NICE advice

SimpliCT laser-guided needle placement in interventional radiology

Medtech innovation briefing
Published: 7 March 2017

www.nice.org.uk/guidance/mib98

Summary

- The **technology** described in this briefing is SimpliCT. It is a laser device used to guide non-vascular puncture procedures in which CT or cone-beam CT imaging is used.
- The **innovative aspect** of SimpliCT is that it is a standalone device that does not need a separate workstation, new software or to be integrated with existing imaging systems.
- The intended **place in therapy** would be in addition to standard freehand puncture in people needing non-vascular procedures in which CT or cone-beam CT imaging is used.

- The **main points from the evidence** summarised in this briefing are from: 2 retrospective, comparative observational studies; 2 prospective, non-comparative observational studies; and 1 case report. The studies include a total of 151 patients having interventional radiology, of whom 100 had a SimpliCT-guided procedure. These studies do not report any clinical-effectiveness outcomes. Comparative evidence shows that fluoroscopy time using cone-beam CT is reduced in non-vascular interventional procedures with SimpliCT laser guidance. However, comparative overall procedure time varies according to the clinical indication and procedure.
- **Key uncertainties** around the evidence and technology are whether a reduction in fluoroscopy time has any meaningful radiation dose benefit for the operator or patient, and whether fewer needle passes result in less patient discomfort and fewer side effects from the procedure. In addition, the identified literature mostly describes the use of SimpliCT with cone-beam CT guidance, which may not be generalisable to UK practice where it is rarely used for biopsy or drainage procedures.
- The **cost** of SimpliCT is £27,845 per unit (exclusive of VAT). Although the **resource impact** depends on the clinical indication, it is likely to be greater than standard care because of the capital investment and overall procedure time needed.

The technology

SimpliCT (NeoRad) uses a laser beam to guide needle placement during image-guided, non-vascular procedures in the interventional radiology setting, such as biopsies, drainages, nerve infiltrations and radiofrequency ablations. The manufacturer claims that visualising the needle path using a laser beam instead of fluoroscopy or CT scans reduces the radiation dose for the operator and patient.

SimpliCT is a battery-operated movable laser unit, mounted on a rail. The rail is either attached to a standard Portegra2 (MAVIG) ceiling suspension arm (which is commonly incorporated in display monitors in NHS interventional radiology suites), or mounted on a mobile floor stand with wheels. The laser unit consists of a plastic housing containing 2 lasers: a line laser for correct horizontal positioning of the device relative to the patient, and a pointing laser for puncture guidance. An angle input wheel and display panel are used to set the needle path angle.

SimpliCT is designed to simplify the current clinical practice of freehand needle placement and reduce the number of needle manipulations needed.

The target site (such as a suspected tumour or cyst) is identified using CT, hybrid positron emission tomography (PET-CT) or cone-beam CT. The entry point on the patient's skin is marked and the desired angle and depth to the target (that is, the coordinates for the needle puncture) are calculated using the software on the existing image display. The operator then manually enters these coordinates into the front panel of SimpliCT, ensuring that the line laser is calibrated to the horizontal plane of the patient. They then move the pointing laser to the entry point, mark the desired depth on the selected needle, manually centre the hub of the needle with the laser, and move the needle into the patient. A further scan of the patient is needed to confirm the correct position of the needle before the planned procedure can begin.

Innovations

SimpliCT can be used with any third-party CT, PET-CT and advanced 3D angiography lab-based systems (rotational C-arm fluoroscopy or cone-beam CT), because it is a standalone device that does not need a separate workstation, new software or to be integrated with existing imaging systems.

SimpliCT is designed to provide additional guidance for the freehand technique in image-guided, non-vascular needle placement, reaching the target site with fewer needle passes and fewer confirmatory imaging scans. SimpliCT may improve the initial accuracy of needle placement, reducing discomfort and side effects from the puncture. The manufacturer claims that using the device provides a lower radiation dose to both the operator and patient.

Current NHS pathway or current care pathway

The current clinical practice for CT- and cone-beam CT-guided puncture procedures is freehand placement of a straight needle using anatomical markers. An initial control image is taken and any necessary corrections to the needle position are made. This usually depends on the difficulty of the procedure and the interventional radiologist's experience. Multiple needle passes and additional scans may therefore be necessary to reach the target.

Many biopsies and drainages in the NHS are done using ultrasound guidance, and cone-beam CT-guided procedures are rarely used for these clinical indications.

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

- 3D-LNS (amedo Smart Tracking Solutions).

Population, setting and intended user

SimpliCT is intended for use in secondary care by radiologists in the interventional radiology suite. Some device-specific training would be needed to operate the laser guidance unit, but the freehand needle placement technique is unchanged from standard practice.

The patient population is people needing straight-needle puncture procedures such as biopsies, drainages, nerve infiltration and radiofrequency ablation.

Costs

Technology costs

The list price of SimpliCT, excluding VAT, is €33,000 (£27,845, using the XE currency converter in December 2016). This includes 1 training session to operate the product.

SimpliCT has no consumables and no maintenance is needed. Calibration is limited to simple alignment with the table during each procedure, so no calibration costs are incurred.

The manufacturer cites an expected lifespan of 10 years for SimpliCT. Assuming a patient throughput of 10 puncture procedures per week, this gives an estimated cost per use of £5.35.

Costs of standard care

The addition of SimpliCT to freehand needle placement may be considered an adjunct cost to standard care. Consumables such as catheters and straight needles would have identical costs for both SimpliCT-guided punctures and standard care.

According to the National Schedule of Reference costs for 2014/15, national average unit

costs are £122 for a complex CT scan and £164 for a contrast fluoroscopy, mobile or intraoperative procedure lasting 20 to 40 minutes. For the purpose of this cost comparison we have judged these imaging types, in the outpatient setting, to be closest to CT- and cone-beam CT-guided puncture procedures in standard care.

For ultrasound-guided biopsies and drainages, which are more common in the NHS, the national average unit cost of a comparable mobile or intraoperative ultrasound scan is £73.

These tariffs are for imaging only and do not include the costs of the puncture procedure itself, which are assumed to be identical for both SimpliCT-guided punctures and standard care.

Resource consequences

The manufacturer has confirmed that SimpliCT is not currently used in the NHS.

The main resource consequence is the capital cost of the device. The comparative evidence identified in this briefing demonstrated that the time taken to complete SimpliCT-guided procedures depends on the clinical indication. SimpliCT-guided biopsies took longer than using freehand puncture (Kroes et al. 2016a), whereas radiofrequency ablation of osteoid osteoma was quicker using SimpliCT-guided puncture (Kroes et al. 2016b). This difference was not statistically significant.

The claimed benefits of greater patient comfort and reduced radiation dose seem plausible, but these may entail considerably greater resource use and costs than standard care.

Regulatory information

SimpliCT was CE marked as a class I device in November 2005.

A search of the Medicines and Healthcare products Regulatory Agency (MHRA) website revealed that no manufacturer field safety notices or medical device alerts have been issued for this technology.

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).

No equality issues were identified with using SimpliCT.

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 5 studies: 2 retrospective, comparative observational studies (Kroes et al. 2016a; Kroes et al. 2016b); 2 prospective, non-comparative observational studies (Brabrand et al. 2004; Krombach et al. 2000); and 1 case report (Varro et al. 2004). The studies include a total of 151 patients, excluding any identified overlapping cohorts, of whom 100 had a SimpliCT-guided procedure.

Table 1 summarises the clinical evidence as well as strengths and limitations of the studies. The table does not include the case report by Varro et al. (2004); this reported on a patient having CT-guided percutaneous radiofrequency ablation of 2 kidney tumours in a single centre in the US, and has limited relevance to the population in the scope of this briefing.

Overall assessment of the evidence

The evidence base for the SimpliCT is currently limited in quantity and quality.

The identified studies report limited technical outcomes, such as accuracy of needle placement and how laser guidance affects imaging time and total procedure time. A reduction in patient and operator radiation doses is implied but not quantified.

No studies have reported comparative clinical-effectiveness outcomes from adding laser-guided needle placement to non-vascular puncture procedures in interventional radiology.

The reported technical outcomes are relevant to the NHS care pathway.

Table 1 Summary of selected studies

Kroes et al. (2016a)	
Study size, design and location	n=51 Retrospective, comparative observational study in a single centre in the Netherlands.
Intervention and comparator(s)	15 prospective CBCT-guided biopsies with laser navigation by SimpliCT in the intervention arm and 36 retrospective records of CBCT-guided biopsies using freehand technique alone in the comparator arm.
Key outcomes	Biopsies using the standard freehand technique took more fluoroscopy time (and hence more radiation exposure to patient and operator) to guide the needle onto the target, compared with those under SimpliCT laser guidance. Comparing these results, the fluoroscopy times were significantly lower ($p<0.001$) in the SimpliCT group. Conversely, overall procedure times were shorter for freehand biopsies.

Strengths and limitations	Prospective cases in the intervention arm (7 thoracic and 8 abdominal biopsies) were compared against historical controls without any propensity matching. Inter-operator variability was eliminated and intra-operator variability was minimised in the intervention arm, because a single interventional radiologist with 4 years' experience of CBCT-guided needle interventions conducted all of the SimpliCT cases. Retrospective freehand controls were selected on the basis of being 'easier'; defined as a target size larger than 20 mm in diameter and a procedure time shorter than 35 minutes (16 thoracic and 20 abdominal biopsies). These were inherently dissimilar to the prospective SimpliCT cases, which is likely to have impacted on the relative effect on fluoroscopy and overall procedure times. The retrospective freehand procedures were conducted by 2 interventional radiologists, potentially adding inter- and intra-operator variability to the comparator results. This research was part-funded by NeoRad.
Kroes et al. (2016b)	
Study size, design and location	n=32 Retrospective, comparative observational study in a single centre in the Netherlands.
Intervention and comparator(s)	17 retrospective records of CBCT-guided radiofrequency ablations of osteoid osteoma with laser navigation by SimpliCT in the intervention arm and 15 retrospective records of CBCT-guided ablations using freehand technique alone in the comparator arm. Subgroup analysis of 18 cases where procedures were assessed to have had a similar degree of difficulty (10 with SimpliCT guidance and 8 with freehand technique).

Key outcomes	For the whole patient cohort, adding SimpliCT laser guidance to the CBCT-guided radiofrequency ablation procedure resulted in a significant reduction in fluoroscopy time (p=0.004). Although overall procedure times were also shorter with SimpliCT, this difference was not statistically significant (p=0.355). These fluoroscopy and overall procedure time outcomes were replicated in the subgroup analysis. Retrospective radiation dose area product data from the imaging system were analysed, but the authors were unable to draw any comparative conclusions from the results, primarily owing to the heterogeneity in the patient populations and too many unknown operational variables.
Strengths and limitations	Although attempts were made to define a subgroup based on position and size of the osteoid osteoma and comparative difficulty of the retrospective cases, the matching process between intervention and comparator arms was flawed, because the laser-guided cases were conducted in a significantly younger (p=0.011) and lower BMI (p=0.006) population. The retrospective procedures were conducted by 3 interventional radiologists, all with 5 or more years of experience in radiofrequency ablation of osteoid osteoma, potentially adding inter- and intra-operator variability to the results. This procedure involved guiding a drill into the bone (rather than a needle) before inserting the ablation catheter. The results from this study are therefore not considered generalisable to straight needle puncture procedures in soft tissue. This research was part-funded by NeoRad.
Brabrand et al. (2004)	
Study size, design and location	n=67 Prospective, non-comparative, non-randomised, multicentre study in Norway, Germany and Sweden. Adults (excluding any pregnant women) consecutively included those needing CT-guided biopsy or cytology (n=49), neurolysis (n=8), aspiration (n=4), drainage (n=4) and others (n=2). The procedures were done by 8 radiologists at 4 centres.

Intervention and comparator(s)	Prospective CT-guided puncture procedures with laser navigation by SimpliCT in the intervention arm. No comparator arm.
Key outcomes	The target was hit in 65 out of 67 patients and in 55 of these, the target was hit with first pass of the needle. In 87.0% of the punctures, the difference between planned and target angle achieved was less than 3°. In 69.8% of the patients, the target was hit within 15 minutes of the initial localising scan. Subjective operator scores found the SimpliCT both useful and easy to use.
Strengths and limitations	Consecutive patients were enrolled, reducing the likelihood of selection bias. The heterogeneity of the case mix in this study is also likely to reflect 'real world' practice, making the study generalisable to the broad population in scope of this briefing. As a multicentre study, the results will be affected by both inter- and intra-operator variability. Caution: the 8 neurolysis patients in this study are the same as those patients reported by Krombach et al. (2000).
Krombach et al. (2000)	
Study size, design and location	n=8 Prospective, non-comparative observational study in a single centre in Germany.
Intervention and comparator(s)	8 patients undergoing 9 CT-guided nerve blocks with laser navigation by SimpliCT in the intervention arm. No comparator arm.

Key outcomes	All 9 nerve blocks were successful on the first needle pass and without complication. The mean difference between planned and actual needle angle was 1.4° (0 to 4°). The mean time between planning the puncture and completion of the needle placement was 8.4 minutes (5 to 17 minutes), while the overall procedure time was 30 to 40 minutes on average. Subjective operator opinion found the SimpliCT both easy to handle and useful for the procedure.
Strengths and limitations	This study was conducted using a prototype of the commercial SimpliCT system. However, the technical specifications of the prototype appear to match those of the commercial SimpliCT system, therefore this study is considered generalisable to the intervention in scope of this briefing. An unspecified number of operators conducted the procedures in this study, therefore the results will be affected by both inter- and intra-operator variability. The population in this study is limited to nerve blocks, which is just 1 of the indications in scope of the intervention.
Abbreviation: CBCT, cone-beam CT.	

Recent and ongoing studies

No ongoing or in-development trials were identified.

Specialist commentator comments

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

None of the 3 specialist commentators had used this technology before but all 3 had some awareness of it, including through product demonstrations.

Level of innovation

All 3 specialist commentators considered SimpliCT to be a novel concept and innovative technique for CT-guided biopsy and drainage procedures.

Potential patient impact

All 3 specialist commentators felt that SimpliCT would have relatively little impact on patient health outcomes.

One commentator observed that procedure time and radiation dose to the patient may be reduced, but that this has not yet been proven. In addition, for cancer patients, any radiation dose reduction from using SimpliCT would be minimal compared with the total radiation dose from diagnosis and follow-up.

Another commentator considered that any benefit of using SimpliCT would be lost if a patient moved during the procedure, unless it could be recalibrated accurately at that stage. They added that SimpliCT could be useful in some situations but it appeared to increase procedure time in many straightforward cases in the evidence base, so the overall benefit is hard to quantify. The third commentator supported this view, stating that SimpliCT may be helpful specifically for procedures in which the target lesion is small and deep, where CT guidance would be more challenging.

In terms of patient experience, 2 of the specialist commentators agreed that using SimpliCT could result in less patient discomfort than standard care by minimising repeated needle adjustments. However, the third commentator did not expect any potential change in patient experience.

Potential system impact

All 3 specialist commentators considered that some operator training would be needed to use the system, although this was likely to be relatively minimal. One commented that SimpliCT may have a role in training operators in freehand puncture.

One commentator observed that needle guides are available for ultrasound procedures and, if suitable, most operators would prefer to use ultrasound guidance, which is more cost effective than CT guidance.

Another commentator saw the potential to increase accuracy of biopsies, which might reduce the number of second attempts needed. However, the number of such cases would be low in terms of system impact.

The 3 commentators agreed that no changes in facilities or infrastructure would be needed to use SimpliCT, but its adoption would not lead to any significant cost savings for the NHS. Two commented that the capital cost of the technology is very high.

General comments

One specialist commentator observed that there is currently a lack of evidence comparing the effectiveness of SimpliCT with that of freehand puncture, including outcomes, radiation exposure and long-term cost savings. Adverse events from needle manipulations depend on sites, types of procedure, patient factors and complexity. If SimpliCT were to result in fewer needle adjustments, then the frequency of complications related to standard CT-guided punctures, such as those reported in Nattenmüller et al. (2014), would be reduced.

Another commentator considered SimpliCT to have limited use in the NHS, because most biopsies and drainages are done using ultrasound guidance. They felt that more studies are needed to demonstrate a reduction in patient and operator radiation dose. Although SimpliCT has a potential role to play, the published literature mostly describes its use in cone-beam CT-guided procedures, which are rarely used in the NHS for biopsies or drainage.

Specialist commentators

The following clinicians contributed to this briefing:

- Dr Geoff Hide, consultant radiologist, Newcastle-upon-Tyne Hospitals NHS Foundation Trust (no conflicts of interest reported).
- Dr Peter Riley, consultant interventional radiologist, University Hospitals Birmingham NHS Foundation Trust (no conflicts of interest reported).
- Dr Teik Choon See, consultant interventional radiologist/clinical director, Cambridge University Hospitals NHS Foundation Trust (no conflicts of interest reported).

Development of this briefing

This briefing was developed for NICE by Newcastle and York external assessment centre. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-2378-6