The use of Opsite, Fixomull and LYCRA® in the management of diabetic neuropathic pain of the foot

Troy T

Abstract

Peripheral neuropathy is the most common, early and often painful manifestation of diabetic neuropathy. There are a multitude of treatments, mainly drug based, which have a variable result in reducing the pain being experienced by the patient. Opsite Flexifix TM, LYCRA® and Fixomull TM Stretch have been found to be useful adjuncts to these treatments. They each seem to work best in treating pain associated with touch allodynia and superficial hyperalgesia. Patients using these products have experienced less pain within the foot, making neuropathic pain more bearable. The need for oral pain relief has been reduced and some patients' sleep patterns have improved. This article will describe the use of Opsite Flexifix TM, LYCRA® and Fixomull Stretch TM in the management of neuropathic pain of the foot secondary to diabetes only, and not other forms of peripheral neuropathy as described in Appendix 1.

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Introduction

Opsite's effectiveness in treating painful diabetic neuropathy was first reported in 1986 by Hyams ¹, an English podiatrist. Hyams noted that the application of Opsite to the ulcerated digits of a diabetic patient markedly reduced the patient's neuropathic pain levels. A study by Foster *et al.* ² in 1994 confirmed the effectiveness of Opsite film in reducing diabetic neuropathic (DN) pain. Prior to Foster's study the pain relieving effects of Opsite on intact skin were anecdotal. Therefore, the purpose of their study was to investigate the effect of polyurethane film in patients with painful diabetic neuropathy affecting the feet and legs.

Although they were unsure as to the mechanism of action of Opsite in this instance, they felt that Opsite worked either by protecting the skin from external stimuli or that continuous skin contact of the film "may have stimulated the light touch afferent fibre to control pain according to Melzack and Wall's spinal gate control theory" ².

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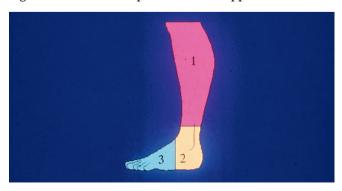
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Opsite Flexifix ™ was first tested on a patient at Sir Charles Gairdner Hospital, Perth in July 1996. Excellent control of severe allodynic pain was achieved in this instance. As the article by Foster *et al.* did not specifically describe the anatomical boundaries up to which the Opsite film was applied to the foot, Opsite Flexifix was initially applied to the level of the patient's knee (areas 1-3 as shown in Figure 1) as the patient had pain to this level. As the pain improved, the Opsite Flexifix was reduced to the level of the ankle (areas 2 & 3 in Figure 1). Eventually it was found to be effective when applied to the foot up to the level of the anterior edge of the ankle (area 3 in Figure 1).

Opsite Flexifix was deemed to be an effective treatment for painful diabetic neuropathy; however, a number of problems were experienced. This prompted the search for another material which would be as effective but without the same

Figure 1. Levels of Opsite Flexifix ™ application.



problems. The sheerness and conformability of Opsite Flexifix (and later Fixomull Stretch TM) were felt to be important properties (Figure 2). LYCRA® based materials offer similar properties; they do not adhere to the skin and can be easily applied and removed by the patient. LYCRA® based materials were therefore tried as an alternative treatment (Figure 3).

Peripheral neuropathy

Peripheral neuropathy is a generalised, sensory-motor polyneuropathy of gradual but progressive onset. It is the earliest, most widely recognised and probably the most common form of diabetic neuropathy. The legs are almost always affected earlier than the hands. Patients initially experience sensory manifestations first such as parathesias, burning sensations and hyperaesthesia which can be quite uncomfortable³.

Pollard identified a number of causes of peripheral neuropathy, which he states "... include diabetes, uraemia, vitamin deficiency and excessive alcohol consumption, connective tissue disorders, inflammatory and post-infective neuropathies and malignancy" ⁴.

Diabetic neuropathy affects 15% of Australians with diabetes ⁵ and between 10.7-62% of the American population ⁶. The prevalence of neuropathic changes in people with diabetes increases linearly with time so that after 25 years approximately 50% of patients will exhibit the signs and symptoms of neuropathy ⁷.

The most common and least well-treated problem encountered with peripheral neuropathy is neuropathic pain ⁷. This pain, which is commonly described by patients as giving the greatest cause for distress, is a burning, stabbing pain that can be present 24 hours a day. The pain is often more severe during the night, causing sleep disturbance. Allodynia and hyperalgesia are also very painful and distressing manifestations of diabetic neuropathy. There are a number of classifications of diabetic neuropathy according to the clinical syndrome or nerve fibre affected ⁵. These are listed in Table 1.

Figure 2: Opsite and Fixomull Stretch.



Treatment of diabetic neuropathy pain

There is no pharmacological treatment that effectively prevents or reverses diabetic neuropathy ⁸. Therefore, management of neuropathic pain is not directed towards providing a cure but on modifying pain perception, suffering and negative behaviours ⁹.

Many of the drugs used to treat painful diabetic neuropathy have wide-ranging physiological effects and therefore care needs to be taken to minimise the potential for complications. Treatment interventions can be classed as medicated and non-medicated treatments as identified in Table 2^{2-15} .

Non-medicated materials for skin applications

Opsite Flexifix

Opsite is "an adhesive-coated polyurethane film. It is permeable to water vapour, oxygen and carbon dioxide and is a barrier to bacteria" ¹⁰. Opsite is normally used in the management of wounds and can be used in treatment of wound healing by primary intention, on donor sites following skin graft ¹¹ and on skin tears. Carville ¹¹ lists a number of advantages and disadvantages associated with semi permeable films inclusive of Opsite, which are listed in Table 3. Opsite Flexifix was used as it comes in 5 and 10cm wide by 10m long rolls and can be applied to large areas of skin.

Application of Opsite Flexifix in the management of neuropathic pain

Opsite Flexifix is normally applied to the foot from the base of the toes to the anterior ankle. Occasionally the whole foot to the ankle is wrapped. Moleskin adhesive sheeting was added to the forefoot and heel contact areas on the plantar surface of the foot to increase the longevity of the film as walking on it can lead to breakdown of the material on the plantar surface.

Figure 3. Venosan 20, custom-made stockings and LYCRA® material.



Table 1. Clinical syndromes and classifications of DN (adapted from Philips & Popplewell⁵).

| Classification | Clinical neurological phenomena | Clinical presentation | | |
|-------------------------|--|--|--|--|
| Symmetric neuropathies | | | | |
| Chronic | Hypoaesthesia, dysthesia or pain affecting the peripheries | Stocking and glove effect initially the feet and then the hands, worse at night. | | |
| Acute | Sudden onset of lower leg and thigh pain with loss of power and muscle wasting | Poor glycaemic control, usually improves with better control. | | |
| • Diffuse | Severe, progressive muscle weakness and wasting | Elderly Type II patient | | |
| Asymmetric neuropathies | | | | |
| Diabetic amyotrophy | Similar clinical picture to acute painful neuropathy | Uni-lateral | | |
| Pressure neuropathy | Vulnerable nerves subjected to pressure | Peroneal nerve/footdrop, median nerve/carpal tunnel syndrome | | |
| Vascular | Ischaemic mononeuropathies secondary to lesions in the vasa nervosum | Cranial nerves III and VII though any nerve can be affected. Recovers with time | | |
| Autonomic | Loss of hypoglycaemic awareness or systemic effects | Urogenital, gastrointestinal, cardiovascular | | |

Disadvantages of using Opsite Flexifix in the management of DN pain

A number of problems in the use of Opsite Flexifix in the management of neuropathic pain have been identified. These relate to fungal infections, personal hygiene and the frequency of dressing changes.

 Opsite Flexifix, when used for prolonged periods in the temperate/Mediterranean climate of Perth, WA, can lead to skin problems, especially fungal infections. These develop under the film and can quickly affect large areas. This was one of the reasons that application was reduced from the height of the knee, initially, then to the ankle, and finally to the anterior ankle with little change in the pain relieving effect noticed by the patients.

It is our experience that the older members of our patient population like to water their lawns in the evening and often get their feet wet. Keeping water out of a foot dressing during showers can also be difficult. Both these activities can result in small amounts of water getting beneath the Opsite Flexifix leading to a fungal outbreak.

- The skin under the Opsite Flexifix is not able to exfoliate and, when combined with sweat, leads to a damp pastelike superficial skin which needs to be exfoliated prior to a new application of film. This was usually done with a soft surgical scrubbing brush.
- Opsite Flexifix needs to be changed about every 10 days and this can be costly in practitioner time and materials.

Fixomull Stretch

Due to problems with procuring Opsite Flexifix in the early days Fixomull Stretch TM was tried and it proved nearly as effective as Opsite Flexifix on some patients, though not all. Fixomull Stretch is a perforated hypoallergenic polyester fabric made by BSN and it comes in widths of 5, 10, 15, 20 and 30cm rolls ¹⁶. In the case of dressings it is used as a fixation or retention tape to secure dressings to the skin. It has also been used in the treatment of burn injury to treat superficial to partial thickness skin loss and can also be used on the skin graft donor site.

The application of Fixomull Stretch in place of Opsite will, in a number of patients, relieve the pain. It is an easier material to handle and apply than Opsite Flexifix though (as an empirical observation) it does not work as effectively in all cases by comparison to polyurethane film. However, if there is no Opsite Flexifix available it is a useful alternative to try. Failure to provide relief should not discourage the practitioner from trying Opsite Flexifix later when available, as Fixomull Stretch is not effective in all patients.

LYCRA® -based materials

LYCRA® is an elastic fibre developed and manufactured by DuPont and LYCRA® is a registered trademark of DuPont for its brand of premium stretch fibres; "LYCRA® belongs to the generic elastane classification of man-made fibres and is described in technical terms as a segmented polyurethane. It is composed of 'soft' or flexible, segments bonded together with 'hard' or rigid, segments. This gives the fibre its built-in, lasting elasticity" ¹⁷.

Table 2. Treatment options for diabetic neuropathic pain (compiled from ²⁻¹⁵).

| Treatment options | Drug | | | |
|--|---|--|--|--|
| Tight glycaemic control | As prescribed | | | |
| Medications for neuropathic pain management | | | | |
| • NSAIDS | Piroxicam, ibuprofen, sulindac | | | |
| Selective serotonin reuptake inhibitors (SSRI) | Fluoxetine(Prozac), sertraline (Zoloft), paroxetine(Aropax) | | | |
| Tri-cyclic antidepressants | Amitryptyline (Tryptanol), imipramine (Tofranil), dothiepin (Prothiaden), doxepin (Sinequan) | | | |
| Anticonvulsants/ antiepileptics | Carbamazapine (Tegretol), Valporate (Epilim), Clonazepam (Rivotril) Gabapentin | | | |
| Muscle relaxants | Baclofen(Lioresal) | | | |
| Opioids analgesics | Ms Contin, kapanol | | | |
| Antiarrythmics | Mexiletine (Mexitil) | | | |
| • α -Adrenergic agonists | Clonidine (Dixarit) | | | |
| γ-linolenic acid | Evening primrose oil, borage oil | | | |
| Capsaicin cream | | | | |
| Non-medication treatments for neuropathic pain management | | | | |
| Opsite film | Flexifix | | | |
| Transcutaneous nerve stimulation | Peripheral nerve or dorsal nerve stimulators can also be implanted | | | |
| Pain management | Psychologist | | | |
| Physical therapy | Physiotherapy (stretching and massage) | | | |
| Surgery | Decompression of the posterior tibial nerve | | | |

Most fabrics which are called LYCRA® are not made of elastane but are usually made of a carrier material such as polyester or polyamid which is woven around LYCRA® to create the fabric. There are a number of ways of combining the LYCRA® with the carrier material and, depending upon the performance and aesthetic requirements of the fabric, this will determine the percentage and type of LYCRA® used. Fabrics can contain as little as 2% LYCRA® to improve drape and shape retention to 20-30% in high performance garments [personal communication, De Oliver Oess, Marketing, Dupont Textiles] ¹⁷.

The addition of LYCRA® to a fabric does not add stretch to a fabric. The ability of a fabric to stretch remains the same with

Table 3. Advantages and disadvantages of semipermeable films.

| Advantages | Disadvantages | |
|---|--|-------|
| Permeable to gases | Non absorber exudate may causing maso | pool |
| Wound moisture vapour able to be evaporated | Not suitable for moderate to he exudating wo | ighly |
| Impermeable to liquids and bacteria; can be used whilst bathing | If not correctly removed, may traumatic to ti | y be |
| Reduces pain, keeps the nerve ends moist | | |
| Allows inspection of wound through dressing | | |

or without LYCRA®. The LYCRA® increases the elasticity of the fabric by causing the fabric to contract (in length and width), thus a fabric which may have 10% stretch may end up contracting by 10% when LYCRA® is added to the fabric weave. The amount of stretch now available within the fabric is 20%. The stretching force of the material can be affected by the fineness of the elastane filaments and by the percentage of elastane incorporated into the fabric [personal communication, De Oliver Oess, Marketing, Dupont Textiles] ¹⁴.

LYCRA®-based fabric samples were requested from custom medical stocking makers and the samples, checked for sheerness and suitable grades of fabric, were applied under mild tension to the feet of patients who were using Opsite Flexifix (Figure 4). The patients were asked to indicate which fabric was closest in feel to the Opsite Flexifix. This turned out to be the hydrophobic LYCRA® material from Second Skin™, a custom pressure garment manufacturer based in Perth, WA. Custom made items take time to make, which makes them expensive and is not necessary for all patients so 'off the shelf' medical stockings were also investigated to see if any had the necessary sheerness properties.

A number of class 1 (below 20mm Hg at the ankle) medical stockings were checked and, whilst most conformed well, it was the Venosan Legline TM 20 stocking which demonstrated the sheerness required.

Venosan Legline 20

Venosan Legline [™] 20 is made by Salzman AG of St Gallen Switzerland. The stocking material consists of 35% elastane (LYCRA®) and 65% Polyamid. The compression ratio of these stockings is 20mmHg at the ankle to 8mmHg at the knee.

These stockings are prescribed on a height to weight ratio scale examples of which are situated on the packaging. The below knee (A-D) stocking in nude colour is the most commonly used type; however, other styles such as mid-thigh and pantyhose are available.

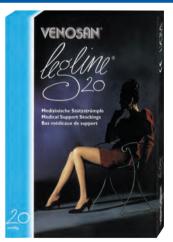
Whilst compression may possibly be useful in peripheral neuropathy as noted by Foster *et al.* ² who reported that compression by a sphygmomanometer cuff and the resultant blood flow reduction saw a decrease in neuropathic pain, the important factors are the secure conformability of the material to the underlying tissue to create the skin contact (Melzack and Wall spinal gate control theory effect) and the sheer effect of the material (change in skin sensitivity to stimuli effect). The polyamid used in the Venosan Legline 20 fabric creates the sheer effect of the stocking not the elastane (LYCRA ®). The sheerness of the stocking is determined by the type of microfibre used and whether it is a single fibre or multistrand microfibre.

For those patients who are unable to use off-the-shelf stockings (if their legs are too large) their stockings are custom-made by Second Skin. The patient is referred for the measurement and fitting of stockings in hydrophobic LYCRA®, which is a sheer,

Figure 4. Second Skin LYCRA® stockings.

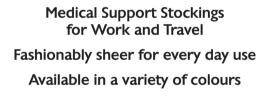


slippery type of fabric. The stockings conform firmly to the limb without a large degree of compression. This material does however require re-tensioning after a period of time as it can stretch and not conform as firmly to the skin. Patients wear the stockings depending upon their pattern of pain. Some wear them only during the day, some only at night in bed to combat the night burning pain, and others wear them both day and night.

















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Appendix 1. Case histories.

Case 1: Patient A

Patient A is a 70 year old male with Type 2 diabetes of 17 years' duration with painful generalised polyneuropathy. No macro vascular disease is present in the lower legs.

Neuropathy developed within 1 year of diagnosis initially, as pins and needles and then burning pain in the feet, legs and thighs. There was intermittent ulceration of the apex of the 2nd toe on the right foot due to hammer toe and resultant apical corn. This has now been resolved following amputation of the terminal phalanx. The patient is on the following medications:

- Diamicron
- Ouinate
- Glucophage
- Endone 5mg prn/bd
- Insulin
- Physeptone 10mg qid
- Evening primrose oil

Patient A, who has been a patient of the Podiatry Department at Sir Charles Gairdner Hospital (SCGH) since 1994, was referred by the SCGH Diabetic Clinic with painful neuropathy in August 1998. The clinic requested assessment for the application of Opsite Flexifix to assist with pain management. Patient A was asked to verbally scale the level of pain out of 10 with 10 being the worst pain imaginable and 0 being no pain. The level of pain being experienced was noted at 7/10.

Biothesiometry to measure vibration threshold was extremely poor (50+ volts). Biothesiometry is used in conjunction with a 10g monofilament to assess the level of sensation within the feet. Vibration perception is the first area of sensory perception to be affected by diabetic neuropathy and the measure gives an indication of the changes which are occurring within the nerves of the foot and the likelihood of developing neuropathic ulcers on the plantar surface of the foot.

Biothesiometry testing is conducted by applying the vibratory probe to the tip of the index finger, the apex of the hallux and the 1st meta-tarsal phalangeal joint. The probe vibrates in response to increasing the voltage applied to the probe via a potentiometer and the voltage point at which the

vibratory sensation is experienced is read from the volt meter situated on the Biothesiometer[®]. Normal measurements are:

- 0-20 volts within normal limits
- 20-30 volts reduced vibratory sense; and
- 30 volts impaired vibratory sense and increased potential for the development of a neuropathic ulcer.

Opsite Flexifix was initially tried in 1996 prior to the referral from the SCGH Diabetic Clinic and had a very good effect in reducing neuropathic pain. Patient A was instructed on self-application; however, he stopped using Opsite Flexifix due to the cost of purchasing the material.

A further application of Opsite Flexifix in 1998 resulted in poor pain control, probably due to application technique, but it was felt that the LYCRA® may be more effective. Patient A was referred to Second Skin for the manufacture of custom-made LYCRA® stockings.

The pain medication used by Patient A at the time of application of the LYCRA® stockings was Physeptone 10mg 4 times per day. In addition, Endone 5mg (maximum of 2 per day as required) was taken to 'top up' the Physeptone when pain control was not adequate.

On review a month later the pain had been reduced by 50% and the daily use of Endone had also reduced by 50%. The patient's self-pain level score had reduced to 3/10.

Patient A generally wears his stockings during the day and takes them off at night when retiring to bed. If the stockings are worn during the day then night pain is minimal with good sleep achieved and conversely if the stockings are not used during the day then night pain is high and a poor night's sleep is the result.

The more the stocking is used during the day, the less 'top up' Endone is required and the less night pain experienced. Endone 'top up' is now mainly required if a lot of walking needs to be done. Patient A has continued to wear stockings since December 1998 with ongoing good effect. He feels that the neuropathic pain in his feet and legs has been reduced to a manageable level, which he can cope with and, more importantly, he has reduced his reliance on analgesics.

Case 2: Patient B

Patient B is a 63 year old male with Type 2 diabetes, angina and a right above knee amputation following emboli during coronary artery bypass graft surgery. His medications are:

- MS Contin 60mg bd
- Atenolol 125mg mane
- Amlodipine 10 mg mane
- Tramadol 50mg prn
- Perhexiline 50mg mane
- Zoloft 100mg once per day
- Enlapril 2.5mg mane
- Clopidogrel 75 mg mane
- Simvastatin 80mg nocte
- Imdur 120mg mane
- Metformin 150mg bd
- Allopurinol 300mg mane
- Omeprazole 20mg mane
- GTN spray prn
- Diazepam 2mg prn/bd
- Doxylamine succinate 25mg nocte
- Nicorandil 15mg bd
- Betoptic eye drops/Xalatan eye drops

Neuropathic burning pain developed in early 1998 in the left forefoot. Opsite Flexifix was applied to the left foot from anterior ankle to toes with a reduction in pain being achieved; however, over the course of 6 months the pain worsened. Opsite Flexifix was discontinued and a Venosan Legline $^{\text{TM}}$ 20 stocking issued with significant pain relief achieved.

In mid 1999 the stockings were changed to custom made stockings for the left leg and a stump stocking for the right above knee amputation. The change was due to regular 'tear' damage to the Venosan Legline 20 stocking stockings as Patient B was fairly 'hard' on the stocking and the custom made stocking was more durable and repairable.

The right stump had developed significant neuropathic pain and, though effectiveness of the stocking was in doubt, it proved to be of significant effect in pain reduction. Daily pain management medication was MS Contin 60 mg bd and when asked to scale the level of pain from 0-10, Patient B noted the level was 8/10 without the stockings and 3/10 with the stockings

Patient B felt that the stockings helped in reducing the pain to a more acceptable level which helped him to cope with the pain.

Case 3: Patient C

Patient C is a 64 year old male with Type 1 diabetes of 43 years' duration who developed neuropathy approximately 10 years ago. The level of neuropathic discomfort has increased significantly over the last year. The pain exhibits as burning and altered body sensations such as crushing feelings in the foot and itching of the foot and leg. His medications are:

- Zoloft 100mg once per day
- Lipex 40mg once per day
- Coversyl 4mg 1 per day
- Panamax 2 x 500mg prn
- Asprin 100mg 1 per day
- Temazepam 10mg nocte
- Rani 150mg

The Panamax 1g is taken as required when the crushing feeling or his restless legs become too painful. Patient C's verbal self-pain scale (0-10) prior to any treatment was 8/10 and a trial application of Fixomull was applied to the feet.

Fixomull reduced the pain score to 5/10 with both the burning and itching reduced.

Custom made stockings were fitted and these were successful in reducing the pain further to a verbal self-pain scale of 1-2/10.

Patient C notes his feet feel near 'normal' when wearing the stockings and the burning and itching feelings have gone and the crushing feeling is much reduced. The need for Panamax has been reduced and is only required on an occasional basis.

The stockings are worn during the day and removed at night on retiring to bed. If the stockings are worn during the day minimal discomfort is experienced. Failure to wear the stockings results in significant discomfort being experienced during the day with pain level rising to 6/10.

Patient C takes Temazepam 10mg on retiring and has no significant discomfort with regard to burning or itching. Restless legs are the main problem experienced at night in bed.

Patient C feels the level of neuropathic discomfort he experiences is well controlled with the LYCRA® stockings and his feet and legs are comfortable and his need for analgesia has been reduced.

Testing for efficacy of fitting a stocking

If it is felt a patient would benefit from using a stocking then Opsite Flexifix is used to see if a stocking will be successful. Empirically there is a good correlation that a positive effect from Opsite Flexifix will result in good efficacy from the LYCRA® stocking. The cost of the Venosan stocking is approximately \$A37. The custom made stocking is much more expensive so testing with Opsite Flexifix before hand is a cheaper option prior to issuing a stocking. Opsite Flexifix or Fixomull Stretch are normally applied to the foot as previously discussed.

Discussion

The level of pain and the reduction of pain experienced by the patients presented in the case histories (Appendix 1) are subjective measures related to those patients. The aim has been to reduce their foot and leg pain to a more acceptable level and make life more bearable. The reaction and response to pain, both acute and chronic, is a very individual response and thus individuals perceive the pain experienced differently.

The improvement in pain, especially with allodynia, is usually experienced very rapidly. However, seeing how the effect progresses over a few days of normal activity and also how any night pains are affected is also useful both for the practitioner and the patient as it gives an indication of the quality of improvement in pain which can be achieved and how this impacts on their daily activity. Pain measurement was by verbal self pain scale where the patient was asked to scale their pain between 0-10 with 0 being no pain and 10 being the worst pain they could imagine. Further development of quantitative measures of pain reduction and quality of life improvement is the focus of ongoing study by the author as part of a Master's programme.

Due to the problems experienced with long term use of Opsite Flexifix and Fixomull Stretch, a more time effective and easier to apply material was needed, essentially one which the patient could apply and remove as required and which did not result on long-term adhesive contact on the skin.

It was also a matter of looking for stockings or materials that were available and which had the desired components of sheerness and conformability. Also important were the easy availability of the items and cost considerations. It seemed that both the sheerness and conformability of the polyurethane film were the two most important features to be replicated and these properties were found to be in LYCRA® based fabrics.

Conclusion

These case studies have demonstrated that Opsite Flexifix and Fixomull Stretch can be used to treat painful diabetic

neuropathy in conjunction with other treatment modalities. These modalities are not advocated for long-term use as they are associated with fungal infections. For long-term management of DN pain these modalities, if found to be successful, should be replaced with LYCRA® based stockings.

Stockings are easier for patients to apply and allow them greater independence with their activities of daily living such as showering and preparation for going to bed. They remove the need for adhesives to be applied to the skin for prolonged periods and are not prone to causing fungal infections. The pain modifying effect of the stockings does not fade with use, providing the stockings continue to conform to the skin, and the practitioner can easily replace them when they wear out.

Patient feedback through the author's clinical practice indicates these modalities reduce pain, improve patients' quality of life and allow some patients to reduce the analgesia required in the treatment of their nerve pain.

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