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Outcomes of Intraoperative OCT–Assisted Epiretinal Membrane Surgery from the PIONEER Study

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Purpose: To assess the retinal architecture changes that occur during epiretinal membrane (ERM) surgery, utilizing intraoperative OCT (*i*OCT).

Design: Prospective multisurgeon single-center study.

Subjects: Subjects from the PIONEER *i*OCT study who underwent surgical intervention for management of ERM.

Methods: All subjects underwent vitrectomy with ERM peeling with optional internal limiting membrane (ILM) peeling. Preoperative, intraoperative, and postoperative quantitative and qualitative OCT assessments were performed. Clinical characteristics including visual acuity outcomes, central subfield thickness, and complications, including ERM recurrence and need for reoperation, were assessed at 3, 6, and 12 months after surgery for membrane peeling, as available.

Main Outcome Measures: Visual acuity outcomes, anatomic outcomes, and complications, including ERM recurrence; microarchitectural alterations (i.e., retinal layer changes) after membrane peeling visualized with *i*OCT.

Results: Seventy-six subjects were identified and included in this analysis of clinical outcomes and quantitative OCT assessment. Twenty-four eyes were excluded due to insufficient intraoperative OCT quality for quantitative assessment. The mean preoperative visual acuity measured 20/63. The mean postoperative visual acuity at 3 months was 20/41 ($P < 0.0001$), at 6 months measured 20/36 ($P < 0.0001$), and at 12 months measured 20/33 ($P < 0.0001$). Preoperative mean central subfield thickness (CST) was 426 μm. At 3 months, the mean CST improved to 377 μm ($P < 0.0001$). The 6-month postoperative CST was 367 μm ($P < 0.0001$) and the 12-month postoperative CST measured 359 μm ($P < 0.0001$). Immediately after membrane peeling, the distance between the retinal pigment epithelium and the ellipsoid zone as well as the distance between the retinal pigment epithelium and the cone outer segment tips/interdigitation zone significantly increased ($P < 0.001$). *i*OCT identified occult residual membranes in 12% of cases and confirmed complete membrane peeling contrary to surgeon impression in 9% of cases. Reoperation was required for recurrent ERM in 1% of eyes.

Conclusions: *i*OCT-assisted ERM peeling resulted in significant improvement in visual acuity, reduction in macular thickness, and low recurrence rate. Additional research is needed with randomized clinical trials to better define the comparative success rates of image-guided ERM surgery to standard surgical visualization techniques. *Ophthalmology Retina 2017;■:1–5 © 2017 by the American Academy of Ophthalmology*

Supplementary files available at www.aaojournal.org.

OCT has become the diagnostic test of choice for assessing many macular diseases, including epiretinal membranes (ERMs).[1,2] Recent advances in the technology have allowed for increased speed and resolution. These advances, combined with more portable solutions and microscope-integrated options, have enabled its use in the operating room for in vivo retinal layer visualization.[3] Intraoperative OCT (*i*OCT) has been demonstrated during surgical management in a number of vitreoretinal conditions, including ERM, macular hole, vitreomacular traction, optic pit–related maculopathy, retinal detachment, and retinopathy of prematurity.[4–12]

The tangential traction and architectural distortion caused by an ERM may result in metamorphopsia and visual loss and increases in prevalence by age group.[13] When the visual symptoms become significant, ERM is treated through a pars plana vitrectomy (PPV) with membrane peeling.[14] Several studies have pointed to OCT for insights into prognostic factors that can affect postoperative visual acuity (VA), such as macular thickness, integrity of the photoreceptor ellipsoid zone (EZ; i.e., inner/outer segment junction),[15,16] and integrity of the interdigitation zone (IZ; i.e., cone outer segment tips [COST] line).[17] Previous small studies demonstrated the potential capabilities of *i*OCT

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during ERM surgery.[8–10] Changes in retinal architecture during ERM surgery that are otherwise undetectable to a surgeon through the en face view of a microscope can be noted with *i*OCT. Through the use of *i*OCT, more recent research has suggested that alterations occur in the outer retinal layers after membrane peeling.[18] Two large-scale prospective studies have reported the significant discordance between surgeon perception and OCT findings in completeness of membrane peeling.[19,20] To date, functional and anatomic outcomes with *i*OCT-assisted surgery have not been reported, to our knowledge.

The Prospective Intraoperative and Perioperative Ophthalmic Imaging with Optical Coherence Tomography (PIONEER) study is a large prospective multisurgeon study that included subjects undergoing vitrectomy for the treatment of a vitreomacular interface disorder.[19] In this report, we examine eyes from the PIONEER study that underwent membrane peeling with concurrent *i*OCT imaging to assess clinical outcomes in ERM patients and to better define the retinal architecture changes that occur during surgical intervention for ERM.

Methods

PIONEER is an institutional review board–approved, prospective, multisurgeon, single-center study that examined the feasibility and utility of *i*OCT for ophthalmic surgery. The methods of the PIONEER study have been previously described.[21] For this report, subjects in the PIONEER study who underwent surgical repair for a preoperative diagnosis of ERM were identified. Preoperative, intraoperative, and postoperative quantitative and qualitative OCT assessments were performed. Clinical characteristics, including VA outcomes, central subfield thickness (CST), and complications including ERM recurrence and need for reoperation, were assessed at 3, 6, and 12 months after surgery for membrane peeling, as available. ERM recurrence was defined as OCT-based visualization of an ERM that involved the foveal center or resulted in significant foveal distortion. Microsoft Excel was used for statistical analysis. The *t* test was used for comparing continuous variables.

Surgical Procedure

All patients underwent standard 3-port small-gauge PPV (23 or 25 gauge) for surgical ERM peel by 1 of 4 surgeons (JPE, SKS, PKK, RS). After completion of the core PPV with elevation of the hyaloid, as needed, indocyanine green (ICG) and/or triamcinolone was applied before membrane peeling at surgeon discretion. This staining was performed based on surgeon technique rather than *i*OCT findings. The membrane peeling technique was based on surgeon preference and was performed with either vitreoretinal forceps or a diamond-dusted membrane scraper combined with vitreoretinal forceps for peel completion. Internal limiting membrane (ILM) peeling was optional and performed at surgeon discretion, often based on *i*OCT findings after initial ERM peeling.

*i*OCT Scanning System

A microscope-mounted *i*OCT system was used for intraoperative imaging. The Bioptigen Envisu SDOIS (Bioptigen, Research Triangle Park, NC) portable probe was attached to the ophthalmic microscope using a custom, microscope-mounted system, as previously described.[11,12] *i*OCT was performed at various surgical milestones as determined by the surgeon, including pre-peel and after membrane peeling (e.g., post-peel). If a second peel attempt was deemed necessary, a second *i*OCT image was also obtained for confirmation of completion. A consistent image acquisition protocol was used, including cubic 10 × 10-mm volume scans (at 0 and 90 degrees), 10 × 5-mm volume scans with oversampling for averaging, and 10-mm radial volume scans. Each scan consisted of 100 B-scans distributed across the area with 1000 A-scans per B-scan. The 10 × 10-mm cube scans translated to a scan density of 1 B-scan every 0.1 mm.

*i*OCT Image Analysis

Qualitative and quantitative analyses of all scanning sequences were performed. Quantitative analysis was performed using a custom OCT analysis software platform. For quantitative assessment of retinal layer thickness, image analysis was performed of retinal zone measurements, including inner retinal thickness (i.e., nerve fiber layer), middle retinal thickness (ganglion cell layer, inner plexiform layer, outer plexiform layer), and outer retinal thickness (i.e., outer nuclear layer, EZ, retinal pigment epithelium [RPE]). Only eyes with sufficient scans of both preincision and postpeel measurements were included in the analysis. Each scan was assessed for several variables before and after surgical peeling: subretinal hyporeflectivity (i.e., EZ-to-RPE distance), central foveal thickness (CFT), and COST (or IZ)-to-RPE distance. The outer boundary used for measurement was the middle of the RPE. The inner boundary varied based on location of interest (e.g., ILM, middle of EZ). The preincision and postpeel measurements were compared using paired *t* test using Microsoft Excel. Surgical peeling technique, as well as specific surgeon, was compared to extent of architectural alterations.

Results

Clinical Characteristics and Demographics

Seventy-six eyes were identified in the PIONEER study to have undergone surgical intervention for the treatment of ERM and met inclusion criteria for this analysis. The median age was 68.4 years (range: 29–86 years). There were 39 male (51%) and 37 female subjects (49%). The mean preoperative VA was 20/63 (range: 20/25 to 20/2000). Fifty-two eyes (68%) were phakic and 24 (32%) were pseudophakic before surgery. All eyes underwent small-gauge PPV. ICG was used in 71 cases (93%) and triamcinolone in 27 cases (36%). Techniques used for membrane peeling included combined diamond-dusted membrane scraper/forceps for 39 eyes (51%) and forceps alone for 37 eyes (49%). No intraoperative complications were noted.

Clinical and Safety Outcomes

The mean preoperative VA measured 20/63 (range: 20/25 to 20/2000). The mean VA was 20/41 at 3 months (range: 20/20 to 20/400, $P < 0.0001$, n = 76), 20/37 at 6 months (range: 20/15 to 20/500, $P < 0.0001$, n = 64), and 20/34 (range: 20/15 to 20/200, $P < 0.0001$, n = 60) at 12 months. Preoperative mean CST was 434 μm (range: 283–649 μm). The mean CST improved to 377 μm at 3 months (range: 209–559 μm, $P < 0.0001$, n = 73), 367 μm at 6 months (range: 211–592 μm, $P < 0.0001$, n = 57), and 359 μm at 12 months (range: 215–531 μm, $P < 0.0001$, n = 48).

Cataract progression was reported in 3 subjects who remained phakic after the initial surgery after membrane peeling. One patient developed a retinal detachment after sustaining direct ocular trauma. OCT-based assessment of ERM recurrence revealed significant recurrent ERM in 2 of 76 eyes (3%). Of those 2