BeneHold™ TASA™
Thin Absorbent Skin Adhesive™

TASA™ for the Management of Category I and II Pressure Ulcers

Case Report

Inspired Advances.
Intelligent Results.
Abstract

This case report series describes clinical experiences from six patients using BeneHold™ Thin Absorbent Wound Dressings incorporating TASA™ (Thin Absorbent Skin Adhesive™) in a large UK Primary Care organization. Wound dressings made using TASA™ are thin (0.12 mm), breathable, and transparent, but they are also 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.

TASA™ dressings are CE-marked medical devices, and were used to manage patients’ Category I and II pressure ulcers. Clinical performance was evaluated with respect to the dressing’s ease of use (application and removal, conformability, mould-ability, rolling and edge-lift), protection of the periwound skin, wear time, fluid handling, wound bed residue, visibility of the wound, and clinical acceptability. The evaluating clinicians used an agreed-upon audit tool to collect data from case reports to document the progression of wounds 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.

The wear time was up to seven days in many cases, and clinicians perceived that wounds progressed toward healing in all but one case, where the wound remained unchanged. Transparency was a noted benefit because it enabled continuous monitoring of the full wound bed and peri-wound skin without the need to disrupt the dressing. The dressing was well-received by both clinicians and patients in all six cases: TASA™ was found to be a promising new technology that could offer significant advantages to improve the quality, cost, and convenience of wound care.
Introduction

Hydrocolloid wound dressings have found widespread use in clinical wound care practice for over thirty years, and are currently used to treat a wide variety of wounds, including foot and leg ulcers, pressure ulcers, and burns. When used appropriately, hydrocolloid adhesives act as occlusive, moisture retentive dressings that can create an environment conducive to rapid wound healing. While there are many different brands of hydrocolloid sheet dressings available today, each with its own unique formulation, the products in this category do share a commonality: the adhesive system is formed by dispersing a substantial fraction of hydrophilic, water-absorbing particles into hydrophobic matrix material. While hydrocolloid dressings offer a number of clinical benefits, it is recognized that many of them have some limitations including dressing-associated odour, and disintegration in the presence of wound exudate. Additionally, the inability to visualize the wound through the dressing has been sometimes cited as a drawback of hydrocolloid dressings.

BeneHold™ Thin Absorbent Skin Adhesive™ (TASA™) is a new adhesive technology that represents an innovative implementation of the traditional hydrocolloid adhesive concept. Wound dressings made using TASA™ resemble semi-permeable film dressings: they are thin, transparent, and highly conformable. However, unlike semi-permeable film dressings they are also able to absorb and retain fluids such as wound exudate, and in that sense their function is as a hydrocolloid. TASA™ dressings combine two different moisture management mechanisms in one material: whereas most semi-permeable film dressings rely entirely on moisture vapor transmission, and most hydrocolloids rely entirely on moisture retention, TASA™ handles moisture in both ways. The way that TASA™ combines hydrophilic and hydrophobic material results in a material that remains integrated (i.e. does not break down) even after absorbing fluid, does not have an odour, and allows for visualization of the underlying wound throughout the entire wear time.

This evaluation was undertaken to determine the clinical acceptability of a wound dressing that incorporates TASA™. It was decided to evaluate the dressing’s performance in managing pressure ulcers because this is a wound aetiology for which hydrocolloid dressings can be particularly beneficial. A meta-analysis of published clinical studies performed by Bouza et al. found that hydrocolloid dressings significantly improve healing rates in Grade II or higher pressure ulcers. There is also evidence that they are more cost effective than conventional gauze dressings, partially because far fewer dressing changes are required. Here we present a series of six case reports describing clinical experiences using TASA™-based wound dressings in the management of Category I and II pressure ulcers.
Methods

Materials
The dressing evaluated was the BeneHold™ Thin Absorbent Wound Dressing featuring TASA™, which is indicated for the management of lightly to moderately exuding wounds, including but not limited to pressure ulcers, partial thickness wounds, minor wounds, protection of clean surgical incisions, skin graft donor sites, superficial skin wounds and as a secondary dressing on full thickness wounds. Its construction and appearance resembles a semi-permeable film dressing: it consists of a layer of Thin Absorbent Skin Adhesive™ (TASA™) laminated to a flexible, elastic, and transparent polyurethane backing film. Whereas the fluid-handling capabilities of most ordinary film dressings are limited exclusively to moisture-vapor transmittance, without any capacity to absorb, TASA™ combines both mechanisms. Using the Paddington cup method, the dressing’s fluid-handling capacity measures approximately 2,000 g/m²/24 hr, representing the sum of contributions from moisture-vapor transmittance (1,300 g/m²/24 hr) and static absorption (700 g/m²/24 hr). Uniquely, there is a significant absorptive component despite the dressing’s ultra-thin profile, just 0.12 mm in thickness.

Aside from its fluid-handling characteristics, the dressing’s other significant physical properties are that it is transparent, and remains so even after it absorbs fluid, allowing for total, continuous visualization of the underlying wound and peri-wound regions. It is conformable so that it can wrap around complex anatomical topologies and can move with the body, for example when it is applied to joints. Furthermore, the dressing utilizes a smooth, low-friction backing film to lessen the effects of friction, and its corners are rounded to reduce the risk of edge lift during wear.

Methodology
The study design was a single-center, non-comparative clinical evaluation whose primary objective was to determine the clinical acceptability of TASA™ in treating Category I and II pressure ulcers. With subject consent, the clinicians chose patients from their case loads within the Worcestershire Health and Care Trust (Worcester, UK) to include in the evaluation whose wounds, in their judgment, were amenable to treatment with TASA™. Patient inclusion was also subject to a predefined set of eligibility criteria designed to narrow the focus of the evaluation. These criteria excluded Category III or IV pressure ulcers, suspected deep-tissue injuries, surgical wounds, traumatic wounds, skin tears, and malignancies. Infected wounds and highly exudative wounds were also excluded. An agreed-upon evaluation tool was developed and Clinical Governance approval was obtained. Ethics committee approval was not required as the product was 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 product’s performance were as follows:

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Wound duration</td>
<td>Debridement</td>
</tr>
<tr>
<td>Wound characteristics</td>
<td>Protection of the peri-wound</td>
</tr>
<tr>
<td>Product used prior</td>
<td>Duration of use</td>
</tr>
<tr>
<td>Ease of application and removal</td>
<td>Typical wear time achieved</td>
</tr>
<tr>
<td>Residue in wound bed</td>
<td>Visibility of the wound</td>
</tr>
<tr>
<td>Typical wear time of this product</td>
<td>Clinician opinion on performance</td>
</tr>
</tbody>
</table>

The evaluating clinicians followed each included patient through 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 caregivers deemed necessary. Weekly assessments were made by the evaluating clinicians 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, prior wound dressing regimens, and relevant allergies and comorbidities. 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 percentages that were epithelializing, granulating, composed of slough, or frankly necrotic. Finally, 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 (e.g. improved, unchanged, deteriorated). Others 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.

Once all patients’ case report forms were completed, the results were compiled and analyzed using descriptive statistics. The main clinical outcomes of interest were dressing change frequency, wound bed condition, and peri-wound skin condition. 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.
Results

Included Patients
Ten case reports were obtained, of which six were judged to meet the full eligibility criteria (Table 1). This group included three males and three females, ranging between 46 and 90 years of age, with an average age of 71 years. Using the International NPUAP- EPUAP Pressure Ulcer Classification System, five of the patients’ wounds were classified as Category II pressure ulcers and the sixth was classified as Category I. These wounds were located on the sacrum (3 patients), the buttocks (1 patient), the lateral malleolus (1 patient), and the spine (1 patient). Of the four case reports that were not included in this analysis, two were excluded because of the patient’s wound type (one was a foot blister and one was a suspected deep tissue injury) and two others were excluded because the evaluation period was ended prematurely: one patient died a week after beginning the evaluation, and the other discontinued use after three days because the wound was more amenable to treatment with a barrier cream, rather than a dressing.

Table 1. Summary of patient demographics and wound characteristics for the six included case reports.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age / Sex</th>
<th>Wound Type</th>
<th>Wound Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>79 / F</td>
<td>Category II Pressure Ulcer</td>
<td>Sacrum</td>
</tr>
<tr>
<td>B</td>
<td>46 / M</td>
<td>Category II Pressure Ulcer</td>
<td>Lateral Malleolus</td>
</tr>
<tr>
<td>C</td>
<td>51 / M</td>
<td>Category II Pressure Ulcer</td>
<td>Buttock</td>
</tr>
<tr>
<td>D</td>
<td>84 / F</td>
<td>Category II Pressure Ulcer</td>
<td>Sacrum</td>
</tr>
<tr>
<td>E</td>
<td>90 / F</td>
<td>Category I Pressure Ulcer</td>
<td>Spine</td>
</tr>
<tr>
<td>F</td>
<td>76 / M</td>
<td>Category II Pressure Ulcer</td>
<td>Sacrum</td>
</tr>
</tbody>
</table>

Case Report A
A 79-year-old female presented with a Category II, sacral pressure ulcer. Following a cerebrovascular accident, the patient’s nutritional status was poor and she was receiving intravenous fluids. The wound measured approximately 6 cm × 4 cm and was healing (the majority of the wound bed was composed of epithelializing tissue), but the peri-wound skin was very tender. Ordinarily, the staff would have dressed this wound with an adhesive foam and removed it daily to check the wound. But instead, TASA™ was applied and left in place for seven days without disruption. The dressing’s transparency was a noted clinical benefit because the ability to observe the wound continuously without disturbing the dressing gave the staff confidence to leave it in place and avoid disturbing the fragile tissue underneath. After one week the wound was completely epithelialized, but the staff continued to dress the area with TASA™ because they felt it was helping to mitigate shear and friction and to protect the still-vulnerable skin in that region.
Case Report B
A 46-year-old male with multiple sclerosis presented with a Category II pressure ulcer on the left lateral malleolus. The wound measured approximately 3 cm × 2 cm and necrotic tissue was present in a small portion of it. It was producing a medium amount of thin, runny exudate and there was a slight odor which the patient found particularly distressing. The decision to dress the wound with TASA™ was made due to the dressing’s capability to absorb the wound exudate and because its high degree of conformability and flexibility suggested that it would remain securely attached to the ankle. Indeed, the dressing remained in place and was changed once every seven days for two weeks, at which point the wound was healed.

Case Report C
A 51-year-old male with motor neuron disease presented with a Category II pressure ulcer on the right buttock. The wound at presentation was being managed with a foam dressing and, although there was granulation tissue in the wound bed, it was stagnant and failing to progress toward epithelialization. The clinical staff changed from using foam to using TASA™, and within one week the wound achieved full epithelialization. Ordinarily, the patient’s dressing would have been changed daily but TASA™ remained in situ for seven days, in part because its transparency allowed the staff to continually monitor the wound, rendering routine dressing changes unnecessary. Even after the wound healed, the patient continued to use TASA™ because both the patient and the clinical staff believed it was reducing friction and shear, and therefore protecting the skin from re-injury.

Case Report D
A frail, 84-year-old female with limited mobility caused by arthritis presented with a Category II, sacral pressure ulcer. The wound measured approximately 2 cm × 2 cm and was 80% covered in slough. The peri-wound skin was excoriated. Because of the difficult-to-dress location, TASA™ was cut into a triangle shape and applied to the wound with the point oriented toward the anus. This method proved successful, as the dressing remained securely in place for seven days at a time. After the first week of using TASA™ the condition of the peri-wound skin improved and was healthy in appearance, and after three weeks the wound bed also improved and was covered in granulation tissue.

Case Report E
A 90-year-old female with scoliosis presented with a Category I pressure ulcer on the spine. The surrounding skin was healthy, and at this stage the skin was unbroken. Because the clinical staff would ordinarily dress this wound with a self-adhesive film, TASA™ was selected for its similar physical attributes: transparency, thinness, conformability, and breathability. The dressing was applied and left in place for one week, after which time the wound remained unchanged but did not further deteriorate.
**Case Report F**

A 76-year-old male presented with a Category II, sacral pressure ulcer exacerbated by moisture. The wound was small, measuring approximately 1 cm × 1 cm, and was covered in granulation tissue. The wound was being managed with self-adhesive foam dressings that were changed daily, but this protocol of repeatedly applying and removing an adhesive was probably contributing to the unhealthy state of the peri-wound skin, which was macerated and excoriated. The patient agreed to switch to TASA™ and continued to use it for three weeks: during the second and third weeks the dressing was changed every three days. By the end of that time, the peri-wound skin was no longer macerated or excoriated, though it was noted to then be somewhat dry. The dressing’s transparency was a noted benefit, particularly from the patient’s perspective because he was used to changing the dressing daily and expressed concern about knowing the wound’s status if the dressing was to be changed less frequently. The ability to see through the dressing allayed those concerns and gave him peace of mind between dressing changes.

**Summary Results**

Five out of the six patients were able to wear the dressing for seven days at a time, with the sixth receiving dressing changes every three days on average. In none of the six cases did the condition of the wound bed or the peri-wound skin deteriorate while using TASA™, and in the majority of cases both showed some improvement (Figure 1). Although the design of the evaluation allowed for TASA™ to be used for a period of four weeks, all six of the patients discontinued it earlier. Three of them used TASA™ for one week, one used it for two weeks, and two used the dressing for a period of three weeks. In three cases the dressing was discontinued because the wound healed, but in the remaining three cases the reasons for discontinuing the dressing were not documented.

**Figure 1. Clinicians’ assessments of wound bed and peri-wound skin changes at the end of the evaluation.**

Clinicians’ and patients’ perceptions of the TASA™ dressing were surveyed at the end of the evaluation (Figure 2 and Figure 3). 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 average score for ease of application was 4.50 (min = 3, max = 5) and the average for ease of removal was 4.67 (min = 3, max = 5), indicating the dressing was very easy to use. The product’s ability to remain integrated was rated by judging the amount of residue remaining in the wound after removal on a similar five-point scale (1 = large amount of residue, 5 = no residue), and the average score was 4.83 (min = 4, max = 5). The clinician also documented the patient’s perception of comfort during wear and pain on removal using a five-point scale (1 = very uncomfortable or very painful, 5 = very comfortable or not painful). The patients rated the dressing as being very comfortable to
wear, with an average score of 4.83 (min = 4, max =5), and most of the patients rated the dressing as being
painless to remove, with an average score of 4.50 (min = 3, max = 5). Because few absorbent dressings are fully
transparent, as TASA™ is, clinicians were asked whether or not transparency offered clinical benefits (Figure 2).
The clinicians unanimously stated that transparency did offer clinical benefits, and in five out of the six cases
stated that this feature contributed to longer wear times.

**Figure 2. Clinicians’ perceptions of the TASA™ dressing with respect to various attributes.**

**Figure 3. Patients’ perceptions of the TASA™ dressing with respect to comfort during wear and pain during removal.**
Discussion

The combination of physical properties offered by TASA™ makes it unique. The dressing’s total fluid-handling capacity is on par with other hydrocolloid wound dressings, but it does not rely entirely on moisture retention: it also allows water vapor transmission through the dressing. In a sense, it combines the absorption capabilities that are characteristic of hydrocolloids with the breathability that is characteristic of film dressings. Whilst other categories of dressings also combine the mechanisms of breathability and absorption (foams being the most notable example), the ultra-thin and transparent format is unique to TASA™.

In this evaluation, six patients’ Category I or II pressure ulcers were dressed with TASA™ because its unique properties were viewed by the clinical staff as being beneficial in those cases. Prolonged wear time was one notable advantage that was realized. In three case reports, the clinicians identified foam dressings as their choice alternative to TASA™, and wrote that they would change that foam dressing daily in order to assess wound status. But since TASA™ is transparent, it offered a unique advantage over opaque foams because it allowed for continuous assessment of wound status without having to remove the dressing. Instead of changing the dressing daily, TASA™ was changed weekly in two cases, and twice weekly in the third case. In a survey conducted by Smith et al., 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 TASA™, the ability to clearly visualize the entire wound bed and peri-wound skin through the dressing enabled clinicians to make a decision about dressing changes based on an objective evaluation of the wound’s status, rather than as a matter of routine, and this helped to eliminate unnecessary dressing changes. Furthermore, the dressing’s ultra-thin profile and high degree of conformability were also key to enabling longer wear times because these properties meant that dressings could readily adapt to complex body contours and not be prone to rolling off from the edges.

From the point of view of product acceptance, the TASA™ wound dressing performed very well. Clinicians found the dressing easy to work with, citing its transparency as a distinct clinical benefit, and patients found that it was comfortable to wear and painless to remove. The patients’ favorable comfort ratings were likely influenced by the dressing’s ultra-thin profile and high conformability: this combination of attributes results in a very unobtrusive dressing that molds to and moves with the body like a second skin.

Interestingly, in two cases the clinicians elected to continue using TASA™ beyond the point of wound healing because they believed the dressing’s smooth backing material would protect the skin from re-injury caused by friction and shear forces. Indeed, there is a growing body of evidence that prophylactic application of wound dressings to vulnerable sites may be a beneficial component of an effective pressure ulcer prevention strategy. Much of the clinical research on the topic has been carried out using soft silicone foam dressings, and a consensus panel has endorsed the prophylactic use of those dressings, but a recent systematic review of the topic concluded that there is no evidence that other dressing types cannot be equally effective. While no formal, randomized clinical trial has been conducted to prove the TASA™ dressing’s efficacy in preventing pressure ulcers, the existing literature on the topic suggests that there was validity to the clinicians’ intuitions in these two reported cases.
In conclusion, the results of the clinical evaluation indicate that TASA™ offers significant clinical advantages by virtue of combining 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 format. However, there are limitations to these results stemming from the clinical evaluation format, as opposed to a randomized, controlled clinical trial. This observational report describes the experiences of one group of clinicians working with a small number of patients, as typically seen within the community environment. Further evaluations have been undertaken to explore the dressing’s performance in a wider variety of wound aetiologies and will be reported later.

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

Conclusions

BeneHold™ Thin Absorbent Skin Adhesive™ (TASA™) represents a new and distinctly differentiated class of adhesives for wound care. Though technically within the category of hydrocolloids, dressings made with TASA™ combine the beneficial properties of semi-permeable films, in that they are thin, transparent, breathable and very conformable, with those of hydrocolloids, in that they can absorb and retain wound exudate. In this evaluation, this unique combination of material properties translated into noticeable clinical benefits. Category I and II pressure ulcers treated with TASA™ generally progressed towards healing, and the dressing was able to stay in place for comparatively long periods of time, which has significant implications for both patient convenience and cost of care. TASA™ is a promising new technology that could offer significant advantages to improve the quality, cost, and convenience of wound care.
References


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