ClearSight™ MRI for breast cancer lumpectomy

TECHNOLOGY

The ClearSight™ MRI system has been developed by ClearCut Medical to provide intra-operative, real time assessment of excised lumps during lumpectomy (breast conserving surgery) in patients with breast cancer. The system is intended to assess margins of excised tissue in the operating room, providing the surgeon with information to inform re-excision decisions. The system is a mobile MRI device mounted on a cart. During the lumpectomy procedure, the excised tissue is placed in ClearPack™ - a disposable, sterile container, where it is marked for orientation. The tissue is then imaged by the system, which produces an immediate image of the tissue surface. Indication of margin status is given within minutes, together with the orientation of positive margins, if detected. The surgeon can then decide whether additional tissue needs to be removed. At the end of the procedure, all excised tissue is sent to the pathology laboratory for final assessment.

The ClearSight™ system uses proprietary ClearCut MRI technology. This performs detailed tissue-microstructure analysis using Diffusion Weighted Magnetic Resonance Imaging (DW-MRI) protocols to detect malignant cells on excised tissue surfaces and therefore distinguish between normal and malignant tissues in real time. The portable MRI system is intended for use during surgical procedures in the operating room, ambulatory surgery centres, radiology and pathology departments and outpatients. The company state initial usage is for breast lumpectomy surgery but applications in prostate, thyroid and skin cancers, as well as biopsy imaging, will be pursued in the future.
The ClearSight™ technology received a CE mark in 2014 and the company anticipate launch for UK clinical use in 2016.

**POTENTIAL FOR IMPACT**

MRI is currently used for cancer diagnostic imaging by radiologists in dedicated rooms outside the operating room. MRI is conducted before performing lumpectomy procedures to assess the location of the malignancy and also after surgery to confirm removal of all malignant tissue. The need for MRI can thus be expensive and time consuming, as well as creating a delay between sample preparation and results.

ClearSight™ uses ClearCut’s proprietary MRI technology for detailed tissue-microstructure analysis to distinguish between normal and malignant tissue. The company state a key innovative feature is that the MRI system is compact and portable, which means it can be located in various sites of care. The system is self-shielded, meaning it does not require specialised shielded rooms for use and does not require radiological expertise or use of contrast agents. As the technology is portable, it can be used intraoperatively in the operating room to provide real time information during the surgical procedure. The company state identification of positive margins during the surgical procedure will allow the surgeon to remove additional tissue as needed, possibly reducing re-excision rates. Reduced re-excision rates provide for fewer repeat procedures and the associated time, anxiety and discomfort experienced by patients, as well as reduced costs. The company claim achieving adequate clear margins may reduce recurrence rates and improve patient outcomes.

If clinical and cost effectiveness can be demonstrated, the ClearSight™ MRI system may offer an additional imaging option for selected patients. This technology is predicted to have an impact on the following domains of the NHS Outcomes Framework ([www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk](http://www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk)):

- **Domain 1** Preventing people from dying prematurely.

**EVIDENCE**

**ONGOING STUDIES**

Studies comparing tissue margins imaged by the ClearSight™ system with histopathology are ongoing.

**INFORMATION FROM**
Lay summary

The ClearSight™ MRI system helps surgeons see abnormal cells in people having surgery for breast cancer. The system uses MRI and uses a powerful magnetic field, radio waves and a computer to produce detailed pictures of parts of the body. These pictures show which cells in the suspected tumour are cancer cells and which are normal. The developer says the system can be used during breast surgery to make sure all the cancer cells are removed.

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