Evaluation of UrgoClean® for the treatment of sloughy, exuding wounds

KEY WORDS
- Exudate management
- Formulary changes
- Product evaluation

Selecting a dressing to manage exuding, sloughy wounds can be a challenge for nurses, aiming to promote rapid removal of non-viable tissue whilst controlling exudate and optimising the conditions for healing. This article discusses the evaluation of a wound care product designed to stimulate both autolysis of slough and absorption of excess exudate from the surface of a wound. The Trust's approach to evaluation will be discussed and outcomes analysed to determine the impact of changing a product on the wound care formulary.

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Slough covering the surface of a wound is formed of dead tissue, fibrin, fibrinogen and proteins that may have contributed to the healing process (Gray et al, 2010). It can adhere to the wound surface and be difficult to remove. Slough can act as a growth medium for bacteria, inhibit angiogenesis, extra cellular matrix formation and the progression of keratinocytes across the surface of a wound (Wounds UK, 2013). Therefore clinicians should aim to remove slough as quickly as possible with the least amount of trauma to the patient.

Approaches to the removal of slough include sharp or surgical debridement, bio-surgery and use of dressings that create a moist environment and promote autolysis. These can take time and the process needs to be carefully monitored as excess fluid can result in maceration and excoriation of the skin surrounding a wound.

Exudate, containing water, nutrients and inflammatory mediators is greatest during the inflammatory stage of healing. This plasma-like fluid normally reduces as the inflammation subsides and the wound begins to granulate (World Union of Wound Healing Societies, 2007; Tickle, 2013). However, excess exudate production can occur in systemic illness, where haemostasis is disrupted, in the presence of bacteria and when poor venous return causes vessels to distend (Hampton, 2004). Its composition alters with MMPs and other degradatory, proteolytic enzymes increasing in numbers (White and Cutting, 2006). Maceration and erosion of the skin surrounding the wound can occur, this is painful and distressing to patients and causes the wound to increase in size.

The best approach to reducing exudate is to identify and address the underlying cause. Topical management of the wound requires a dressing that will absorb exudate and hold it away from the skin's surface. These include topical negative pressure, super absorbent dressings, alginates, hydrofibres and foams.

While exudate is generally thought to promote removal of non-viable tissue persistent slough can exist on an exuding wound, and, as prolonged presence of slough stimulates bacterial infiltration and an inflammatory response, exudate production can increase (*Figure 1*). This poses a challenge for nurses aiming to soften and remove slough without increasing the risk of damage to the wound and surrounding skin.

Practitioners need to assess what is required for healing and balance the desired outcomes with unwanted consequences of any intervention (Hampton, 2004). Using the right product is important, inappropriate use of a dressing will not achieve the right results for the patient, practitioner and manufacturer (Anderson, 2002), as healing will not be achieved and the product will wrongly be viewed as ineffective.

CLINICAL AND COST-EFFECTIVE CARE

In the current economic climate there is a growing focus upon provision of high quality, cost effective wound care and the NHS requires resources to

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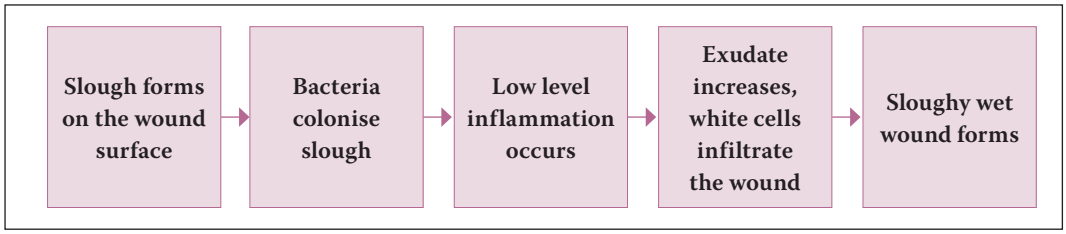


Figure 1. Slough formation on chronic wounds.

be utilised efficiently to achieve the best possible patient outcome (Geraghty, 2013). Practitioners involved in the development of a wound care formulary should have an understanding of health economics which informs decision-making (Wounds UK, 2008), however not all tissue viability specialists are provided with extensive education within this area. The National Prescribing Centre (2012) notes that procurement should focus upon increasing productivity and reducing waste, while other authors highlight the importance of the wound care formulary as a tool to support clinical decision making through rationalization of dressings (Kilroy-Findley, 2006).

To this end, tissue viability teams aim to ensure that all dressings on the formulary are both clinically and cost effective. Unless there is clear evidence to support the current products on a formulary these dressings should be replaced with clinical and cost effective alternatives. This also helps to ensure that nurses with limited wound care knowledge and experience do not feel overwhelmed by the range of dressings available (Kilroy-Findley, 2006).

When new products become available, it is the responsibility of the Trust's tissue viability specialist nurse to review the available evidence and take the lead in evaluation. In the author's Trust there is a robust organisational process for the acquisition of new medical devices. This is vital as the addition or removal of a product from a formulary needs to be well-managed, meet statutory requirements and enhance the care provided for patients.

Wound care product evaluation must be carried out in controlled unbiased conditions without placing patients at risk. The author has devised an approach to product evaluation which meets national requirements, reflects the Trust's medical devices acquisition framework and ensures patient safety. This involves working closely with dressings manufacturers and incorporates the elements of product evaluation shown in *Box 1*.

Box 1. Dressing evaluation process

1. Review and analysis of clinical evidence.
2. Trial by tissue viability nurses.
3. Trial by independent practitioners.
4. Cost analysis.
5. Impact analysis.

EVALUATION OF URGOCLEAN

UrgoClean® (Urgo Medical) is a new product suitable for sloughy and exuding wounds. It consists of a pad or ribbon of polyacrylate non-woven fibres, with an acrylic core that absorbs exudate and entraps slough (Eloy et al, 2010). The pad is coated with a soft-adherent lipido-colloid layer (TLC Technology) that gently holds the product in place and promotes healing. This also enables atraumatic removal of the dressing.

The National Prescribing Centre (2010) states that dressings must meet essential safety and performance requirements and must be supported by clinical evidence. This view is supported by NICE (2012), which expands on this opinion and suggests decision-making must incorporate critical appraisal of the literature and contextualising of evidence.

To this end, a review of evidence to support UrgoClean was undertaken. As there are few randomised controlled trials carried out to demonstrate the efficacy of wound care products laboratory tests and case studies often form the basis of clinical evidence.

Eloy et al (2010) used scanning electron microscopy to demonstrate how the fibres of UrgoClean held debris and absorbed fluid after contact with a wound. While these authors demonstrated the product's ability to perform, they

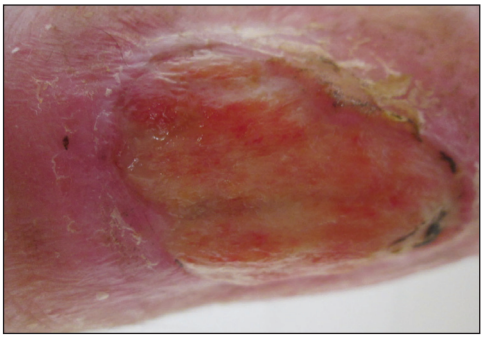
did not expand upon the condition of the wound during or after use of the dressing.

The impact of UrgoClean on pressure ulcers was examined in 15 patients and wound size reduced by an average of 29% (Rethore et al, 2010). Deep cavity wounds in 43 patients reduced on average by 55% in a 4-week period (Meaume et al, 2010). The authors also note that patients reported a reduction in wound pain when the dressing was *in situ*.

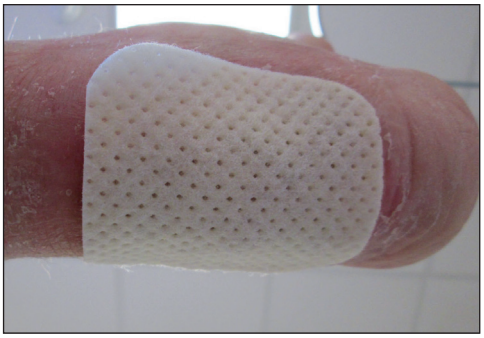
This suggests that the dressing not only controlled the level of slough and exudate, but also optimised conditions within the wound margins allowing patients to heal themselves. While the evidence suggests UrgoClean performs better than other dressings, specific healing rates and patient acceptability are not discussed in detail, and so an evaluation of the product was undertaken in the author's Trust.

Box 2. Case study one.

Mrs J presented in the dermatology department with vasculitis spreading across both her lower limbs. This quickly resulted in ulceration and exposure of both Achilles tendons. She was in pain and had reduced mobility. The vasculitis was treated with systemic and topical steroids, and she was referred to the tissue viability team for wound care. UrgoClean was used on both wounds throughout the healing process. Mrs J's wounds rapidly improved, with granulation migrating across the tendons. Her mobility increased and she developed confidence in the dressing. UrgoClean was continued when she was discharged from the acute care environment.



Granulation migrating over Mrs J's exposed tendon.



UrgoClean *in situ* over the surface of the wound.

SPECIALIST USE OF URGOCLEAN

UrgoClean was initially used by the tissue viability team on wounds which would normally be managed with absorbent alginate or hydrofibre dressings, such as in *Box 2*. The dressing was found to be very absorbent and controlled the exudate well, none of the patients reported any discomfort, and the lead nurse was impressed by the level of healing achieved as wound measurements demonstrated size reduction at every dressing change. In addition, the ribbon stayed in one piece and did not adhere or disintegrate, easing removal from cavity wounds and facilitating a longer wear time with all patients. As these results reflected excellent performance of the dressing, it was decided to move to the next level of evaluation.

To reduce the risk of bias and ensure the dressing performs as well in clinical practice, it was then trialled independently in two acute surgical wards. Urgo Medical provided education on the dressing for staff who used it in place of hydrofibre and alginate dressings. Initially there was some resistance to this, as one of the authors of this paper was asked to lead the evaluation in her clinical area, but had great confidence in the effectiveness of hydrofibres and did not see the need to alter her current practice.

The product was trialled on 10 patients across both wards over a 4 week period. Not all evaluations were complete due to the transfer of three patients to the community. All patients verbally agreed to use of UrgoClean prior to its application. The majority experienced improvements in their wounds, no wounds deteriorated and no patients experienced adverse reactions to the dressings.

Information collected was influenced by the level of skill and time nurses had to complete the evaluation, and the requirements of the tissue viability team and the medical devices procurement framework. The focus was upon evaluation rather than collection of research data.

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Table 1. Patient outcomes.

Patient	Wound appearance	Exudate level	Impact of UrgoClean	Patient view	Nurse view
1	Heel ulcer, broken skin, blue/purple.	Low.	No change in wound appearance. Dressing removed easily despite low levels of exudate.	9/10 Comfortable.	9/10 Good, easy to use.
2	Dehiscence of abdominal surgical wound.	High exudate, macerated wound edges.	Very good absorption reduced maceration. Removal of slough in the wound base .	5/10 Patient continued to experience wound pain unrelated to dressings.	8/10 Dressing held up on a very heavily exuding wound and is a lot more absorbent than alginates.
3	Trauma injury – skin tear.	High exudate, macerated wound edges.	Dramatic improvement, free from slough within days. Now completely healed.	9/10	7/10
4	Grade 3 pressure ulcer on sacrum.	Moderate exudate macerated wound edges.	The wound and skin improved with the dressing *in situ.*	7/10	9/10 Rapid healing, the dressing was easy to apply and remove.
5	Dehiscence of abdominal surgical wound.	High exudate.	The wound improved with the dressing *in situ*. Increased wear time.	7/10 Mobility and comfort improved.	9/10
6	Bilateral leg ulcers.	High exudate macerated edges.	Dramatic improvement. Patient went for skin grafts on very long-standing ulcers.	10/10 After many years of treatment, this product achieved a visible difference.	9/10 Difficult to conform to parts of the wound, nonetheless an excellent result.
7	Trauma injury due to car door.	High exudate.	Slough removed and the exudate was controlled very well.	10/10	10/10

Patient outcomes are identified in *Table 1*.

Nurses reported that the product was quick and easy to apply and remove, and was acceptable to all patients. They were impressed by the ability of the dressing to absorb exudate, remove slough and promote healing while protecting the patient's skin. There were no reported issues with patient concordance. The time between dressing changes was prolonged, there were no reports of additional pain, and evidence of reduced pain scores on the evaluation forms. All nurses reported that they wanted to continue using the dressing having experienced patient improvements like that described in *Box 3*.

EVALUATION OF RESULTS

The team then met to discuss the results of the evaluation and all agreed that UrgoClean would be an excellent alternative to the products currently in use. An impact analysis was then carried out to identify possible barriers replacing stocks of alginate and hydrofibre dressings with UrgoClean (*Table 2*).

As the NHS evolves, partnerships with industry are viewed as vital to improving the quality and efficacy of care (Department of Health, Social Services and Public Safety, 2008), and will light the way for new treatment modalities and pathways of care for patients (Fletcher and Ousey, 2010). Working with industry to understand the product design, composition and action reduces the risk of incorrect dressing usage.

The surgeons demonstrated the extent to which they value the tissue viability team and did not wish to undertake a further evaluation of the dressing. However, it was recognised that as two very well-

Table 2. Impact analysis.

Issue to be addressed	Action required	Lead person	Outcome
Surgeons use alginates in theatre	Attend surgeons meeting and inform of potential dressing change and discuss any issues arising	Tissue viability team and company representative	Surgeons happy with evaluation undertaken by tissue viability team
Can possible cost savings be made?	Carry out cost analysis	Tissue viability lead nurse and NHS Logistics	Cost analysis carried out (*Table 3*) with potential cost saving to the organisation identified
Staff across the organisation will require training on the new dressing	Liaise with company representative to provide Trust-wide education	Tissue viability team	Training provided in every clinical area
	Arrange education for link practitioners	Tissue viability team	Company representative provided education
Staff experience problems using the new product	Anticipate problems	Tissue viability team and company representative	No problems
	Devise process for addressing any teething troubles and arrange follow up with company representative	Tissue viability team and company representative	Delays in obtaining UrgoClean were addressed by the company. Some wards had to increase their stocks of the product to replace several other products.

established dressings were to be removed from the formulary, clinicians across the organisation might experience some anxiety about the impending change. This was addressed through working closely with the company and delivering an extensive educational programme to increase the awareness of practitioners in the action and use of UrgoClean.

Education was undertaken by the tissue viability team, Urgo Medical and tissue viability link practitioners. Link practitioners attended a meeting where the product was introduced by the company, tissue viability specialists and evaluators. Evaluation outcomes and dressing indications, contra-indications and application was shared. The link practitioners were then charged with facilitating the change over from alginates and hydrofibres to UrgoClean in their clinical areas, through educating and supporting colleagues. This was further supported by Urgo Medical, who undertook clinically-based education. The tissue viability team also promoted use of the dressing and evaluation results were shared in the tissue viability newsletter.

One issue requiring further educational input was identified during the evaluation process. The UrgoClean pad was difficult to mould to the shape of some limbs, however it could easily be cut into strips, or scrunched up before application. This does not impact upon cost or nursing time.

COST ANALYSIS

In association with NHS Logistics, a cost analysis was carried out based upon the use of hydrofibre and alginate dressings for highly exuding wounds over the 12-month period April 2012–March 2013. The potential saving of over £3,000 (*Table 3*) should expand with reduced dressings usage due to increased wear time. Impact analysis and working in partnership with Urgo Medical and NHS Logistics ensured a smooth transition to the new product.

Since its introduction in June 2013, no negative reports of the dressing have been received from practitioners across the Trust. A further cost analysis will be undertaken in 12 months to determine if predicted cost savings have been realised.

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Table 3. Cost analysis (April 2012–March 2013).

Amount required for 12 months	Total cost	Amount required for 12 months	Total cost	Cost difference
Flat sheet alginate: 1206 dressings	£14,592.41	UrgoClean: 1206 dressings	£13,671.54	£920.87
Extra absorbent alginate: 758 dressings	£9,485.62	UrgoClean: 758 dressings	£8,202.05	£1,283.57
Hydrofibre: 309 dressings	£6,507.88	UrgoClean: 309 dressings	£5,000.28	£1,507.60
Total	**£30,585.91**		**£26,873.87**	**£3,712.04**

CONCLUSION

The evaluation of UrgoClean for the management exuding and sloughy wounds was undertaken in the authors' Trust as an alternative to alginate and hydrofibre dressings. The product was found to control exudate whilst promoting autolysis of slough. In addition the patients experienced a reduction in pain and there was good evidence of rapid wound healing. An impact analysis was carried out to identify variables influencing the introduction of the product. A clear strategy and educational framework with support from Urgo Medical ensured a streamlined transition to the new dressing and cost analysis identified a projected cost saving of over £3,000, which may be further enhanced with prolonged wear time and faster healing achieved by the new product over time. A review of the cost to change will be carried out in 12 months time to determine if the dressing is performing as expected and clinical and cost effective outcomes are being achieve for the organisation, staff and patients. WUK

Box 3. Case study two.

One patient recruited into the Trust-wide evaluation of UrgoClean had experienced bilateral, sloughy wet ulcers for over 12 years, associated with rheumatoid arthritis. These were very painful and had a massive impact upon his quality of life. He had received treatment with a variety of dressings, none of which had controlled the build-up of slough or exudate, or promoted healing successfully. Prior to the use of UrgoClean, he required a cocktail of analgesics at dressing changes, none of which successfully managed the pain. This meant that he feared visits by the district nurses or changing the dressing in hospital.

Fentanyl was used for pain relief and UrgoClean implemented, resulting in an immediate reduction in pain. This gave him greater confidence with each dressing change. UrgoClean was used for 11 weeks and the ulcers improved dramatically, the slough was debrided and he had clean, granulating ulcers. He was then referred to plastic surgery for skin grafting over the newly formed granulation tissue. He felt that he had made progress and he could then claim back his life. Upon completion of the trial, the patient was reluctant to go back to his previous dressings and the UrgoClean was continued until the grafts were undertaken.

REFERENCES

Anderson I (2002) Practical issues in the management of highly exuding wounds. *Nurs Times* 18(3): 145–8

Department of Health, Social Services and Public Safety (2008) *Best practice guidance on joint working between the HSC and the pharmaceutical industry and other relevant commercial organisations*. DHSSPS, Belfast. Available at: www.dhsspsni.gov.uk/best_practice.pdf (accessed 20.02.2014)

Eloy R, Clermont G, Nicot D, Morel N (2010) Mechanism of action of UrgoClean. Poster presentation. Available at: http://bit.ly/1hxTp78 (accessed 20.02.2014)

Fletcher J, Ousey K (2010) The challenge ahead for tissue viability nurses. *Wounds UK* 6(3): 8–9

Gray D, White R, Cooper P (2010) Applied wound management and using the wound healing continuum in practice. *Wound Essentials* 5: 131–9

Geraghty J (2013) Industry and the clinician: collaboration is the key. *Br J Nurs* 22(12): S3

Hampton S (2004) A guide to managing the surrounding skin of chronic, exuding leg ulcers. *Prof Nurs* 19(12): 30–2

Kilroy-Findley A (2006) Creating a wound care formulary for RMNs. *Wounds UK* 2(4): 14–26

Meaume S, Rat P, Dupont N et al (2010) Local management of deep wounds: Results of a clinical study with UrgoClean Rope. Poster presentation. Available at: http://bit.ly/1hxTp78 (accessed 20.02.2014)

National Prescribing Centre (2010) Evidenced-based prescribing of advanced wound dressings for chronic wounds in primary care *MeRec Bull* 21(1): 1–6

National Prescribing Centre (2012) *Prescribing of Dressings: Guiding Principles for Improving the Systems and Processes for the Supply and Prescribing of Wound Dressings*. National Prescribing Centre, London. Available at: http://bit.ly/1k8tzeH (accessed 20.02.2014)

NICE (2012) *Developing and Updating Local Formularies. Medicines and Practice Guideline 1*. Available at: www.nice.org.uk/mpc/medicinespracticeguidelines/MPG1.jsp (accessed 20.02.2014)

Rethore V, Meaume S, Sebbane G et al (2010) Management of pressure ulcers at sloughy stage with UrgoClean. Poster presentation. Available at: http://bit.ly/1hxTp78 (accessed 20.02.2014)

Tickle J (2013) Living day-to-day with a heavily exuding wound: recommendations for practice. *Wound Essentials* 8(1): 77–81

White R, Cutting KF (2006) Modern exudate management: a review of wound treatments. *World Wide Wounds*. Available at: http://bit.ly/1hyvlFs (accessed 20.02.2014)

World Union of Wound Healing Societies (2007) *Principles of Best Practice. Wound Exudate and the Role of Dressings. A Consensus Document*. MEP, London

Wounds UK (2008) *Best Practice Statement. Development of a Wound Care Formulary*. Wounds UK, London

Wounds UK (2013) *Effective Debridement in a Changing NHS: A UK Consensus*. Wounds UK, London