Bimanual technique in proliferative diabetic retinopathy using an optical fiber-free intravitreal surgery system: a case control study

LI-JUN SHEN, ZHAO-YANG WANG, JIA QU, QIN-MEI WANG

The School of Ophthalmology and Optometry, Eye Hospital, Wenzhou Medical College, Wenzhou, Zhejiang - China

PURPOSE. *To evaluate the results of bimanual membrane peeling technique with an optical fiber-free intravitreal surgery system (OFFISS) in eyes with fibrovascular proliferation due to diabetic retinopathy.*
METHODS. *Fifteen eyes of 14 consecutive patients with severe fibrovascular proliferation due to diabetic retinopathy who underwent bimanual vitrectomy using the OFFISS and 15 eyes of 15 nonconsecutive patients with similar fundus condition who underwent vitrectomy using a conventional microscope system were compared in a retrospective, consecutive case-control series.*
RESULTS. *Reattachment rates at 3 months following surgery for the cases and controls were 93% and 100%, respectively, and final reattachment rates for both were 100%. The best-corrected visual acuity improved by two lines or more in 100% of the cases as compared to 87% of the controls (p=0.48). The mean VA (logMAR) improved 1.08 in the cases and 0.93 in the controls at final examination (p=0.46). Surgical complications were rare in both groups (p>0.05). The mean duration of membrane peeling of the cases was significantly lower than the controls (p=0.01).*
CONCLUSIONS. *For complicated surgical manipulations such as membrane peeling in diabetic vitrectomy for severe fibrovascular proliferation, bimanual vitrectomy using the OFFISS is a more effective and safer alternative to the conventional vitrectomy method. (Eur J Ophthalmol 2009; 19: 273-9)*

KEY WORDS. *Bimanual technique, Optical fiber free intravitreal surgery, Proliferative diabetic retinopathy, Vitrectomy*

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INTRODUCTION

Vitreous surgery has become a well-established treatment for fibrovascular proliferation from proliferative diabetic retinopathy, and the only therapeutic approach which can prevent or relieve the effects of contraction of the posterior vitreous surface and fibrovascular proliferations. Favorable anatomic and visual outcomes have been achieved in selected cases with severe fibrovascular proliferations due to diabetic retinopathy after vitrectomy (1-3).

The most critical part of vitrectomy for proliferative diabetic retinopathy involves meticulous sectioning and removal of fibrovascular membranes which may be associated with significant complications. Hence, using a bimanual approach during vitrectomy for fibrovascular tissue removal is especially desirable in eyes with extensive fibrovascular proliferations. A variety of specially designed instruments have been used to facilitate bimanual membrane dissection in previous studies (4-6).
The optical fiber-free intravitreal surgery system (OFFISS)

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is a new surgical instrument developed for bimanual vitrectomy recently, and has been used successfully in cases with preretinal membrane due to diabetic retinopathy or proliferative vitreoretinopathy (7). However, there are no reports about systemic study of comparable characteristics of OFFISS and conventional vitrectomy. The current study reevaluated the results of the bimanual vitrectomy using the OFFISS in 14 patients with severe fibrovascular proliferation due to diabetic retinopathy to determine whether bimanual approach has a different prognosis for retinal reattachment and visual acuity improvement compared to conventional unimanual approach.

METHODS

Patients who underwent primary vitrectomy using a bimanual approach with the OFFISS for severe fibrovascular proliferation due to diabetic retinopathy were retrieved from a group of all patient with proliferative diabetic retinopathy treated with vitrectomy between 2002 and 2006. There were 14 consecutive patients (15 eyes) identified in this retrospective study. These 14 patients (15 eyes) were matched to a group of 15 nonconsecutive patients (15 eyes) with the same fundus condition who underwent conventional vitrectomy at a similar time (case controls). The case controls were matched by approximate duration of their diabetes, extent of fibrovascular proliferation, and retinal anatomic status. Duration of diabetes was assumed to be less reliable in matching cases as many patients cannot precisely date the onset of their diabetes. The extent of fibrovascular proliferation had to be exact matches for all case controls.

A complete ophthalmologic examination was performed on all patients before surgery including measurement of visual acuity (VA), intraocular pressure, and evaluation of fibrovascular proliferation. The extent of fibrovascular proliferation was diagnosed by preoperative biomicroscopic examination and/or B-scan ultrasonography, and confirmed with fundus examination under an operating microscope after removal of dense media opacities during vitrectomy. Patients were examined 1 day, 2 weeks, 6 weeks, 3 months, 6 months, and at variable intervals following surgery. Most patients were examined at least 1 year following surgery. Slit-lamp examination including intraocular pressure and fundus examination through the intraocular gas bubble or silicone oil bubble were performed 1 day and 2 weeks following surgery primarily to detect surgical complications. Best-corrected VA was measured at baseline and 6 months following surgery in all eyes. Retinal anatomic status was recorded at each examination.

All surgeries were performed as a three-port pars plana vitrectomy by the same experienced surgeon. The intraocular procedures were performed in the cases using an OFFISS attachment (Topcon Company, Japan) which provided a good view for posterior segment maneuvers without a fiberoptic end illuminating probe as described previously (6), and using a traditional operating microscope in the case controls. Briefly, the posterior hyaloid was separated from the retina and excised after a core vitrectomy. Surgical maneuvers such as membrane peeling, segmentation, and delamination were performed to remove preretinal and epiretinal fibrovascular tissue in unimanual or bimanual fashion. Laser endophotocoagulation was performed during vitrectomy even in the presence of preexisting photocoagulation. After fluid–air exchange, long acting perfluoropropane (C_3F_8) or silicone oil was used as an extended tamponade. Silicone oil was usually used in eyes with complicated retinal detachment from fibrovascular proliferations. Silicone oil was removed 3 to 8 months following surgery if the retina was totally reattached. Silicone oil was removed from all operated eyes before the last follow-up visit. The results of VA and BCVAs were converted to logarithm of minimum angle of resolution (logMAR) values. The duration of membrane removal was recorded by video in the surgery. Data were collected by retrospective review of patient charts and analyzed using SPSS for windows, version 10.0 (Cary, NC).

RESULTS

Preoperative demographic data for cases and controls

The demographic data of the cases and controls are summarized in Table I. The mean age of the cases was 58 years (range 50–70). The mean age was 58 years for the controls (range 55–69). Four of 14 cases (29%) were men, compared with 4 of 15 controls (27%). The mean preoperative vision (LogMAR) was 2.01 for cases and 1.85 for controls (Tab. I). The duration of diabetes, previous panretinal photocoagulation, traction retinal detachment, combined traction and rhegmatogenous retinal detachment were similar between groups, with no significant difference between cases and controls (Tab. I).

Anatomic and visual result

The retina was reattached successfully 1 day following surgery in all eyes included in this study. Fourteen of 15 eyes (93%) of the cases and 15/15 eyes (100%) of the controls had retina reattached at 3 months following surgery. One eye of the cases needed reoperation because of anterior hyaloidal fibrovascular proliferation. All eyes had retina reattached at the final examination.

The mean BCVA was 1.08 in the cases and 0.96 in the controls at 3 months following surgery and 0.93 and 0.91 at end of follow-up, respectively (Tab. II). The mean VA improved 1.08 in the cases and 0.93 in the controls at final examination (Tab. II). The gain in VA was statistically significant at the final examination for both cases and controls. The vitrectomy surgery was beneficial to both the cases and case controls.

The mean duration of follow-up was similar for cases compared to controls. Therefore, the vitrectomy surgery significantly improved the VA in eyes with severe fibrovascular proliferation due to diabetic retinopathy regardless of bimanual or unimanual approach.

TABLE I - DEMOGRAPHIC DATA OF THE CASES AND CONTROLS

Characteristics	Cases, n = 15	Case controls, n = 15	p value
Age, yr	58.13±5.66	58.00±5. 94	0.63*
Gender (M/F)	4/11	4/11	1.00†
Approximate duration of diabetes, yr	11.33±3.75	10.73±3.41	0.16*
Preoperative visual acuity, LogMAR	2.01±0.77	1.85±0.70	0.13*
Previous panretinal photocoagulation			
No	5 (33)	4 (26)	1.00†
Partial	10 (67)	10 (67)	1.00‡
Complete	0 (0)	1 (7)	1.00†
Extent of fibrovascular proliferation			
Within arcade but more than 2 disc	1 (7)	1 (7)	1.00†
Beyond vascular arcade	14 (93)	14 (93)	1.00†
Traction retinal detachment	9 (60)	11 (73)	0.44‡
Combined traction and rhegmatogenous retinal detachment	1 (7)	2 (13)	1.00†

Values are mean ± SD or n (%).
*Paired t-test.
†Fisher exact test.
‡Chi-square test.

TABLE II - COMPARISON OF ANATOMIC AND VISUAL RESULTS FOR CASES AND CONTROLS

Results	Cases, n = 15	Case controls, n = 15	p value
Retina reattached at 3 mo	14 (93)	15 (100)	1.00†
Retina reattached at end of follow-up	15 (100)	15 (100)	NS
VA at 3 mo, LogMAR	1.08±0.42	0.96±0.43	0.42*
Gain of two or more lines at end of follow-up	15 (100)	13 (87)	0.48†
BCVAs at end of follow-up, LogMAR	0.93±0.38	0.91±0.46	0.89*
Change in BCVAs at end of follow-up	1.08±0.72	0.93±0.73	0.46*
Postoperative follow-up ≥6 mo	15 (100)	15 (100)	NS
Postoperative follow-up ≥12 mo	13 (87)	11 (73)	0.65‡

Values are mean ± SD or n (%).
*Paired t-test.
†Fisher exact test.
‡Chi-square test.
NS = not significant.

Complications

Common intraoperative and postoperative complications are summarized in Table III. Postoperative elevated IOP and vitreous hemorrhage were similar between the cases and controls. Six eyes had recurrent mild hemorrhage that was cleared spontaneously within 2 weeks. The elevated IOPs of nine eyes returned to a normal range after applying topical and oral antiglaucoma medication during the follow-up period. Two eyes of the cases had developed iatrogenic retinal break during vitrectomy, one eye due to membrane dissection and another eye due to using blunt vitrectomy cutter to excise peripheral vitreous, and was treated with photocoagulation combined with silicone oil tamponade. Four eyes of the controls had developed iatrogenic retinal break, two eyes due to membrane dissection and two eyes due to frequent change of surgical instruments, and also treated successfully with photocoagulation combined with silicone oil tamponade. There was no statistically significant in iatrogenic retinal break between the cases and case controls.

Duration of membrane removal

The mean duration of membrane removal was 26 minutes (range 17–46) for the cases and 36 minutes (range 25~52) for the controls. There was statistical significance in mean duration of membrane removal between the cases and case controls (paired *t* test, p=0.01).

DISCUSSION

Although timely use of panretinal photocoagulation has been shown to reduce the onset and progression of diabetic retinopathy (8, 9), severe fibrovascular proliferation in the posterior fundus due to no or inadequate laser treatment is common, and accounts for a large portion of severe visual impairment cases in diabetic patients in China.

Muramatsu et al reported a more favorable visual outcome of vitrectomy in eyes with progressive fibrovascular proliferation in the posterior fundus due to proliferative diabetic retinopathy (3). The Diabetic Retinopathy Vitrectomy Study demonstrated that in eyes with severe fibrovascular proliferation and useful vision, early vitrectomy resulted in final VA of 20/40 or better in 44% of cases (1, 2). The advantage of early vitrectomy in recovery of good vision was apparent in eyes with the most severe fibrovascular proliferation. Fibrovascular proliferations overlying the disc within the temporal vascular arcade and extending beyond arcade could be detected in all eyes of our series during vitrectomy after removal of media opacities. In our study, the primary anatomic success rate in 97% of 30 eyes and attainment of a VA of 20/40 or better in 52% of eyes at end of follow-up is similar to other published reports (1-3).

In our study, the primary anatomic success rate was 93% for cases and 100% for case controls, and visual outcome was also comparable between cases and controls. There seems to be no additional beneficial effect in terms of anatomic success and visual improvement in treating these cases with different surgical approach. Although there was no significant difference in intraoperative iatrogenic retinal break between cases and case controls, the rate of iatrogenic retinal break was relatively high in the controls. Ora serrata dialysis near sclerotomy, which is most likely caused by frequent change of multiple surgical instruments during membrane removal, had occurred in two eyes of the controls and no eyes of cases. Posterior retinal tears membrane dissection had occurred in two eyes of the controls and one eye of the cases. In the eyes with bimanual membrane dissection, peripheral iatrogenic break had occurred in one eye because of using a blunt vitrectomy cutter to excise peripheral vitreous. Therefore, the bimanual ap-

TABLE III - COMPARISON OF COMPLICATIONS FOR CASES AND CONTROLS

Complications	Cases, n = 15	Case controls, n = 15	p value
Iatrogenic retinal break	2 (13)	4 (27)	0.65*
Elevated intraocular pressure	3 (20)	2 (13)	1.00*
Vitreous hemorrhage	1 (7)	4 (27)	0.33*

Values are mean ± SD or n (%).
*Fisher exact test.

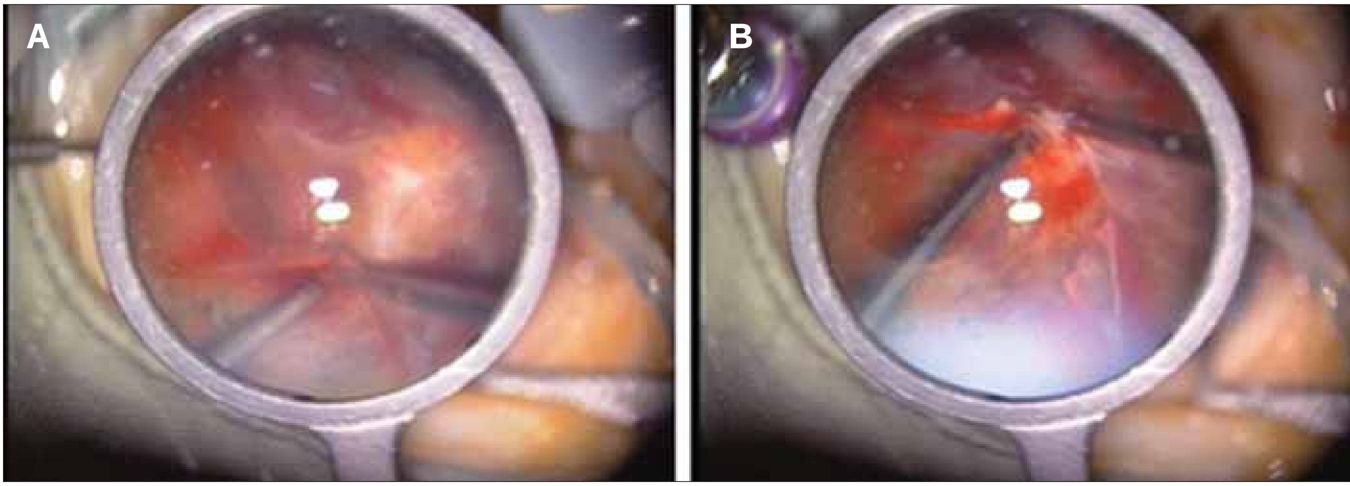

Fig. 1 - *Photograph of diabetic vitrectomy using optical fiber-free intravitreal surgery system during membrane peeling.* **(A)** *The fibrovascular membrane spanning discs from superior temple vascular arcade to inferior temple vascular arcade, one hand with a membrane stripping crook to raise the edge of the membrane, and the other hand with a vitrectomy cutter to excise the membrane.* **(B)** *Fibrovascular membrane adhered tightly to discs. One hand with a membrane stripping forceps to hold the edge of membrane, and the other hand with intraocular scissor to shear the adhered tissues under the membrane.*

proach with less frequency of surgical instruments change had a beneficial effect in terms of safety in membrane dissection.

There was significant difference in the mean duration of membrane removal between cases and controls. Less duration of membrane removal in eyes treated with bimanual approach may be attributed to less frequency of surgical instruments change, precise diathermy hemostasis, and enhanced effectiveness of bimanual dissection. With the help of the OFFISS, both hands of the surgeon are free. In most instances, we used one hand to control a pick for membrane peeling and another hand to control vitrectomy cutter for membrane removal (as shown in Fig. 1), and did not encounter any major difficulty in membrane dissection and removal.

The advantages of OFFISS surgery, including a wider field of view (40×40°) and bimanual technique, have been discussed in a previous study (7). Although the OFFISS can provide clear stereo viewing of the posterior fundus with a wider field of view relative to conventional operating microscope, detail visualization of the peripheral fundus is always difficult. Horiguchi et al (7) used a 120 D lens to improve visualization of the peripheral fundus during vitrectomy using the OFFISS. To our experience, sclera indentation was more easy and effective than use of a 120 D lens for peripheral fundus visualization. As both hands of the surgeon were free, peripheral fundus could be depressed into field of view by the surgeon for visualization, excising peripheral vitreous, and photocoagulation of peripheral retina, as shown in Figure 2. In eyes without a lens or lens implant, we did not encounter any difficulty during vitrectomy using the OFFISS.

Fig. 2 - *Photograph of diabetic vitrectomy using the optical fiber-free intravitreal surgery system during peripheral manipulations. Excision of the peripheral vitreous at the same time as the episcleral indentation.*

Other advantages of the bimanual approach in eyes with severe fibrovascular proliferation due to diabetic retinopathy included less duration of membrane removal as compared to conventional unimanual approach, precisely positioning bleeding site, and peripheral manipulations without help of a surgery assistant.

Several instruments have been developed to facilitate the bimanual technique, for example the self-illumination system (10) and the multiport illumination system (11). However, the instruments for self-illumination are expensive and have limitations; for example, the choice of possible instruments is limited, and the light usually goes very close to the retinal tissue inducing light stress, and the area of illumination is restricted. Furthermore, it required a larger sclerotomy opening for the insertion of instruments. Disadvantages of multiport illumination system include the inability to use many angled instruments that will not fit through the 20-gauge cannulas, and a longer initial setup time and larger sclerotomies to place two additional sclera sutures and to insert the cannulas. The OFFISS using a 40-D lens and a prismatic inverting device provides an excellent view of the ocular tissues and allows both hands to be free to use any two microinstruments for vitrectomy. Because this system does not include disposable parts, we believe that the cost is less than other systems.

However, the posterior fundus could not be clearly visualized during fluid–gas exchange in eyes with a lens or lens implant, and further intravitreal manipulations could not be carried out while a big gas bubble was present in the vitreous cavity. This was because injection of an intravitreal bubble in phakic and pseudophakic eyes resulted in increase of refractive power (5). We used a biconcave contact lens combined with a fiberoptic illuminating probe to improve visualization when further tissue dissection and/or transvitreal photocoagulation of retinal breaks were needed. In other words, we reverted to a conventional approach for this step. Since other major steps, such as vitreous removal, membrane peeling, retina reattachment, and photocoagulation, have already been completed with the help of the OFFISS, this switch does not affect the surgical outcome.

In conclusion, vitrectomy is an effective surgical approach for treating severe fibrovascular proliferation due to diabetic retinopathy. It yields a satisfactory outcome in retinal reattachment and visual acuity improvement. Although there was no significant difference in the surgical outcome between cases and controls, there seemed to be beneficial effects in term of effectiveness and safety in treating the cases with bimanual approach. The main disadvantage of the OFFISS is the poor visualization of the fundus during fluid–gas exchange in phakic and pseudophakic eyes. The reflections become more prominent and may sometimes affect the fundus viewing. In this case, the operator can slightly adjust the position of microscope or the eye to minimize the reflection. As we experienced, this reflection does not affect fundus viewing during surgery in eyes with a clear lens or lens implant.

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Reprint requests to:
Zhao-Yang Wang, MD
The School of Ophthalmology and Optometry
Eye Hospital
Wenzhou Medical College
270 Xueyuan Road
Wenzhou, Zhejiang, China 325027
wmcophthalmology@yahoo.com.cn
zhaokekewzy@hotmail.com

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