

Annual General Meeting
Notting Hill, Vic, Australia
30th November 2015



Unlocking the world of **Live Micro Imaging (LMI) technology**

Chairman Address – Patrick O'Connor

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CHAIRMAN'S ADDRESS TO AGM

Good Afternoon ladies and gentlemen, and welcome to the 2015 Annual General Meeting of the members of Optiscan Imaging Limited.

My name is Patrick O'Connor, and I am Chairman of the board of Optiscan.

I would like to introduce my fellow directors present today, Peter Delaney and Bruce Andrew.

I now formally declare the meeting open, as there is clearly a quorum present.

The course of business today will cover a brief Chairman's address, and I will then hand over to Peter Delaney to provide an update on our technology and the future directions and opportunities that are emerging.

We will then deal with the statutory items of business, being the resolutions included in the Notice of Meeting.

When those formalities have been completed, you will have the opportunity to raise any questions that are not dealt with in the presentations or during consideration of the formal resolutions.

Joanne Lonergan, from our auditors, Ernst & Young is available to respond to any questions you may have concerning the conduct of the audit and the preparation and content of the auditor's report.

Chair Address

Many of you may be aware that I joined the board in July of this year. I have for many years served as a public company director and Chairman in a range of organisations. I was happy to accept the appointment to the board in July, and I look forward to the opportunity to contribute to the progress of the company.

The company has been battling against the tide for some time, trying to achieve progress with a small team and tight funding base. That said, there have been important achievements this year, and good progress has been made.

When I look at the profile of the company today, I see an innovative technology with proven efficacy that has been licensed now by two major global device companies. Optiscan has completed the development of a second generation imaging platform that has recently had its first market release in the form of the CellLIVE research system being distributed by MR Solutions.

The company has also announced that its collaboration with Carl Zeiss Meditech in microsurgery has been significantly enhanced, with important new cash flows in excess of \$2 million over the next year.

After spending much of the past few years focused on these key engineering projects and collaborations, Optiscan is now approaching an exciting stage where it can turn to the horizon, and consider new opportunities and applications. This is the first opportunity in some time to return to the core business model of Optiscan, that is, to identify medical applications where patient outcomes can be enhanced by the application of our imaging systems.

Gastroenterology or "GI" applications will always be close to the top of this list. The company's devices were well established in leading institutions and user groups under the Pentax agreement, and many thousands of procedures have since been conducted. This has created a vast array of literature and publications supporting the use of the system. Importantly, this has also led to the granting of CPT codes in the US, a critical endpoint in proving recognition of the effectiveness of the technology.

We have already commenced some internal work on how to chart a path to take our new, second generation system to the user groups in this established market.

While we are excited about the prospects in this field, there are others that could prove to be important near term opportunities, and I will leave Peter to discuss those shortly.

There are of course many other commercial and financial issues that are addressed by the board. Cash and funding is always on the agenda, and that is the case right now. We are anxiously awaiting the issue of a tax refund arising from the R&D Tax Incentive Scheme. Our return was lodged back in September, and it has taken considerably longer to issue than has been the case in recent years. We have made several approaches but have been advised that it will issue in due course. Unless it issues while this meeting is in progress, this delay will trigger a requirement to issue 1M shares under the terms of a loan agreement announced in June this year.

This delay also places pressure on our overall funding position, and the board is currently in active discussion about funding the near term requirements of the company.

It is important to get this right.

Before I close, and hand over to Peter, I would like to comment on the structure of the board. Many of you will know there is a legal requirement to maintain a minimum of three directors, and for obvious reasons, this has been position adopted by the board. The board is very much aware of the importance of renewal and it will be a priority to both expand and refresh the composition of the board.

I will now hand over to Peter.

**Director of Technology Address
AGM 2015**



Live Cellular Imaging for Medicine and Science

Forward looking statements

This presentation contains "forward-looking" statements within the meaning of the United States' Private Securities Litigation Reform Act of 1995. Any statements contained in this presentation that relate to prospective events or developments, including, without limitation, statements made regarding Optiscan's endoscope technology, business and partners are deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those indicated by these forward-looking statements, including risks related to our available funds or existing funding arrangements, a further downturn in our customers' markets, our failure to introduce new products or technologies in a timely manner, regulatory changes, risks related to our international operations, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantages, as well as other factors. Subject to the requirements of any applicable legislation or the listing rules of any stock exchange on which our securities are quoted, we disclaim any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this presentation.

Optiscan - who are we, what do we do

- Optiscan has developed high powered medical imaging using laser based confocal microscopes and miniaturised scanners
- The cutting edge technology provides powerful imaging in real time reducing costs and improving patient outcomes
- The technology has already been licensed to major global players including Pentax and Carl Zeiss
- Optiscan's business was disrupted by the GFC, but since that time has achieved:
 - completion of a second generation platform,
 - release of research system,
 - near completion of the collaboration with Carl Zeiss
 - assessment of the next application and product opportunities
- With \$100M invested in its technology, and little effective competition in the market, an inflection is point close, with the market cap currently less than \$10M.

Optiscan strategy and business model

Optiscan Strategy

Maintain global leadership in microscopic imaging for medical markets

Leverage imaging platform by identifying new medical imaging needs

Pursue focused commercialisation through market leading distribution partners

Revenue sources

- Margin from sales of endo-microscope miniaturised scanners and control systems
- Royalties and up front payments from licensing of technology
- Partner payment for product development

Brief History of Optiscan - Milestones

- ✓ **1994, 1997** Optiscan founded 1994, lists on ASX 1997
- ✓ **2001** World's First human confocal endomicroscopy by Optiscan –“endomicroscopy” is born
- ✓ **2002** \$20m agreement with Pentax to develop world's first flexible endomicroscope
- ✓ **2006** Market release of Pentax ISC-1000
- ✓ **2007** Zeiss collaboration signed,
Market release of research system, the Optiscan FIVE-1
- ✓ **2008-2011** Development of second generation processor, scanner and sterility solution
- ✓ **2012** First sales of second generation HD flexible endomicroscopes built as custom systems
- ✓ **2014** Distribution agreement with MR Solutions for sale of “CellLIVE” research system;
Sterile sheath success for Zeiss project
- ✓ **2015** Market launch of “CellLIVE”, second generation research system
Zeiss collaboration enhanced

Optiscan's Product Platform



- Realtime imaging of cellular detail in 3D
- In the living body – *without* biopsy
- Full HD large screen imaging – stunning detail
- Miniaturised flexible and rigid imaging probes
- Can be used in endoscopes, termed “*endomicroscopy*”

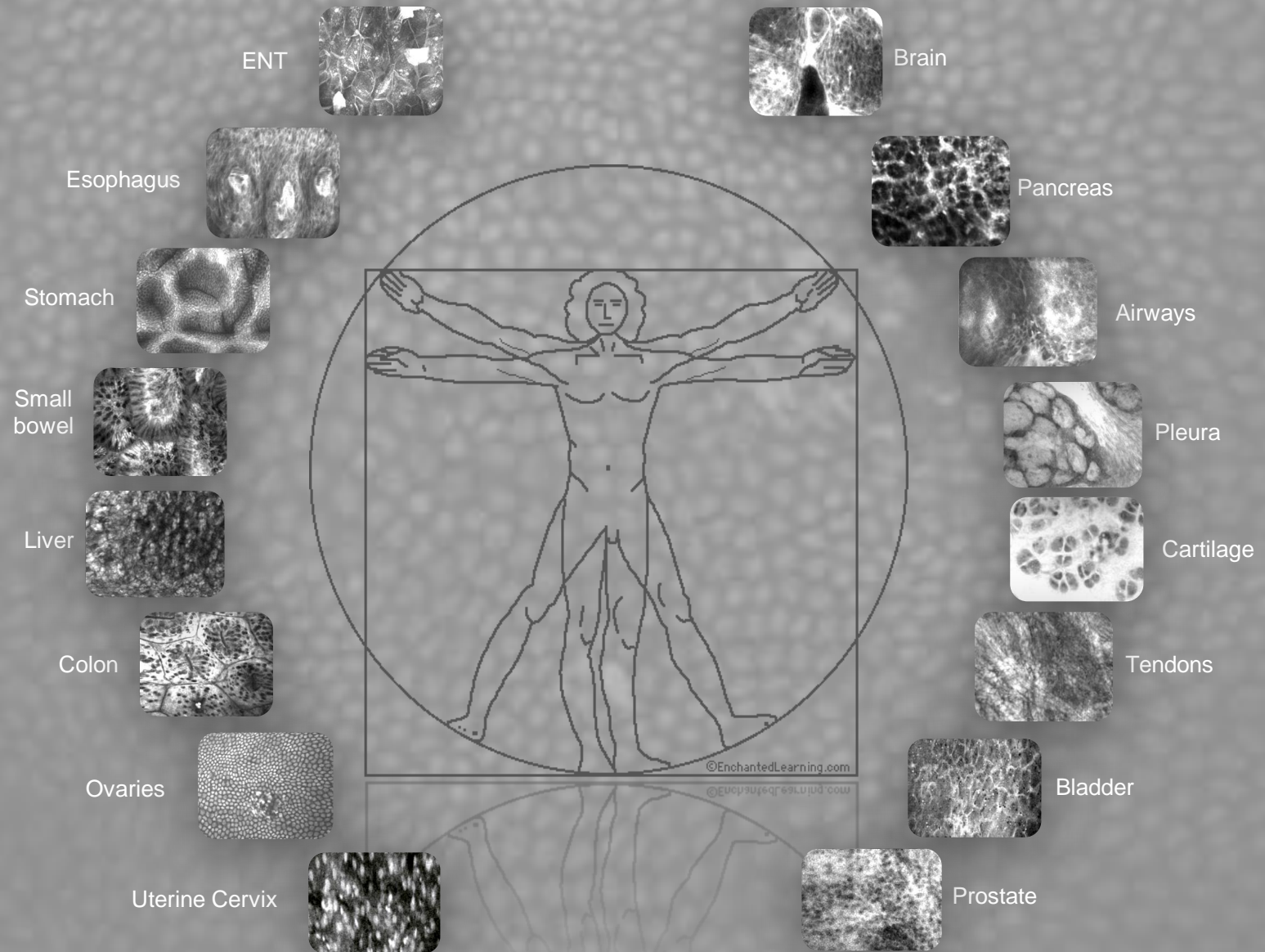
Optiscan Miniaturised Microscope Technology

- Optiscan is the pioneer in the development and application of miniaturised *microscopic imaging* technology for medical markets
- Microscopes so small they can be used inside the living body
- Optiscan invents, develops, manufactures and supplies miniaturised confocal technology for “endomicroscopes”
- The Company’s patented technology platform is proven and versatile:
 - Multiple clinical medical imaging applications
 - Pre-clinical (research market) applications
 - Comprehensive portfolio of patents, creating significant barriers to entry

Market Need for Endomicroscopy

- In many medical procedures (such as endoscopy), conventional visualisation with cameras/endoscopes is inconclusive.
- To reach diagnosis, a biopsy sample is removed for analysis at pathology.
- The two major limitations of this approach are:
 - The biopsy may “miss” the relevant diseased tissue, resulting in false negatives and processing of numerous irrelevant biopsies;
 - The result is delayed – treatment awaits follow up procedures.
- Endomicroscopy allows real-time cellular information that:
 - Can ensure that a biopsy site contains relevant tissue (“smart biopsy”);
 - Gives doctors confidence to proceed directly with intervention/treatment (“see & treat”).
- Clinical studies have validated the above in several common procedures.
- Major applications include detection and better removal of cancers.

- Platform Technology – applicable to any field of endoscopy/surgery
- Strong clinical evidence already established in several fields



Optiscan's Commercialisation Model

- Partnership with/licensing to global marketers
- Present partnerships
 - MR Solutions - Pre-clinical (research)
 - Carl Zeiss Meditec – Microsurgery
- Other fields remain open for partnership
 - Gastrointestinal (GI) endoscopy
 - Women's Health
 - Arthroscopy (cartilage and tendons)
 - Other

Pre-Clinical Imaging



Unlocking the world of **Live Micro Imaging (LMI) technology**



- UK based MR Solutions specialises in small animal (pre-clinical) imaging
 - MRI, PET, SPECT Scanners
- Optiscan technology adds optical microscopy, a key growth area for pre-clinical research
- Global distribution agreement established February 2014
- The product is called *CellLive™*
- See system at www.mrsolutions.com/products/imaging-systems/confocal-microscopy
- *CellLive™* was launched at the World Molecular Imaging Conference (WMIC), Hawaii, September 2015

Market for pre-clinical imaging and MRS *CellLIVE*TM

- The pre-clinical imaging market was estimated at US\$800M in 2012 with projected 14.5% annual growth for 5 years
- Two main forms of imaging:
 - Radiological - PET, MRI, SPECT
 - Optical – whole body fluorescence and microscopy
- Whole body optical imaging now has a footprint of well over 1,000 instruments. Key limitations include artefacts due to low contrast and resolution, which drives the need for microscopy
- MR solutions product offerings include above radiological instruments, and now optical imaging
- The MRS *CellLIVE*TM represents a key product offering to meet the growing need for optical microscopy as a pre-clinical imaging modality

CellLive™

Powerful, handheld fluorescence confocal endomicroscope imaging system



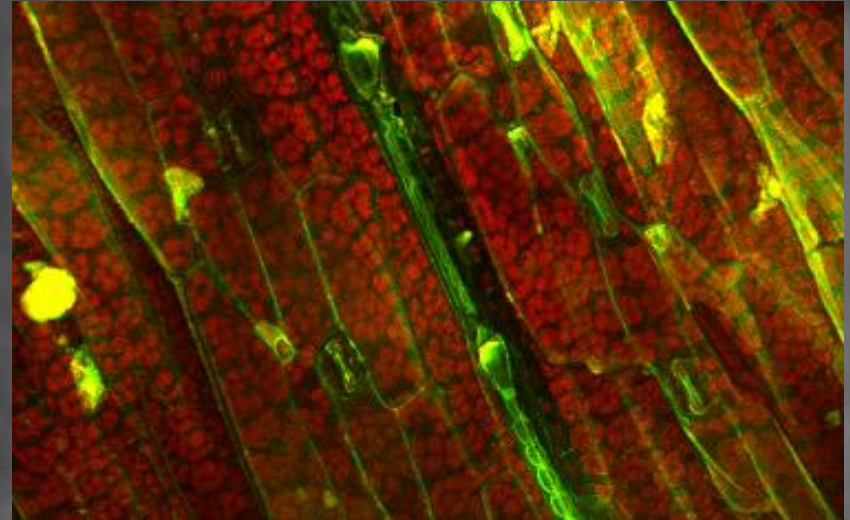
- Wavelength:** 488.0 nm
- Laser:** <1mW at the sample
- Filter Wheel:** 8 position - standard
12 position - on request
- Scanner dimensions:** 3mm x 30mm
- Scan Area:** 500 x 500 μm
(Scan mode dependent)
- Scan Depth:** 250 μm
- Resolutions:** < 0.5 μm x-y; <4.5 μm z
- Z-step:** 3 μm ; precision 1 μm
- Acquisition:** Single Frames
Time Series
Z-Stacks
- Processor Dimensions:**
410mm x 150mm x 420





CellLIVE™ - Key Features

MRS CellLIVE is a powerful, handheld fluorescence confocal endomicroscope imaging system that is designed specifically for in vivo research



- Astounding ultra high resolution
- Colour imaging with new spectral detection filter set
- Integrated scientific analysis software
- Full 3D capability

MR Solutions *CellLIVE™* - Summary

- The system launched at WMIC is unique in the market for pre-clinical research, with unmatched performance, offering for the first time:
 - Full 3D imaging capabilities
 - Integrated analysis and measurement tools
 - Unique spectral imaging capabilities, enabling colour imaging of multiple molecular labels in a single animal
 - Ultra-high resolution of less than one micron (1/1000th of a millimetre)
- MR Solutions is an innovator in the preclinical imaging market specialising in compact MRI and PET scanners for animal research.
- MR Solution's market footprint and targeted marketing is thus well aligned to take the *CellLIVE™* into the global preclinical research market
- While the sales cycle for major scientific instruments is long (often awaiting award of research funding grants), Optiscan believes the market for the *CellLIVE™* will grow to some tens of units per year within the first several years.
- In November 2015, MRS placed their first order to Optiscan for “try before buy” seeding stock so as to convert the growing prospect pipeline.



Neurosurgery



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Opportunity in Neurosurgery

- Brain tumour resection surgery (craniotomy)
 - Estimated 600,000 procedures pa globally could benefit from endomicroscopy
- Identification of optimal biopsy sites is often vexed
 - Brain swelling
 - Brain shift (relative to pre-operative MRI scans)
- Determination of whether resection margins are cancer free is also problematic
- Neurosurgeons already use high magnification (microsurgery), but this falls well short of offering cellular detail of healthy brain or cancer cells
- Real-time microscopic imaging can overcome these limitations



Carl Zeiss Meditec Partnership - Microsurgery

- Esteemed in optical imaging
- Market leader in neurosurgical visualisation

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Neurosurgery

Countless neurosurgeries worldwide are performed on surgical microscopes from ZEISS – and for good reason. They are designed to suit the high demands of neurosurgery.



Surgical Microscopes

Optical precision, flexibility and ease of use in neurosurgery provided by surgical microscopes from ZEISS.

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Optiscan's technology extends the boundary of neurosurgical visualisation

- Optiscan has partnered with Carl Zeiss Meditec – the market leader in microsurgical visualisation for neurosurgery
- By adding Optiscan's technology, the surgeon's armamentarium is extended to offer cellular detail – this is unprecedented
- Real-time microscopy offers surgeons observations of the cellular makeup of particular sites of interest during surgery **before** choosing their next actions
- The device is a rigid endoscope or hand-held probe placed directly onto tissue of interest, generating live images.
- Development details and specification remains confidential
- Pre-clinical and clinical investigations have been published

Future Products



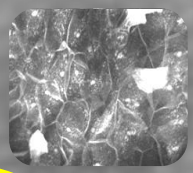
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Ongoing Commercialisation Opportunities

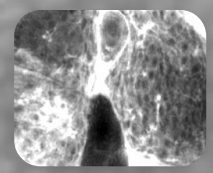
- Over the past year, Optiscan has maintained a stringent focus on the existing commercial partnerships above
- The era of endomicroscopy offers numerous additional opportunities
 - The latest technology platform is “productisation ready”
 - Strong clinical evidence exists for several of these fields
 - Market size for some of these opportunities is very large

Gastro-Intestinal (GI) endoscopy

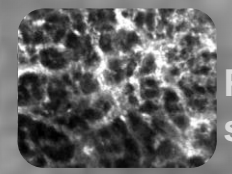
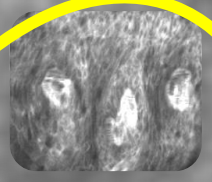
ENT



Brain

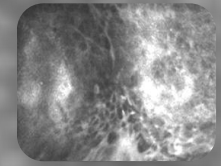
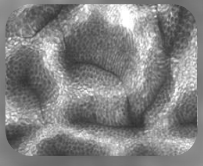


Esophagus



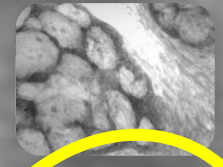
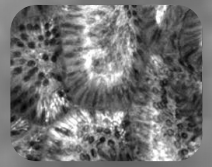
Pancreas

Stomach



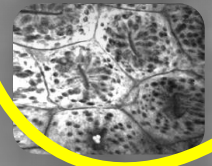
Airways

Small bowel



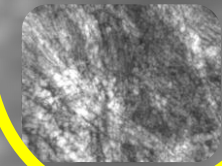
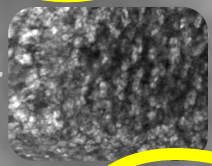
Pleura

Colon



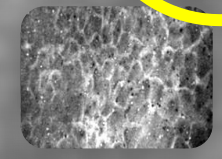
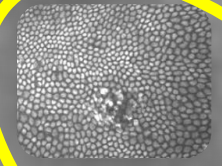
Cartilage

Liver



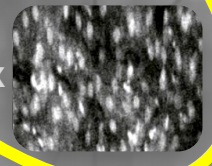
Tendons

Ovaries

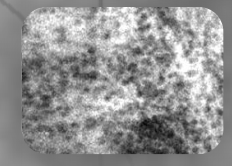


Bladder

Uterine Cervix

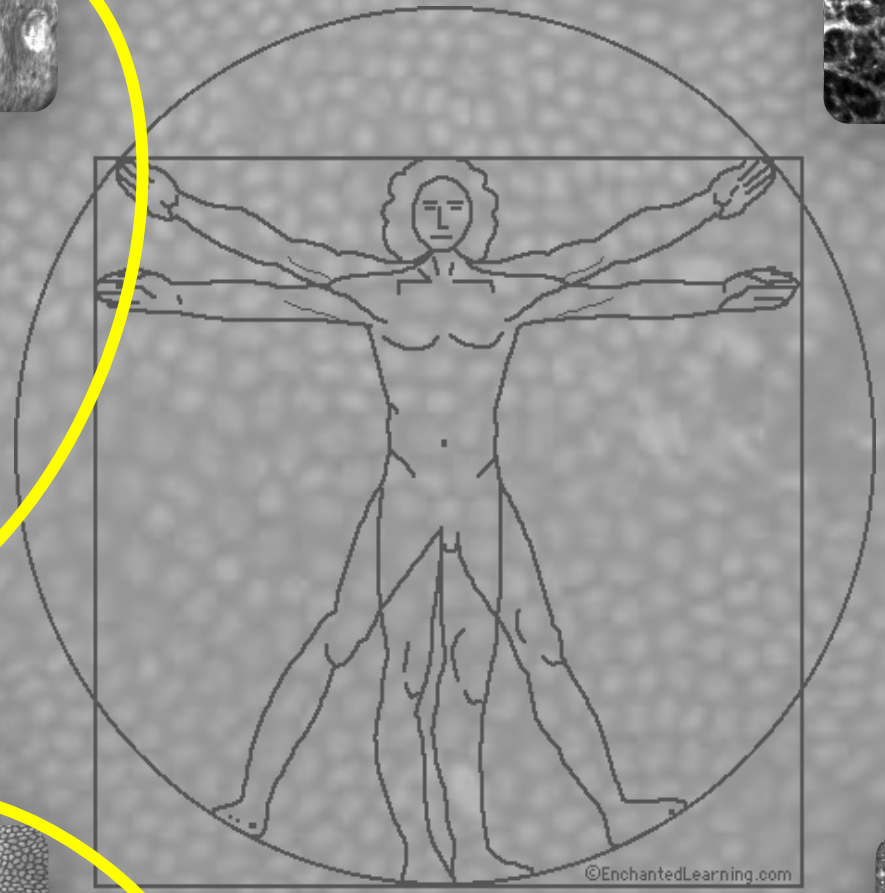


Women's Health



Prostate

Arthroscopy



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GastroIntestinal (GI) Endomicroscopy

- GI endoscopy represents a devices market >US\$3Billion
- Market features large procedure volumes
 - Upper > 2million procedure pa (USA)
 - Lower > 4million procedures pa (USA)
- Largest body of clinical evidence of any application
- Hundreds of clinical studies and reviews published
- Exquisite clinical results
- Proven in both upper and lower endoscopy procedures (gastroscopy and colonoscopy)

Flexible endoscope applications now cover most major gastrointestinal disorders

Confocal endomicroscopy Kerry Dunbar and Marcia Canto

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Current Opinion in Gastroenterology 2008, 24:631-637

Purpose of review

Confocal laser endomicroscopy is an emerging field of endoscopic imaging allowing gastroenterologists to obtain in-vivo histology of the gastrointestinal mucosa. The present review will address the more recent advances in confocal laser endomicroscopy and discuss its future.

Recent findings

Interest in confocal laser endomicroscopy and in-vivo diagnosis of gastrointestinal disorders has increased in the last few years. Confocal laser endomicroscopy can localize intraepithelial neoplasia in chronic ulcerative colitis and enable 'smarter' mucosal biopsy when combined with chromoendoscopy. Confocal laser endomicroscopy may accurately diagnose neoplasia in the esophagus, stomach, colon, and bile duct. Moreover, in-vivo visualization of morphologic epithelial abnormalities, such as intraepithelial bacteria and 'gaps in the gut', may increase our understanding of the possible pathogenic mechanisms of disease. Fluorescent peptide markers that target neoplasia are also being developed as a complementary approach to visualization of in-vivo histopathology.

Summary

Confocal endomicroscopy is a developing area of gastrointestinal endoscopy with expanding clinical and research applications. The present review focuses on recent advances in confocal endomicroscopy.

Keywords

accuracy, confocal endomicroscopy, fluorescein, microendoscopy, novel imaging, performance characteristics, sensitivity, specificity

Cur Opin Gastroenterol 24:631-637
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0267-1379

Introduction

Confocal laser endomicroscopy (CLE) can provide high-resolution in-vivo assessment of mucosal histology. The present article describes available CLE imaging systems and contrast agents and reviews the CLE literature from 2007 and 2008, including CLE applications throughout the gastrointestinal tract, studies of the learning curve of CLE, and targeted contrast agents.

Confocal endomicroscopy systems

There are two confocal endomicroscopy systems currently in use. The Pentax EC3870K with the ISC-1000 confocal endomicroscopy processor (Pentax, Tokyo, Japan and Optiscan Pty Ltd, Notting Hill, Victoria, Australia) is a conventional endoscope with a miniaturized confocal microscope at the tip. This system provides excellent image clarity and the ability to use the confocal endoscope in a way similar to a regular endoscope, as it has the standard endoscope accessory channel. Images can be collected by sectioning down through the mucosa

ization is necessary to obtain good quality images, which can be achieved using suction, and tissue biopsies can be targeted to the area of imaging through a 'suction polyp' found next to the imaged area. Examples of endomicroscopic images collected with the Pentax CLE system are shown in Fig. 1.

The second CLE system, the Cellvizio-GI (Mauna Kea Technologies, Paris, France), is a probe-based endomicroscopy system. The confocal miniprobe can be passed down the accessory channel of any standard endoscope, providing rapid image capture and 'stitching' of adjacent images to create an image 'mosaic' in real time. Three miniprobes are available with different imaging depth, field of view, and lateral resolution. Image stabilization can be achieved by using a plastic cap on the endoscope tip.

A comparison of the technical specifications of the two systems is presented in Table 1. The three major imaging differences between the confocal endomicroscope and the confocal miniprobe are the scanning rate, resolution,

- Barrett's esophagus and Barrett's Cancer
- Oesophageal squamous cell carcinoma
- Non-erosive reflux disease
- Reflux esophagitis
- H.pylori
- Gastritis
- Gastric intestinal metaplasia
- Gastric cancer
- Celiac disease
- Ulcerative Colitis
- Colorectal Cancer surveillance
- Microscopic colitis
- Graft Versus Host Disease (GVHD)
- Pouchitis (in colectomy patients)
- Paediatrics

GI Endomicroscopy - Summary

- Largest market opportunity for Optiscan
- Multiple clinical indications for use
- **3 Category 1 CPT codes in place**
- Reimbursement in place
- Optiscan offers compelling technical leadership
- Highest level clinical results support Optiscan's technology
- High Strategic Significance – Optiscan is pursuing partnering opportunities to commercialise its latest generation platform into GI endoscopy



Future Products in General Surgery

- Women's Health
 - Cervical cancer
 - - clinical efficacy established
 - Endometriosis
 - Feasibility studies warrant further investigation
 - Compelling business case
 - Ovarian cancer
 - Potential additional applications as molecular screening creates indication for early surgical intervention (laparoscopy)
- Arthroscopy
 - Imaging of cartilage and tendons that cannot be biopsied
 - Long term investigation by users of Optiscan's technology
 - Cadaveric human and live animal imaging results are stellar
 - Research investigators are transitioning to human studies

12 Month Outlook

- Complete Zeiss development project
- Initial sales of CellLIVE pre-clinical systems
- Enter into additional commercial partnership(s)
- Advance development of new applications with innovative engineering and design



The global leader in microscopic
imaging technologies for medical
markets