The LightPath™ Imaging System for intra-operative tumour assessment

TECHNOLOGY

The LightPath™ Imaging System developed by Lightpoint Medical, is a molecular imaging technology that has the potential to detect cancer in real-time during surgery.

This technology is intended for use in patients with invasive breast cancer or ductal carcinoma in situ undergoing wide local excision surgery, or men with high risk non-metastatic prostate cancer undergoing a radical prostatectomy.

The LightPath™ System is used intra-operatively to generate optical images of the uptake of positron emission tomography (PET) imaging agents to help differentiate between tissue affected or unaffected by cancer, which may be helpful in assessing surgical margins. The LightPath™ system is compatible with commercially-available PET imaging agents and uses Cerenkov Luminescence Imaging (CLI) which has the potential to combine the benefits of optical imaging (low cost and high resolution) with the power of PET imaging (high diagnostic performance and widespread availability of approved imaging agents).

The company received CE marking for the LightPath™ in October 2015 and anticipate clinical use within the NHS in October 2016.

POTENTIAL FOR IMPACT

Breast cancer is usually treated with surgery, and the presence or absence of a negative margin of healthy tissue around the excised tumour is important in determining the management pathway. This determination happens post-surgically where the specimen is sectioned and stained to help determine whether it is cancerous. This process can take several days or weeks to complete. Moreover, in breast cancer the absence of a negative
margin (known as a positive margin) generally requires a second operation or re-excision. About 25% of women with a lumpectomy need a re-excision which can cause discomfort and stress and may lead to complications. Currently, no real-time non-destructive intraoperative method exists to rapidly assess the microscopic status of lumpectomy margins.

The main surgical option for prostate cancer is radical prostatectomy, where the entire prostate gland is removed. During this operation it is still important for the surgeon to know whether there is a margin of healthy tissue around the cancerous area. In prostate cancer, a positive margin does not lead to further surgery, but to the use of more aggressive therapy. It is also associated with an increased risk of biochemical recurrence, as determined by an increase in Prostate Specific Antigen (PSA). Currently, no intraoperative methods are available to rapidly and effectively assess the status of tumour margins in prostatectomy specimens in order to inform the need for further excision during the prostatectomy procedure.

According to the company, the LightPath™ Imaging System has the potential to help guide cancer surgery, providing more accurate treatment whilst sparing healthy tissue. The company claim the technology has the potential to reduce the possible requirement for additional interventions or a change in current therapy. Consequently, use of the LightPath™ Imaging System could lead to rapid molecular imaging in the operating room, reduction of re-operation rates and removal of complex tissue sample preparation. Additionally, the identification of a positive surgical margin during surgery, by using the LightPath™ Imaging System, could result in the initiation of appropriate additional therapy earlier.

If effective, this technology is predicted to have an impact on the following domain of the NHS Outcomes Framework (www.england.nhs.uk/resources/resources-for-ccgs/out-frwk):

Domain 1 Preventing people from dying prematurely.

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS


ONGOING STUDIES


NIHR Horizon Scanning Research & Intelligence Centre


**INFORMATION FROM**

This Alert is based on information from the company and a time-limited internet search.

**Lay summary**

The **LightPath™** Imaging System detects cancer in tissues during surgery for breast or prostate cancer. To treat both of these types of cancer, it may be difficult to know which area of the tissue is cancerous and it can take several days or weeks to be sure. This may mean the patient needs more than one surgical procedure or has to have other drug and radiation treatment. The **LightPath™** Imaging System combines two types of imaging techniques which shows tissue which is affected and unaffected by cancer, as well as showing if there is cancer in the tissue surrounding the tumour whilst the surgery is being undertaken. The manufacturer claims the device may provide more accurate breast and prostate cancer treatment whilst sparing healthy tissue.