Impact of hidradenitis suppurativa-specific wound dressing system on patient quality of life and dressing-related pain: pilot study

Objective: It is theorised that adhesive-free wound care developed specifically for patients with hidradenitis suppurativa (HS) can improve their quality of life (QoL). Our study aimed to investigate the impact of a novel wound care device on Dermatology Life Quality Index (DLQI) scores, and other factors related to experienced pain, time spent changing dressings, comfort, ease of use and body image.

Method: A 21-day, single-arm, unblinded, pilot trial was conducted to assess ease of use and the impact of effective wound care on various aspects of wound management in patients with HS. Participants were provided two trial garments and trial dressings as required, to use over a 21-day period in the home setting. A seven-item questionnaire and the DLQI questionnaire was completed on days 0, 7, 14 and 21.

Results: All 15 participants were female, aged >18 years old and with a diagnosis of HS. Mean DLQI score at baseline (day 0) was 19.3, which was reduced to 4.53 on day 21, a significant improvement in 100% of participants ($p<0.001$). High levels of dressing-related pain, assessed using an 11-point Visual Analogue Scale, reduced from 5.53 at baseline to 0.8 on day 21. Other significant improvements in terms of patient comfort, time spent on changing dressings, body confidence and the dressing's ability to retain exudate were also noted.

Conclusion: The results illustrated the improvement made to study participants' day-to-day activities and QoL when effective HS-specific wound care products were provided. Wound care is an essential component in the treatment journey of patients.

Declaration of interest: SM is the founder and a shareholder of HidraMed Solutions, Ireland, a start-up wound care company creating solutions for people living with HS. SM is also a HS patient.

Dermatology Life Quality Index • hidradenitis suppurativa • pain • quality of life • wound • wound care • wound dressing • wound healing

Hidradenitis suppurativa (HS) is a distressing, debilitating and progressive disease of the skin, characterised by recurring inflammatory nodules, abscesses, and draining lesions and tunnels, typically affecting, but not limited to, the axillae, buttocks, perianal and inguinal areas.[1] Prevalence rates vary from 0.05–4.0% but the best estimate is that 1% of the adult population are affected.[2] Symptoms usually develop in early adulthood and affect patients for decades.[2]

Treatment of HS has historically been of limited efficacy and has included long-term antibiotics, hormonal approaches and immunosuppressive therapies, as well as various forms of surgical intervention.[3] Adalimumab (a monoclonal anti-tumour necrosis factor (TNF) antibody previously used in psoriasis, inflammatory arthritis, and inflammatory bowel disease) was the first medication to receive a US Food and Drug Administration (FDA) approval for moderate to severe HS; however, even now there is no reliably effective treatment for a significant proportion of patients with HS.[3]

HS remains a widely unrecognised and underdiagnosed disease.[4] Although various treatment guidelines have been developed, delayed diagnosis, the lack of evidence-based and curative or approved therapies, leads to variable treatment and enormous patient distress.[3,5]

Patients with HS manage painful, recurring and draining lesions or wounds, and effective wound management is a severely overlooked and unmet need.[6]

Quality of life impact

Patients with HS experience high rates of depression and sexual dysfunction.[7,8] Body image is also impaired and HS influences self-image more negatively than in other dermatological diseases,[9] which has been associated with higher levels of depression and anxiety.[10] Even mild HS can negatively affect a patient's mental wellbeing.[11]

The painful lesions and dynamic nature of HS negatively impacts social functioning, particularly employment, work productivity and career advancement.[12] In a study of patients with HS in employment, 58% (n=30) reported a work absence due to HS, with a mean absence rate of 34 days per year.[12] Subsequent follow-up found that 23% (n=7) reported

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that disease-related issues prevented career progression or promotion, and 10% (n=3) of the patients were dismissed from their jobs due to frequent absenteeism or inability to perform.[12]

A recent study showed that patients with HS have a significantly lower annual income than matched controls, and for those in employment, lower annual income growth is seen.[13] Patients with HS were also found to have higher annual indirect costs (absenteeism, disability costs) and higher healthcare costs.[13]

HS wound care imposes a substantial burden on patients with respect to frequency of dressing changes and time spent on managing wounds.[14] A North American study showed that the median time spent per month on wound care was 300 minutes (n=378, range: 5–3000 minutes), while another study showed patients could spend up to 16 hours (960 minutes) per month on wound care, such as applying, adjusting and removing dressings.[14,15]

It is well documented that quality of life (QoL) in patients with HS is the most severely impacted.[16] When compared with other dermatoses, HS has the highest impact on QoL, caused by pain and embarrassment, and the inability to live a normal life,[17] as demonstrated by elevated Dermatology Life Quality Index (DLQI) scores,[17,18,19] a validated 10-item questionnaire completed by patients.[20]

HS lesions require frequent dressings changes.[21] There is a distinct lack of HS-specific wound dressing products.[22] Existing wound dressings are designed for use on flat or convex areas of the body; however, HS affects curved, concave surfaces, that are typically moist and mobilised.[22] Many advanced dressings that may benefit patients are not readily available to them due to cost or restricted insurance/healthcare coverage.[23]

Dressing-related pain

A major contributor to reduced QoL is pain.[24,25,26] Pain has been reported as the most bothersome and disabling symptom of HS.[27] However, many current QoL measurement tools do not incorporate debilitating aspects of the disease, such as pain or malodourous discharge.[28]

HS wounds impose an under-recognised and unacknowledged burden on patients.[28] While various international HS treatment guidelines recognise the importance of wound management in HS, there is a dearth of evidence as to which dressing is the most appropriate for use in HS.[3]

Medical adhesives can damage the already tender and painful skin around a HS wound.[22] Medical adhesive-related skin injuries (MARSI) affect skin integrity, cause pain and increase the risk of infection.[29] The most commonly used dressings for HS are adhesive dressings, or non-adhesive dressings with adhesive tape, with an average of 2.8 dressing changes per day.[14] A high proportion of patients with HS report adhesive sensitivity and an overwhelming proportion report dressing-related pain.[14]

Makeshift dressings

Patients have learned to adapt and modify existing dressing products to try to meet their needs, usually incorporating a variety of products such as bandages and tapes to attempt secure dressing retention.[22] Many patients also improvise their dressings using materials such as sanitary napkins, adult diapers and paper towels. In one study, 93.5% (n=845) of patients, reported that they had experienced a dressing leak and/or fall off, and dissatisfaction with dressing comfort and ease of use of existing products.[14]

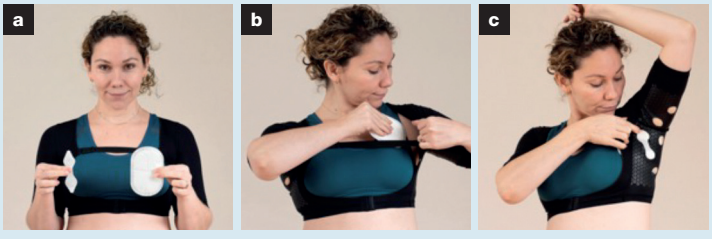
Another study demonstrated an improvement in QoL by providing patients with an assortment of off-the-shelf dressings to manage their HS.[23] It is theorised that wound care developed specifically for HS could significantly improve patient QoL.[6,21] Our study aimed to investigate the impact of a novel wound care device, HidraWear (HidraMed Solutions, Ireland) on DLQI, and other factors related to the experience of pain, time spent changing dressings, comfort, ease of use and body image.

Description of HidraWear wound dressing system

This novel trial dressing system is intended for home use by people with HS that require routine wound management. Comprising of a uniquely designed super-absorbent wound dressing pad with fastening tab and a retention aid (garment), it replaces traditional wound dressings and represents a solution for patients with HS living with hard-to-heal (chronic) wounds. The trial dressing system removes the need for the dressings to be adhesively attached to the skin while still holding the dressing in position, as well as facilitating quick and easy dressing changes, enabling patients to self-manage wound care more effectively. It consists of three parts as shown in Fig 1.

The garment facilitates easy insertion, removal, precise positioning and adjustment of the non-adhesive wound dressing onto the affected wound space. A perforated section is located over the affected area, for example, the axilla. The dressing is placed inside the garment under the perforations. The back of the dressing has a customised loop coating that allows the fastener to adhere to it through the perforations. The fastener is then placed on the outside of the garment on the footprint of the dressing. The dressing is secured in place through a hook and loop mechanism.

Fig 1. HidraWear (HidraMed Solutions, Ireland) wound dressing system. Step 1: put on the garment **(a)**. Step 2: insert the dressing, and place over the wound area **(b)**. Step 3: secure the dressing in place with the external fastening tab **(c)**



Method

A 21-day, single-arm, unblinded, pilot trial was conducted to assess ease of use and the impact of the trial dressing system on various aspects of wound management in patients with HS. The primary objective was to evaluate the ease of use of the trial dressing system compared with the patient's previous product use. The secondary objectives were to evaluate if the trial dressing system:

- Was comfortable for patients
- Improved patient QoL
- Was faster to use than current products
- Reduced dressing-related pain
- Provided secure dressing retention.

Outcome measures

Primary outcome measures:

- Experience of patients' own product use (day 0) versus the trial dressing system (day 21)
- Ease of use at day 0 versus day 21 using an 11-point visual analogue scale (VAS).

Secondary outcome measures:

- QoL score using the DLQI questionnaire, day 0 versus day 21
- Dressing-related pain using an 11-point VAS, day 0 versus day 21
- Time spent on dressing changes, day 0 versus day 21
- Additional equipment used eg., mirror, scissors etc.
- Could dressing be applied without raising arms over head?
- Necessity to stretch/contort body to apply dressing
- Did patient need assistance?

Inclusion criteria

Patients were considered for inclusion in the study if they were:

- Female
- Aged >18 years
- Diagnosed with HS
- Experiencing HS affecting the axillae
- Experiencing exuding lesion that required wound dressing.

Recruitment and selection

To eliminate bias, the sponsor and lead author was not involved in the study processes or day-to-day management. An independent research organisation, the Clinical Research Platform (CRP) was engaged and conducted the trial independently. A research nurse employed by CRP recorded the data. Patient recruitment and selection was conducted by the CRP:

- The CRP informed its network of primary care providers in Dublin, Ireland and surrounding areas. Primary care providers referred relevant patients to the study
- HS specialist dermatologists were informed of the study and referred patients
- Information on the study was shared via an Irish patient support group.

A total of 31 patients were screened between September 2019 and September 2020, and from those who met the inclusion criteria, 16 were enrolled and one patient withdrew for personal reasons, and their data was not collected.

Patients were trained in the use of the device and invited to use it in the home setting.

A seven-item questionnaire was created by the researchers. Each question used an 11-point VAS, wherein a score of zero was the best possible score and a score of 10 was the worst possible score, to measure the patient's experience of product ease of use, time consumption, dressing comfort, dressing-related pain, confidence in the dressing's ability to contain exudate, and body confidence. The DLQI questionnaire was also completed on days 0, 7, 14 and 21.

Day 0

Patients visited the trial site or had a home visit from the research nurse. Following consent and enrolment, patients were asked to demonstrate or explain their usual method of dressing their wound using their usual wound dressing products. Using the seven-item questionnaire, patients assessed this activity based on ease of use, comfort, experienced pain, confidence in dressing retention and time. The patients completed a DQLI survey.[20] The research nurse assessed the activity based on whether the patient needed assistance, used additional equipment, contorted, or stretched their body, or could dress the wound without raising their arms above their head.

Weekly check-in with patients

On days 7 and 14, patients were asked to complete the DQLI survey and seven-item questionnaire at home.

Day 21

Patients returned to the trial site or were visited by the research nurse for review. Patients were asked to demonstrate how they dressed their wound using the trial dressing system and completed the seven-item questionnaire and the DLQI survey. The nurse assessed the patients, as on day 0.

Statistical analysis

Exploratory data analysis includes graphical (including case profile plots) and numerical (including mean±standard deviation (SD)) summaries for each criterion over time. Inferential statistical analyses include separate linear mixed-effect models for each criterion to model the changes over time. A random intercept for each patient was incorporated in all models while the within-individual correlation over time was specified as unstructured. The time when the measurements were recorded was modelled as a fixed effect, particularly as a categorical variable to allow the comparison in the average change at each timepoint.

All statistical analyses were carried out using R (version 4.1.0) and the lme4 package. The significance

Table 1: Dressings used prior to study

Dressing type	n
Mepore (Mölnlycke)	7
Plain gauze with unspecified tape	4
Tissue paper	3
Cotton shirt/cloth	2
Allevyn (Smith+Nephew)	2
Maternity pads/sanitary towel	2
Mepilex (Mölnlycke)	1
Unbranded non-adhesive pad with tape	1
Melolin (Smith+Nephew)	1
Adaptic (Acelity/3M)	1
Mefix tape (Mölnlycke)	1
Aquacel (Convatec)	1
Inadine (Acelity/3M)	1
Opsite (Smith+Nephew)	1

level was set at alpha=0.05. Model assumptions were visually assessed for each response at each timepoint using residual plots from the fitted model.

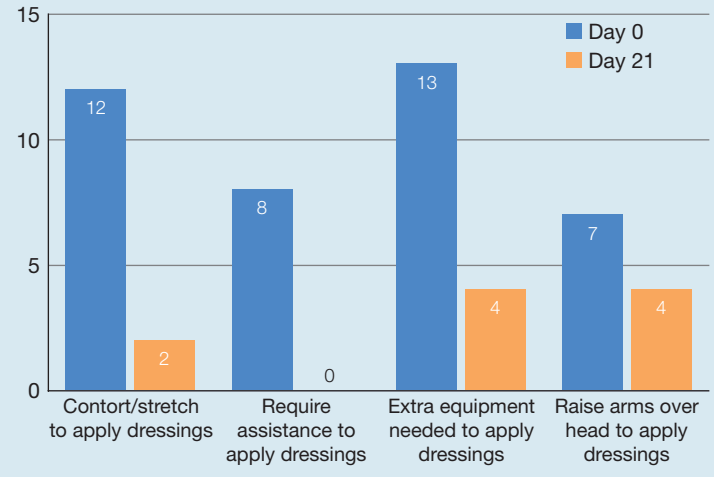
Statement of ethics

Ethics approval was granted by The Hermitage Clinic, Old Dublin Road, Dublin, Ireland, (study approval reference number: HMC005/2019). Written consent was obtained from all patients prior to study commencement. The study was performed in accordance with the protocol regulations Code of Federal International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP), and the most recent guidelines of the Declaration of Helsinki.

Monitoring visits were conducted by an external organisation (Afortiori Development) to provide independent outcome assessment and quality assurance during the study.

Monitoring included personal visits and telephone communication to assure that the investigation was conducted according to the protocol, standard operating procedures, GCP guidelines, and applicable regulatory requirements. Quality control procedures were applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.

Fig 2. Usability comparison, day 0 versus day 21



Results

A total of 15 patients completed the study. All were female, >18 years of age, with HS affecting the axilla.

Patients were found to use a variety of dressings to manage their wounds prior to beginning the trial, with some using more than one type of dressing at the same time. The most commonly used dressing was a Mepore adhesive dressing (Molnlycke, Sweden) (n=7), followed by a variety of traditional dressings and makeshift solutions (Table 1).

Using their usual wound dressing products outlined above, on day 0: 12 patients needed to contort and stretch their body to apply dressings; eight required assistance to apply their dressings; 13 required additional equipment such as scissors, pins, tape, or a mirror; and seven could not apply a dressing without raising their arms above their head (Fig 2).

After 21 days, only two patients needed to stretch or contort their body to apply the dressing, none needed assistance to apply a dressing, four required additional equipment (a mirror), and 11 patients could apply the dressing without raising their arms above the head (Fig 2).

Reduction in dressing-related pain

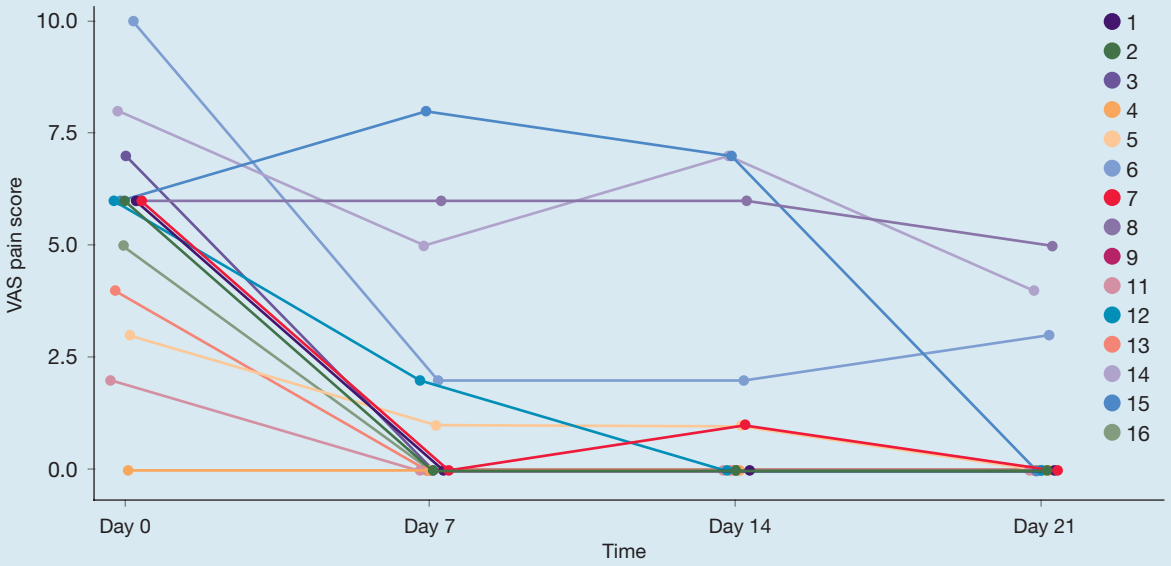
High levels of dressing-related pain were measured at baseline (day 0) with a mean reported pain score of 5.53, where a score of 10 points represents the most severe pain, and a score of zero represents no pain at all. Dressing-related pain was significantly reduced throughout the study, with an overall mean score of 0.8 (95% confidence interval (CI): 3.6–5.9; $p<0.001$) by day 21, where the CI represents the likely improvement from day 0 to day 21 (Fig 3, Table 2).

Further to that, of the patients who required pain relief in advance of a dressing change at baseline (day 0, n=5), none required pain relief in advance of a dressing change by day 21.

DLQI

At baseline (day 0), the DLQI scores indicated that HS had a 'very large' or 'extremely large' effect on daily life in 53.3% (n=8) of patients; had a 'very large' effect on 40% (n=6) of patients, and had a 'moderate' effect on 6.7% (n=1) of patients. The mean DLQI score at day 0 was 19.3 (Table 3)

Fig 3. Dressing-related pain (as measured using Visual Analogue Scale (VAS)) (n=15)



DLQI scores continued to improve and at day 21, a clinically meaningful improvement of the DLQI had occurred in 100% (n=15) of patients (Fig 4), whereby a reduction in score by ≥5 points met the minimal clinically important difference (MCID). The mean score on day 21 was 4.53 (Table 3). HS had an 'extremely large' effect on 0% of patients (n=0), a 'very large' effect on 13.3% (n=2) of patients, a 'moderate' effect on 20% (n=3), a 'small' effect on 40% (n=6) and 'no' effect on 26.7% (n=4). Patients experienced a significant improvement in dermatological QoL (95% CI: 12.1–17.5; p<0.001) (Table 2).

The DLQI scores showed that patients' ability to work or study improved, along with their ability to perform everyday tasks such as socialising, shopping, housework, or gardening. Issues with personal and sexual relationships were reduced throughout the trial period.

Body confidence

Patients were found to have higher confidence in the trial dressing system's ability to retain exudate and remain securely in place (95% CI: 5.9–8.5; p<0.001) (Table 2). On an 11-point VAS, the mean baseline score of 8.4 in dressing retention and leak prevention was reduced to 1.2 on day 21 (Fig 5).

Patients also experienced an improvement in body confidence, reducing a mean baseline score of 8.5 on a 10-point scale, where a score of 10 correlated to poor body confidence, to 4.2 on day 21 (95% CI: 3.6–5.8, p<0.001) (Fig 6, Table 2).

Ease of use

Patients found that using the trial dressing system was more comfortable than traditional dressings. The mean baseline score (10=extremely uncomfortable) was 8.1, which was reduced to 1.0 on day 21 (95% CI: 6.0–8.2; p<0.001) (Table 2). The trial dressing was found to be easier to apply, adjust and remove than traditional dressings, with a baseline score of 6.5 (10 being 'very difficult') reduced to 0.6 (zero being 'extremely easy') on day 21 (95% CI: 4.6–7.1; p<0.001) (Table 2). Patients also found they spent less time tending to their wounds, with a mean baseline score of 6.9 (10 being 'very

Table 2: The average reduction in wound care impact criteria from day 0 to day 21

Item	Mean score day 0	Mean score day 21	Effect*	LCI†	UCI‡	p-value
Dressing-related pain	5.5	0.8	4.7	3.6	5.9	<0.001
DLQI	19.3	4.5	14.8	12.1	17.5	<0.001
Confidence in dressings	8.4	1.2	7.2	5.9	8.5	<0.001
Body confidence	8.5	3.8	4.7	3.6	5.8	<0.001
Dressing comfort	8.1	1	7.1	6	8.2	<0.001
Dressing ease of use	6.5	0.6	5.9	4.6	7.1	<0.001
Time spent changing dressings	6.9	0.7	6.3	5.2	7.4	<0.001

*Average reduction; †LCI—lower 95% confidence interval; ‡UCI—upper 95% confidence interval; DLQI—Dermatology Life Quality Index

time-consuming') reduced to 0.7 (zero being 'very quick') at day 21 (95% CI: 5.2–7.4; p<0.001) (Table 2).

Discussion

This pilot study demonstrated that a wound care product tailored to the needs of patients with HS can have a very significant beneficial effect on QoL, particularly with regard to the most distressing symptoms of the condition, namely pain, discharge, comfort, time constraints and ability to work or study.

Table 3: Mean Dermatology Life Quality Index Scores (n=15)

Time	Mean	Standard deviation
Day 0	19.3	5.73
Day 7	10.2	6.3
Day 14	7.87	5.26
Day 21	4.53	3.93

Fig 4. Dermatology Life Quality Index (DLQI) scores over time

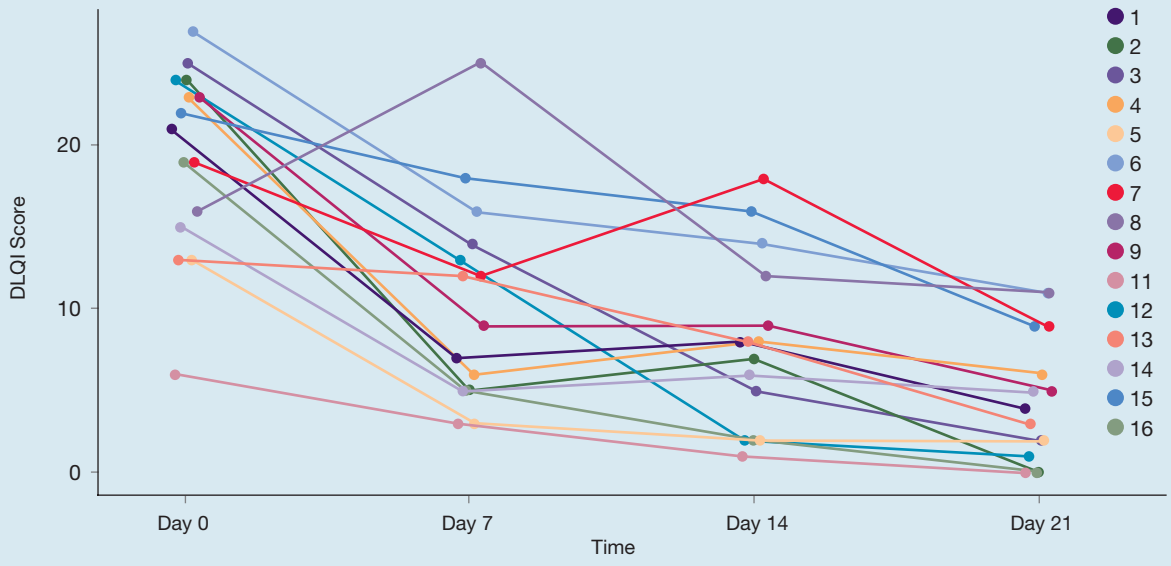


Fig 5. Confidence in the trial dressing's ability of dressing to contain/prevent leaks

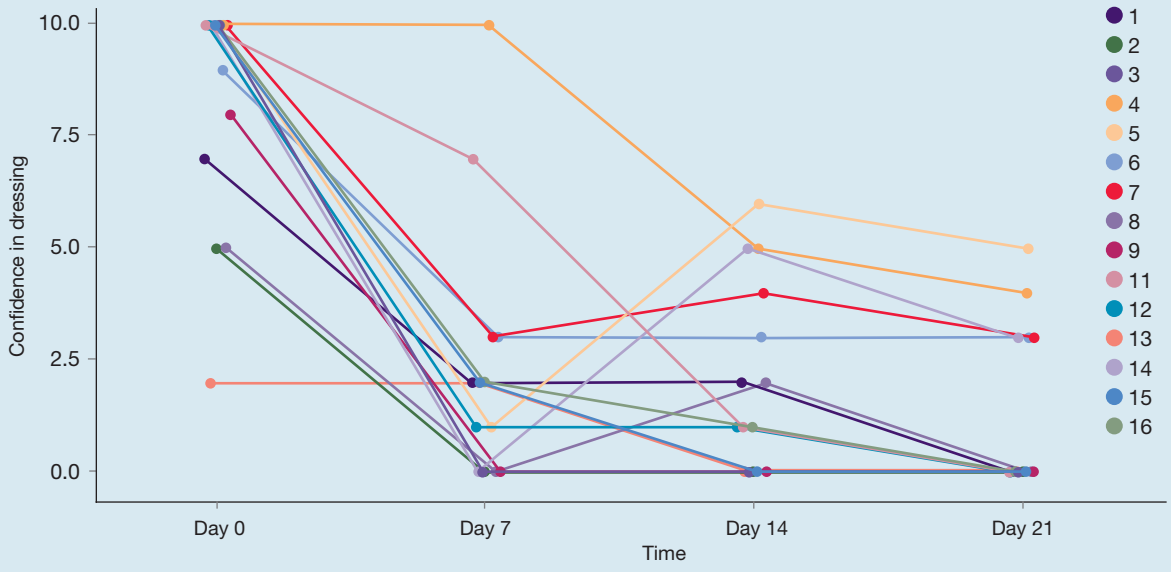
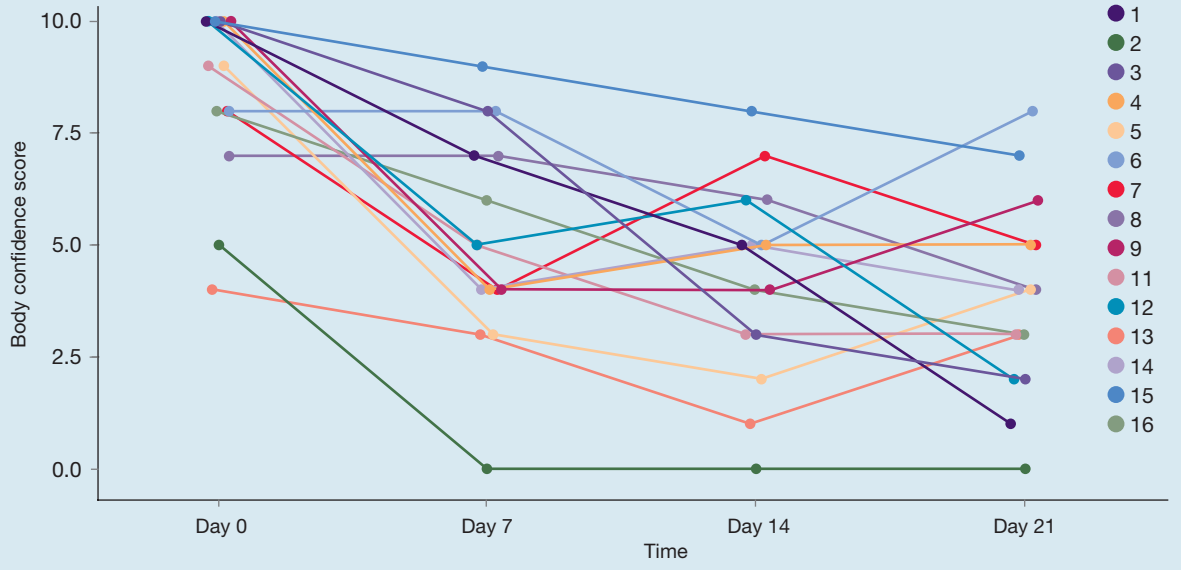


Fig 6. Body confidence improvement over time (0=good, 10=poor)



Quality of life and wellbeing

In our study, it was particularly notable that, according to patients, this non-pharmaceutical adjunct to treatment achieved a greater improvement in patients' QoL than traditional pharmaceutical approaches, which have significant costs and potential toxicities associated with them, and that tailoring products specifically to these difficult-to-dress areas can have a greater improvement in DLQI versus off-the-shelf dressings.

The results from this pilot study are significant when compared with therapeutic clinical studies measuring DLQI and pain as endpoints. For example, a study[30] of the therapeutic agent adalimumab, resulted in a DLQI score of 14.1 in the interventional group after 12 weeks of treatment, meaning the disease had a very large effect on QoL, versus a DLQI score reduction from 19.4 to a clinically meaningful improvement score of 4.6 after three weeks of using the trial dressing system. In terms of comparable wound dressing offerings, a study of 19 patients[23] reduced DLQI scores from a median of 15.5 to 12.5 after six weeks using a selection of off-the-shelf dressings, whereas the patients using the trial dressing system saw a reduction from a median score of 19.4 to 4.6 in three weeks.

Similarly, in the Pioneer II study,[30] a multicentre phase III trial of adalimumab measuring clinical response, pain and DLQI scores among other outcomes, the mean reported pain on the numeric scale rating was 5.7 at week 12, while pain scores using the trial dressing system were reduced from 5.5 on day 0 to 0.8 on day 21.

Mental health impact

The mental health benefits of using the trial dressing system must be considered. HS negatively impacts body image and self-image,[9] which are associated with higher levels of mental health comorbidities.[10] The improvement in body confidence when using the trial dressing system was significant, and the trial dressing system was designed to this effect, empowering the patient to self-care and manage their wounds.

It is reasonable to suppose that patients' social functioning and ability to work would improve when using the trial dressing system in parallel with the observed improvement in DLQI and pain. Patients using the trial dressing system showed a greater ability to work or study. A reduction in time spent on tending to wounds was seen during the trial, which enabled patients to spend more time on other activities.

It is also reasonable to believe that increased confidence in the trial dressing system's ability to reduce leaks and retain the dressings securely in place would reduce anxiety over stains and odour, and that improved comfort levels and ease of use will contribute to improved wellbeing in general.

Further to that, HidraWear products are now available through the national health services in Ireland, the UK, the Netherlands and Germany, and through insurance in the US, reducing the out-of-pocket expenditure for patients. Access to appropriate dressings is to provide comfort and help patients manage discharging wounds, and the trial dressing system, among other dressings, is recommended by clinicians treating HS.[31]

Dressing-related pain

As the trial dressing system requires no adhesive skin contact, the risk of Medical Adhesive Related Skin Injuries (MARSIs) is completely removed. The super-soft material is fully breathable, with outward facing seams to reduce friction and shear. Patients using the trial dressing system saw a dramatic reduction in dressing-related pain, which again will contribute to an improvement in QoL.

Limitations

This was a single-arm, pilot study that aimed to assess ease of use and other factors of importance to patients. It was not therefore designed to determine the effects on healing or to compare with other dressings in the field, and results should be interpreted in this light. The use of an independent research agency for recruitment and all aspects of data collection is an important strength and reduces the potential for ascertainment bias or selection bias. The study was limited to females with axilla lesions and thus cannot be truly applied to males or lesions elsewhere in the body, but the findings are important and will help in the design of future, larger trials. While an improvement in ease of use, comfort, time and secure dressing retention was captured, an improvement in QoL scores may be compromised due to other affected areas impacting negatively on the patient's daily life.

The study did not measure disease severity or clinical improvement of wounds, as the study was aimed at measuring usability, efficacy and QoL improvements. Further, larger scale studies are required.

Conclusion

The results illustrated the improvement that can be made to patients' day to day activities and QoL when HS-specific wound care products are provided. The data presented herein demonstrated the benefits of a new HS-specific wound management product, HidraWear. Further research with a larger sample size is necessary to determine the impact on healing outcomes and recurrence. **JWC**

Acknowledgement

A special acknowledgement to the editor and reviewers for their assistance and constructive feedback. A very special acknowledgment to the patients with HS who gave of their time and participated in the study.

Data availability statement

The data that supports these findings are not publicly available but can be made available on request. Please contact the author.

Funding sources

The authors did not receive financial reimbursement for the study. External consultant fees to the CRP and study monitors to ensure study integrity, and ethical and regulatory compliance for the study was funded by HidraMed Solutions.

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