

ASX/Media Release

Barrett's Esophagus: Trial results build momentum for Endo-microscopy at DDW

19 May 2005, *Digestive Diseases Week, Chicago, USA:* Two separate presentations were made by physicians conducting flexible endo-microscope trials in detection of early stage cancer of the esophagus amongst patients with Barrett's Esophagus.

The larger of the studies was a two-centre trial completed in Germany with patients undergoing endoscopic procedures at the Dr Horst-Schmitt Kliniken (HSK), Wiesbaden and the University Hospital, Mainz. The presentation at DDW was given by Dr Ralf Kiesslich.

The trial involved a preliminary study comparing endomicroscopy images to traditional pathology to develop a simple Barrett's classification system for endo-microscope images. Then in a blinded protocol using this classification, 42 patients were assessed in two subgroups, one with known Barrett's Esophagus and the other suffering from Gastro Esophageal Reflux Disease (GERD) – which leads to Barrett's Esophagus.

The objectives of the German trial were to evaluate the use of the endo-microscope to predict the outcome of pathology after biopsy and to measure the reproducibility of the results (statistics describing inter observer and intra observer agreement).

The key outcomes reported at DDW yesterday were:

- 97.5% overall accuracy to predict the diagnosis of early cancer (as determined by pathology of biopsies) in both subgroups
 - Barrett's Esophagus subgroup; Sensitivity 98.8%, Specificity 94.4%, Accuracy 97.5%
 - GERD subgroup; Sensitivity 91.7%, Specificity 99.0%, Accuracy 97.5%
- Mean kappa scores of 0.843 for inter observer agreement and 0.892 for intra observer agreement (indicating very high agreement).

The second study is being conducted by Dr Norm Nishioka and colleagues at Massachusetts General Hospital in the USA. An interim report of findings after assessment of 12 patients with known Barrett's Esophagus was given by Dr John Evans.

Dr Evans reported that the endo-microscope allowed certain key cellular characteristics of Barrett's esophagus to be clearly observed at the time of endoscopy, suggesting that confirmation of the condition should be straightforward using the instrument. He also discussed preliminary endo-microscope image types for Barrett's associated early cancer.

The interim conclusions were;

- If use of contrast agents could replicate the exact features normally observed by pathologists in the conventionally prepared sections of biopsied tissue, then previously established criteria for diagnosis could be applied to endo-microscope images.
- With the protocol used to date, a new classification system (such as that developed by the German investigators) would be required to further the assessment of diagnostic value.

The two DDW presentations were well attended and drew keen interest during question time, particularly from the many delegates who currently face problematic issues managing this widespread condition.

"Management of Barrett's esophagus is one of the biggest problems in gastrointestinal endoscopy" said Peter Delaney, Optiscan's Director of Technology. "With these 2 European centres already showing excellent results, and investigation underway in a leading US hospital, we have great confidence that doctors will increasingly turn to endo-microscopy to address the clinical diagnostic and management challenges of Barrett's Esophagus."

"The strength of our first inter observer agreement results demonstrates that endo-microscopy can be consistently and successfully used by endoscopists," he said. "This result is an important milestone towards eventual widespread adoption of our technology."

Background on Barrett's Esophagus

Barrett's Esophagus, is a condition that develops in a large proportion of people who suffer from heartburn or gastric reflux. It involves subtle changes to the lining of esophagus which if unmanaged has the potential to progress to dangerous and aggressive esophageal cancer.

Improvement in the diagnosis and management of Barrett's Esophagus receives significant focus by leading Gastroenterologists. At DDW, more than 70 presentations described various improvements in techniques and technologies for diagnosis, management and surgical procedures for treating Barrett's Esophagus and its progression to esophageal cancer.

Almost 500,000 Australians suffer from Barrett's Esophagus, with approximately 200,000 being endoscopically screened annually for cancer of the esophagus. The procedure is cumbersome with typically 35 biopsies surgically removed for subsequent microscopic examination in pathology laboratories. The procedure is tedious for doctors, has unpleasant side effects for patients, and the resulting early cancer detection rate is disappointingly low.

Esophageal cancer is very aggressive, so it's early detection is essential. About 6,000 Australians are diagnosed with cancer of the esophagus every year and 2,000 die.

Background on Optiscan

Optiscan is a global leader in microscopic imaging technologies for medical markets.

Optiscan's unique and patented technologies enable high-powered microscopes to be miniaturised and used inside the body. The technology enables microscopic imaging of up to 1000 times magnification to be achieved. Doctors can use the technology to instantly see cellular level details of tissue without the requirement to surgically remove tissue (biopsy).

Pentax is the second largest producer of flexible endoscopes in the US\$900Mpa global flexible endoscope market.

Gastroenterologists use flexible endoscopes to view inside the gastro intestinal tract. They are an essential piece of equipment in the screening, early diagnosis and treatment of colon, large intestine, stomach and oesophageal cancers and pre-cancers.

Pentax has been licensed by Optiscan to use its patented miniaturised microscope technology and develop the world's first fully functional flexible endo-microscope.

Pentax's flexible endo-microscope combines existing industry standard endoscope functionality and Optiscan's unique microscopic imaging technology into one instrument. Doctors have two

screens, one with the regular view (from 10 to 100 times magnification) and one showing the microscopic detail from Optiscan's technology (1000 times magnification).

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