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Determination of Feasibility and Utility of Microscope-integrated OCT During Ophthalmic Surgery: the DISCOVER Study RESCAN Results

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Abstract

Importance—Optical coherence tomography (OCT) has transformed the clinical management of a myriad of ophthalmic conditions. Applying OCT to ophthalmic surgery may have implications for surgical decision-making and patient outcomes.

Objective—To assess the feasibility and impact on surgical-decision making of microscope-integrated intraoperative OCT (*i*OCT) system.

Design, Setting, and Participants—DISCOVER is an IRB-approved single-site multi-surgeon investigational device prospective consecutive case series. Participants included subjects undergoing ophthalmic surgery. Clinical characteristics were collected and *i*OCT imaging was obtained during surgical milestones as directed by the operating surgeon. A surgeon questionnaire was issued to each surgeon and completed after each case to evaluate the role of *i*OCT during surgery and its particular role in select surgical procedures. This report highlights the 1-year results (March 2014-February 2015) of the RESCAN 700 portion of the study.

Main outcomes measures—Percentage of cases with successful acquisition of *i*OCT imaging (i.e., feasibility). Percentage of cases that *i*OCT imaging altered surgical decision-making (i.e., utility)

Results—During year-1 of the DISCOVER study, 227 total eyes were enrolled (91 anterior segment cases and 136 posterior segment) to undergo imaging with the RESCAN 700 system. Successful imaging (e.g., the ability to acquire an OCT image of the tissue of interest) was obtained in 224 of 227 eyes (99%). During lamellar keratoplasty, the *i*OCT data provided information that altered surgeon decision-making in 38% of the cases (e.g., complete graft apposition when the surgeon believed there was interface fluid). In membrane peeling procedures, *i*OCT information was discordant with surgeon impression of membrane peel completeness in

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19% of cases (e.g. lack of residual membrane, presence of occult membrane) impacting additional surgical maneuvers.

Conclusions and Relevance—The DISCOVER study demonstrates the feasibility of real-time *i*OCT with a microscope-integrated *i*OCT system for ophthalmic surgery. The information gained from *i*OCT appears to allow surgeons to assess subtle details in a unique perspective from standard en face visualization which can affect surgical decision-making some of the time, although the impact of these changes in decision-making on outcomes remains unknown. A prospective randomized masked trial is needed to confirm these results.

Introduction

Optical coherence tomography (OCT) has evolved from an experimental instrument to a critical clinical diagnostic modality and may have the potential to become a seamless surgical-guidance tool. Recent literature studies examining intraoperative OCT (*i*OCT) support the potential role for *i*OCT in ophthalmic surgery.[1-10] These studies have examined the role for *i*OCT in multiple procedures and conditions, including epiretinal membranes, macular hole, vitreomacular traction, retinal detachment repair, lamellar keratoplasty, and cataract surgery. [1,3-6,8] The field of OCT-guided surgery remains a young and emerging field. Many early reports were retrospective with small sample sizes.[3-6,8] The PIONEER study, examining the utility of a microscope attached external OCT device during ophthalmic surgery, provided the first large prospective data set to examine the feasibility and utility of *i*OCT.[1]

However, the vast majority of previous studies focused on systems that were not integrated into the OCT that did not allow for real-time feedback or heads-up surgeon interfaces. The future of *i*OCT will likely be founded in integrative technologies. New systems are now emerging that provide the surgeon with microscope-integrated technology and may enable rapid “real-time” feedback on the anatomic changes that occur during surgical manipulations.[6,11-14] The key features of these systems in maximizing outcomes and minimizing surgical disruption remain unclear, as well as the specific procedures that would benefit from microscope-integrated *i*OCT.

In order to better understand the feasibility and utility of microscope integrated *i*OCT, the **D**etermination of feasibility of **I**ntraoperative **S**pectral domain microscope **C**ombined/integrated **O**CT **V**isualization during **E**n face **R**etinal and ophthalmic surgery (DISCOVER) study was initiated. This report provides the 1-year results for the assessment of feasibility and utility (i.e., impact on surgical decision-making) of microscope-integrated *i*OCT for ophthalmic surgery for one of the prototypes in the DISCOVER study, the RESCAN 700 (Carl Zeiss Meditec, Oberkochen, Germany).

Methods

DISCOVER (**D**etermination of feasibility of **I**ntraoperative **S**pectral domain microscope **C**ombined/integrated **O**CT **V**isualization during **E**n face **R**etinal and ophthalmic surgery) is a Cleveland Clinic IRB-approved prospective multi-surgeon investigational device study.

The study adhered to the tenets of the Declaration of Helsinki. A written, informed consent was obtained from all patients participating in DISCOVER.

The study included an intraoperative protocol for imaging during surgical milestones and immediate surgeon feedback. Data variables collected included indication for surgery, procedure, visual acuity, ocular comorbidities, details regarding surgical maneuvers/techniques (e.g., instrument type, surgical approach), type of OCT imaging obtained during surgery, and adverse events. Although scheduled study visits were completed following the first postoperative visit, IRB-approval includes an additional 2-year period of postoperative review of clinical variables, imaging outcomes, and clinical outcomes.

The DISCOVER study includes 3 microscope-integrated OCT prototypes: the RESCAN 700, the Bioptigen integrated prototype (Bioptigen, Research Triangle Park, NC), and an internally developed Cole Eye integrated prototype (Cleveland Clinic, Cleveland, OH). This report will focus on the RESCAN 700 results during year 1 (i.e., March 2014-February 2015). The imaging protocol directed surgeons to obtain imaging during and/or after surgical milestones, as determined by the operating surgeon. The RESCAN 700 system includes a microscope-integrated OCT system, as previously described.[2] Imaging data was reviewed by the surgeon intraoperatively and was reviewed independently postoperatively. Surgeons visualized the OCT data stream through the oculars utilizing the heads-up display or with an external display monitor, based on their preference. A research coordinator assisted with OCT acquisition, collecting surgeon feedback, and data collection.

Prespecified surgeon feedback questionnaires were completed for all cases focusing on several specific areas of interest related to the microscope-integrated system and surgical procedure, including the perceived value of *i*OCT to the procedure (e.g., impact on surgical decision-making), preferred ergonomics of the system (e.g., heads-up display, review mode), and issues related to workflow (e.g., interference with the case). Additionally, in select prespecified procedures (e.g., membrane peeling procedures, lamellar keratoplasty) an additional feedback form was completed related to the value of *i*OCT for that specific procedure.

Results

Clinical Demographics

At 1-year, 227 eyes were enrolled in the RESCAN 700 Arm of the DISCOVER study, ***Table 1***. There were 121 females (53%) and 106 males (47%). The mean age of patients in the study was 62 years. (range:19-91). Overall, successful acquisition of *i*OCT images was obtained in 224 of 227 [99%; 95% Confidence Interval (95%CI): 98-100%] eyes. *i*OCT images were not obtained in 2 patients due to surgeon-decision to not image and 1 case was not imaged due to software malfunction.

Anterior Segment iOCT Summary

In the anterior segment arm, 91 eyes were enrolled. The most common procedures included were Descemet Stripping Automated Endothelial Keratoplasty (DSAEK, 43%), and Deep Anterior Lamellar Keratoplasty (DALK, 9%), ***Table 1***. During DSAEK (***Figure 1,***

Supplemental Video 1) and Descemet Membrane Endothelial Keratoplasty (DMEK, ***Figure 2***), *i*OCT provided information related to graft position/orientation. In addition, *i*OCT provided visualization of interface fluid and graft/host apposition. Surgical manipulations (e.g., manual sweeping, increased air infusion pressure) were performed to minimize interface fluid (***Figure 1***). In DALK, *i*OCT provided real-time feedback of trephination depth, allowing for visualization of instrument-tissue interaction and providing immediate information related to the residual stromal bed (***Figure 2***). Imaging with *i*OCT confirmed location of intraocular implants, including glaucoma procedures (e.g., relative tube-endothelial location) and corneal inlay procedures (***eFigure 1***). During phacoemulsification, multiple steps of the procedure were visualized with *i*OCT including capsulorrhexis, hydrodissection, groove depth, and intraocular lens placement (***eFigure 2***).

Ergonomics and Value of Microscope integrated iOCT in Anterior Segment Surgery

Surgeons reported that microscope-integrated *i*OCT provided valuable feedback in 82 of 91 (90%; 95%CI: 84-96%) cases. According to surgeons in the study, 40 of 91 (44%; 95%CI: 34-54%) total anterior segment cases were changed or modified due to the *i*OCT findings. For example, during a DSAEK procedure, *i*OCT revealed subclinical graft detachment in the operating room that allowed the surgeon to intervene with rebubbling prior to stopping the case. During a corneal inlay procedure, wound depth was increased to optimize implant placement. During glaucoma surgical interventions, *i*OCT provided valuable data in select cases on optimal tube placement (e.g., verifying sulcus placement, relative tube-cornea location, ***eFigure 1)***.

Surgeons preferred real-time *i*OCT feedback in 63 of 91 cases (69%; 95%CI: 60-79%), compared to 21 of 91 (23%; 95%CI: 14-32%) cases where static feedback was more optimal. The heads-up display system was preferred to the screen in 84 of 91 (92%; 95%CI: 86-97%) cases, compared to viewing the OCT information on the video display. There were no reports of the *i*OCT system interfering with surgery. Contamination (e.g. contaminated glove, surgical instrument) occurred in 12 of 91 (13%; 95%CI: 6-20%) anterior segment cases. None of these contaminations resulted in surgical field contamination.

Intraoperative OCT Guidance of Surgical Decision-Making: Lamellar Keratoplasty

For DSAEK cases, *i*OCT was noted by surgeons to provide valuable feedback in 41of 41 (100%) cases. In 17 of 41 (41%; 95%CI: 26-56%) DSAEK cases, additional maneuvers were performed based on *i*OCT. In DSAEK procedures, following tissue placement and prior to *i*OCT imaging, surgeons believed the tissue was completely apposed in 26 of 41 (63%; 95%CI: 48-78%) cases and the remaining 15 of 41 (37%; 95%CI: 22-52%) cases did not believe the tissue was completely apposed. In 5 of 26 (19%; 95%CI: 4-34%) cases that the surgeon believed the graft was fully apposed, *i*OCT identified persistent interface fluid, facilitating additional maneuvers during the procedure. In 7/15 (47%; 95%CI: 22-72%) cases where the surgeon did not believe the tissue to be entirely apposed, *i*OCT revealed complete adherence of the graft confirming apposition, minimizing surgical time and unnecessary manipulations. In 11/41 (27%; 95%CI: 13-41%) DSAEK cases, *i*OCT identified the absence of interface fluid, contrary to the impression of the surgeon, eliminating the need for serial sweeps during surgery and reducing operative time.

For DALK surgery, surgeons indicated the achievement of big-bubble was noted clinically and confirmed on *i*OCT in 3 of 8 cases (38%; 95%CI: 4-72%). *i*OCT identified subclinical big-bubbles in 2 of the 5 (40%; 95%CI: 0-83%) remaining cases, which guided additional maneuvers for dissection. In 3 of 8 (38%; 95%CI: 4-72%) cases, *i*OCT impacted both stromal resection and helped facilitate identification of dissection depth.

Posterior Segment iOCT Summary

In the posterior segment arm, 136 eyes were enrolled. The most frequent indications for surgeries were epiretinal membrane (ERM, 25%), retinal detachment (RD, 20%), proliferative diabetic retinopathy (PDR, 9%), vitreous hemorrhage (VH, 9%), and macular hole (MH, 7%), ***Table 1***. In ERM and MH cases, *i*OCT identified residual membranes, allowed for visualization of tissue-instrument interactions, and confirmed completion of surgical objectives (***Figure 3***). Absolute shadowing was noted with real-time membrane peeling with metallic instruments (***Figure 3***). In select cases, true OCT-guided membrane peeling was performed when the standard view was poor due to corneal edema both with real-time visualization of tissue-instrument interactions and with identification of residual membranes that were not otherwise visible. *i*OCT was particularly valuable incomplex cases of membrane peeling, such as myopic foveal schisis or vitreoschisis with multi-laminar membranes (***eFigure 3, Supplemental Video 2***).

During RD repair cases, *i*OCT provided visualization of completeness of retina/RPE apposition following perfluorocarbon liquid tamponade, as well as recurrence of subfoveal fluid after air-fluid exchange. Peripheral assessment with *i*OCT of retinal abnormalities facilitated discrimination between areas of subretinal fluid and white without pressure (***Figure 4***). In PDR cases, *i*OCT provided visualization of surgical planes and helped to discriminate between retinal tissue and fibrovascular scars, as well as, discriminating between traction retinal detachment and focal retinal traction (***Figure 4, Supplemental Video 3***). Optimal depth visualization with *i*OCT during choroidal biopsy was also possible (***eFigure 4, Supplemental Video 4***).

Ergonomics and Value of Microscope-integrated iOCT in Posterior Segment Surgery

Overall, surgeons indicated that microscope-integrated *i*OCT provided valuable feedback in 97 of 136 (71%; 95%CI: 63-79%) cases. Surgeons reported that in 49 of 136 (36%; 95%CI: 28-44%) cases, information provided through *i*OCT resulted in changes to the surgical approach. One example during retinal detachment surgery, *i*OCT identified that a subretinal band in a PVR case was entirely flat under PFO when *en face* visualization gave the impression of elevation. Given the *i*OCT findings, additional membrane peeling was abandoned, minimizing surgical manipulation. A second example during another retinal detachment case, the surgeon believed there was a focal area of detachment that was confirmed by *i*OCT to be entirely flat in the retinal periphery (**Figure 3**). In a myopic schisis case, a prominent membrane was peeled from the retinal surface, but *i*OCT revealed a prominent persistent underlying membrane that was not perceptible to the surgeon (***eFigure 3, Supplemental Video 2****).*

Surgeons preferred real-time *i*OCT feedback in 93 of 136 cases (68%; 95%CI: 60-76%), compared to 39 of 136 (29%; 95%CI: 21-37%) cases where static feedback was more optimal. The heads-up display system was preferred to the external screen in 95 of 136 (70%; 95%CI: 62-78%) cases, compared to viewing the OCT information on the video display. In 7 of 136 (5%; 95%CI: 1-9%) of cases, surgeons reported that the *i*OCT system interfered with surgery, including software malfunctions, microscope failure, and unresponsive foot-pedal. No adverse events occurred secondary to these issues. In 22 of 136 (16%; 95%CI: 10-22%) cases contamination during surgery (e.g. contaminated glove, surgical instrument) occurred. None of these contaminations included the surgical field.

Intraoperative OCT Guidance of Surgical Decision-Making: Membrane Peeling

In all cases of membrane peeling, indocyanine green was utilized prior to initial peeling of preretinal membranes and the internal limiting membrane. Prior to *i*OCT imaging, 41 of 67 (61%; 95%CI: 49-73%) cases surgeons believed membrane peeling was complete. In 9 of those 41 cases (22%; 95%CI: 9-35%), *i*OCT identified residual occult membranes that the surgeon determined needed additional peeling. In 26 of 67 cases (39%; 95%CI: 27-51%), the surgeons believed membrane peeling was incomplete prior to *i*OCT scanning. In 4 of 26 (15%; 95%CI: 1-29%) cases where the surgeon believed there was additional membrane peeling required, the *i*OCT informed the surgeon that membrane peeling was entirely complete and no further peeling was required. Ultimately, in 13 of 67 (19%; 95%CI: 10-28%) membrane peeling procedures, *i*OCT findings were discordant with surgeon impression and resulted in direct alterations to the surgical procedure.

Intraoperative OCT Guidance of Surgical Decision-Making: Retinal Detachment

Surgeons utilized *i*OCT in 24 cases of retinal detachment repair. Persistent subretinal fluid under perfluorocarbon liquid was identified in 17/24 (53-89%) cases. *i*OCT feedback that impacted surgical decision-making included identification of a MH under perfluorcarbon liquid (n=1), residual membranes requiring peeling (n=2), identification of optimal placement for drainage based on subretinal fluid (n=1), and differentiation between choroidal hemorrhage and subretinal fluid (n=1). Overall, surgeons indicated that *i*OCT provided feedback that altered surgeon decision-making in 5/24 (21%; 95%CI: 5-37%) cases.

Adverse Events

One serious adverse event (i.e., myocardial infarction) occurred postoperatively during the course of the study following vitrectomy surgery. The most common postoperative day 1 adverse events in both groups included corneal epithelial defects [31 of 227 (13%)] and abnormal intraocular pressure values [29 of 227 (13%)]. Seven of seven epithelial defects in the anterior segment arm occurred in eyes undergoing procedures where epithelial defects would be expected (e.g., corneal transplant, dermoid removal). In posterior segment cases, the majority of epithelial defects were in cases with more complex preoperative diagnoses (15 of 24), including proliferative diabetic retinopathy and retinal detachment. Less frequent adverse events included vitreous hemorrhage (4 of 227, 2%), fibrin (3 of 227, 1%), and hyphema (2 of 227, 1%). One partial graft dislocation occurred in a subject who underwent DSAEK surgery during the study.

Discussion

Gateway studies in real-time OCT technology are enabling transformation in ophthalmic surgical care that could facilitate image-guided surgery in ways not previously feasible. Previous studies have found compelling results for the role for *i*OCT in many ophthalmic surgical conditions, including both anterior and posterior procedures.[1,4-6,13,15,16] This report from the DISCOVER study provides a large prospective examination of the feasibility and utility of the microscope-integrated *i*OCT. The rapid advancements transpiring in the *i*OCT field are pushing the limits to new levels of what is achievable in image-guided surgery and real-time surgeon feedback.[2,6,11,14,17] Microscope-integrated *i*OCToffers immediate image-guidance during surgery allowing the surgeon to gauge procedural progression and completion. This live feedback may facilitate improvements in surgeon judgment, action and knowledge during procedural processes.

Although this study represents the largest prospective clinical study to date on microscope-integrated *i*OCT, there are important limitations that must be acknowledged. This study was non-comparative, non-randomized and was not masked. All surgeons knew that they would be using the *i*OCT system and this may have impacted their level of aggressiveness during the surgical procedure. Additionally, this report has focused on the intraoperative and early postoperative implications of the *i*OCT on surgeon decision-making. Long-term patient outcomes is currently being collected and additional data will be helpful in the future to better understand the role of *i*OCT. This report also focuses on a single integrated *i*OCT system. One-year enrollment for the other DISCOVER systems is still underway and that data is expected later this year. Currently, randomized masked controlled studies are also being planned to provide more definitive answers to the overall value of *i*OCT in patient outcomes.

In this report, *i*OCT imaging was successfully achieved at a very high rate (99%). For lamellar keratoplasty procedures, *i*OCT was reported to alter the surgical procedure in 33% of cases. The most common reason for *i*OCT changing the approach to the surgical procedure was discordance between surgeon perception of graft adherence and the objective *i*OCT information. Similarly for posterior segment membrane peeling procedures, *i*OCT provided new information to the surgeon in 19% of cases that was not in agreement with surgeon impression. In these cases, the most common reason for altering a surgical procedure was related to completeness of peel. These numbers are similar to other reported studies. In the PIONEER study, surgeons reported that in lamellar keratoplasty cases, *i*OCT definitively changed the surgical approach in 9% of cases.[1] In retinal membrane peeling procedures, *i*OCT changed surgical approach in 13% of cases.[1] Similar to DISCOVER, these were cases where the subjective interpretation of the *en face* view by the surgeon was discordant with the objective *i*OCT information.[1]

Generally, surgeons reported immediate feedback related to tissue anatomy changes to be most valuable (e.g., completeness of membrane peel, graft adherence). True "real-time" visualization of surgical maneuvers was less commonly reported as critical. Select cases such as viscodissection and choroidal biopsies appeared to be particularly helpful with real-time feedback. One current major limitation of real-time visualization is the lack of OCT-compatible instrumentation.[11-13] Metallic instruments result in significant shadowing with suboptimal light scattering properties for OCT visualization. Improvement in OCT-compatible instrumentation may advance the field even further.[11-13] Although the systems in DISCOVER represent a significant iterative step forward related to integrative technologies, deficits remain in the technology for true seamless integration. Current deficits include automated OCT aiming/tracking, optimizing heads-up display, instrument-depth tracking, and software analysis for *i*OCT alterations, in addition to OCT-compatible instrumentation.[11,18,19] Optimizing heads-up display for maximizing surgeon feedback while minimizing distraction will be important.[11] Significant advances have been achieved with *i*OCT software analysis packages, including assessment of interface fluid and volumetric pathology analysis for features, such as macular hole.[5,18-20]

The definitive role for *i*OCT continues to emerge. Research from the PIONEER study has shown that minimizing interface fluid in DSAEK procedure may reduce postoperative interface haze.[16] Additionally, alterations in the outer retina (ellipsoid zone-retinal pigment epithelium height) may be important findings understanding the complete architectural normalization following MH repair.[20] An exciting potential emerging role for *i*OCT is in targeted therapeutic delivery with image-guided tissue placement and objective volumetric measurement may have a critical role in the future in regenerative medicine and gene-therapy.

The 1-year results of the RESCAN portion of the DISCOVER study provide additional evidence for the feasibility, utility and potential clinical implications of microscope-integrated *i*OCT. As additional barriers to seamless integration are cleared, such as software analysis and automated tracking, the ease and role for *i*OCT in ophthalmic surgery may continue to expand. Ongoing research in long-term patient outcomes related to the PIONEER, DISCOVER and other ongoing studies will continue to add to our knowledge base and improve our understanding of how this may add value to our surgical procedures.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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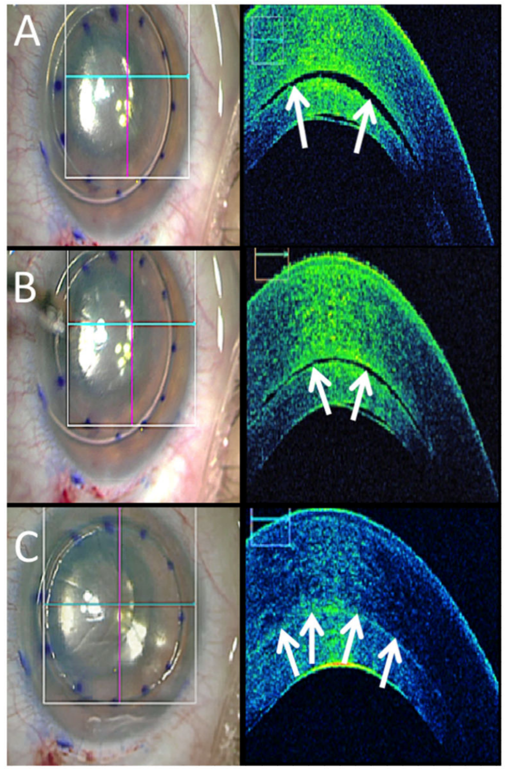

Figure 1. Time-lapse *i*OCT of DSAEK

(A) *En face* view following air-bubble infusion (left). B-scan (right) with interface fluid (arrows). (B, C) Following corneal massage, *en face* view unchanged (left), but B-scans (right) reveals resolving interface fluid (arrows).

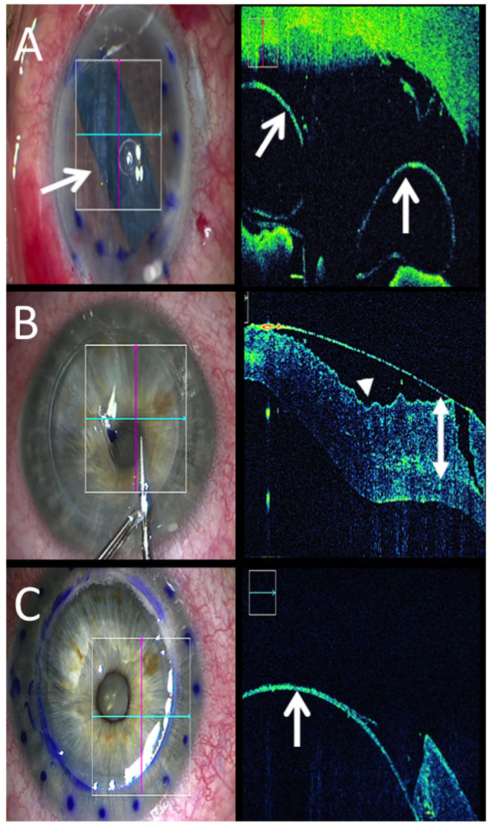

Figure 2. Lamellar keratoplasty and *i*OCT

(A) *i*OCT confirms optimal graft orientation (arrows) follow DMEK graft placement (arrow, left). (B*)* *i*OCT reveals striae (arrowhead) and trephination depth (double arrow) during DALK. (C) Subsequent *i*OCT during DALK confirms dissection to Descemet membrane (arrow).

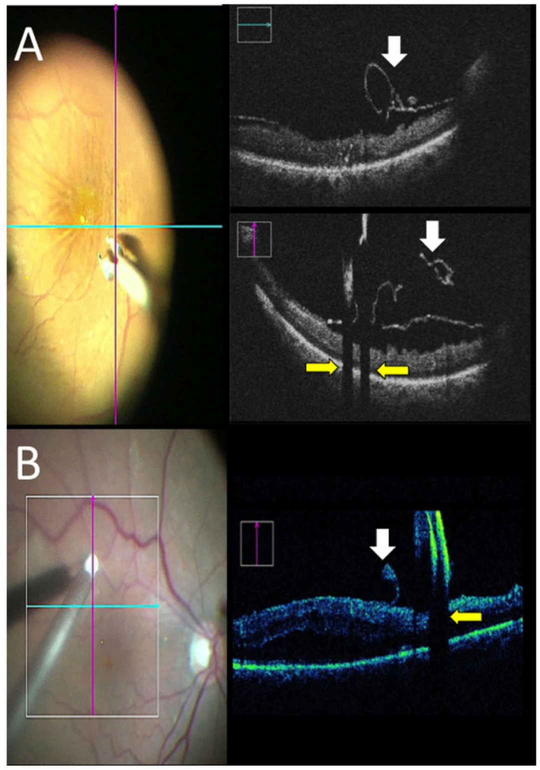

Figure 3. Real-time *i*OCT of membrane peeling

(A) *i*OCT during peeling identifies membranes (right top and right bottom, white arrows) with shadowing from metal (yellow arrows). (B) *i*OCT of membrane scraper with shadowing from diamonds (yellow arrow) and membrane edge (white arrow).

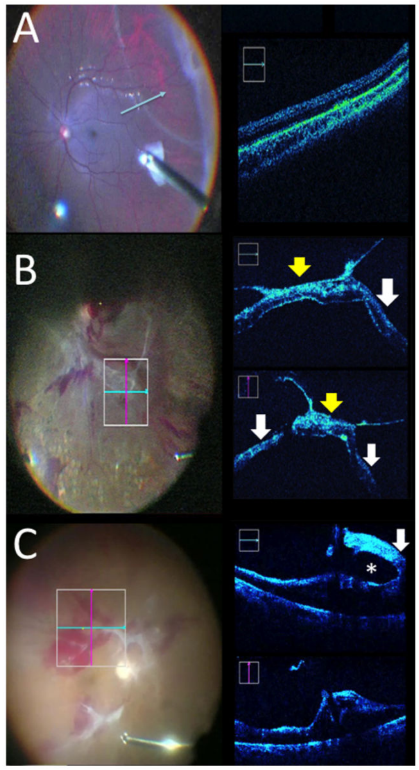

Figure 4. *i*OCT for RD and PDR

(A) Possible RD (arrowheads) determined to be flat by *i*OCT (right). (B) PDR with *i*OCT-confirmed TRD (white arrows) with dense membranes (yellow arrows). (C) PDR with focal traction (white arrow) and visible surgical plane (asterisk).

Table 1

Baseline Demographics and Clinical Characteristics of the DISCOVER Study

		Anterior		Posterior	
Enrollment		91		136	
Eye	Right Left	48 43		67 69	
Lens Status	Pseudophakic Phakic Aphakic	34 52 5		57 75 4	
Preoperative Diagnosis		Fuchs Dystrophy Bullous Keratopathy Keratoconus Failed PK Cataract Glaucoma Failed DSAEK Other	34 (37%) 10 (11%) 8 (9%) 7 (8%) 7 (8%) 7 (8%) 5 (5%) 13 (14%)	Epiretinal membrane Retinal detachment Proliferative diabetic retinopathy Vitreous hemorrhage Panuveitis Full-thickness macular hole Traction retinal detachment Other	34 (25%) 28 (21%) 12 (9%) 12 (9%) 12 (9%) 10 (7%) 5 (4%) 21 (16%)
Procedures		DSAEK DALK CE/IOL DMEK Tube shunt PK Trabeculectomy Other	43 (47%) 8 (9%) 7 (8%) 7 (8%) 4 (4%) 4 (4%) 2 (2%) 16 (18%)	PPV Fluocinolone implant without PPV Scleral buckle without PPV Other	126 (93%) 7 (5%) 1 (1%) 2 (1%)

CE: cataract extraction; IOL: intraocular lens; PPV: pars plana vitrectomy; DSAEK: Descemet stripping automated endothelial keratoplasty; PK: penetrating keratoplasty; DALK: deep anterior lamellar keratoplasty; DMEK: Descemet membrane endothelial keratoplasty; SB: scleral buckle