

CURRICULUM VITAE

MICHAEL A. NOVAK, MD

OFFICE ADDRESSES

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EDUCATION

College

Adelbert College, Case Western Reserve University
Cleveland, Ohio
1969–1973, BA

Medical School

Case Western Reserve University School of Medicine,
Cleveland, Ohio
1973–1977, MD

POSTGRADUATE TRAINING

Internship

Medicine
University Hospitals of Cleveland
Cleveland, Ohio
1977–1978

Residency

Ophthalmology
The Wilmer Ophthalmological Institute of the Johns Hopkins Hospital
The Johns Hopkins University School of Medicine
Baltimore, Maryland
1978–1981

Fellowship Retina and Vitreous Diseases and Surgery
The Wilmer Ophthalmological Institute of the Johns Hopkins Hospital
The Johns Hopkins University School of Medicine
Baltimore, Maryland
1981–1982

Chief Resident, Assistant Chief of Service
The Wilmer Ophthalmological Institute of the Johns Hopkins Hospital
The Johns Hopkins University School of Medicine
Baltimore, Maryland
1982–1983

LICENSURE AND BOARD CERTIFICATION

Licensed to practice medicine in Ohio
Diplomate, American Board of Ophthalmology, 1982

PROFESSIONAL POSITIONS

Retina Associates of Cleveland, 1983–
Practice limited to retinal diseases and surgery. Associates: Lawrence J. Singerman, MD;
Hernando Zegarra, MD; Z. Nicholas Zakov, MD; Scott D. Pendergast, MD; David G.
Miller, MD; Joseph M. Coney, MD; Jerome P. Schartman, MD; Llewelyn J. Rao, MD;
Lili G. Kaplan, MD; Shawn A. Lewis, MD

ACADEMIC APPOINTMENTS

Assistant Clinical Professor of Ophthalmology
Case Western Reserve University School of Medicine
1983–2002

Instructor in Ophthalmology
The Johns Hopkins University School of Medicine
1982–1983

PROFESSIONAL SOCIETIES AND COMMITTEES

Diabetes Education Committee
Hillcrest Hospital
1991

Diabetes Advisory Committee
International Diabetes Center
Marymount Hospital
1988

Quality Assurance Committee
Department of Surgery
St. Luke's Hospital
1986, 1987, 1988

Library Committee
St. Luke's Hospital
1986, 1987

Investigational Review Board
Hillcrest Hospital
1985, 1986

HONORS AND AWARDS

Best Doctors in America, 2011-2015; *Top Doctors*, 2015

Member, Phi Beta Kappa

Honor Award
American Academy of Ophthalmology, 1992

Teaching Award
Mount Sinai Medical Center of Cleveland
Ophthalmology Residents Program, 1986, 1987

Teaching Award
St. Luke's Hospital of Cleveland
Ophthalmology Residents Program, 1985

Co-recipient, First Annual Outstanding Teacher Award
Case Western Reserve University Hospitals
Ophthalmology Residents Program, 1985

MEMBERSHIPS

American Academy of Ophthalmology
American Society of Retinal Specialists (formerly the Vitreous Society)
American Medical Association
Association for Research in Vision and Ophthalmology
Cleveland Academy of Medicine
Cleveland Ophthalmological Society
Diabetes Association of Greater Cleveland
Member, Board of Trustees, 1988
European VitreoRetinal Society
Macula Society

Ohio Medical Association
Ohio Ophthalmological Society
Member, Board of Governors, 1986–1988
Retina Society
Wilmer Residents Association

HOSPITAL & ASC AFFILIATIONS

Akron General Medical Center; Akron, Ohio
Austintown Surgery Center / Surgery Center of Canfield; Canfield, Ohio
Cleveland Eye and Laser Surgery Center; Cleveland, Ohio
Lippy Surgery Center; Warren, Ohio
Summa Health; Akron, Ohio

TEACHING ACTIVITIES

- Ophthalmology residents, Case Western Reserve University
- Retina Clinic and surgery supervision, MetroHealth Medical Center, 1983 – (2-3 hours every other week)
 - Clinical Conferences and Fluorescein Angiography Conferences, 1983 – (5-8 hours per year)
- Ophthalmology residents, St. Luke's Medical Center of Cleveland
- General Clinic and Retina Clinic, 1983–1986
 - Lectures and Clinical Conferences, 1983–1999 (12 hours per year)
- Ophthalmology residents, Mount Sinai Medical Center of Cleveland
- Retina Clinic and surgery supervision, 1983–2000 (3-4 hours every other week)
 - Lectures and Clinical Conferences, 1983–2000 (4-6 hours per year)
- American Academy of Ophthalmology Meeting Annual Courses:
- Complications of vitreous surgery, 1982 (3 hours)
 - Evaluation and management of proliferative retinopathies, 1983–1990
 - Management of rubeosis iridis and neovascular glaucoma, 1990, 1991
 - Guidelines for Evaluating and Treating Choroidal Neovascularization, 1998, 1999
- American College of Surgeons Clinical Congress
- Postgraduate course: Update on ophthalmic laser surgery – central serous chorioretinopathy, 1985

RESEARCH ACTIVITIES

NIH-funded Grants

DRCRnet Protocol S. Prompt panretinal photocoagulation versus ranibizumab+deferred panretinal photocoagulation for proliferative diabetic retinopathy
Principal investigator, 2012–

DRCRnet Protocol M. Effect of diabetes education during retinal ophthalmology visits on diabetes control

Principal investigator, 2011–

Home vision monitoring in AREDS2 for progression to neovascular age-related macular degeneration

Principal Investigator, 2011–2013

DRCRnet Protocol N. Evaluation of intravitreal ranibizumab for vitreous hemorrhage due to proliferative diabetic retinopathy

Principal Investigator, 2010–2012

DRCRnet Protocol O. Comparison of time-domain OCT and spectral domain OCT retinal thickness measurement in diabetic macular edema

Principal Investigator, 2009–2010

DRCRnet Protocol I. Intravitreal ranibizumab or triamcinolone acetonide in combination with laser photocoagulation for diabetic macular edema

Principal Investigator, 2007–2014

Age-Related Eye Disease Study 2

Principal investigator, 2006–2012

DRCRnet Protocol V. Treatment for central involved diabetic macular edema in eyes with very good visual acuity

Co-investigator, 2014–

DRCRnet Protocol U. Short-term evaluation of combination corticosteroid+anti-VEGF treatment for persistent central-involved diabetic macular edema following anti-VEGF therapy in pseudophakic eyes

Co-investigator, 2014–

Study of COmparative Treatments for REtinal Vein Occlusion 2 (SCORE2)

Co-investigator, 2014–

DRCRnet: Genes in Diabetic Retinopathy Project

Co-investigator, 2012–

DRCRnet Protocol R. Phase II evaluation of topical NSAIDS on eyes with non-central involved DME

Co-investigator, 2011–2013

Comparison of age-related macular degeneration treatments trials: Lucentis-Avastin trial (CATT)

Co-investigator, 2008–2012

DRCRnet Protocol K. Course of response to focal photocoagulation for diabetic macular edema

Co-investigator, 2007–2008

DRCRnet Protocol H. A Phase 2 evaluation of anti-VEGF therapy for diabetic macular edema: bevacizumab (Avastin)

Co-investigator, 2006–2008

DRCRnet Protocol E. A pilot study of peribulbar triamcinolone acetonide for diabetic macular edema

Co-investigator, 2005–2007

Standard Care vs. COrticosteroid for REtinal Vein Occlusion (SCORE) Study

Co-investigator, 2004–2009

Diabetic Retinopathy Clinical Research Network (DRCRnet) Protocol #1A. A pilot study of laser photocoagulation for diabetic macular edema

Co-investigator, 2004–2007

DRCRnet Protocol B. A randomized trial comparing intravitreal triamcinolone acetonide and laser photocoagulation for diabetic macular edema

Co-investigator, 2004–2007

Family Investigation of Nephropathy and Diabetes (FIND)

Co-investigator/Study Ophthalmologist, 2003–

Complications of Age-related Macular Degeneration Prevention Trial (CAPT)

Co-investigator, 1998–2007

Submacular Surgery Trials

Co-investigator, 1995–2004

Choroidal Neovascularization Prevention Trial – Pilot Study

Co-investigator, 1995–2001

Endophthalmitis Vitrectomy Study

Co-investigator, 1988–1994

Vitrectomy for Prevention of Macular Holes Study

Co-investigator, 1988–1994

Collaborative Ocular Melanoma Study (COMS)

Following and Enuclating Ophthalmologist, 1987–2003

Diabetes Control and Complications Trial

Ophthalmologist, 1983–1994

Krypton Argon Regression of Neovascularization Study

Co-investigator, 1983–1993

Macular Photocoagulation Study
Co-investigator, 1983–1993

Other National Clinical Trials

OMEGA: A randomized, double-masked, dose-ranging, multi-center, phase II study comparing the safety and efficacy of OT-551 with placebo to treat geographic atrophy associated with age-related macular degeneration
Principal investigator, 2006–2009

A multi-center, double-masked, randomized, vehicle-controlled, parallel group evaluation of the safety and efficacy of OT-551 ophthalmic solution to prevent formation or delay progression of nuclear cataract formation in post-vitrectomy patients
Principal investigator, 2005–2007

Visudyne Patient Registry
Principal investigator, 2005–2007

Efficacy and safety study of squalamine ophthalmic solution in subjects with neovascular AMD (MAKO)
Co-investigator, 2016–

Phase II, multicenter, randomized, single-masked, sham-controlled study of safety, tolerability and evidence of activity of intravitreal APL-2 therapy in patients with geographic atrophy (GA)
Co-investigator, 2015–

Phase III double masked study of safety and efficacy of abicipar pegol in patients with neovascular age-related macular degeneration
Co-investigator, 2015–

LHA510 proof-of-concept study as a maintenance therapy for patients with wet age-related macular degeneration
Co-investigator, 2015–

Randomized, double-masked, multicenter, three-arm study comparing the efficacy and safety of RTH-258 versus aflibercept in subjects with neovascular age-related macular degeneration
Co-investigator, 2015–

Intravitreal administration of Fovista (anti PDGF-B pegylated aptamer) administered in combination with either Avastin or Eylea compared to Avastin or Eylea monotherapy in subjects with subfoveal neovascular age-related macular degeneration
Co-investigator, 2015–

An 18-month Phase 2a open label, randomized study of Avastin, Lucentis, or Eylea (anti-VEGF therapy) administered in combination with Fovista (anti-PDGF BB pegylated aptamer)
Co-investigator, 2015–

A study of lampalizumab intravitreal injections administered every two weeks or every four weeks to patients with geographic atrophy (EXPOSURE)

Co-investigator, 2015–

Phase III, multicenter, randomized, double-masked, sham-controlled study to assess the efficacy and safety of lampalizumab administered intravitreally to patients with geographic atrophy secondary to age-related macular degeneration (PROXIMA)

Co-investigator, 2015–

Phase 2, multi-center study to compare the efficacy and safety of a chemokine CCR2/5 receptor antagonist with ranibizumab in adults with diabetic macular edema

Co-investigator, 2014–

A study investigating the efficacy and safety of lampalizumab intravitreal injections in patients with geographic atrophy secondary to age-related macular degeneration (CHROMA)

Co-investigator, 2014–

Phase 3, randomized, double-masked, controlled trial to establish the safety and efficacy of intravitreal administration of Fovista (anti PDGF-B pegylated aptamer) administered in combination with Lucentis compared to Lucentis monotherapy in subjects with subfoveal neovascular age-related macular degeneration

Co-investigator, 2013–

Phase 2b/3 multicenter, randomized, double-masked, dose-ranging study comparing the efficacy and safety of emixustat hydrochloride (ACU-4429) with placebo for the treatment of geographic atrophy associated with dry age-related macular degeneration (SEATTLE)

Co-investigator, 2013–

Prospective, randomized, double-masked, multicenter, two-arm study comparing the efficacy and safety of ESBA1008 versus Eylea® in subjects with exudative age-related macular degeneration (OSPREY)

Co-investigator, 2013–

Phase 2 multicenter randomized clinical trial of ciliary neurotrophic factor (CNTF) for macular telangiectasia type 2 (MacTel)

Co-investigator, 2013–

Efficacy and safety of squalamine lactate eye drops in subjects with neovascular (wet) age-related macular degeneration

Co-investigator, 2012–

Safety and tolerability of intravenous LFG316 in wet age-related macular degeneration

Co-investigator, 2012–2013

Single and repeat dose study of the safety and efficacy of AGN-150998 in patients with exudative age-related macular degeneration

Co-investigator, 2012

A multicenter, randomized, sham-control, proof-of-concept study of intravitreal LFG316 in patients with geographic atrophy associated with age-related macular degeneration

Co-investigator, 2012–

Ocriplasmin for treatment for symptomatic vitreomacular adhesion including macular hole (OASIS)

Co-investigator, 2012–2014

A study of safety, tolerability, and evidence of activity of FCFD4514S administered monthly or every other month to patients with geographic atrophy

Co-investigator, 2011–2013

Phase I multicenter open-label safety and tolerability clinical trial of ciliary neurotrophic factor (CNTF) in patients with macular telangiectasia Type 2 (MacTel)

Co-investigator, 2011–

Multicenter, 2 stage (open label, dose escalation, followed by masked, randomized) single dose study of the safety and efficacy of AGN-208397 in patients with macular edema (ME) associated with retinal vein occlusion (RVO)

Co-investigator, 2011–2012

Phase 2b dose-ranging study of pazopanib eye drops versus ranibizumab intravitreal injections for the treatment of neovascular age-related macular degeneration

Co-investigator, 2010–2011

Phase III, double-masked, multicenter, randomized, active treatment-controlled study of the efficacy and safety of 0.5 mg and 2.0 mg ranibizumab administered monthly or on an as-needed basis (PRN) in patients with subfoveal neovascular age-related macular degeneration (HARBOR) (Genentech)

Co-investigator, 2009–2012

Impact of Lucentis on psychological morbidity in patients with macular edema and neovascularization secondary to retinal vein occlusion

Co-investigator, 2009–2012

Phase 2, randomized, double-masked, controlled trial to establish the safety and efficacy of intravitreal injections of E10030 (anti-PDGF pegylated aptamer) given in combination with Lucentis® in subjects with neovascular age-related macular degeneration

Co-investigator, 2010–2011

Phase 1a, multicenter, open-label, single-dose, dose-escalation study of the safety, tolerability, pharmacokinetics, and immunogenicity of intravitreal injections of FCFD4514S in patients with geographic atrophy

Co-investigator, 2009–2010

Phase II, randomized, double-masked, placebo- controlled, add-on study to assess the efficacy of oral aliskiren 300 mg one daily for diabetic macular edema

Co-investigator, 2009–2010

Geographic Atrophy Treatment Evaluation (GATE) Study

Co-investigator, 2009–2012

Phase 2, randomized, double-masked, placebo-controlled, dose-ranging clinical study to assess the safety and efficacy of subconjunctival injections of sirolimus in patients with DME secondary to diabetic retinopathy

Co-investigator, 2008–2010

Natural History of Geographic Atrophy Progression (GAP) Study

Co-investigator, 2008–2009

Phase 2, randomized, double-masked, placebo-controlled, dose-ranging clinical study to assess the safety and efficacy of subconjunctival injections of sirolimus in patients with diabetic macular edema secondary to diabetic retinopathy

Co-investigator, 2008–2010

Phase 1, single ascending dose and parallel group trial to establish the safety, tolerability, and pharmacokinetic profile of multiple intravitreal injections of Volociximab ($\alpha 5\beta 1$ integrin antagonist) as monotherapy or given in combination with Lucentis 0.5mg/eye in subjects with neovascular AMD (Ophthotech 3000)

Co-investigator, 2008–2011

Safety and efficacy of 700ug dexamethasone posterior segment drug delivery system (DEXDDS) applicator system in combination with laser photocoagulation compared with laser photocoagulation alone in the treatment of diffuse macular edema (DME)

Co-investigator, 2008–2009

Anecortave acetate for treatment of steroid- induced intraocular pressure (IOP) elevation

Co-investigator, 2008–2010

Phase 1, single ascending dose trial to establish the safety, tolerability, and pharmacokinetic profile of intravitreal injections of E10030 (anti-PDGF pegylated aptamer) monotherapy and of E10030 given in combination with Lucentis 0.3mg/eye in subjects with neovascular AMD

Co-investigator, 2007

A multicenter, randomized, placebo-controlled, double-masked, parallel group, dose-ranging clinical trial of intravitreal microplasmin in patients undergoing surgical vitrectomy: The MIVI III (Microplasmin for Vitreous Injection III) Trial

Co-investigator, 2007–2008

A masked, multicenter, randomized, controlled trial to assess the safety and efficacy of 700 μ g dexamethasone posterior segment drug delivery system (DEX PS DDS) applicator system in combination with laser photocoagulation compared with laser photocoagulation alone in the treatment of subjects with diffuse diabetic macular edema

Co-investigator, 2007–2009

A study of ranibizumab injection in subjects with clinically significant with macular edema center involvement secondary to diabetes mellitus (RIDE)

Co-investigator, 2007–2012

Indocyanine green (ICG) angiographic evaluation of ranibizumab (Lucentis®) treatment of pigment epithelial detachment (PED) associated with age-related macular degeneration (AMD)

Co-investigator, 2007–2009

COBALT: COmbining Bevasiranib And Lucentis Therapy. A phase III, randomized, double-masked, parallel-assignment study of intravitreal bevasiranib sodium, administered every 8 or 12 weeks as maintenance therapy following three injections of Lucentis®, compared with Lucentis® monotherapy every 4 weeks in patients with exudative age-related macular degeneration (AMD)

Co-investigator, 2007–2008

Denali: a 24-month randomized, double-masked, controlled, multicenter, phase IIIB study assessing safety and efficacy of verteporfin (Visudyne® photodynamic therapy administered in conjunction with ranibizumab (Lucentis®) versus ranibizumab (Lucentis®) monotherapy in patients with subfoveal choroidal neovascularization secondary to age-related macular degeneration

Co-investigator, 2007

Age-related Macular Degeneration: Detection of Onset of new Choroidal neovascularization (AMD DOC) study comparing preferential hyperacuity perimetry (PHP) with supervised Amsler grid in detecting AMD for earlier treatment in high-risk fellow eyes (Johns Hopkins)

Co-investigator, 2007–2009

Small Interfering RNA In Macular Degeneration Study (SIRIUS): A 2 year, multicenter, randomized, controlled, masked, dose-finding trial to assess the safety and efficacy of multiple intravitreal injections of AGN211745 in subjects with subfoveal choroidal neovascularization secondary to age-related macular degeneration

Co-investigator, 2007–2008

Sirion Phase II randomized, double-masked, placebo-controlled, dose-comparison study of the safety and efficacy of fenretinide in the treatment of geographic atrophy in age-related macular degeneration

Co-investigator, 2006–2010

Phase IV, open label, multicenter trial of maintenance intravitreal injections of Macugen® (pegaptanib sodium) given every 6 weeks for 48 weeks in subjects with subfoveal neovascular age-related macular degeneration (AMD) initially treated with a modality resulting in maculopathy improvement (Eyeteck 1023)

Co-investigator, 2006

Study of the efficacy and safety of intravitreal injection of Macugen for neovascular lesions of AMD with recent onset

Co-investigator, 2006–2008

Macugen (pegaptanib sodium) for pathological myopia complicated by subfoveal choroidal neovascularization

Co-investigator, 2006–2010

Macugen (pegaptanib sodium) for angioid streaks complicated by choroidal neovascular membrane

Co-investigator, 2006–2010

A Phase IIIb, multicenter study to evaluate the safety and tolerability of ranibizumab in naïve and previously treated subjects with choroidal neovascularization secondary to age-related macular degeneration (SAILOR)

Co-investigator, 2006–2007

The effect of ruboxistaurin on clinically significant macular edema in patients with diabetes mellitus, as assessed by optical coherence tomography

Co-investigator, 2005–2011

A 6-month, Phase III, multicenter, masked, randomized, sham-controlled trial (with 6-month open-label extension) to assess the safety and efficacy of 700 µg and 350 µg dexamethasone posterior segment drug delivery system (DEX PS DDS) applicator system in the treatment of patients with macular edema following branch retinal vein occlusion or central retinal vein occlusion

Co-investigator, 2005–2007

A 3-year, Phase III, multicenter, masked, randomized, sham-controlled trial to assess the safety and efficacy of 700 µg and 350 µg dexamethasone posterior segment drug delivery system (DEX PS DDS) applicator system in the treatment of patients with diabetic macular edema

Co-investigator, 2005–2007

*RNAi Assessment of *Cand5* in Diabetic Macular Edema (RACE)*

Co-investigator, 2005–2007

Natural history and genetics study of macular telangiectasia (MacTel)

Co-investigator, 2005–

Phase IV study of daily dosing (vs. previous “on demand”) of Cialis vs. Viagra vs. placebo and its effect on visual functioning in healthy males or those with mild erectile dysfunction

Co-investigator, 2005–2006

Veritas: A 24-month randomized, double-masked, sham controlled, multicenter, phase III B study comparing photodynamic therapy with verteporfin (Visudyne®) plus two different dose regimens of intravitreal triamcinolone acetonide (1 mg and 4 mg) versus Visudyne® plus intravitreal pegaptanib (Macugen®) in patients with subfoveal choroidal neovascularization secondary to age-related macular degeneration

Co-investigator, 2005–2006

Cand5 Anti-VEGF RNAi Evaluation (CARE)

Co-investigator, 2005–2007

Interval Dose Evaluation of Anecortave Acetate (IDEAA)

Co-investigator, 2005–2008

Ocular side effects of Cialis vs. Viagra vs. placebo

Co-investigator, 2005–2006

A Phase II, dose ranging, open-labeled, multi-center study to evaluate the safety and efficacy of combretastatin A4 phosphate for treating subfoveal choroidal neovascularization in subjects with pathologic myopia

Co-investigator, 2005–2006

An open-label study for the evaluation of tolerability of four dose levels of Cand5 administered by single intravitreal injection in patients with wet age-related macular degeneration

Co-investigator, 2004–2007

A Phase 4, randomized, active controlled, double masked, single dummy, multi-center comparative trial, in parallel groups, to compare the safety and efficacy of intravitreal injections of Macugen® given every 6 weeks for 102 weeks plus sham photodynamic therapy (PDT), to Macugen plus PDT® with Visudyne in subjects with predominantly classic subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD) (Eyeteck 1012)

Co-investigator, 2005–2007

Protocol A43221001: A Phase 1 / 2 randomized, masked, placebo-controlled, single and multiple-dose, sequential dose escalation study of the safety and efficacy of AG-013958 in subjects with subfoveal choroidal neovascularization associated with age-related macular degeneration

Co-investigator, 2005–2006

A Phase II randomized, double-masked, multi-center trial, in parallel groups, to determine the safety, efficacy and pharmacokinetics of intravitreal injections of pegaptanib sodium compared to sham injection for 30 weeks in patients with recent vision loss due to macular edema secondary to central retinal vein occlusion (Eyeteck 1011B)

Co-investigator, 2004–2006

Open label, non-comparative protocol for use of 0.3mg intravitreal Macugen injections every 6 weeks in patients with AMD (Eyeteck 1010)

Co-investigator, 2004–2005

A Phase II prospective, randomized, double-masked, sham controlled, dose-ranging, multi-center trial to assess the effect of pegaptanib sodium on fovea thickening in patients with exudative subfoveal age-related macular degeneration (Eyeteck 1009)

Co-investigator, 2004–2006

Anecortave Acetate Risk-Reduction Trial (AART)

Co-investigator, 2004–2008

Protein kinase C β inhibitor study B7A-MC-MBDL. Reduction in the occurrence of center-threatening diabetic macular edema

Co-investigator, 2004–2010

A randomized, single-masked, multicenter, Phase 2 evaluation of the effect of photodynamic therapy using verteporfin (Visudyne[®] Therapy) in combination with intravitreal injection of either 0 mg, 1 mg, or 4 mg of triamcinolone acetonide in occult subfoveal and minimally classic subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD): Visudyne with Intravitreal Triamcinolone Acetonide (VisTA) Trial

Co-investigator, 2004–2006

A phase III, multicenter, randomized, double-masked, active treatment-controlled study of the efficacy and safety of rhuFabv2 (ranibizumab) compared with verteporfin (Visudyne) photodynamic therapy in subjects with predominantly classic subfoveal neovascular age-related macular degeneration

Co-investigator, 2003–2006

The Implantable Miniature Telescope (IMT[™]) in patients with central vision impairment associated with age-related macular degeneration or Stargardt's macular dystrophy

Co-investigator, 2003–2005

A randomized, double-masked, multi-center trial of the safety, tolerability and pharmacokinetics of 1 mg/eye and 3 mg/eye intravitreal injections of pegaptanib sodium (anti-VEGF pegylated aptamer) given every 6 weeks for 54 weeks, in patients with exudative age-related macular degeneration (Eyeteck 1006)

Co-investigator, 2002–2006

A Phase II randomized, controlled, double-masked, dose-finding, multi-center, comparative trial, in parallel groups, to establish the safety and preliminary efficacy of intravitreal injections of EYE001 (anti-VEGF pegylated aptamer), given every 6 weeks for 12 to 30 weeks to patients with clinically significant diabetic macular edema (CSME) involving the center of the macula (Eyeteck 1005)

Co-investigator, 2002–2003

Intravitreal Steroid Injection Studies (ISIS)

Co-investigator, 2002–2006

Oculex Study: A Phase 2 randomized, multicenter, dose-ranging, controlled, parallel-group trial to assess the safety and effectiveness of dexamethasone posterior segment drug delivery system (DEX PS DDS[®]) in the treatment of persistent macular edema

Co-investigator, 2001–2003

Fluocinolone Acetonide in Diabetic Macular Edema (FAME 4) Study. A multicenter, randomized, masked, controlled study to evaluate the safety and efficacy of Retisert[™], an intravitreal fluocinolone acetonide implant, in the treatment of patients with diabetic macular edema

Co-investigator, 2001–2007

Phase II/III randomized, double-masked, controlled, dose-ranging, multicenter comparative trial, in parallel groups, to establish the safety and efficacy of intravitreal injections of EYE001 (anti-VEGF pegylated aptamer) given every six weeks for 54 weeks in patients with age-related macular degeneration

Co-investigator, 2001–2005

Protein kinase C β inhibitor studies B7A-MC-MBCM. Diabetic Retinopathy Study 2

Co-investigator, 2001–2006

Phase IB open-label multicenter trial to establish the safety and pharmacokinetic profile of three consecutive injections of EYE001 (anti-VEGF pegylated aptamer) in patients with age-related macular degeneration without previous or concomitant photodynamic therapy with Visudyne[™]

Co-investigator, 2000–2002

TTT4CNV Study: Transpupillary thermotherapy for subfoveal occult choroidal neovascularization in age-related macular degeneration

Co-investigator, 2000–2004

Evaluation of efficacy and safety of a sub-Tenon's injection of anecortave acetate sterile suspension versus placebo in patients with exudative age-related macular degeneration (AMD) following treatment with photodynamic therapy (PDT) using Visudyne[™]

Co-investigator, 2000–2001

Open-label, multicenter, safety study of the treatment of predominantly classic choroidal neovascularization secondary to age-related macular degeneration using photodynamic therapy with verteporfin for injection

Co-investigator, 1999–2000

Evaluation of safety and duration of efficacy of anecortave acetate sterile suspension versus placebo following a single sub-Tenon's injection for the inhibition of neovascularization in patients with exudative age-related macular degeneration

Co-investigator, 1998–2001

Study of the matrix metalloprotease inhibitor, AG3340, in patients with subfoveal choroidal neovascularization associated with age-related macular degeneration

Co-investigator, 1998–2001

Verteporfin in Photodynamic Therapy Study

Co-investigator, 1998–2003

Protein kinase C β inhibitor studies B7A-MC-MBBK and B7A-MC-MBBM, Diabetic Macular Edema Study and Diabetic Retinopathy Study

Co-investigator, 1998–2002

Treatment of Age-related Macular Degeneration with Photodynamic Therapy

Co-investigator, 1996–2002

Vitrace™ for Vitreous Hemorrhage Study

Co-investigator, 1998–1999

Age-related Macular Degeneration and Thalidomide Study

Co-investigator, 1996–2000

Perfluoron™ (perfluoro-n-octane) for use in the treatment of complicated retinal detachment

Co-investigator, 1995–1996

Oculon Study: Evaluation of the efficacy of OC-2 in the inhibition of cataract formation associated with vitrectomy surgery

Principal Investigator, 1993–1994

Hydrokinetic retinal manipulation using the viscous fluid perfluorocarbon perfluorophenanthrene study

Co-investigator, 1993–1994

SELECTED PRESENTATIONS AT LOCAL, NATIONAL, AND INTERNATIONAL MEETINGS AND SYMPOSIA

1. ForeseeHome monitoring program for early detection of wet AMD. Optometric Retinal Update Seminar. Cleveland, Ohio, June 16, 2016.
2. Patient experience in a retinal office. Optometric Retinal Update Seminar. Akron, Ohio, April 6, 2016.
3. Update on treatment of rhegmatogenous retinal detachment. Optometric Retinal Update Seminar. Akron, Ohio, November 4, 2015.
4. Results of the Age-Related Eye Disease Study 2 (AREDS2). Optometric Retinal Update Seminar. Warren, Ohio, September 10, 2013.

5. Results of the Age-Related Eye Disease Study 2 (AREDS2). Optometric Retinal Update Seminar. Westlake, Ohio, June 18, 2013.
6. Retinal update on anti-VEGF therapy (with Drs. Coney, Miller, Rao, Schartman, and Zegarra). Ophthalmologists' Update Seminar. Vermilion, Ohio, December 20, 2012.
7. Lifestyle modifications to prevent the development & progression of macular degeneration. Advisory Council for Curing Blindness. Case Western Reserve University School of Medicine. Cleveland, Ohio, November 8, 2012.
8. Update of lifestyle modifications to treat patients with macular degeneration. Optometric Retinal Update Seminar. Youngstown, Ohio, September 20, 2012.
9. Retinal update on anti-VEGF therapy (with Drs. Coney, Miller, Rao, Schartman, and Zegarra). Ophthalmologists' Update Seminar. Vermilion, Ohio, August 12, 2012.
10. Posterior segment manifestations of ocular worm infestations. Optometric Retinal Update Seminar. Beachwood, Ohio, March 15, 2012.
11. Update of lifestyle modifications to treat patients with macular degeneration. Optometric Retinal Update Seminar. Westlake, Ohio, June 28, 2011.
12. Recent advances in the treatment of diabetic macular edema. Cleveland Ophthalmological Society. Cleveland, Ohio, October 12, 2010.
13. Advances in the treatment of diabetic macular edema. Optometric Retinal Update Seminar. Westlake, Ohio, August 19, 2010.
14. A patient's experience with a retinal specialist. Optometric Continuing Education Program and Open House. Lorain, Ohio, January 13, 2009.
15. Interesting retinal cases. Optometric Retinal Update Seminar. Westlake, Ohio, June 18, 2008.
16. Update on lifestyle and dietary modifications for patients with age-related macular degeneration (AMD). Optometric Retinal Update Seminar. Youngstown, Ohio, September 18, 2008.
17. Update on lifestyle and dietary modifications for patients with age-related macular degeneration (AMD). Optometric Retinal Update Seminar. Westlake, Ohio, July 15, 2008.
18. Interesting vitreoretinal cases. Optometric Retinal Update Seminar. Beachwood, Ohio, February 21, 2008.
19. Rhegmatogenous retinal detachment. Optometric Retinal Update Seminar. Youngstown, Ohio, September 5, 2007.

20. Rhegmatogenous retinal detachment. Optometric Retinal Update Seminar. Westlake, Ohio, July 17, 2007.
21. Modern treatment of rhegmatogenous retinal detachment. Optometric Retinal Update Seminar. Beachwood, Ohio, February 15, 2007.
22. Update on lifestyle and dietary modifications for patients with age-related macular degeneration. Optometric Retinal Update Seminar. Youngstown, Ohio, September 28, 2006.
23. Lifestyle and for people with age-related macular degeneration. Seminar on Age-related Macular Degeneration, in conjunction with Macula Vision Research Foundation SupportSight. Solon, Ohio, June 3, 2006.
24. Retinal detachment. Parma Community General Hospital Retinal Update. Parma, Ohio, March 21, 2006.
25. Lifestyle and dietary modifications for patients with age-related macular degeneration. Optometric Retinal Update Seminar. Beachwood, Ohio, February 9, 2006.
26. Nutrition and dietary modifications - can what I eat affect macular degeneration? Seminar on Nutrition and Macular Degeneration (joint presentation of Retina Associates of Cleveland and Macula Vision Research Foundation SupportSight). Middleburg Heights, Ohio, October 29, 2005.
27. Complications of vitrectomy. Cleveland Ophthalmological Society Meeting. Cleveland, Ohio, October 11, 2005.
28. An overview of macular degeneration. Optometric Retinal Update Seminar. Westlake, Ohio, August 11, 2005.
29. Macular degeneration. Lakewood Hospital Medical Grand Rounds. Lakewood, Ohio, April 2005.
30. Lifestyle & dietary modifications for patients with age-related macular degeneration. Optometric Retinal Update Seminar. Beachwood, Ohio, February 15, 2005.
31. Case report: blindness following glue embolization of a right temporal arteriovenous malformation. American Academy of Ophthalmology Meeting. New Orleans, Louisiana, October 2004.
32. Infectious endophthalmitis. Parma Community General Hospital. Parma, Ohio, October 5, 2004.
33. Posterior segment manifestations of ocular worm infestations. Optometric Retinal Update Seminar. Westlake, Ohio, July 29, 2004.

34. Case report: a patient with diabetes and cystoid macular edema. Cleveland Ophthalmological Society. Cleveland, Ohio, February 10, 2004.
35. Update on vitamins, nutrition, and age-related macular degeneration. Optometric Retinal Update Seminar. Westlake, Ohio, August 12, 2003.
36. Vitamins, nutrition, and age-related macular degeneration. Optometric Retinal Update Seminar. Beachwood, Ohio, February 20, 2003.
37. Vitamins, nutrition, and age-related macular degeneration. Optometric Retinal Update. Cleveland, Ohio, August 2003.
38. Posterior vitreous separation, retinal tears and detachments. Optometric Retinal Update. Cleveland, Ohio, February 26, 2002.
39. Diffuse unilateral subacute neuroretinitis. Cleveland Ophthalmological Society. Cleveland, Ohio, February 12, 2002.
40. Sheen retinal dystrophy (co-authors: Polk TD, Gass JDM, Green WR, Johnson MW). Cleveland Ophthalmological Society. Cleveland, Ohio, February 6, 1996.
41. Blindness and diabetes. Hillcrest Hospital. Diabetes Educational Update: From Head to Toe. June 7, 1995, Cleveland, Ohio.
42. Vitreous surgery for the vitreomacular traction syndrome (co-author: Rice TA). The Macula Society Seventeenth Annual Meeting, February 24, 1994, Rancho Mirage, California. The Vitreous Society Annual Meeting, 1994, Aspen, Colorado. The Retina Society Annual Meeting, 1994, Williamsburg, Virginia.
43. Ohio Ophthalmological Society. June 6, 1993, Columbus, Ohio.
44. The aging eye. Lakewood Hospital Health Talks. August 26, 1992, Lakewood, Ohio.
45. Neovascular glaucoma (co-author: Lamping KA). University Hospitals, Ophthalmology Grand Rounds. June 2, 1992, Cleveland, Ohio.
46. Vitreous surgery for idiopathic macular holes. University Hospitals, Department of Ophthalmology Faculty and Alumni Symposium. May 29, 1992, Cleveland, Ohio.
47. Ohio Ophthalmological Society. May 9, 1992, Columbus, Ohio.
48. Diabetes and your eyes. Euclid Hospital Diabetes Recheck Clinic. May 6, 1992, Cleveland, Ohio.
49. Macular degeneration. Lakewood Hospital. March 31, 1992, Lakewood, Ohio.
50. Diabetes and your eyes. Hillcrest Hospital Diabetes Education Program. November 7, 1991, Cleveland, Ohio.

51. Acetazolamide for cystoid macular edema from diabetic maculopathy. Cleveland Ophthalmological Society. October 1, 1991, Cleveland, Ohio.
52. Holes, tears, and lattice degeneration—this year's management. Case Western Reserve University School of Medicine Continuing Education in Ophthalmology, Current Concepts in Retinal Diseases. September 22, 1989, Cleveland, Ohio.
53. Corneal pathology, Part II. St. Luke's Hospital. May 1989, Cleveland, Ohio.
54. Diabetic retinopathy. Healthlines, Cleveland Academy of Medicine radio program, WCLV. January and February 1989, Cleveland, Ohio.
55. The pupil. Greater Cleveland Ophthalmic Medical Assistants and Technicians Society. November 1988, Cleveland, Ohio.
56. Calcium oxalate retinopathy associated with methoxyflurane abuse (co-authors: Roth AS, Levine MR). American Academy of Ophthalmology Meeting, 1987.
57. Indications for ultrasonography. Kresge Eye Institute, Wayne State University School of Medicine. Update in Ophthalmic Ultrasound. Detroit, Michigan, 1986.
58. Pre-Academy Fluorescein Angiography Club, American Academy of Ophthalmology Meeting, 1985–2005.
59. Management of posterior segment trauma. University Hospitals of Cleveland, Cleveland, Ohio, November 1985.
60. Fluorescein angiography study of idiopathic epiretinal membranes (coauthors: Wesberry Jr J, Singerman LJ, Rice TA). Wilmer (Johns Hopkins) Residents Association Annual Meeting, 1985. Ohio Ophthalmological Society, 1987.
61. Diabetic retinopathy. Fairview General Hospital, Cleveland, Ohio, February 1986.
62. Red krypton and argon laser photocoagulation in central serous chorioretinopathy (co-authors: Singerman LJ, Rice TA). Association for Research in Vision and Ophthalmology Annual Spring Meeting, 1985. Ohio Ophthalmological Society, 1986.
63. New concepts in central serous retinopathy (co-authors: Singerman LJ, Rice TA, Passloff R). Wilmer (Johns Hopkins) Residents Association Annual Meeting, 1984.
64. Preoperative and surgical prognostic risk factors in successful diabetic vitrectomies (co-authors: Michels RG, Rice TA, Auer C). American Academy of Ophthalmology Meeting, 1983.
65. Diabetic vitrectomy and postoperative vitreous hemorrhage (co-authors: Michels RG, Rice TA, Auer C). Wilmer (Johns Hopkins) Residents Association Annual Meeting, 1983.

66. Specular microscopy of Schnyder central crystalline dystrophy of the cornea (co-author: Hirst LW). International Congress of Ophthalmology Meeting, 1982.
67. The lens and diabetic vitrectomy (co-authors: Rice TA, Michels RG). Wilmer (Johns Hopkins) Residents Association Annual Meeting, 1982. American Academy of Ophthalmology Meeting, 1982.
68. Macular coloboma and congenital cytomegalovirus infection (co-authors: Jabs DA, Welch RB). American Academy of Ophthalmology Meeting, 1981.
69. Acute posterior vitreous detachments and their complications (co-author: Welch RB). Wilmer (Johns Hopkins) Residents Association Annual Meeting, 1981. Association for Research in Vision and Ophthalmology Annual Spring Meeting, 1981.
70. Clinical case report of familial giant cell arteritis. Wilmer (Johns Hopkins) Residents Association Annual Meeting, 1979.

PUBLICATIONS

Journal Articles

1. Chen Z, Miao F, Paterson AD, Lachin JM, Zhang L, Schones DE, Wu X, Wang J, Tompkins JD, Genuth S, Braffett BH, Riggs AD; DCCT/EDIC Research Group, Natarajan R. Epigenomic profiling reveals an association between persistence of DNA methylation and metabolic memory in the DCCT/EDIC type 1 diabetes cohort. *Proc Natl Acad Sci U S A*. 2016;113(21):E3002-11.
2. Lenherr SM, Clemens JQ, Braffett BH, Cleary PA, Dunn RL, Hotaling JM, Jacobson AM, Kim C, Herman W, Brown JS, Wessells H, Sarma AV; DCCT/EDIC Research Group. Glycemic control and urinary tract infections in women with type 1 diabetes: Results from the DCCT/EDIC. *J Urol*. 2016;196:1129-1135.
3. Sharma S, Toth CA, Daniel E, Grunwald JE, Maguire MG, Ying GS, Huang J, Martin DF, Jaffe GJ; Comparison of Age-related Macular Degeneration Treatments Trials Research Group. Macular morphology and visual acuity in the second year of the comparison of age-related macular degeneration treatments trials. *Ophthalmology*. 2016;123:865-875.
4. Shah N, Maguire MG, Martin DF, Shaffer J, Ying GS, Grunwald JE, Toth CA, Jaffe GJ, Daniel E; Comparison of Age-related Macular Degeneration Treatments Trials Research Group. Angiographic cystoid macular edema and outcomes in the Comparison of Age-Related Macular Degeneration Treatments Trials. *Ophthalmology*. 2016;123:858-864.
5. AREDS2 Research Group, Al-Holou SN, Tucker WR, Agrón E, Clemons TE, Sperduto RD, Ferris FL 3rd, Chew EY. The association of statin use with cataract progression

- and cataract surgery: The AREDS2 Report Number 8. *Ophthalmology*. 2016;123:916-917.
6. Wells JA, Glassman AR, Jampol LM, Aiello LP, Antoszyk AN, Baker CW, Bressler NM, Browning DJ, Connor CG, Elman MJ, Ferris FL, Friedman SM, Melia M, Pieramici DJ, Sun JK, Beck RW; Diabetic Retinopathy Clinical Research Network. Association of baseline visual acuity and retinal thickness with 1-year efficacy of aflibercept, bevacizumab, and ranibizumab for diabetic macular edema. *JAMA Ophthalmol*. 2016 Feb;134(2):127-134.
 7. Daniel E, Shaffer J, Ying GS, Grunwald JE, Martin DF, Jaffe GJ, Maguire MG; Comparison of Age-Related Macular Degeneration Treatments Trials (CATT) Research Group. Outcomes in eyes with retinal angiomatous proliferation in the Comparison of Age-Related Macular Degeneration Treatments Trials (CATT). *Ophthalmology*. 2016;123:609-616.
 8. Bressler SB, Ayala AR, Bressler NM, Melia M, Qin H, Ferris FL 3rd, Flaxel CJ, Friedman SM, Glassman AR, Jampol LM, Rauser ME; Diabetic Retinopathy Clinical Research Network. Persistent macular thickening after ranibizumab treatment. *JAMA Ophthalmol*. 2016 Mar 1;134:278-285.
 9. Writing Committee for the Diabetic Retinopathy Clinical Research Network, Gross JG, Glassman AR, Jampol LM, Inusah S, Aiello LP, Antoszyk AN, Baker CW, Berger BB, Bressler NM, Browning D, Elman MJ, Ferris FL 3rd, Friedman SM, Marcus DM, Melia M, Stockdale CR, Sun JK, Beck RW. Panretinal photocoagulation vs intravitreal ranibizumab for proliferative diabetic retinopathy: a randomized clinical trial. *JAMA*. 2015 Nov 13:1-11.
 10. Aiello LP, Ayala AR, Antoszyk AN, Arnold-Bush B, Baker C, Bressler NM, Elman MJ, Glassman AR, Jampol LM, Melia M, Nielsen J, Wolpert HA; Diabetic Retinopathy Clinical Research Network. Assessing the effect of personalized diabetes risk assessments during ophthalmologic visits on glycemic control: a randomized clinical trial. *JAMA Ophthalmol*. 2015;133:888-896.
 11. Eny KM, Orchard TJ, Miller RG, Maynard J, Grant DM, Costacou T, Cleary PA, Braffett BH, Paterson AD; DCCT/EDIC Research Group. Caffeine consumption contributes to skin intrinsic fluorescence in type 1 Diabetes. *Diabetes Technol Ther*. 2015;17:726-734.
 12. Bressler SB, Almkhatar T, Bhorade A, Bressler NM, Glassman AR, Huang SS, Jampol LM, Kim JE, Melia M; Diabetic Retinopathy Clinical Research Network Investigators. Repeated intravitreal ranibizumab injections for diabetic macular edema and the risk of sustained elevation of intraocular pressure or the need for ocular hypotensive treatment. *JAMA Ophthalmol* 2015;133:589-597.

13. Willoughby AS, Ying GS, Toth CA, Maguire MG, Burns RE, Grunwald JE, Daniel E, Jaffe GJ; Comparison of Age-Related Macular Degeneration Treatments Trials Research Group. Subretinal hyperreflective material in the Comparison of Age-Related Macular Degeneration Treatments Trials. *Ophthalmology* 2015;122:1846-1853.
14. Diabetic Retinopathy Clinical Research Network, Wells JA, Glassman AR, Ayala AR, Jampol LM, Aiello LP, Antoszyk AN, Arnold-Bush B, Baker CW, Bressler NM, Browning DJ, Elman MJ, Ferris FL, Friedman SM, Melia M, Pieramici DJ, Sun JK, Beck RW. Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema. *N Engl J Med* 2015 Mar 26;372:1193-1203.
15. Altaweel MM, Daniel E, Martin DF, Mittra RA, Grunwald JE, Lai MM, Melamud A, et al; Maguire MG; Comparison of Age-related Macular Degeneration Treatments Trials (CATT) Research Group. Outcomes of eyes with lesions composed of >50% blood in the Comparison of Age-Related Macular Degeneration Treatments Trials (CATT). *Ophthalmology* 2015;122:391-398.
16. Chew EY, Clemons TE, Peto T, Sallo FB, Ingerman A, Tao W, Singerman L, Schwartz SD, Peachey NS, Bird AC; MacTel-CNTF Research Group. Ciliary neurotrophic factor (CNTF) for macular telangiectasia Type 2 (MacTel): Results from a phase I safety trial. *Am J Ophthalmol* 2015;159:659-666.
17. Simpson CL, Wojciechowski R, Oexle K, Murgia F, Portas L, Li X, Verhoeven VJ, et al; DCCT/EDIC Research Group. Genome-wide meta-analysis of myopia and hyperopia provides evidence for replication of 11 loci. *PLoS One* 2014 Sep 18;9(9):e107110. doi: 10.1371/journal.pone.0107110. eCollection 2014.
18. Folgar FA, Jaffe GJ, Ying GS, Maguire MG, Toth CA; Comparison of Age-Related Macular Degeneration Treatments Trials Research Group. Comparison of optical coherence tomography assessments in the comparison of age-related macular degeneration treatments trials. *Ophthalmology* 2014 Oct;121(10):1956-1965.
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20. Maguire MG, Daniel E, Shah AR, Grunwald JE, et al; Comparison of Age-Related Macular Degeneration Treatments Trials (CATT Research Group). Incidence of choroidal neovascularization in the fellow eye in the comparison of age-related macular degeneration treatments trials. *Ophthalmology* 2013;120:2035-2041.
21. Jaffe GJ, Martin DF, Toth CA, et al; Comparison of Age-related Macular Degeneration Treatments Trials Research Group. Macular morphology and visual acuity in the comparison of age-related macular degeneration treatments trials. *Ophthalmology* 2013;120:1860-1870.

22. Cheng CY, Schache M, Ikram MK, et al; Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions, and Complications Research Group. Nine loci for ocular axial length identified through genome-wide association studies, including shared loci with refractive error. *Am J Hum Genet* 2013;93:264-277.
23. Bressler SB, Qin H, Melia M, et al; Diabetic Retinopathy Clinical Research Network. Exploratory analysis of the effect of intravitreal ranibizumab or triamcinolone on worsening of diabetic retinopathy in a randomized clinical trial. *JAMA Ophthalmol* 2013;131:1033-1040.
24. Danis RP, Domalpally A, Chew EY, et al; AREDS2 Study Group. Methods and reproducibility of grading optimized digital color fundus photographs in the Age-Related Eye Disease Study 2 (AREDS2 Report Number 2). *Invest Ophthalmol Vis Sci* 2013;54:4548-4554.
25. Age-Related Eye Disease Study 2 Research Group. Lutein + zeaxanthin and omega-3 fatty acids for age-related macular degeneration: the Age-Related Eye Disease Study 2 (AREDS2) randomized clinical trial. *JAMA* 2013 May 15;309:2005-2015.
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27. Hagstrom SA, Ying GS, Pauer GJ, et al; Comparison of AMD Treatments Trials Research Group. Pharmacogenetics for genes associated with age-related macular degeneration in the Comparison of AMD Treatments Trials (CATT). *Ophthalmology* 2013;120:593-599.
28. Diabetic Retinopathy Clinical Research Network. Randomized clinical trial evaluating intravitreal ranibizumab or saline for vitreous hemorrhage from proliferative diabetic retinopathy. *JAMA Ophthalmol* 2013;131:283-293.
29. Niskopoulou M, Balaskas K, Leung I, Sallo FB, Clemons TE, Bird AC, Peto T; MacTel Study group. Is indocyanine green angiography useful for the diagnosis of macular telangiectasia type 2? *Br J Ophthalmol* 2013;97:946-948.
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- acuity outcomes after vitrectomy for diabetic macular edema: Diabetic Retinopathy Clinical Research Network. *Retina* 2010;30:1488-1495.
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