

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE
CENTRE FOR HEALTH TECHNOLOGY EVALUATION
EVALUATION PATHWAY PROGRAMME FOR MEDICAL TECHNOLOGIES

Medical technologies guidance

SCOPE

moorLDI2 Burns Imager

1 Technology

1.1 *Description of the technology*

The purpose of moorLDI2 Burns Imager is to generate a colour coded map of blood flow in an area of skin which has been burned. This can be used, with clinical assessment, to support decisions on wound dressings and grafting requirements.

The moorLDI2-BI includes a scan head, scan controller and a touch-screen panel computer, all mounted on a mobile stand that can be used in the ward, operating theatre, consulting room or special laser room. The scanner is mounted on a flexible arm and linked to the computer which has a bespoke software package with modules for imaging, storage, review and analysis.

In laser Doppler blood flow imaging, a low power Helium-Neon red laser beam is directed at the burn wound via a mirror. It is scanned in raster fashion across the burn area by rotating the mirror about vertical and horizontal axes. There is no direct contact with the tissue being assessed. Penetration depth is the full dermis. Laser light scattered from moving blood cells in the tissue undergoes a Doppler frequency shift, the average frequency shift being proportional to the average speed of the blood cells. Some of the scattered laser light is collected by the mirror and then focussed, by light-collecting lenses, on photodiode detectors. The resulting photocurrent is processed to calculate the blood flow in the tissue and this information is displayed as a colour-coded map of the wound area. Burn wound sizes from small (part of a finger) to large (torso) can be mapped in this way. The scan takes from 80s to about 5 minutes depending on the size and required resolution of the wound.

Results are displayed as a colour-coded blood flow image and a colour video image of the burn wound. Healing potential results are also reported in three categories < 14 days, 14-21 days and > 21 days.

This product is available to the NHS on an annual leasing basis which includes maintenance and software updates.

1.2 Regulatory status

MoorLDI2 Burns Imager is CE marked and registered with the FDA (510K K060976) and with Canada Health (Licence no. 75477) for use as a burn wound assessment imager

2 Reasons for developing guidance on moorLDI2 Burns Imager

The Medical Technologies Advisory Committee (MTAC or 'the Committee') recognised that moorLDI2 Burns Imager may be beneficial for helping with decision-making for burns patients specifically for those with intermediate level burns (i.e. level 2 or level 3). There is evidence that use of moorLDI2 Burns Imager with clinical assessment results in more accurate decision-making for this group of patients compared to clinical assessment alone.

The Committee noted that although this technology has been available in the UK since 2003 it is not widely used.

The Committee considered that an evaluation of the potential cost savings due to reduced length of hospital stay and reduced number of operations would be informative.

3 Relevant diseases and conditions

In the United Kingdom, about 175 000 people attend accident and emergency departments each year with burns from various causes. This represents about 1% of all emergency department admissions. Approximately 16,000 burns patients are admitted to hospital each year and about 1000 of them need active fluid resuscitation. The number of burns related deaths average 300 a year.

There are four levels of burn injury. Epidermal (level1) and superficial dermal wounds (level 2) tend to heal without scarring or surgical intervention within 21 days. Deep dermal (level 3) and full thickness burns (level 4) heal more quickly and with fewer complications if they are promptly excised and grafted. This technology is most useful for distinguishing between the superficial dermal (level 2) and deep dermal (level 3) wounds.

4 Patient benefit

4.1 Current management options (the comparator)

Clinical evaluation is the most widely used method of assessing burn wound depth. This method is based on the subjective, visual and tactile assessment of the external characteristics of a burn wound. The accuracy of this method relies almost entirely on the experience of the doctor.

4.2 Clinical outcomes relevant to the technology

The key outcomes for this technology are the accuracy of the assessment of burn depth and healing potential. This information is the basis of the development of an appropriate burn care treatment plan.

Other important outcomes are the sensitivity, specificity, negative predictive value and positive predictive value of the wound healing potential before 14 or 21 days.

Key clinical utility outcomes associated with the technology are avoiding unnecessary operations, number of dressing changes, complications and length of stay in hospital.

5 Care pathway and system impact outcomes

5.1 Care pathway impact

The technology is primarily relevant to the improvement of treatment decisions for patients with intermediate level burns. The moorLDI2 Burns Imager can be used 48-72 hours post-burn to identify the healing potential for individual burn wounds. This information can be used to develop an appropriate burn treatment plan.

The assessment of burn depth is a key decision that needs to be made in burn care treatment. However especially at the early stage it is difficult to distinguish the more superficial dermal burns which will heal well from deep dermal burns where a prolonged healing time will result in hypertrophic scarring. The diagnosis of burn depth is particularly difficult in children due to the prevalence of mixed depth scald burns, children's thin skin and their unpredictable response to injury. Strict categorization of burn depth is complicated by burn wound conversion where superficial burns may progress into deeper wounds due to progressive death of severely injured cells, oedema and tissue hyoxia.

5.2 System impact

Use of moorLDI2 Burns Imager to potentially improve the accuracy and timeliness of burn healing decisions may result in reduced length of hospital stay, principally by avoiding unnecessary operations for some burns patients. Use of moorLDI2 Burns Imager to potentially facilitate earlier decisions about the need for operations for some patients, enables earlier healing which lessens the risk of poor scarring and also provides more accurate mapping information for grafting operations on patients with mixed depth burns.

5.3 Other organisational factors

The relevant staff will need training on the use of the imager and interpretation of the results. This can be achieved with a two day workshop.

6 Health inequalities and equality impact

The National Institute for Health and Clinical Excellence (NICE) is committed to promoting equality and eliminating unlawful discrimination. We aim to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women, and*
- eliminate unlawful discrimination on grounds of race, disability, age, sex and gender, sexual orientation, and religion or belief in the way we carry out our functions and in our employment policies and practices.*

6.1 Health inequalities

Children under the age of 5 and the elderly over the age of 75 are at the highest risk of burns. Young children have a higher risk of poor scarring. Elderly patients often have medical problems and higher risks associated with surgery.

6.2 Equality impact

MoorLDI2-BI is suitable for use according to the manufacturer's instructions by all patients irrespective of age, gender, class and ethnicity.

7 Approach to cost measurement and health economic analysis

The cost analysis should begin from the time when the decision has to be made about how the burn is to be managed, generally about 48 hours post-burn when the wound has stabilised and the patient has been admitted as an in-patient. The cost analysis should take into account all additional costs associated with the use of moorLDI2 Burns Imager including equipment,

maintenance and staff costs compared to using clinical assessment of burn depth alone. Savings obtained through the use of moorLDI2 Burns Imager in terms of dressings, staff costs, operations costs, and length of stay should all be included in the model. Costs of treating possible complications, out-patient visits and follow-up appointments associated with the follow-up treatment of the burn wounds should also be considered. This should be balanced against cost-savings from avoidance of unnecessary operations and avoidance of additional scarring caused by unnecessary surgery.

The annual leasing list price is £25,000 per annum which includes maintenance and software updates.

8 External organisations

8.1 Professional organisations

8.1.1 Specialist societies contacted for Expert advice

British Burn Association (BBA)

British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS)

Association of Burns and Reconstructive Anaesthetists (ABRA)

8.2 Patient organisations

NICE's Patient and Public Involvement Programme contacted the following organizations for patient commentary

:British Skin Foundation

Changing Faces

Children's Burn Trust (CBT)

Counsel and Care

CritPaL - Patient Liaison Committee of the Intensive Care Society

Dan's Fund for Burns

ICU Steps

Let's Face It

Royal College of Surgeons Patient Liaison Group

Skin Care Campaign

The Patients Association

8.3 NHS trusts or other organisations with experience of the technology

This technology is already in use in the following hospitals:

Chelsea & Westminster Hospital

Royal Manchester Children's Hospital
St. Andrew's Centre for Plastic Surgery & Burns, Broomfield Hospital.
Queen Victoria Hospital, Blond McIndoe Centre, East Grinstead
Birmingham Children's Hospital
Salisbury District Hospital
Stoke Mandeville Hospital
Royal Victoria Infirmary, Newcastle Upon Tyne
Burns and Plastic Surgery Unit, Queen Elizabeth Hospital, Birmingham

9 Other issues

This topic is relevant to:

Department of Health (2007) [NHS Emergency Planning Guidance 2005: Planning for the management of burn-injured patients in the event of a major incident](#)

10 Related NICE guidance

11 Statement of the decision problem

	Final scope issued by NICE
Population	Patients with intermediate level burns
Intervention	moorLDI2 Burns Imager
Comparator(s)	Clinical assessment of burns biopsy, ultrasound, injection of vital dyes to stain living tissue, fluorescein injection, thermography
Outcomes	Burn depth and healing potential within 14 or 21 days. Sensitivity, specificity, positive predictive value, negative predictive value of wound healing potential before 14 or 21 days. Length of hospital stay, number of operations and their duration, number of dressing changes, wound complications
Cost analysis	Comparative cost analysis of the use of moorLDI2 Burns Imager with clinical assessment and the use of clinical assessment alone for decision-making in the treatment of burn wounds. Cost analysis should account for hospital and clinic care, staff training, long-term burn management and other relevant costs.
Subgroups to be considered	None identified
Special considerations, including issues related to equity or equality	None identified