Evaluation of the sequential use of products embedded into a structured care pathway for leg ulcer management

KEY WORDS
- Chronicity
- Improved patient outcomes
- Leg ulceration
- Pathways of care
- Reduced healing time

Leg ulceration is one of the most studied areas of wound care (Chapman, 2017) and the cornerstones of care focus on adjusting or addressing lifestyle choices associated with diet, exercise and limb elevation, skin care, compression therapy and removing any barriers to healing. The vision of the NHS for the next five years is for clinicians to encourage self-care, establish best practice and to standardise care provision to reduce unwarranted variation (NHS England, 2017). This paper presents the findings from a pathway-driven ten-patient evaluation, which used pre-defined wound care products alongside a clearly laid-out wound care treatment plan.

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The cost of wound care to the UK economy has been estimated at £5.3bn per annum (Guest et al, 2015). Leg ulcers are one of the most prevalent wound types experienced by patients. The care of leg ulcers consumes £2bn of the £3bn per annum spent on chronic wounds (Guest et al, 2017) and the largest cost is associated with nursing time. Despite this, healing rates from audit data suggest that as few as 50% of patients heal at one year (Guest et al, 2017). Guest et al (2017) predicted that an average clinical commissioning group, which managed around 15,000 wounds in 2015/2016, will need to manage 25,000 wounds by 2019/2020. This added burden will impact on the lives of patients and caregivers and pose an extra financial strain on the NHS. However, increasing healing rates by 6% per annum will halt growth and in turn reduce expenditure. Clinicians now have more choices than ever with regards to available compression systems and wound management protocols, due to advances in technology and knowledge of wound healing. However, it can be difficult for practitioners to make their choices based on the best available evidence. This paper presents the findings from a pathway-driven ten-patient evaluation, using pre-defined products as opposed to leaving room for local interpretation.

METHOD

This evaluation study used a non-comparative case series design. Ten patients with leg ulcers were recruited following the screening of the caseloads from eight district nursing teams. *Box 1* lists the inclusion and exclusion for participation. The district nurses identified patients that met the required criteria and made the initial approach. The community research team followed up with a visit to discuss the evaluation once the patient agreed to take part. Potential participants were given an information sheet and as much time as they required to decide if they wished to take part. Informed consent was taken for individuals that wished to proceed.

All study participants had leg ulcers and were suitable for the application of compression bandages that provided reduced or full compression (20–40 mmHg). The evaluation focused on the effectiveness of using URGO medical products sequentially to manage infection, deslough and reduce healing time. The products were UrgoClean Ag, UrgoClean, UrgoStart and UrgoKTwo/ UrgoKTwo Reduced. Participants had either venous or mixed aetiology leg ulcers with signs of local infection, slough and or granulation in the wound bed. Where the participants had several wounds, one was selected as the reference wound. The evaluation period was up to a maximum of 12 weeks. Dressing changes were performed by the community research team during the evaluation,

Box 1. Inclusion and exclusion patient criteria

Inclusion criteria:

- Male or female, aged ≥18 years old
- Any patient considered suitable for compression bandaging
- Any wound type suitable for application of Urgo dressing products
- Ability to follow verbal and written instructions in English
- Ability to give written informed consent to participation and medical photography for third party use
- Patients who have been assessed and ABPI recorded within 6 months of study commencement

Exclusion criteria:

- Known allergy/hypersensitivity to the dressing
- Participants who will have problems following the protocol
- Those people who lack capacity
- Patients with an ABPI recorded >6 months (reassessment will be required)

Box 2. Baseline data collected

Baseline measures:

- Start date, care setting, gender, age, medical history, current medications, wound diagnosis
- Condition of wound bed (% epithelialising, % slough, % granulation tissue, % necrosis)
- Wound location, wound duration
- Wound size (cm)
- Peri-wound skin condition (healthy, inflamed, dry/flaky, macerated, non-blanching erythema, other)
- Level of exudate
- Indicators of local/systemic infection
- Previous wound management products (primary, secondary, retention, compression)
- Wound photograph prior to the first test
- Dressing application as per manufacturer's standard procedures
- First dressing application details: Type of dressing, use as primary or secondary dressing, ease of application, and other concurrent wound treatment products (ointments, topical treatments, emollients, anti-fungal, other). Dressing change log measures
- ABPI

At each subsequent dressing changes:

- Dressing characteristics (type, size)
- Date of dressing change
- Reason for dressing change
- Wound photograph with dressing in-situ and no dressing according to the manufacturer's standard procedures
- Dressing removal discomfort (via 10-point VAS anchored by extreme intensities "no pain to worst pain possible")
- Ability of the dressing to stay in place
- Level of exudate
- Peri-wound skin condition (healthy, inflamed, dry/flaky, macerated, non-blanching erythema, other)
- Wound size (cm)
- Condition of wound bed (% epithelialising, % slough, % granulation tissue, % necrosis)
- Wound status change from previous dressing change (improved, unchanged, deteriorated)
- ABPI

all of whom had previous tissue viability training. The frequency of dressing changes was determined by clinical need. All patient visits were recorded on a standardised data collection form, completed at each dressing change and photographs were taken with the dressing *in-situ* and without a dressing. *Box 2* shows the data and outcome measures collected.

RESULTS

The evaluation recruited 11 patients; one patient was lost to follow up following a non-related emergency admission to hospital soon after recruitment. No data is shown for this patient. This section shows the results of the ten patients who completed the 12-week evaluation or healed and exited the evaluation during the 12-week period. Notable characteristics are shown in *Table 1.*

Key points at enrolment, the patients' age ranged from 66 to 89, five male and five female participants provided written consent, the ankle to brachial pressure index (ABPI) ranged from 0.66–1.07, only one of the participants was not in compression prior to participation in the study. Of the 10 patients, four had venous ulceration and six had mixed aetiology ulceration. The volume of wounds ranged from 72 cm^3–12,500 cm^3. The duration of the wounds ranged from 8–184 weeks (median 60 weeks); only three patients had the wound for less than 6 months at enrolment *(Table 2).* Using the Any Qualified Provider Definitions as described by Dowsett and Elson (2013), all ulcers would have been referred to as complex when considering patient comorbidities, the duration of the wounds and the wound size at enrolment *(Box 3).*

Wound sizes were recorded weekly and volume reduction calculated for each patient. Volume reduction for each patient is shown in *Table 2.* Wound volume reduction greater than 40% at 4 weeks is seen as a prognostic indicator of healing (Meaume et al, 2005). The pathway of care followed best practice guidance for leg ulceration in that all patients received compression therapy (O'Meara, 2012; Harding et al, 2015). Patients with >30% slough in the wound bed at enrolment had UrgoClean applied as a primary contact layer to facilitate desloughing; patients with signs of critical colonisation and devitalised tissue had UrgoClean Ag applied; those with less than 30% slough had UrgoStart applied. Despite the duration of the wounds,

Table 1. Participant characteristics at enrolment	
Gender	5 male / 5 female
Age	Range 66–89
Diagnosis	4 venous / 6 mixed picture ulceration / arteriovenous
Comorbidities	3 diabetes, 6 PAD, 2 rheumatoid arthritis, 1 patient neuropathic
Medications	All patients were taking at least one medication at outset – 3 patients taking medications that would affect healing – none were taking antibiotics at the outset of the evaluation and none were commenced any during the 12-week period
Wound duration	Range 8–184 weeks (average 57.3 weeks)
ABPI	Range 0.66–1.07
Range Tissue Type at enrolment	Slough 20–80%, granulation 0–80%, necrosis 0%
Volume in mm³ at enrolment	Range 72cm³ to 12,500 cm³
Exudate level	6 low, 4 moderate levels
Pain score	6 patients reported no pain; of the 4 who did, scores ranged from 2–5 on a Likert scale (0=no pain to 10=worst pain)
Products previously used	PICO, Profore, Coban Full and Reduced, Andoflex, UrgoTul, Flaminal, Tegaderm Alginate ag, Aquacel
Emollients	Hydromol
Topical corticosteroids	1 patient using a moderately potent steroid for eczema
Evaluation treatment at commencement	5 patients started treatment in UrgoClean and 5 in UrgoClean Ag Accompanied by 4 in UrgoKTwo Reduced and 6 in UrgoKTwo dictated by the ABPI at enrolment

Table 2. Wound chart

Patient number	Duration at enrolment	Aetiology	Volume in cm at enrolment	Volume in cm at week 4	Reduction (%) at week 4	Volume in cm at week 12 or week healed	Reduction (%) at week 12 versus baseline
1.01	40 weeks	Venous	7.2	1.8	75%	1.0	86%
1.02	68 weeks	Mixed	8.0	6.46	20%	375.0	53%
1.03	184 weeks	Venous	15.0	6.3	58%	0.6	96%
1.04	8 weeks	Venous	32.0	Healed	100%	N/A	N/A
1.05	120 weeks	Venous	448.0	367.5	18%	280.0	48%
1.06	14 weeks	Mixed	40.0	27.0	32.5	Healed	100%
1.07	52 weeks	Mixed	426.4	245.0	43%	90.0	79%
1.08	60 weeks	Mixed	75.0	8.0	90%	8.0	90%
1.09	16 weeks	Mixed	1250.0	240.0	80%	Healed	100%
1.10	60 weeks	Mixed	90.0	Healed	100%	N/A	N/A

seven patients had >40% volume reduction at 4 weeks (range 18–100%). Additionally, Patient 10, with a mixed aetiology of 60 weeks, healed at week 3 and Patient 4, with a venous ulcer of 8 weeks, duration healed at week 4. At the end of the evaluation four patients had healed, the wound duration of these patients ranged from 8–60 weeks (median 15 weeks) and volume at enrolment ranged from 32–1,250 cm³. The aetiology of the healed patients was mixed (3) and venous (1) healing for these patients occurred at week 3, 4, 11 and 12. At the end of the evaluation period, eight patients had greater than 75% wound reduction compared to baseline measurements. One venous patient and one mixed patient with 68 and 120-week duration reduced by 53% and 48% wound reduction respectively. Given the patients' collective comorbidities and wound duration at enrolment, their wounds at the outset would have been predicted as being slow to heal. Both had bilateral ulceration, one patient's ulceration was in the sub-malleolar region and the other greater than 10 cm². However, Patient 1.01, 1.03 and 1.07 also had complex wounds and comorbidities yet their wounds, whilst not healed, responded well by way of volume reduction and symptom management

Box 3. Any qualified provider definitions

Simple

- Venous leg ulcer with ABPI >8 and <1.3
- Wound area <100 cm^2
- Ulcer present for <1 year at first presentation to the service

Complex

- Venous leg ulcer with ABPI >8 and <1.3
- Wound area is >100 cm^2
- Patient has lymphovenous disease
- Ulcer infected and/or patient has history of recurrent infection
- Patient has elevated protease activity (measured using a recognised diagnostic tool)
- Patient has a history of non-concordance
- Wound has failed to reduce in size by 20–40% despite best practice at 4 weeks

during the evaluation. The pathway for Patient 1.07 is shown pictorially in *Figure 3*. *Figure 4* shows the progression of two of the patients that healed (Patient 1.09 and Patient 1.10).

Patient feedback was collected at each dressing change, all patients found the bandages and dressings comfortable during wear time. The patients particularly liked having regular updates about progress and enjoyed looking at images of the wound; they looked forward to being given reports of volume reduction. At the end of the study, they all expressed an interest in continuing with their treatment plan. None of the patients exited the study by choice. Patients valued the small team of nurses involved in their care, communication between team members was good and timely, and every visit documented the care provided and progress made. A paper data collection tool was used to document the wound metrics, making it easy to determine progress or deterioration. This enabled real-time feedback to patients, adding to their satisfaction and compliance.

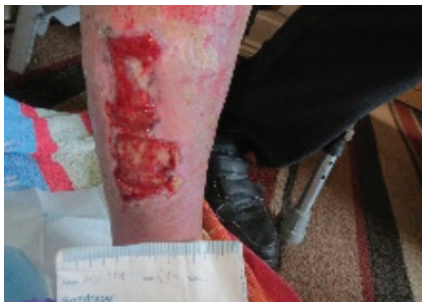
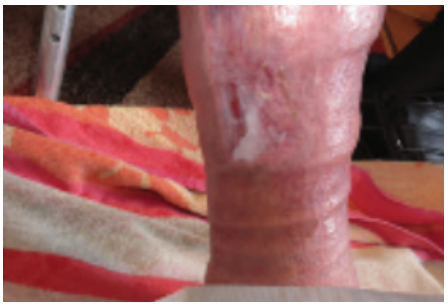
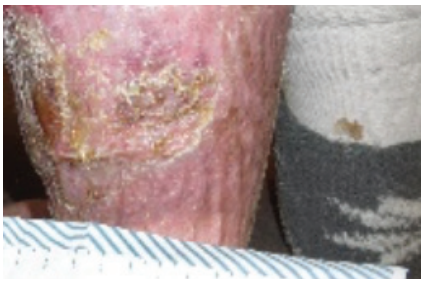
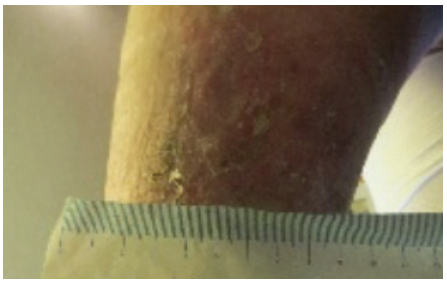
Some patients moved from UrgoStart to UrgoClean or UrgoClean Ag to UrgoClean and then UrgoStart. Some of the patients' wounds deteriorated on initial transition to UrgoStart, which was put down to local covert infections that resolved with the application of UrgoClean Ag. These patients were transitioned back to UrgoStart once local signs of wound infection had resolved. No patient had systemic antibiotics during the 12-week evaluation. Eight patients exited the study in UrgoStart (Patient 1.05's wound remained too sloughy and Patient 1.06's wound healed at week 11). The patients who healed during the evaluation have remained healed since the transition to hosiery.

DISCUSSION

Last year saw a change in wound care with the introduction of Betty's Story (NHS England, 2017) that focused on the reduction of unwarranted variation. This year, the Legs Matter Campaign is raising further awareness about leg and foot-related problems (Legs Matter! 2018). Pathways of care have long been purported the saviour of modern healthcare (Panella, 2003; NHS England, 2016), however, the NHS remains data rich and information poor with metrics and healing rates difficult to obtain easily (Guest et al, 2017). Feedback from local teams suggests they want easily accessible information on one page that signposts them to what to do, inclusive of product-specific advice. In other words, they want pathways to be evidence-based and access to clearly signposted step-by-step instructions, including what products to use. This is unsurprising given the backdrop of roughly 1,000 unique products available on drug tariff (NHS Business Services Authority, 2018). Most settings have wound management formularies and

Figure 3. Pathway for patient 1.07

Figure 4. Healing trajectory for patients 1.09 and 1.10

Patient	Enrolment	Healing
1.09		
1.10		

associated advice, however, most shy away from prescribing a specific product.

The Urgo pathway mimics part of the pathway used in the randomised controlled trial (RCT) CHALLENGE, which used UrgoStart on leg ulcer patients (Meaume et al, 2012). This unique double-blind RCT showed that UrgoStart, in conjunction with compression therapy, accelerated the healing of venous leg ulcers as compared to neutral dressings. The study also showed that the UrgoStart dressings significantly improve patient's quality of life, especially reducing their anxiety and pain (Meaume et al, 2012; Meaume et al, 2017).

During the evaluation some patients' wounds deteriorated upon transition to UrgoStart; novice practitioners might be put off if wounds deteriorate. However, the team found it a good indicator of underlying subclinical infection. The two patients (Patient 1.05 and 1.06) that exhibited signs of covert infection post-commencement saw symptoms quickly resolve with the use of the UrgoClean Ag. After four dressing changes, or between 10 days and 2 weeks, the patients recommenced UrgoStart. This would align with emerging evidence on biofilm and its role in wound chronicity (Bianchi et al, 2016). As such, any pathway needs to have this element of care considered. Patient 1.04 healed at week 4, while still on Urgo Clean, so there was no need to transition him. Patients who were enroled towards the end of the study transitioned into UrgoStart sooner, as clinicians' confidence in the product grew. On reflection, some earlier patients could have made this transition sooner but, initially the team were under the impression that it could only be used on a clean wound bed as opposed to one with <50% devitalised tissue. The pathway focused on a handful of products, chosen based on the needs of the enroled patients (i.e. venous patients received full compression and mixed aetiology patients received reduced compression). Differing local wound symptoms were addressed by the primary contact product, using the clinical findings to inform choice at each dressing change. The pathway enabled clear communication between the professionals involved and the patient and specialist teams. Wound assessment, notably wound measurement and wound bed descriptors (expressed in % values), facilitated early detection of deterioration and was used to prompt changes in local wound management strategies, using the chosen products interchangeably in a sequential manner, but being free to move both forward and backwards along the continuum dependent on patient symptoms led to the results demonstrated in *Table 2*.

Care should be taken when trying to generalise

this data and making it available to wider community teams. It should be noted that the community research team had immediate access to specialist advice and review from the lead nurse for tissue viability, who was the lead investigator on the study. That said, no patient deviated from the pathway during the evaluation and all tolerated the Urgo products.

CONCLUSION

The use of a sequential use of products – UrgoClean to manage desloughing, UrgoClean Ag to manage local signs of infection and UrgoStart to promote neovascularisation and reduce barriers to healing associated with high levels of matrix metalloproteinases – alongside optimising patient compression with bandaging, led to volume reduction in all patients during the 12-week evaluation and healing of four patients. The community research team found the pathway easy to follow and the patients reported the dressings to be comfortable. Those that had not healed at the end of the evaluation expressed a wish to continue with the therapies. Reducing variation in leg ulcer care is a priority for 2017 (NHS England, 2016; 2017). Given the burden of wounds (Guest et al, 2015) and the associated costs per CCG (Guest et al, 2017), reduced healing time must be a priority not only from the health economic perspective of payors, but more importantly from a patient's perspective. Evidence in leg ulcer care demonstrates that if patients are being diagnosed early and start appropriate intervention, they are more likely to heal (Dowsett and Elson, 2013). Patients do better in specialist care (Guest et al, 2017), however, there is a finite resource. As such, we need simple, effective ways of managing patients prior to patients reaching chronicity. This entails either equipping staff with the knowledge and skills to enable them to make informed wound care decisions, or setting red flags and simple pathways that direct care and are flexible enough to meet the changing wound dynamic. This pathway enabled this degree of autonomy based on clinical findings. WUK

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