NICE advice

AlignRT in breast cancer radiotherapy

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is the AlignRT patient position monitoring system. This briefing focuses on its use during breast cancer radiation therapy.
- The **innovative aspect** is that it may avoid inaccurate treatment by precisely tracking a patient's position during radiotherapy and notifying the linear accelerator to hold the radiation beam if the patient moves.
- The intended **place in therapy** would be in a standard radiation treatment room with a linear accelerator. It would be used as an alternative to existing patient location monitoring systems using X-ray/CT and as an adjunct to radiographer visual monitoring of patient movement.
- The **main points from the evidence** summarised in this briefing are from 4 observational studies involving a total of 228 adults in tertiary care settings in the US and Europe. They suggest that AlignRT is effective in maintaining accurate patient positioning during breast cancer radiotherapy.

- **Key uncertainties** are that there is no evidence from direct comparisons of AlignRT with location monitoring or from studies specifically using AlignRT as the main intervention.
- The **cost** of AlignRT is £150,000 to £225,000 per unit (excluding VAT), plus a yearly service charge of £20,000. The cost per treatment will depend on the throughput per device for the variety of radiotherapy procedures the device can be used for.

The technology

AlignRT (Vision RT) is a system for monitoring the precise location and movement of a patient during setup for and treatment with radiotherapy. This briefing focuses on its uses in breast radiotherapy. NICE has published a medtech innovation briefing on the use of Align RT in intracranial stereotactic radiosurgery.

AlignRT uses 3 stereo video camera pods to monitor a patient's position. It is accurate to within 1 mm of translation and 1 degree of rotation. The pods are mounted on the wall or ceiling, and each includes a red-light projector and 2 camera sensors. Before surgery, each camera pod projects a visible red light with a pseudo-random speckle pattern onto the patient's body. The AlignRT software generates a real-time 3D surface image of the patient. This real-time image is aligned with a previous reference image taken from an earlier CT scan (done to image the target location for treatment planning, or previous surface capture). By aligning the real-time and reference surfaces, the patient's position can be monitored accurately.

If needed, the patient's position can be adjusted through the AlignRT interface with the automatic treatment couch control system, to align them with the reference surface.

If AlignRT detects any patient movement during treatment, it can instruct the linear accelerator to stop the radiation beam, or prompt the user to manually pause treatment. This is intended to prevent radiation being delivered to neighbouring tissue and organs, which can lead to unwanted side effects and ineffective treatment.

AlignRT can integrate with the linear accelerator and record and verify systems settings. It is also marketed as part of the Varian EDGE radiosurgery system (Varian Medical Systems), in which it is called OSMS (optical surface monitoring system).

Innovations

Monitoring and maintaining a patient's position is especially important when treating the breast (particularly the left breast), because movements from breathing can result in unintended irradiation. AlignRT can position and monitor the patient with the couch and gantry at different angles. AlignRT also tracks the entire patient surface, whereas most similar devices only monitor a few points.

Current NHS pathway

Location monitoring during radiotherapy varies and the best approach is decided by a multidisciplinary team. Patients are positioned using standard CT and X-ray systems so that any movement is minimised. A range of breath-holding techniques and devices may also be used to ensure that the correct lung volume is maintained when the patient holds their breath. The Royal College of Radiologists UK consensus statements on post-operative radiotherapy for breast cancer (2016) notes that in patients with left-sided breast cancer, the heart should routinely be spared from the radiotherapy field. In addition, the statement notes that breath-hold techniques should be available in all UK radiotherapy departments.

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to AlignRT:

- Catalyst (C-Rad)
- Identify (HumediQ)
- Active Breathing Coordinator (Elekta)
- Real-Time Position Management System (Varian).

Population, setting and intended user

AlignRT would be used for patients with breast cancer in whom radiotherapy is suitable. Radiotherapy would be done in specialist tertiary centres and AlignRT would be used by an appropriately trained therapy radiographer.

Costs

Technology costs

The list price of AlignRT is £150,000 to £225,000 (excluding VAT). There is also a yearly service charge of £20,000.

Assuming a 10-year lifespan, the total cost would be about £40,000 per year. If AlignRT were used for 250 patients each year, the cost per patient treatment course would be £160.00, or £10.67 per fraction for a 15-fraction treatment plan.

AlignRT can be used during radiotherapy for other cancers, which may reduce the cost per treatment.

The company provides training and this is included in the cost of AlignRT. Training consists of 2.5 days of in-person training for a therapeutic radiographer and physicist at the company's offices, with the intention that these staff then pass on their learning to the department. A representative from the company later visits the site for several days to help implement clinical use.

Costs of standard care

The most commonly used technique to move the heart further away from the treatment area is breath holding, which has no direct cost.

Resource consequences

AlignRT represents an additional cost to current methods such as breath-holding techniques. Except for the cameras being installed, adopting AlignRT is not expected to necessitate any changes in facilities or infrastructure.

AlignRT is currently used in some NHS centres during radiotherapy for breast cancer.

Regulatory information

AlignRT was CE marked as a class IIb device in June 2016.

Between 2014 and 2016, there were 4 manufacturer field safety notices or medical device alerts for AlignRT. All were resolved, including through product upgrades.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Breast cancer is more common in women, and the risk of breast cancer increases with older age. People with cancer are protected under the Equality Act from the point of diagnosis. Sex and age are also protected characteristics.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing summarises 4 studies, including 228 patients having over 2,000 individual radiotherapy treatment fractions. Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence for AlignRT is limited to small, non-comparative, observational studies. Three of the studies were done in the US and 1 was done in Europe, so their generalisability to

NHS practice is unclear.

The evidence shows that AlignRT plus controlled breath holding results in less inadvertent irradiation than free breathing. The effectiveness of this method strongly relies on the portion of the heart in the radiotherapy field. In 1 study (Zagar et al. 2015), no portion of the heart was left within the primary radiotherapy field and at 6 months, none of the patients assessed had post-radiotherapy cardiac perfusion. The study authors noted that in previous publications using similar technologies, rates of post-radiotherapy cardiac perfusion ranged from 1% and 50%, and the proportion of the left ventricle still in the radiotherapy field was between 1% and 10%. The study by Ferrara (2010) alluded to savings in radiotherapy suite time from the use of AlignRT, by reducing the time needed for other imaging procedures.

Table 1 Summary of selected studies

Gierga et al. (2012)	
Study size, design and location	Observational study of 20 patients with breast cancer and unfavourable cardiac anatomy diagnosed using a CT scan (443 radiotherapy treatments; 2,398 individual breath holds). US study.
Intervention and comparator(s)	Patients had an initial planning CT scan and weekly MV imaging to guide the radiation treatment and accurately target the breast tissue. The radiotherapy was delivered in small fractions over several days and weeks. Patients also had a daily surface image scan with AlignRT. No comparator; study used AlignRT to assess patient movement using the voluntary breath-hold technique to avoid cardiac radiation exposure.
Key outcomes	The study showed that 22% of patients were outside of a 5 mm movement tolerance during the breath hold and these correlated with the volume of breast tissue.
Strengths and limitations	This study included a relatively small number of patients but involved numerous individual treatment sessions. It shows that daily surface imaging can be incorporated into radiotherapy workflows and assist in accurate patient alignment. The time taken in using this technique was not recorded.
Zagar et al. (2017)	

Study size, design and location	Prospective observational study on DIBH to avoid cardiac radiation exposure assessed using AlignRT surface imaging. 20 patients (over 400 separate radiation treatment fractions) with left-sided breast cancer already planned to use DIBH. US study.
Intervention and comparator	No comparator. AlignRT was used at the start of each treatment to check alignment with the planning images. Patients had SPECT of the heart before radiotherapy and at 6-month follow-up to assess cardiac perfusion.
Key outcomes	No change in cardiac perfusion was detected at 6-month follow-up.
Strengths and limitations	This is a small study with no comparator group. It shows that AlignRT plus controlled breath holding during radiotherapy may minimise cardiac perfusion. It is uncertain if the surrogate marker for heart injury used in this study at 6 months would appropriately identify patients at risk of heart injury over the long term.
Tanguturi et al. (2015)	
Study size, design and location	150 patients with left breast cancer prospectively enrolled in a US registry.
Intervention and comparator(s)	Patients had radiotherapy using either FB or DIBH, depending on their clinical condition. All DIBH patients had their position monitored by AlignRT.
Key outcomes	38 patients used FB and 110 used DIBH. The time taken for treatment was not statistically significantly different but there was more variability in the DIBH treatment times. 107 DIBH patients had >20 cGy lower mean heart dose of radiation. Paired comparisons with FB patients (paired based on RT plans) showed statistically significantly lower heart and lung radiation doses. Higher rates of mean heart dose were associated with younger patients of larger BMI and larger lung volume.
Strengths and limitations	This is a relatively large study but had no control group. It shows that a breath-holding technique, with AlignRT-controlled patient positioning, resulted in lower inadvertent heart and lung radiation exposure compared with free breathing, but with similar treatment times.
Ferrara et al. (2010)	

Study size, design and location	38 patients with breast cancer as 1 arm of a randomised study on errors in patient positioning during radiotherapy. Italian study.
Intervention and comparator(s)	No comparator. AlignRT was used before treatment to measure error between a reference patient CT position and actual position.
Key outcomes	Mean setup time was 7.9 minutes (range 3 to 16) and there was no additional time needed for AlignRT measurements. 657 images were collected. Patient positioning and setup with AlignRT was consistent with usual positioning methods.
Strengths and limitations	This was a small study reported only as an abstract, but it shows that no extra time is needed to use AlignRT during radiotherapy treatment.
Abbreviations: DIBH, deep-inspiration breath holding; FB, free breathing; MV, megavoltage; SPECT, single-photon emission computed tomography.	

Recent and ongoing studies

- Active Breathing Coordinator-based vs VisionRT-based Deep Inspiration Breath-hold for Radiation for Breast Cancer (VisionRT). A randomised, controlled, open-label trial of 10 women having radiation for left-sided breast cancer, comparing ABC-assisted and VisionRT-assisted deep inspiration breath holding. ClinicalTrials.gov identifier: NCT02694029. Estimated completion date: December 2018. Location: US.
- Preoperative Accelerated Partial Breast Irradiation for Triple Negative Breast Cancer Using Proton Beam Scanning. Pilot study of proton beam therapy for 20 people with triple-negative breast cancer, which will use AlignRT for daily target localisation. ClinicalTrials.gov identifier: NCT03340402. Estimated completion date: November 2023. Location: US.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Eight specialists contributed to this briefing. Six of the experts were familiar with the technology and 4 had used it in clinical practice.

Level of innovation

Two experts felt there was nothing novel about AlignRT in terms of breathing during breast cancer radiotherapy. However, another expert felt the technology offered added safety benefits because it is non-ionising and reduces the dose delivery to healthy tissues. This expert also noted that AlignRT reduces the number of repeat setups and removes the need for patient tattooing. One expert noted that AlignRT displays the whole chest which helps to avoid irradiating the heart. Another expert stated that positioning accuracy for whole-breast treatment is up to 10 mm and that smaller movements are unlikely to have any clinical significance.

Potential patient impact

One expert noted that patients felt AlignRT improves deep-inspiration breath holding, and 2 felt that it increases setup speed. Several experts noted that it improves dose delivery accuracy and 1 explained that the lack of ionising radiation was beneficial. Another expert noted that the technology will be of benefit for nodal treatment.

Potential system impact

One expert noted that changes may be needed to facilities to accommodate the new technology. Another felt that using AlignRT may reduce waiting times because of better patient throughput. This expert also noted that it could reduce long- and short-term side effects after radiation.

General comments

One expert noted that for AlignRT to work, a patient needs to be treated on the same surface used for planning. There may also be a need for a replacement linear accelerator if the machine is in use or breaks down. Another expert also noted that surface anatomy alone may not be an accurate surrogate for positioning because the tumour bed may move between treatment planning and treatment. This expert also felt that AlignRT does not remove the need for other localisation systems. Another expert highlighted the need to

demonstrate long-term outcomes before AlignRT is widely adopted. One expert noted that any cost savings may depend on the clinical accuracy of the technology and the quality of the treatment plan rather than the difference between a conventional setup and an AlignRT setup.

Specialist commentators

The following experts contributed to this briefing:

- Ms Jacqui Dorney, specialist service lead UK, Genesis Care. Employed by a commercial provider of radiotherapy services which has adopted the AlignRT technology.
- Dr Helen McNair, lead research radiographer, The Royal Marsden NHS Foundation Trust. No relevant conflicts of interest.
- Ms June Dean, Cambridge University Hospitals NHS Foundation Trust. No relevant conflicts of interest.
- Dr Keith Langmack, head of radiotherapy physics, Nottingham University Hospitals NHS Trust. No relevant conflicts of interest.
- Dr Frances Yullie, consultant in clinical oncology, Western General Hospital, Edinburgh. No relevant conflicts of interest.
- Mrs Clare Hartill, research and development lead radiographer, Guy's and St Thomas' NHS Foundation Trust. No relevant conflicts of interest.
- Ms Regina Gonzalez, radiotherapy physicist, Guy's and St Thomas' NHS Foundation Trust. No relevant conflicts of interest.
- Dr David Eaton, radiotherapy physicist, Guy's and St Thomas' NHS Foundation Trust. No relevant conflicts of interest.

Development of this briefing

This briefing was developed by NICE in accordance with published process and methods.

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