POSITION PAPER 54

11 May 2017

SDMA
SURGICAL DRESSING MANUFACTURERS ASSOCIATION

Appropriate Testing of Wound Care Products

How Wound Care Products are Tested

There are four basic types of test that can be used to assess wound care products:

- Laboratory performance testing (physical testing carried out in a laboratory to a defined standard or rationale – including proving compliance to published standards or specifications).
- Safety testing (biochemical and microbiological testing carried out in a laboratory to a published standard – including such things as sensitisation, cytotoxicity, inflammatory response, skin irritation, biocompatibility, sterility, shelf life and transit simulation tests).
- Clinical assessment (clinical testing – including clinical trials, case studies, study series and observational studies). The scale of a clinical study will be dependent upon the nature of the product, the associated claims and its classification under regulatory standards.
- Usability testing (carried out by individuals to simulate an aspect of user experience – including practical functional tests and table-top simulations in aspects of performance).

The main international standard for the laboratory testing of wound care products is BS EN 13726. This provides laboratory test methods for absorbency, fluid handling, breathability, adherence and other physical characteristics of wound dressings. Alongside this are many descriptive standards and specifications (monographs), most notably those found in issues of the British Pharmacopeia – which also includes many test methods.

Laboratory tests and standards change with time and continued expert vigilance is required to ensure that the most appropriate and current tests are carried out

All four types of product testing, together with a risk analysis, may form significant elements of a product's technical file – which evidences a products compliance to the regulations and suitability for use.

Published tests do not exist for all aspects of product performance or suitability in use. There are aspects relating to product use which are subjective, e.g. ease of use, legibility of labelling, clinical efficacy and outcomes, and safety in use. These aspects are considered by a manufacturer during a risk analysis process designed to minimise risk in use. Output from the risk analysis will be reflected in the Instructions for Use (IFU).

CE-Marking

For a wound care product to be placed on the market in the UK (or anywhere in the EU) it is required to be CE-marked. The CE-mark shows that the manufacturer has ensured that the product satisfies the requirements essential for it to be fit for its intended purpose, complies with EU safety, health and environmental requirements. To prove this, the manufacturer has to compile a technical file that includes a clinical evaluation report based on some or all of the types of testing described above. It also includes:

- a detailed risk analyses
- proof of compliance with standards
- instructions for use
- correct labelling
- identification of contra-indications
- proof of product claims
- proof of sterility and shelf life
- a detailed biological evaluation
- and indications for use.

Compiling supporting literature for any wound care product is a regulatory requirement and forms a crucial part of the product evaluation carried out by suppliers. In addition, post-market surveillance (PMS) and post-market clinical follow-up (PMCF) are mandated, to show continual evaluation of a product's performance in clinical use is being monitored. Depending on the product, additional laboratory testing will be carried out by the manufacturer – such as microbiological assessments and biocompatibility.

Importantly, all test methods and standards used by a manufacturer must be fully referenced and the results analysed using a holistic methodology.

Strengths and Weakness of Product Testing

Each type of product testing has characteristic strengths and weaknesses, which must be considered when wound care products are assessed. Comparative assessments need to consider laboratory testing, usability testing and clinical outcomes to reach a balanced conclusion – all of which need to be appropriate to the clinical settings and patient groups involved. Taking each type of product testing in turn:

	Positives:	*Negatives:*
Laboratory Testing (both physical and biochemical)	Laboratory testing is by its nature reproducible – it can compare products from one occasion to another and from one test centre to another. It has a low potential for bias and is compliant to accepted standards and test methods. All test methods and materials are clearly defined.	It can have low relevance to clinical practice and does not always correlate with clinical outcomes. It does not always correlate with clinical outcomes, which may vary between patient sets, underlying pathologies and clinical settings. Existing standard test methods may not be suitable for new products.
Clinical Studies	When well-designed, clinical studies can provide realistic evidence of patient outcomes that have a low potential for bias. The results from clinical studies can also be transferable.	Variations in patient physiologies, clinical settings, clinical skills, anatomical positions, clinical objectives and similar aspects, may all lead to variable outcomes. Clinical studies can be very costly to carry out and may involve ethical considerations. The end point of evaluations can vary depending on objectives, external factors and patient compliance, health and comorbidities.

Usability Testing (e.g. table-top testing)	Has relevance to user experience and user convenience. May be helpful in assessing certain product aspects such as usability, handling, ease of use, appropriateness of size of products, ease of opening, ease of application, and aesthetics. It may include a critical review of the IFU and supporting literature.	Methodologies can lack standardisation and thus have poor reproducibility and low comparative values. There is a significant potential for bias. Testing is often subjective – and can include non-scientific protocols. It is also open to influence by individual personal experience or preferences. If the technical abilities of participants in designing and conducting tests is limited, selection of test criteria and the subsequent lack of 'weighting' between critical and non-critical aspects can misrepresent products. Crucially, there is a lack of relevance to clinical efficacy, patient outcomes or costs of treatment

Table-Top Testing – further commentary

Table-top testing (or evaluation) is a form of usability testing often carried out as an adjunct to procurement activities. It usually involves a group of assessors and can be very helpful when judging product aspects such as usability, handling, ease of use, appropriateness of size, ease of opening, ease of application, and aesthetics. It may also include a critical review of the IFU and supporting literature. It can demonstrate function but cannot reliably be used for comparative purposes for the selection of products for specific clinical needs.

Although it may provide useful user feedback, results from table-top testing need to be used in an informed manner, due to the following characteristics of this type of testing:

- Testing and reporting is often subjective – with non-scientific protocols. It is thus open to subconscious influences resulting from individual personal experience or preferences.
- Methodologies can lack standardisation and thus reproducibility. With subjective outcomes, this can invalidate results. The testing can demonstrate utility, but cannot be used for comparative purposes or to define suitability for a specific clinical need.
- Testers' experience and knowledge of local, technical and regulatory requirements – and even clinical use – may be limited and the rationale of the testing inappropriate.
- Table top testing is clearly not appropriate for assessing wound care product characteristics such as wear time, time before a dressing change is needed, time to strike-through, compatibility with other wound care products, adherence to the wound, adherence of adhesives to the skin, skin stripping, pain management, patient comfort, conformability during movement, and so on. (*It must be acknowledged that some of the above limitations also apply to laboratory testing, which may sometimes produce results that do not correlate with clinical outcomes and may vary between patient sets and clinical settings*).
- Lack of relevance to clinical practice – the product that may be easiest to handle in table-top testing may well not be the best for patient experience or outcomes – nor the have the best cost in use.
- Comparative studies like these, that do not use recognised standards, or are selective on non-critical criteria, can misrepresent products and result in misleading information.
- Product scoring systems often used in table-top testing risk over-simplification of product performance and hence can be detrimental to both patient outcomes and healthcare costs.

Overall, they offer a glimpse of product characteristics that is often dependent on the assessor's knowledge and experience in clinical practice.

Commentary

Reliance can be placed on the CE-mark to demonstrate safety and efficacy for the intended uses.

Comparative studies need to consider an appropriate combination of laboratory testing, user testing including healthy volunteer acceptance and clinical evidence to reach a balanced conclusion – these need to be relevant to the clinical settings and patient groups.

Table-top evaluations have little value when comparing the clinical performance medical devices, but may provide opportunities for improvement or identify areas needing investigation. They have a role in the assessment of packaging, handling, ease of application, nursing convenience, and similar aspects. Importantly, they can have little validity in other areas and might lead to sub-optimal product choices if used in isolation, and without a review of supporting clinical evidence.

Over-simplification of wound care product assessment is likely to be detrimental to a patient's quality of life, outcomes and healthcare costs.

It is when tissue viability nurses and/or clinical specialists conduct informed clinical evaluations that the most appropriate and effective products for their clinical practices are successfully identified. Industry plays an important role in ensuring a variety of technologies for the prevention and treatment of wounds is available to facilitate informed choice.

Industry provides innovative, cost effective treatments to healthcare providers to help meet the challenges of an increasing health burden on society. Industry working with clinicians provide evidence based solutions and educate health care practitioners to advance the science of wound prevention and management.

Only a balanced and thorough evaluation of all the aspects of wound care product testing can have a credible outcome. This will ensure the variety of dressings needed to cost effectively prevent or manage a wide variety of wounds across a diverse set of patients and clinical settings is fully understood.

The following basic protocol might be considered for comparative testing of wound care products:

1. *Visual cues*
   Handling performance

2. *Performance parameters related solely to the device*
   Performance parameters related to human physiological processes

3.1 Fluid management
- *Absorption (influenced by cover, adjunct, seal)*
- *Absorption rate (influenced by method of absorption)*
- *MVTR (influenced by cover-occlusion temperature)*
- *Effects of hydrostatic pressure (for example: compression movement)*

3.2 Wear time
- *Time on patient*
- *Strike-through and time between changes*
- *Wash testing (where appropriate)*

3.3 Conformability
- *Anatomical shape*
- *In the presence of movement*
- *Texture of skin*
- *Friction, shear and pressure generated by movement*

3.4 Adherence and adhesion
- *Temperature effect*
- *Moisture effect*

3.5 Pain relief and patient comfort

3.6 Evaluation of sensitivities, allergenic and other biochemical effects

3.7 Establishing the skill of appliers
- *Correct application*
- *Cutting to size*
- *Reproducibility*

3.8 Establishing the validity and reliability of the protocol