Clinical performance and positive impact on patient wellbeing of ALLEVYN™ Life

Clinicians and patients may have different priorities when considering the goals of managing wounds. While clinicians tend to focus on wound closure, patients are often concerned about maintaining comfort and dignity in their normal activities. A new dressing (ALLEVYN™ Life; Smith & Nephew) was designed to incorporate specific dressing features designed to address key wound-related issue of wellbeing. This article evaluates the clinical performance of ALLEVYN Life, as well as its ability to address the real life issues facing patients living with wounds, and assesses its impact on patient wellbeing.

KEY WORDS
- ALLEVYN Life
- Clinical evaluation
- Patient wellbeing

A key goal for clinicians in wound management is wound healing or closure. While this is clearly an important clinical aim, patients with wounds may have different priorities, such as reducing pain or malodour, preventing leakage of exudate, masking unsightly strikethrough, and being able to continue with normal activities without discomfort, embarrassment, or inconvenience.

These real-life concerns are broadly embodied in the concept of "wellbeing". Patients with low levels of wellbeing have low socioeconomic impact due to the costs of health care provision but also more widely due to protracted sickness absence from work (Augustin, 2013; Hurd, 2013). The ability to influence the wellbeing of these patients may positively influence these socioeconomic factors. Low levels of patient wellbeing has been linked to poor treatment concordance and compliance and impaired wound healing (Cole-King and Harding, 2001; Persoon et al, 2004; Solowiej et al, 2009; Solowiej et al, 2010a; b; Vedhara et al, 2010; Alexander, 2013). The longer the wound remains unhealed, the lower the sense of wellbeing resulting in further wound healing impairments by mechanisms as yet unknown.

Wellbeing was defined in a recent consensus document as "a dynamic matrix of factors, including physical, social, psychological, and spiritual" (Wounds International, 2012). The consensus document also highlighted eight principles that encapsulate the patient's wound management experience, and can be summarised as empowerment, management of risk, the everyday, stigma, the outside, movement, cleanliness and protection (Wounds International, 2012; *Box 1*).

Box 1. The principles of wellbeing in relation to dressing characteristics (adapted from Wounds International [2012]).

Empowerment
A person's need to take control of the physical, psychological and emotional elements of wound care.

Management of risk
A person's use of certain behaviours surrounding his/her wound management (e.g. the weighing up of certain activities and the level of risk attached to them).

The everyday
The 24/7 impact of wound management on the patient's everyday living.

Stigma
How the response of other people can affect those living with a wound.

The outside
The appearance of dressings and products.

Movement
How a person's activities "fit" with the wound dressings used.

Cleanliness
The person's requirement for cleanliness may conflict with the need to keep dressings in place for up to 7 days.

Protection
The role of dressings and wound management products to protect the body from physical damage and infection.

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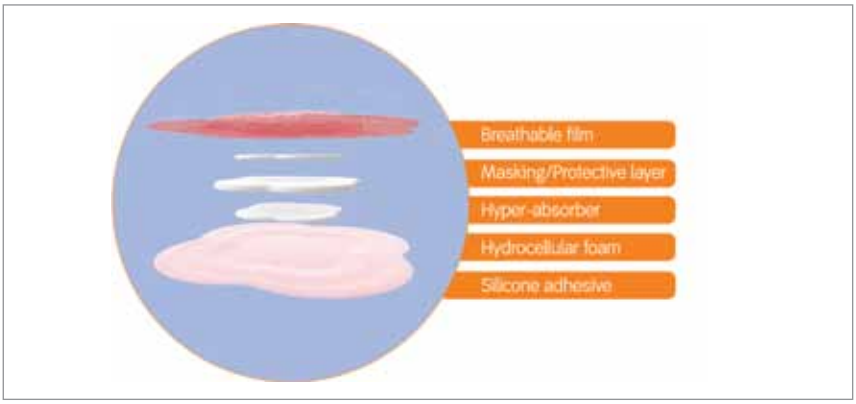
Figure 1. Layered construction of ALLEVYN™ Life (Smith & Nephew).



BACKGROUND

ALLEVYN™ Life (Smith & Nephew) is an innovative new member of the ALLEVYN family of wound dressings. It has been designed with patient wellbeing as a key consideration. The concept being that if specific wellbeing-related dressing features are improved or enhanced, this may have a positive influence on overall patient wellbeing. The dressing incorporates features intended to combat the challenging aspects of living with a wound. These include:

- A protective, masking layer that aesthetically conceals the presence of exudate and reduces its visual impact between dressing changes.
- A hyperabsorbent layer that locks fluid away, preventing leakage during wear.
- A unique, quadrilobe shape with a wide silicone border designed to fit the contours of the human body so the dressing conforms securely and allows the patient to shower.

The advanced layered construction of ALLEVYN Life is illustrated in *Figure 1*.

This study was undertaken to evaluate and provide evidence for the performance of ALLEVYN Life over a short treatment phase in a clinical setting, as well as to assess the impact of the dressing on patients' wellbeing.

METHODS

The study was a prospective, noncomparative evaluation of ALLEVYN Life in the treatment of exuding wounds to assess the dressing's performance against clinical indicators and wellbeing parameters from the patients' perspective. The primary objective was to assess the overall acceptability of ALLEVYN Life and subjectively compare with the usual dressing.

Adult patients with an uninfected wound suitable for treatment with ALLEVYN Life were screened for enrolment. Where patients had more than one wound, only the largest eligible wound was included in the evaluation.

Exclusion criteria were: pregnancy, women of reproductive age not using contraception, patients with known sensitivity to dressing components, those with a history of poor compliance, and those who have participated previously in this study.

Patients were informed of the study and its requirements and asked to give informed consent prior to enrolment. Ethics approval was obtained prior to enrolment as per local requirements.

Patients meeting the eligibility criteria received treatment with ALLEVYN Life for a maximum of four dressing changes, or up to 14 days, whichever came first. No ancillary product was supplied and the evaluating clinicians used appropriate secondary dressings according to local protocols.

Treatment commenced on day 0 (baseline) and dressing changes took place when deemed necessary by the evaluating clinician. Wounds were cleaned and the dressing applied according to the manufacturer's instructions and local protocols.

A questionnaire was completed for each patient by the clinician at baseline, at each dressing change, and on treatment discontinuation. Wound dimensions were measured and changes in dimensions compared between baseline and study end. Differences were measured using the Wilcoxon signed ranks test.

Any patient who interrupted the evaluation treatment for more than 3 days was withdrawn from the study. Patients who did not respond to therapy were withdrawn only when it became necessary to change the treatment on clinical grounds.

RESULTS

Patient and wound information

A total of 148 patients (80 men, 68 women) were recruited. The mean age of patients was 69.1 years (range, 20–99 years). Patients being treated in a number of different clinical settings were recruited, including wound clinic, hospital, long-term nursing home, doctor's practice, and in their own home. Wound aetiology and exudate levels at baseline are shown in (*Table 1*). Wounds occurred

on a range of body regions with the majority (79.6%) on the lower extremities.

Clinical performance

Wounds were treated with ALLEVYN™ Life for a median of 19 days (range, 2–80 days). Mean dressing wear time was 4.0 days. Similar wear times were observed regardless of wound type and exudate level.

Overall, there was significant evidence of a reduction in wound area, depth and volume between baseline and treatment discontinuation ($P<0.001$ for all three separate evaluations; *Table 2*). A minority of patients (14.9%) achieved wound closure by the final study assessment.

There was an increase in the median percentage wound area containing granulation tissue between baseline (20%) and treatment discontinuation (70%). The percentage of nonviable tissue decreased from a median of 20% of the wound area at baseline, to 0% by study end.

The number of patients with healthy skin surrounding the evaluation wound increased between baseline and study end (from 31.7% to 45.9%). The presence of fragile, inflamed, macerated, or dry and flaky skin all reduced. Exudate level decreased in 57.5% of patients, and were stable in 36.3%, consistent with a general improvement of the condition of the wound.

Adverse events

Ten (7%) patients reported non-serious, product-related adverse events. These included contact dermatitis, pain on removal, and maceration at wound edge. There were no serious product-related adverse events.

Clinician satisfaction with specific performance parameters

The majority of clinicians (86%) were satisfied with ALLEVYN Life for all performance characteristics assessed (*Figure 2b*). Areas of particular satisfaction were ease of application/removal (98%) and conformability (91%).

Clinicians were also asked to rate the performance of ALLEVYN Life compared with their previous or usual dressings. Comparisons with previous dressings were against alternative brands of foam dressings in the majority (67%) of cases. For all performance parameters, ALLEVYN Life was rated as "better than the usual dressing" in the majority (>50%) of responses (*Figure 2a*). Particular strengths were ease of application (62%) and removal (69%), exudate masking (66%), and conformability (67%).

Effect of ALLEVYN Life on patient wellbeing

Overall, 83.3% of patients were satisfied with the performance of ALLEVYN Life. The majority of patients were satisfied with ALLEVYN Life in all the performance parameters assessed (*Figure 3b*). The highest numbers of satisfied patients were recorded for comfort during wear (84%), wound protection (83%), and pain on removal (81%). In fact, no pain on dressing removal was reported in 83.4% of assessments.

ALLEVYN Life was also subjectively rated by patients in comparison to their previous dressing. ALLEVYN Life was rated as better than the usual dressing for a majority of performance parameters (*Figure 3a*). The characteristics rated most favourably were wound protection (77%), comfort during wear (72%), and dressing retention (70%).

The effect of ALLEVYN Life on the difficulty of living with a wound was also assessed. ALLEVYN Life was deemed to have had a positive effect in 44.9% of assessments. The extent to which the wound restricted the daily activities decreased between baseline and treatment discontinuation in 49.7% of patients; there was no difference in 41.5%, and greater restriction in 8.9%, of patients.

Table 1. Patient and wound demographics.

Mean age (years)	69.1 (20–99)
Men *n* (%)	80 (54.1)
Wound aetiology	*n* (%)†
Pressure ulcer	13 (9.1)
Diabetic foot ulcer	19 (13.3)
Leg ulcer	64 (45)
Traumatic wounds	25 (17.5)
Other‡	20 (14)
Exudate level at baseline *n* (%)†	
Heavy	27 (18.5)
Moderate	85 (58.2)
Light	33 (22.6)

†Where the numbers do not equate to 148, this is due to individual missing data points; ‡A range of wound types were classified as "other" (e.g. secondary wound healing after nevus resection, abdominal suture, abscess).

Table 2. Reduction in wound area, depth, and volume.

	Median dimensions at baseline	Median dimensions by treatment discontinuation	Median percentage reduction by treatment discontinuation (%)	Median percentage reduction per week (%)
Wound area	6.8 cm^2	2.2 cm^{2*}	45.0	15.5
Wound depth	2.0 mm	0.0 mm*	50.0	17.5
Wound volume	0.9 cm^3	0.1 cm^{3*}	64.4	20.6

*Denotes statistical significance ($P<0.001$).

Figure 2. Clinician assessments (a) of the performance of ALLEVYN™ Life (Smith & Nephew) in comparison with the previous dressing used, and also (b) their level of satisfaction with ALLEVYN Life.

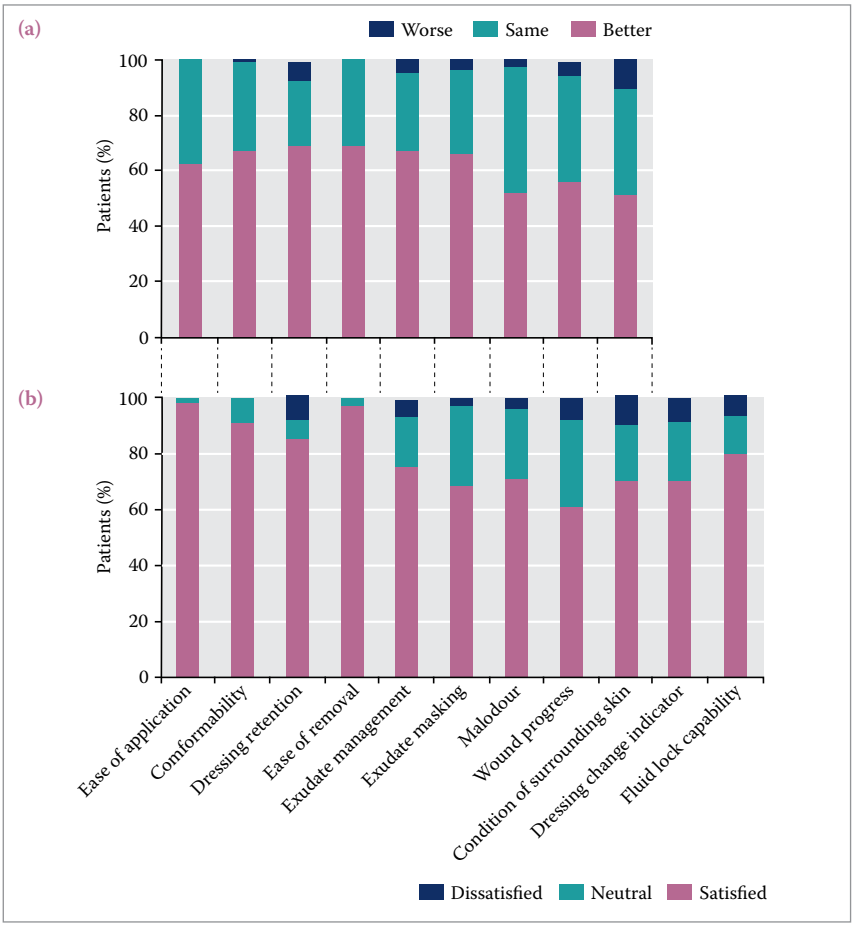


Table 3. Specific attributes of ALLEVYN™ Life (Smith & Nephew) classified against the principles of wellbeing (Wounds International, 2012) where >55% (except where shown by*) of patients rated ALLEVYN Life as "better than previous dressing" and were "satisfied".

ALLEVYN Life feature	Principles of wellbeing: Empowerment	Risk management	The everyday	Stigma	The outside	Movement	Cleanliness	Protection
Minimum pain on dressing removal		✔						✔
Comfort (fit / conformability)			✔			✔		
Malodour control*			✔	✔			✔	
Prevention of leakage	✔		✔	✔			✔	
Sensation of cleanliness							✔	
Wound protection		✔	✔					✔
Exudate masking				✔	✔		✔	
Dressing retention	✔	✔				✔		✔
Dressing change indicator	✔							

If specific wellbeing-related dressing features are improved or enhanced, this may have a positive influence on overall patient wellbeing. *Figures 2* and *3* demonstrate that patients and clinicians reported a high degree of satisfaction with ALLEVYN Life and reported that in many cases the dressing performed better than their previous choice of wound dressing. ALLEVYN Life was designed to incorporate specific design features (listed in the left hand column of *Table 3*) which could potentially impact on the eight identified principles of wellbeing (Wounds International, 2012).

Table 3 illustrates where specific dressing features can impact directly on specific principles of wellbeing. In all but one specific dressing feature, more than 55% of patients reported that ALLEVYN Life was "better" than their previous dressing. In one category (malodour) 48% of patients believed that ALLEVYN Life was "better" than the previous dressing, a further 48% believed that ALLEVYN Life performed the same as their previous dressing, with 71% of patients overall being satisfied with the performance of the dressing with regard to malodour.

DISCUSSION

ALLEVYN Life is an innovative new advanced wound management dressing specifically designed to address the real-life concerns of patients living with wounds. Specifically, a number of design features were incorporated into the dressing for the purpose of improving patient wellbeing. The concept was that, if those individual dressing features that impact on wellbeing can be enhanced or incorporated, then the wellbeing of those patients wearing the dressing will be improved as a result.

The data shows that patients and clinicians were largely satisfied in terms of the following parameters linked to overall patient wellbeing: reduced pain on removal, comfort during wear, odour, leakage, sensation of cleanliness, wound protection, exudate masking and dressing retention.

Patient wellbeing is an important factor when considering patient compliance with therapy and is even linked with delayed healing (Wounds International, 2012). However, a key goal of wound care clinicians is to facilitate an improvement in the condition of the wound and ideally, wound healing. The study results also demonstrate that ALLEVYN Life meets the needs of clinicians delivering an

acceptable level of clinical performance. A significant reduction in wound area, depth and volume as well as an improvement in the condition of the wound was observed over the course of the study. Given the chronic nature of the majority of these wounds, complete healing within the relatively short study duration was not anticipated but regardless wound improvement was observed overall.

CONCLUSION

This study suggests that dressing design features incorporated within ALLEVYN Life appear to be of benefit to both patient and clinician and could have a positive impact on wound healing as well as leading to improved patient wellbeing. WUK

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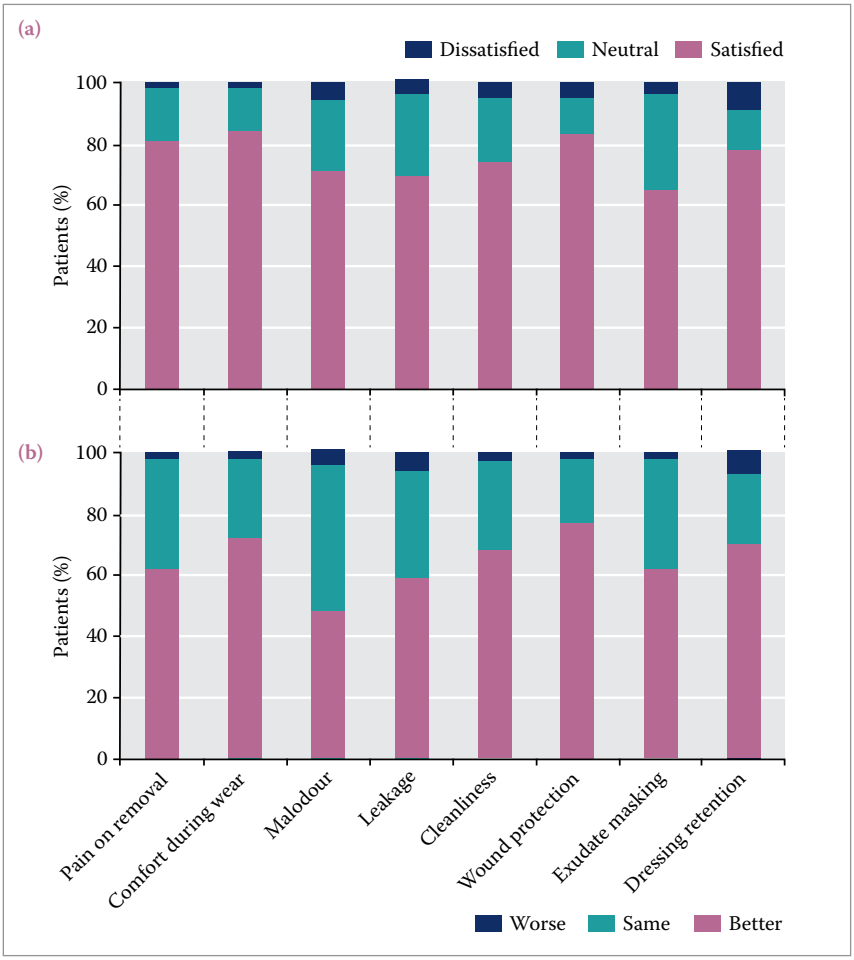
Figure 3. Patient assessments of (a) their level of satisfaction with ALLEVYN™ Life (Smith & Nephew), and (b) the performance of ALLEVYN Life in comparison with the previous dressing used.



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