

Clinical Studies using VivoSight Optical Coherence Tomography Scanners

Michelson Diagnostics: Optical Coherence Tomography (OCT) Research Program

Clinical Dermatology

Subject	Optical Coherence Tomography as a tool to delineate basal cell carcinoma prior to Mohs micrographic surgery
Authors	Rebecca G. Pomerantz *, Debbie Zell, MD *, Gordon McKenzie, PhD **, Daniel Siegel, MD *.
Institution	*Long Island Skin Cancer, Smithtown, New York, USA. **Michelson Diagnostics Ltd, Orpington, UK.
Publication	<i>Journal of the American Academy of Dermatology.</i>
Status	Submitted. Research ongoing.

Subject	OCT as an enhancement to dermoscopy for skin cancer
Citation	Cunha, D., Richardson, T., Sheth, N., Orchard, G., Coleman, A. & Mallipeddi, R. (2010) "Comparison of ex vivo optical coherence tomography with conventional frozen- section histology for visualizing basal cell carcinoma during Mohs micrographic surgery" <i>British Journal of Dermatology</i> , 163 (Suppl. 1), pp. 101 - 117.
Status	Ongoing. Publications being prepared.

Subject	OCT for multi-modality imaging of NMSC
Citation	Konig, K., Speicher, M., Buckle, R., Reckfort, J., McKenzie, G., Welzel, J., Koehler, M. J., Elsner, P. & Kaatz, M. (2009) "Clinical optical coherence tomography combined with multiphoton tomography of patients with skin diseases" <i>Journal of Biophotonics</i> , 2 (6-7), pp. 389-397.
Status	Published.



Maxillofacial

Subject	Imaging of oral neoplasms using OCT
Citations	<p>Jerjes, W., Upile, T., Conn, B., Betz, C., Jay, A., Jamil, W., Vourvachis, M., El Maaytah, M., Radhi, H., McKenzie, G., Sandison, A. & Hopper, C. (2009) "Oral leukoplakia and erythroplakia subjected to optical coherence tomography: preliminary results" <i>British Journal of Oral & Maxillofacial Surgery</i>, 46(7), pp. e7.</p> <p>Hamdoon, Z., Jerjes, W., Upile, T., McKenzie, G., Betz, C., Sandison, A., Jay, A. & Hopper, C. (2009) "Immediate ex-vivo optical coherence tomography of suspicious oral lesions" <i>Head & Neck Oncology</i>, 1(Suppl 1), pp. O16.</p> <p>Jerjes, W., Upile, T., Conn, B., Hamdoon, Z., Betz, C. S., McKenzie, G., Radhi, H., Vourvachis, M., El Maaytah, M., Sandison, A., Jay, A. & Hopper, C. (2010) "In vitro examination of suspicious oral lesions using optical coherence tomography" <i>British Journal of Oral & Maxillofacial Surgery</i>, 48(1), pp. 18-25.</p>
Status	Ongoing. Published. Multiple papers being prepared for publication.

Tissue Engineering

Subject	OCT to monitor the formation of tissue engineered skin
Citation	Smith, L. E., Bonesi, M., Smallwood, R., Matcher, S. J. & MacNeil, S. (2010) "Using swept-source optical coherence tomography to monitor the formation of neo-epidermis in tissue-engineered skin" <i>Journal of Tissue Engineering and Regenerative Medicine</i> , 4 (8), pp. 652-658.
Status	Published.

Non-clinical Dermatology

Subject	Microneedle Imaging
Citations	<p>Donnelly, R. F., Garland, M. J., Morrow, D. I., Migalska, K., Singh, T. R., Majithiya, R. & Woolfson, A. D. (2010) "Optical coherence tomography is a valuable tool in the study of the effects of microneedle geometry on skin penetration characteristics and in-skin dissolution" <i>Journal of Controlled Release</i>, 147(3), pp. 333-341.</p> <p>Donnelly, R. F., Majithiya, R., Singh, T. R., Morrow, D. I., Garland, M. J., Demir, Y. K., Migalska, K., Ryan, E., Gillen, D., Scott, C. J. & Woolfson, A. D. (2011) "Design, optimization and characterisation of polymeric microneedle arrays prepared by a novel laser-based micromoulding technique" <i>Journal of Pharmaceutical Research</i> 28(1), pp. 41-57.</p>
Status	Published.

For clinical use in the US FDA 510(k) K093520 applies:

- The VivoSight Topical OCT system is indicated for use in the two-dimensional, cross-sectional, real-time imaging of external tissues of the human body. This indicated use allows imaging of tissue microstructure, including skin, to aid trained and competent clinicians in their assessment of a patient's clinical conditions.
- US Federal law restricts this device to sale by or on the order of a physician.

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