10/10/2021 1:40PM

A Randomized Clinical Trial of Pneumatic Vitreolysis for Vitreomacular Traction: DRCR Retina Network Protocol AG

- Clement K. Chan, MD, FACS
- Calvin E. Mein, MD

OBJECTIVE Evaluate management strategies for vitreomacular traction without macular hole.

PURPOSE To compare pneumatic vitreolysis (PVL) versus observation for management of vitreomacular traction (VMT).

METHODS A multi-center randomized clinical trial conducted by the DRCR Retina Network, Protocol AG, compared PVL with C3F8 gas versus sham injection (observation) for VMT without macular hole (confirmed by central reading center). At baseline, best-corrected visual acuity was between 20/32 and 20/400. Rescue vitrectomy could be given per prespecified criteria. The primary outcome was release of central VMT without rescue at 24 weeks (confirmed by central reading center). Secondary outcomes included receipt of rescue vitrectomy, change in visual acuity from baseline, and change in shape discrimination hyperacuity from baseline. All participants were followed for 24 weeks.

RESULTS Forty-six participants with VMT and no macular hole were enrolled in Protocol AG. The mean participant age was 72 years and 67% were female. In study eyes (one per participant), mean visual acuity score was 68.5 letters (approximate Snellen equivalent 20/50), mean shape discrimination hyperacuity was 0.35 logMAR (approximate Snellen equivalent 20/50), 7% had an epiretinal membrane in the central subfield, and median length of vitreomacular adhesion in the central subfield was 495 µm. Results have been analyzed and reviewed by the Data and Safety Monitoring Committee, but per National Eye Institute requirements for NIH-funded clinical trials, primary results cannot be made publicly available before publication. Submission and publication of the manuscript are anticipated before presentation of the results at the 2021 ASRS annual meeting.

CONCLUSION Conclusions will follow from the results presented.

IRB APPROVAL Yes — *IRB Approval Letter may be requested*.

10/10/2021 1:46PM

A Single-Arm Study of Pneumatic Vitreolysis for Macular Hole:DRCR Retina Network Protocol AH

- Calvin E. Mein, MD
- Clement K. Chan, MD, FACS

OBJECTIVE Is pneumatic vitreolysis (PVL) safe and effective for treatment of small full thickness macular holes ?

PURPOSE To evaluate PVL for the treatment of full thickness macular holes (FTMH).

METHODS A single-arm study conducted by the DRCR Retina Network, Protocol AH , evaluated PVL using C3F8 gas for FTHM less than or equal to 250 microns (confirmed by central reading center). At baseline, best-corrected visual acuity was between 20/25 and 20/400 in AH. Rescue vitrectomy could be given per prespecified criteria. The primary outcome was closure of FTMH without rescue at 8 weeks (confirmed by a central reading center). Secondary outcomes included receipt of rescue vitrectomy, visual acuity change from baseline, macular hole closure without rescue at 24 weeks, and release of central vitreomacular traction without rescue at 24 weeks. All participants were followed for 24 weeks.

RESULTS Thirty-fiv e participants with VMT and FTMH were enrolled in Protocol AH. The mean participant age was 69 years and 69% were female. Among study eyes (one per participant), mean VA score was 55.8 letters (approximate Snellen equivalent 20/80), 3% had an epiretinal membrane in the central subfield, and mean width of FTMH at the narrowest point was 82 microns. Results have been analyzed and reviewed by the Data and Safety Monitoring Committee, but per National Eye Institute requirements of NIH-funded clinical trials, primary results cannot be made publiclly available before publication. Publication of the manuscript are anticipated before presentation of the results at the 2021 ASRS annual meeting.

CONCLUSION Conclusions will follow from the resluts presented.

IRB APPROVAL Yes — *IRB Approval Letter may be requested*.

10/10/2021 1:52PM

A Titanium Macular Buckle Implant Designed for an Easy Placement in Myopic Macular Holes

- Levent Akduman, MD

OBJECTIVE To introduce a new design for an easy to place titanium macular buckle implant and the surgical technique for placing it in myopic macular holes.

PURPOSE A 60-year-old patient with degenerative myopia presented with macular hole in both eyes. The one in the right eye was a recurrent long-standing hole over 5 years from the initial diagnosis. He refused surgery for the better seeing left eye. The right eye vision was 20/400. The patient wanted macular hole repair in the right eye only if a macular buckle could be incorporated in the surgery.

METHODS Since there was no commercially available macular buckle in the United States, a custom-made titanium buckle was designed and manufactured for this patient (Figure 1). In addition to the standard pars plana vitrectomy, internal limiting membrane peel, and gas tamponade, the titanium macular buckle was placed externally to provide indentation over the macula.

RESULTS The titanium macular buckle provided 1 mm of indentation, shortening the axial length from 28.88 mm to 27.94 mm. The macular hole was closed postoperatively. Postoperative best corrected visual acuity was 20/400 at 1 month with no complications from the titanium macular buckle implant or the surgical technique. In Figure 2, the image on the left shows preoperative OCT and the image on the right shows postoperative OCT. The tip of the implant is seen in the OCT right underneath the macular indentation.

CONCLUSION This titanium macular buckle implant designed for an easy placement could be an invaluable addition for the surgical success in repair of degenerative myopic macular pathologies, including myopic macular holes.

IRB APPROVAL No — I received a determination that the study/activity qualified for **exempt status or that it did not require IRB approval** from an IRB or another authorized oversight body *(IRB Exemption Letter may be requested)*.

Figure 1. Titanium macula buckle implant designed for an easy placement in myopic maculopathies.

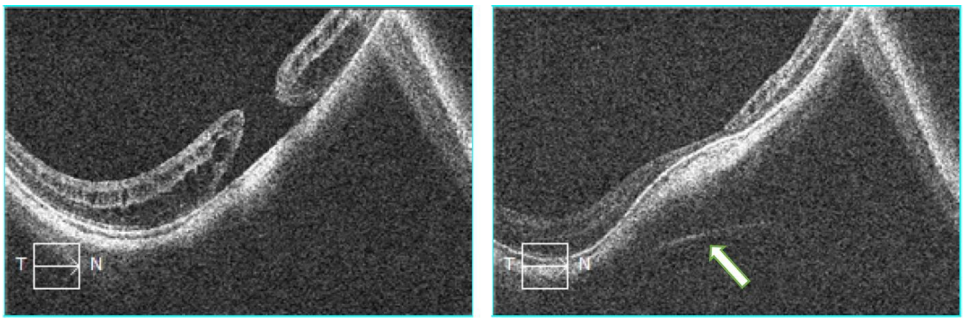

Figure 2. The image on the left shows preoperative OCT and the image on the right shows postoperative OCT. The tip of the implant is seen in the OCT right underneath the macular indentation.

10/10/2021 1:56PM

First Human Results with the Highest Count (256 Electrode) Epiretinal Prosthesis Purpose

- Mark S. Humayun, MD, PhD
- huizhuo xu, MD
- Jing Zou, MD
- Wangling Chen
- Changlin Pang, PhD
- Xianggui Wang, MD
- Shanxiang Li, MD
- Didier Sagan
- Xingwu Zhong, MD
- Philip Weiss
- Yangyi Yao, Ph.D
- Jiayi Xiang
- Margot S Dayan
- Yu-Chong Tai, PhD

OBJECTIVE To report the safety and efficacy from a pilot study of the highest density (256 electrode) epiretinal prosthesis to date in subjects with end-stage Retinitis Pigmentosa (RP).

PURPOSE Retinal prosthetics such as the Argus II have successfully restored a degree of sight to those blinded by retinitis pigmentosa, however, the visual acuity of current devices is limited. A 256 electrode epiretinal prosthesis (Intelligent Micro Implant Eye; IMIE256) addresses many of the limitations of previous retinal prostheses. Herein, we present for the first time the results from this implant.

METHODS After obtaining informed consent, five subjects (age range 56-60 years) with light perception or worse vision were each implanted in their worse seeing eye with the 256 epiretinal prosthesis. The implantation procedure was similar to that previously published for Argus II except that the entire implant was positioned in the superotemporal quadrant. After two weeks postop, visual testing was started which included: identifying the position and direction of movement of a light source, pattern/number/letter recognition, indoor and

outdoor walking. All adverse events were recorded. All results presented are at the 90 days postop checkpoint; the timepoint all subjects had met as of this report.

RESULTS All five subjects underwent implantation without complications. Their retinal electrode arrays were well positioned as shown in Figures 1&2. Figure 1: Ninety days Postoperative Fundus Photos of 256 electrode epiretinal prosthesis (A) Figure 2: Ninety days Postoperative OCT Images of 256 electrode epiretinal prosthesis There were two serious adverse events (SAE's) observed in the first postop week, and both were in one subject (Subject#2). The first was slight upward translation of the electrode array requiring repositioning and the second was reduced IOP after repositioning requiring silicone oil tamponade. Both SAE's resolved after the above interventions. The visual testing yielded following results: (1) Grating Visual Acuity test, 5/5 subjects achieved 20/800, (2) Tumbling E test, 4/5 subjects could see at 20/1200 level, (3) The mean percent difference between success rate with the system ON versus the system OFF on the Door Location Task and Line Walking tests were both 80%.

CONCLUSION The 256 implant efficacy and safety results are better than Argus II (e.g., Argus II success rate of 24% vs 80% with this implant on Door Location Task). These improvements are likely due to the smaller electronic case size and denser electrodes. While these results are encouraging, this study is limited by the small sample size and shorter follow-up period and further investigation is warranted.

IRB APPROVAL Yes — *IRB Approval Letter may be requested*.

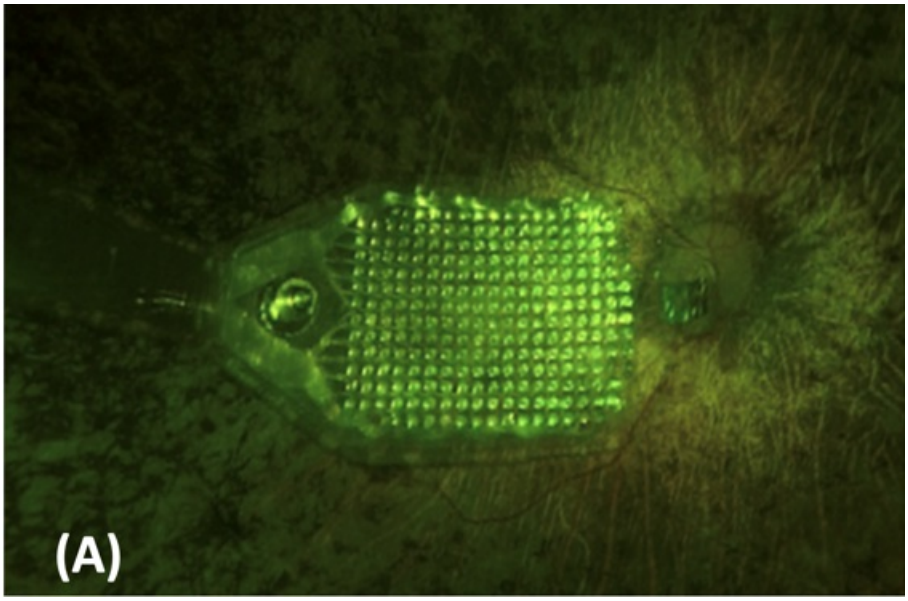

Figure 1: Ninety days Postoperative Fundus Photos of 256 electrode epiretinal prosthesis (A)

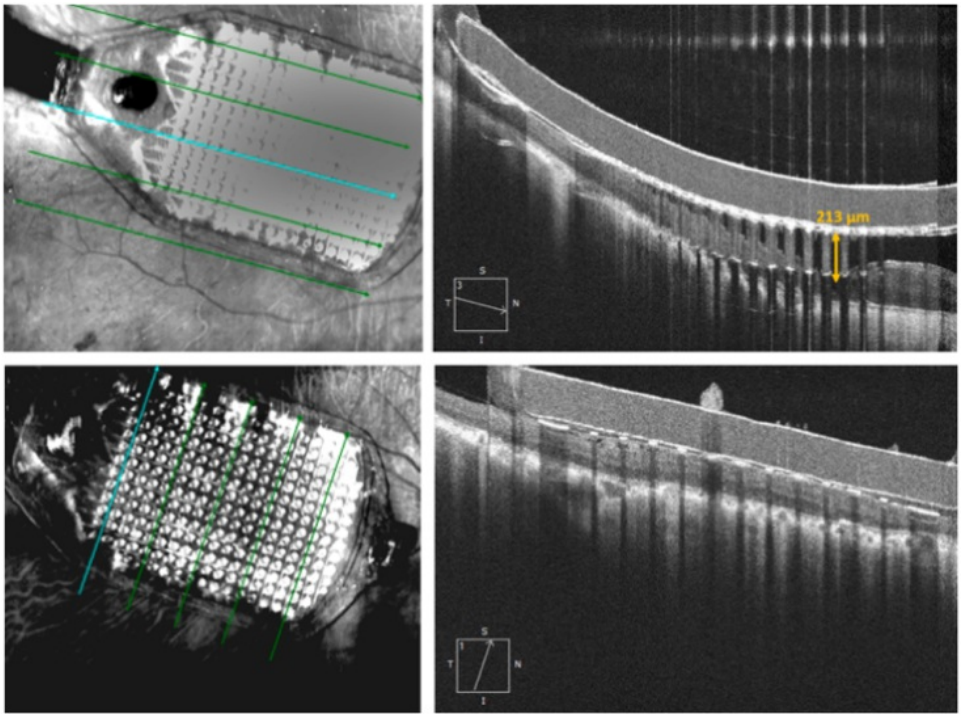

Figure 2: Ninety days Postoperative OCT Images of 256 electrode epiretinal prosthesis

10/10/2021 2:10PM

Visual Recovery and Complication Rates in Anterior Chamber Intraocular Lens Implantation Patients

- Uday R. Desai, MD
- Kevin Leikert, DO
- Jennifer Aye, DO
- Sean Ojha
- Nauman Imami, MD
- Nitin Kumar, MD
- Himanshu Aggarwal

OBJECTIVE We wanted to examine the visual results and complication rates of patients who had an anterior chamber intraocular lens (ACIOL) placement as a result of poor capsular or zonular support.

PURPOSE Recent modalities for treating patients with insufficient capsular or zonular support have included a variety of techniques that fixate the intraocular lens in the sclera. We wanted to evaluate the visual results and complication rates of our patients that underwent ACIOL placement and compare them to recent reports of patients with scleral-fixated IOL's.

METHODS This was a retrospective chart review. We searched our billing database for CPT codes 67036 (pars plana vitrectomy), 66850 (pars plana lensectomy), and 66985 (secondary intraocular lens implantation). The search included patients from 2013 to 2020. A total of 181 charts were identified. Inclusion criteria included those patients that had an ACIOL placed and had at least 1 month of follow up. Patients were excluded if they did not have at least 1 month of follow up. This resulted in a total of 28 eyes of 25 patients. Visual results and complications including corneal pathology, glaucoma, and cystoid macular edema (CME) were analyzed.

RESULTS Preop VA was mean of 20/726 with a median of CF at 2 feet. Best postop VA was

mean of 20/78 with median of 20/30. Best final VA was mean of 20/128 with median of 20/50. Best and final visions were significantly better than preop vision ($p<0.001$). 15/28 eyes (54%) had a final VA less than 20/40. Of these 11/15 (73%) had prexisting pathology that accounted for the suboptimal vision. 3/28 eyes (11%) had corneal pathology seen in follow up. Of these 1/3 (33%) had preexisting pathology. Seven percent (2/28) of patients had cornea changes attributed to the ACIOL. 9/28 eyes (32%) had glaucoma seen in follow-up. Of these 5/9 (56%) had preexisting glaucoma. Of the remaining 4 patients only one (4%) was thought to be related to the ACIOL. 5/28 eyes (18%) were diagnosed with CME postoperatively. Of these 2/5 (40%) were related to preexisting epiretinal membrane or diabetic macular edema. Eleven percent (3/28) of patients had CME attributed to the ACIOL.

CONCLUSION Recent reports of scleral-fixated IOL's show mean postop VA ranging from 20/35 to 20/50. IOP elevation occurred in 3-23% of cases and CME occurred in 13-21% of cases. Our results for visual recovery and postoperative complications after ACIOL placement are not too dissimilar to those reported after scleral-fixated IOL placement. ACIOL placement is still an effective option in these cases.

IRB APPROVAL Yes — *IRB Approval Letter may be requested*.

10/10/2021 2:14PM

Cystoid Macular Edema After Scleral-Fixation of the Akreos AO60 Intraocular Lens

- Sneha Padidam, MD
- NICHOLAS ROUGRAFF, BA
- Joshua D Levinson, MD

OBJECTIVE What is the incidence and risk factors of cystoid macular edema after scleral fixation of the Akreos AO60 intraocular lens with Goretex suture?

PURPOSE To determine the incidence and risk factors for cystoid macular edema (CME) after scleral fixation of the Akreos AO60 intraocular lens (IOL) with Goretex suture

METHODS This is a retrospective consecutive interventional case series of eyes that underwent combined pars plana vitrectomy and scleral fixation of the Akreos AO60 IOL with using Gore-Tex suture at a large retina practice between June 2015 and December 2019. CME was defined as cystic changes noted on Spectral Domain Optical Coherence Tomography (SD-OCT). The primary outcome measure was the incidence of CME. The secondary outcomes studied were potential risk factors associated with CME.

RESULTS Two-hundred-and-two eyes met inclusion criteria. Of these eyes, 52 had post-operative CME (25.7%). There was a higher incidence of CME in patients who were left aphakic after cataract extraction compared to those with a dislocated intraocular lens, dislocated crystalline lens or were aphakic for other reasons (p=0.003). There was no statistically-significant difference in number of patients with history of retinal detachment, history of trauma/zonular instability or history of prior pars plana vitrectomy between the eyes that did or did not develop CME. There was no difference in incidence of CME in eyes where the Gore-tex suture placed was less than 3 mm from the limbus or placed greater than or equal to 3 mm from the limbus.

CONCLUSION This study represents the largest consecutive series of scleral-fixated Akreos AO60 IOLs. There was noted to be significant risk of developing CME, with approximately 1 in 4 patients developing clinically significant CME. Given the high incidence of CME, patients should be counselled about this risk and further investigation is warranted to identify contributing risk factors.

IRB APPROVAL Yes — *IRB Approval Letter may be requested*.

10/10/2021 2:20PM

Wavefront Aberrometry in Pseudophakic Patients Before and After Vitrectomy for Bothersome Floaters

- Daniel A. Adelberg, MD, FASRS

OBJECTIVE Is there an objective change in vision after vitrectomy in pseudophakic patients with persistent bothersome floaters utilizing a highly precise diagnostic modality-wavefront aberrometry?

PURPOSE Wavefront aberrometry was utilized to determine objective changes in pseudophakic patients with symptomatic floaters after 27 gauge vitrectomy. This study examines whether patients with symptomatic floaters are bothered by subjective or objective factors. This study explores vitreous degeneration and potential mechanisms of improvement in patients undergoing treatment with vitrectomy.

METHODS A noncomparative, nonconsecutive single surgeon case series was performed of pseudophakic patients who underwent 27 gauge vitrectomy for persistent floaters and clinical assessment included preoperative and postoperative wavefront aberrometry. Demographic and clinical analysis included age, sex, duration of symptoms, intraocular lens type, posterior capsular opacification, prior YAG capsulotomy, Snellen visual acuity, subjective improvement in vision after vitrectomy, and multiple measures of higher order aberrations with wavefront aberrometry. Patients were excluded if wavefront aberrometry was not performed, and if patients were phakic to reduce a potential confounding variable.

RESULTS Seventy six (76) eyes of sixty six (66) patients underwent 27 gauge vitrectomy for persistent floaters. Patients had a mean age of 67 years and a mean symptom duration prior to vitrectomy of 14 months. There were no intraoperative or postoperative complications. Snellen visual acuity improved from preoperative 20/32 to 20/25 ($p = 0.004$). Patient estimated subjective improvement in vision after surgery was a mean of 92%. Wavefront aberrometry demonstrated a highly significant reduction in higher order aberration percentage (HO%) ($p<0.000001$) with a mean preoperative HO% of 53.9 and mean postoperative HO% of 38.3. Subgroup analysis demonstrated that a significant reduction

was found in patients with no prior posterior capsulotomy($p=0.001$), prior YAG capsulotomy ($p<0.00001$), and presence of a multifocal IOL ($p=0.006$).

CONCLUSION Wavefront aberrometry demonstrates an objective , significant reduction in higher order aberrations after vitrectomy in pseudophakic patients with bothersome floaters. Vitreous degeneration in some pseudophakic patients contributes to visual abnormalities associated with higher order aberrations, and vitrectomy can improve the refractive status of these patients.

IRB APPROVAL No — I **did not receive IRB approval** or a determination that the study/activity was exempt or that it did not require IRB approval. **Complete a Human Subject Research application** for review by the ASRS Human Research Committee. **Your abstract will not be considered without a completed application.** The ASRS HRC will review the information provided to determine whether the study qualifies as exempt or otherwise not requiring IRB approval. The ASRS HRC is not constituted as an IRB and thus cannot provide IRB approval for activities that require such.

10/10/2021 2:26PM

Small Gauge Pars Plana Vitrectomy for Visually Significant Vitreous Floaters

- Matthew A. Cunningham, MD
- Jaya B Kumar, MD
- Samuel K. Steven Houston, MD, FASRS
- Elias C Mavrofrides, MD
- Thomas A. Barnard, MD

OBJECTIVE Is pars plana vitrectomy an effective and safe way to address visually significant vitreous opacities?

PURPOSE This study evaluates our experience at a retina-only private practice with small-gauge pars plana vitrectomy (PPV) for visually significant vitreous floaters. We review the surgical outcomes, complication rates, and percentage of second-eye surgery for the same indication.

METHODS Retrospective, interventional case series of consecutive patients undergoing PPV for significant vitreous floaters, from September 2014 to December 2018 at a vitreoretinal surgery practice. The preoperative visual acuity, complication rates, and visual outcome following surgery were evaluated in 104 eyes (81 patients). Inclusion criteria included significant visual disturbance due to vitreous floaters for >6 months, pseudophakia, and the presence of a PVD confirmed on clinical exam. Exclusion criteria included history of venous or arterial occlusive disease, advanced glaucoma or age-related macular degeneration, previous retinal detachment, endophthalmitis, or uveitis.

RESULTS A total of 104 eyes in 81 patients underwent PPV for visually significant floaters; 35 (43.2%) patients had PPV in both eyes. The mean preoperative visual acuity (VA) was 0.16 ± 0.17 logMAR units (~20/29 Snellen Equivalent) and improved to 0.12 ± 0.15 logMAR units (~20/26 Snellen Equivalent, Wilcoxon test, p=0.0083) at the last follow-up after PPV. All patients had improvement in VA at the final postoperative visit, with a VA of 20/40 or better achieved in 93.3% of cases. The complication rate of vitreous hemorrhage postoperatively was 0.96%. There were no cases of postoperative retinal tears, beaks, or

endophthalmitis.

CONCLUSION Small gauge PPV in the carefully selected patient is an effective and safe procedure to eliminate symptoms. VA following PPV for vitreous floaters significantly improved yielding high patient satisfaction. Nearly half patients (43.2%) underwent PPV in the other eye.

IRB APPROVAL Yes — *IRB Approval Letter may be requested*.