Vitrectomy Outcomes in Eyes with Diabetic Macular Edema and Vitreomacular Traction

Diabetic Retinopathy Clinical Research Network Writing Committee on behalf of the DRCR.net*

Purpose: To evaluate vitrectomy for diabetic macular edema (DME) in eyes with at least moderate vision loss and vitreomacular traction.

Design: Prospective cohort study.

Participants: The primary cohort included 87 eyes with DME and vitreomacular traction based on investigator's evaluation, visual acuity 20/63–20/400, optical coherence tomography (OCT) central subfield >300 microns and no concomitant cataract extraction at the time of vitrectomy.

Methods: Surgery was performed according to the investigator's usual routine. Follow-up visits were performed after 3 months, 6 months (primary end point), and 1 year.

Main Outcome Measures: Visual acuity, OCT retinal thickening, and operative complications.

Results: At baseline, median visual acuity in the 87 eyes was 20/100 and median OCT thickness was 491 microns. During vitrectomy, additional procedures included epiretinal membrane peeling in 61%, internal limiting membrane peeling in 54%, panretinal photocoagulation in 40%, and injection of corticosteroids at the close of the procedure in 64%. At 6 months, median OCT central subfield thickness decreased by 160 microns, with 43% having central subfield thickness <250 microns and 68% having at least a 50% reduction in thickening. Visual acuity improved by ≥10 letters in 38% (95% confidence interval, 28%–49%) and deteriorated by ≥10 letters in 22% (95% confidence interval, 13%–31%). Postoperative complications through 6 months included vitreous hemorrhage (5 eyes), elevated intraocular pressure requiring treatment (7 eyes), retinal detachment (3 eyes), and endophthalmitis (1 eye). Few changes in results were noted between 6 months and 1 year.

Conclusions: After vitrectomy performed for DME and vitreomacular traction, retinal thickening was reduced in most eyes. Between 28% and 49% of eyes with characteristics similar to those included in this study are likely to have improvement of visual acuity, whereas between 13% and 31% are likely to have worsening. The operative complication rate is low and similar to what has been reported for this procedure. These data provide estimates of surgical outcomes and serve as a reference for future studies that might consider vitrectomy for DME in eyes with at least moderate vision loss and vitreomacular traction.

Financial Disclosure(s): Proprietary or commercial disclosure may be found after the references.
Ophthalmology 2010;117:1087–1093

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Diabetic macular edema (DME) is a disorder of major and increasing public health importance throughout the world.[1–4] The only proven effective therapy for DME at this time is focal/grid laser photocoagulation as performed in the Early Treatment Diabetic Retinopathy Study (ETDRS).[5–7] However, even with photocoagulation, some eyes have persistent edema and visual loss. The Diabetic Retinopathy Clinical Research Network (DRCR.net) has shown that although approximately one third of eyes treated with focal/grid photocoagulation improved by ≥10 letters at 2 years, approximately 20% lost ≥10 letters, and approximately 50% still had evidence of central edema at 2 years.[8] Other pharmacotherapeutic interventions are under investigation to determine if certain drugs, either alone or in combination with focal/grid laser, result in superior visual acuity outcomes compared with laser alone.

The vitreous has been implicated as a cause of macular edema in people with diabetes via several mechanical and physiologic mechanisms, all of which are postulated to lead to increased vascular permeability.[9–34] Suggested mechanisms include (1) destabilization of the vitreous by abnormal glycation and cross-linking of vitreal collagen, leading to traction on the macula, (2) accumulation and concentration of factors causing vasopermeability in the premacular vitreous gel, and (3) accumulation of chemoattractant factors in the vitreous, leading to cellular migration to the posterior hyaloid, contraction, and macular traction.[9,10,12,14–16,19,23,24,27,28,30] The observation that release of mechanical traction on the macula with subsequent reduction in DME, either by spontaneous posterior vitreous detachment or with vitrectomy, lends support to this line of reasoning.[11,13,14,17,20,21,25,32] Furthermore, the evidence that vitrectomy produces improved retinal oxygenation,[28,29] taken together with the evidence that increased oxygenation can reduce DME,[35] suggests an additional physiologic advantage potentially conferred by vitrectomy.

A prospective observational protocol was developed by the DRCR.net to evaluate visual and anatomic outcomes

ISSN 0161-6420/10/$–see front matter
doi:10.1016/j.ophtha.2009.10.040

after vitrectomy performed without concomitant cataract surgery in eyes with DME. A primary cohort was defined that included eyes that not only had vitreomacular traction based on clinical examination by their surgeon, but also had at least moderately impaired visual acuity and definite thickening within the central subfield on optical coherence tomography (OCT). This report describes the visual acuity and OCT outcomes in this primary cohort.

Methods

The study was conducted by the DRCR.net at 50 clinical sites in the United States. The protocol and Health Insurance Portability and Accountability Act-compliant informed consent forms were approved by multiple institutional review boards. Each subject gave written informed consent to participate in the study. The study is listed on www.clinicaltrials.gov, under identifier NCT00709319 and the protocol is available on the DRCR.net website (www.drcr.net; accessed September 2, 2009). This paper reports data collected through the 6-month primary outcome phase of the protocol with additional safety data collected through the final follow-up at 1 year. A future report will evaluate factors associated with the outcome of vitrectomy in 241 eyes with DME, including the 87 eyes in the primary cohort described in this report.

Study Population

Eligible participants had to be ≥18 years old with type 1 or type 2 diabetes. Data were collected on 241 individuals who had a vitrectomy as treatment for DME. The current study included a predefined subset of eyes that met the following criteria for the primary analysis: (1) vitreomacular traction as the indication for vitrectomy based on investigator assessment, (2) best-corrected visual acuity of 20/63–20/400 (electronic [E]-ETDRS letter score between 19 and 63), (3) retinal central subfield thickness >300 microns on Zeiss Stratus OCT (Carl Zeiss Meditec, Dublin, CA), and (4) cataract extraction not performed in conjunction with vitrectomy. Major exclusion criteria included (1) a history of macular photocoagulation, intravitreal corticosteroids or other treatment for DME within 3.5 months before enrollment, (2) peripheral scatter photocoagulation within 4 months before enrollment, (3) prior pars plana vitrectomy, (4) other major ocular surgery (including cataract extraction, scleral buckle, or other intraocular surgery) within 6 months before enrollment or anticipated within the 6 months after enrollment, or (5) YAG capsulotomy performed within 2 months before enrollment. Only 1 eye per participant could be enrolled.

Intervention

A standard pars plana vitrectomy was performed according to the investigator's usual routine. General guidelines included (1) 3 pars plana sclerotomies, (2) removal of the vitreous gel with peeling of the posterior hyaloid, if attached, and removal of the peripheral vitreous leaving only a small residual vitreous skirt, (3) engagement and peeling of epiretinal membranes judged visually significant, (4) examination of the peripheral retina at the close of the procedure, and (5) treatment of peripheral breaks with laser or cryotherapy. Additional collected information included gauge of vitrectomy instrumentation and other maneuvers performed, such as removal of the internal limiting membrane, use of agents to improve visualization of membranes, use of corticosteroids at the close of the procedure, and use of concomitant laser.

Follow-up Visits

Follow-up visits were performed at 3, 6, and 12 months within prespecified time windows. At each visit, an interval history was elicited, which included medical and surgical treatment of the study eye. At baseline and at each follow-up visit, best-corrected visual acuity was measured at 3 meters by a certified tester using an electronic procedure based on the ETDRS method (E-ETDRS).[36] The OCT images were obtained through a dilated pupil by a certified operator using the Zeiss Stratus OCT. The OCT scans were 6 mm long and included the 6 radial line pattern (fast macular scan option with Zeiss Stratus OCT) for quantitative measures and the cross-hair pattern (6–12 to 9–3 o'clock) for qualitative assessment of retinal morphology. Seven-field fundus photographs were obtained at baseline, 6, and 12 months.

The OCT images and fundus photographs were sent to the DRCR.net Reading Center at the University of Wisconsin—Madison for grading. Fourteen percent of the 87 baseline scans and 27% of the 155 follow-up scans were judged by the Reading Center to have inaccurate automated central subfield thickness measurements. In these cases, center point thickness was measured manually and the resultant value used to impute a value for the central subfield thickness (based on a correlation of the two measures of 0.99) as previously published.[7] Grading of fundus photographs for proliferative diabetic retinopathy (PDR) included both active neovascularization and prior panretinal photocoagulation (PRP) even without active neovascularization.

Additional Treatment for Diabetic Macular Edema

By protocol, injectable medications, focal laser, or other treatments for DME were to be deferred until completion of the 6-month visit. Between 6 and 12 months, treatment of DME was at investigator discretion.

Statistical Methods

A sample size was planned to be approximately 100 eyes that met all the criteria for the primary cohort. This was a convenience sample based on the expected number of subjects to be enrolled in a given time period. However, based on actual recruitment, the 100 subject goal was not reached.

The main outcomes were best-corrected visual acuity and OCT-measured central subfield thickness at 6 months. The visual acuity letter score was used for analyses; approximate Snellen equivalents are presented to facilitate interpretation. Signed-rank tests were performed on changes in central subfield thickness from baseline to follow-up visits. Missed visits were excluded from the analysis. SAS version 9.1 (SAS Inc, Cary, NC) was used for all analyses.

Results

Between 2005 and 2008, 87 subjects who met the primary cohort criteria for this study were enrolled at 35 sites. The baseline characteristics are presented in Table 1. The presence of vitreomacular traction, as identified by the investigator, was a requirement for inclusion in this cohort. However, epiretinal membranes were only identified as "probably" or "definitely present" by the investigator in 71% of study eyes. Presumably, the vitreomacular traction was not associated with a clinically apparent epiretinal membrane in the other 29%. In 27 eyes (31%), the surgeon listed "unresponsive to other therapies" as an additional indication for the vitrectomy. Surgery characteristics are presented in Table 2. Visit completion was 95% at the 3-month visit, 93% at the

Table 1. Baseline Characteristics (n = 87)

Gender, female, n (%)	39 (45)
Age (yrs)	
Median	66
25th, 75th percentile	60, 72
Race, n (%)	
White	69 (79)
African American	7 (8)
Hispanic	5 (6)
Other	6 (7)
Diabetes type, n (%)	
Type 1	14 (16)
Type 2	73 (84)
Duration of diabetes (yrs)	
Median	20
25th, 75th percentile	12, 25
HbA1c (%)	
Median	7.1
25th, 75th percentile	6.7, 7.9
Prior treatment for DME,* n (%)	51 (59)
Macular photocoagulation	38 (44)
Intravitreal corticosteroid	26 (30)
Peribulbar corticosteroid	3 (3)
Other	4 (5)
E-ETDRS Visual Acuity letter score (Snellen equivalent)	
Median	52 (20/100)
75th, 25th percentile	41, 58 (20/80, 20/160)
63–54 (20/63–20/80)	37 (43)
53–44 (20/100–20/125)	25 (29)
43–19 (20/160–20/400)	25 (29)
Central subfield thickness† (microns)	
Median	491
25th, 75th percentile	356, 586
301 to <400	28 (34%)
400 to <500	15 (18%)
500 to <600	24 (29%)
≥600	16 (19%)
Retinal volume (mm^3)	
Median	9.2
25th, 75th percentile	8.5, 11.8
Retinopathy severity,‡ n (%)	
Microaneurysms only	1 (1)
Mild/moderate NPDR	6 (8)
Moderate severe NPDR	14 (18)
Severe NPDR	4 (5)
PDR	51 (67)
Prior scatter photocoagulation, n (%)	39 (45)
Lens status, n (%)	
Phakic	37 (43)
Pseudophakic/aphakic	50 (57)
Epiretinal membranes present,‖ n (%)	
No	21 (24)
Probable	19 (22)
Definite	43 (49)
Cannot determine	4 (5)
Status of vitreous,‖ n (%)	
Attached	49 (56)
Partially attached	28 (32)
Detached	5 (6)
Uncertain	5 (6)
Reasons for vitrectomy,* n (%)	
Vitreomacular interface abnormality	87 (100)
Unresponsive to other therapies	27 (31)

DME = diabetic macular edema; ETDRS = Early Treatment Diabetic Retinopathy Study; HbA1C = glycosylated hemoglobin; NPDR = nonproliferative diabetic retinopathy; PDR = proliferative diabetic retinopathy.
*Same subjects could be listed for multiple reasons.
†Missing for 4 eyes.
‡Missing for 11 eyes.
‖From investigator's observations at enrollment.

Table 2. Surgery Characteristics (n = 87)

Characteristic	n (%)
Vitrectomy system	
19/20 gauge	35 (40)
25 gauge	43 (49)
23 gauge	9 (10)
Epiretinal membrane peeled	53 (61)
Internal limiting membrane removed	47 (54)
Agents used to improve visualization*	52 (60)
Triamcinolone acetonide	30 (34)
Indocyanine green	24 (27)
Trypan blue	2 (2)
Laser used*†	48 (55)
Focal to break(s)	14 (16)
PRP, no prior PRP	19 (22%)
PRP, prior PRP	16 (18%)
Focal/grid to DME	4 (5%)
With endoprobe	21 (24%)
With laser indirect ophthalmoscope	7 (8%)
Other‡	4 (5%)
Peripheral cryotherapy given	
No	80 (92)
Yes, not treated for breaks	6 (7)
Yes, treated for breaks	1 (1)
Corticosteroids used at close*	56 (64)
Intravitreal	37 (43)
Peribulbar	4 (5)
Subtenon's	13 (15)
Subconjunctival	18 (21)
Lens removed	0
Posterior capsulotomy performed	7 (8)
Epiretinal membrane present	
No	31 (36)
Probable	13 (15)
Definite	43 (49)
Status of vitreous	
Attached	59 (68)
Partially attached	22 (25)
Detached	5 (6)
Uncertain	1 (1)
Complications from vitrectomy	6 (7)
Anesthesia complications	0
Surgical complications	6 (7)

PRP = panretinal photocoagulation.
*Same subjects could be listed for multiple categories.
†Laser technique was not recorded on the study data form in all cases.
‡Includes scatter over peripheral schisis (n = 1) and barrier laser (n = 3).

6-month visit, and 90% at the 12-month visit. Four subjects died (2 before and 2 after the 6-month visit) and four subjects dropped out of the study (2 before and 2 after the 6-month visit).

Visual Acuity

Median visual acuity was approximately 20/100 at baseline, 3 months, and 6 months. At 3 months, 22% of eyes had experienced an improvement of 10 or more letters from baseline (Fig 1). Conversely, 23% of the eyes had worsened by ≥10 letters from baseline. At 6 months, 38% of eyes were improved by ≥10 letters (95% confidence interval [CI], 28%–49%) and 22% had worsened by ≥10 letters (95% CI, 13%–31%). Among the 18 eyes that improved by ≥10 letters from baseline to 3 months, none had additional improvement of at least ≥10 letters from 3 to 6 months. One phakic eye lost 16 letters from 3 to 6 months. Among the 19

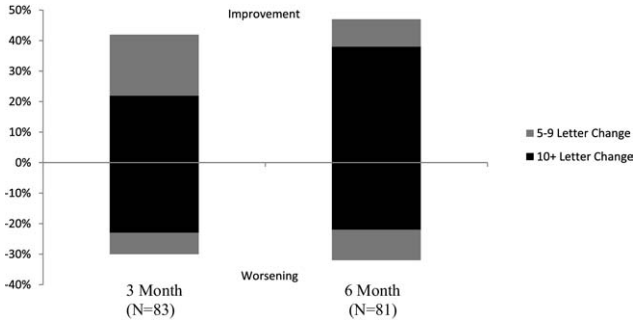

Figure 1. Distribution of change in visual acuity from baseline.

eyes that lost ≥10 letters from baseline to 3 months, 3 eyes (16%) lost an additional ≥10 letters from 3 to 6 months. All 3 of these eyes still were phakic at 6 months. Also, among the eyes that lost ≥10 letters from baseline to 3 months, 9 (47%) gained ≥10 letters from 3 to 6 months, including 3 eyes that underwent cataract surgery between 3 and 6 months after vitrectomy.

Retinal Thickness

Median retinal central subfield thickness at baseline was 491 microns (interquartile range, 356–586 microns). At both 3 and 6 months, there was a median 160-micron decrease from baseline in the central subfield thickness ($P<0.001$; Fig 2). At 3 months, 82% and 68% had a decrease in thickness from baseline of 50 and 100 microns or more, respectively, whereas only 3 (4%) eyes experienced an increase in thickness of ≥50 microns. At 6 months, the reduction in thickness from baseline of 50 and 100 microns or more were seen in 82% and 66% of the eyes, respectively, whereas 68% decreased in thickening by ≥50%. Reduction of central subfield thickness to <250 microns occurred in 33 eyes (43%). Eyes with greater central subfield thickness at baseline tended to have a greater reduction in thickness after surgery ($P<0.001$). Results for OCT-measured retinal volume were similar to the central subfield results (data not shown).

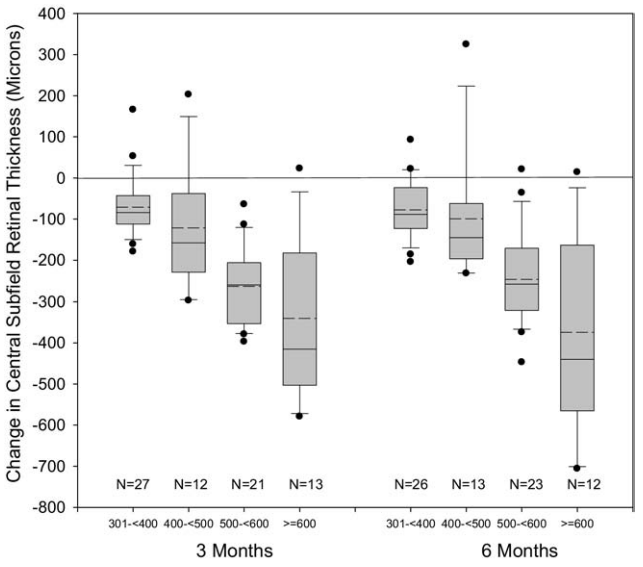

Figure 2. Distribution of change in optical coherence tomography (OCT) central subfield thickness in categories according to baseline thickness. Box-whisker plot demonstrating mean (dashed horizontal line), median (solid horizontal line), 25–75th percentiles (extremes of the box), 10–90th percentiles (whiskers), and 5–95th percentiles (solid circles) of change in OCT central subfield.

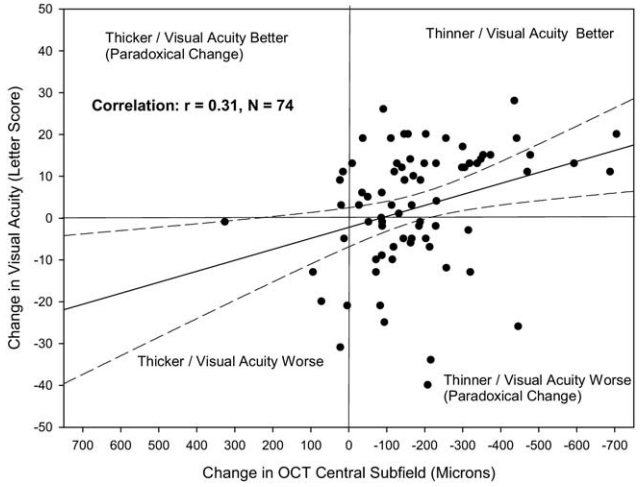

Figure 3. Comparison of change in optical coherence tomography (OCT) central subfield and change in visual acuity from baseline to 6 months. The solid line represents the regression line and the dotted lines represent the 95% confidence interval for the mean.

From baseline to 3 months, 55 (81%) of 68 eyes with OCT measurements at baseline, 3 months, and 6 months had a reduction in OCT central subfield of ≥50 microns, 10 (15%) changed by <50 microns, and 3 (4%) worsened by ≥50 microns. Among the 55 eyes that improved by ≥50 microns from baseline to 3 months, 8 (15%) improved by ≥50 more microns from 3 months to 6 months, 36 (65%) changed by <50 microns, and 11 (20%) worsened by ≥50 microns. Among the 10 eyes that changed by <50 microns from baseline to 3 months, 8 changed by <50 microns from 3 months to 6 months and 2 worsened by ≥50 microns. Among 3 eyes that worsened by ≥50 microns from baseline to 3 months, 2 improved by ≥50 microns between 3 and 6 months and 1 changed by <50 microns.

The correlation between changes in OCT central subfield thickness from baseline to 6 months and changes in visual acuity during this time was −0.31 (Fig 3). Except for cases with very large decreases in central subfield thickness (>350 microns), a given decrease in OCT was associated with a wide range of changes in visual acuity.

Postoperative Complications and Treatments

Of the 87 subjects, 16 (18%) experienced postoperative complications in the first 6 months (Table 3). Of greatest importance, 4 eyes developed a vitreous hemorrhage, 2 eyes developed a retinal detachment, 1 eye developed endophthalmitis, and 1 eye developed vitreous hemorrhage and retinal detachment; 4 of these 8 eyes lost ≥10 letters from baseline to 6 months. One additional eye had a retinal detachment after the first 6 months.

Twenty-eight (78%) of 36 eyes that were phakic at the time of vitrectomy (by definition, the cohort did not include eyes that had cataract surgery at the time of vitrectomy) and completed 6-month visit developed lens changes by 6 months based on investigator assessment, including 5 eyes that underwent cataract surgery by 6 months (Table 4). Cataract surgery was performed in 12 eyes between 6 and 12 months, for a total of 17 (46%) of the 37 eyes that were phakic before vitrectomy having cataract surgery within 12 months after vitrectomy.

Table 3. Postoperative Complications (0–6 months; n = 87)*

Postoperative Complications	n (%)
Total	16 (18)
Vitreous hemorrhage	5 (6)
Development of additional vitreomacular interface abnormalities	2 (2)
Elevated IOP requiring treatment	7 (8)
Retinal detachment	3 (3)
Retinal tear	0
Endophthalmitis	1 (1)
Macular ischemia	0
Double vision	2 (2)
Lamella hole	1 (1)
Choroidal effusion	1 (1)
Other	2 (2)

IOP = intraocular pressure.
*Same subject could have >1 complication.

Postoperatively, no eye had PRP performed, 4 eyes had macular laser performed, 2 eyes had intravitreal injections of corticosteroid, and 2 eyes received injections of antivascular endothelial growth factor within the first 6 months.

Twelve-Month Outcomes

Between 6 and 12 months, 20 (26%) of 78 study eyes that completed the 12-month visit received some form of treatment for DME and 58 (74%) did not, including 10 eyes that received laser (including 1 eye listed below that also received intravitreal corticosteroids), 8 eyes that received intravitreal corticosteroids (including 1 eye that also received laser listed above and 1 eye that also received peribulbar steroids listed below), 2 eyes that received peribulbar steroids (including 1 eye noted above that also received intravitreal corticosteroids and 1 eye that listed below that also received intravitreal bevacizumab), and 3 eyes that received intravitreal bevacizumab (including 1 eye noted above that also received peribulbar steroids).

At 1 year, median visual acuity was approximately 20/80 (interquartile range, 20/50–20/160), with 30 (38%) of the 78 eyes having improved by ≥10 letters from the preoperative visual acuity and 20 (26%) having worsened by ≥10 letters. Of the 29 eyes that had improved by ≥10 letters from baseline at 6 months, 22 still had 10 more letters improvement from baseline to 1 year, and only 1 worsened by ≥10 letters from baseline to 1 year. Of the 17 eyes that lost ≥10 letters from baseline at 6 months, 12 still had lost ≥10 letters from baseline at 1 year, and only 1 had improved by ≥10 letters from baseline to 1 year.

Median OCT central subfield thickness at 12 months was 256 microns (interquartile range, 205–340), with the median change from the preoperative OCT measurement being a decrease in thickness of 153 microns (interquartile range, 286–61). In 33 (47%) of the 70 eyes with a 12-month OCT, central subfield thickness was <250 microns.

Discussion

In this prospective study of 87 eyes undergoing vitrectomy for DME associated with at least moderate visual loss and investigator-determined vitreomacular traction, the median change in visual acuity at 6 months was an improvement of 3 letters, with visual acuity improving by ≥10 letters from baseline to 6 months in 38% (95% CI, 28%–49%) and worsening by ≥10 letters in 22% (95% CI, 13%–31%). Reduction in OCT central subfield thickness to <250 microns occurred in almost half, and most eyes had a reduction of thickening of ≥50%. As one might expect, eyes with greater retinal thickness at baseline tended to have greater reduction in retinal thickness after surgery, likely reflecting, at least in part, a floor effect on the amount of thickness reduction that can occur when the macula is only mildly thickened. Few changes in results were noted between 6 months and 1 year, even though additional procedures to treat DME were performed in 20 subjects and cataract surgery in 12 subjects.

With respect to safety, the operative complication rate, including vitreous hemorrhage, retinal detachment, or other serious adverse events, was similar to what has been reported for this procedure.[9,10,12–19,22–27,30–34,37] Most phakic eyes developed lens changes by 6 months after vitrectomy, which may account for some decrease in visual acuity between 3 and 6 months.

The surgical techniques recorded seem to mirror recent vitreoretinal surgical practice trends in North America,[38] characterized by the increased use of smaller gauge vitrectomy systems, injection of triamcinolone acetate and other agents to aid in intraoperative visualization of membranes, and widespread use of epiretinal and internal limiting membrane peeling in the treatment of patients with macular disorders. However, the relative benefits or risks of these preferences on visual acuity outcomes remain unknown.

There are several strengths to this study, including the prospective collection of visual acuity and anatomic out-

Table 4. Investigator Assessment of Lens Changes from Baseline to 6 Months in Eyes Phakic at Baseline (n = 36†)

	6 Months			
Baseline	*Absent*	*Present < Standard*	*Present ≥ Standard*	*Cataract Extraction*
Nuclear sclerosis (n = 36)				
Absent	1 (3%)	1 (3%)*	0*	1 (3%)*
Present < standard	0	13 (36%)	8 (22%)*	4 (11%)*
Present ≥ standard	0	2 (6%)	6 (17%)	0*
Posterior subcapsular cataract (n = 36)				
Absent	15 (42%)	6 (17%)	3 (8%)	4 (11%)
Present < standard	1 (3%)	4 (11%)	1 (3%)	1 (3%)
Present ≥ standard	0	0	1 (3%)	0
Cortical cataract (n = 36)				
Absent	12 (33%)	6 (17%)*	0*	3 (8%)*
Present < standard	4 (11%)	7 (19%)	2 (6%)*	2 (6%)*
Present ≥ standard	0	0	0	0*
Highest grade among all 3 types of lens opacity				
Absent	1 (3%)	0	0	1 (3%)
Present < standard	0	14 (39%)	8 (22%)	4 (11%)
Present ≥ standard	0	2 (6%)	6 (17%)	0

*Cataract progression. By definition of the cohort, no eyes had cataract extraction at the time of vitrectomy.
†One eye that was phakic at baseline did not complete the 6-month visit.

comes after vitrectomy for DME in the presence of vitreoretinal traction. This is also the first large surgical series to have OCT measurements at baseline and during follow-up. Other strengths of this study include uniform entry criteria and >90% follow-up through 6 months. Although this study did not mandate standardizing the precise surgical maneuvers used, data regarding the details of surgery were acquired in a standardized fashion.

A potential study weakness is that the assessment of the presence or absence of vitreomacular traction was made by the individual investigators based on their clinical judgment, without standardized criteria and without central reading center assessment or independent confirmation. However, the lack of centralized assessment may have more generalizability when applying these results to clinical practice, where there generally is no independent confirmation of vitreomacular traction.

The lack of a concurrent control group also is a study weakness. Our study was designed as a prospective cohort investigation rather than as a randomized trial of vitrectomy versus laser or observation because of a lack of equipoise on the part of the participating surgeons, who were uncomfortable randomizing eyes with traction and decreased vision to a nonvitrectomy trial arm.

The study protocol to defer macular photocoagulation until after 6 months may also have affected the visual acuity and retinal thickness outcomes. In addition, approximately two thirds of these cases had PDR. It is possible that the visual outcome for cases with this degree of vascular compromise or retinal ischemia associated with PDR is worse than DME treatments in the absence of PDR. Also, many of these eyes may have had limited potential for improvement and a relatively high chance of losing vision due to complications of PDR or associated capillary nonperfusion in the macula. Even though approximately 40% of the study eyes received PRP intraoperatively, which in the setting of preexisting DME might have exacerbated the macular edema, very few eyes experienced an increase in edema. Among the eyes that received PRP, the average change in OCT from baseline to 6 months seemed to be similar to the average change in eyes that did not receive PRP. An additional consideration may be that eyes in the study had relatively poor visual acuity (median 20/100) and a relatively thickened macula (median central subfield thickness, 491 microns) at the time of vitrectomy. Perhaps earlier intervention in these compromised eyes would have improved visual results.

There are few reports in the literature with which to compare these DRCR.net results. Hikichi et al[39] reported a series of 53 consecutive nondiabetic eyes followed with vitreomacular traction in the pre-OCT era, 64% of which lost ≥2 lines of vision over the course of follow-up. In the absence of a spontaneous peripheral vascular disease in this series, 87% lost vision at the final visit. Since the report by Smiddy et al[40] in 1988 describing successful surgery for nondiabetic eyes with macular traction and visual decrease, many surgeons have elected to operate rather than to follow patients with evident vitreomacular traction and significant visual impairment. The report by Lewis et al[17] in 1992 and subsequent series extended this surgical indication to include diabetic patients with evidence of tangential hyaloidal traction. This study did not examine the impact of vitrectomy for DME when traction was not identified by the investigator. Reports in the literature on vitrectomy for such eyes, in the absence of traction, include mixed visual acuity results. Although some studies suggested positive outcomes,[9,14,16,30,33] recent studies have shown anatomic but not visual improvement after surgery.[10,19,24]

In summary, this report adds prospective visual acuity and OCT data to our understanding of the effect of vitrectomy on DME in eyes with a visual acuity of 20/63–20/400 in the presence of vitreomacular traction and central subfield thickening confirmed on OCT, when cataract surgery is not performed at vitrectomy. Vitrectomy performed for this indication with the techniques reported herein usually resulted in a reduction in macular thickening. Visual acuity results were less consistent with some eyes improving (estimated between 28% and 49%) and some eyes worsening (estimated between 13% and 31%). Whether vitrectomy provides an improvement over other therapies or over the natural history of DME in this setting requires further investigation.

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Footnotes and Financial Disclosures

Originally received: July 10, 2009.
Final revision: October 20, 2009.
Accepted: October 23, 2009.
Available online: March 17, 2010. Manuscript no. 2009-932

Financial Disclosure(s):
A complete list of all DRCR.net investigator financial disclosures can be found at www.drcr.net.

Supported through a cooperative agreement from the National Eye Institute and the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Department of Health and Human Services EY14231, EY14269, EY14229.

Dr Neil M. Bressler – financial relationships – grants to investigators at The Johns Hopkins University are negotiated and administered by the institution which receives the grants, typically through the office of Research Administration. Individual investigators who participate in the sponsored project(s) are not directly compensated by the sponsor, but may receive salary or other support from the institution to support their effort on the project(s).

Dr Neil Bressler is Principal Investigator for the following: Allergan, Bausch & Lomb, Bristol-Meyers Squibb, Carl Zeiss Meditec, EMMES Corporation, Genentech, Lumenis, Notal Vision, Novartis, Othera, QLT, Regeneron, Steba Biotech.

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However, we do not believe that any of these constitutes a financial conflict of interest for this manuscript.

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Sites are listed in order by number of subjects enrolled into the study. The number of subjects enrolled is noted in parenthesis preceded by the site location and the site name. Personnel are listed as (I) for Investigator, (C) for Coordinator, (V) for Visual Acuity Tester and (P) for Photographer.

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