

Summary

Primary Care Medicine, including Family Practice and Pediatrics, has traditionally relied on physical exam skills and simplistic instruments for critical diagnostic decision making, monitoring, and referral to medical specialists. The otoscope and ophthalmoscope are two historical and ubiquitous instruments that largely only illuminate and magnify tissue surfaces in the ear and eye, respectively. This Partnership will develop a new Primary Care Imaging system integrating optical coherence tomography (OCT) imaging with these instruments in a handheld scanner and portable system to advance the technological diagnostic and monitoring capabilities in primary care, and more effectively manage and refer patients based on quantitative data.

A partnership composed of collaborating academic, clinical, and industrial institutions and investigators will develop and clinically evaluate this new point-of-care diagnostic technology. OCT is the optical analogue to ultrasound imaging, but generates 3-D images based on the backscatter of near-infrared light rather than sound. This Primary Care Imaging system with a MEMS-based handheld scanner and interchangeable tips enables high-resolution real-time 3-D imaging of the multiple tissue sites commonly examined during primary care outpatient exams including the eyes, ears, oral and nasal mucosa, skin, and cervix. For this project, system demonstration will focus on two increasingly prevalent diseases encountered in the primary care office, namely otitis media (middle ear infections) and diabetic retinopathy.

Recent evidence has strongly associated chronic, recurrent episodes of otitis media with the presence of middle ear bacterial biofilms, and currently no non-invasive means exists to detect and quantify, let alone longitudinally monitor, these structures, which act as reservoirs to antibiotic-resistant bacterial for seeding recurrent infections. OCT enables quantitative assessment of middle ear biofilms and effusions, with the potential to significantly improve the antibiotic regimens and clinical management of this common disease. The rapidly rising prevalence of obesity has already been followed by increases in diabetes among increasingly younger patients, along with the associated complications of this disease, such as diabetic retinopathy. The successful use of OCT in ophthalmology can subsequently be advanced to the front-line of primary care to monitor patients for early evidence of diabetic retinopathy, and to quantify longitudinal changes during treatment.

With an increasing reliance on effective primary care patient management for the expected increase in numbers of patients, new advanced diagnostic and quantitative technologies and instruments are needed in the outpatient primary care clinic for the early detection of disease, for quantitative monitoring of disease progression or regression, and for more efficient and evidence-based referrals to medical specialists. This Primary Care Imaging system addresses this critical need, and for the first time, brings advanced diagnostic imaging technology to the primary care office.

Specific Aims

Primary Care medicine, including the medical specialties of Family Practice and Pediatrics, has traditionally relied on relatively simple diagnostic tools in the outpatient clinic. The more technical tools include the otoscope and ophthalmoscope, which are ubiquitous in the Primary Care setting. Still, these tools amount to little more than illumination and magnification devices to visualize the surface features of the eyes, ears, skin, and oral mucosa of patients. Through this Partnership, we intend to develop a system for Primary Care Imaging by integrating high-resolution 3-D optical imaging capabilities into these instruments, and in fact, combine functionality into a single hand-held device and portable or wall-mounted system that can rapidly acquire, analyze, and display image data for the primary care physician, for staff, and for patients at the point-of-care. Optical coherence tomography (OCT), which has already demonstrated success for medical specialists in ophthalmology, will be integrated into this single hand-held unit. Along with video image data, the system will capture digital 3-D OCT images of eye, ear, skin, and oral mucosa tissue for more quantitative diagnostic decision making, more accurate patient monitoring, and more efficient and appropriate patient referral.

Our hypothesis in our design-driven project is that this Primary Care Imaging system will enable real-time high-resolution point-of-care 3-D optical imaging in the outpatient clinic to facilitate the early detection and quantitative monitoring of diseases commonly encountered by the primary care physician. We will investigate two specific examples where our PCI system will have a significant impact. First, we will develop and conduct patient studies using OCT-enhanced otoscopy for the early detection and monitoring of middle ear biofilms, which have been linked to chronic otitis media, and have complicated the treatment and management of this common infection. Second, we will develop and conduct patient studies using OCT-enhanced ophthalmoscopy for the early detection and monitoring of diabetic retinopathy, which needs to be accurately identified early by the primary care physician, yet presents diagnostic challenges.

We will achieve our overall goal and prove our hypothesis through four specific aims:

Aim 1: Develop and construct the Primary Care Imaging system. The Primary Care Imaging system will include a handheld MEMS-based scanner with interchangeable tips for tissue-site specific imaging of the eye, ear, skin, and oral mucosa, a compact control unit, and a user-friendly interface.

Aim 2: Develop computer-aided detection (CAD) and quantification algorithms for OCT-enhanced otoscopy and ophthalmoscopy. The CAD and quantification algorithms will automatically quantify image-based data and provide interpretive results for the primary care physician to rapidly assess for the presence of abnormalities and disease, and for monitoring progression or regression during longitudinal patient visits.

Aim 3: Determine the diagnostic and clinical value of OCT-enhanced otoscopy for detecting and quantifying middle-ear biofilms. OCT-otoscopy will be performed in patient studies to first acquire an image database with clinical correlations from patients with a variety of ear pathologies including acute and chronic otitis media, otitis media with effusion, otosclerosis, and pre-post tympanostomy tube placement. OCT-otoscopy will be uniquely used to characterize the presence of middle ear biofilms, which has been directly linked to patients with chronic otitis media. The presence and structural characteristics of middle ear biofilms will be tracked longitudinally during antibiotic treatment. Results from OCT-otoscopy will also be correlated with commercial tympanometry measurements. It is expected that OCT-otoscopy will enable the noninvasive detection, characterization, and monitoring of middle ear biofilms, which will be used to define optimal antibiotic and surgical treatment regimens.

Aim 4: Determine the diagnostic and clinical value of OCT-enhanced ophthalmoscopy for detecting and quantifying diabetic retinopathy. OCT-ophthalmoscopy will be performed in patient studies to first acquire an image database with clinical correlations from patients with diabetic retinopathy. OCT-ophthalmoscopy images will be compared directly with those from a commercial OCT system designed for the specialists' clinic. OCT-ophthalmoscopy will be used to characterize retinal thickness and blood flow for early changes in diabetic retinopathy. Quantitative measurements from image-based data will be used to determine early-onset changes that are relevant to the primary care physician. With an increasing number of overweight, obese, and diabetic patients, it is expected that OCT-ophthalmoscopy will offer the potential for early detection, characterization, and quantitative monitoring of diabetic retinopathy by the primary care physician.

