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Diagnosis and assessment of Vulvar Lichen Sclerosus (VLS) using Optical Coherence Tomography Angiography

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Abstract:

Lichen sclerosus (LS) is a chronic inflammatory skin condition that has a predilection for the anogenital skin in women. The true prevalence of vulvar LS is unknown, underdiagnosed, and underreported [1]. Studies have estimated LS affects up to 3% of postmenopausal women, with a rising incidence [2]. The disease also affects premenopausal women and children. Overall, this is an underserved condition and the related delay in diagnosis can have a profound burden on patients' quality of life and health outcomes, leading to irreversible scarring, infection, vulvar architectural distortion, genitourinary complications, itch, and pain syndromes [3]. There is a limited understanding of disease pathogenesis and no FDA-approved treatment options, with current guidelines recommending lifelong treatment. In the context of Vulvar Lichen Sclerosus, Skin biopsies are considered the standard method for detecting LS. However, they have certain drawbacks, as they are invasive, particularly in the sensitive vulvar area, and can be time-consuming. Approximately 5% of women with LS eventually develop vulvar squamous cell carcinoma (SCC), and half of all vulvar cancers arise in the presence of LS [4]. Therefore, patients need frequent monitoring, often requiring additional biopsies to assess the development of SCC or its precursors in long-standing LS lesions. Given the challenges associated with diagnosing VLS and monitoring SCC development in the context of an inflammatory skin condition, there is a high demand for noninvasive, high-sensitivity, real-time imaging techniques that can be performed in vivo. Hence, our study involves the design and development of a 1.7- μm optical coherence tomography angiography (OCTA) technique for diagnosing and monitoring of VLS lesions.

Materials and Methods:

System setup:

Figure 1 illustrates the block diagram of our swept source OCT system. The system consists of a Mach-Zehnder interferometer (MZI) with a 1.7 μm center wavelength-swept light source. The output energy is split by a 90:10 coupler. 90% of the energy is supplied to the sample arm and the remaining 10% is supplied to the reference arm. The system is equipped with a Fiber Bragg Grating (FBG) for increased phase stability. The reference arm consists of a collimator, lens, and mirror. The sample arm supplied with 90% energy consists of a hand-held probe with a threaded adapter to adjust the focal length. The handheld probe is equipped with a dual-axis galvanometer and a scan lens for 3D OCT imaging. Two circulators with a center wavelength of 1650 nm are used to separate the illumination light and back-reflected light. The interference signal generated by the sample and reference arm in the 50:50 coupler is detected by the photodetector. The data acquisition software is written in C++ which allows for faster data processing.

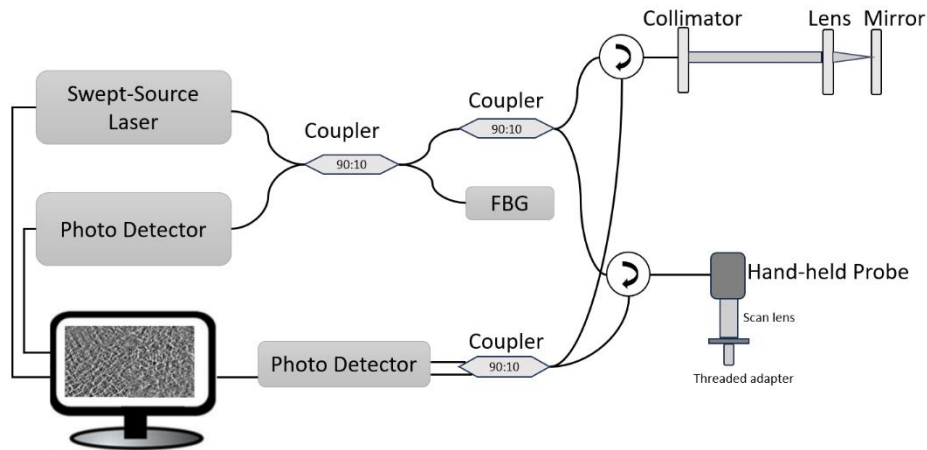


Fig. 1 Schematic of 1.7-micron OCTA

In vivo human experiment:

Experiments were carried out in accordance with the protocol approved by the Institutional Review Board at the University of California, Irvine. 6 vulvar LS patients were recruited from the Department of Dermatology, University of California, Irvine. The OCTA imaging was performed in the presence of a clinician. The imaging session took approximately 30 seconds to complete. The handheld probe was sterilized after application on each subject. The imaging area of subjects included the labia majora and labia minora area as well as the adjacent healthy tissue.

Results:

To demonstrate the capability of OCT imaging to provide valuable tissue information of the vulvar tissue, we conducted a pilot study, in which a total of six subjects participated. Among these subjects, one individual served as a control, while the remaining five subjects were diagnosed with Vulvar Lichen Sclerosis. OCT measurements were performed on all six subjects to gather data and analyze the vasculature. We demonstrated the enface projection view of blood vessel networks in the Labia Majora, Inter labial Sulci and Labia Minora tissues in post-menopausal patients. The 6x6 mm OCTA images reveal the vasculature of the vulvar LS, as well as the supporting vessels. The OCTA images of 6 subjects are analyzed and the vascular density and diameter are quantified in Table 1. OCTA elucidates the vascular changes on the vulvar skin surface. The quantitative assessment provides an in-depth idea of the vascular density and diameter of the lesions and adjacent vessels on the surface of the skin. OCTA images of skin lesions from a 1.7 μm center-wavelength light source system acquired are highly effective in visualizing the morphology and improving the penetration depth by 25% compared to the conventional 1.3 μm OCT systems [5]. Hence, this system will be helpful to obtain simultaneous information on structural and functional changes in vulvar lesions.

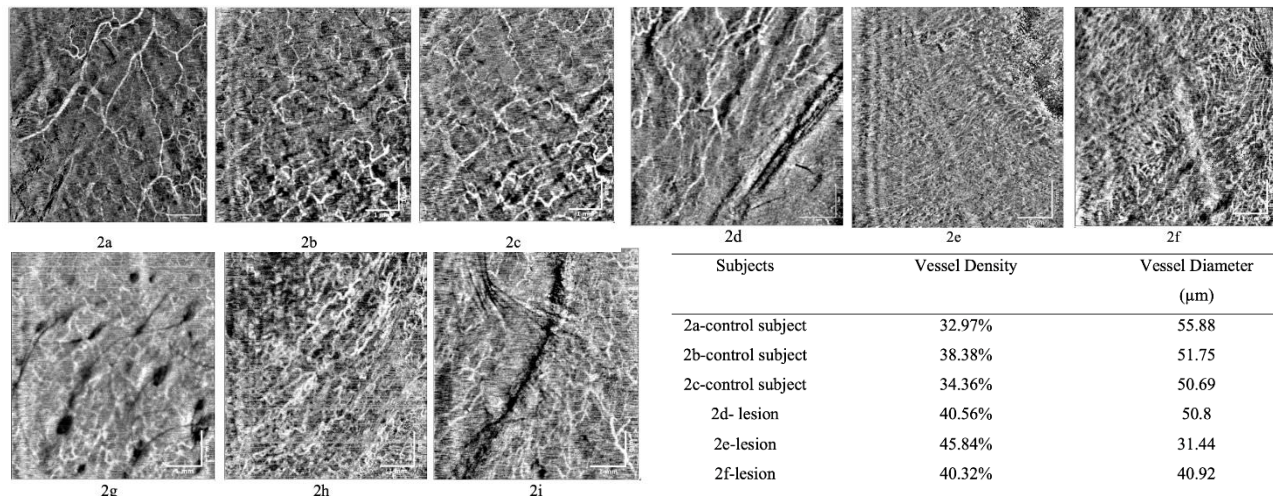


Fig. 2. En-face OCT images of Vulvar tissue

Subjects	Vessel Density	Vessel Diameter (μm)
2a-control subject	32.97%	55.88
2b-control subject	38.38%	51.75
2c-control subject	34.36%	50.69
2d- lesion	40.56%	50.8
2e-lesion	45.84%	31.44
2f-lesion	40.32%	40.92
2g- lesion	34.669%	51.55
2h- lesion	39.82%	41.38
2i- lesion	37.09%	58.272

Table 1. Vessel Density and Vessel Diameter in control and VLS patients.

Conclusion:

In this study, we demonstrated that OCTA, as a functional extension of OCT can be used to non-invasively scan vulvar lesions in vivo. We scanned 6 subjects with lesions in different areas including labia majora, Interlabial sulci, and labia minora. We were able to quantify the vascular density and diameter of lesions. OCT angiography (OCTA), as a functional augmentation of OCT, allows for the visualization of cutaneous microvasculature via the detection of fluctuations in amplitude and/or phase of sequential OCT signal with high resolution and sensitivity. This instrument will help in therapeutic monitoring, and earlier detection of malignant transformation, in vulvovaginal conditions.

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