ORBIT: A Phase IV Clinical Study - Lessons Learned From Patient Selection Criteria for Ocriplasmin Intravitreal Injection

- Mathew W. MacCumber, MD, PhD
- David S. Boyer, MD
- Jeffrey S. Heier, MD
- Peter K. Kaiser, MD
- Jay S. Duker, MD
- Dante Joseph Pieramici, MD

OBJECTIVE To report results of the Phase IV ORBIT clinical trial studying ocriplasmin treatment for symptomatic vitreomacular adhesion (VMA) with respect to efficacy and patient selection.

PURPOSE The goal of the Phase IV ORBIT study is to prospectively and systematically collect real-world data on clinical efficacy and safety outcomes on patients receiving ocriplasmin according to standard- of -care in US retina clinics. Another objective of the study is to further define patient criteria that will improve success compared to the Phase III MIVI-TRUST results.

METHODS ORBIT is a multicenter, prospective, observational Phase IV study that has enrolled 542 patients from 90 clinical sites. Patients are enrolled at the time of ocriplasmin injection and followed for up to 12 months. Treatment decisions, including the frequency and timing of patient visits after injection, are at the discretion of the treating physician following standard of care, and are not mandated by the study design. Clinical effectiveness and safety data are entered in electronic case report forms, based on investigator assessments. SD-OCT images are uploaded to a central reading center for independent review.

RESULTS Here we present the complete patient baseline data and the efficacy results up to 6 months follow-up according to various patient characteristics. Pharmacological VMA resolution at 1 week, 1 month, and 6 months will be reported according to baseline characteristics: adhesion size, lens status, injection position, presence of FTMH, and presence of an ERM. Final 6 month data, as well as safety reports will be presented.

CONCLUSION Data collected from the ORBIT study will provide a real-world efficacy and safety profile of ocriplasmin, better characterize post-injection patient experiences, and help identify patients who may respond best to ocriplasmin therapy. The results presented here will further characterize patient selection for ocriplasmin treatment including patient injection position.

TAKE HOME MESSAGE Patient selection is critical when considering ocriplasmin treatment for patients with symptomatic vitreomacular adhesion to improve efficacy and safety outcomes.

HUMAN RESEARCH This study involves human research.
IRB Approval Status: Approved by institutional review board

Differences in Surgical Performance in Peeling the ILM for Macular Holes Between Fellows-in-Training and Experienced Vitreoretinal Surgeons

- Robert Gizicki, MD
- Michael YK Mak, BHSc
- Rajeev H. Muni, MD, MSC, FRCS(C)
- Filiberto Altomare, MD, FRCSC
- Alan R. Berger, MD, FRCS(C), B. Sc.
- David T.W. Wong, MD, FRCS(C)
- Louis Giavedoni, MD FRCS (C), DABO
- David R. Chow, MD, FRCS(C)

OBJECTIVE To investigate the differences in surgical maneuvers between vitreoretinal fellows and experienced vitreoretinal surgeons when peeling the ILM in the setting of surgical repair for macular holes.

PURPOSE To investigate the differences in surgical maneuvers between vitreoretinal fellows in training and experienced vitreoretinal attending surgeons when peeling the ILM in the setting of surgical repair for macular holes.

METHODS Prospective comparative case series of recorded surgeries for macular hole repair performed by vitreoretinal fellows-in-training and experienced vitreoretinal surgeons at St Michael's hospital (Toronto, Canada) during an 18 month period. Evaluation of all the video recordings was masked. Total peel time (in seconds), total attempts at initiating and extending ILM flaps, intra-surgical complications (retina or RPE contusion, hemorrhage related to grasping of retinal tissue, iatrogenic retinal tears) and surgical efficiency (ratio of approaches that led to case progression to total approaches) were quantified.

RESULTS 39 surgeries were evaluated over the study period, of which 22 were performed by fellows and 17 by attending surgeons. In 24 cases ICG was used to stain the ILM and in 15 cases triamcinolone was use to highlight the ILM. Mean total peel time was significantly shorter for attendings compared to fellows (317s vs 487s, p=0.0056). Surgical efficiency was significantly better for attendings compares to fellows (45% vs 37% of approaches led to progression of case, p=0.038). There was no significant difference between the groups in total attempts of flap initiation, flap extension, overall total number of movement attempts or intra-surgical complications. Use of ICG or triamcinolone did not affect significantly surgical performance of either fellows or attendings.

CONCLUSION As compared to fellows-in-training, attending vitreoretinal physicians peel ILM in macular hole surgery in a faster and more efficient way.

TAKE HOME MESSAGE In peeling the ILM for macular holes, experienced vitreoretinal surgeons accomplished the surgical objective in a faster and more efficiently.

T-Shaped Macular Buckling Combined With 25-Gauge Pars Plana Vitrectomy for Macular Hole, Macular Schisis and Macular Detachment in Highly Myopic Eyes

- Marco Mura, MD

OBJECTIVE Learn the added value of a combined approach macular buckle and pars plana vitrectomy in the management of macular holes in high myopic patients

PURPOSE To report our experience using the T-shaped macular buckle (MB) with or without pars plana vitrectomy as a primary surgery or with a previous failed surgical approach in patients affected by high myopia and macular hole (MH) with or without macular detachment (MD) and with or without macular schisis (MS). The primary goal was to evaluate complete closure of the MH and reattachment of the retina.

METHODS Retrospective case series of 21 consecutive patients who underwent T-shaped MB implant alone or combined with PPV at the Academic Medical Center in Amsterdam, The Netherlands, between January 2013 and November 2014. The mean axial length was 31,22 mm . The mean follow up period was 7 months.

RESULTS Retinal reattachment was achieved in 100% of cases while MH closure was achieved in 90.5%. No major perioperative complications were observed. BCVA improved in 71.4% of patients.

CONCLUSION MB combined with PPV should be considered as the preferred surgical approach both in primary and recurrent retinal detachment secondary to MH in high myopic eyes.

TAKE HOME MESSAGE Combined macular buckle and pars plana vitrectomy increase closure rate of macular holes in high myopic patient and improve outcome

HUMAN RESEARCH This study involves human research.

IRB Approval Status: Approval waived

The Evolution of Pre-Existing Epiretinal Membranes Following Cataract Extraction

- Gayatri S. Reilly, MD
- Luke B. Lindsell, OD, MD
- Kevin Wells, MD
- Julia Michelle White, BA

OBJECTIVE To assess the evolution of a pre-existing epiretinal membrane (ERM) following cataract extraction.

PURPOSE Little guidance is available regarding management of patients with an ERM planning to undergo cataract extraction (CE/IOL). Clinical and optical coherence tomography (OCT) data were analyzed to assess the evolution of a pre-existing ERM following CE/IOL, as well as to identify characteristics that may predict the need for a future pars plana vitrectomy and membrane peel (PPV/MP).

METHODS A retrospective chart review was conducted from records at The Retina Group of Washington between January 1, 2010 and December 31, 2013. The ICD-9 code (362.56) for ERM was used to identify charts for review. Patients were required to have an ERM prior to CE/IOL and have follow-up of at least 6 months. 4,112 charts were reviewed and 190 eyes met inclusion criteria. Clinical data was collected for all patients and OCT data was collected when available (70 eyes).

RESULTS 190 eyes with an ERM were evaluated pre and post CE/IOL. 55/190 underwent PPV/MP following CE/IOL. Mean time from CE/IOL to PPV/MP was 5.6 months. Development of CME following CE/IOL was found to be a predictor of requiring a PPV/MP (p=0.012). Average time of development of CME post-CE/IOL was 67.9

days. Patients undergoing PPV/MP had worse pre- and post-CE/IOL visual acuity (pre-CE/IOL VA: PPV/MP=20/50, no PPV/MP=20/30, p=0.015; post-CE/IOL VA: PPV/MP=20/50, no PPV/MP=20/30, p<0.001). Eyes requiring PPV/MP, mean pre-CE/IOL central foveal thickness (CFT) and mean change from pre- to post-CE/IOL were both increased compared to the eyes that did not have a PPV/MP(pre-CE/IOL CFT: PPV/MP=453um, no PPV/MP=342um, p<0.001; change in CFT: PPV/MP=+40.2um, no PPV/MP=+18.5um, p<0.001). Loss of foveal contour on OCT at the pre-CE/IOL visit demonstrated an increased odds ratio for needing a PPV/MP (OR=7.01, p=0.01). Final VA was similar in both groups (PPV/MP=20/30, no PPV/MP=20/30, p=0.168).

CONCLUSION ERMs are common in patients that undergo CE/IOL. Eyes with poorer pre and post CE/IOL visual acuity, higher CFT, loss of foveal contour, and those that developed CME post-CE/IOL were most likely to undergo a PPV/MP. Average time to the development of CME post-CE/IOL was 67.9 days. It is important to counsel patients on the possibility of needing a PPV/MP to achieve their full visual potential.

TAKE HOME MESSAGE Eyes with poorer pre and post CE/IOL visual acuity, higher CFT, loss of foveal contour, and those that developed CME post-CE/IOL were most likely to undergo a PPV/MP.

HUMAN RESEARCH This study involves human research.
IRB Approval Status: Approved by institutional review board