NICE advice

moorLDLS-BI for burn depth assessment

Medtech innovation briefing
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This advice should be read in conjunction with MTG2.

Summary

- The **technology** described in this briefing is moorLDLS-BI for laser doppler line scanning. It is a non-invasive imaging system that uses laser doppler technology to map the blood flow for burn depth assessment.
- The **innovative aspect** is the use of a line-scanning approach that minimises scan time. It takes 4 seconds to scan areas up to 15 cm × 20 cm, compared with the moorLDI2-BI scan time, which is between 80 seconds and 5 minutes, depending on the burn area.
- The intended **place in therapy** would be in specialist burn centres, in addition to clinical-based evaluation, for people who have burn injuries. The experts indicated it is particularly appropriate for use in children.

- The **main points from the evidence** summarised in this briefing are from 2 randomised controlled trials and 3 cross-sectional studies, including a total of 557 people with burns being referred to burn centres for assessment and treatment. They suggest that using the moorLDLS-BI was associated with reduced burn healing time and the accuracy of the moorLDLS-BI imager was comparable to that of clinical evaluation and moorLDI2-BI, a similar technology used for scanning larger areas.
- **Key uncertainties** around the evidence are that the evidence on clinical benefits using moorLDLS-BI is limited in quantity and quality. The evidence would benefit from well-controlled trials comparing moorLDLS-BI with clinical assessment alone and other existing technologies. The evidence on the use of the technology in people with dark skin remains unclear.
- The **cost** of moorLDLS-BI is £63,421 (excluding VAT) with an annual servicing cost of about £6,145, or it can be leased at an inclusive cost of about £20,000 per year. As an add-on intervention for burn assessment, the **resource impact** would be greater than clinical evaluation by healthcare professionals.

The technology

moorLDLS-BI (Moor Instruments Ltd) is a non-invasive imaging system that uses laser doppler technology to map the blood flow in a burn. It uses an array of low-power laser beams mounted on a scanning arm that moves across the area. The laser beam is directed using a mirror, which rotates to scan the burn wound. The mirror is between 10 cm and 20 cm from the wound, so there is no direct contact with the burned skin. Laser light scattered from moving blood cells in the tissue undergoes doppler frequency broadening. Some of the scattered laser light is focused onto photodiode detectors and the resulting photocurrents are processed. The amplitude of laser doppler signal is proportional to the average speed and the concentration of moving blood cells in the tissue. Results are displayed as a colour-coded blood flow image and a colour video image of the burn wound. Healing potential results, based on the blood flow image, are calculated and reported in 3 categories: less than 14 days, 14 to 21 days and more than 21 days.

The moorLDLS-BI system includes a scan head, scan controller and a touch-screen panel computer. The system is mounted on a mobile stand that can be used in a ward, operating theatre or consulting room, as well as in rooms designed specifically for laser equipment. The system uses a class 3R laser, which is considered safe when handled carefully. The company notes that the risk of injury is relatively low for short and unintentional exposure,

and the company can supply the product with protective eyewear.

moorLDLS-BI may not be reliable for skin areas with tattoos because the laser light can be excessively absorbed. Identifying the level of burn injury can also be confounded by other factors such as oedema, tissue hypoxia and burn wound conversion.

Innovations

moorLDLS-BI was developed using a line-scanning approach to minimise scan time. The moorLDLS-BI takes 4 seconds per scan. The maximum scan area for the moorLDLS-BI is about 15 cm × 20 cm. For larger burn wounds multiple scans are needed. The company notes that moorLDLS-BI is ideal for use in children because of its short scanning time and can also be used in adults who need repeat imaging to cover separate wounds or adjacent areas of large burns.

Current care pathway

In England and Wales burn care is organised using a tiered model of care outlined in the British Burn Association's National Burn Care Review. In this model of care, the most severely injured are cared for in recognised burn centres, while those needing less intensive clinical support are cared for in either burn units or burn facilities.

Clinical evaluation is the most widely used method of assessing burn wound depth and healing potential. This method is based on visual and tactile assessment of the external characteristics of the burn. The accuracy of clinical examination depends on the experience of the healthcare professional.

There is no NICE guideline on burn management, but NICE has published a medical technologies guidance on moorLDI2-BI: a laser doppler blood flow imager for burn wound assessment. The moorLDI2-BI is a sister product of moorLDLS-BI and is intended for larger burn area imaging (up to 50 cm × 50 cm). The guidance supports using moorLDI2-BI in the NHS for guiding treatment for burn wounds with uncertain depth and healing potential.

Population, setting and intended user

The moorLDLS-BI is intended for use by healthcare professionals to help evaluate people's burn wounds at specialist burn centres, 48 hours to 5 days after burns. The technology is

not intended to be used as a standalone prediction for burn healing.

The company notes that there is potential for moorLDLS-BI to be used outside specialist centres to aid referral decisions from burn units or facilities. The moorLDLS-BI system can be used in the operating room, outpatient department, treatment or dressing rooms, or at the patient's bedside. The moorLDLS-BI could help healthcare professionals decide whether early excision and graft surgery are needed.

Costs

Technology costs

The moorLDLS-BI can be purchased at a cost of £63,421 with an annual servicing cost of about £6,145, or it can be leased at an inclusive cost of about £20,000 per year. The protective eyewear supplied by the company, for patient use, is included in the cost of the technology. Lifespan of the technology is around 10 years.

Costs of standard care

Clinical evaluation is the most widely used method of assessing burn wound depth. The hourly costs per person for burn clinical assessment in the NHS are £186 per clinician, and £105 per nurse per hour. The training cost covering 2 days (16 hours) training for 1 clinician, 2 registrars and 3 nurses is £5,160. Hospital stays are £387 per adult per day and £866 for per child. If surgery is needed, its cost is £2,319 per hour (NICE's medical technologies guidance on moorLDI2-BI).

Resource consequences

The moorLDLS-BI is currently in use in 7 burn services in the NHS, including 5 services for children and 2 services for adults.

If the moorLDLS-BI system is adopted in the NHS it would present an additional cost to standard care. If the use of the system is shown to have long-term benefits such as improved wound-assessment accuracy, then costs could be saved from improved wound healing by earlier decision making about treatment and reduced length of stay.

Regulatory information

The moorLDLS-BI system is a CE-marked class IIa medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

moorLDLS-BI is suitable for use according to the manufacturer's instructions by all patients irrespective of age, gender, class and ethnicity. The company notes that moorLDLS-BI will not be reliable in people with undebrided dark skin burn wounds because of separation between dermis and epidermis causing optical interruption (reduced penetration and excess scatter at the epidermal-dermal interface). But, moorLDLS-BI is suitable for people with naturally dark skin.

This technology may not be suitable for people with tattoos, particularly black ink ones. This is because these strongly absorb light so scans at these sites are unreliable.

Clinical and technical evidence

A literature search was done for this briefing in accordance with NICE's interim process and methods statement for medtech innovation briefings. 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

Five studies are summarised in this briefing, including a total of 557 people with burns. Two studies are randomised controlled trials that compared clinical outcomes (such as the length of stay) for moorLDLS-BI with clinical assessment (Hop et al. 2016; Venclauskiene et al. 2014). Both are non-UK studies.

The other 3 are cross-sectional studies designed to compare the accuracy of predicting

wound healing using moorLDLS-BI with clinical evaluation (Hoeksema et al. 2014; Holland et al. 2014 and Hoeksema et al. 2011). People from 2 UK burn centres were included in Hoeksema et al. (2014).

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The current evidence suggests that the moorLDLS-BI system is safe and that using the device in burn assessment would be feasible.

Trials suggested that the use of moorLDLS-BI was associated with shorter wound-healing time compared with clinical assessment. The difference between the 2 groups was significant in the small trial (n=57, Venclauskiene et al. 2014) but not in the large trial (n=202, Hop et al. 2016). So, more trials are needed to show the clinical benefits of the technology. A group of people from a Belgian clinic overlapped in the 2 Hoeksema et al. studies.

Hop et al. (2016, an abstract)

Study size, design and location

A multicentre randomised controlled trial in Belgium of 202 people with burns of indeterminate depth.

Intervention and comparator

People were randomised into 2 groups:

- moorLDLS-BI combined with clinical assessment
- clinical assessment only (standard care).

Key outcomes

The study reported that mean time to wound healing was 14.3 days (95% confidence

interval [CI] 12.8 to 15.9) in the moorLDLS-BI group and 15.5 days (95% CI 13.9 to 17.2) in the standard care group (p=0.258). In the moorLDLS-BI group there was a statistically significant increase in the number of immediate treatment decisions (either surgical or non-surgical) compared with the standard care group (p<0.001), where more decisions to postpone treatment were made. In a subgroup analysis, people who needed surgery showed a significant earlier decision for surgery and a shorter wound-healing time in the moorLDLS-BI group than in the standard care group.

Strengths and limitations

This is a randomised controlled trial. Strengths and limitations were not assessed because limited information was reported in the abstract. An expert noted that the study design could be biased towards positive outcomes from laser doppler imaging (LDI).

Hoeksema et al. (2014)

Study size, design and location

A cross-sectional study of the accuracy and convenience of the moorLDLS-BI for predicting burn wound healing in 204 people from 5 burn centres in the UK, US, Australia and Belgium.

Intervention and comparator

People were scanned using moorLDLS-BI to assess their burns and subsequent healing. The assessment used clinical photographs as the gold standard for proof of healing and non-healing at 14 days and 21 days after the burn. The photographs were assessed by experienced healthcare professionals. The healing potential prediction from moorLDI2-BI was used as a non-standard reference when clinical photographs were not available.

Key outcomes

A total of 596 wounds from 204 people were available for analysis from the clinical investigation. There were 77 wounds used for scalar definition and 321 used for healing potential accuracy assessment for LDI and moorLDLS-BI, comparing them with actual healing based on clinical photos. There were 198 wounds categorised separately because they were skin grafted or there were no clinical photos or clinical information available. The accuracy assessment using moorLDLS-BI of these wounds were compared with results

from moorLDI2-BI scanner.

For observed healing, the accuracy of the moorLDLS-BI was 94.2% compared with clinical records in 321 wounds with a sensitivity of 91.9% and specificity of 96.0%. The accuracy of the moorLDI2-BI was 93.5%, the sensitivity 90.3% and the specificity 95.2%.

The agreement between moorLDLS-BI and moorLDI2-BI was 94.9% for healing potential within 14 days, 93.6% for healing potential between 14 days and 21 days and 98.8% for healing potential after more than 21 days.

Strengths and limitations

This study had predefined inclusion and exclusion criteria. A potential selection bias was identified because people who were unable to remain still enough for an adequate LDI to be taken, were excluded. A selection of wounds (n=198) was not able to be assessed because they were skin grafted or there were no clinical photos or precise clinical information.

Holland et al. (2014)

Study size, design and location

A cross-sectional study in Australia comparing the sensitivity, specificity and accuracy of moorLDLS-BI with those of moorLDI2-BI in predicting burn wound healing in 50 children under 16 with acute burns.

Intervention and comparator

Between February 2010 and March 2011 children who were referred to the burn centre with an acute burn had their burn wounds scanned concurrently using moorLDLS-BI and moorLDI2-BI scanners. All scans were done between 42 hours and 5 days of the burn.

Wound healing or the need for surgical intervention were assessed by the treating clinician.

Key outcomes

Of the 50 children enrolled, 1 was excluded from subsequent analysis because follow-up

clinical images were not available. Of the remaining 49 children, 90 scans were done on 59 burn wounds. Most of the burns were scalds (n=30, 61%), followed by contact (n=11, 23%), flame (n=5, 10%) and friction (n=3, 6%). Of the 59 burn wounds, 48 healed within 14 days, 6 healed within 14 to 21 days and 5 did not heal within 21 days.

Overall accuracy of the scanners was 95% (moorLDLS-BI) and 94.5% (moorLDI2-BI). The sensitivity of moorLDLS-BI for predicting healing within 14 days was 98% compared with moorLDI-BI. The sensitivity of moorLDLS-BI for predicting healing between 14 and 21 days and after 21 days was 70% and 92%, respectively. The specificity of moorLDLS-BI for predicting healing within 14 days, between 14 and 21 days and after 21 days was 79%, 95% and 97%, respectively.

Strengths and limitations

This is a comparison study of 2 scanners with similar modalities. The moorLDLS-BI scanner evaluated in this study was subsequently donated to the study site by the company.

Venclauskiene et al. (2014)

Study size, design and location

A prospective randomised study of 57 people in Lithuania with burns comparing clinical burn depth examination and LDI.

Intervention and comparator

People with burn wounds were randomised 72 hours after the burn into 2 groups: clinical burn depth examination (CDE) or LDI using a moorLDLS-BI.

The depth of the injured tissue was assessed during CDE and LDI scan. The depth of injured tissue was divided into superficial (1 and 2A burn degree) and deep burns (2B and 3 burn degree). The burn wound biopsy was done by a surgeon in the same burn location to detect the correlation of findings of CDE and LDI scan.

Key outcomes

During a 2-year study period, 32 people were assigned to the CDE group and 25 people to

the LDI group using moorLDLS-BI. moorLDLS-BI scan correlated with biopsy in 22 out of 25 patients (88%), while CDE correlated with biopsy in 23 out of 32 patients (71.9%).

The mean length of stay in hospital was significantly higher in the CDE group (47 days, standard deviation [SD]=34.4) compared with the LDI group (25 days, SD=10.8; p=0.005). The mean cost of treating burns was significantly higher in the CDE group (€4,941.30, equivalent to £4,446.90) than in the LDI group (€2,562.80, equivalent to £2,306.52; p=0.001).

People in the CDE group with deep burns who had surgery had a significantly longer stay in hospital and had significantly more expensive treatment compared with people in the LDI scan group.

Strengths and limitations

This is a single-centre study. The study author noted that biopsy is considered the most accurate way to diagnose the depth of burn wounds. The burn wound biopsy should be done within 48 to 72 hours after burns but biopsies in this clinical study were done 72 hours after burns. Time intervals between biopsy and clinical examination or laser doppler scan were not reported in the study.

Hoeksema et al. (2011)

Study size, design and location

A cross-sectional study assessing the accuracy and convenience of the moorLDLS-BI to help predict healing times in 44 people with burns in Belgium.

Intervention and comparator

moorLDLS-BI and LDI images were obtained at 2 to 5 days after burn. Photographs and records of healing were obtained at scan day (2 to 5 days after burn) and 14 days and 21 days after burn.

Key outcomes

A total of 120 burns from 44 people were included. Average LDI flux values within burn areas were calculated and assigned to corresponding healing time predictions. The

moorLDLS-BI had an overall accuracy of 92% compared with 94% for the current moorLDI-BI imager.

Strengths and limitations

The preliminary results are from 1 of 5 centres within an international multicentre study, and its results were included in Hoeksema et al. (2014). Strengths and limitations were not assessed because limited information was reported in the abstract.

Sustainability benefits

The company states that the use of LDI assessments could reduce resource use associated with surgery: drapes and anaesthesia consumables, resterilisation of instruments and time. There is no evidence to support this.

Recent and ongoing studies

None.

Expert comments

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

All 4 experts who provided comments were familiar with or had used this technology before.

Level of innovation

Three expert commentators thought the technology is a minor variation on an existing laser doppler imaging (LDI) procedure. One expert suggested that LDI has been used as the gold standard for burn depth assessment since NICE published guidance on LDI2-BI. Another expert noted that healthcare professionals may vary in defining the standard care of burn assessment. For example, some consider clinical assessment as standard care but others would consider LDI as standard care. Two experts indicated that the moorLDLS-BI

would be an add-on intervention that complements clinical assessment but would not replace real-time assessment. The experts noted that similar technology such as thermal imaging could be clinically applicable for burn depth assessment.

Potential patient impact

Short scan time and the potential to avoid unnecessary surgery are the benefits identified by all experts. One expert thought that moorLDLS-BI is more appropriate for children who find it difficult to keep still. They noted that if a child could not keep still for long enough for an LDI scan, the depth assessment might not be accurate based on clinical assessment alone, and subsequently may lead to unnecessary surgery and scarring. All experts agreed that people with major burns or burns of indeterminate depth are most likely to benefit from using moorLDLS-BI, which could help decision making about their treatment.

Potential system impact

The main benefits for the healthcare system identified by 3 experts were the potential to reduce the number of unnecessary surgical procedures such as skin graft operations and reducing the need for unnecessary dressing care. The experts thought a potential reduction in costs that are associated with hospital stay, follow-up dressings, and treatment for scarring because of avoidance of unnecessary surgical procedures would outweigh the capital costs for the equipment or costs of providing the service.

General comments

The experts thought moorLDLS-BI could be used as an add-on intervention with clinical evaluation for burn depth assessment. None of the experts were aware of any safety issues. All experts agreed that training is needed to use the technology safely and to interpret the results. One expert acknowledged that in some burn services, the technology has not been used regularly. The reasons for infrequent use were unclear. Two experts thought more evidence is needed to show the benefits of moorLDLS-BI compared with clinical assessment. Another expert also suggested further research is needed to evaluate cost effectiveness and the long-term outcomes for people who use LDI.

Expert commentators

The following clinicians contributed to this briefing:

- Naiem Moiemen, consultant burns and plastic surgeon, University Hospitals Birmingham Foundation Trust. Did not declare any interests.
- Kayvan Shokrollahi, consultant burns and plastic surgeon, St Helens and Knowsley Hospitals NHS Trust. Did not declare any interests.
- Sarah Pape, consultant plastic surgeon, the Newcastle upon Tyne Hospitals NHS Foundation Trust. Did not declare any interests.
- Steven Jeffery, consultant plastic surgeon, Birmingham City University, contributed to this briefing. Did not declare any interests.

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