

**INTERNATIONAL CLINICAL DIABETIC RETINOPATHY
DISEASE SEVERITY SCALE
DETAILED TABLE**

Proposed Disease Severity Level	Findings Observable upon Dilated Ophthalmoscopy	Derivation from ETDRS Levels	Risk Assessment	Management Options*
No apparent Retinopathy	€ No abnormalities	Levels 10: DR absent		Optimize medical therapy of glucose, blood pressure and lipids
Mild Non-Proliferative Diabetic Retinopathy	Microaneurysms only	Level 20: Very mild NPDR		Optimize medical therapy of glucose, blood pressure and lipids
Moderate Non-proliferative Diabetic Retinopathy	More than just microaneurysms but less than Severe NPDR	Levels 35,43: moderate NPDR less than 4:2:1 Level 47: moderate NPDR less than 4:2:1	One year early PDR: 5.4 – 11.9% One year high risk PDR: 1.2-3.6% One year early PDR 26.3% One year High Risk PDR: 8.1%	Refer to an ophthalmologist Optimize medical therapy of glucose, blood pressure and lipids Refer to an ophthalmologist Optimize medical therapy of glucose, blood pressure and lipids
Severe Non-Proliferative Diabetic Retinopathy	Any of the following: € Extensive (>20) intraretinal hemorrhages in each of 4 quadrants € Definite venous beading in 2+ quadrants € Prominent IRMA in 1+ quadrant € <u>And no</u> signs of proliferative retinopathy	53A-E: severe to very severe NPDR, 4:2:1 rule	One year risk for early PDR: 50.2% (severe NPDR) One year High Risk PDR: 14.6% (severe NPDR) – 45.0% (very severe NPDR)	Consider scatter (panretinal) laser treatment for patients with type 2 diabetes Optimize medical therapy of glucose, blood pressure and lipids
Proliferative Diabetic Retinopathy	One or more of the following: € Neovascularization € Vitreous/preretinal hemorrhage	Levels 61, 65, 71,75, 81,85: PDR, high-risk PDR, very severe or advanced PDR		Strongly consider scatter (panretinal) laser treatment, without delay for patients with vitreous hemorrhage or neovascularization within one disc diameter of the optic nerve head Optimize medical therapy of glucose, blood pressure and lipids

* These management options are provided as general practice patterns of care. Individualized treatment plans will vary, based on several clinical considerations and factors, based on the patient's circumstances, risk factors, systemic condition, etc. There are many modifiers or risk factors not included in this classification, but which are important in risk of disease progression and in managing individual patients. These factors should be taken into account by the clinician in decisionmaking, and in informing the patient and primary care physician/diabetologist.

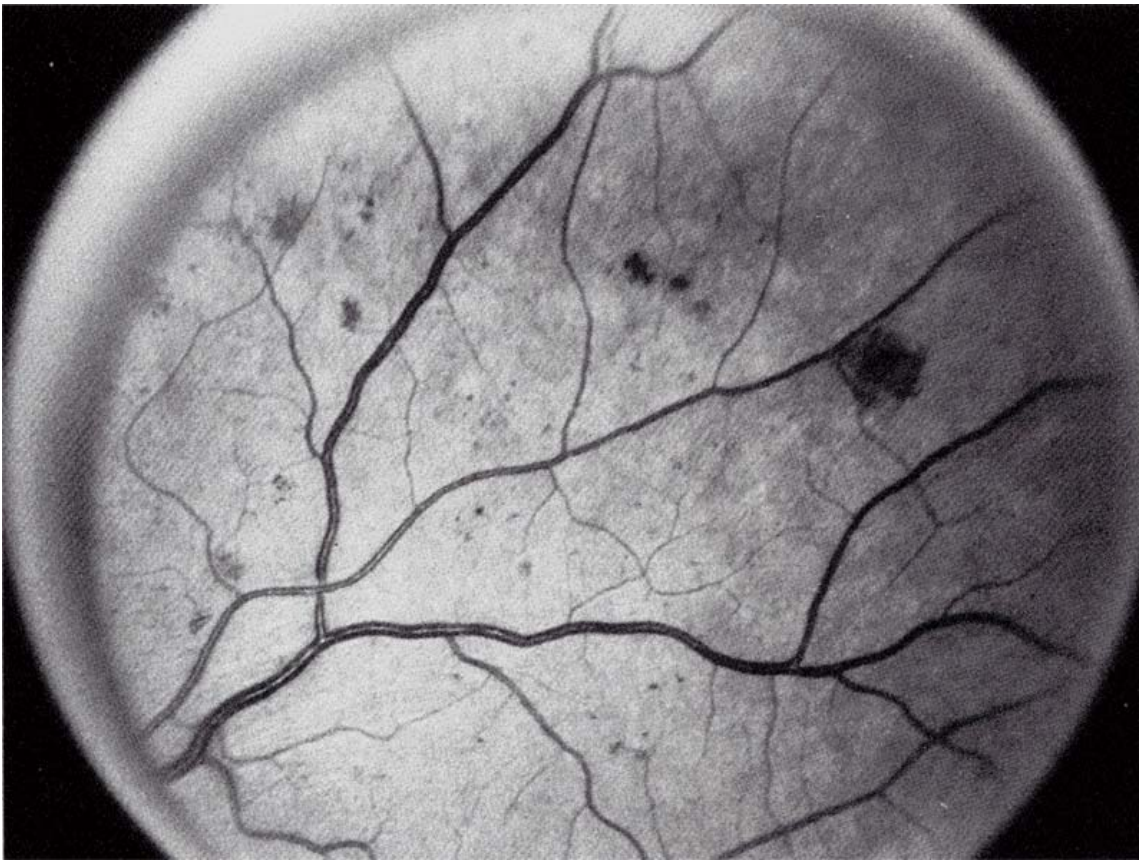


PHOTO 2A: Hemorrhages of this severity in 4 quadrants = “severe NPDR”.



PHOTO 8A: IRMA of this severity in 1 quadrant = “Severe NPDR”

Color Diabetic Grading Standard Photographs



Standard 2A-left



Standard 2A-right



Standard 8A-left



Standard 8A-right

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Detailed Discussion of Treatment Recommendations (based on AAO Diabetic Retinopathy Preferred Practice Pattern, 1998)

Normal NPDR

The patient with a normal retinal exam should be re-examined annually because within 1 year, 5% to 10% of patients who are initially normal will develop diabetic retinopathy. Existing retinopathy will worsen by a similar percentage.

Laser surgery, color fundus photography, and fluorescein angiography are not indicated.

Mild NPDR

Moderate NPDR

Patients with retinal microaneurysms and hard exudates or other abnormalities should have a repeat examination within 6 to 12 months, because disease progression is common. In one study of Type 1 patients, 16% with mild retinopathy (hard exudates and microaneurysms only) progressed to proliferative stages within 4 years.

Laser surgery and fluorescein angiography are not indicated for this group of patients. Color fundus photography is not particularly helpful as a baseline for future comparison

Severe NPDR

The categories of Severe NPDR, very severe NPDR and non high-risk PDR are combined for discussion because the ETDRS data showed their similar clinical course, and subsequent recommendations for treatment are similar. In eyes with severe NPDR, the risk of progression to proliferative disease is high. Half of the patients with severe NPDR will develop PDR within 1 year, and 15% will be high-risk PDR. For patients with very severe NPDR, the risk of developing PDR within 1 year is 75%, and 45% will be high-risk PDR. Therefore, these patients should be re-examined within 3 to 4 months.

The value of laser surgery for this group of patients was studied by the ETDRS. The ETDRS compared early panretinal photocoagulation with deferral of photocoagulation, defined as careful follow-up (at 4-month intervals) and prompt panretinal photocoagulation if progression to high-risk PDR occurred. Although the study did not provide definitive guidelines, the ETDRS suggested that panretinal photocoagulation is not recommended in eyes with mild or moderate NPDR, provided follow-up can be maintained. When retinopathy is more severe, panretinal photocoagulation should be considered and usually should not be delayed if the eye has reached the high-risk proliferative stage. Careful follow-up at 3 to 4 months is important: if the patient will not or cannot be followed closely, then laser photocoagulation may be indicated. If laser surgery is elected, full panretinal photocoagulation is a proven surgical technique that has been described in the literature. Laser photocoagulation may be indicated particularly when access to health care is difficult.

Recent additional analyses of visual outcome in ETDRS patients with severe NPDR to non-high-risk PDR suggest that the recommendation to consider scatter photocoagulation prior to the development of high-risk PDR is particularly appropriate for patients with Type 2 diabetes. The risk of severe vision loss or vitrectomy was reduced by 50% in those who were treated early compared with the deferral until high-risk PDR developed. For patients with Type 1 diabetes, the timing of the scatter photocoagulation will depend on the compliance with follow-up, status and response to treatment of the fellow eye, impending cataract surgery, and/or pregnancy.

The goal of laser treatment is to reduce the rate of visual loss. Preoperatively, the ophthalmologist should assess macular edema, discuss side effects of treatment and risks of visual loss, and obtain informed consent from the patient. If retrobulbar or peribulbar injections are used prior to photocoagulation, plans should be made to manage anticipated complications. Serious complications are rare, but they do occur. The ETDRS protocol provides detailed guidelines for treatment. Postoperatively, the eye should be patched if retrobulbar or peribulbar block was used. The patient should be seen at follow-up visits every 1 to 4 weeks until completion of panretinal photocoagulation, and then every 1 week to 4 months thereafter.

When scatter photocoagulation for severe NPDR to non-high-risk PDR is to be carried out in eyes with macular edema, it is preferable to perform focal photocoagulation before scatter photocoagulation. Based on clinical trials, there is evidence that scatter photocoagulation as used in the DRS and ETDRS may exacerbate the macular edema and cause increased rates of moderate visual loss (loss of 3 lines, or 15 or more letters of visual acuity) compared to untreated control eyes. Scatter laser surgery should not be delayed, however, if PDR is well into the high-risk stage (i.e., NVD is extensive or vitreous/preretinal hemorrhage has occurred recently).

Fluorescein angiography may be used to determine the presence or absence of areas of non-perfusion and/or occult areas of retinal neovascularization and to establish the cause of a documented loss of visual acuity. Color fundus photography may be helpful in the future management of these patients.

Proliferative DR

DRS high-risk characteristics for severe visual loss with high-risk PDR include:

- New vessels within 1 disc diameter of the optic nerve head that are larger than disc area.
- Vitreous or preretinal hemorrhage associated with less extensive new vessels at the optic disc, or with new vessels elsewhere $\frac{1}{2}$ disc area or more in size.

Most patients with high-risk PDR should receive laser scatter treatment without delay. The risk of severe visual loss among patients with high-risk PDR can be substantially reduced by means of scatter photocoagulation as described in the DRS and ETDRS. Scatter photocoagulation causes regression of neovascularization. This proven technique has been fully described in the literature. Following scatter photocoagulation, additional laser treatment may be required.

Indications for additional treatment may include the following:

- Failure of the neovascularization to regress
- Increasing neovascularization of the retina or iris
- New vitreous hemorrhage
- New areas of neovascularization

For patients who have CSME in addition to high-risk PDR, giving both focal and panretinal photocoagulation at the first treatment session may be considered. Since panretinal photocoagulation can exacerbate macular edema, the scatter treatment is often divided into two or more treatment sessions. Fluorescein angiography is usually not necessary in order to apply the panretinal photocoagulation effectively. However, in the presence of CSME, it may be helpful prior to focal photocoagulation. Fluorescein angiography is sometimes helpful in assessing the extent of capillary non-perfusion, identifying subtle areas of neovascularization and establishing the cause of documented loss of visual acuity. Color fundus photography may be helpful in evaluating the response to surgery or disease progression.

Early vitrectomy to clear vitreous opacities may be undertaken to permit photocoagulation in some patients with vitreous opacities and active proliferation of neovascularization. Vitrectomy also may be helpful in selected patients with extensive active neovascular or fibrovascular proliferation. The value of early vitrectomy tends to increase with the increasing severity of neovascularization.

High-Risk PDR Not Amenable to Photocoagulation

It may be impossible to perform laser photocoagulation surgery on some patients with severe vitreous or preretinal hemorrhage. In other cases, advanced, active PDR may persist despite extensive panretinal photocoagulation. In some of these cases, vitreous surgery may be indicated. Vitreous surgery is frequently indicated in patients with traction-macular detachment (particularly of recent onset), combined traction-rhegmatogenous retinal detachment, vitreous hemorrhage precluding scatter photocoagulation, severe PDR, and non-clearing vitreous hemorrhage. Patients with vitreous hemorrhages and rubeosis iridis also should be considered for prompt vitrectomy and intraoperative PRP.

The DRVS showed that early vitrectomy for Type 1 patients with severe vitreous hemorrhage is beneficial, but this early surgery did not appear to offer an advantage to Type 2 patients. The DRVS was conducted before the advent of some modern surgical techniques (e.g., endolaser, certain bimanual techniques, and perfluorocarbon), so the results of the DRVS probably should be viewed as only general guidelines for the current surgical management of diabetic retinopathy. Thus, early vitrectomy for Type 2 diabetic patients with severe non-clearing vitreous hemorrhage should probably be considered, particularly if active neovascularization is present. Rarely, pars plana vitrectomy for management of carefully selected patients with diffuse CSME unresponsive to previous macular laser photocoagulation may improve visual acuity when significant vitreomacular traction is present. However, the value of vitrectomy in CSME has not been proved in a controlled clinical trial.

Vitreous surgery has the potential for serious complications, including severe visual loss and eye pain. It should not be undertaken without careful consideration of the potential risks and benefits. For example, if the risk of the spread of extramacular traction retinal detachment into the macula is low, it is best to defer vitreous surgery unless definite progression threatening the vascular center is documented, or the patient has another indication for vitreous surgery. Deferral is particularly appropriate when new vessels have regressed substantially and retinopathy appears to be inactive.