Appendix F. Extended study characteristics and outcomes for studies reporting the impact of interventions for diabetic retinopathy on HRQL

Study	Study Characteristics	Study Population	HRQL Instrument(s)	Results
Laser photocoagulation				
Tranos, 2004[44] **Country:** UK **Date of study:** February 2001 to August 2002 **Study setting:** outpatient clinic	**Study design:** prospective cohort **Inclusion criteria:** 1) age ≥17 yr; 2) English speaking; 3) evidence of DME by slit lamp biomicroscopy; 4) pass on an abbreviated version of the Folstein Mini-Mental State examination **Exclusion criteria:** 1) previous laser photocoagulation for PDR or DME 2) vitreous hemorrhage present at recruitment or after enrollment; 3) clinically significant coexisting ocular pathology such as glaucoma and ARMD **Intervention (n):** *G1 (all pt)*—laser tx; focal laser tx (38), grid laser tx (17)	**Total population (n):** 64 **Total eyes in study (n):** NR **Withdrew (n):** developed vitreous hemorrhage (2), proliferative diabetic changes requiring panretinal photocoagulation (4), moved and had ongoing follow-up by a non study ophthalmologist (3) **Analyzed n (%):** 55 (85.9) **Age, mean±SD(range):** 65.1±9.7 (NR) **Males n (%):** 17 (30.9) **Type of DM n (%):** NR **Visual acuity:** NR **DR n (%):** 55 (100) **DME n (%):** 55 (100) **Type of DR n (%):** *mild NPDR*—13 (23.6); *moderate NPDR*—32 (58.2); *severe NPDR*—10 (18.2)	**Instrument/technique:** NEI-VFQ-51 **Method of administration:** pt self-completed with verbal instructions and assistance from research staff **Respondent:** Pt **Time points of administration:** before and 3–4 mo after tx **Baseline score mean±SD(range):** *NEI-VFQ-51* *G1*—77.9 (17.6)	*VFQ-51 composite score*— 82.8 ±15.1 improvement: 4.9±8.9 ($p < 0.001$) *Subscales*—statistically significant improvement on 8 of 11 vision-related domains *Distance vision*—baseline: 42.7±8.4 letters; improvement: 2.2±6.2 *Near vision*—baseline: 56.4±9.1 letters; improvement: 2.1±5.0

ARMD = age-related macular degeneration; BCVA = best corrected visual acuity; BRVO = branch retinal vein occlusion; CRVO = central retinal vein occlusion; CS = contrast sensitivity; DM = diabetes mellitus; DME = diabetic macular edema; DR = diabetic retinopathy; Diabetes Treatment Satisfaction Questionnaire = DTSQ; ERM = epiretinal membrane; ETDRS = Early Treatment Diabetic Retinopathy Research Group; hx = history; LTF = lost to followup; MH = macular hole; mo = month; NPDR = non proliferative diabetic retinopathy; NR = not reported; OCT = optical coherence tomography; PDR = proliferative diabetic retinopathy; pt = patient; QOL = quality of life; RD = rhegmatogenous retinal detachment; RBX = Ruboxistaurin; T1D = type 1 diabetes mellitus; T2D = type 2 diabetes mellitus; tx = treatment; VA = visual acuity; VF = visual function; VFQ–25 = National Eye Institute Visual Function Questionnaire-25; yr = year(s)

Appendix F. Extended study characteristics and outcomes for studies reporting the impact of interventions for diabetic retinopathy on HRQL (continued)

Study	Study Characteristics	Study Population	HRQL Instrument(s)	Results
Mozaffarieh, 2005b[50] **Country:** Austria **Date of study:** June 2002 to March 2004 **Study setting:** outpatient clinic	**Study design:** prospective cohort **Inclusion criteria:** 1) undergoing 1st laser tx for DME or PDR **Exclusion criteria:** NR **Intervention (n):** *G1*—pt with PDR: panretinal photocoagulation tx for neovascularization on the disk, or elsewhere in accordance to ETDRS guidelines (56); *G2*—pt with DME: macular laser tx, as defined by ETDRS guidelines for retinal edema threatening the fovea (49)	**Total population (n):** 123 **Total eyes in study (n):** **Withdrew (n):** died (2), LTF (3), did not complete/return questionnaire (13) **Analyzed n (%):** 105 (85.4) **Age, mean±SD(range):** NR **Males n (%):** NR **Type of DM n (%):** NR **Visual acuity:** NR **DR n (%):** 56 (53.3) **Type of DR n (%):** PDR—56 (53.3) **DME n (%):** 49 (46.7)	**Instrument/technique:** DTSQ; Degree of satisfaction (questionnaire developed for study) **Respondent:** Pt **Time points of administration:** *DTSQ*—after initial tx (baseline) and final (9 mo.) tx; *Degree of satisfaction*—after final (9 mo.) tx **Baseline score mean±SD(range):** *DTSQ*—29.6±5.6; 45.7% of all pt scored ≥31 (max 36); for 5 of 6 subscales, 59.1% of pt scores ≥25	*DTSQ (mean±SD)*—27.9±5.2 *Degree of satisfaction*—69.5% of pt completely satisfied, 20.9% partially satisfied, 9.6% dissatisfied *Patient reported VA*—24.7% of all pt reported improvement in VA; 71.4% of pt reported no change in VA; 3.8% of pt reported deterioration in VA

ARMD = age-related macular degeneration; BCVA = best corrected visual acuity; BRVO = branch retinal vein occlusion; CRVO = central retinal vein occlusion; CS = contrast sensitivity; DM = diabetes mellitus; DME = diabetic macular edema; DR = diabetic retinopathy; Diabetes Treatment Satisfaction Questionnaire = DTSQ; ERM = epiretinal membrane; ETDRS = Early Treatment Diabetic Retinopathy Research Group; hx = history; LTF = lost to followup; MH = macular hole; mo = month; NPDR = non proliferative diabetic retinopathy; NR = not reported; OCT = optical coherence tomography; PDR = proliferative diabetic retinopathy; pt = patient; QOL = quality of life; RD = rhegmatogenous retinal detachment; RBX = Ruboxistaurin; T1D = type 1 diabetes mellitus; T2D = type 2 diabetes mellitus; tx = treatment; VA = visual acuity; VF = visual function; VFQ–25 = National Eye Institute Visual Function Questionnaire-25; yr = year(s)

Appendix F. Extended study characteristics and outcomes for studies reporting the impact of interventions for diabetic retinopathy on HRQL (continued)

Study	Study Characteristics	Study Population	HRQL Instrument(s)	Results
Vitrectomy				
Emi, 2008[42] **Country:** Japan **Date of study:** NR **Study setting:** NR	**Study design:** cohort **Inclusion criteria:** 1) Pt dx with DR; 2) Pt who underwent vitrectomy **Exclusion criteria:** NR **Intervention (n):** *All groups*—pars plana vitrectomy (87) **Patient groups n (%)** *G1*—vitreous hemorrhage: 41 (47.1); *G2*—DME: 28 (32.2); *G3*—fibrovascular membrane: 18 (20.7)	**Total population (n):** 87 **Total eyes in study (n):** 87 **Withdrew (n):** 0 (0) **Analyzed n (%):** 87 (100%) **Age, mean±SD(range):** *G1*—60.4 (7.1) *G2*—63.6 (5.0) *G3*—55.3 (9.0) **Males n (%):** *G1*—23 (56.1) *G2*—18 (64.3) *G3*—9 (50) **Type of DM n (%):** NR **Visual acuity:** NR **DR n (%):** 87 (100%) **Type of DR n (%):** NR	**Instrument/technique:** VFQ–25 **Respondent:** Pt **Time points of administration:** *VFQ–25*—baseline; 6 mo after tx **Baseline score mean±SD(range):** VFQ–25, scores per item: *G1*—Item 1: 37; Item 2: 42; Item 3: 94; Item 4: 47; Item 5: 58; Item 6: 75; Item 7: 54; Item 8: 62; Item 9: 69; Item 10: 35; Item 11: 89; Item 12: 65; *G2*—Item 1: 42; Item 2: 45; Item 3: 93; Item 4: 57; Item 5: 71; Item 6: 86; Item 7: 64; Item 8: 78; Item 9: 81; Item 10: 54; Item 11: 96; Item 12: 77; *G3*—Item 1: 45; Item 2: 47; Item 3: 93; Item 4: 74; Item 5: 83; Item 6: 93; Item 7: 72; Item 8: 79; Item 9: 89; Item 10: 51; Item 11: 87; Item 12: 85	VFQ–25 6 mo scores per item (mean): *G1*—Item 1: 39; Item 2: 68; Item 3: 91; Item 4: 70; Item 5: 77; Item 6: 87; Item 7: 74; Item 8: 78; Item 9: 79; Item 10: 68; Item 11: 95; Item 12: 80 *G2*—Item 1: 42; Item 2: 53; Item 3: 94; Item 4: 58; Item 5: 72; Item 6: 79; Item 7: 65; Item 8: 73; Item 9: 80; Item 10: 58; Item 11: 91; Item 12: 79 *G3*—Item 1; 45; Item 2: 63; Item 3: 80; Item 4: 66; Item 5: 75; Item 6: 87; Item 7: 66; Item 8: 72; Item 9: 75; Item 10: 52; Item 11: 95; Item 12: 80

ARMD = age-related macular degeneration; BCVA = best corrected visual acuity; BRVO = branch retinal vein occlusion; CRVO = central retinal vein occlusion; CS = contrast sensitivity; DM = diabetes mellitus; DME = diabetic macular edema; DR = diabetic retinopathy; Diabetes Treatment Satisfaction Questionnaire = DTSQ; ERM = epiretinal membrane; ETDRS = Early Treatment Diabetic Retinopathy Research Group; hx = history; LTF = lost to followup; MH = macular hole; mo = month; NPDR = non proliferative diabetic retinopathy; NR = not reported; OCT = optical coherence tomography; PDR = proliferative diabetic retinopathy; pt = patient; QOL = quality of life; RD = rhegmatogenous retinal detachment; RBX = Ruboxistaurin; T1D = type 1 diabetes mellitus; T2D = type 2 diabetes mellitus; tx = treatment; VA = visual acuity; VF = visual function; VFQ–25 = National Eye Institute Visual Function Questionnaire-25; yr = year(s)

Appendix F. Extended study characteristics and outcomes for studies reporting the impact of interventions for diabetic retinopathy on HRQL (continued)

Study	Study Characteristics	Study Population	HRQL Instrument(s)	Results
Okamoto, 2010[40] **Country:** Japan **Date of study:** June 2005 to April 2007 **Study setting:** outpatient clinic	**Study design:** prospective cohort **Inclusion criteria:** indications for vitrectomy in: *G1*—PDR: recurrent or persistent nonclearing vitreous hemorrhage, traction, or combined traction-rhegmatogenous RD and adherent posterior hyaloid causing excessive macular traction; *G2*—DME*:* clinically significant according to ETDRS guidelines and when ≥ 3 mo had passed after ≥1 session of laser tx and when logMAR BCVA in the affected eye was 0.2 or worse **Exclusion criteria:** 1) pt with hx of vitreoretinal surgery and ocular disorders except for mild refractive errors and mild cataract; 2) pt who had undergone bilateral vitrectomy within 3 mo **Intervention (n):** *G1& G2*—received pars plana vitrectomy *G3*—normal controls (100)	**Total population (n):** 399 **Total eyes in study (n):** 399 **Withdrew (n):** 0 **Analyzed n (%):** 399 (100) **Age, mean±SD(range):** *G1*—57.7±12.9; *G2*—62.7±9.0 **Males n (%):** *G1*—53 (13.3); *G2*—23 (5.8) **Type of DM n (%):** NR **Visual acuity:** *G1*—BCVA: 1.37±0.75; CS: 5.4±7.2 *G2—BCVA:* 0.76±0.49; CS: 9.2±6.5 **DR n (%):** 99 (24.8) **Type of DR n (%):** PDR—99 (100) **Other included retinal diseases n (%):** **D**ME—38 (9.5); BRVO—20 (5.0); CRVO—12 (3.0); MH—42 (10.5); ERM—33 (8.3); RD—55 (13.8)	**Instrument/technique:** VFQ–25 **Method of administration:** *VFQ–25*—self-completed with instructions and assistance from research staff **Respondent:** Pt **Time points of administration:** before and 3 mo after tx **Baseline score mean±SD(range):** *G1*—52.8±19.0; *G2*—53.0±20.5	*VFQ–25 (mean±SD)* *G1*—63.6±17.5; *G2*—59.0±21.0 *VA (mean±SD)* *G1*—BCVA: 0.53±0.62; p<0.0001; CS: 14.0±7.9; p<0.0001 G2—BCVA: 0.55±0.51; p<0.001; CS: 12.7±7.1; p<0.0001

ARMD = age-related macular degeneration; BCVA = best corrected visual acuity; BRVO = branch retinal vein occlusion; CRVO = central retinal vein occlusion; CS = contrast sensitivity; DM = diabetes mellitus; DME = diabetic macular edema; DR = diabetic retinopathy; Diabetes Treatment Satisfaction Questionnaire = DTSQ; ERM = epiretinal membrane; ETDRS = Early Treatment Diabetic Retinopathy Research Group; hx = history; LTF = lost to followup; MH = macular hole; mo = month; NPDR = non proliferative diabetic retinopathy; NR = not reported; OCT = optical coherence tomography; PDR = proliferative diabetic retinopathy; pt = patient; QOL = quality of life; RD = rhegmatogenous retinal detachment; RBX = Ruboxistaurin; T1D = type 1 diabetes mellitus; T2D = type 2 diabetes mellitus; tx = treatment; VA = visual acuity; VF = visual function; VFQ–25 = National Eye Institute Visual Function Questionnaire-25; yr = year(s)

Appendix F. Extended study characteristics and outcomes for studies reporting the impact of interventions for diabetic retinopathy on HRQL (continued)

Study	Study Characteristics	Study Population	HRQL Instrument(s)	Results
Vitrectomy and panretinal photocoagulation				
Emi, 2009[43] **Country:** Japan **Date of study:** NR **Study setting:** outpatient clinic	**Study design:** cohort **Inclusion criteria:** NR **Exclusion criteria:** NR **Intervention (n):** *G1*—no DR: no treatment (131) *G2*—simple DR: photocoagulation, laser surgery (60) *G3*—PDR: par plana vitrectomy (136)	**Total population (n):** 327 **Total eyes in study (n):** NR **Withdrew (n):** 0 (0) **Analyzed n (%):** 327 (100%) **Age, mean±SD(range):** *G1*—62.7 (10.0) *G2*—60.6 (10.1) *G3*—59.6 (9.6) **Males n (%):** *G1*—89 (67.9) *G2*—39 (65.0) *G3*—80 (58.8) **Type of DM n (%):**NR **Visual acuity:** *logMAR (mean)*: *G1*—right eye: 1.09; left eye: 1.1; *G2*—right eye: 0.64; left eye:0.61; *G3*—right eye: 0.21; left eye: 0.19 **DR n (%):** 196 (60) **Type of DR n (%):** simple DR: 60 (18.3); PDR: 136 (41.6) **Other included retinal diseases n (%):** NR	**Instrument/technique:** VFQ–25 **Time points of administration:** *VFQ–25*—baseline; 1 yr after tx **Baseline score mean±SD(range):** VFQ–25 scores, per item: *G1*—Item 1: 43; Item 2: 73; Item 3: 95; Item 4: 85; Item 5: 93; Item 6: 97; Item 7: 92; Item 8: 93; Item 9: 98; Item 10: 90; Item 11: 98; Item 12: 91 *G2*—Item 1: 39; Item 2: 58; Item 3: 90; Item 4: 68; Item 5: 84; Item 6: 90; Item 7: 76; Item 8: 78; Item 9: 87; Item 10: 78; Item 11: 92; Item 12: 89 *G3*—Item 1: 40; Item 2: 43; Item 3: 92; Item 4: 51; Item 5: 64; Item 6: 78; Item 7: 58; Item 8: 71; Item 9: 75; Item 10: 46; Item 11: 89; Item 12: 73	VFQ–25 1 yr scores per item (mean): *G1*—Item 1: 49; Item 2: 75; Item 3: 94; Item 4: 86; Item 5: 93; Item 6: 98; Item 7: 92; Item 8: 93; Item 9: 99; Item 10: 90; Item 11: 100; Item 12: 90 *G2*—Item 1: 41; Item 2: 60; Item 3: 89; Item 4: 66; Item 5: 80; Item 6: 88; Item 7: 70; Item 8: 70; Item 9: 83; Item 10: 76; Item 11: 92; Item 12: 84 *G3*—Item 1: 42; Item 2: 61; Item 3: 88; Item 4: 61; Item 5: 77; Item 6: 82; Item 7: 70; Item 8: 73; Item 9: 81; Item 10: 60; Item 11: 92; Item 12: 78

ARMD = age-related macular degeneration; BCVA = best corrected visual acuity; BRVO = branch retinal vein occlusion; CRVO = central retinal vein occlusion; CS = contrast sensitivity; DM = diabetes mellitus; DME = diabetic macular edema; DR = diabetic retinopathy; Diabetes Treatment Satisfaction Questionnaire = DTSQ; ERM = epiretinal membrane; ETDRS = Early Treatment Diabetic Retinopathy Research Group; hx = history; LTF = lost to followup; MH = macular hole; mo = month; NPDR = non proliferative diabetic retinopathy; NR = not reported; OCT = optical coherence tomography; PDR = proliferative diabetic retinopathy; pt = patient; QOL = quality of life; RD = rhegmatogenous retinal detachment; RBX = Ruboxistaurin; T1D = type 1 diabetes mellitus; T2D = type 2 diabetes mellitus; tx = treatment; VA = visual acuity; VF = visual function; VFQ–25 = National Eye Institute Visual Function Questionnaire-25; yr = year(s)

Appendix F. Extended study characteristics and outcomes for studies reporting the impact of interventions for diabetic retinopathy on HRQL (continued)

Study	Study Characteristics	Study Population	HRQL Instrument(s)	Results
Phacoemulsification cataract surgery				
Mozaffarieh, 2005a[49] **Country:** Austria **Date of study:** May 2001 to May 2003 **Study setting:** outpatient clinic	**Study design:** prospective cohort **Inclusion criteria:** 1) undergoing standardized first-eye phacoemulsification cataract surgery **Exclusion criteria:** 1) pt dx with glaucoma, uveitis, hx of ocular trauma or any other co-existing, visually limiting condition other than those associated with DR; 2) pt with a progression of DR in the non-operated fellow eye **Intervention (n):** *G1*—pt with no apparent retinopathy (17) *G2*—pt with mild NPDR (19) *G3*—pt with severe NPDR (16) *G4*—pt with PDR (15) *All groups*—received phacoemulsification cataract surgery	**Total population (n):** 74 **Total eyes in study (n):** 74 **Withdrew (n):** died (1), did not complete/return questionnaire (6) **Analyzed n (%):** 67 (90.5) **Age, mean±SD(range):** 57.8 (42–68) (all); *G1*—57.9 (48–67); *G2*—55.5 (42–66); *G3*—59.1 (49–67); *G4*—59.1 (44–71) **Males n (%):** NR **Type of DM n (%):** T2D—65 (97) **Visual acuity: mean (range)** *G1*—Snellen: 0.29 (0.05–0.50); logMAR VA*:* 0.62 (0.30–1.30); *G2*—Snellen: 0.29 (0.05–0.50); logMAR VA: 0.60 (0.30–1.30); *G3*—Snellen: 0.28 (0.05–0.50); logMAR VA: 0.67 (0.30–1.30); *G4*—Snellen: 0.24 (0.05–0.40); logMAR VA: 0.71 (0.40–1.30) **DR n (%):** 50 (74.6) **Type of DR n (%):** mild NPDR 19 (28.3); severe NPDR 16 (23.9); PDR 15 (22.4) **Other included retinal diseases n (%):** 3 patients with severe NPDR had DME	**Instrument/technique:** VF–14; patient satisfaction questionnaire **Time points of administration:** *VF–14*—before and 3 mo after tx; *Snellen chart*—before and 3 mo after tx; *Patient satisfaction questionnaire*—3 mo after tx **Baseline score mean±SD(range):** *VF–14:* *G1*—52.21 (32.14–78.57); *G2*—55.92 (30.36–85.71); *G3*—46.65 (30.36–64.29); *G4*—40.12 (25.00–67.86)	*VF–14 (mean [range])* *G1*—94.54 (85.71–100) *G2*—91.92 (62.50–100) *G3*—55.92 (41.07–69.64) *G4*—45.12 (0–78.57) *Patient satisfaction*—65.7% of pt completely satisfied *G1*—82.4% *G2*—79.0% *G3*—56.3% *G4*—40%; surgery met expectations— *G1*—70.6% *G2*—73.6% *G3*—31.2% *G4*—26.6% *Visual Acuity (mean [range])* *G1*—Snellen: 0.85 (0.60–1.00); *logMAR VA:* 0.07 (0–0.22); *G2*—0.80 (0.50–1.00); logMAR VA*:* 0.10 (0–0.30); *G3*—Snellen*:* 0.49 (0.10–0.70); logMAR VA: 0.40 (0.15–1.00) *G3*—Snellen: 0.37 (0.01–0.60); logMAR VA: 0.56 (0.22–2.00)

ARMD = age-related macular degeneration; BCVA = best corrected visual acuity; BRVO = branch retinal vein occlusion; CRVO = central retinal vein occlusion; CS = contrast sensitivity; DM = diabetes mellitus; DME = diabetic macular edema; DR = diabetic retinopathy; Diabetes Treatment Satisfaction Questionnaire = DTSQ; ERM = epiretinal membrane; ETDRS = Early Treatment Diabetic Retinopathy Research Group; hx = history; LTF = lost to followup; MH = macular hole; mo = month; NPDR = non proliferative diabetic retinopathy; NR = not reported; OCT = optical coherence tomography; PDR = proliferative diabetic retinopathy; pt = patient; QOL = quality of life; RD = rhegmatogenous retinal detachment; RBX = Ruboxistaurin; T1D = type 1 diabetes mellitus; T2D = type 2 diabetes mellitus; tx = treatment; VA = visual acuity; VF = visual function; VFQ–25 = National Eye Institute Visual Function Questionnaire-25; yr = year(s)

Appendix F. Extended study characteristics and outcomes for studies reporting the impact of interventions for diabetic retinopathy on HRQL (continued)

Study	Study Characteristics	Study Population	HRQL Instrument(s)	Results
Mozaffarieh, 2009[47] **Country:** Austria **Date of study:** NR **Study setting:** outpatient clinic	**Study design:** prospective cohort **Inclusion criteria:** 1) presence of bilateral cataract **Exclusion criteria:** 2) pt in whom lenticular opacity did not allow accurate diagnosis of preoperative level of DR; 2) pt with glaucoma, uveitis, hx of ocular trauma or any other coexisting, visually limiting condition; 3) level of DR in the fellow eye was different from first eye at the 6 mo followup **Intervention (n):** *G1*—pt treated with a single surgery (41) *G2*—pt treated with a second surgery (48) *Both groups:* phacoemulsification cataract surgery	**Total population (n):** 102 **Total eyes in study (n):** **Withdrew (n):** died (2), lost to followup (7), excluded at 6 mo (4) **Analyzed n (%):** 89 (87.3) **Age, mean±SD(range):** 63.5 (49–78) (total) *G1*—56.9 *G2*—58.9 **Males n (%):** 49 (55.1) (total) *G1*—24 (58.6) *G2*—25 (52) **Type of DM n (%):** NR **Visual acuity:** NR **DR n (%):** 66 (74.2) **Type of DR n (%):** mild DR—23 (25.8); moderate DR—22 (24.7); PDR—21 (23.6) **Other included retinal diseases n (%):** 1 patient with moderate DR had DME	**Instrument/technique:** VF–14 **Time points of administration:** *VF–14*—before tx, 1, 3, 6, 8, 12 mo after tx **Baseline score mean±SD(range):** *G1*—No DR: 69.3±12.4; mild NPDR: 39.3±5.2; severe NPDR: 40.9±8.6; PDR: 35.3±4.4 *G2*—No DR: 46.8±8.7; mild NPDR: 63.4±16.3; severe NPDR: 54.6±8.8; PDR: 50.6±11.4	*VF–14(mean±SD)—* *G1* 1 mo—no DR: 97.1±2.6; mild NPDR: 86.7±14.2; severe NPDR: 40.9±8.6; PDR: 36.3±3.9 3 mo—no DR: 97.1±2.6; mild NPDR: 86.7±14.2; severe NPDR: 50.2±6.4; PDR: 38.1±14.9 6 mo—no DR: 96.8±2.0; mild NPDR: 86.5±13.6; severe NPDR: 48.8±6.7; PDR: 37.9±14.0 8 mo—no DR: 79.5±5.5; mild NPDR: 73.2±8.1; severe NPDR: 47.7±10.4; PDR: 41.5±9.8 12 mo—no DR: 79.5±5.5; mild NPDR: 72.2±8.3; severe NPDR: 46.1±10.7; PDR: 39.9±9.0 *G2* 1 mo—no DR: 93.3±4.2; mild NPDR: 96.4±2.3; severe NPDR: 54.6±8.7; PDR: 49.2±10.9 3 mo—no DR: 93.4±4.3; mild NPDR: 96.4±2.3; severe NPDR: 61.2±6.4; PDR: 57.1±11.6 6 mo—no DR: 93.0±4.3; mild NPDR: 94.6±2.5; severe NPDR: 60.9 6.6; PDR: 53.0±10.9 8 mo—no DR: 93.5±3.1; mild NPDR: 95.9±3.5; severe NPDR: 50.9±16.3; PDR: 53.8±17.6 12 mo—no DR: 95.3±1.9; mild NPDR: 95.3±2.2; severe NPDR: 47.8±16.0; PDR: 47.6±15.0

ARMD = age-related macular degeneration; BCVA = best corrected visual acuity; BRVO = branch retinal vein occlusion; CRVO = central retinal vein occlusion; CS = contrast sensitivity; DM = diabetes mellitus; DME = diabetic macular edema; DR = diabetic retinopathy; Diabetes Treatment Satisfaction Questionnaire = DTSQ; ERM = epiretinal membrane; ETDRS = Early Treatment Diabetic Retinopathy Research Group; hx = history; LTF = lost to followup; MH = macular hole; mo = month; NPDR = non proliferative diabetic retinopathy; NR = not reported; OCT = optical coherence tomography; PDR = proliferative diabetic retinopathy; pt = patient; QOL = quality of life; RD = rhegmatogenous retinal detachment; RBX = Ruboxistaurin; T1D = type 1 diabetes mellitus; T2D = type 2 diabetes mellitus; tx = treatment; VA = visual acuity; VF = visual function; VFQ–25 = National Eye Institute Visual Function Questionnaire-25; yr = year(s)

Study	Study Characteristics	Study Population	HRQL Instrument(s)	Results
Anti-VEGF				
Mitchell 2011 Multicenter (73 centers in Australia, Canada, Europe and Turkey) **Date of study:** NR **Study name:** RESTORE	**Study design:** RCT **Inclusion criteria:** ≥18 years with either type 1 or type 2 diabetes mellitus; HbA1c ≤ 10%; stable medication for management of DM; visual impairment due to DME in ≥1 eye that was eligible for laser tx; BCVA between 78–39 (20/32–20/160 Snellen); decreased vision not due to other causes than DME **Exclusion criteria:** concomitant conditions preventing vision improvement; active inflammation in other eye; uncontrolled glaucoma; panretinal laser photocoagulation (w/ in 6 mo) or focal/grid laser photocoagulation (w/ in 3 mo); antiangiogenic drugs w/in 3 mo; hx of stroke, hypertension or change in hypertensive tx (w/ in 3 mo) **Intervention (n):** *G1*—r**anibizumab 0.5 mg** + sham laser (116) *G2*—**ranibizumab 0.5 mg + laser** (118) *G3*—**laser** + sham injection (111)	**Total population (n):** 345 **Total eyes in study (n):** 345 **Randomized:** 345 **Withdrew (n):** 42 **Analyzed [HRQL at 12 mo] (n; %)** 303 (88) **Age, mean±SD:** *G1*—62.9±9.29 G2—64.0±8.15 G3—63.5±8.81 **Males n (%):** *G1*—73 (63) G2—70 (59) G3—58 (52) **Type of DM n (%):** T1D—41 (12); T2D—302 (88); unknown—2 (<1) **VA (letter score), mean±SD:** *G1*—64.8±10.11 G2—63.4±9.99 G3—62.4±11.11 **Type of DME n (%):** *Focal*—185 (54) *Diffuse*—143 (41) *Unknown*—17 (5)	**Instrument:** NEI-VFQ-25 **Method of administration:** NR **Respondent:** Pt **Time points of administration:** baseline, 3 mo, 12 mo **Baseline score, mean±SD:** *NEI-VFQ-25* *G1*—NR G2—NR G3—NR	*VFQ-25, composite score at 12 mo* G1—baseline: NR; improvement: 5.0 *G2*—baseline: NR; improvement: 5.4 *G3*—baseline: NR; improvement: 0.6 *VFQ-25, subscales at 12 mo* General vision G1—baseline: NR; improvement: 8.9 G2—baseline: NR; improvement: 8.0 G3—baseline: NR; improvement: 1.1 Distance activities G1—baseline: NR; improvement: 5.3 G2—baseline: NR; improvement: 5.6 G3—baseline: NR; improvement: 0.4 Near activities G1—baseline: NR; improvement: 9.0 G2—baseline: NR; improvement: 9.1 G3—baseline: NR; improvement: 1.1 Remaining vision related subscales—NR

BCVA = best corrected visual acuity; BRVO = branch retinal vein occlusion; CRVO = central retinal vein occlusion; CS = contrast sensitivity; CSMO = Clinically Significant Macular oedema; DM = diabetes mellitus; DME = diabetic macular edema; DR = diabetic retinopathy; ETDRS = Early Treatment Diabetic Retinopathy Research Group; hx = history; LTF = lost to followup;; mo = month; NPDR = non proliferative diabetic retinopathy; NR = not reported; OCT = optical coherence tomography; PDR = proliferative diabetic retinopathy; pt = patient; QOL = quality of life; T1D = type 1 diabetes mellitus; T2D = type 2 diabetes mellitus; tx = treatment; VA = visual acuity; VF = visual function; VFQ-25 = National Eye Institute Visual Function Questionnaire-25; yr = year(s)

Study	Study Characteristics	Study Population	HRQL Instrument(s)	Results
Sultan 2011 Multicenter (60 centers in Australia, Europe, India, North America, South America) **Date of study:** Sep 2005 – Nov 2009 **Study name:** Macugen 1013	**Study design:** RCT **Inclusion criteria:** ≥18 yr; DME involving center of the macula not assoc with ischemia; foveal thickness ≥250µm; BCVA 65–35 (20/50–20/200 Snellen); intraocular pressure ≤21mmHg; clear ocular media; adequate papillary dilation, hematologic, liver & renal function **Exclusion criteria:** any abnormality likely to confound assessment of VA; atrophy/scarring/fibrosis of center of macula; subfoveal hard exudates or retinal pigment epithelial atrophy; YAG laser, peripheral retinal cryoablation, laser retinopexy, focal or grid photocoagulation within prior 16 wk; panretinal photocoagulation within prior 6 mo or needed within in 9 mo; intraocular surgery within in 6 prior mo; hx of vitrectomy; previous filtering surgery or placement of drainage device; significant media opacities; pathologic high myopia; prior radiation in region of study eye; uncontrolled DM **Intervention (n):** *G1*—pegaptanib 0.3 mg (133) *G2*—sham injection (127)	**Total population (n):** 288 **Total eyes in study (n):** 288 **Withdrew (n):** 28 (at wk 54); 95 (at wk 102) **Analyzed [HRQL, 54 wk] n (%):260 (90)** **Age, mean±SD:** *G1*—62.3±9.3 G2—62.5±10.2 **Males n (%):** *G1*—81 (61) G2—68 (54) **Type of DM n (%):**T1D—18 (7); T2D—242 (93) **VA (letter score), mean±SD:** *G1*—57.0±8.9 G2—57.5±8.1 **Type of DME n (%):** 100 (100%)	**Instrument/technique:** NEI-VFQ-25 **Method of administration:** in person in India; via telephone for all other centers **Respondent:** Pt **Time points of administration:** baseline, 18, 54 & 102 wk **Baseline score mean±SD(range):** *NEI-VFQ-25* *G1*—65.9 G2—67.9	*VFQ-25, composite score* at 54 wk: *G1*—70.4; improvement 4.5 G2—69.2; improvement 1.3 *Between group differences*—2.92; range -0.32 to 6.16 (p = 0.077) *VFQ-25 subscales at 54 wk:* Near vision activities—between group differences: 5.70; 0.48-10.91 (p = 0.033) Distance vision functioning—between group differences: 8.50; 2.74-14.25 (p = 0.044) Social functioning—between group differences: 7.99; 2.90-13.09 (p = 0.002) Between group differences were not statistically significant for the 8 remaining vision related subscales *VFQ-25, composite score* at 102 wk (n = 207): *G1*—69.8; improvement 4.6 G2—66.2; improvement 0.1 *Between group differences*—4.47; range -0.26 to 8.68 (p = 0.038)

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