Low Cost Optical Coherence Tomography for Point of Care

NCT03323307

Document Date: August 5, 2019

Purpose of the Study

We propose to introduce a low cost handheld retinal OCT device for retinal imaging in order to reduce the cost from currently $40k-60k to under $10k. We will obtain a retinal OCT scan with the prototype handheld OCT scanner in adult patients scheduled in the retina clinic at the UNC Kittner Eye Center undergoing standard OCT testing as part of their visit. This pilot study will aim to compare the data of this prototype device with data from currently available high resolution OCT machines.

Background and Significance

Optical coherence tomography (OCT) has become the gold standard for diagnosing eye diseases such as diabetic retinopathy and macular degeneration. The ability of OCT to create depth resolved, cross sectional images allows physicians to examine the various layers of the retina and see the earliest signs of disease. While OCT has seen wide adoption, the high cost of imaging systems ($40,000-$100,000+) has resulted in this technology being available primarily at large eye centers. However, for some patients such as advanced diabetics, travel to a central eye care facility can be a barrier to receiving needed follow up exams. In most communities, the primary eye care provider is an optometrist who may not provide OCT imaging due to the high system cost. Further, the high price of OCT systems has resulted in limited use in developing countries where the value of clinical OCT is understood, but currently systems are too expensive. To address this unmet need, we have developed a prototype OCT system with a target sales price of $10,000 which provides system performance comparable to other entry level OCT imaging systems at a fraction of their cost. By delivering OCT imaging at this price, we seek to make OCT accessible to most clinics and at the point of care. We have spoken with ophthalmologists and optometrists who confirm the need for a low cost system in the detection and monitoring of diabetic retinopathy, glaucoma, retinopathy of prematurity, and macular degeneration.

Study Design and Procedures

The device is a standard optical coherence tomography configuration, consisting of a light source, an interferometer and a detector. Light from a superluminescent diode (SLD) is split into the reference and sample arms of the interferometer. Light in the sample arm is directed toward the eye through a scanning mirror. A 3 mm diameter beam is focused onto the retina by the eye's lens and swept across the surface as the mirror is scanned.

For this system, the light source is an SLD from Exalos, producing mean power of 3.5 mW and a center wavelength of 832.6 nm. The bandwidth is 47.6 nm, resulting in a coherence length (depth resolution) of 6.4 micrometers. After passing through the interferometer and other

optical elements, the resulting sample arm contains 0.6 mW of optical power in a 3 mm diameter beam incident on the cornea. The resulting optical power density at the cornea is 0.08 mW/mm^2 = 0.008 W/cm^2

ANSI limit for maximum exposure to the eye is < 0.7 mW in the 800-900 nm range through a 7 mm pupil aperture for continuous exposure of up to 8 hours. Thus the low cost OCT device would be below this threshold with a 7 mm diameter beam. However, with the smaller beam of 3 mm, which does not fill the eye's pupil aperture, the focusing power is reduced. Therefore, the power is significantly (4-5x) below the maximum permissible exposure.

Subjects will be informed of the study when they present to the clinic for a regular clinical care visit. Besides the standard OCT which is obtained during the routine visit, OCT of both retinas will be performed using the Low Cost handheld OCT prototype. The OCT software will calculate central macular thickness as well as macular volume. Dr. Ulrich will compare the quality of obtained images and measurements between the standard and the new OCT device.

Subject Recruitment and Compensation

Adult patients scheduled in the retina clinic at the UNC Kittner Eye Center will be recruited.

Inclusion Criteria
1) At least 18 years of age at the time of examination (no upper age limit)
2) Patients scheduled to receive standard OCT testing as part of their visit.
Exclusion Criteria
none

Subjects will receive a $20 stipend for their time. The subject will receive payment upon completion of the study visit.

Consent Process

All subjects will be consented by the study coordinator, and will be assured that their willingness to participate will not impact their future care at UNC. Dr Ulrich will speak with potential participants at the very beginning of the visit, explain the details of the study, and answer all questions. All subjects will be assured that their participation in this study is strictly voluntary, this will be a one-time procedure adding approximately 5 minutes to the standard eye scan, and their future care with UNC Kittner Eye Center will not be impacted in any way if they decline to participate. At this point the technician will work up the patient as usual. This gives the patients about 45 minutes to think about participating in the study. Later when they are examined by Dr. Ulrich in a private exam room, any further questions are being answered and written consent will be obtained by the study coordinator if the patient chooses to

participate. Again, the completely voluntary nature of participation in this study will be stressed to the patient.

Risk / Benefit Analysis

Potential Risks
Potential risks include:

1. breach of confidentiality
2. side effect from study procedures and/or devices

Breach of confidentiality
Data collected as part of this study will be stored in password-protected electronic databases on password-protected servers within the Department of Ophthalmology at UNC and will be accessible only by essential study personnel. Information recorded on paper data sheets will be treated as strictly confidential and will be stored within locked files in the Department of Ophthalmology. Access to electronic and paper files will be restricted to the personnel listed on this study. Only the PI and Study Coordinator will have access to the key linking identifiers from PHI with study data.

Side Effect from Study Procedures and/or Devices
There is no known risk from the use of a retinal OCT except for some potential discomfort from the bright blue light used in the scanner.

Potential Benefits
There is no direct benefit to subjects participating in this research study. However, the benefit to society may be in lowering the cost of OCT machines, thus increasing their use in ophthalmic practices.

Alternative Treatments
There are no alternative treatments to participating in this research. It is not intended to be therapeutic, but to acquire basic scientific knowledge.

Data Analysis and Statistical Considerations

Central macular thickness and total macular volume measurements from the new OCT device will be compared with standard OCT. Every scanner has a slightly different values for "normal eyes", meaning the central foveal thickness might read 300 microns on one scanner and 280 on a different one. We will try to establish a database/values for eyes without retinal disease on the new OCT system. Given the low number of patients in this pilot study, we do not plan to compare the new scanner with existing ones statistically (we will not determine p-values). The

quality of OCT images obtained with the new OCT device will be judged as adequate or inadequate by the UNC site PI.

Data and Safety Monitoring

Reporting of Adverse Events

An adverse event is defined as any untoward medical occurrence in a clinical research subject participating in the clinical study of the OCT system. Any AE that occurs between the time a study participant signs the informed consent form and the time she or he departs the study at the end of the visit will be captured and recorded. Study participants will be instructed to contact the study site staff to report any AEs they may experience after completion of their participation. AE resolution will consist of evaluating instrument design and application to assess the potential source and implementing design changes to mitigate the risk of further AE. If necessary, AEs will be reported according to IRB guidelines.

Safety Monitoring

During the proposed trial of the OCT system, status reports will be submitted to the Duke PI from the UNC site. These reports will include all adverse events reported for the study, determined to be related or unrelated to the study protocol. The study team will meet, as needed, throughout the period of study to review any reported adverse events and address any potential safety concerns.

Data accuracy and protocol compliance

Data acquired during the clinical study will be reviewed by Duke lab personnel to assess if the data appear to be consistent with expected operating characteristics of the device. In the event that data do not appear satisfactory, a review of protocol compliance will be conducted. If the protocol has been followed, a technical inspection of the device by Duke lab personnel will be scheduled and further study will be suspended until instrument function has been verified.