Allevyn Heel in the Management of Heel Ulcers

Kammerlander G, Eberlein T, Andriessen A*

WFI-Wundmanagement GmbH, CH 8424 Embrach, Switzerland

**Smith + Nephew Wound Management Global Business Unit*

Address for correspondence and reprints:

Prof G Kammerlander

WFI-Wundmanagement GmbH

CH 8424 Embrach

Switzerland

Abstract

This study examined the effectiveness of Allevyn Heel dressing in the management of heel ulcers. Twenty-two patients were enrolled, the majority of whom had heel pressure ulcers, and with about a fifth of patients each having diabetic or arterial heel ulcers. Ulcers were assessed before treatment, and after the start of the dressing regimen at Weeks 2 and 4 and at the end of the study.

Patients received Allevyn Heel treatment for a mean of 47.2 days, with dressings left in place for an average of 2.2 days before being changed. By the end of treatment, 32% of ulcers had completely or almost healed, with a further 27% showing granulation. An overall improvement in the condition of ulcers was observed for about 90% of cases. Almost all of the patients (91%) reported that Allevyn Heel was comfortable to wear, and application and removal of the dressing was considered easy in 98% of instances.

Allevyn Heel proved beneficial in this small-scale study for the management of heel ulcers resulting from pressure, diabetic and vascular causes. This extends the range of wounds that are suitable for management with Allevyn, although a larger-scale study is needed to confirm the utility of Allevyn Heel for these types of heel wounds.

Introduction

Development of heel ulcers is due to either pressure, shear forces or friction in a small area of skin covering a bony projection where subcutaneous tissue is lacking[1]. There are a number of risk factors for heel ulceration, including immobility, chronic illness, orthopaedic surgery - such as hip replacement or pinning - age and nutrition. A modified Braden scale

can be used for risk assessment of pressure ulcers, including heel ulcers, in order to predict the likelihood of heel pressure ulcer development[2, 3]. Although advances in pressure reduction have led to a reduced occurrence of sacral ulcers, a concomitant increase was noted in the incidence of heel pressure ulcers[4]. Variations in clinical practice can influence the likelihood of heel ulcers developing, and the need for extra protection for heels in addition to the use of special beds and mattress overlays has been identified[5].

Heel ulcers can also results from neuropathy or vasculopathy or both in diabetic patients[6], and the heel was found to be one of the most common areas for development of pressure ulcers in patients admitted with major burns to a burn centre[7]. In the latter case, both prevention and wound management contribute to limb salvage and avoidance of disability. As such, heel ulcers are still a major health care problem[1].

Once ulcers have developed, effective wound management is required, and Allevyn Heel has been specifically designed for treatment of heel wounds and ulcers. Allevyn Heel has been adapted from Allevyn, a hydrocellular dressing composed of three layers: a polyurethane non-adherent layer in contact with the wound, a central hydrocellular layer which is hydrophilic and absorbent, and an outer layer of polyurethane film[8]. Allevyn Heel has been designed to give better anatomical fit and comfort for use on heel wounds, and allows a moist wound environment. In a preliminary study, Allevyn Heel was shown to reduce pressure by an average of 20% in the heel[9].

The purpose of the present study was to examine the effects of Allevyn Heel for at least 6 weeks in the management of pressure ulcers.

Methodology

Patients were recruited from centres in Austria, Germany and Switzerland. Male and female patients, aged at least 18 years, were eligible to enter the study if the following requirements were met:

- they presented with pressure ulcers on the heel, which required a moist wound healing environment and management of exudates. Wounds that contained non-viable tissue (black necrotic tissue, yellow slough, pus, debris) were included
- patients were willing and able to comply with the study requirements and gave their informed consent

Patient record forms were completed for one wound only. Where a patient presented with more than one wound, one wound of adequate size was chosen. Patients who were known to be poorly compliant with medical treatment were excluded from both trials.

Wound Dressing

A wound of adequate size was selected such that the dressing overlapped intact skin by at least 2 cm. The dressing was fixed with a retention bandage or surgical tape and was to be left in place for a maximum of 7 days. Patients continued in the study until they had received 15 dressing changes, or until the wound had healed, or until the patient was withdrawn.

Wound Measurement

Wounds were photographed at the initial assessment (Week 0), and at Weeks 2, 4 and at the end of the study. Wounds were covered with Allevyn Heel, which could have been left in place for a maximum of 7 days. Frequency of dressing changes was at the discretion of the clinician, and depended on the quantity and nature of exudates from the ulcer. The total area

of the wound was determined from tracings of the ulcer margin and from digital photographs.

Wound Stage

Local wound stages were assessed using a modified DWCS classification model[10]. The modified model is based on the optical characteristics of wounds, which are classified on the basis of four colours and four mixed types:

- black wounds - necrotic tissue (black to yellow, black - yellow - red)
- yellow wounds - sloughy tissue (yellow to red)
- red wounds - granulating tissue (red to pink)
- pink wounds - epithelium (wound healed)

This is shown diagrammatically in Table 1. The stage of wounds was monitored at Weeks 0, 2, 4 and at the end of the study.

Efficacy

The following were calculated to determine the effectiveness of Allevyn Heel:

- percentage of patients with wounds healed
- percentage reduction in wound area
- percentage change in the stage of the wound
- percentage improvement in wounds
- time between dressing changes
- comfort/ease-of-use of the dressing

Results

A total of 22 patients were enrolled into the trial, of whom 10 (45%) were male and 12 (55%) were female. The mean age was 78.4 years (range: 66–94 years). The average baseline wound area was 11.0 cm^2 and the median baseline wound area was 8.0 cm^2 (range: 2.0 – 57.0 cm^2). Most patients presented with pressure ulcers; other types were arterial ulcers, diabetic ulcers and 'other' as shown in Figure 1.

The average duration of treatment per wound was 47.2 days, with an average number of 21.9 dressing changes per wound. Dressings were left in place for an average of 2.2 days.

Wound stage classification at the beginning and end of treatment is shown in Table 2. Before treatment, 5 (23%) wounds were necrotic, and a further 5 (23%) showed slough. By the end of treatment, 2 (9%) wounds had completely healed, 5 (23%) had almost healed (granulation plus epithelium) and 6 (27%) wounds showed granulation. The wound area at the start of treatment and at the end of treatment is shown in table 3. The average percentage reduction in wound area was 48.6% and the median percentage reduction in wound area was 61.7%.

An overall improvement in the wound condition occurred in about 90% of cases, as shown in Figure 2. A total of 20/22 (91%) patients reported the dressing to be comfortable to wear, and application and removal of Allevyn Heel was reported as easy in 98% of dressing changes.

Discussion

Heel ulcers have not always been specifically targeted for prevention of ulceration, although an increased incidence of pressure ulcers at an institution necessitates effective treatment for heel ulcers[4]. In diabetic patients, reconstructive arterial surgery for heel lesions has met with inadequate success, leading to a recommendation for either prevention or better local wound care[6]. There are a number of factors which predict healing of diabetic heel pressure ulcers, including normal renal function, measurable pedal pulse, and posterior tibial artery patency below the ankle[11].

Allevyn dressing has proved beneficial in the management of exudating and sloughy wounds[8, 12, 13], leg ulcers[14] and skin graft donor site wounds[15]. The usefulness of Allevyn Heel, specifically designed and shaped for heel wounds, was demonstrated in this study in a group of 22 patients - the majority with pressure ulcers but with 36% having arterial or diabetic heel ulcers. Allevyn Heel proved successful in managing ulcers, with 32% of ulcers having healed or nearly healed at the end of treatment, with a further 27% of ulcers showing granulation. Improvement in the condition of heel ulcers was also very good, with over 90% of wounds showing change for the better.

In summary, Allevyn Heel proved beneficial in this small-scale study for the management of heel ulcers resulting from pressure, diabetes and vascular causes. This extends the range of wounds that are suitable for management with Allevyn, although a larger-scale study is needed to confirm the utility of Allevyn Heel for these types of heel wounds.

Tables and Figures

Figure 1: Wound Types of Patients Recruited into The Study

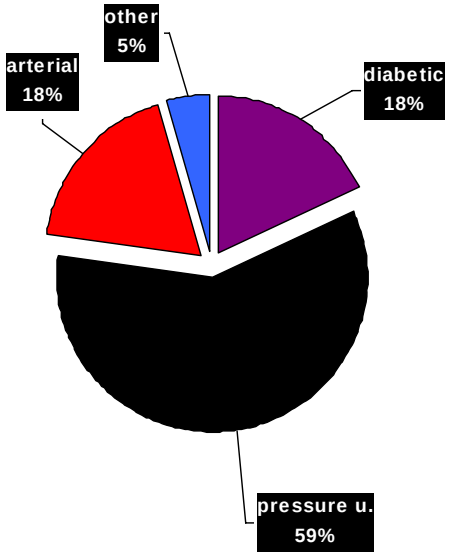
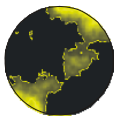
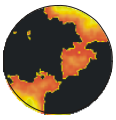
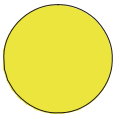
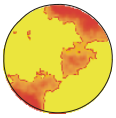
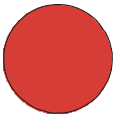
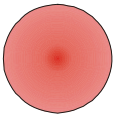
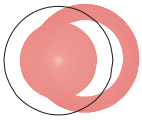


Figure 2: Evolution of Wounds Treated with Allevyn Heel

Table 1: Wound Classification Stage

Criterion 1 (Interpretation of colours)	Criterion 2 (Interpretation of exudate production)
 **black** (necrosis)	- black (necrotic) - **slight** - black (necrotic) - **moderate - copious** - **necrosis adhered to wound edges** - **necrosis particularly non adhered**
 **black - yellow** (necrosis+ slough)	- **slight** - **moderate** - **copious**
 **black - yellow - red** (necrosis+ slough + granulation)	- **slight** - **moderate** - **copious**
 **yellow** (slough)	- **slight** - **moderate** - **copious**
 **red- yellow** (granulation+ slough)	- **slight** - **moderate** - **copious**
 **red** (granulation)	- **slight** - **moderate** - **copious**
 **red- pink** (granulation+ epithelium)	- **slight** - **moderate** - **copious**
 **pink (epithelium)**	- **unstable, athropic skin** - **partly eczema present in skin** - **dry skin** - **normal skin constitution**

Criterion - 3

(Identification of local signs and symptoms of clinical infection)

Table 2: Wound Stage at Start of Treatment and End of Treatment with Allevyn Heel

Wound Stage	Start of Treatment	End of Treatment
Necrotic	5 (23%)	0
Necrotic + slough	5 (23%)	2 (9%)
Slough	7 (32%)	4 (18%)
Granulation + slough	5 (23%)	3 (14%)
Granulation	0	6 (27%)
Granulation + epithelium		5 (23%)
Completely re-epithelialised		2 (9%)
TOTAL	22	22

Table 3 Wound Area (cm^2) at Start of Treatment and End of Treatment and Percentage Reduction in Wound Area with Allevyn Heel

Statistic	Start of Treatment	End of Treatment	% Reduction
Mean	11.0	7.3	48.6
Median	8.0	2.0	61.7
Std	11.5	12.3	40.2
Minimum	2.0	0	0
Maximum	57.0	56	100
TOTAL	22	22	22

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