LiveOCT: An ultrahigh axial resolution line-field spectral domain optical coherence tomography system

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Abstract: Despite potential clinical benefits, UHR OCT has not made it to market. LiveOCT is a project to put a LF-SD-OCT system for UHR corneal measurements on the market. Currently it is undergoing clinical study.

1. Introduction

Ultrahigh (< 3 µm in air (n_G = 1)) axial resolution (UHR) optical coherence tomography (OCT) systems have been well reported [1] in academic literature. The increased resolution enables measurement features not resolvable with standard resolution systems. One such feature is the Bowman's layer, where thickness measurement would provide clinicians with an additional tool for diagnosis and monitoring of Keratoconus [2, 3]. However, no UHR OCT system has yet come onto the market for general ophthalmic use. One reason is that published UHR OCT systems often use light sources which on their own cost as much as current clinical OCT systems on the market, such as femto-second lasers [1] or high-performance supercontinuum sources [4].

LiveOCT is a project funded by the NIHR to develop a commercial ready clinical line field (LF) OCT system. The LF format reduces the noise drawback of low-cost supercontinuum light sources [5], making manufacture with the current price range of OCT devices on the market feasible. Here we will present an overview of the device, its development process and its performance as it goes into clinical study.

2. Method

Two versions of the device will be tested, one using a conventional Linnik interferometer and one using a Mirau interferometer setup. Figure 1 shows the schematic diagram of the Mirau variant.

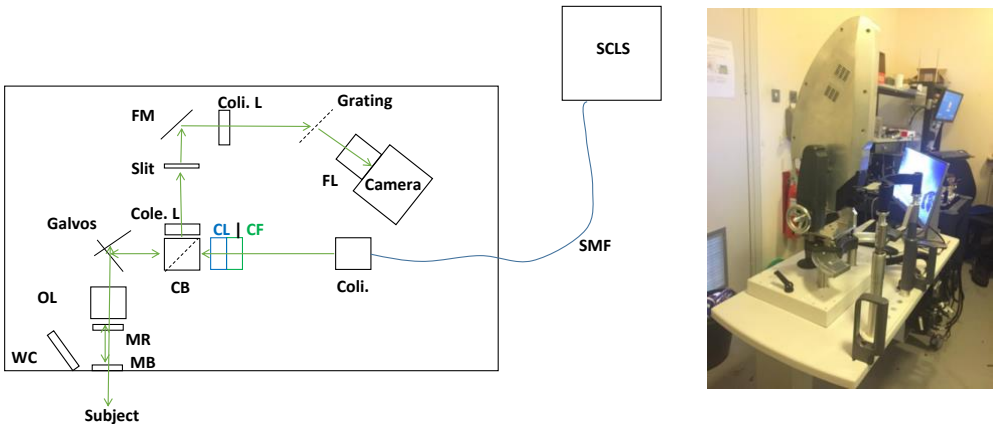

Fig. 1. (Left) A schematic diagram of the Mirau vareint of the LiveOCT. SCLS – supercontinuum light source, SMF – single mode fibre, Coli. – collimator, CF – custom filter, CL – Cylindrical lens, CB – cube beamsplitter, OL – objective lens, MR – Mirau reference, MB – Mirau beamsplitter, WC – webcam, Cole. L – collection lens, FM – folding mirror, Coli. L - collimation lens, FL – final (camera) lens. (Right) Photograph of the LiveOCT system.

To achieve a notice of no objection from the UK's MHRA to carry out the clinical study, the development process, device and clinical study are complaint to international standards including BS EN ISO 14971:2019 (Risk management of medical devices), BS EN ISO 15004-1:2020 (Fundamental requirements of ophthalmic

instruments), BS EN ISO 10993-1:2020 (Biological evaluation of medical devices. Evaluation and testing within a risk management process), BS EN ISO 15004-2:2007 Clause 5.2 c) → Class 1 BS EN 60825-1:2001 (Light safety requirements), IEC 60601-1:2005 + AMD1:2012 (Medical devices general safety and essential performance requirements), BS EN 62304:2006 + AMD1:2015 (Medical device software lifecycle requirements) and BS EN ISO 14155:2020 (Clinical investigation of medical devices).

3. Results

Table 1 shows the performance of the two LiveOCT devices as they went into clinical study. This performance was sufficient to be able to capture *in vivo* UHR OCT images of the cornea.

Table 1. The measured performance values of the Live OCT devices going into the clinical study.

	Linnik Device	Mirau Device
Image (A-Scan) depth (n_G.mm)	1.23	1.23
B-Scan length (mm)	2.29	2.29
Axial resolution (n_G.µm)	2.4	2.4
Lateral resolution (µm)	~ 20	~ 20
Axial image rate (k A-Scans/s)	204.8	204.8
Single frame sensitivity (dB)	79 dB	77 dB
Single frame dynamic range (dB) (Glass interface signal / empty standard deviation)	65 dB	63 dB
Integration time (µs)	250	500

3. Discussion and conclusion

Factors such as lower sensitivity mean the device is not as easy for the user as current OCT devices. With its specialised UHR capability, the devices usability is expected to be more comparable to in vivo confocal microscopy. However, despite this, clinically relevant measures were able to be reliable taken from in vivo image taken during development, which will be the subject of a separate publication. The objective of the clinical study is to show LiveOCT devices can be reliably used to take measurements in real patients, that no commercial device currently can and bring some of the benefits of UHR OCT into clinical practice.

Compact Mirau interferometric objectives reduce the required size for LF SD OCT systems and allow the possibility of clinical OCT systems with interchangeable objective lenses, akin to changing objectives on a microscope. If an application required higher lateral resolution but not high depth of field (e.g. cell counting), the operator could swap the objective of such a system to suit.

LiveOCT is a project that aims to bring affordable UHR OCT into general clinical use. The performance and usability may have more in common with existing in vivo confocal systems than current standard OCT system. Future publications will evaluate the clinical relevance of the produced in vivo images.

3. References

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