BeneHold™ TASA™ Thin Absorbent Wound Dressing for management of neuropathic diabetic foot ulcers: a case series

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Citation: Jones NJ, Ivins N, Thota P et al (2017) BeneHold™ TASA™ Thin Absorbent Wound Dressing for management of neuropathic diabetic foot ulcers: a case series. *The Diabetic Foot Journal* 20(2): 114–9

Article points

1. BeneHold™ Thin Absorbent Skin Adhesive (TASA™) is a new generation of dressing that maintains a moist wound environment on contact with low to mild levels of exudate.
2. This 6-week case series evaluation demonstrated a decrease in wound surface area and an increase in granulation tissue.
3. These findings suggest that TASA can promote wound healing in neuropathic diabetic foot ulcers when used appropriately in conjunction with standard care.

Key words

- Dressings
- Ulceration
- Wound healing

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Maintaining a moist environment plays an important role in promoting wound healing in neuropathic diabetic foot ulceration. BeneHold™ Thin Absorbent Skin Adhesive (TASA™) is a new generation of adhesive technology enabling dressings that maintains a moist wound environment on contact with low to mild levels of exudate. This case series evaluation recruited 15 patients presenting with neuropathic foot ulceration in excess of 6 weeks' duration at a local community podiatry foot clinic. Objective measures, including wound tracings and photographs, were obtained at baseline and repeated once a week over a 6-week evaluation period. Patients were provided with best practice standard therapy. The wound healing trajectory over the study period demonstrated a decrease in mean wound surface area (1.08 cm² vs. 0.02 cm²) and an increase in mean percentage of granulation tissue at wound base (87.7% vs. 98.1%) at the end of the study. Complete wound re-epithelialisation was achieved in 11 (85%) of the 13 patients who completed the study. These findings suggest that TASA can promote healing of neuropathic diabetic foot ulcers when used appropriately in conjunction with standard care.

Diabetic foot ulceration (DFU) is a global health burden with significant psychosocial and economic ramifications. It has been estimated that the annual incidence of diabetic foot ulceration ranges between 2–4% of people with diabetes in developed countries and this prevalence may be even higher in developing countries due to socio-economic differences and variations in standards of care (Boulton et al, 2005).

Diabetes plays a critical role in the development of peripheral neuropathy and peripheral arterial disease (Bakker et al, 2012). The lack of protective sensation in peripheral neuropathy exposes the superficial skin to repetitive trauma which, over time, stimulates the formation of callus to protect the integrity of the cutaneous structures. This protective mechanism in the absence of adequate offloading can result in focal areas of high pressure, which then become susceptible to soft tissue breakdown (Lavery et al, 1998).

It is well documented that maintaining a moist environment and appropriate offloading play an important role in enhancing wound healing in neuropathic DFUs (Moura, et al, 2013). An optimal local wound environment needs to be maintained to encourage healing.

The ideal wound environment is free of necrotic tissue, bioburden and infection. The wound bed should consist of healthy granulation tissue without evidence of concomitant undermining, tendon or bone involvement (Grey and Harding, 2006).

For the purpose of this case series, the focus is on the importance of performing a comprehensive wound assessment to inform the selection of an appropriate dressing for neuropathic DFU.

BeneHold™ TASA™

BeneHold™ Thin Absorbent Skin Adhesive™ (TASA™) is part of a new generation of adhesive technology enabling dressings that combine the absorbency of a hydrocolloid with the durability and

Page points

1. This case series enrolled patients with neuropathic diabetic foot ulceration of greater than 6 weeks' duration, ABPI > 0.8 and ulcers with low to mild exudate levels.
2. Standard care was provided within the community diabetic foot clinic by the podiatrist.
3. Objective measures including wound tracings and photographs were taken at baseline and once a week over the 6-week duration.

conformability of an acrylic film dressing (Stephen-Haynes et al, 2005; 2016).

The dressing is transparent, and on contact with mild levels of exudate it remains clear and intact, so that wound care professionals can inspect the wound without removing the dressing. TASA maintains a moist wound environment on contact with low to mild levels of exudate. It is not indicated for moderately to heavily exuding wounds due to the risk of macerating the surrounding skin. The dressing should not be applied to wounds presenting with clinical features of infection.

This case series sought to evaluate the benefits of the TASA dressing in maintaining a moist wound environment to promote accelerated healing of neuropathic DFUs. A range of healing outcomes were measured in conjunction with best practice standard therapy over a 6-week period.

Method

This case series evaluation recruited 15 patients with a history of neuropathic foot ulceration from a local community podiatry diabetic foot clinic. The TASA wound dressing evaluated in the case series is a CE-marked medical device and was used as per the manufacturer's instructions by qualified medical personnel.

Patients were recruited for this study between March 2015 and February 2016. Inclusion criteria were DFU for longer than 6 weeks, ABPI > 0.8 and low to mild exudate levels. Patients who were unable to provide informed consent were excluded from the evaluation.

Peripheral arterial disease (ischaemic or neuro-ischaemic DFUs) was excluded following a baseline assessment with a Doppler and ABPI to establish wound classification. Peripheral neuropathy assessments were conducted using a 10g monofilament to test for peripheral sensations on three sites on the plantar surface of the foot. Anatomical changes in patients' feet were recorded and proprioception of the feet was also assessed. Infected wounds and suspected osteomyelitis cases were excluded.

Eligible patients meeting the inclusion and exclusion criteria signed consent in the presence of a dedicated research nurse responsible for collecting baseline data.

Standard care was provided within the community diabetic foot clinic by the podiatrist. Appropriate offloading devices were prescribed in line with best practice.

Objective measures including wound tracings and photographs were undertaken at baseline and repeated once a week over the 6-week duration. These measures were recorded on a wound assessment intervention and evaluation form by a member of the research nursing team.

Table 1. Patient outcomes.

Participant ID	Days to healing	Reduction in wound size (cm^2)	Wound status	Wound pain (change from baseline)
#1	42	0.99	Healed	No change
#2	49	1.8	Healed	No change
#3	41	0.25	Healed	Improved
#4	7	0.16	Healed	Improved
#6	14	6	Healed	Improved
#7	14	1.04	Healed	No change
#8	13	0.36	Healed	No change
#9	–	1.19	Improved	No change
#10	21	0.04	Healed	No change
#11	7	0.72	Healed	No change
#12	7	0.08	Healed	Improved
#13	35	0.81	Healed	No change
#15	–	0.39	Improved	No change

The frequency of dressing changes were determined by either the patient or community nurse redressing the wound between visits.

The main outcomes of interest were wound healing times and wound healing status, which were recorded in line with standard care. The wound healing status was assessed by measuring the wound surface area (cm^2), which was calculated as length (cm) × width (cm) and subjective assessment of the condition of the wound bed (percentage of granulation tissue). Secondary outcomes of interest were conformability and durability of the dressing, presence of exudate levels, condition of the surrounding skin, subjective pain and any clinical features of infection.

Exudate levels were graded on a Likert-type scale of 1 to 5 (1=none, 2= light, 3=moderate, 4=-heavy, 5=copious) and pain was graded on a Likert-type scale of 1 to 4 (Graded: 1=mild, 2=moderate, 3=severe, 4=non-evaluable). Information relating to these outcomes was documented by the research nurse at baseline and at the end of follow-up for each patient. Wound healing status was directly assessed by the nurse at the end of the evaluation period.

At the end of the 6-week evaluation period outcomes were recorded on an Excel database (Microsoft 2010) and analysed using descriptive statistics in the form of rates, means, ranges and percentages.

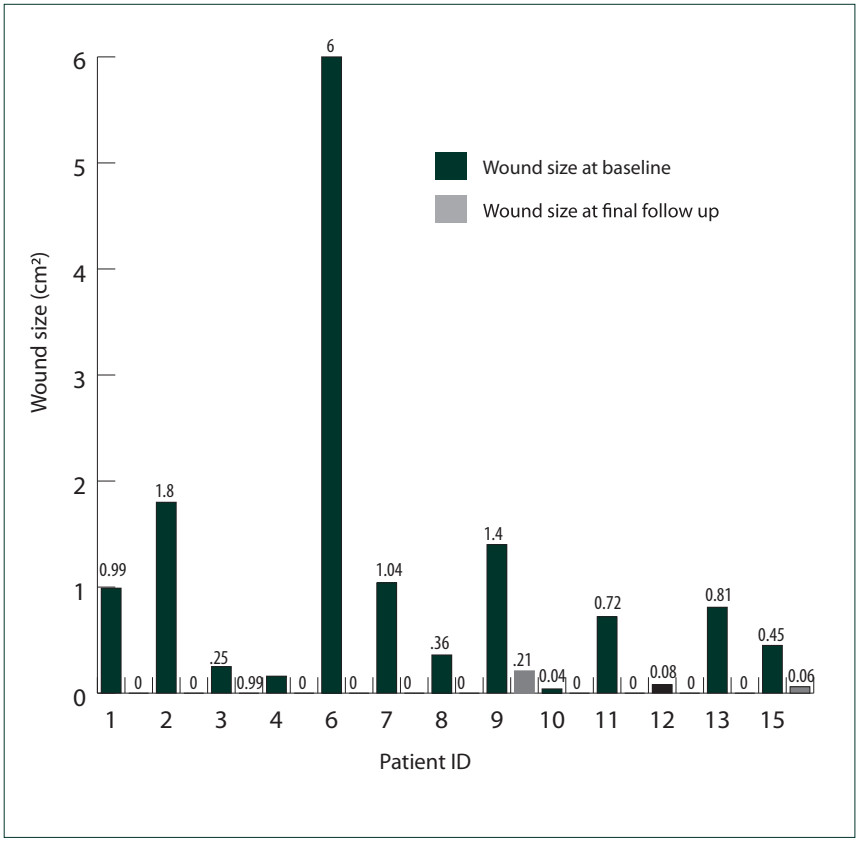

Figure 1. Change in wound area from baseline to final follow up.

Results

Baseline patient characteristics

Fifteen patients, eight (54%) male and seven (46%) female, were included in the case series evaluation. Their ages ranged from 43 to 84 years, with a median age of 65 years. All DFUs presented with low levels of exudate and the wound size at baseline ranged from 0.04cm^2 to 6.0cm^2.

Patient outcomes

Two patients were withdrawn early from this study. One patient (#5) was withdrawn due to a change in exudate levels from low to heavy between weeks 2 and 3. A month later, this patient was referred to the complex wound clinic for treatment of underlying osteomyelitis, which was a complication unrelated to the dressing. Another patient (#14) was withdrawn when skin tears developed on the surrounding peri-wound skin during the week 4 dressing change.

A wound healing trajectory was observed over the 6-week period. The mean wound surface area decreased over time (*Figure 1*) and a corresponding increase in the mean percentage of granulation tissue from 87.7% to 98.1% was documented at the wound base. Complete wound epithelialisation was achieved in 11 (85%) of the 13 patients (*Table 1*).

All 13 patients reported 100% satisfaction with the durability of BeneHold TASA between dressing changes. The mean time to healing was 16.6 days (range 7–49 days). Only one dressing-related adverse event was recorded during this study (patient #14, who developed skin tears).

Figures 2 and *3* show DFUs healing with BeneHold TASA over the 6-week study period.

Discussion

DFUs pose a significant burden in clinical practice due to the risks associated with peripheral neuropathy, peripheral arterial disease and

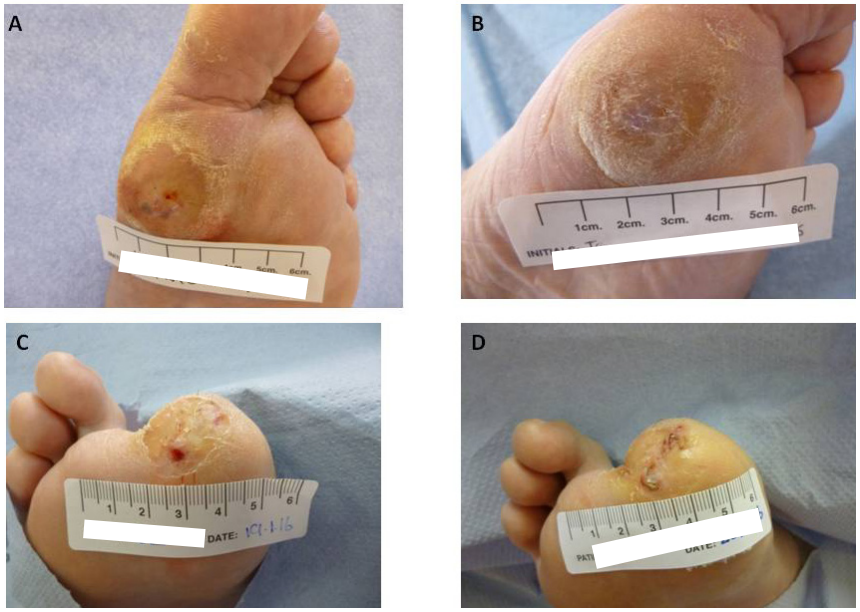

Figure 2. Representative images of DFU healing with BeneHold TASA. (a) DFU of >40 weeks duration at presentation. (b) After 21 days of treatment with TASA. (c) DFU of 26 weeks duration at presentation. (d) After 7 days of treatment with TASA.

susceptibility to infection, which can significantly impair the wound healing process. While there are several dressings available to optimise a moist wound environment and promote healing, there is a limited consensus on factors which influence this decision-making process. This case series evaluation demonstrates how performing a comprehensive wound assessment can help inform the selection of an appropriate dressing and limit the risk of adverse events.

Over recent years, the rationale for dressing selection has often been based on preference or ease of application rather than on empirical evidence. This has contributed to the overuse of antimicrobial dressings and the misuse of hydrocolloid dressings in routine clinical practice.

This inappropriate use has resulted in a decline in the use of hydrocolloid dressings over recent years due to concerns about allergic contact dermatitis (Seheiz et al, 1996), maceration (Pudner et al, 2011) and infection (Foster et al, 1997).

Subjective barriers reported with using hydrocolloids in the treatment of DFUs include the inability to monitor wound bed status, poor adherence of the dressing to the foot due to factors associated with functional biomechanics during the gait cycle, opportunistic skin flora (which may increase the risk of infection), and concerns that concomitant lower limb oedema associated with a decline in kidney function may increase wound exudate levels (Kannon and Garrett, 1995). These precautions are well documented in the literature and need to be balanced against the strength of evidence that supports the appropriate use of hydrocolloids in wound healing.

Knowles et al (1993) reported that healing and infection rates were similar in a hydrocolloid cohort compared with the other cohorts using alternative dressings. Gill et al (1999) further argued that hydrocolloids were effective at promoting debridement of sloughy or necrotic tissue through autolysis and that many of the adverse events were associated with the inappropriate use of hydrocolloid dressings in the absence of a comprehensive wound assessment.

The TASA dressing has been designed to overcome some of the subjective barriers associated with the use of hydrocolloids in the treatment of DFU.

This clinical evaluation focused on the use of BeneHold TASA Thin Absorbent Wound Dressing for the management of neuropathic DFUs. This dressing has previously been shown to be effective in promoting wound healing (Stephen-Haynes et al, 2014; 2016). In a clinical evaluation, TASA dressing was demonstrated to substantially improve outcomes in wounds of various aetiologies (Stephen-Haynes et al, 2014).

In a case series evaluating wound healing, wear times and ease of handling, TASA dressings were found to be effective in the management of skin tears and were well received by both clinicians and patients (Stephen-Haynes et al, 2016).

The transparency of TASA dressing allows for monitoring of wound bed status. The reported outcomes from the case series suggest that the dressing was conformable and attained a good level of adherence to the foot even in the presence of altered biomechanics due to peripheral neuropathy.

It is acknowledged that a high burden of skin flora on the foot could increase the risk of infection and lower limb oedema may influence wound exudate levels. However, these complications were not observed over the 6-week duration of the case series. It must be noted that selecting a TASA dressing should be approached

with caution in patients with a long history of recurrent infections and moderate to heavily exuding neuropathic DFU.

Promotion of healthy granulation tissue was documented in all 13 patients. There was a serial reduction in mean wound surface area documented between baseline and endpoint. Eleven patients had achieved complete healing within 49 days of applying BeneHold TASA in conjunction with best practice standard therapy.

While accepting that TASA should only be indicated after performing a comprehensive wound assessment, the wound healing outcomes presented in this case series are encouraging, given that all patients completing the study had one or more positive outcomes documented over the 6-week period.

This is the first study to assess TASA in the management of neuropathic DFUs. Although further research needs to be conducted on how these findings might be applied in the wider population of people with neuropathic DFUs, this case series evaluation highlights the benefits associated with the appropriate use of BeneHold TASA Thin Absorbent Wound Dressings in maintaining a moist wound environment and accelerating the time to heal in conjunction with best practice standard therapy. ■

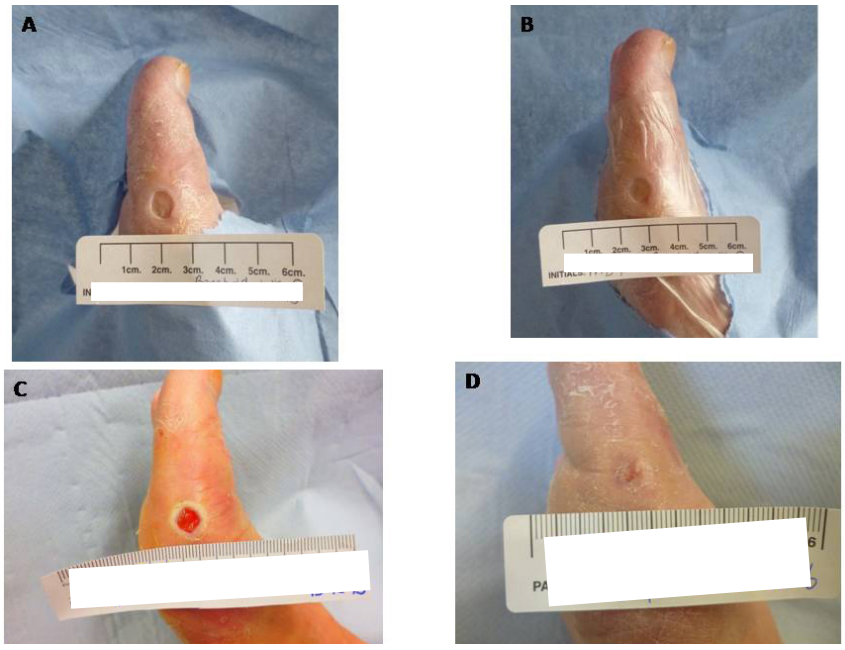

Figure 3. Representative images of DFU healing with BeneHold TASA. (a) DFU on first metatarsal head of >6 weeks duration at presentation. (b) TASA dressing applied. (c) Week 2. (d) Complete epithelialisation was achieved after 35 days of treatment with TASA.

Conflict of interest

This article was supported by Vancive Medical Technologies, an Avery Dennison business, Chicago, USA. BeneHold™, TASA™ and Vancive Medical Technologies™ are trademarks of Avery Dennison Corporation. Priyaleela Thota and Neal Carty are employees and stockholders of Avery Dennison which, as the manufacturer of the BeneHold TASA, has a financial interest in the study's test product.

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