

Venous leg ulcer management: single use negative pressure wound therapy

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Venous leg ulceration (VLU) affects a significant proportion of the patient population with prevalence estimates ranging from 1.48/1000 patients (Moffatt et al, 2010) to 0.48/1000 (Callam et al, 1985). Venous ulcers are often complicated in relation to chronicity, exudate levels, likelihood of infection and incidence of recurrence. Venous ulcers often stem from failure of valves within the lower limbs and calf muscle pump insufficiency. This leads to stasis of the blood in the venous system and will eventually result in venous hypertension (Partsch, 2007). Changes in the circulation caused by this hypertension may lead to localised ischaemia and changes in the appearance of the skin. The skin is more susceptible to damage and when damage occurs, ulceration may follow due to the underlying circulatory issues.

As with all clinical conditions the cornerstone of treatment for patients with VLU begins with accurate

assessment and diagnosis (Dowsett, 2005). Once patients have been assessed as having venous insufficiency, by careful history taking and the patient's ankle brachial pressure index (ABPI) measurement, compression therapy should be the primary treatment offered.

The aims of graduated compression therapy are to provide pressure of 40 mmHg at the patient's ankle, reducing to approximately 17 mmHg at the knee. The action of these bandages will reduce pressure in the superficial veins, assist venous return towards the heart and reduce oedema in the limb (Moffatt, 2004).

Partsch (2007) outlines the benefits of compression as:

- ◆ Accelerating blood flow in the venous system
- ◆ Improving the function of valves and reducing reflux
- ◆ Moving blood into the central components of the body
- ◆ Improving the venous pump by compressing the calf muscle.

Multilayer (principally 4-layer) compression systems were developed in order to maximise the therapeutic benefits of elastic compression on the limbs of patients with venous disease (Moffatt 2004). There are now a number of compression systems available which allow for better patient choice and which may influence patient concordance with the chosen therapy. Systems available include:

- ◆ Two layer bandage systems
- ◆ Short stretch inelastic systems
- ◆ Modified compression (elastic) three layer systems
- ◆ Compression hosiery

Non healing venous leg ulcers

The gold standard treatment for venous leg ulceration is the use of multilayer compression bandaging, which for many patients is a successful treatment (Moffatt et al, 2004). However, for some patients, their leg ulcer will not heal even when compression therapy has been applied. In one study, 12.7% of patients did not respond to compression therapy, indicating that for a significant group of patients,

ABSTRACT

A number of leg ulcer specialist/tissue viability specialists from across the UK were invited to evaluate PICO (Smith and Nephew, Hull) as a treatment for venous leg ulcers also in conjunction with a variety of compression bandages and garments. Patients across 5 sites had PICO applied in conjunction with compression therapy. This group of treating clinicians were then asked to give feedback on the outcome of the patients on whom they had used the new device. All feedback was recorded at a meeting and this was used to create a guideline for use.

KEY WORDS

Venous leg ulcer ◆ non-healing ◆ compression therapy ◆ negative pressure wound therapy (NPWT) under compression

there may be a need for adjunctive therapies to assist in the healing process (Milic et al, 2010). Static or non-healing leg ulcers may have underlying pathology which is causing them not to heal, for example infection may be a factor, the presence of lipodermatosclerosis and/or poorly functioning calf muscle pump due to fixed ankle and reduced ankle mobility (Moffat et al, 2010; Milic et al, 2010).

Many patients with venous leg ulcers will have other co-morbidities that may contribute to slow healing, such as obesity, anaemia, diabetes, cardiovascular disease and lymphoedema.

In addition to underlying disease processes there are a number of extraneous variables which can impact on ulcer healing; poor assessment skills, poor bandaging technique

and lack of specialist services may all have a role to play.

Non-healing may also be related to non-concordance with the therapy, possibly due to the patient's lifestyle and more importantly pain may be an issue when compression is used.

Negative-pressure wound therapy in treatment of VLU

Negative pressure wound therapy (NPWT) has been shown in both acute and chronic wounds to improve local perfusion, improve granulation tissue formation, manage exudate and reduce oedema (Argenta and Morykwas, 1997). Veurstaek et al (2006) trialled the use of negative-pressure wound therapy on 60 venous leg ulcer patients,

Table 1 Evidence-based recommendations for the use of NPWT in venous leg ulcers (Vig et al, 2011)

Treatment goal	Recommendation	Grade (A-D)	Evidence level (1-4)
Primary goal: to achieve wound closure	If first line therapy (compression) is not efficacious, NPWT should be considered to prepare the wound for surgical closure as part of a clinical pathway	B	L1
Treatment variables	Use of gauze may be considered to reduce pain during dressing changes in susceptible patients	C	L1 L3

Table 2. Criteria for identifying simple and complex venous leg ulcers (Department of Health, 2012).

Criteria for inclusion in Care Pathway 1 – Simple venous leg ulcers

- Venous leg ulcer(s) with ABPI greater than 0.8 and less than 1.3
- Wound area is less than 100 cm²
- Ulcers will not have been present for more than 1 year

Criteria for inclusion in Care Pathway 2 – Complex venous leg ulcers

- Venous leg ulcer with ABPI greater than 0.8 and less than 1.3
- Wound has been present for more than 1 year on first presentation to the service
- Patient has Lymphovenous disease (in some circumstances this comorbidity will not necessarily result in a classification of complex and will be agreed with providers/local health economy)
- Patient has current infection and/or has history of recurrent infections
- Patient has elevated protease activity (measured with a recognised diagnostic tool)
- Wound area is greater than 100 cm²
- Patient has history of non-concordance
- Wound has failed to reduce in size by 20 - 40% despite best practice at 4 weeks

After four weeks of treatment, a decision will be finalised as to whether the patient will require a simple or complex pathway of care. This decision must be recorded in the notes and the referrer given a detailed explanation of the care plan and decision on why the patient has been categorised as simple or complex. The provider will then continue with the treatment plan until the wound is healed. (DH 2012, www.supply2health.nhs.uk)

and found a decrease in wound bed preparation time of 7 days compared with 17 days in the control group, and complete healing times of 29 versus 45 days. The authors of that study also concluded that the shorter healing times lead to reduced treatment costs compared with standard wound care regimes in complex venous ulceration.

Kieser et al (2011) studied the leg ulcers of 7 patients (12 ulcers) who had been receiving compression therapy but had shown little or no improvement in their ulcer status during this time. Negative-pressure wound therapy was used in conjunction with 4-layer compression bandaging to investigate any potential improvement in the ulcer status. The authors found that using NPWT increased the amount of granulation tissue and an initial reduction in ulcer surface area. Kieser et al (2011) conclude that short term NPWT may be a useful therapy to improve healing in non-healing or refractory leg ulcers.

In 2011, an expert panel (Vig et al, 2011) examined the literature on the use of NPWT in patients with venous leg ulceration and reached consensus on the use of NPWT in venous leg ulcer patients. The panel concluded that although more evidence is needed, there may be a role for NPWT as an adjunct to compression bandaging in patients whose leg ulcers are not healing with compression bandaging (Table 1).

In 2011, a small portable single-use negative-pressure wound therapy system, PICO (Smith and Nephew, Hull) has been developed to provide negative pressure wound therapy based on a simple-to-apply dressing, and a portable battery operated pump, which can be carried in the patient's pocket or handbag.

PICO is a lightweight topical negative-pressure pump which operates through a dressing which is applied like a normal dressing to the wound (Figure 1). The pump creates negative pressure at -80 mmHg in the dressing, which then delivers this to the wound bed.

One of the indications for the use of PICO is on non-healing venous leg ulcers, either with or without compression bandaging.

'Any qualified provider' pathway for the provision of leg ulcer services

Recent changes in NHS legislation have allowed health care commissioners to provide and deliver expert leg ulcer and wound healing services to a greater number of patients. AQP has allowed for greater patient choice from a number of qualified providers and focuses on improving patient outcomes such as healing rates and patient satisfaction.

Eight leg ulcer/tissue viability specialists from across the UK (listed as the authors of this paper) were invited to evaluate PICO as a treatment for VLU in conjunction with a variety of compression bandages and garments.

The AQP document recommends streaming patients into two pathways, simple and complex.

The group of clinicians felt that this criteria was a

useful starting point for streaming patients who may require negative pressure to help manage non-healing leg ulceration (Table 2).

A convenience sample of patients across 5 community trust leg ulcer clinics had PICO applied in conjunction with compression therapy. The group of clinicians were then asked to feedback on the outcome of the patients on which they had used the device. The questions and responses are included in tables 3, 4, 5, 6, 7, 8 and 9. All feedback was recorded at a meeting and this was used to create a guideline for use (Figure 2).

Case study

A lady presented to the tissue viability service with a history of long-standing bilateral leg ulceration. While healing had been achieved on an episodic basis re-ulceration had always occurred. The patient had previously been managed via the GP practice and had been treated with compression bandaging and hosiery. The current episode of ulceration had proved recalcitrant to treatment and prompted referral of the patient to the tissue viability centre for assessment and management.

Initial examination revealed an extensive area of ulceration to the left medial gaiter area. In recent weeks the ulcer had been increasing in size despite treatment with compression bandaging. The majority of the wound bed was covered in a layer of slough with no evidence of epithelial advancement. Doppler assessment was performed and identified bi-phasic waveforms in both the popliteal and pedal arteries. The subsequent holistic assessment established that the ulceration was primarily venous in origin however other evidence was suggestive of some degree of arterial insufficiency.

Despite treating with appropriate wound management



Figure 1. PICO (Smith & Nephew) is a lightweight topical negative pressure pump that operates through a dressing which is applied like a normal dressing to the wound.

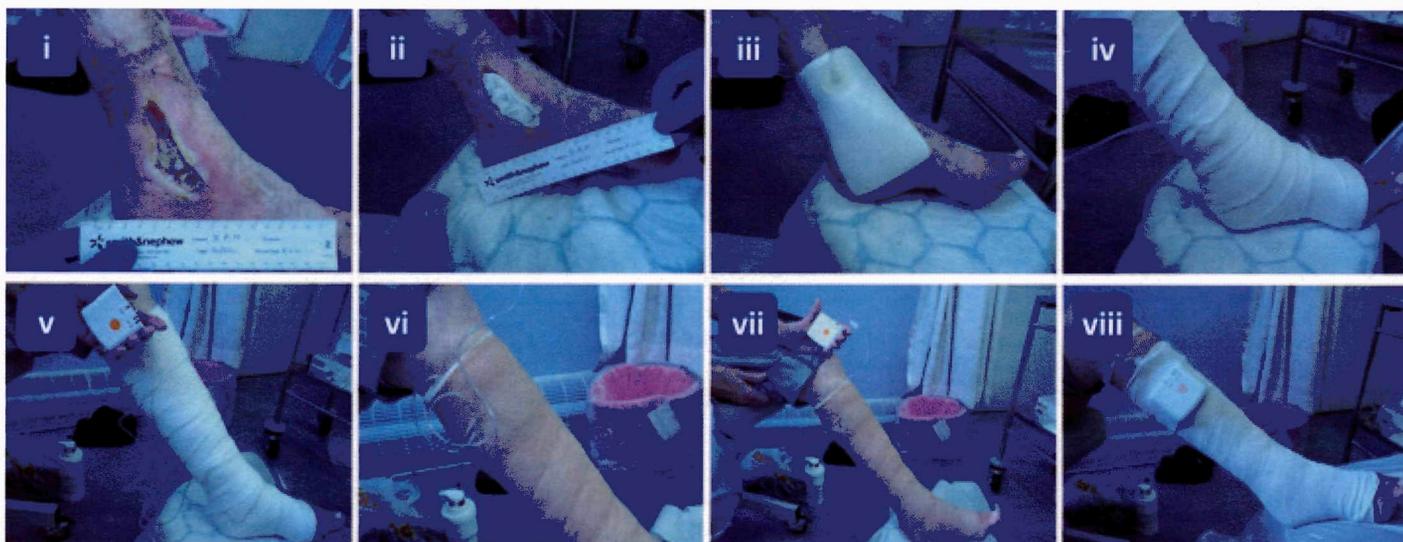


Figure 2i-2viii: The cavity in the wound was packed with saline soaked PHMB gauze (2ii) and a PICO dressing was applied over the wound (2iii). The PICO pump connector was passed through the Profore layer 1 to avoid indentation of the tubing on to the skin of the patient's leg (2iv and 2v). The Profore layer 3 and layer 4 were applied (2vi and 2vii). Tubular gauze was applied toe to knee and a double over to form a pocket to place the pump (2viii).

products and compression bandaging there had been no significant advancement towards healing for some time.

Following discussion with the patient it was decided to attempt to accelerate healing using a new portable and discreet NPWT device (PICO). PICO was used in conjunction with the 4-layer bandaging system which was already being used to treat her ulcer.

The shallow cavity in the wound was first lightly packed with saline soaked PHMB gauze and a 15cm by 20cm PICO dressing was applied over the wound (Figure 1.ii and iii). The PICO pump connector was passed through the Profore™ layer 1 to avoid indentation of the tubing on to the skin of the patient's lower leg (Figure 2 iv and v). The tubing was then held in place over the Profore layer 1 with the Profore layer 2 bandage. The Profore layer 3 and layer 4 were then applied in the usual manner (Figure 2vi and vii). Tubular gauze was applied toe to knee and a double over to form a pocket to place the pump in as the patient preferred not to have the tubing running up her

leg into a pocket as she was also anxious not to misplace the pump at night when sleeping (Figure 2viii). Following initial application the patient returned to clinic for dressing changes on a twice weekly basis.

PICO NPWT was employed over a period of three weeks. During this 21-day period of treatment the wound made significant progress toward healing (see Figure 3). The condition of the wound bed improved considerably with islands of epithelial tissue emerging within the wound. The PICO system proved effective in managing the wound exudate with the peri-wound skin remaining healthy throughout and the wound margins had begun to contract. At this point PICO usage was discontinued.

The patient reported that she was very comfortable with the new therapy and did not suffer any effects of indentation from the tubing. She felt that the small discrete nature of the device coupled with the way the system had been enabled her to maintain her independence and her dignity throughout.

Figure 3i before PICO was used and **Figure 3ii** after PICO was used. During this 21-day period of treatment the wound made significant progress toward healing



Tables 3-9 The following questions were sent to the group prior to the meeting and each was discussed on the day to help reach consensus.

Table 3	
In your experience which factors contribute to non-healing of venous leg ulcers?	Rationale
<p>Patient and ulcer-related issues:</p> <ul style="list-style-type: none"> • Patient may have many underlying co-morbidities, such as cardiovascular disease, lymphoedema, diabetes and rheumatoid disease. • Infection • Fixed ankle joint • Slough or necrosis on the wound bed • Unusual limb shape • Condition of the peri-wound skin • Eczema <p>The group agreed that there were patient-related reasons and extraneous reasons for this to occur.</p> <p>Extraneous reasons:</p> <ul style="list-style-type: none"> • Incorrect diagnosis • Poor assessment • Lack of access to specialist services • Poor application of bandages • Failure to choose correct product • Failure to apply adequate compression 	<p>The patient's medical and social history can have a significant impact on their ability to heal and this should influence treatment decisions.</p> <p>Assessment is key at this step in the process.</p> <p>Evidence/Further Reading:</p> <ul style="list-style-type: none"> • Moffatt et al, 2010 • Milic et al (2010)

Table 4	
Which patients are you most likely to consider using PICO as an adjunct to compression therapy?	Rationale
<ul style="list-style-type: none"> • In patients where compression therapy alone has not been sufficient to stimulate healing • The wound has not reduced in size despite compression bandaging • Long ulcer duration with slow or no healing • Socio-economic reasons? • Ulcer size larger than 10cm²? 	<p>First line treatment should always be compression therapy. If this is not sufficient then other options including negative pressure may be considered.</p> <p>Evidence/Further reading:</p> <ul style="list-style-type: none"> • SIGN (1998) • Vig et al, 2011 • Vuerstaek et al, 2006

Table 5	
Which type of compression would you use over PICO?	Rationale
<ul style="list-style-type: none"> • PICO is suitable for use under all types of compression • Across the group all forms of compression bandaging and hosiery are used depending on the patient assessment • PICO can also be used under compression hosiery • Consensus: All patients with confirmed venous disease should be treated with full compression from toe to knee. 	<p>All participants felt that in order to achieve best outcomes, full compression must be used in order to treat the underlying disease process and maximise healing.</p> <p>Evidence/further reading:</p> <ul style="list-style-type: none"> • Moffatt (2004) • Moffatt, 2004

Table 6	
What should be the duration of PICO Therapy on this patient group?	Rationale
<ul style="list-style-type: none"> • PICO should be used for a period of 2-4 weeks • The patient should be reviewed at least weekly • After 4 weeks, PICO should be stopped • If the ulcer fails to progress once PICO is discontinued, further therapy may be initiated with regular reviews. 	<p>The best response to negative pressure wound therapy is normally found in the first 2-4 weeks of therapy.</p> <p>Evidence/further reading:</p> <ul style="list-style-type: none"> • Dowsett et al, 2011

Table 7	
How often would you check the dressing?	Rationale
<p>The dressing should be checked at least once per week and at most twice weekly. Or if the patient reports a problem, pain or leakage. In the case of adverse events such as cellulitis</p>	<ul style="list-style-type: none"> • To ensure dressing is intact and managing exudate adequately • To reduce overall cost of therapy, optimal treatment window should be observed.

Table 8	
Where should you position the PORT when using PICO under compression?	Rationale
<ul style="list-style-type: none"> • The PORT should be positioned at the highest point on the leg away from the wound bed where possible • The tubing should be placed on top of the first layer of multilayer and two-layer bandage systems • Under hosiery a small hole may be cut to allow the tubing to be brought out to the surface. • Bandaging can then be carried out over the PORT • Avoid kinking of the tubing 	<ul style="list-style-type: none"> • To minimise the risk of the PORT becoming saturated at an early stage • To allow the dressing to function to its maximum potential • To protect the skin on the leg from direct pressure <p>Evidence/further reading:</p> <ul style="list-style-type: none"> • PICO instruction for use guide.

Table 9	
Which venous leg ulcers would not be suitable for using PICO NPWT?	Rationale
<ul style="list-style-type: none"> ♦ Heavily exuding leg ulcers ♦ Large swollen legs ♦ Circumferential leg ulcers ♦ Wounds which track to the dorsum of the foot and other areas which are difficult to achieve a seal ♦ Any patient where NPWT is contra-indicated ♦ Where there are multiple lesions or bilateral leg ulcers 	<ul style="list-style-type: none"> ♦ Some leg ulcers will not be ideally suited for PICO. ♦ In some cases such as heavily exuding ulcers and circumferential ulcers these may be more suited to the use of standard negative pressure wound therapy e.g. Renasys.

Table 10: Hints and Tips for application of PICO NPWT under compression

- ◆ Where possible avoid using emollients on the surrounding skin in order to assist with adherence
- ◆ Apply skin protectant/barrier layer prior to application of the dressing
- ◆ If surrounding skin is in poor condition, consider using a hydrocolloid dressing as an initial layer around the wound margin.

Conclusion

Leg ulcers, regardless of their origin, are a significant problem for the patient and those caring for them. Venous leg ulceration is treatable with correct application of compression therapy. Some patients may experience non-healing of these ulcers despite the use of appropriate compression and for this patient group, alternative therapies may be sought. The basis for treatment of these patients is thorough and accurate assessment of their ulcer and any underlying conditions which may be affecting the patient's wellbeing. For some patients underlying infection may need to be addressed, however, this may not always be the case. NPWT has proven to be a useful therapy in other wound types and therefore, may have a role to play in kick starting the healing process in patients where the ulcer has been slow to heal. Some research has suggested that NPWT may provide the necessary stimulation to venous leg ulcers which are not healing or slow to heal (Vuerstaek et al, 2006; Vig et al, 2011). PICO has the potential to help kick-start non-healing venous leg ulcers which could potentially help to reduce the overall healing times for some patients. It is hoped that this article and *Figure 3* may help clinicians to identify the patients who may benefit most from this important therapeutic intervention.

BJCN

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To download the full Venous Leg Ulcer Pathway please scan this QR Code or follow the web link : <http://1116.s-n.ms/>

LEARNING POINTS

- ◆ Thorough assessment and accurate diagnosis are essential in leg ulcer management
- ◆ Safe and effective compression bandaging is the main cornerstone of treatment for patients with venous leg ulcers
- ◆ Some patients may not respond to compression therapy alone
- ◆ Further assessment may be necessary and infection should be ruled out
- ◆ Negative pressure wound therapy may help to stimulate healing in this patient group.
- ◆ Regular assessment of the effectiveness of the therapy is essential to ensure maximum benefit for the patient.

A decision-making process on the use of PICO

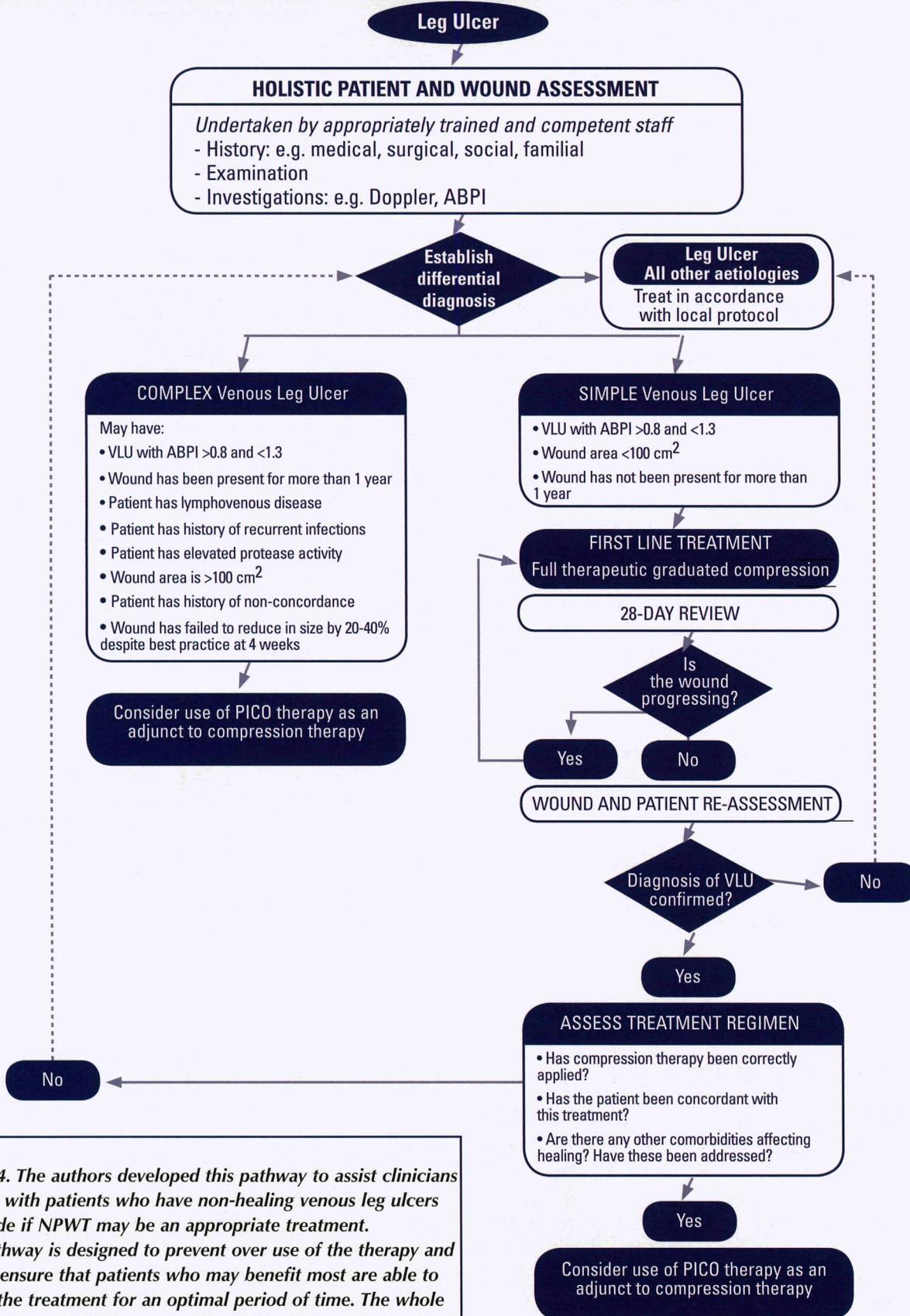


Figure 4. The authors developed this pathway to assist clinicians dealing with patients who have non-healing venous leg ulcers to decide if NPWT may be an appropriate treatment. The pathway is designed to prevent over use of the therapy and also to ensure that patients who may benefit most are able to access the treatment for an optimal period of time. The whole pathway is available from a Smith and Nephew representative.

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