Lamina Puncture for Central Retinal Vein Occlusion

Results of a Pilot Trial

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Objective: To evaluate the effect of treatment by lamina puncture, a novel procedure to create a perivascular opening within the optic nerve head by a transvitreal approach, on visual acuity after central retinal vein occlusion (CRVO) in older patients.

Methods: The patients comprised a nonrandomized, consecutive, interventional case series of older patients being seen with CRVO. Patients 65 years or older with CRVO and a visual acuity of 20/200 or worse were treated with vitrectomy and lamina puncture of the optic disc. Preoperative visual acuity, clinical examination results, and fluorescein angiography results were compared with postoperative results.

Results: Twenty patients (12 men and 8 women), an average age of 72 years, were enrolled. The mean duration of CRVO was 5.4 months; 14 eyes had nonischemic CRVO when first seen, while 6 had substantial ischemia. The mean preoperative visual acuity was in the counting fingers range, and the mean postoperative visual acuity was also in the counting fingers range. Complications included 5 eyes with iris neovascularization, of which 4 progressed to neovascular glaucoma; also, preoperative ischemia seemed to predispose to neovascular complications.

Conclusion: Lamina puncture does not restore visual acuity in older patients with CRVO.

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CENTRAL RETINAL VEIN OCclusion (CRVO) is a substantial cause of visual loss and remains a particularly frustrating retinal disease that has defied visually restorative treatment. The disease itself has a variable clinical course, and this has led to controversy in its management by various medications, therapies, and surgical procedures (Hayreh[1] provides a review). The variable natural history is undoubtedly a reflection of the variability in the obstruction of flow in the central retinal vein. The obstruction may range in degree from partial (nonischemic) to complete (ischemic), with partial obstruction and later recovery more typically observed in younger patients. Severe obstruction and ischemia is more frequently observed in older patients and is associated with a decreased chance of spontaneous visual improvement. Pathologic evaluation results of available eyes (more typically in the advanced ischemic category) document a thrombus in the vicinity of the lamina cribrosa in most cases.[2]

Recently, Opremcak and associates[3] reported on the efficacy of radial optic neurotomy (RON) for CRVO, in which an incision is made in the margin of the optic disc during a transvitreal approach. They hypothesized that there is a "compartment syndrome" in which compression on the central retinal vein may be relieved by a marginal incision at the optic nerve head. Lit and coworkers,[4] directing their efforts at the presumed thrombus in the perilaminar region within the optic nerve, developed a technique called lamina puncture, in which a transvitreal approach is used to create an opening within the optic disc adjacent to the central retinal vein. The rationale for this technique was to permit dilation of the obstructed central retinal vein into this newly created perivascular space, to dislodge the presumed thrombus present in the perilaminar location by the manipulation of the vessel, or both. The feasibility of lamina puncture was demonstrated in experimental animals, and the results of a pilot trial of patients are reported herein.

METHODS

This pilot trial was approved by the institutional review board at the Massachusetts Eye and Ear Infirmary; and informed consent, including explanation of the experimental nature of this treatment, was obtained from all patients. Inclusion criteria were as follows: (1)

typical CRVO on fundus examination and fluorescein angiography, (2) visual acuity of 20/200 or worse, (3) patient 65 years or older, and (4) duration of CRVO of less than 1 year. Patients were characterized for the presence or absence of preoperative ischemia and/or macular edema, but these features were neither inclusion nor exclusion criteria. Macular edema was assessed by stereobiomicroscopic fundus examination and fluorescein angiography, but optical coherence tomography was not routinely performed. Specific exclusion criteria were as follows: (1) fellow eye visual acuity of 20/100 or worse, (2) use of systemic anticoagulants that could not be interrupted, or (3) glaucoma, optic atrophy, or other ocular disease that would render evaluation of the effects of surgery problematic. Visual acuity was measured at specified intervals postoperatively on the Early Treatment Diabetic Retinopathy Study chart, and supplemented by clinical examination, fundus photography, and fluorescein angiography. Visual field assessment was restricted to finger confrontation, after failed attempts to obtain successful automated perimetry in this group of patients with profound visual loss.

Lamina puncture was performed during a pars plana vitrectomy. All patients received a retrobulbar injection of 2% lidocaine hydrochloride (Xylocaine) and 0.75% bupivacaine hydrochloride (Marcaine) in a 50:50 mixture, and intravenous sedation was provided as routine. A core vitrectomy was performed, with removal of the central and midperipheral vitreous, but the posterior hyaloid was not specifically removed apart from 1 patient (patient 9), in whom a thickened hyaloid with an epiretinal membrane was identified preoperatively. Once the core vitrectomy was performed, the intraocular pressure was increased by elevating the infusion pressure and a specially designed lamina puncture blade was introduced across the vitreous cavity. The design of the blade featured a sharp point, with one edge of the blade being extremely sharp and the back edge being dulled for passage along the temporal margin of the central retinal vein. A prototype blade was used for the first 9 patients, followed by use of a commercially available blade for the subsequent patients. Invariably, the central retinal vein was in the nasal aspect of the optic disc cup and temporal to the artery, and this resulted in the incision being made in the cup just temporal to the central retinal vein (**Figure 1**). The blade was inserted to a depth of 0.5 mm, and the central retinal vein was massaged with the dull side of the blade within the depth of the incision. In all patients, the same incision was reentered with the blade in identical fashion, and massage again performed, to ensure the adequacy of incision and massage. Following lamina puncture, the intraocular pressure was lowered to normal and the procedure was concluded. Postoperative care was typical for straightforward pars plana vitrectomy, and included topical antibiotics, anti-inflammatory agents, and dilating eyedrops.

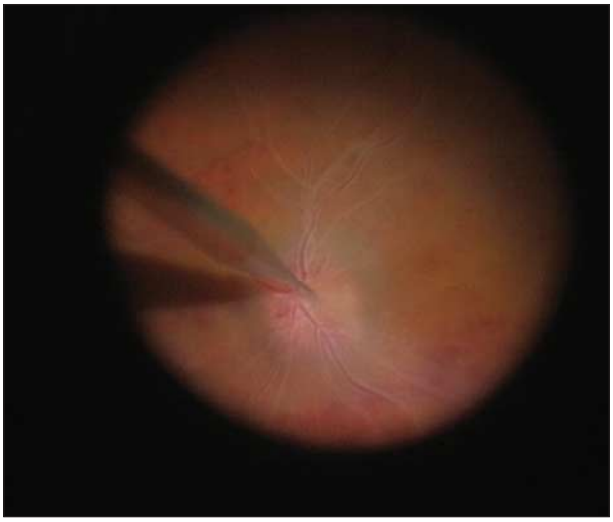

Figure 1. Intraoperative photograph of a patient undergoing lamina puncture in the left eye. The blade is entering the optic disc just temporal to the central retinal vein, with the sharp side of the blade directed toward the temporal aspect of the disc within the cup.

RESULTS

Twenty consecutive patients (12 men and 8 women) were enrolled in this study (average age, 72 years). Of these patients, 12 were receiving treatment for hypertension when first seen and 3 had diabetes mellitus. The mean duration of CRVO was 5.4 months (range, 0.5-10 months), and the mean duration of follow-up was 19 months (range, 3-41 months). The mean preoperative visual acuity was in the counting fingers range (range, 20/125–hand motions) and is shown in **Table 1**. Of the 20 patients, 14 had a CRVO that was categorized as primarily nonischemic and 6 had ischemia that was typically of a severe grade (**Figure 2**). Eight patients had minor exceptions to inclusion or exclusion criteria and were included on a compassionate plea basis: 4 patients were younger than 65 years (aged 58, 55, 51, and 59 years), 2 had an enrollment visual acuity better than 20/200 (20/125 and 20/160), and 2 had a visual acuity worse than 20/100 in the fellow eye. Preoperative macular edema was observed in 18 eyes, was indeterminate in 1 eye, and was clearly absent in 1 eye. Two eyes had mild preoperative vitreous hemorrhage, but the hemorrhage was confined to the inferior vitreous.

The mean postoperative visual acuity remained in the counting fingers range (range, 20/80–no light perception) and is also shown in Table 1. Although 10 patients had some degree of visual improvement (difficult to evaluate in many patients, given the low levels of vision), only 6 had postoperative visual acuities of 20/200 or better (range, 20/80-20/200) and all but 1 of these were within 2 lines of their initial acuity. Five eyes developed iris neovascularization, which was isolated or associated with neovascular glaucoma, vitreous hemorrhage, or both. Specifically, 1 eye in this neovascular group had rubeosis alone, which was managed successfully with panretinal photocoagulation (final visual acuity, 20/400), and 4 progressed to neovascular glaucoma, with or without vitreous hemorrhage, and had poor visual outcomes despite multiple interventions, including vitrectomy, panretinal photocoagulation, and glaucoma treatment (final visual acuities: hand motions, counting fingers at 3 ft [90 cm], no light perception, and no light perception). All of the 5 postoperatively rubeotic eyes were in the subgroup that displayed retinal ischemia on preoperative evaluation. Three additional eyes had late postoperative vitreous hemorrhage, 1 of which spontaneously cleared (final visual acuity, 20/400) and 2 of which required vitrectomy (final visual acuities, 20/500 and 20/800). One eye had a postoperative retinal detachment that was successfully repaired (final visual acuity, counting fingers at 2 ft [60 cm]). Two eyes had postoperative endophthalmitis; both eyes were positive for disease by culture

Table 1. Clinical Characteristics of 20 Patients Treated With Lamina Puncture for CRVO

Patient No./Sex/ Age, y	Symptom Duration, mo	Preoperative Ischemia	Preoperative ME	Preoperative VA	Postoperative VA	Follow-up, mo	Comment
1/F/74	3	Yes	?	HM	HM	41	NVI/NVG/VH; postoperative Rx with vitrectomy, laser, and cryotherapy
2/F/71	5	Yes	Yes	HM	CF at 90 cm	38	NVI/NVG/VH; postoperative Rx with vitrectomy and laser; late collaterals at disc and macular scar
3/F/91	0.5	No	No	HM	20/640	9	CRVO in fellow eye
4/M/78	2.5	No	Yes	20/640	20/500	34	VH (twice); postoperative Rx with vitrectomy; CE; late collaterals at disc and macular scar
5/M/84	6	No	Yes	20/500	20/400	40	Transient postoperative VH cleared spontaneously; hard exudates at fovea
6/M/81	9	Yes	Yes	20/400	20/200	9	Late collaterals at disc and macular scarring
7/M/84	3	Yes	Yes	20/800	NLP	36	NVI/NVG; failing laser therapy and medications; CRVO in fellow eye
8/M/75	4	No	Yes	20/320	20/80	13	Apparent reperfusion of central retinal vein at surgery; marked resolution of ME
9/F/58	8	No	Yes	HM	HM	31	Thick hyaloid/ERM preoperatively; removed at surgery; postoperative sclerosis of retinal vessels, ERM, lamellar hole, and cataract
10/M/68	10	No	Yes	20/320	20/200	15	Late collaterals at disc
11/M/65	4	Yes	Yes	CF at 60 cm	NLP	22	NVI/NVG, despite PRP
12/F/77	7	No	Yes	20/400	20/800	20	Postoperative VH Rx with vitrectomy; late collaterals at disc, PCO, and ERM
13/M/55	10	No	Yes	20/160	20/200	3	*Staphylococcus epidermidis* endophthalmitis Rx with tap and injection
14/M/74	7	No	Yes	20/320	20/800	9	Prior failed IVK (twice); apparent reperfusion of vein intraoperatively; *Staphylococcus lugdunensis* endophthalmitis Rx with tap and injection; disc pallor; ERM and CE
15/F/82	4	No	Yes	20/400	CF at 120 cm	18	IVK and PRP postoperatively by an outside physician
16/M/51	10	No	Yes	20/125	20/160	11	Prior IVK; late collaterals at disc and cataract
17/F/59	2	No	Yes	CF at 120 cm	20/100	3	Mild ERM postoperatively; ME resolved
18/F/69	4	No	Yes	20/200	20/320	8	ME worsened after surgery
19/M/82	1	Yes	Yes	20/500	20/400	3	Postoperative NVI; Rx with PRP
20/M/71	8	No	Yes	20/400	CF at 60 cm	16	Postoperative RD with PVR; Rx with vitrectomy; late macular hole and collaterals at disc

Abbreviations: CE, cataract extraction; CF, counting fingers; CRVO, central retinal vein occlusion; ERM, epiretinal membrane; HM, hand motions; IVK, intravitreal Kenalog (triamcinolone acetonide); ME, macular edema; NLP, no light perception; NVG, neovascular glaucoma; NVI, neovascularization of iris; PCO, posterior capsular opacity; PRP, panretinal photocoagulation; PVR, proliferative vitreoretinopathy; RD, retinal detachment; Rx, treatment; VA, visual acuity; VH, vitreous hemorrhage; ?, indeterminate.

and were sterilized with intravitreal antibiotics (final visual acuities, 20/200 and 20/800). Cataract developed in 4 eyes and was removed in 2. Macular edema was markedly reduced in 2 of the 18 eyes in which it was present preoperatively, but the remainder displayed substantial continued edema on examination and fluorescein angiography. Confrontation visual fields did not disclose gross visual field changes after surgery, but the examination was limited by the low levels of visual acuity. Only 2 patients (patients 8 and 14) seemed to have a convincing degree of central retinal vein reperfusion at surgery and/or postoperatively, of whom the former achieved resolution of macular edema and a 20/80 result; the second case was complicated by postoperative endophthalmitis. Other postoperative retinal findings in some eyes included sheathing of the retinal vessels (2 eyes), collateral vessels on the disc (7 eyes), and macular pigmentary scarring (3 eyes), and are detailed in Table 1.

COMMENT

Central retinal vein occlusion is an extremely important cause of visual loss, and presumably results from a thrombus in the central retinal vein in most cases. The condition has been the subject of innumerable reports, and claims of efficacy have been made for treatment with medications, laser, and surgery. Despite these claims for successful therapies, the highly variable natural history of CRVO, coupled with the lack of randomization in most published pilot series, has defeated the adoption of uniform treatment strategies and the subject remains controversial. The present study reports on the use of a novel surgical technique—lamina puncture—and documents the failure of this technique to restore visual acuity in older patients with CRVO. This conclusion has been reached by careful comparison of these consecutive, non-

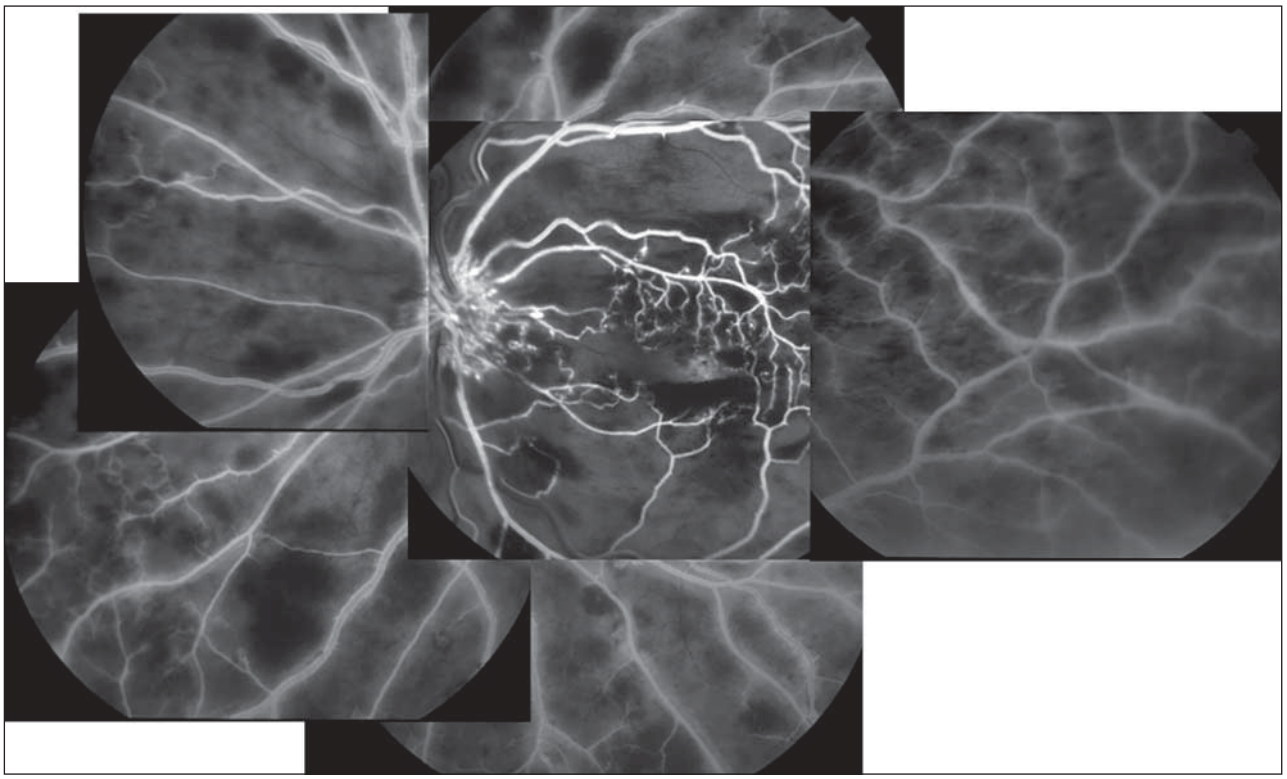

Figure 2. A composite fluorescein angiogram of a patient with severe preoperative ischemia. This degree of ischemia was characteristic of the 6 ischemic eyes enrolled in this trial.

randomized, interventional cases with available information regarding the natural history of CRVO.

The best evidence for the natural history of CRVO is provided by the Central Vein Occlusion Study (CVOS),[5] in which 714 eyes with CRVO were followed up for 1 to 3 years. The CVOS found that the final visual acuity was related to the initial visual acuity, and separated acuity levels into 3 categories: 20/40 or better, 20/50 to 20/200, and worse than 20/200. For eyes with an initial visual acuity of 20/40 or better, final acuities were 20/40 or better in 65%, 20/50 to 20/200 in 25%, and worse than 20/200 in 10%. For eyes with an initial visual acuity of 20/50 to 20/200, final acuities were 20/40 or better in 19%, 20/50 to 20/200 in 44%, and worse than 20/200 in 37%. For eyes with an initial visual acuity of worse than 20/200 (of particular relevance to the present study), final acuities were 20/40 or better in 1.5%, 20/50 to 20/200 in 19%, and worse than 20/200 in 79%. Taking these percentages and applying them mathematically to the 20 eyes undergoing lamina puncture in this trial, an outcome of 20/50 to 20/200 would be predicted in 3.25 eyes of the 17 enrolled with a visual acuity worse than 20/200, and the identical final acuity in the 2 of the 3 eyes enrolled with a visual acuity in the 20/50 to 20/200 range as well. Consequently, the total of 5.25 eyes that would be projected to have a 20/50 to 20/200 visual acuity based on the natural history alone does not differ significantly from the 6 eyes with such visual acuity obtained after lamina puncture, and it must be concluded that lamina puncture for CRVO is not efficacious.

Other surgical approaches to the optic nerve have been proposed for CRVO, including external division of the scleral ring,[6,7] optic nerve sheath decompression,[8] and, most recently, RON.[3,9-16] Sectioning of the posterior scleral ring from an external approach for CRVO and other conditions was originally reported by Vasco-Posada.[6] He described treatment of 22 patients with total thrombosis of the central retinal vein, of whom 12 were older than 40 years. Apart from 2 patients in whom no response to treatment was observed, all other visual results were in the 20/20 to 20/50 range. The identical technique was reevaluated by Arciniegas,[7] who treated 44 patients with CRVO, of whom 25 were older than 50 years and only 13 were older than 60 years. He found that the visual acuity was unchanged postoperatively in 48% and decreased in 13% but was improved in 39% of the patients. Both of these series describing scleral ring surgery are difficult to interpret because of inclusion of patients with widely different ages and CRVO severity, and this technique has not been subsequently adopted. Dev and Buckley[8] explored optic nerve sheath decompression in 8 patients (mean age, 65 years) with progressive CRVO, and they found an improved mean visual acuity of 20/160 to 20/70 at 1 year. These researchers believed that these results exceeded the natural history, but this conclusion has not been clearly established.

Opremcak and coworkers[3] reported the initial results of a pilot series of 11 patients treated with RON, and substantial improvement was noted, with visual acuity improving by 2 or more lines in 7 of 11 patients, and with 2 patients achieving a final visual acuity of 20/40 from an initial visual acuity of 20/400 for both eyes. The researchers claimed that these results exceeded the expected natural history, and the procedure has been used and evaluated by

Table 2. Published Visual Acuity Results in 71 Eyes After Radial Optic Neurotomy for CRVO*

Source	Preoperative Visual Acuity	Postoperative Visual Acuity
Opremcak et al,[3] 2001 (11 eyes)	NLP	CF
	20/400	20/40
	HM	LP
	20/400	20/40
	20/400	20/400
	20/400	CF
	20/400	20/60
	20/400	20/70
	CF	20/100
	CF	20/60
	HM	20/100
Garcia-Arumi et al,[9] 2003 (14 eyes)	20/1000	20/400
	20/400	20/400
	20/400	20/300
	20/350	20/250
	20/300	20/200
	20/200	20/80
	20/200	20/50
	20/200	20/40
	20/125	20/50
	20/125	20/50
	20/400	20/100
	20/400	20/80
	20/400	20/400
	20/200	20/25
Friedman,[10] 2003 (2 eyes)	20/200	20/100
	20/300	20/80
Weizer et al,[11] 2003 (4 eyes)	5/200	20/80
	1/200	5/200
	6/200	1/200
	5/200	20/250
Williamson et al,[12] 2003 (4 eyes)	CF	CF
	HM	CF
	CF	20/200
	CF	20/200
Patelli et al,[13] 2004 (5 eyes)†	20/640	20/400
	20/640	20/400
	20/640	20/400
	20/640	20/400
	20/640	20/400

(continued)

Table 2. Published Visual Acuity Results in 71 Eyes After Radial Optic Neurotomy for CRVO* (cont)

Source	Preoperative Visual Acuity	Postoperative Visual Acuity
Nomoto et al,[14] 2004 (15 eyes)	20/300	20/250
	20/100	20/100
	CF	20/250
	CF	CF
	HM	20/200
	20/200	20/200
	20/70	20/160
	HM	HM
	20/70	20/70
	20/100	20/50
	20/300	20/200
	20/100	20/25
	HM	20/400
	CF	20/400
	CF	20/70
Spaide et al,[15] 2004 (6 eyes)†	20/400	20/400
	20/400	20/400
	20/400	20/400
	20/400	20/400
	20/400	20/400
	20/400	20/400
Martinez-Jardon et al,[16] 2005 (10 eyes)	HM	LP
	HM	HM
	20/300	20/300
	HM	20/500
	20/300	20/200
	20/300	20/400
	HM	HM
	20/500	HM
	HM	HM
	20/500	20/500

Abbreviations: CF, counting fingers; CRVO, central retinal vein occlusion; HM, hand motions; LP, light perception; NLP, no LP.
*The 8 series are listed in chronological order.
†The mean visual acuity is reported for all eyes.

others.[9-16] The rationale, mechanism of action, and overall efficacy of RON for CRVO have all been the subjects of controversy.[17-24] Several researchers[9,10,14,15] have commented on the development of chorioretinal shunt and collateral vessels at the disc, and have suggested that the development of such vessels, and not mechanical relaxation of a putative compartment syndrome, is a possible mechanism for any RON effect. Others[9,11,13,15,16] have noted a tendency for resolution of macular thickening following the procedure, but overall improved visual acuity results have not been convincingly demonstrated.

An analysis may be made for results after RON in the published literature, as was performed previously for the lamina puncture, compared with natural history projections by CVOS data. Major series[3,9-16] to date include 71 cases; these results are collected in **Table 2**. These 71 eyes include 13 with an initial visual acuity in the 20/50 to 20/200 range and 58 with an acuity worse than 20/200. Reported final acuities include 5 eyes with a visual acuity of 20/40 or better, 26 with a visual acuity of 20/50 to 20/200, and 40 with a visual acuity worse than 20/200; for simplicity, these results may be expressed as 5/26/40 across the 3 CVOS visual acuity categories. Projected results based on CVOS data would indicate corresponding final results of +3/17/50, which seems parallel to the results with RON that have been reported. The parallel is further strengthened by the fact that some of the RON eyes in reported series were documented to have had preoperative vitreous hemorrhage,[3] which would have improved with the vitrectomy alone, and others had intervention for cataract,[12] which would also have improved results not related to the RON portion of the procedure. It is also possible that vitrectomy itself offers some modest improvement in visual acuity because of postulated benefits on macular edema and retinal oxygenation, as has been demonstrated in experimental models of branch retinal vein occlusion.[25] Taken as a group, the available evidence in these nonrandomized pilot studies strongly suggests that RON for CRVO is not an effective treatment for visual restoration.

Substantial complications were noted in the present series in eyes undergoing lamina puncture. Six eyes developed iris neovascularization, and 4 of these progressed to neovascular glaucoma, with poor visual results despite multiple interventions. These neovascular complications were clustered in the subgroup of eyes with extensive preoperative ischemia. Postoperative vitreous hemorrhage developed in 3 eyes and required vitrectomy in 2. A postoperative retinal detachment developed and was repaired in 1 eye. Two eyes had postoperative endophthalmitis and were treated with intravitreal antibiotics; both of these eyes had visual outcomes consistent with other eyes in this series, and no specific factor for such a cluster of infections in this small series could be identified. Important complications have also been reported after RON. These include neovascularization of the iris/neovascular glaucoma,[3,11,16] choriovitreal neovascularization,[11] serous retinal detachment,[26] central retinal artery occlusion,[27] central retinal artery laceration,[16] visual field loss,[12] retinal detachment,[28] vitreous hemorrhage,[28] and choroidal neovascularization.[29]

Other strategies are being explored for CRVO, including intravitreal triamcinolone acetonide, which is being evaluated in several studies and is undergoing randomized prospective study in a large National Eye Institute–sponsored trial.[30] Similarly, treatment of CRVO with intravitreal anti–vascular endothelial growth factor agents, such as pegaptanib and ranibizumab, is ongoing in pilot and randomized trials, and results will be available soon. Central retinal vein occlusion remains a critically important cause of major visual loss, and merits our highest and most careful attention to ongoing research and treatment.

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Additional Information: Drs D'Amico and Lit are coinventors on a US patent for the lamina puncture blade, and participate in any future royalties under established Harvard University guidelines for faculty/corporate relationships.

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