Clinical evaluation of a thin absorbent skin adhesive dressing for wound management

J. Stephen-Haynes, ^{1,2} RGN, DN, DipH, BSc (Hons), ANP, PG DipResearch, PGDip Ed, Professor in Tissue Viability and Consultant Nurse; R. Callaghan, ² RGN, BSc (Hons), Tissue Viability Specialist Nurse; A. Wibaux, ³ PharmD, Principal Scientist; P. Johnson, ³ MD, Vice President of Research and Development and Medical and Scientific Affairs; N. Carty, ³ PhD, Research Scientist and Manager, Medical and Scientific Affairs

I Professional Development Unit, Birmingham City University,
2 Worcestershire Health and Care NHS Trust
3 Vancive Medical Technologies, an Avery Dennison business
20 N. Wacker Dr, Suite 2240, Chicago, IL 60606 USA.

Email: neal.carty@averydennison.com

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- **Objective:** This article assesses the use of BeneHold Thin Absorbent Skin Adhesive (TASA) wound dressings in a large UK primary care organisation. These wound dressings are thin (0.12mm), breathable, transparent, and are able to absorb and retain wound exudate. This non-comparative evaluation was undertaken to explore the clinical advantages this differentiated combination of physical properties offered.
- Method: The dressings are CE-marked medical devices, and were used on patients with acute and chronic wounds that were assessed and classified as light to moderately exuding. Clinical performance was evaluated with respect to the dressing's ease of use (application and removal, conformability, mould-ability, rolling and edge-lift), debridement, protection of the peri-wound, wear time, fluid handling, wound bed residue, visibility of the wound, and clinical acceptability. The evaluating clinicians used an agreed audit tool to collect data from case reports to document the progression of wounds of various aetiologies, including chronic and acute, for a maximum period of four weeks. Qualitative feedback on dressing performance was also collected at the evaluation's end, both from the clinicians' and patients' perspectives
- Results: Some 15 patients were assessed. The wear time was up to seven days in many cases, and on average was 3.9 days longer than their previous dressings. Clinicians perceived that wounds progressed toward healing in all but two cases, where the wounds remained unchanged. Out of five cases where wounds presented with necrosis, all underwent significant autolytic debridement underneath the new dressings. Transparency was a noted benefit from both the clinicians' and patients' perspectives because it enabled continuous monitoring of the full wound bed and peri-wound skin without the need to disrupt the dressing.
- Conclusion: The dressing was well-received by both clinicians and patients in all fifteen cases. The thin absorbent skin adhesive dressing was found to be a promising new technology that could offer significant advantages to improve the quality, cost, and convenience of wound care. Further work is underway to validate these findings in larger and more homogeneous patient groups.
- **Declaration of interest:** N.C.,A.W., and P.J. are employees of Vancive Medical Technologies, an Avery Dennison business, which has a financial interest in the product that was evaluated. This study was funded by an educational grant from Vancive Medical Technologies, an Avery Dennison business.

wound healing; dressings; evaluation studies; hydrocolloid dressing

J. Stephen-Haynes, ^{1,2} RGN, DN, DipH, BSc (Hons), ANP, PG DipResearch, PGDip Ed, Professor in Tissue Viability and Consultant Nurse;

R. Callaghan,² RGN, BSc (Hons), Tissue Viability Specialist Nurse; A. Wibaux,³ PharmD, Principal Scientist; P. Johnson,³ MD, Vice President of Research and Development and Medical and Scientific

N. Carty,³ PhD, Continued on next page

Affairs;

ound dressings are often described and categorised according to the materials from which they are made, for example foams, films, hydrocolloids, alginates, hydrogels. However, as the modern wound-care formulary becomes increasingly diverse, this form-centered taxonomy becomes less and less effective in communicating a dressing's clinically relevant function. BeneHold Thin Absorbent Skin Adhesive (TASA) is a new adhesive technology that challenges the usual categorisation schemes. The wound dressings resemble semipermeable film dressings; they are thin, breathable, and transparent. However, unlike semipermeable film dressings they are also able to absorb and retain wound exudate, like a hydrocol-

loid. Their thinness minimises edge lift and their smooth film surface is clinically reported to minimise friction and wound shear. Though they are technically categorised as hydrocolloids, within this article we report how these physical properties differentiate the dressings in comparison with what hydrocolloids have traditionally offered.

The basic functional requirement for any wound dressing is to provide an environment conducive to wound healing, which includes protecting and covering the wound, staying firmly in place without causing skin trauma during removal, while maintaining an optimal moisture balance to maximise the rate of healing.^{1,2} This must be fulfilled in the context of patient comfort, minimising the dressing's bulk, avoiding the inconvenience of frequent

and/or complicated dressing changes, and mitigating pain.3 Of these requirements, moisture management is one of the most enigmatic. In qualitative terms, the phrase 'moisture balance' commonly refers to the notion of taking serum, exudate, and other forms of moisture away from the wound, but not excessively to the point of creating a desiccated local environment.4,5 Wound dressings usually accomplish this by some combination of three key mechanisms: allowing moisture to transpire through the dressing's surface in the vapour phase (moisture vapour transmission), capturing it within pores, between fibres, or in other open spaces (absorbency), or capturing it through the formation of a cohesive gel in combination with some component of the dressing itself (retention).2 In many cases, one of these mechanisms dominates with little or no role played by the other two. For example, most semipermeable film dressings rely entirely on moisture vapour transmission, and most hydrocolloids rely entirely on moisture retention.1 But perhaps a greater diversity of wounds can be effectively treated if multiple moisture-handling mechanisms are engineered into a dressing's design.

The thin absorbent skin adhesive manages moisture in a unique way by combining the high breathability of semipermeable film dressings together with the moist wound healing properties of hydrocolloids. When used on light to moderate exuding wounds, this differentiated combination of physical properties offers a number of clinical advantages.

Methods

The study design was a single-center, non-comparative clinical evaluation whose primary objective was to determine the clinical effectiveness of the thin absorbent skin adhesive. An agreed evaluation tool was developed and clinical governance approval was sought and obtained. Ethics committee approval was not required as the product is a CE-marked medical device being used by qualified medical personnel as intended and is commercially available.

The parameters upon which the clinicians based their appraisal of the products performance were as follows:

- Wound type treated
- Wound duration
- Wound characteristics
- Product used prior
- Ease of application and removal
- Residue in wound bed
- Typical wear time
- Debridement
- Protection of the peri-wound
- Duration of use
- Visibility of the wound
- Clinician opinion on performance.

With subject consent, the clinicians chose 15 patients from their caseloads within the Worcestershire Health and Care Trust (Worcester, UK) to include in the evaluation whose wounds, in their judgment, were lightly or moderately exuding.

The evaluating clinicians followed each included patient for a maximum of four weeks of treatment with the new dressing. The dressing was discontinued earlier if the wound healed or if the wound status changed such that it was no longer appropriate for use. Throughout the evaluation period, dressings were changed as often as clinical care givers deemed necessary. The evaluating clinicians made weekly assessments using a standard case report form.

The case report form consisted of three main sections: relevant history, weekly wound assessments, and overall clinician feedback. Documented medical history included wound aetiology, previous wound dressing regimens, relevant allergies and comorbidities.

Wound assessment

In the weekly wound assessments, the evaluator documented infection status, peri-wound skin condition, the volume and consistency of wound exudate, and the frequency with which the dressing had been changed that week. The evaluator was also asked to record the wound's dimensions and to visually estimate the composition of the wound bed tissue in terms of epithelialised, granulated, slough, and necrotic tissue.

Improvement in the wound bed was directly assessed by the evaluating clinician through a survey question that allowed three responses: improved, unchanged, or deteriorated. The clinicians were not given any specific criteria by which to judge improvement or deterioration. Other questions in the survey captured more detailed assessments of wound condition on a week-by-week basis, but this question was designed to capture the clinician's judgment of overall wound bed progression throughout the entire evaluation period

Changes to the peri-wound skin condition were assessed by comparing the documented peri-wound skin condition at presentation with that at the end of the evaluation.

Evaluation of dressing performance

The clinician's opinion of the dressing's performance was surveyed at the evaluation's end. Most of these questions were posed either on a five-point rating scale or in relation to the patient's pre-evaluation medical history (for example, improved, unchanged, deteriorated). The remaining questions were open-ended or simple yes/no responses. This section also included questions regarding the patient's perception of dressing features, including comfort during wear and pain on removal.

Research Scientist and Manager, Medical and Scientific Affairs
I Professional Development Unit, Birmingham City University,
2 Worcestershire Health and Care NHS Trust
3 Vancive Medical Technologies, an Avery Dennison business
20 N. Wacker Dr, Suite
2240, Chicago, IL 60606 USA.

Email: neal.carty@ averydennison.com

The evaluating clinician rated how easy the dressing was to apply and remove using a five-point scale where five was the best (very easy to apply or remove) and one was the worst (very difficult). The clinician also documented the patient's perception of comfort during wear and pain on removal using a similar five-point scale (1=very uncomfortable or very painful, 5=very comfortable or not painful). The patients rated whether or not transparency was helpful to them on a five-point scale (1=unhelpful, 5=very helpful).

Once all 15 patients' case report forms were completed, the results were compiled and analysed using descriptive statistics.

Results

The main clinical outcomes of interest were dressing change frequency, wound-bed condition, peri-wound skin condition, and the clinician's assessment of adhesive trauma, both to the wound bed and the peri-wound skin. From the point of view of product acceptance, the main topics of interest were ease of handling, both during application and removal, durability of adhesion, patient comfort, and the benefits (if any) of the product's transparency, both from the patient's and clinician's perspectives.

Patient characteristics

The evaluation included seven male and eight female patients, ranging between 18–98 years of age, with an

average age of 75 years. The patients' wounds were widely varied in their aetiologies and anatomical locations (Table 1). Eleven were chronic wounds that were being dressed with a different product before starting the evaluation, except two cases where the wound was not being dressed at all because moisture complications combined with an awkward location meant that nothing would stay in place effectively. The remaining four were acute wounds.

At the end of the evaluation, 12 patients had participated throughout the full four-week duration. One patient discontinued the evaluation after three weeks because the wound healed. Another patient changed to a different type of dressing after two weeks because the short-term goal of softening the eschar had been accomplished and best practices dictated that another approach was warranted. Finally, one patient had a skin tear which, per local protocol, was only treated for one week. This was enough time for uneventful healing.

Baseline characteristics

Sampling bias naturally arose because patient inclusion was at the clinician's discretion, not via randomisation. This meant that non-routine cases were more likely to be included in the evaluation, for instance, where other dressing regimens had been already been tried with unsatisfactory results and an alternative was needed. All eleven of the chronic wounds treated with the thin absorbent skin adhe-

sive dressing could be described as such and despite clinicians' attempts to treat them using other dressings they were all in a stagnant condition, not progressing towards healing, when they were chosen for inclusion in the evaluation. In five of those cases, the wound beds were covered with necrotic tissue and attempts to achieve autolytic debridement were failing. Chronic and acute wounds alike that were located in difficult-to-dress locations, such as joints, creases, and high-friction areas, were also preferentially included in the evaluation because the dressing thinness and mouldability automatically suggested it would be better able to adhere under those challenging circumstances compared with traditional, thicker dressings.

Excessive moisture was a complicating factor in seven of the fifteen cases: two because of incontinence and five because of the volume of wound exudate. A low volume of exudate was noted in three of the remaining cases, and in the final five cases, moisture was not a noteworthy complication. When excessive moisture was present it was usually associated with peri-wound skin damage, presenting as either maceration or redness, and it was often noted as contributing to poor adhesion of the patient's prior dressing. Overall, peri-wound skin abnormalities were reported in twelve cases, including redness (4 cases), maceration (3 cases), dryness (3 cases), dressing-related damage (1 case), and fragile skin (1 case).

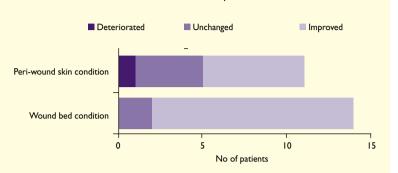
Among those patients who were using a different wound dressing immediately before to treatment (Table 1), foams were the predominant category (five out of ten cases). Other dressing regimens included adhesive films (1 case) and non-adhesive absorbent pads (1 case), and in three cases the prior dressing was unspecified. In many cases the dressings were being changed frequently: the least frequent was three times a week and the most was as many as three times per day. Four patients' dressings were being changed daily or more frequently. Loss of adhesion due to moisture complications and/or awkward anatomical locations was the primary factor requiring frequent dressing changes. Also, the desire to visually inspect the wound bed, purposeful removal, was also an important factor influencing dressing change frequency.

Progression toward healing

Nearly all of the wounds showed signs of improvement by the evaluation's end, and none deteriorated (Fig 1). When asked if the wound was improved, unchanged, or deteriorated in one case the clinician did not respond, in 12 cases the wound bed was rated as 'improved', and in the remaining two cases it was rated as 'unchanged.'

There were six instances where an abnormal presentation transitioned to healthy skin, and the peri-

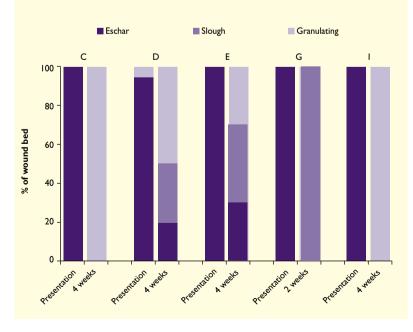
Fig I. Clinicians' assessments of wound bed and peri-wound skin improvements at the end of the evaluation. The assessment of the peri-wound skin was not applicable in four cases, where it was healthy on presentation (n=3) and the skin tear (n=1). The wound bed assessment was not assessed in one patient as clinician did not fill in form

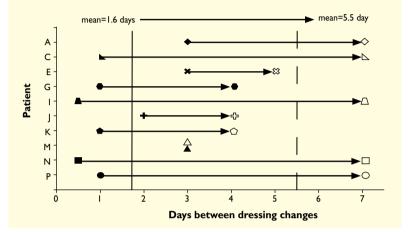


wound skin was therefore judged to have improved. In four other instances, red, dry, or macerated skin documented at presentation remained unchanged. One patient's peri-wound skin presented as dry and was documented as slightly macerated at the evaluation's end: this case was judged to have deteriorated. Patients who presented with healthy peri-wound skin were not considered, provided the skin remained healthy throughout the entire evaluation period, and one further exclusion was made for the skin tear patient because, besides fragility, no other peri-wound skin abnormality was observed.

The five chronic wounds that were covered with necrotic tissue at presentation showed marked progression toward autolytic debridement during the

Fig 2. The progression of five chronic wounds covered with necrotic tissue at presentation. The letter refers to patient details presented in Table I





evaluation period (Fig 2). In two instances, wounds covered with 100% necrotic tissue underwent complete autolytic debridement and ended the evaluation with a wound bed covered entirely with granulation tissue (Fig 2C and I). In two other cases there was significant reduction in necrotic tissue and the wounds ended the evaluation with less than 30% of the area covered with eschar and the remaining area covered with a mixture of granulation tissue and slough (Fig 2d and e). The fifth wound progressed from 100% eschar to 100% slough, and was then

transitioned to a different dressing type after two weeks of treatment (Fig 2 G).

The average rating of trauma to the wound bed was 4.87 (range: 4–5) and the average rating of trauma to the peri-wound skin was 4.60 (range: 2–5). These ratings indicate that the dressing was not causing re-injury to the healing wound upon removal and was not worsening the peri-wound skin condition through adhesive trauma. In all 15 cases the dressing was also found to remove cleanly without leaving any adhesive residue in the wound.

Dressing change frequency

At the end of the evaluation period, the dressings were being changed, on average, every 5.5 days. In seven cases dressing change was only occurring once per week, and in the most frequent case it was every three days. Compared with the dressings patients were using immediately prior, this represented a significant improvement in wear time (Fig 3). The ten patients who were using a different wound dressing immediately prior to starting this evaluation were having those dressings changed, on average, every 1.6 days, and in six cases they were being changed either daily or more frequently. The average increase in wear time that was realised by switching was 3.9 days. By the end of the evaluation, five patients were having their dressings changed once per week; four of those had been in the once-a-day (or more) category with their prior dressings (Fig 3 C, I, N and P). The only patient who did not have an increased wear time maintained a dressing change frequency of every three days (Fig 3m), both with both dressings. The other nine patients all had less frequent dressing changes when compared to their prior dressings.

Clinician and patient perceptions

Clinicians' and patients' perceptions of the thin absorbent skin adhesive dressing were surveyed at the end of the evaluation (Fig 4 and Fig 5). The average score for ease of application was 4.33 (range: 2–5) and the average for ease of removal was 4.53 (range: 2–5), indicating the dressing was very easy to use. The patients unanimously rated the dressing as being very comfortable to wear (average score of 5.0), and all but two patients rated the dressing as painless to remove, for an average patient score for pain on removal of 4.71 (range: 3–5).

Because few absorbent dressings are fully transparent, clinicians were asked whether or not transparency offered clinical benefits, and were also asked to document patients' perceptions of this attribute (Fig 4 and Fig 5). The clinicians unanimously stated that transparency did offer clinical benefits, and in all but one case stated that this feature contributed to longer wear times giving an average score of 4.25

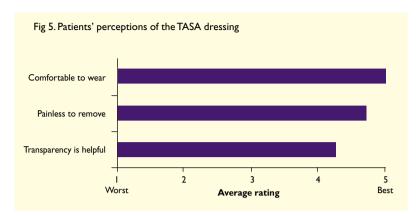
(range: 3–5). In three cases the patient's wound was in a location that was not readily visible, and so no response was provided.

Discussion

The unique combination of physical properties offered by the thin absorbent skin adhesive sets it apart from other categories of wound dressings. The dressing's total fluid-handling capacity is on par with hydrocolloid wound dressings,7 but the mechanisms by which it manages moisture are fundamentally different from that class of adhesives, which rely primarily on moisture retention and usually have very limited breathability. On the other end of the spectrum, film dressings manage moisture exclusively by the mechanism of water vapour permeation and have no ability to absorb or retain moisture. The absorbent skin adhesive dressing balances both mechanisms. Certainly, other categories of dressings also combine the mechanisms of breathability and absorption (foams being the most notable example), but to do so in an ultra-thin and transparent format is unique to this product.

In this evaluation, the dressing's properties translated into tangible clinical benefits, most notably, increased wear time. Initially, the patients selected for treatment were receiving wound-dressing changes on average every 1.6 days, and six of the ten patients' dressing were being changed daily or more frequently. This dressing-change frequency is relatively high in comparison to what is typically reported for dressings applied to pressure ulcers and venous ulcers (in the range of 2-3 days between dressing changes).8-12 However, the difference is not surprising considering that the study was not randomised; clinicians were more apt to evaluate a new dressing in cases where the prior dressing was not performing satisfactorily. Nevertheless, this selection is representative of a real challenge within clinical practice where some estimates suggest daily dressing changes are performed in 10-20% of wounds, excluding surgical wounds in the acutecare setting, 11,12 having a significant impact on clinician time and within primary care requiring additional visits. Using this thin absorbent skin adhesive dressing, dressings were left in place an average of 3.9 days longer, and following the same logic employed by Smith et al.9 the per-patient, annual savings that could be realised by that extension amounts to an estimated £2,420 per patient per year, a 70% cost reduction (Table 2).

Several factors supported the nearly four-day increase in dressing wear time, as compared with the patients' prior dressing regimens. In the survey conducted by Smith *et al.*⁹ clinicians were asked to explain the reasons why dressings were changed, and the results showed that clinical routine was an often-cited reason for performing what were likely



otherwise unnecessary changes. With the absorbent skin adhesive dressing, the ability to clearly visualise the entire wound bed and peri-wound skin through the dressing enabled clinicians to make an objective evaluation of whether a dressing change was needed, and this was a major factor in reducing the number of changes that were performed as a matter of routine. The dressing's ultra-thin profile and high degree of conformability were also contributing factors, because these properties meant that it could readily adapt to complex body contours and was less prone to roll off from the edges as compared to the patients' prior dressings.

The observed healing responses suggest that the dressing helped to maintain an appropriate moisture balance in these wounds. Because autolytic debridement demands a moist environment, its initiation or acceleration in the five significantly necrotic wounds is one indicator that the dressing retained a beneficial level of moisture underneath it. Wound bed condition improved in nearly every case, which was remarkable considering that significant moisture complications were noted in nearly half of them. This suggests that the dressing was able to remove excess moisture, but without causing wounds to dry out, and also without losing

Table 2. Estimated per-patient, annual costs to treat wounds with average dressing change frequencies of once every 1.6 days or once every 5.5 days

	I.6 days between changes	5.5 days between changes	difference
Labour costs ^a	£2060	£600	-£1460
Materials costs ^b	£1360	£400	-£960
Total	£3420	£1000	-£2420

^aEstimated cost of one dressing change is £9.04, derived by multiplying a nursing labour cost of £39/hr by an average dressing change time of 13.9 min.⁹ Estimated cost of one wound dressing is £5.96.

practice

adhesion. Overall, the evaluating clinicians perceived that the thin absorbent skin adhesive dressing provided an environment conducive to healing, and in most cases there was benefit to the peri-wound skin, as well.

Besides this thin absorbent skin adhesive, absorbent acrylic dressings are the only other class of fully transparent wound dressings that are also capable of moisture retention. Similarly, previous evaluations demonstrated their utility in facilitating autolytic debridement¹³ and treating pressure ulcers.¹⁴ In both cases, the dressing's transparency was noted as a clinical benefit, primarily because the ability to inspect the wound meant that unnecessary dressing changes were avoided. The same was true in this evaluation, but in addition to that the patients' perceptions of the benefits of transparency were also probed. Interestingly, most of the patients rated this feature as being highly beneficial and remarked that it offered peace of mind that the wound was not deteriorating underneath. Patients were highly satisfied with the dressing because its extremely low profile (less than 25% the thickness of absorbent acrylics, and far thinner in comparison to foams) and excellent conformability also made it very comfortable to wear.

On aggregate, the results of the clinical evaluation indicate that the thin absorbent skin adhesive dressing offers significant clinical advantages by virtue of combination of total transparency, conformability, and ultra-low profile, together with an innovative adhesive technology that enables both breathability and moisture retention in one easy-to-use dressing

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format. However, there are limitations to these results stemming from the clinical evaluation format, as opposed to a randomised, controlled clinical trial. This study describes the experiences of one group of clinicians working with a diverse collection of wounds, as typically seen within the community environment. While patient selection was at the clinicians' discretion, and within a single center, the results are indicative of the likely outcomes and confirm two previous studies' results. ^{13,14} Further evaluation is being undertaken to explore the dressing's performance in specific wound aetiologies and will be reported later.

While clinical evaluations can offer valuable perspectives, especially on newly available product offerings, a more formal, controlled, and comparative trial in a larger, multi-centre patient population will be necessary to prove that this dressing offers superior healing outcomes relative to other treatment modalities.

Conclusions

The thin absorbent skin adhesive dressing represents a new and distinctly differentiated adhesive technology for wound-care applications. Wounds treated with the dressing generally progressed towards healing, and the dressing provided a moist environment that facilitated autolytic debridement. The dressings were changed less frequently, which has significant implications for both patient convenience and cost of care. This is a promising new technology that could offer significant advantages to improve the quality, cost, and convenience of wound care.

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