Introducing HydroClean® plus for wound-bed preparation: a case series

Maintaining adequate moisture at the wound bed is important in facilitating the removal of slough and necrosis. In clinical practice, this is addressed through cleansing and one of a number of debridement techniques. Autolytic debridement is recognised as the most frequently used technique, but is criticised for being slower than other methods. The results of a small evaluation using HydroClean® plus — a hydro-responsive dressing suggest that there may be opportunities for an alternative method of autolytic debridement.

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The role of moisture in wound healing has become well established since the original study by Winter was published in 1962[1]. The concept of moist wound healing has been an integrated part of clinical practice for many years; a moist environment is considered to increase the rate of healing faster than a drier environment[2].

The concept of maintaining the correct moisture balance was developed further with the introduction of wound bed preparation, which provided a framework within which clinicians can address the local conditions in the wound to promote an environment in which healing can occur[3]. Throughout this process, the role of fluid balance is significant, as inadequate moisture can contribute to a dehydrated wound bed and the subsequent development of devitalised tissue[4]. The presence of devitalised tissue in the wound can interfere with the healing process by prolonging the inflammatory response, and blocking the migration of epithelial cells[5]. It can also lead to other problems, as it provides a suitable environment for bacterial growth, thereby increasing the risk of infection[6], and can encourage increased exudate production[4]. Devitalised tissue can also impede wound assessment as its presence can hide the true area and depth of a wound[7]. Introducing fluid to the wound bed is one of the simplest methods of preparing the wound bed when there is an increased necrotic burden.

Wound cleansing in wound bed preparation

Wound cleansing is a simple way to deliver moisture to the wound to facilitate the removal of devitalised tissue and contaminants such as bacteria, proteases and tissue debris[8]. This practice was reviewed, and while it was recognised that it made an important contribution to wound bed preparation, it was suggested that current practice may be ritualistic, is unsupported by evidence and its therapeutic value has not been fully investigated[8,9].

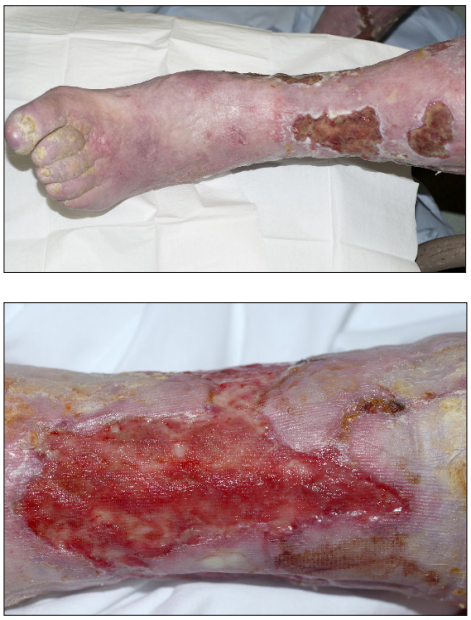
Clinical practice in the 1980s and 90s focused on wound cleansing to assist with the removal of adhered dressings, facilitate wound assessment and rehydrate the wound bed, and it was only recommended if the wound was diagnosed as clinically infected. In comparison to current knowledge, it was thought that all exudate contained nutrients and bacteria that were beneficial and should be left on the wound bed[10]. However, with current studies demonstrating the detrimental effects of proteases in chronic wound exudate which may delay wound healing[11,12], and the risk of biofilm formation from bacteria in the wound potentially increasing the risk of wound infection[13–15], effective wound cleansing is important. It is also recognised that further research in this area is required[16].

Using moisture in wound debridement

Wounds will naturally debride through the process of autolysis, as proteolytic enzymes and macrophages facilitate the separation of necrosis and slough from the wound bed[4]. By employing one or more of the techniques available to speed up this process, the progression to healing can be improved[17].

Wound debridement is an essential intervention in promoting progression in wounds where healing is delayed, and may be considered the most important concept of wound bed preparation[18]. The speed of debridement is important[19], however, the

Case study 1: A patient with a long-standing venous leg ulcer.



The patient, who was a 71-year-old female, could not tolerate full compression therapy. There was reported to be 95% sloughy tissue on the wound bed, and a moderate level of exudate (top). HydroClean plus was used for 7 days, during which time three dressing changes were undertaken, and a combination of a wool and retention bandage was used to hold the dressing in place.

Although there was no change to the wound size, the status of the wound bed had improved: 95% was observed to be granulation tissue, and the exudate level was low (bottom). Following this, compression to the leg was gradually increased to more therapeutic levels.

preferred technique for clinicians may be restricted by cost, skill or availability[20].

Autolytic debridement can be encouraged by using wound care products that encourage a moist wound environment by donating fluid to rehydrate dry eschar or absorb excess exudate[5,20]. It has been described as the most frequently used method[21], and is often adopted by non-specialist nurses because it is considered safe and selective[22]. However, this technique is criticised because it is slow[20] and can increase the potential for infection and maceration.

The evaluation of a new dressing (HydroClean plus, HARTMANN) provided an opportunity to observe the outcomes of using a product that is designed to both cleanse the wound and promote autolytic debridement through the donation and absorption of fluid to prepare the wound bed.

HydroClean plus

HydroClean plus is a unique dressing product developed to provide a cleanse–debride–absorb function to facilitate wound-bed preparation. The dressing cleanses wounds by releasing Ringer's solution, which removes the harmful components of chronic wound exudate and encourages autolysis of necrosis and slough. This is then absorbed into the superabsorbent polyacrylate hydrogel particles that are contained in the dressing. The safe and effective antimicrobial agent polyhexamine biguanide (PHMB) has been used to coat the superabsorbent polyacrylate particles, providing an antibacterial function that kills any bacteria absorbed into the dressing. The dressing has a silicone interface to prevent adhesion to the wound bed. Previous studies using this product on both acute and chronic wounds have indicated that it can rapidly and effectively prepare the wound bed by reducing both slough and necrotic tissue, can contribute to a reduction in wound-associated pain, and is highly acceptable to clinicians[23,24].

Evaluation process

A multi-centre product evaluation of HydroClean plus was undertaken on patients who were routinely seen by three clinical services in the UK. Patients with acute or chronic wounds that contained devitalised tissue (necrosis and/or slough) in the wound bed were deemed suitable for treatment with HydroClean plus.

The principles of research governance were observed, where all local procedures for ethical approval were followed within each facility before the evaluation started. Basic ethical principles, such as informed consent and maintaining patient confidentiality, were undertaken as identified in the Declaration of Helsinki[25].

Patients were recruited from the adult (≥18 years) population from within two specialist wound care services, and a community-based podiatry service that treats 'at risk' feet and regularly manages foot ulcers in patients with medical conditions, such as rheumatoid arthritis and diabetes, which are complex and challenging to manage.

The study design required that the dressing was evaluated within 'standard' practice, and as such no other changes to care delivery would be made. The primary objective was to evaluate HydroClean plus dressing in facilitating wound-bed preparation and wound progression in acute and chronic wounds. Of particular interest was the ability of the autolytic debridement action of the dressing to quickly and safely remove slough and necrosis to facilitate healing. The secondary objectives were to evaluate how the dressing performed when used in routine wound care, in particular the ease of application and removal, and whether the dressing was acceptable to both the patient and clinician. It was also important to undertake a simple economic evaluation to establish whether there was the potential for cost savings.

Wound healing was observed as 100% epithelialisation of the wound. Total debridement was identified as 100% granulation tissue in the wound bed. The threshold of <20% slough

Table 1. Wound aetiology of the participating patients.	
Wound aetiology	Number of patients (n=20)
Foot ulcer	3
Venous leg ulcer	3
Mixed leg ulcer	2
Arterial leg ulcer	1
Surgical wound	5
Grade IV pressure ulcer	3
Grade III pressure ulcer	1
Cellulitic lesion	2

was used as a measure of clinical efficacy in a review by the National Institute for Health and Care Excellence[26].

The wound aetiology, size, location, duration, exudate level, wound-bed status and periwound skin condition were also documented. The patient's pain related to the wound was established at baseline through the use of a visual analogue scale. Any wound care products used immediately before the use of HydroClean plus were also recorded.

The wound outcomes were assessed and recorded at each dressing change, using basic techniques that are reflective of routine practice. At each dressing change, the wound size (area and depth) was recorded to demonstrate wound progression. The area was estimated by measuring the maximum length and width of the wound, then multiplying this figure to give the area in cm^2. Any pain associated with application, during wear or the removal of HydroClean plus was established using the visual analogue scale, and was also documented.

Results/outcome

A total of 20 patients were recruited from a range of treatment settings, which included acute and community hospitals, their home and wound clinics. Sixty-five per cent (*n*=13) of patients were male and 35% (*n*=7) female, with ages ranging from 28 to 95 years (mean 68.3 years). Relevant comorbidities were recorded in 19 patients. Seven patients had diabetes. Of the 20 participants, five were taking systemic antibiotics for an existing wound infection, nine required analgesia for wound pain and two required immunosuppressant therapy for pre-existing conditions, one of which was retroviral therapy for HIV.

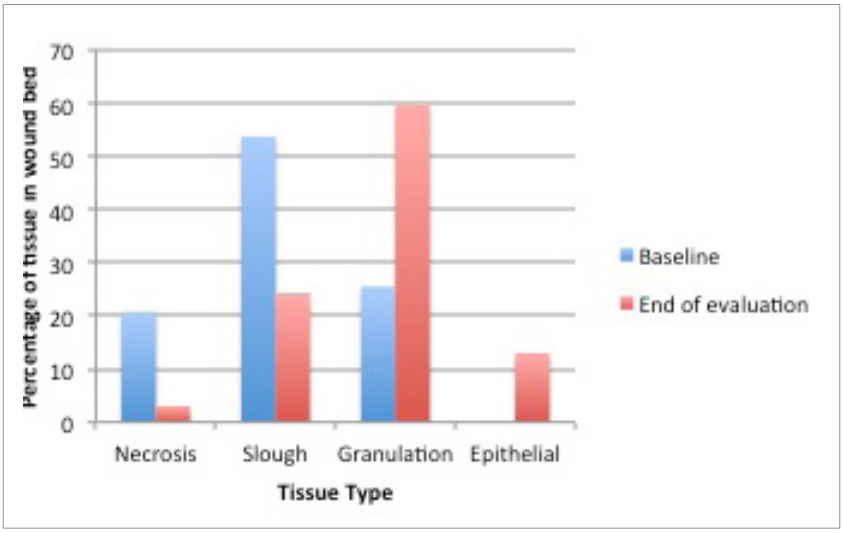


Figure 1. *Overall percentage of devitalised and healthy tissue at baseline and end of the study.*

The patients presented with a wide range of wounds *[Table 1]*. The wound duration was recorded in 18 cases, and ranged from 4 to 75 weeks (mean 20 weeks). Despite less than half of the patients taking analgesia, 19 patients were experiencing wound pain, with an overall mean of 2.5 using a pain scale where 0 is no pain and 5 the worst pain. Twelve patients (60%) had wounds that were malodorous.

Overall data were collected on 97 dressing changes, with the evaluation period ranging from 4 to 31 days (mean 15 days). The number of applications of HydroClean plus ranged from two to nine (mean five) per patient, with 72 (74%) dressing changes undertaken every 3 days and the remaining 25 (26%) on alternate days. Of the dressing changes, 55 (56%) were undertaken by nursing staff, 23 (24%) by podiatrists and 19 (20%) by the patient or his/her informal carer.

The reason for the dressing change was recorded at each episode of care, with 84% (*n*=81) of dressing changes undertaken routinely. Seven patients experienced strikethrough. This was resolved by increasing the frequency of dressing change in four patients.

The dressing was evaluated within 'standard' care. Wound cleansing was recorded in 74 dressing changes (76%); antimicrobial solutions were used in 66 procedures, 0.9% normal saline for one procedure and tap water for seven procedures.

A range of secondary dressings were used, depending on the aetiology and location of the wound, the exudate level, and the use of other devices. In 29 changes (30%), adhesive foam dressings were used. Gauze or non-woven dressings were used in 34 applications (35%), where the patient required less bulky dressings in diabetic foot ulcer treatment within offloading footwear. Wool padding with a retention or reduced compression bandage was used in 29 dressing changes (30%) in patients with mixed aetiology or venous leg ulceration. Although full compression therapy had been recommended for three patients, it was refused by two of them because the wound was painful. After treatment, however, the wound pain had reduced and the patients were able to progress to a higher level of compression. An adhesive film dressing was used on one patient for five dressing changes.

Supporting therapies, such as compression bandaging or offloading of pressure, were used where it was assessed as necessary and recorded in 35 dressing changes (36%). Additional debridement was undertaken during 13 dressing changes. This was sharp debridement, which involved the removal of devitalised tissue

Table 2. Exudate levels in patients (*n*=20) at the start and at the end of the evaluation.

Level of exudate	Baseline	End
High	3	2
Moderate	13	6
Low	4	10
None	0	2

and callus from the wound margins. It was performed by the podiatrists as part of their 'best practice' for foot ulcer management[16].

Wound progression

The primary aim of the evaluation was to observe whether HydroClean plus could facilitate wound bed preparation and wound progression. Two patients (10%) progressed to healing. A reduction in wound size and/or depth was achieved in a further nine (45%) patients. Two wounds (10%) were totally debrided (100% granulation tissue in the wound bed) and six wounds (30%) were debrided to 80–99% healthy tissue. The overall percentage of healthy and non-viable tissue at the start and end of the evaluation is shown in *Figure 1*. In two patients (10%), there was no improvement, but this was associated with their general condition and was not thought to be product related.

Exudate management

HydroClean plus was used on wounds with all levels of exudate. It is recommended by the manufacturer for all levels of exudate. In 95% (*n*=92) of dressing changes, the clinicians were satisfied with the way in which HydroClean plus managed exudate. The remaining 5% (*n*=5) of changes were undertaken by the patient and no information was recorded. *Table 2* gives the exudate levels at baseline and at the end of the evaluation period. At the start of the evaluation, 16 patients had wounds with high or moderate exudate, whereas only eight had these exudate levels at the end of the study. One of the three wounds with high exudate levels improved during this time.

Periwound skin condition

HydroClean plus was used on patients with both healthy and damaged skin, and the condition of the surrounding skin was recorded at each dressing change. There was an increase in the percentage of patients with healthy periwound skin from 25% to 55%.

Pain and odour

Initially 95% (*n*=19) of patients were experiencing some degree of wound pain. This proportion had dropped to 35% (*n*=7) of patients at the end of the evaluation. The mean pain score, which was 2.5 at the start of the evaluation, had reduced to less than 1, with the number of patients taking analgesia dropping from nine to four.

Malodour was observed in 12 patients (60%) at the start of the evaluation, whereas at the end there were no malodorous wounds. This is an encouraging observation.

Patient and clinician satisfaction

Both clinicians and patients were highly satisfied with the way in which HydroClean plus performed on application, removal and during wear. Of the dressing applications, 92 (95%) were recorded as being easy. Of the remaining five changes, four were rated as average and one as difficult. The dressing was reported as conforming to the wound in 94 out of 97 instances. The difficulties reported in dressing application and conformity related to the patient self-treating a wound in a difficult-to-dress location.

Patients reported that the dressing was comfortable to wear at 99% (*n*=96) of dressing changes. The dressing stayed in place and was easy to remove in all 97 instances. None of the patients reported pain on dressing removal.

At the end of each evaluation, the clinician was asked to rate the overall performance of the dressing on the relevant patient, using a scale of 1 (poor) to 10 (excellent) against pre-set parameters. *Table 3* indicates the level of satisfaction, with the maximum score being 200. The scores were realistic, with ease of application and removal and maintaining a moist wound environment all achieving 197 out of a possible 200. Patient satisfaction and the ability of the dressing to manage exudate were slightly lower, but as they were still over 190 were acceptable.

Healing progression

Although the maximum evaluation period for HydroClean plus was 4 weeks, only five patients used the product for this length of time. None of the patients requested that the dressing be discontinued, so the decision to change the dressing was made on the basis of clinical judgement or patients being discharged from the service. At the end of the evaluation:

- Two patients (10%) had progressed to healing
- Fourteen (70%) were discharged or had progressed to other therapies
- One patient (5%) was lost to follow up
- Three patients (15%) continued to use HydroClean plus. This continued use was at their request because the dressing was comfortable and the patients could observe their wounds improving.

Cost–benefit analysis

The cost of care was estimated using a cost–benefit analysis for three health states. The price of dressings used were those already

Table 3. Overall satisfaction with dressing performance (maximum score = 200).	
Aspect of dressing performance	Rating given by clinician
Management of exudate	183
Maintenance of moist wound bed	197
Ease of application	197
Ease of removal	197
Patient satisfaction	192

available and listed in the *UK Drug Tariff*[27] or those proposed for reimbursement. Clinician time costs were those recommended by the Personal Social Services Research Unit[28], and time for dressing changes were based on those used by National Institute for Health and Care Excellence[26]. Using these times and costs, the following figures were estimated:

- 10% (*n*=2) of patients progressed to healing with a mean time to debride and achieve healing of 7.5 days, producing an overall cost saving of £87.78
- 10% (*n*=2) of patients reached 100% granulation tissue in the wound bed, and therefore total debridement of the wound had been achieved at a mean time of 5.5 days. As there was no previous cost of treatment for one patient, the cost of treatment was £37.68 more expensive when HydroClean plus was used; however as the patient was previously receiving no treatment, it could be assumed that the wound may have deteriorated and required treatment, which would have eventually incurred a cost
- In 35% (*n*=7) of patients, 80–99% of devitalised tissue was removed by the dressing, and this was considered to be a successful outcome[29]. The actual cost saving compared to standard treatment with this patient group was £289.52 overall or £41.36 per patient.

Discussion

The results of this 20-patient clinical evaluation suggest that HydroClean plus was effective in removing devitalised tissue from the wound bed, and in facilitating wound progression in the cases observed. The results also suggest that it may provide an alternative method of autolytic debridement to those currently in use, with a potentially faster mode of action. Within the evaluation, the mean time to debride to 100% granulation tissue for four patients in the study was 6.5 days. This compares favourably with other products used for debridement[29]. This is important for non-specialist nurses, who may not have access or the skills to undertake the speedier methods of debridement and rely on traditional products that promote autolysis.

HydroClean plus was highly acceptable to both clinicians and patients, who found it easy to apply and remove. All of the patients reported that it was comfortable on application, wear and removal, and it performed well with other supporting therapies relevant to managing complex wounds. Within the evaluation, a reduction in both pain and malodour was observed with use.

There were no adverse events in this evaluation, indicating that the product is safe for use by non-specialist practitioners. As a primary dressing product, it also performed well with a range of secondary dressings.

Although there are limitations to the cost-benefit analysis used, the data suggests that there are potential cost savings associated with using this dressing.

The dressing appeared to be 'moist' on presentation, but in use did not seem to increase the levels of exudate, negatively influence the frequency of dressing changes, or present a high number of episodes of strikethrough. It was used successfully on a small number of patients with diabetic foot ulcers, where the use of moist dressings is often discouraged[16].

Changes to the periwound skin were observed in some patients, which may have developed as a result of the high fluid content of HydroClean plus. The mode of action of the dressing where the wound fluid is diluted and the deleterious effects of Matrix Metalloproteases are absorbed into the superabsorbent particles within the dressing, would suggest that these are consistent with hyperhydration rather than maceration as described by Rippon et al[30].

Conclusion

This evaluation explored the outcomes when HydroClean plus was used on a small cohort of patients with varying wound types. Overall the outcomes were good, demonstrating that the dressing was effective at removing devitalised tissue, was comfortable for patients and easy to use. It also suggests that there may be potential cost savings associated with the use of this dressing because of the speed of debridement and reduction in clinical time, all of which merit further investigation.

The outcome of using this dressing, which the manufacturer suggests can cleanse–debride–absorb has stimulated a number of discussions into elements of treatment associated with the delivery of moisture to the wound. Further research into wound cleansing, and consideration of the benefits of hyperhydration need further investigation[30].

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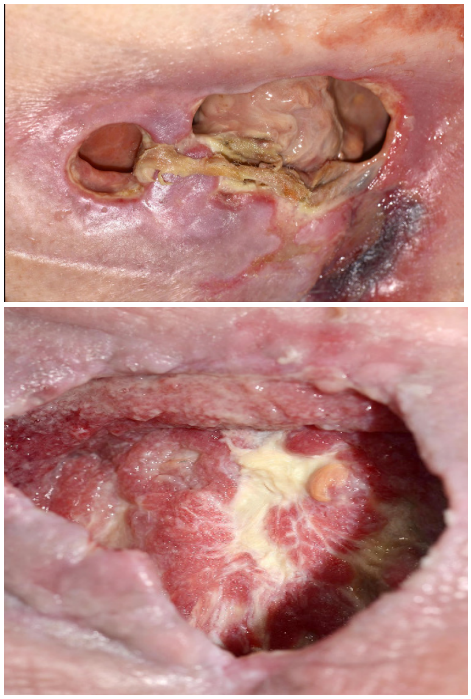
Case study 2: HydroClean plus when used as a cavity dressing on a grade IV pressure ulcer.



The patient was a 74-year-old female with a grade IV pressure ulcer. The wound had been present for 4 weeks and was extremely painful (scoring 4 on the Wong–Baker pain rating scale). On presentation the wound was malodorous with a high level of exudate, which resulted in maceration of the periwound skin (top).

Over a period of 9 days, HydroClean plus was used for three dressing changes. HydroClean plus was used under an adhesive foam dressing, which was used to secure it. At the end of this period, the wound bed was prepared and the full extent of the cavity could be assessed (bottom). The exudate level was low, there was no odour and the periwound skin was observed to be healthy. The patient was also pain free.

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