

VivaScope

Selected clinical studies using VivaScope microscopes¹

Field	Organ	Application	Study results vs. the final histology reports	Study design	Microscope generation	Clinical partner (principal investigator)	Reference	PubMed link (year) (PubMed ID: PMID)
Dermatology	Skin	Review	Revolution in fast pathology in dermatology	A comprehensive review of 79 publications	G4-G3	Dept. of Dermatology, Hospital Clinic of Barcelona, IDIBAPS, University of Barcelona, Barcelona, Spain (Dr. S. Puig & Dr. J. Malvehy)	Malvehy, J. et al. (2020) Ex vivo confocal microscopy: Revolution in fast pathology in dermatology. <i>British Journal of Dermatology</i> , 183(6), pp. 1011-1025.	PMID: 32134506 (2020)
		Oral squamous cell carcinoma (OSCCs)	High potential in rapid diagnosis and evaluation of the fresh excised OSCCs	38 OSCCs 35 patients	G4	Dept. of Oral and Maxillofacial Surgery, University Hospital Heidelberg, Heidelberg, Germany (Dr. V. Shvakhova)	Shvakhova, V. et al. (2021) Features of oral squamous cell carcinoma in ex vivo fluorescence confocal microscopy. <i>International Journal of Dermatology</i> , 60(2), pp. 236-240.	PMID: 33368199 (2021)
		BCC subtypes	99% specificity and 88% sensitivity	79 BCCs 78 patients	G4	Dept. of Dermatology, Hospital Clinic of Barcelona, IDIBAPS, University of Barcelona, Barcelona, Spain (Dr. J. Malvehy & Dr. J. Perez-Anker)	Anker, J. P. et al. (2020) Basal cell carcinoma characterization using fusion ex vivo confocal microscopy: A promising change in conventional skin histopathology. <i>British Journal of Dermatology</i> , 183(2), pp. 468-476.	PMID: 31520341 (2020)
		BCC margin control	96.5% specificity and 73.6% sensitivity	101 BCCs 78 patients	G4	Dept. of Dermatology, Venerology and Allergology, University Hospital Leipzig AöG, Leipzig, Germany (Dr. S. Grunewald)	Grüss, M. et al. (2021) Routine application of ex vivo confocal laser scanning microscopy with digital staining for examination of surgical margins in basal cell carcinoma. <i>JDG: Journal of the German Society of Dermatology</i> . Online ahead of print.	PMID: 33168122 (2021)
		Inflammatory skin disease	Inflammatory patterns were very well distinguished e.g. infiltrated lymphocytes and neutrophils	6 mm punch biopsies 33 patients	G4	Dept. of Dermatology, Venerology and Allergology, University of Leipzig, Leipzig, Germany (Dr. S. Grunewald & J. Mentzel)	Mentzel, J. et al. (2020) Ex vivo confocal laser scanning microscopy with digital staining is able to map characteristic histopathological features and tissue reaction patterns of inflammatory skin diseases. <i>Journal of the European Academy of Dermatology and Venereology</i> , 35(4), pp. e031-e035.	PMID: 33085808 (2020)
		Normal morphology	Distinguished almost all skin morphological features in a pilot study	26 healthy skins	G4	Dept. of Dermatology, Venerology and Allergology, University Hospital Leipzig AöG, Leipzig, Germany (Dr. S. Grunewald)	Schumann, M. et al. (2020) Evaluation of digital staining for ex vivo confocal laser scanning microscopy. <i>Journal of the European Academy of Dermatology and Venereology</i> , 34(7), pp. 1496-1499.	PMID: 31762568 (2020)
Urology	Prostate	Biopsy	100% specificity and 79% sensitivity	121 MRI-based prostate biopsy samples 10 patients	G4	Dept. of Pathology, Klinikum Lippe GmbH, Detmold, Germany (Jill Tietze, Torsten Hansen & Prof. K. Sievert)	Tsao, L. et al. (2021) Feasibility study for ex vivo fluorescence confocal microscopy (FCM) on diagnostic prostate biopsies. <i>Quantitative Imaging in Medicine and Surgery</i> , 11(4), pp. 1322-1332.	PMID: 33816571 (2021)
		Biopsy	93.5% specificity and 83.3% sensitivity	89 samples 13 patients	G4	Dept. of Urology, University of Modena and Reggio Emilia, Modena, Italy (Prof. G. Bianchi, Prof. R. Montorsi & Prof. B. Rocco)	Pulitti, S. et al. (2019) Ex vivo fluorescence confocal microscopy: The first application for real-time pathological examination of prostatic tissue. <i>BJU International</i> , 124(3), 469-476.	PMID: 30958852 (2019)
		Biopsy	97.5% specificity and 88% sensitivity	80 samples	G4	Dept. of Surgical, Medical, Dental and Morphological Sciences with Interest in Transplant, Oncological and Regenerative Medicine, University of Modena and Reggio Emilia, Modena, Italy (Prof. R. Montorsi & Prof. B. Rocco)	Bertoni, L. et al. (2020) Ex vivo fluorescence confocal microscopy: Prostatic and preprostatic tissue assays and evaluation of the learning curve. <i>Vitrochis Acta</i> , 47(6), pp. 571-520.	PMID: 31907306 (2020)
		Biopsy	81% Cohen's K agreement	57 core biopsies	G4	Dept. of Urology, Fundacion Instituto Valenciano de Oncologia, Valencia, Spain (Dr. A. Calatrava, J. Casanova & Dr. Jose Rubio)	Naranco, J. et al. (2020) Evaluation of fluorescent confocal microscopy for intraoperative analysis of prostate biopsy cores. <i>European Urology Focus</i> , 5240-4560(2020)52(5)-8.	PMID: 32952840 (2020)
		Margin control	Cohen's K agreement was 94% for fatty tissue and 97.14% for muscular/vascular tissues	41 prostate margins 20 patients	G4	Dept. of Urology, University of Modena and Reggio Emilia, Modena, Italy (Prof. R. Montorsi & Prof. B. Rocco)	Rocco, B. et al. (2020) Real-time assessment of surgical margins during radical prostatectomy: A novel approach that uses fluorescence confocal microscopy for the evaluation of Peri-prostatic soft tissue. <i>BJU International</i> , 125(4), 487-489.	PMID: 31907142 (2020)
		Biopsy	97.2% specificity and 86.3% sensitivity	427 core biopsies 54 patients	G4	Dept. of Urology, University of Modena and Reggio Emilia, Modena, Italy (Prof. R. Montorsi & Prof. B. Rocco)	Rocco, B. et al. (2020) Digital biopsy with fluorescence confocal microscope for effective real-time diagnosis of prostate cancer: A prospective, comparative study. <i>European Urology Oncology</i> . Online ahead of print.	PMID: 32952095 (2020)
	Margin control	A novel approach to evaluate prostate margins	8 prostate margins	G4	Dept. of Urology, University of Modena and Reggio Emilia, Modena, Italy (Prof. R. Montorsi & Prof. B. Rocco)	Rocco, B. et al. (2020) Digital frozen section of the prostate surface during radical prostatectomy: A novel approach to evaluate surgical margins. <i>BJU International</i> , 126(2), pp. 336-338.	PMID: 32451370 (2020)	
	Kidney	Biopsy	K agreement was strong (1 to 0.93) for most tissue compartments	24 renal samples	G4	Nephrology and Renal Transplantation Dept., Hospital Clinic of Barcelona, University of Barcelona, Barcelona, Spain (Dr. J. Malvehy & Dr. A. Garcia-Herrera)	Villareal, J. Z. et al. (2020) Ex vivo confocal microscopy performs real-time assessment of renal biopsy in non-neoplastic diseases. <i>Journal of Nephrology</i> . Online ahead of print.	PMID: 32675939 (2020)
		Biopsy	Detection of tumor and normal tissue in 100% of cases	4 renal core biopsies	G4	Dept. of Urology, Fundacion Instituto Valenciano Oncologia, Valencia, Spain (M Carmen Mo, Dr. A. Calatrava & Dr. J. Rubio)	M, M. C. (2020) Ex-vivo confocal fluorescence microscopy for rapid evaluation of renal core biopsy. <i>Minerva Urologica e Nefrologica</i> , 72(1), pp. 109-113.	PMID: 31883726 (2020)
	Bladder & ureter	TURBT & flexible-URS	100% agreement	5 bladder and 1 ureter samples 4 patients	G4	Dept. of Urology, University of Modena and Reggio Emilia, Modena, Italy (Prof. G. Bianchi & Prof. B. Rocco)	Pulitti, S. et al. (2019) Ex vivo fluorescence confocal microscopy in the assessment of urothelial carcinoma grading in bladder and ureter: Our preliminary experience. <i>European Urology Supplements</i> , 18(1), pp. e026-e027.	14th annual EAU congress (2019)
TURBT		High sensitivity and specificity in agreement with the final histopathologic images	50 TUR-bladder	G4	hAklepis Clinic, Barnek, Dept. of Urology, Hamburg, Germany (Dr. C. Netusch)	Becker, L. et al. (2020) Pilot study to confirm the diagnostic precision of confocal fluorescence microscopy in urothelial carcinoma of the urinary bladder (German). 14. North-congress of Urology, lecture HF 12-03.	North-congress of urology HF 12-03 (2020)	
Hepatology	Pancreas	Biopsy & CytosMatrix	Cohen's K agreement was 95% 100% sensitivity	EUS-Fine Needle Biopsy samples 81 patients	G4	Dept. of Operative Endoscopy, Campus Bio-Medico University Hospital, Rome, Italy (Dr. Anna Crescenzi & Dr. F. M. Di Matteo)	Stigliano S. et al. (2021) Role of fluorescence confocal microscopy for rapid evaluation of EUS fine-needle biopsy in pancreatic solid lesions. <i>Gastrointestinal Endoscopy</i> . Online ahead of print.	PMID: 33796339 (2021)
Enterology	Intestine	Endoscopic biopsy	Immediate diagnosis of tubular adenoma with high-grade dysplasia	Case report	G4	Melanoma Unit, Dept. of Dermatology, Hospital Clinic of Barcelona, IDIBAPS, University of Barcelona, Barcelona, Spain (Dr. J. Malvehy & Dr. Miriam Cuatrecasas)	Anker, J. P. et al. (2020) Colonic perforation after piecemeal mucosectomy diagnosed by confocal microscopy. <i>Gastrointestinal Endoscopy</i> , 92(4), pp. 971-973.	PMID: 32376329 (2020)
Multiple	Multiple ²	IR-guided ³ needle biopsy	97.3% specificity and 91.6% sensitivity	105 core needle biopsies ² 65 patients	G4	Division of Pathology and Laboratory Medicine, The University of Texas MD Anderson Cancer Center, Houston, USA (Dr. S. Krishnamurthy & Prof. S. Gupta)	Krishnamurthy, S. et al. (2020) Comparison of real-time fluorescence confocal digital microscopy with hematoxylin-eosin-stained sections of core-needle biopsy specimens. <i>JAMA Network Open</i> , 3(3), e200476.	PMID: 32344465 (2020)
		Margin control	97.3% specificity and 95.5% sensitivity	118 surgical specimens	Prototype G4	Division of Pathology and Laboratory Medicine, The University of Texas MD Anderson Cancer Center, Houston, USA (Dr. S. Krishnamurthy & Prof. S. Gupta)	Krishnamurthy, S. et al. (2018) Confocal fluorescence microscopy platform suitable for rapid evaluation of small fragments of tissue in surgical pathology practice. <i>Actives of Pathology & Laboratory Medicine</i> , 14(3), pp. 305-313.	PMID: 30376375 (2018)
Generation 3 of the VivaScope 2500 microscope (G3) was the old version and provided only black & white images. Generation 4 (G4) is 4 times faster and provides pseudo-color H&E-like digital images.								
Dermatology	Skin	BCC margin control	The study classified BCC subtypes with an overall agreement ⁴ of κ=0.9	69 BCCs 66 patients	G3	Dept. of Dermatology, Hospital Clinic of Barcelona, IDIBAPS, University of Barcelona, Barcelona, Spain (Dr. A. Benmassar & Dr. J. Malvehy)	Benmassar, A. et al. (2018) Fast evaluation of 69 basal cell carcinomas with ex vivo fluorescence confocal microscopy. <i>JAMA Dermatology</i> , 149(7), pp. 839-847.	PMID: 29562776 (2018)
		BCC margin control	99% specificity and 88% sensitivity	80 BCCs 74 patients	G3	Melanoma Unit, Dept. of Dermatology, Hospital Clinic of Barcelona, IDIBAPS, University of Barcelona, Barcelona, Spain (Dr. A. Benmassar & Dr. J. Malvehy)	Benmassar, A. et al. (2014) Ex vivo fluorescence confocal microscopy for fast evaluation of tumour margins during Mohs surgery. <i>British Journal of Dermatology</i> , 170(3), pp. 360-365.	PMID: 24017437 (2014)
		SCC margin control	Margin assessment agreed in 41 of 43 mosaics	34 tumor margins 13 patients	G3	Skin Cancer Unit, IRCCS Santa Maria Nuova Hospital, Reggio Emilia, Italy (Dr. C. Longo & Prof. G. Pellacani)	Longo, C. et al. (2015) Ex vivo fluorescence confocal microscopy in conjunction with Mohs micrographic surgery for cutaneous squamous cell carcinoma. <i>Journal of the American Academy of Dermatology</i> , 73(2), pp. 321-322.	PMID: 25015978 (2015)
		BCC & SCCs margin control	99% specificity and 93% sensitivity	64 BCC and SCC 74 patients	G3	The Ronald O. Perleman Dept. of Dermatology, New York University School of Medicine, New York, USA (Dr. Daniel S. Ganeau)	Niu, E. W. et al. (2016) Use of digitally stained multimodal confocal mosaic images to screen for Non-melanoma skin cancer. <i>JAMA Dermatology</i> , 152(10), pp. 1315-1341.	PMID: 27623676 (2016)
		BCC margin control	Tumor features were well matched (χ ² analysis) to H&E images for the diagnosis of invasive SCC	102 SCC 57 patients	G3	Dept. of Dermatology and Allergology, University Hospital LMU, Munich, Germany (Dr. D. Hartmann & Dr. T. Braunmühl)	Hartmann, D. et al. (2018) Ex vivo confocal microscopy features of cutaneous squamous cell carcinoma. <i>Journal of Biophotonics</i> , 11(4), e001700318.	PMID: 29227042 (2018)
		BCC margin control	100% specificity and 100% sensitivity	42 BCCs 41 patients	G3	Dept. of Ophthalmology, University Hospital of St-Etienne, Saint-Etienne, France (Dr. E. Croitti & Dr. J. Luc Pennat)	Espartero, M. et al. (2011) In vivo ex vivo reflectance confocal microscopy to help the surgery of basal cell carcinoma of the eyelid. <i>Clinical & Experimental Ophthalmology</i> , 45(5), pp. 442-447.	PMID: 21796104 (2011)
		Cutaneous inflammation	Successfully distinguished the main inflammatory features of lesions in a pilot study	147 cutaneous lesions	G3	Dept. of Surgical, Medical, Dental and Morphological Sciences with Interest in Transplant, Oncological and Regenerative Medicine, University of Modena and Reggio Emilia, Modena, Italy (Dr. C. Longo & Prof. G. Pellacani)	Bertoni, L. et al. (2018) Ex vivo fluorescence confocal microscopy for intraoperative, real-time diagnosis of cutaneous inflammatory diseases: A preliminary study. <i>Experimental Dermatology</i> , 27(10), pp. 1152-1159.	PMID: 30035578 (2018)
		BCC margin control	95.8% specificity and 79.8% sensitivity	753 BCC margins	G3	Dept. of Dermatology, University of Modena and Reggio Emilia, Modena, Italy (Dr. C. Longo, Dr. M. Ragazzi & Prof. G. Pellacani)	Dika, E. et al. (2019) Comment on "Diagnostic accuracy of ex vivo fluorescence confocal microscopy for Mohs surgery of basal cell carcinomas: A prospective study on 753 margins". <i>British Journal of Dermatology</i> , 180(6), pp. 1559-1559.	PMID: 30521918 (2019)
Serology	Breast	Margin control & biopsy	93% specificity and 93% sensitivity	70 samples 31 patients	G3	Rice University, Department of Bioengineering, 6500 Main Street, BRC 502, Houston, Texas 77030, USA (Jessica L. Dobb & Rebecca Richards-Kortum)	Dobb, J. L. et al. (2013) Feasibility of confocal fluorescence microscopy for real-time evaluation of neoplasia in fresh human breast tissue. <i>Journal of Biomedical Optics</i> , 18(10), 106006.	PMID: 24165742 (2013)
Neurology	Brain	Margin control & biopsy	Identified tumor tissue features quickly without tissue loss in a pilot study	20 samples 19 patients	G3	Dept. of Pathology, University Hospital of Saint Etienne, North Hospital, Saint Etienne CEDEX 2, France (Dr. F. Forest, J.L. Perrot & Dr. M. Peuch)	Forest, F. et al. (2015) Ex vivo confocal microscopy imaging to identify tumor tissue on freshly removed brain sample. <i>Journal of Neuro-Oncology</i> , 124(2), pp. 157-164.	PMID: 26021548 (2015)
		Biopsy	Diagnosed the brain aspergillosis Ex Vivo & rapidly in a pilot study	Case report	G3	Dept. of Pathology, University Hospital of Saint Etienne, North Hospital, Saint Etienne CEDEX 2, France (Dr. F. Forest, J.L. Perrot & Dr. M. Peuch)	Forest, F. et al. (2018) Rapid characterization of human brain aspergillosis by confocal microscopy on a thick squash preparation. <i>Cytopathology</i> , 27(3), pp. 221-222.	PMID: 29120196 (2018)
Multiple	Multiple ²	Margin control & lymph node	The images of the pilot study were as accurate as the conventional histology	35 samples 30 patients	G3	Pathology Unit, IRCCS Santa Maria Nuova Hospital, Reggio Emilia, Italy (Dr. C. Longo, Dr. M. Ragazzi & Prof. G. Pellacani)	Ragazzi, M. et al. (2014) Fluorescence confocal microscopy for pathologists. <i>Modern Pathology</i> , 27(3), pp. 460-471.	PMID: 24602574 (2014)

1) Click here for the full list of publications.

2) Interventional radiology (IR)-guided core-needle biopsies from bone, kidney, liver, lung, lymph nodes, pleura and soft tissues.

3) Imaged 118 tissue fragments from surgical excision specimens: 40 breast, 23 lung, 39 kidney, and 16 liver.

4) For example: the pairwise criteria (n=138) had 100% Sp & 96% Se for surrounding dermis; 96% Sp & 96% Se for hair follicles and 91% Sp & 96% Se for Eccrine gland cells.

5) Imaged 12 breast lumpectomies, 8 thyroid, 7 colorectal resections and 8 lymph nodes (6 axillary and 2 cervical lymph nodes).