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# Reimbursement or bust for Hologic's 3D mammography tech

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Hologic's decision to streamline operations to put greater emphasis on women's health has been rewarded, with its Selenia Dimensions 3D mammography system comprehensively beating standard digital mammography in a large-scale postmarketing trial. The study should help the company gain US reimbursement of the 3D technology, although the possibility of the technique being incorporated into breast cancer screening guidelines is still remote.

3D mammography is a cornerstone of Hologic's product offering after the divestment of its transplant diagnostics unit Lifecodes to Immucor last week for just under $100m. Lifecodes had come to Hologic through its $3.8bn acquisition of the molecular diagnostic specialist Gen-Probe last August. The Bedford, Massachusetts company's share price jumped 7% when the trial data were released on Wednesday, and increased a further 1.5% yesterday; the Lifecodes sale did not noticeably move the stock.

**Sensitive and specific**

3D mammography, also known as tomosynthesis, captures multiple images from many angles around the breast, and these are then used to create a 3D reconstruction. In a 2D scan, just one X-ray image is taken. The Selenia Dimensions system can generate two- and three-dimensional images of the breast.

Data from the Oslo breast cancer screening study showed that using 3D mammography along with digital 2D scans offered improvements in both sensitivity and specificity over 2D mammography alone.

Researchers found that the 3D technique caused a significant improvement in sensitivity, with a 40% increase in detection of invasive breast cancers – those it is important to diagnose early – and a 27% increase in the detection of invasive and in situ cancers combined. A significant 15% decrease in false-positive rates was also seen, showing that the new technology is more specific, too.

**Recommendation and reimbursement**

Currently, the vast majority of women undergo breast cancer screening with standard 2D digital mammography, which is recommended every two years in those between the ages of 50 and 74.

The Oslo trial, in which more than 12,000 mammograms were conducted, is a validation for Hologic's Selenia Dimensions device. However, the lack of randomisation – the gold standard for testing one technique against another – means that tomosynthesis is unlikely to be recommended in screening guidelines any time soon. Its greater expense compared with standard digital mammography is also a mark against it.

When the system gained US approval nearly two years ago, analysts made a point of saying that reimbursement would be necessary to drive sales, and that clinical data would be necessary to gain reimbursement. The global breast imaging technologies market is forecast to be worth $5bn by 2017, and Oslo study data sets Hologic up for a bigger slice of the pie.

| Trial | Trial ID |
|---|---|
| Oslo breast cancer screening trial | NCT01248546 |

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