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Intraoperative OCT-assisted Surgery for Proliferative Diabetic Retinopathy in the DISCOVER Study

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Purpose: To delineate the feasibility and role of intraoperative OCT (iOCT) in surgical decision-making during vitreoretinal surgical interventions for proliferative diabetic retinopathy (PDR).

Design: Prospective, single-site, multisurgeon consecutive case series.

Participants: Patients enrolled in the DISCOVER study (Determination of Feasibility of Intraoperative Spectral Domain Microscope Combined/Integrated OCT Visualization during En Face Retinal and Ophthalmic Surgery) who underwent vitreoretinal surgery for sequelae of PDR.

Methods: Subjects were identified from participants in the first 2 years of the DISCOVER study who underwent vitreoretinal surgery for complications of PDR. Intraoperative imaging with a microscope-integrated iOCT system was performed at surgical milestones as determined by the surgeon. Data collected included clinical characteristics, image features, and survey-based surgeon feedback.

Main Outcome Measures: Main outcomes were (1) the percentage of cases with successful acquisition of iOCT (feasibility) and (2) the percentage of cases in which iOCT altered surgical decision making (usefulness).

Results: Eighty-one eyes with PDR underwent vitreoretinal surgery in the DISCOVER study. Successful iOCT imaging was obtained for 80 of 81 eyes (98.8%). Of these, 36 (44.4%) were female and 44 (54.3%) were male. The surgeon preferred real-time feedback in 47 cases (58.6%) and static review in 29 cases (36.3%); it was indeterminate in 4 cases (5%). Surgeons reported that in 2 cases (2.5%) the iOCT interfered with the surgery (e.g., microscope malfunction). In 41 of the 81 cases (50.6%), surgeons reported that iOCT provided valuable information (e.g., identification of dissection planes, identification of retinal hole). In addition, the iOCT data provided information that specifically altered the surgeon's decision making (e.g., determination of peel completion, choice of tamponade) in 21 of 81 cases (26%). No adverse events were attributed to the iOCT system.

Conclusions: The results suggest that iOCT is feasible during complex vitreoretinal surgeries in patients with PDR using a microscope-integrated OCT platform. Using iOCT seems to frequently offer key information that may impact surgical decision making and, potentially, patient outcomes. *Ophthalmology Retina 2017;■:1–7 © 2017 by the American Academy of Ophthalmology*

Surgical intervention for proliferative diabetic retinopathy (PDR) can be challenging due to the complex nature of vitreoretinal relationships and severe alterations to tissue anatomy. Some of the common indications for surgical intervention in PDR include nonclearing vitreous hemorrhage, tractional retinal detachment, combined rhegmatogenous and tractional retinal detachment, epiretinal membrane, vitreomacular traction, and anterior segment neovascularization.[1]

The introduction of OCT in 1991 revolutionized our understanding and visualization of the vitreoretinal interface. The information gathered from OCT imaging is crucial in surgical planning, particularly for PDR cases where the vitreoretinal interface is complex and challenging to maneuver. As such, integration of OCT into the operating room may transform the surgical approach to complex PDR cases. Intraoperative OCT (iOCT) may play an instrumental role by helping to identify surgical dissection planes, tractional membranes, and consequent areas of retinal detachment.[2] Rapid, real-time feedback to the surgeon can help to determine and guide surgical maneuvers during this delicate surgery. Numerous studies have been performed to delineate the role of iOCT in ophthalmic surgery, anterior and posterior segments alike.[2–27]

To date, only limited information has been published related to the potential role of iOCT in PDR. The purpose of this study was to evaluate the feasibility and usefulness of iOCT during vitreoretinal surgery for PDR-related sequelae in the DISCOVER study (Determination of Feasibility of Intraoperative Spectral Domain Microscope Combined/Integrated OCT Visualization during En Face Retinal and Ophthalmic Surgery).

Methods

The DISCOVER study is a prospective single-site, multisurgeon study evaluating the role of microscope-integrated iOCT during ophthalmic surgery. The study protocol was approved by the

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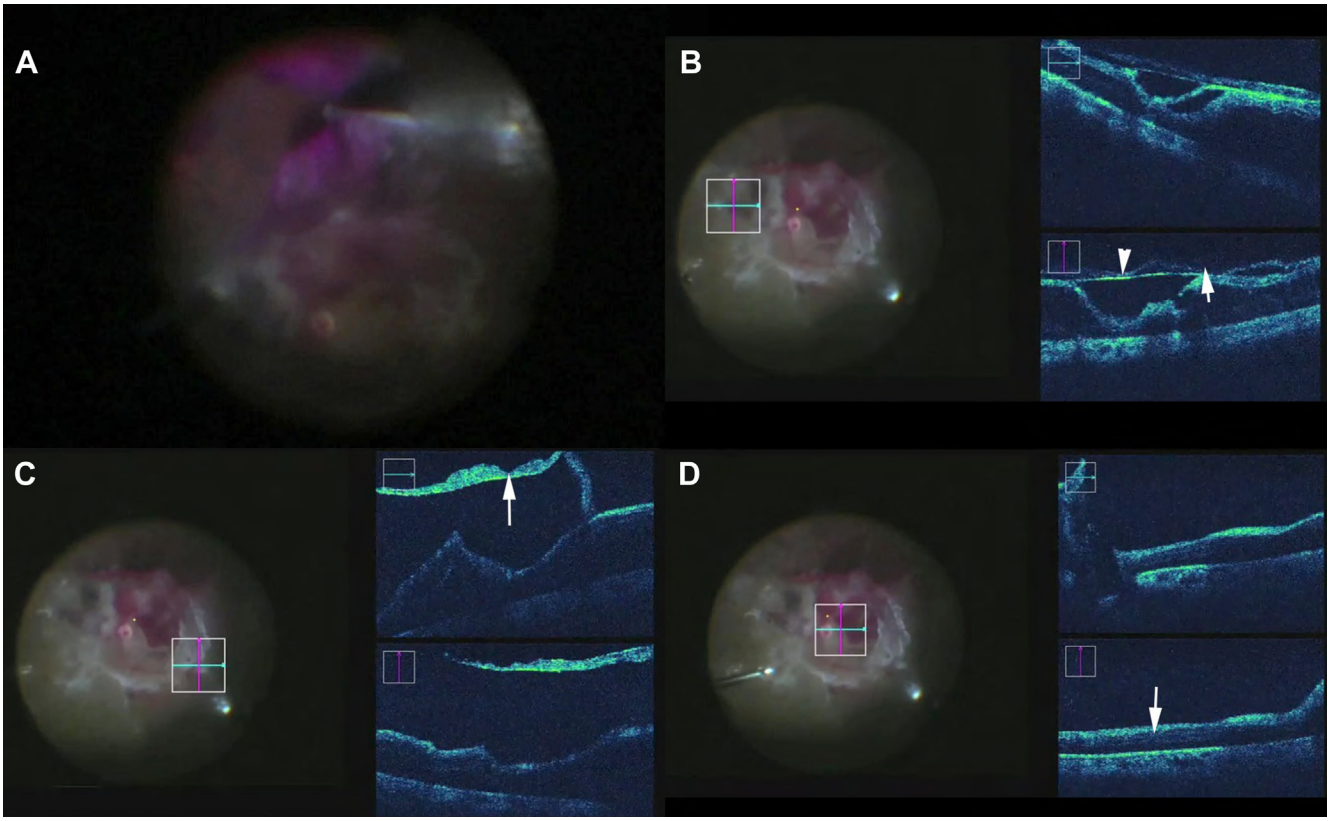

Figure 1. Young woman with type 1 diabetes presenting with nonclearing vitreous hemorrhage (NCVH) and underlying tractional retinal detachment. **A**, An NCVH with poor preoperative and intraoperative view. **B**, After clearance of the hemorrhage, membrane assessment with intraoperative optical coherence tomography (iOCT) shows preretinal membrane without adherence to underlying retinal elevation, thereby identifying a plane for initiating dissection (*arrowhead*) and an adjacent area with preretinal membrane adhered to underlying retina (*arrow*). **C**, Further highlights show prominent elevation of membrane away from retina (*arrow*) with safe space for dissection. **D**, After membrane, peeling iOCT confirms the macula is flat (*arrow*).

Institutional Review Board of the Cleveland Clinic and adhered to the tenets of the Declaration of Helsinki.[28] Written informed consent was required from all patients participating in the DISCOVER study. For this report, all enrolled DISCOVER subjects from the first 2 years of the study who underwent surgery for sequelae from PDR were included.

The study protocol allowed for intraoperative imaging before, during, and after surgical milestones at the surgeon's discretion. Data variables collected included indication for surgery, type of procedure, visual acuity, ocular comorbidities, details regarding surgical maneuvers/techniques (e.g., instrument type and surgical approach), type of OCT images obtained during surgery, and adverse events.

Two microscope-integrated OCT prototypes, a RESCAN 700 prototype (Carl Zeiss Meditec, Oberkochen, Germany) and the EnFocus prototype (Bioptigen, Research Triangle Park, NC; Leica, Wetzlar, Germany), were used in the DISCOVER study during PDR cases. Visualization with OCT with the RESCAN 700 prototype included both OCT datastream injection into the microscope ocular and display on an external monitor. Imaging was reviewed based on surgeon preference. The EnFocus prototype was an add-on imaging platform for a Leica scope. The OCT data were reviewed on an external monitor on a separate cart. Review of iOCT data was categorized as "real time" or "static." Real-time use was defined as iOCT visualization during surgical maneuvers and tissue manipulation. Static use was defined as iOCT visualization during surgical pauses without active tissue manipulation. A research coordinator facilitated acquiring OCT images during the surgery and also compiled surgeon feedback and data postoperatively, using a standardized data collection form and surgeon questionnaire.

Prespecified surgeon feedback questionnaires were completed for all cases focusing on several specific areas of interest related to the microscope-integrated system and operative procedure, including the perceived value of iOCT to the procedure (e.g., information that was helpful but not necessarily of enough significance to change decision making), alterations in surgical decision making (e.g., changing the operative procedure based on the iOCT data), the preferred mode of feedback from the system (e.g., real-time vs static review), and workflow (e.g., interference with the case). In addition, in select prespecified procedures (e.g., membrane peeling), an additional feedback form was completed related to the value of iOCT for that specific procedure.

Results

Clinical Demographics

A total of 81 eyes were enrolled for imaging during vitreoretinal surgery for sequelae of PDR. The mean age of patients was 48.8 years (range, 23–77). Of patients enrolled in the study, 36 (44.4%) were female and 44 (54.3%) were male. There were 35 right eyes (43.2%) and 46 left eyes (56.79%) imaged. Additionally, 65 eyes (80.2%) were phakic, and 16 eyes (19.8%) were pseudophakic at