen acuity: 20/125, range: 20/20,000 to 20/20), and mean final postoperative BCVA was 0.23 ± 0.17 logarithm of minimum angle of resolution (median Snellen acuity: 20/32, range: 20/100–20/20) ($P < 0.001$). Of the 13 eyes with macula-on RRDs, BCVA improved by 13.5 ± 16.9 letters ($P = 0.014$) after 6 months. Of the 25 eyes with macula-off RRDs, BCVA improved by 43.6 ± 22.9 letters ($P < 0.001$) after 6 months. Visual acuity of 20/40 or better was seen in 12 of 13 eyes (92.3%) in the macula-on group and in 19 of 25 eyes (76.0%) in the macula-off group during the final follow-up.

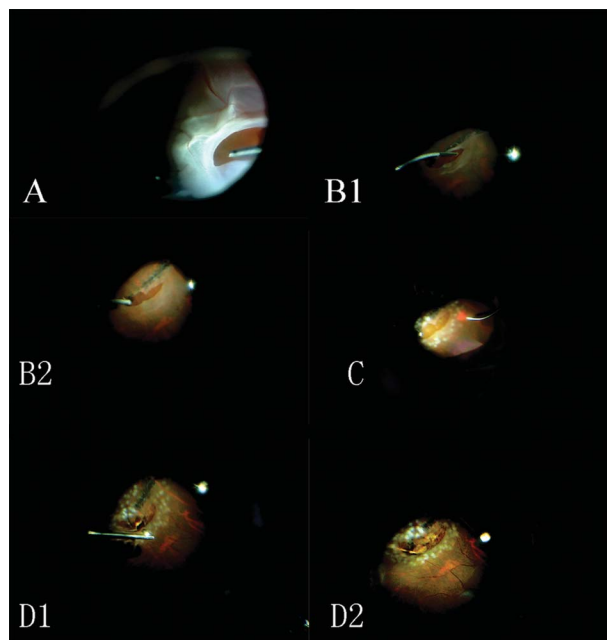


Fig. 4. Eye of patient 38, a 53-year-old woman. Surgeon's view through a 160 contact fundus lens. **A.** Three-quadrant retinal detachment with a single break located at 10 o'clock. **B1.** Fluid-air exchange. Direct aspiration of subretinal fluid was performed. **B2.** Complete drainage of subretinal fluid from the borders of the retinal break. **C.** Endolaser photocoagulation around the borders of the retinal break. **D1.** Healaflow was injected around the retinal tear using a 27-G needle. **D2.** The surface of the retinal tear was fully covered with Healaflow.

Discussion

The current study involved evaluation of 38 consecutive eyes with primary RRD that underwent a 27-gauge PPV combined with Healaflow patch and air tamponade from 2017 to 2018. Our preliminary results suggest that Healaflow is effective and safe to patch the retinal break, and combined with air tamponade, results in a high reattachment rate in the treatment of RRD. This new surgical protocol showed favorable results with regard to anatomical and functional recovery. We used Healaflow combined with air bubble injection for the first time to treat RRD. The potential benefit of the application of Healaflow to patch the retinal break might be because of the viscosity and in vivo stability. The primary reattachment was achieved in 37 cases (97.4%); the final reattachment rate was achieved in all 38 cases. The visual recovery was faster than that of vitrectomy using long-acting gas tamponade because the air bubble absorbed within 2 weeks. The patients did not undergo any positioning after the surgery. Therefore, the postoperative comfort was greatly improved.

We used Healaflow based on three considerations. First, PVR usually occurs within 3 months after the surgery. Since Healaflow is a long-acting viscoelastic

Table 1. Baseline Clinical Characteristics of Patients (n = 37) With Primary RRD

Characteristics	
No. of cases	38
Eyes (right/left)	17 (44.7%)/21 (55.3%)
Gender (male/female)	21 (56.8%)/16 (43.2%)
Age (years)	59.5 ± 9.5
Follow-up (mos)	8.9 ± 3.8
High myopia	6 (15.8%)
Phakic eye	33 (86.8%)
Pseudophakic eye	5 (13.2%)

agent, it can be retained in the body for a long time, isolating and preventing the migration and proliferation of the retinal pigment epithelium and other inflammatory cells. Second, we performed air-liquid exchange, drained the subretinal fluid, fully absorbed the subretinal fluid during the surgery, and used Healaflow patch for retinal tears. Healaflow patching prevented the liquid from entering the subretinal space through the break after the air was absorbed. We can distinguish typical Healaflow surface from the B-ultrasonography 1 week after operation (see **Figure, Supplemental Digital Content 2**, <http://links.lww.com/IAE/B145>). Patching of the Healaflow at the area with the retinal tear provides prolonged support and covering effect for the retina, which seals after the

Table 2. Characteristics of Retinal Breaks (Intraoperative Examination)

Characteristics	
Mean no. of quadrants	2.2 ± 0.6
Single/multiple breaks (cases)	21 (55.3%)/17 (44.8%)
Horseshoe tears/atrophic holes	40 (60.6%)/26 (39.4%)
Retinal breaks, size	
Small breaks	36 (54.6%)
Medium breaks	16 (24.2%)
Large breaks	14 (21.2%)
Retinal breaks, position	
8-4 o'clock	54 (81.8%)
4-8 o'clock (including 4 and 8)	12 (18.2%)
Retinal breaks	
Anterior	49 (74.3%)
Equatorial	15 (22.7%)
Posterior	2 (3.0%)
Macula on/off	13 (34.2%)/25 (65.8%)
Preoperative BCVA (logMAR)	1.02 ± 0.82 (median Snellen acuity: 20/125, range: 20/20,000-20/20)
Final BCVA (logMAR)	0.23 ± 0.17 (median Snellen acuity: 20/32, range: 20/100-20/20)

logMAR, logarithm of minimum angle of resolution.

inflammatory reaction produced by endolaser photocoagulation. Successful retinal reattachment was ensured. Third, Healaflow has been used in the treatment of patients with persistent ocular hypotony and atrophy of the eyeball.¹⁴ Our in vitro experiment also confirmed that Healaflow could continue to be attached and insoluble for at least two weeks in a 37°C water bath. Although this cannot fully simulate the changes in Healaflow in the human eye in its constant movement state, animal experiments have verified the safety and effectiveness of vitreous cavity filling in rats.¹⁵ In addition, some experiments on animals investigating the treatment of RRD showed that different biomaterials, such as polyethylene glycol and Seprafilm, can be used as a retinal patch to seal retinal breaks during PPV. Both biomaterials were shown to be safe and feasible.^{16,17}

Most of the studies that have been conducted earlier are retrospective case studies, including phakic and pseudophakic RRDs. Previous literature on vitrectomy combined with air tamponade for the treatment of RRD is summarized in Table 3.^{18–25} Regarding the anatomical results, the primary reattachment rates of 97.4% and final anatomical success rate of 100% in our study are favorable compared with those reported in other studies (Table 3). The single patient who experienced retinal redetachment was successfully treated with a second procedure that included relaxing retinotomy around the retinal break, repeat patching with Healaflow, air tamponade, and free posture. Among the 8 earlier studies, the reattachment rates with a single procedure were 70%-97.2%, and the final reattachment rates were 100%. These results suggest that air has an equivalent final reattachment rate and final visual recovery. There were many reasons for the high rate of retinal reattachment in our study. Key procedures, such as completely removing vitreous gel and all associated traction around the tears, performing fluid–air exchange to reattach the retina thoroughly, meticulously searching for all existing retinal breaks in the peripheral retina, performing adequate retinopexy, covering, and isolating all retinal breaks and the thorough air tamponade in the vitreous cavity at the end of the surgery, would have all contributed to the outcome.

The final visual acuity of better than or equal to 20/50 in our study is comparable with previous reports using air tamponade (81.6%). Among the 8 previous studies, 4 reported a final visual acuity better than or equal to 20/50 in 60% and 96% of patients, which is similar to our study (Table 3). The visual outcome in these studies was variable due to the difference in the inclusion criteria, and the severity of pathology in the

Table 3. Summary of Published Articles Regarding Pars Plana Vitrectomy Air Tamponade for Primary RRD

	Methods	N	Lens Status	Follow-up (mos)	Primary Reattachment, %	Final Reattachment, %	Final BCVA \geq 20/40, %
Zhou et al ⁴	23-G, air, RRD, PVR A or B	24	Phakic/pseudophakic	13	84.38	100	Not described
Martinez-Castillo et al ¹⁹	20-G, air, inferior breaks RRD, PVR A or B	15	Pseudophakic	6	93.3	100	86.7
Tan et al ²⁰	25-G, air, RRD, PVR A or B	128	Phakic/pseudophakic	3	81	Not available	Not available
Martinez-Castillo et al (Ophthalmology 2005) ²¹	20-G, air, inferior breaks RRD, PVR A or B	40	Pseudophakic	7	90	100	70.8
Martinez-Castillo et al ²²	20-G, air, SF6, or C3F8, RRD, PVR A or B	147	Pseudophakic	6–24	94.5	100	60.1–79.3
Zhang et al ²³	23/25-G, air, superior breaks-RRD, PVR A or B	75	Phakic/pseudophakic	12	92.7–97.2	100	Not available
Hotta et al ²⁴	Conventional PPV, air, superior breaks RRD, PVR A or B	27	Not available	6–26	89	100	96.0
Ruamviboonsuk et al ²⁵	25-G, air, superior breaks-RRD, PVR A or B	20	Phakic/pseudophakic	10	70	100	Not available
This series	27-G, air, Healaflow, RRD, PVR A or B	38	Phakic/pseudophakic	3–15	97.4	100	81.6

eyes included. In the current study, 25 eyes had macular-off RRD with initial BCVA less than 20/200. One week after the surgery, 19 cases had a final visual outcome of greater than or equal to 20/50 (50.0%), which was much shorter compared to that described in previous reports.

Our research also did not apply prone positioning after the surgery. This greatly improved patient comfort while achieving the similar clinical outcomes. Patients with RRD need prone position after traditional vitrectomy. The duration of requirement of the prone position is variable depending on the different vitreous cavity fillers. However, a few literature reports state that the prone position is not needed after vitrectomy. In a study by Martínez-Castillo et al,²² all eyes underwent vitrectomy with tamponade using air, 20% sulfur hexafluoride (SF₆) or 12% perfluoropropane (C₃F₈), and without prone position resulting in similar reattachment rate.

The progress of cataract was slow in phakic eyes after the surgery. Only two patients required cataract surgery half a year after the first surgery. One of the most frequent postoperative complications in this study was the elevation of IOP. This could be the consequence of the degradation of the Healaflow during the postoperative period. This can be managed using topical medications without any permanent damage. Some authors have suggested that either air or gas can be chosen for repairing RRD.^{26,27} By contrast, we have used Healaflow patch and air tamponade. The properties of buoyant force and surface tension of the intraocular gas play a critical role in sealing the retinal breaks.^{26–28} The difference between air and long-acting gas is in terms of longevity and expansion rate.²⁹ The expansion could result in severe postoperative complications such as elevated IOP and retinal artery occlusion. The air has a shorter half-life, the almost complete filling of air in the vitreous cavity after vitrectomy leads to a large arc of contact at the retinal interface, after covering the retinal breaks while seldom leads to high IOP. Healaflow obstructs the liquid from entering the subretinal space based on its viscosity and long-term effects. Besides, the area of air contact at the retinal interface in the first week after vitrectomy is large enough to allow for subretinal fluid absorption and stronger retina-choroidal scar induced by intraoperative laser retinopexy. Adding long-acting tamponade, therefore, should be unnecessary for eyes with simple RRD treated with vitrectomy and fluid–air exchange. The limitations of this study include its small sample size, a rather short follow-up period, and the absence of a control group. A randomized non-inferiority trial is required to confirm the results of this study.

In summary, the use of Healaflow patch and air tamponade with sutureless vitrectomy is beneficial for patients with simple primary RRD without complicating factors, such as PVR Grade C or higher, large retinal break, or underlying high myopia, as it can facilitate early visual recovery with lesser complications compared with long-acting tamponade. However, the result is preliminary, and longer follow-up and observation and animal model of this surgical approach would strengthen the evidence of this study.

Key words: 27-G pars plana vitrectomy, complications, Healaflow, minimally invasive surgery, rhegmatogenous retinal detachment.

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