# Enabling wound healing and preventing limb amputation: a cost–benefit case study of Hydro-Responsive Wound Dressings

KEY WORDS
- Cost savings
- Devitalised tissue
- Hydro-responsive wound dressings
- Limb salvage
- Wound bed preparation

Diabetic foot ulceration can deteriorate to the extent that amputation is a likely clinical option. Ulceration and amputation have a significant impact on patient mortality and quality of life. This case study exemplifies how a patient with a large dorsal non-healing ulcer and a dehisced surgical wound/graft site was treated successfully with new hydro-responsive wound dressings (HydroClean® plus and HydroTac®). There were significant cost savings using hydro-responsive wound dressings (£261.38) in relation to standard wound care (£534.89), plus potential savings from preventing an above-knee amputation (£10,911.55). The potential for amputation is included as the patient was typical of individuals with poorly-controlled diabetes. The results of this case study are not generalisable, but they highlight the need for trial-based research into dressings used for diabetic foot ulceration.

MARY COOKE
*Lecturer, University of Manchester, Division of Nursing, Midwifery & Social Work. Manchester*

PAUL CHADWICK
*Consultant Podiatrist, Podiatry and Foot Health, Salford Royal NHS Foundation Trust*

SAMANTHA HAYCOCKS
*Advanced Podiatrist, Salford Royal NHS Foundation Trust*

MARK RIPPON
*Visiting Clinical Research Fellow, School of Human and Health Sciences, University of Huddersfield, Huddersfield*

SUE SIMM
*Clinical development manager, Paul Hartmann Ltd, Heywood*

Diabetes is a significant healthcare challenge. The new diabetes prevalence model, produced by the Public Health England National Cardiovascular Intelligence Network, estimates the total number of adults with type 1 and 2 diabetes in England to be 3.8 million, approximately 90% of which are type 2, characterised by insulin resistance (McInnes, 2012; Public Health England, 2016). Every year, the condition is associated with an estimated 70,000–75,000 deaths in England (15–16% of all deaths that occur annually), many of which are preventable (NHS, 2011). Diabetes accounts for approximately 10% of the NHS budget, 80% of which is related to complications such as blindness, kidney failure, cardiovascular and cerebrovascular disease, and amputation (Public Health England, 2016).

Diabetes-related foot complications have been identified as the single most common cause of morbidity among people with diabetes (Lim et al, 2017). Peripheral artery disease is a major contributory factor in the development of ulceration in diabetes, and its presence is a strong predictor of non-healing and amputation (Caruana et al, 2015; Lenselink et al, 2017). Surgical interventions such as popliteal bypass grafting have been shown to be beneficial in the treatment of peripheral artery disease in people with diabetic foot ulcers (DFUs) (Marso and Hiatt, 2006).

There are significant challenges in treating wounds associated with comorbidities, pathological changes, medication and poor glycaemic control allied with the impairment of cellular and biochemical mechanisms involved in wound healing in diabetes (Ackermann and Hart, 2013). Uncontrolled deformity, deep infection and/or ischaemia-hypoxia are associated with DFUs that are challenging to treat (Anderson and Hamm, 2014). High glucose levels impair various aspects of wound healing (Hu and Lan, 2016). It has also been shown that in primary closure of surgical wounds in high-risk patients, poor glycaemic control is significantly associated with worse outcomes (Endara et al, 2013) and surgical infection and dehiscence is commonplace (Janis, 2013).

Diabetes is a leading cause of amputation, with the NHS reporting that people with diabetes are more than 20 times more likely to undergo an amputation than the general population without diabetes (Kerr, 2017; NHS, 2017). Several key factors predispose to ulceration and amputation (Alavi et al, 2014):
- Neuropathy
- Circulatory problems
- Charcot foot
- Foot trauma
- Ulceration (for amputation).

**Table 1. Case study series inclusion and exclusion criteria***

| | Criteria |
|---|---|
| Inclusion | ▸▸ Patients with a diabetic foot ulcer<br>▸▸ Over 18 years of age<br>▸▸ Signed informed consent form<br>▸▸ Required removal of devitalised tissue as part of routine treatment |
| Exclusion | ▸▸ Under 18 years old<br>▸▸ Known allergy/hypersensitivity to any components of the dressing<br>▸▸ Will have problems following the protocol<br>▸▸ Severe underlying disease judged by the investigator to interfere with treatment |

*All patients signed an informed consent form before opting into the study.

Around 7,000 people with diabetes undergo leg, foot or toe amputations each year in England (Kerr, 2017; NHS, 2017) and it was recently estimated that the number of diabetes-related amputations has reached 135 per week in England (Diabetes UK, 2017). Many of these procedures are avoidable. Of the total number of patients admitted to hospital with a record of diabetes, 8.7% required ulcer care or amputation (Kerr, 2017). The presence of foot disease has been estimated to be associated with a 2.51-fold increase in length of hospital stay (Kerr et al, 2014) and ulceration has been associated with an 8.26-day increase in length of stay (Kerr, 2017).

Significant treatment costs are associated with the clinical challenges of treating wounds in patients with diabetes. A recent report commissioned by Diabetes UK estimates that in England in 2014–15, the NHS spent between £972 million and £1.13 billion on healthcare related to foot ulceration and amputation in diabetes patients; equivalent to 0.72–0.83% of the entire NHS budget (Kerr, 2017). Approximately £1 in every £140 spent in the NHS is being spent on DFU treatment, including amputation (Kerr, 2017). Around two-thirds of this expenditure is on care in primary, community and outpatient settings (Kerr, 2017; NHS, 2017). Any measures that can be undertaken to prevent amputation, reduce patient mortality and improve quality of life will have a positive and significant financial impact for the healthcare service provider.

This case study relates to the treatment of a patient with two wounds: a large dorsal non-healing ulcer and a dehisced surgical wound/graft site that was the result of a popliteal-pedal bypass. This particular case was chosen because it exemplifies the considerable clinical challenges (with probable amputation) that were overcome by using hydro-responsive wound dressings (HRWDs).

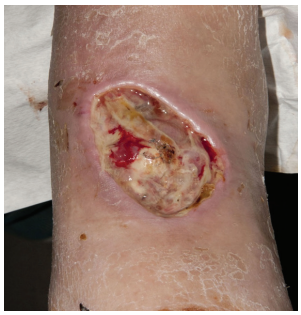
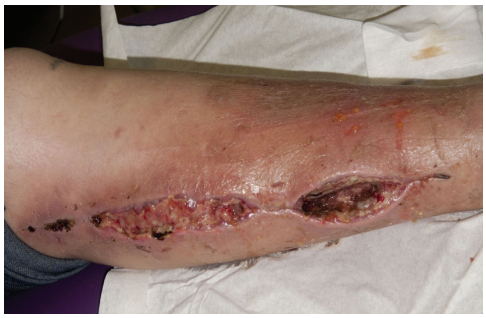
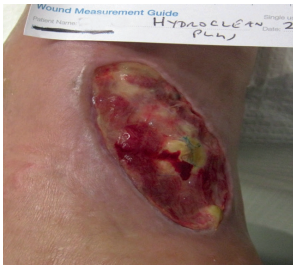
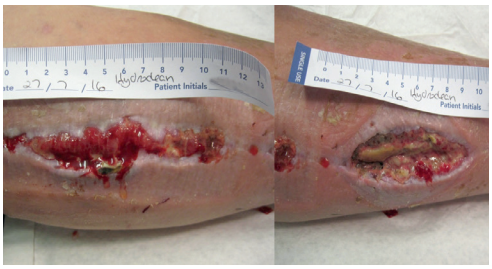
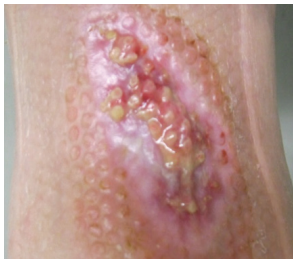
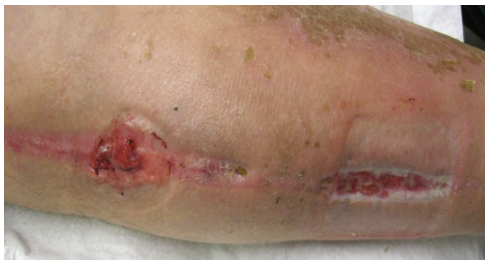
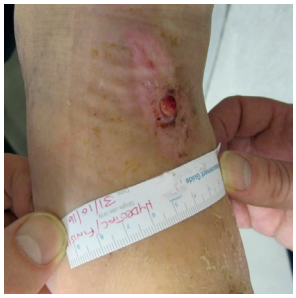
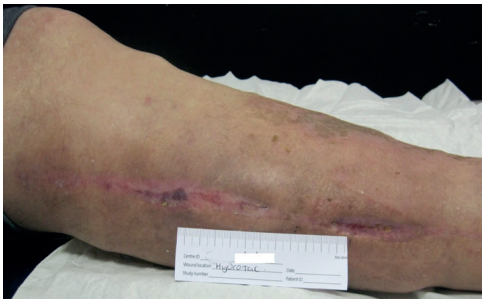
## HYDROTHERAPY

Wound management protocols and guidelines are useful tools to aid wound care practitioners in the delivery of effective wound care (Ousey et al, 2016a). HydroTherapy simplifies the choice of wound dressings by basing therapy around two complementary HRWDs: HydroClean® plus and HydroTac®. Together, these dressings provide a rapid wound cleansing action, promote healthy granulation tissue and sustain epithelialisation as part of a healing response (Ousey et al, 2016b).

HydroClean plus cleanses, debrides and absorbs by promoting an optimal level of hydration and maximising autolytic debridement processes at the wound site. The dressing comprises a soft and comfortable pad, which contains a hydro-responsive matrix at its core. Superabsorbent polyacrylate particles containing Ringer's solution form part of the matrix and provide continuous rinsing and absorption, supporting effective wound bed preparation. Ringer's solution is an isotonic salt solution balanced relative to the body's fluids that has been reported to have clinical benefits (Colegrave et al, 2016). Pre-activation of the superabsorbent polyacrylate with Ringer's solution allows for rapid and sustained cleansing of the wound bed (König et al, 2005; Humbert et al, 2014; Ousey et al, 2016c; Spruce et al, 2016).

HydroTac dressing is made up of a hydrogel wound contact layer that is covered by foam, with an air-permeable, water- and bacteria-proof film backing. The side of the dressing in contact with the wound features AquaClear Technology that actively releases moisture and increases growth factor concentration, leading to the stimulation of epithelial closure in a laboratory model system, and speeding up epithelial wound closure. (Ousey et al, 2016b; Smola et al, 2016).

**Figure 1. Treatment progression of the dorsal foot wound (left) and dehisced proximal leg surgical wound (right) with HydroTherapy**

| Dorsal wound (graft visible) | Dehisced surgical wound |
|---|---|
| Start of treatment with HydroClean plus (13/07/16) | |
|  |  |
| One week into treatment with HydroClean plus (20/07/16) | |
|  |  |
| Two weeks into treatment with HydroClean plus (03/08/16) | |
|  |  |
| By 5 weeks into treatment, HydroTac is started (21/09/16) | |
|  |  |

## CASE STUDY

The male patient in this case study was drawn from a case study series evaluation undertaken at a podiatry outpatient clinic in an acute NHS Trust. The inclusion and exclusion criteria for the study series are given in *Table 1*. HWRDs were used initially to remove devitalised tissue (HydroClean plus) and prepare the wound bed for the second phase, to support and enable re-epithelialisation (HydroTac). The patient agreed to complete a formal quality of life questionnaire as part of a more considered health economics investigation.

### Clinical history

The patient had a previous history of hypertension, atrial fibrillation and type 2 diabetes ($HbA_{1c}$ of 51 mmol/mol) with neuropathy, peripheral vascular disease and stage 5 chronic kidney disease. Between 2010 and 2017, his right fifth toe and left hallux were amputated. He then underwent a successful popliteal-pedal bypass to the right leg in 2015.

He presented to the podiatry team with a non-healing ulcer to left third and fifth metatarsal heads, with evidence of osteomyelitis He had recently had a popliteal-pedal bypass to the left leg, which had occluded. This resulted in an open medial leg wound due to surgical wound dehiscence (*Figure 1*, top right). He also had a large dorsal wound with visible vein bypass graft (*Figure 1*, top left). Arterial flow was described as 30% by a consultant vascular surgeon and the patient was warned about possible loss of limb should the wounds fail to progress.

### Wound treatment history

Over 33 weeks, the patient had been treated mainly with Activon® honey and Kerramax Care™ wound dressings. Subsequent to that, the patient was treated with a variety of wound dressings, with the primary surface contact ranging from Advazorb® or ALLEVYN Life® foam dressing, AQUACEL® Ag™ and ACTICOAT Flex®. Secondary dressings included Kliniderm®, Flivasorb® with fixation, yellow line K-Band®, K-Soft® and K-Lite®. Sharp debridement was performed on nine occasions, including the application of Prontosan® wound irrigation solution. Due to osteomyelitis, the patient was taking long-term co-amoxiclav 625 mg three times a day. The patient's peri-wound skin ranged from being slightly macerated-excoriated to

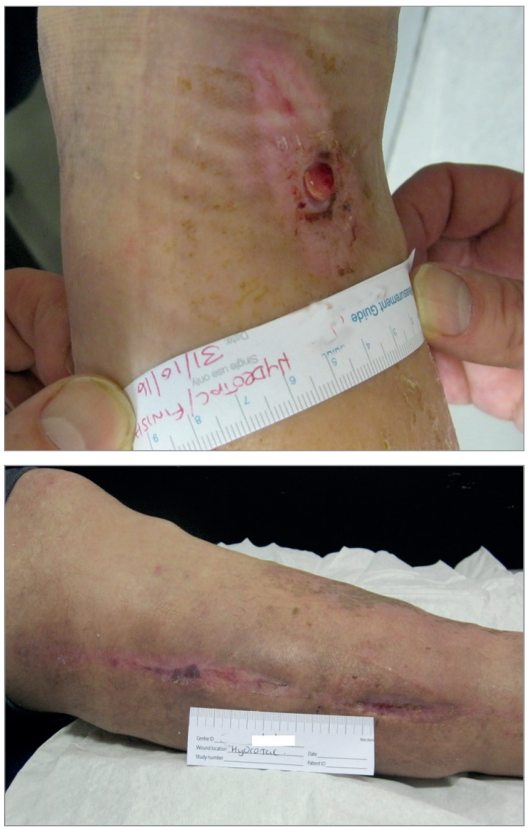


Figure 2. (a) The dorsal foot wound on 31/10/16 showing almost complete healing and (b) the dehisced proximal leg wound on 12/10/16 showing complete healing

very dry, so a range of skin care products were also used including Epaderm® 50/50, Sorbaderm® barrier cream and liquid paraffin.

### Quality of life

Neuropathy reduced the patient's pain level awareness to 'only slight' on most days. However, when he acquired cellulitis, his pain levels as measured on a visual analogue scale were raised to a score of 5–8.

The patient was reviewed by an external podiatry team on Mondays, on Wednesdays he was reviewed by the multidisciplinary team in the outpatient clinic and on Fridays the district nurses visited him at home. He often found attending appointments very tiring. His daughter would take him to the hospital appointments, which she did not mind doing, but they always had to ensure they were there early as the clinic got very busy very quickly. The patient stated that he lost a whole morning with each clinic visit (with some interventions taking up to an hour). The appointment was even longer on the occasions that he saw the multidisciplinary team for review.

### New treatment with HydroTherapy

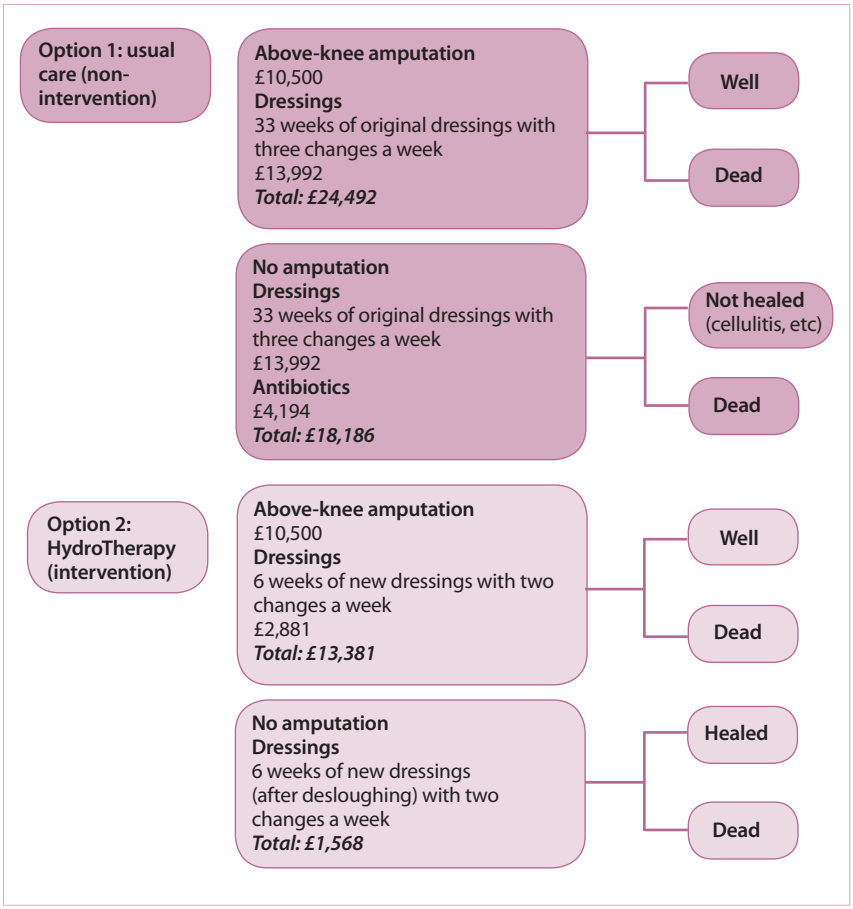
The patient was treated with HRWDs. HydroClean plus was successful in removing devitalised tissue (slough or eschar) that was present in the wounds. This was followed by the use of HydroTac, which supported re-epithelialisation and enabled progression of healing *(Figure 1)*. *Figure 2* demonstrates the remarkable progress of these wounds in terms of healing. More importantly, however, limb amputation was avoided.

## HEALTH ECONOMICS OVERVIEW

Cost-effectiveness analysis (CEA) is an alternative to cost–benefit analysis (CBA). CEA is useful when analysts face constraints that prevent them from conducting a CBA (Hill, 2012). The most common constraint is the inability to monetise benefits due to lack of data. While CEA has been widely applied for project analysis, its application has varied widely and quality can be poor unless randomised controlled trials are used. Healthcare professionals can only apply published CEA results when policy and service commissioners agree on the evidence base of the specific intervention. Consistency in research results is often lacking, hence decisions for many high-cost interventions are made by referral to the National Institute for Health and Care Excellence (NICE).

Here, a single case study was used to frame a basic CEA of a specific dressing process for a complex DFU and was compared with standard care that had already been supplied. A decision analysis model *(Figure 3)* was adopted to compare the specific outcomes of usual care and HydroTherapy, both with the potential to lead to amputation and death. Due to limited datasets, no further depth of analysis was possible (normally a randomised-controlled study provides data from at least 100 cases that can be sampled). The costs of treatment

**Figure 3. Cost analysis of diabetic foot ulcer treatment for original dressings (usual care) versus HydroTherapy treatment at the entry point**




are in monetary units and the results in non-monetary units, such as the healing outcome. The comparison is an expression of the CEA. The technique compares the relative costs to the outcomes (effects) of two or more courses of action.

Data were identified and anonymised from the patient's case history notes by clinical staff responsible for the case. Only direct NHS costs were collected. These comprise consumption of resources resulting from a treatment or therapy and are all directly attributable (e.g. diagnosis, drug therapy, medical care, inpatient treatment, etc.). Indirect (non-medical) costs (e.g. transport costs, patient expenditure, etc.) were not included, and neither were intangible costs (discomfort or pain). Opportunity cost was not calculated. This is a hybrid case where cost-effectiveness is merged with cost–benefit using the monetary value of the intervention, bearing in mind the potential for cost minimisation demonstrated by the outcome.

## Cost identification

A comprehensive retrospective analysis of the direct costs of treatment of both wounds was undertaken related, but not limited, to:

- Wound treatment — primary dressing, secondary dressing, fixation, ancillaries, debridement, exudate management, compression
- Medication — pain, infection
- Peri-wound treatments — skin creams, skin barriers
- Identification of the level of nurse delivering treatment, podiatrist and consultant interest (Smith et al, 2005).

Clinical outcomes at each assessment and at the final stage were also recorded. The unit used for the measurement of activity was 1 week. Where shared value is recorded, it is one part of an hour per week where, for example, a consultant intervention for outpatient debridement was included.

The case study provides an opportunity to consider the comparative effectiveness and costs of a specific wound dressing intervention compared with usual care or best supportive care. Normally, calculations for CBA use economic statistics to infer specificity, pooled sensitivity and even probabilities. These are not available here, and a single case cannot be weighted as in CBA because this individual may not be typical of a wider population. In studies with large datasets, modelling for complexities of diabetes requires a large cohort of patients in order to consider the opportunity costs, and possibly cost utility of the wellbeing gained by a sample from a range of alternative interventions. Thus, this evaluation provides only a simple basic probability of an outcome where two options are compared (intervention and non-intervention).Amputation is used as an alternative outcome to calculate total expected outcome (cost) and predict the probability cost and outcome of these comparative dressings used in sequence, see *Figure 3.*

**ACKNOWLEDGEMENT**

*This study was supported by Hartmann Ltd.*

**Table 2. Cost comparisons for usual care and HydroTherapy, with costings for amputation included**

| | Option 1: Cost of usual care (£)‡ | Option 2: cost of HydroTherapy (£)† | Cost of above-knee amputation (£) |
|---|---|---|---|
| Dressing materials (average) | 263.47 | 113.95 | 113.95 |
| Dietician (0.5 hour) | 36.81 | 36.81 | 36.81 |
| District nurse home visit (0.5 hour) | 45.00 | N/A | 45.00 |
| District nurse, outpatient clinic (1.0 hour) | 73.81 | 73.81 | 73.81 |
| Consultant, outpatient clinic (0.3 hour) | 31.36 | N/A | 31.36 |
| Podiatrist, outpatient clinic (0.5 hour) | 36.81 | 36.81 | 36.81* |
| Physiotherapy | N/A | N/A | 73.81 |
| Surgical amputation | N/A | N/A | 10,500 |
| Antibiotics (weekly) | 13.16 | N/A | N/A |
| Non-surgical debridement procedure (0.25 hour per week) | 34.20 | N/A | N/A |
| Total cost over 1 week | 534.89 | 261.38 | 10,911.55 |
| Cost over 33 weeks | 18,186.26 | 8,625.54 | 124,492.70 |
| Cost over 6 weeks | 3,208.14 | 1,568.28 | 13,380.85 |

‡See wound treatment history; †HydroClean plus followed by HydroTac; *Podiatrist clinic visit for remaining foot

The patient received 33 weeks of 'usual care' dressings and de-sloughing treatment interventions, including antibiotics for a series of osteomyelitis infections, some episodes of which led to cellulitis. There was monthly non-surgical sharp debridement of the wound, supported by two visits each week to the outpatient clinic for a variety of dressing changes and a weekly home visit for further dressing interventions. Despite usual care, the wounds had not healed. After cleansing at 33 weeks, a post-progression dressing (HydroClean plus) was introduced to topically de-slough the wound. Non-surgical debridement was rapid, and HydroTac was used after 5 weeks. Healing took 6 weeks. A cost comparison is given in *Table 2*. It is not possible to consider the cost minimisation analysis, because there were different outcomes over differing time scales (Claxton, 1999; Smith et al, 2005).

## Results

It is unlikely the data from an individual can be applied using a dressing that has not been scientifically compared in a trial where the outcome would provide sufficient data to indicate net gain from the treatment intervention (Claxton et al, 2002) so we are unable to provide quality-adjusted life years as an outcome (Hayes et al, 2016). Allowing for the potential for cost and effectiveness of this dressing, we used an assumed calculation of 10 years gained as the effectiveness measure for a quality-adjusted life year. The lowest Effectiveness Cost ratio/life saved value (related to HydroTherapy) illustrates the best outcome of cost and effect (*Table 3).* At 6 weeks, the usual care costs almost twice that of HydroTherapy, but the opportunity for success remains similar. The variations in dressing technique, thrice weekly service use and monthly non-surgical debridement raises long-term opportunity costs, few discounts and the risks of sequential infections. Added to these outcomes, societal effects include a higher risk of eventual amputation; both usual care and amputation attract poor quality of life scores and opportunity costs. Amputation (which was a real alternative in the case of the patient) was by far the most costly option. The impact of such an outcome on quality of life is always significant and this intervention would not have reduced mortality significantly.

## CONCLUSIONS

HydroTherapy using HydroClean plus and HydroTac was effective in removing devitalised tissue, reducing cellulitis and promoting healing, supporting limb salvage in this case study. In his own words, the patient is 'enjoying life'. He obviously still gets worried about his leg but 'it's all healed [...] the leg wound and top of the foot is no bother now. I can go bowling, which I do now nearly every afternoon in the Summer and I also like fishing which I can do again now.'

HRWDs were cost neutral compared with standard care dressings and treatment was more successful in a shorter period of time in this case. In patients with $HbA_{1c}$ 51 mmol/mol and a DFU with low exudate levels that does not need

**Table 3. Cost-effectiveness at 6 weeks to determine relative cost and effect**

| | Option 1: Cost of usual care (£)[‡] | Option 2: cost of HydroTherapy (£)[†] | Cost of above-knee amputation plus dressings (£) |
|---|---|---|---|
| Cost measure | 3,208.14 | 1,568.28 | 10,000 + 2,880.85 = 13,380.85 |
| Effectiveness measure/ life saved | 10 | 10 | 10 |
| CE ratio cost/life saved | 320.80 | 156.80 | 1,338.00 |
| Effectiveness Cost | 5.67 | 5.5 | 8.2 |

[‡]See wound treatment history; [†]HydroClean plus followed by HydroTac

debridement, HRWDs are therefore a viable treatment option. In this instance it was calculated that there were significant reductions in costs, as the routine cost of standard care equated to £543.89 compared to £261.38 for HydroTherapy. The costs that might have arisen from an above-knee amputation were also saved. WUK

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