NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Review decision

Review of MTG2 moorLDI2-BI: a laser doppler blood flow imager for burn wound assessment

This guidance was issued in March 2011. The moorLDI2-BI (Moor Instruments Ltd) is a laser doppler blood flow imaging system for burn depth assessment. This can be used in addition to clinical evaluation to guide decisions about the need for surgical treatment of burn wounds.

The 1st review date for this guidance was May 2017, and the 2nd review date for this guidance was June 2021.

NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance. Other factors such as the introduction of new technologies relevant to the guidance topic, or newer versions of technologies included in the guidance, will be considered relevant in the review process, but will not in individual cases always be sufficient cause to update existing guidance.

1. Decision

The guidance remains valid and does not need updating.

2. Original objective of guidance

To assess the case for adoption of moorLDI2-BI for assessing the depth of burn wounds in people in whom there is uncertainty about the depth and healing potential of burn wounds that have been assessed by experienced clinicians.

3. Current guidance

1.1 The case for adopting the moorLDI2-BI in the NHS is supported when it is used to guide treatment decisions for patients in whom there is uncertainty about the depth and healing potential of burn wounds that have been assessed by experienced clinicians.

1.2 There is evidence of benefit for patients and for the NHS when the moorLDI2-BI is used in addition to clinical evaluation compared with clinical evaluation alone, in burn wounds of intermediate (also known as indeterminate) depth. By demonstrating which areas of any burn wound require surgical treatment and which do not, the moorLDI2-BI enables decisions about surgery to be made earlier and for surgery to be avoided in some patients.

1.3 The estimated average cost saving when the moorLDI2-BI is used in addition to clinical evaluation is £1248 per patient scanned (if the equipment is purchased) or £1232 per patient scanned (if the equipment is leased). This is based on an assumption of a 17% reduction in the number of skin graft operations at a cost of £2043 each.

An amendment was made to the guidance in May 2017 because the price of the product, and some NHS resource costs, changed.

4. Rationale

There is no functional change to the technology, and no change to the care pathway since the original guidance was published.

There is new clinical evidence to suggest the use of moorLDI2-BI for assessing burn wound depth has higher accuracy compared with clinical assessment. The cost of the technology has increased from £49,950 in 2011 to £63,421 in 2021. An updated cost model shows that moorLDI2-BI remains cost savings by a saving of £1,485 per patient if the equipment is purchased, or £1,459 per patient if it is leased. The saving is a consequence of the increase in device cost being offset by reduction in service costs and reduction in on-site training from two days to one day every two years.

5. Evidence

The search strategy from the original assessment report was re-run. References from January 2017 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with details of any changes to the technology itself, the cost of the technology or the CE marked indication for use for their technology. The results of new evidence are presented in section 5.4.

Searches were conducted on the FDA Maude and MHRA websites. No event was identified.

5.1 Technology availability and changes

The technology is still available in the NHS. Since the guidance was published in March 2011 there was a change to the mobile cart (the MS2-MKII), digital signal processing (DSP) has replaced analogue processing, and a USB camera has replaced the firewire camera in 2014. None of these changes had any significant effect on performance; they were introduced for additional safety or to replace obsolete parts.

5.2 Clinical practice

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.

5.3 NICE facilitated research

None.

5.4 New studies

Twenty studies which use the moorLDI2-BI for assessment of burn injuries have been published since the guidance was reviewed in 2017. Seven studies were included in this review. The other 13 studies were excluded:

- Information on study details (no results, no peer review publication) was available at the trial registry (NCT04660162).

- 4 systematic reviews (Claes et al. 2021c, Wang et al. 2020; Jaspers et al. 2019, Shin et al. 2016): the relevant primary studies on moorLDIs were included in the original guidance and the 1st guidance review.

- No relevant outcomes on laser doppler imaging were reported for the following studies: Stoop et al. 2021, Carrière et al. 2019, and Jaspers et al. 2016.

- The intervention was not relevant to the scope in the following studies:

    - the laser doppler imaging device was not specified as moorLDI2-BI in the following studies: Asif et al.2019, Róna and Ruzsa 2017.

    - the Laser Doppler Imaging machine (Aïmago EasyLDI manufactured by the Laboratory of Biomedical Imaging (LIB) of the Swiss Federal Institute of Technology in Lausanne (EPFL) (Mermod et al. 2017)

    - Not laser doppler imaging (Abubakar et al. 2020)

- The study type was not relevant: Robson 2001

- Non-English language study (Legemate et al. 2018)

The company also provided a list of studies (n=10) and one article since the 1st guidance review. The article was a news media story. Of the 10 studies,

- 7 studies were in the NICE IS search results (Claes et al. 2021a, Claes et al. 2021b, Claes et al. 2021c, Claes et al. 2020, Jaspers et al. 2019, Jan et al. 2018, Wearn et al 2018).

- The other 3 (Bairagi et al, 2019, Asif et al. 2020, Goel et al. 2020) were not in the search. Bairagi et al 2019 is a study protocol. Asif et al 2020 and Goel et al. (2020) are relevant to the decision problem and are included in this review (see below).

Claes et al. (2021a, 2021b)

A mixed method study explored barriers and problems when using LDI. Twenty seven of 51 burn centres originally approached across 10 countries on 3 different continents (Europe, Australia and Asia) responded to a questionnaire.

LDI scan was often used by different members of staff including surgeons or surgical residents (20/43, 47%), or nurses (18/43, 42%). In 11% of cases (5/43), the scans were performed by other members of the burn team such as research workers, care coordinators or clinical scientists.

Eighty-nine percent of the burn centres (24/27) considered the accuracy of the LDI scan as ranging from mainly accurate to almost completely accurate. In 11% of the burn centres (3/27) the LDI scan was considered accurate in 50% of burn wounds. Most of the burn centres identified the percentage of burns misdiagnosed by LDI as lower than 2% (13/23, 57%), followed by 2 to 5% (4/23, 17%), 5 to10% (3/23, 13%), >20% (2/23, 9%) and 10 to 20% (1/23, 4%).

LDI was used in combination with clinical assessment in the final decision for further treatment (74%, 20/27). LDI was useful as a confirmation of the clinical opinion (19%, 5/26), with 8% (2/26) thought LDI was not useful because it significantly misleads.

Whenever there was a discrepancy between the clinical diagnosis and the LDI, 40.6% of the responses (13/32) was to rely more on the clinical diagnosis. In 25% of the responses (8/32), the burn centre would delay the final decision to operate and in 15.6% of the responses (5/32), the burn surgeon would consider other factors and re-scan the next day.

Claes et al. (2020)

A case study of 2 people with burn injuries. Laser doppler imaging was used to assess the depth of the burns. The results of LDI confirmed the clinical assessment in both cases.

Charuvila et al. (2018)

A cross-sectional study in 29 people with mid-dermal or mixed depth burns presenting within 2 to 5 days after burns in a UK burn centre. Burns were first assessed clinically. LDI Imaging and spectrophotometric intracutaneous analysis (SIA) imaging were used subsequently. After imaging, treatment decisions were made according to standard protocols. The study reported that LDI correctly predicted 21 out of 23 people who had their burns healed within 21 days and 6 out of 22 people who either healed after 21 days or had early surgery. The sensitivity of LDI for predicting the suitability for surgery was 27% with a specificity of 91% compared with sensitivity of 36% using SIA with a specificity of 87%.

Jan et al (2018)

A cross-sectional study in people presenting in the burn unit in a US hospital. A total of 92 wounds in 34 people were included in the analysis. LDI correctly diagnosed the depth of burn wounds in 8 (8.6%) more cases than clinical examination alone. LDI had 9 incorrect assessments compared with 17 by clinical assessment. The sensitivity of LDI for predicting the actual burn depth was 92.75% (95%CI 81 to 96%) with a specificity of 82% (95%CI 58 to 94%) using clinical assessment as the reference standard.

Wearn et al. (2018)

A prospective cross-sectional study in people with an acute burn, aged 18 or older who were admitted to a UK burn centre. A total of 20 burn wounds in 16 people were included in the analysis.

Burn depth estimation was performed by four methods:

- Laser Doppler Imaging with a Moor LDI2-B1
- Thermographic imaging with the FLIR SC660 thermal imaging camera
- Clinical assessment with 2D photography and
- Real-time clinical assessment.

Accuracy of LDI for predicting wound healing potential on

- day 0: sensitivity 33.3% with a specificity of 90.7%
- day 3: sensitivity 55.6% with a specificity of 100%

Accuracy of clinical assessment with 2D photography

- day 0: sensitivity 33.3% with a specificity of 68.8%
- day 3: sensitivity 50.0% with a specificity of 76.2%

Accuracy of real-time clinical assessment

- day 0: sensitivity 33.3 % with a specificity of 100%

Accuracy of thermographic imaging

- day 0: sensitivity 55.6% with a specificity of 55.8%
- day 3: sensitivity 44.4% with a specificity of 76.6%

Asif et al. (2020)

A before-after comparative study in 100 people aged 18 years or older with indeterminate-depth burns who received an LDI scan in the US. A group of 30 healthcare professionals (group1=8 physicians; group 2=17 nurses and physician assistants; group 3=5 other healthcare professionals) analysed 100 digital images with and without LDI resulting.

On average, the post-LDI assessment was 20.9% more accurate than the pre-LDI assessment (95% confidential interval [CI] 17.4 to 24.5%). The post-LDI assessment was 1.4 times (relative risk, RR = 1.4, CI [1.12-1.75]) more likely to correctly predict the need for excision and skin grafting than the pre-LDI assessment alone.

Goel et al. (2020)

A cross-sectional study in 45 people with burn wounds for 1 to 5 days who attended the outpatient department at 1 UK hospital. The study compared the effectiveness of LDI in assessing burn depth and therefore predicting healing times based on wound temperature with thermal imaging cameras (the FLIR ONE device).

- The LDI had a sensitivity of 93.33% (95% CI = 72.71 to 99.86%) and a specificity of 40.00% (95% CI =15.70–84.30%) in predicting that a burn injury would heal within 21 days.
- The FLIR ONE had a sensitivity of 66.67% (95% confidence interval [CI] = 52.71 to 89.86%) and a specificity of 76.67% (95% CI =12.52 to 85.51%) in predicting that a burn injury would heal within 21 days.

5.5 Cost update

As part of the NICE guidance review process, the economic model used in the original evaluation has been updated. The cost savings in the original model came from a shorter hospital stay and fewer operations. The original model and parameters submitted by the company were accepted, with an updated operating theatre hourly cost.

The cost of the technology has increased to £63,421 since the last guidance review. The company also confirmed a reduction in training time from 2 days every 2 years to 1 day every 2 years; therefore, the cost associated with NHS staff members attending onsite training was adjusted accordingly. Other costs including hourly staff costs and theatre costs were also updated (details see the cost update report).

Update of cost parameters has not changed the direction of cost saving; moorLDI2-BI still results in cost savings per patient scanned over a 1-year time horizon. The model estimated savings of £1,485 per patient with application of moorLDI after purchase, or £1,459 per patient if the equipment is leased. The saving is associated with a reduction in service costs and reduction in on-site training assuming only 1 training session every 2year.

6. Summary of new information and implications for review

Three experts who used the technology submitted their comments for the guidance review. All experts acknowledged that the technology is available for burn wound assessment in the NHS. One expert thought that the technology would only be used in specialised burn services, and used as an aid to assess burn wound depth. The combination of laser doppler assessment and clinical evaluation has been shown to be more accurate than diagnosis alone. The technology is validated for use between days 2 and 5 post burn injury and the LDI can aid in deciding how long it may take for the wound to heal. This information is used to help decide whether surgery is needed. One expert noted that the company has an additional product on the market, the Moor LDLS-BI, which is smaller, scans smaller areas, and scans more rapidly. The company confirmed these 2 scans are different technologies that use different methods to scan. Two experts are aware that there are other similar technologies such as thermal imaging that are available for burn depth assessment. But the current care pathway has not changed.

All experts agreed that training is needed to be able to use the technology safely and effectively. Two experts thought the technology is expensive. The cost includes the purchase of the equipment plus ongoing maintenance and training costs. One expert noted specifically that the training cost is expensive, and each training session can only have around 4-6 people. Several sessions every year are needed to train rotating medical staff. There is no budget for such costs. Only training provided by Moor is valid.

7. Implications for other guidance producing programmes

There is an option within the MTEP process to update the guidance within another piece of NICE guidance. There is no NICE guidance on burn management.

8. Implementation

The device is still available in the UK.

9. Equality issues

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

No equality issues were raised in the original guidance. moorLDI2-BI is suitable for use according to the manufacturer's instructions by all patients irrespective of age, gender, class and ethnicity. moorLDI2-BI is suitable for people with naturally dark skin.

Review decision sign off:

Anastasia Chalkidou **20 September 2021**

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	Consequences	Selected – 'Yes/No'
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	Consequences	Selected – 'Yes/No'
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	Yes
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

Appendix 2 – supporting information

Relevant Institute work

Published

moorLDLS-BI for burn depth assessment. Medtech innovation briefing [MIB251] (2021).

Mersey Burns for calculating fluid resuscitation volume when managing burns. Medtech innovation briefing [MIB58] (2016).

The Versajet II hydrosurgery system for surgical debridement of acute and chronic wounds and burns. Medtech innovation briefing [MIB1] (2014).

Appendix 3. Reference

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Legemate, C.M., Middelkoop, Esther, Hop, M. Jenda et al. (2018) Burn depth assessment with laser Doppler imaging. Nederlands Tijdschrift voor Geneeskunde 162(6): d2374

Mermod, T., Kolly, S., El Ezzi, O. et al. (2017) Tissue perfusion assessment of paediatric burns by laser doppler imaging (LDI). Current Pediatric Research 21(1): 69-76

NCT04660162 (2020) Comparison of Laser Speckle Contrast Imaging and Laser Doppler Imaging. https://clinicaltrials.gov/show/NCT04660162

Robson (2001) The use of laser doppler imaging in measuring wound-healing progress. Archives of surgery (Chicago, Ill. : 1960) 136(1): 116

Rona, S. and Ruzsa, Z. (2017) Laser doppler assessment of the limb before and after below-the-knee angioplasty in critical limb ischemia. Vasa - European Journal of Vascular Medicine 46(supplement96): 16

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