Prospective RCT comparing two hydrocolloid dressings in acute trauma wounds in South Korea

- **Objective:** To compare the efficacy of two hydrocolloid dressings (Medifoam H; Genewel Co. Ltd. and DuoDERM; ConvaTec Inc.) for the management of lacerations, abrasions, and minor operation incisions.
- **Method:** Patients with lacerations, abrasions, and minor operation incisions were randomly allocated to receive either Medifoam H or DuoDERM. Data collected included wound assessment (amount of exudate, wound infection, rate of wound closure, and the percentage of necrotic, sloughy, fibrous, granulation, and epithelial tissue present in the wound bed) and patient evaluation of itching, burning, leakage of exudate, pain and discomfort incurred from dressing and dressing change.
- **Results:** In total, 66 patients were included in the study. No significant difference in wound assessment or in patient evaluation was detected between two groups.
- **Conclusion:** The data collected from this study gave no evidence for any difference in efficacy between Medifoam H and DuoDERM for minor, acute trauma wound management.

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wound healing; hydrocolloid dressing; occlusive dressing

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The skin is the largest organ in the human body and consists of three layers: the epidermis, dermis, and subcutaneous fat layer. The thickness of the layers varies depending on the region of the body. Wounds that involve the epidermis and which extend into the dermal layer can occur for a variety of reasons, such as trauma, ulceration, surgical procedures, and pressure.

Since Winter's seminal 1962 study,[1] which showed increased wound epithelialisation at a moist donor site under an occlusive bandage, several studies have reported the beneficial effects of moist wound healing.[2–8] Concerns that this may increase the risk of infection have been raised; however, in most cases, this fear has not been substantiated.[7] Moreover, a moist wound environment plays an important role in facilitating the recruitment of both vital host defences and the necessary cell population that helps to promote the healing process.[8]

Hydrocolloid dressings have been available for wound management since the late 1970s. Numerous studies have been undertaken to evaluate their efficacy in the management of a variety wounds.[2–6] Currently, there are several products that aim to produce a less painful wound dressing that provides an occlusive, moist environment conducive to wound healing. The ultimate goal of these products is to decrease treatment time and discomfort. Only a standardised comparison of these products will allow clinicians to make informed decisions about wound management. Therefore, in this study, we directly compared the efficacy of Medifoam H (Genewel Co. Ltd.) and DuoDERM (ConvaTec Inc.) in a prospective, randomised study to determine their relative impact on wound healing efficacy and safety. The null hypothesis was that there is no difference between these two dressings.

Method

This was a single-centre, equally randomised (1:1), active-controlled, open–label, phase IV study conducted in the Catholic University of Korea. The study took place at the department of plastic and reconstructive surgery of Seoul St Mary's Hospital in Seoul, South Korea, from March to August 2012.

Prior to enrolling patients in the study, approval was obtained from the Institutional Review Board of the Catholic University of Korea.

Study population

Patients that sustained a laceration, abrasion, superficial burn, or who were undergoing minor surgery that wound require wound dressing and follow-up, were eligible to be enrolled in the study. There were no sex or age exclusion criteria. Laceration and sutured wounds had to be <10cm in length. Abrasions and second degree burns had to have a total surface area <100cm^2 and a of depth <2mm.

Fig 1. Flow of participants through each phase of the trial

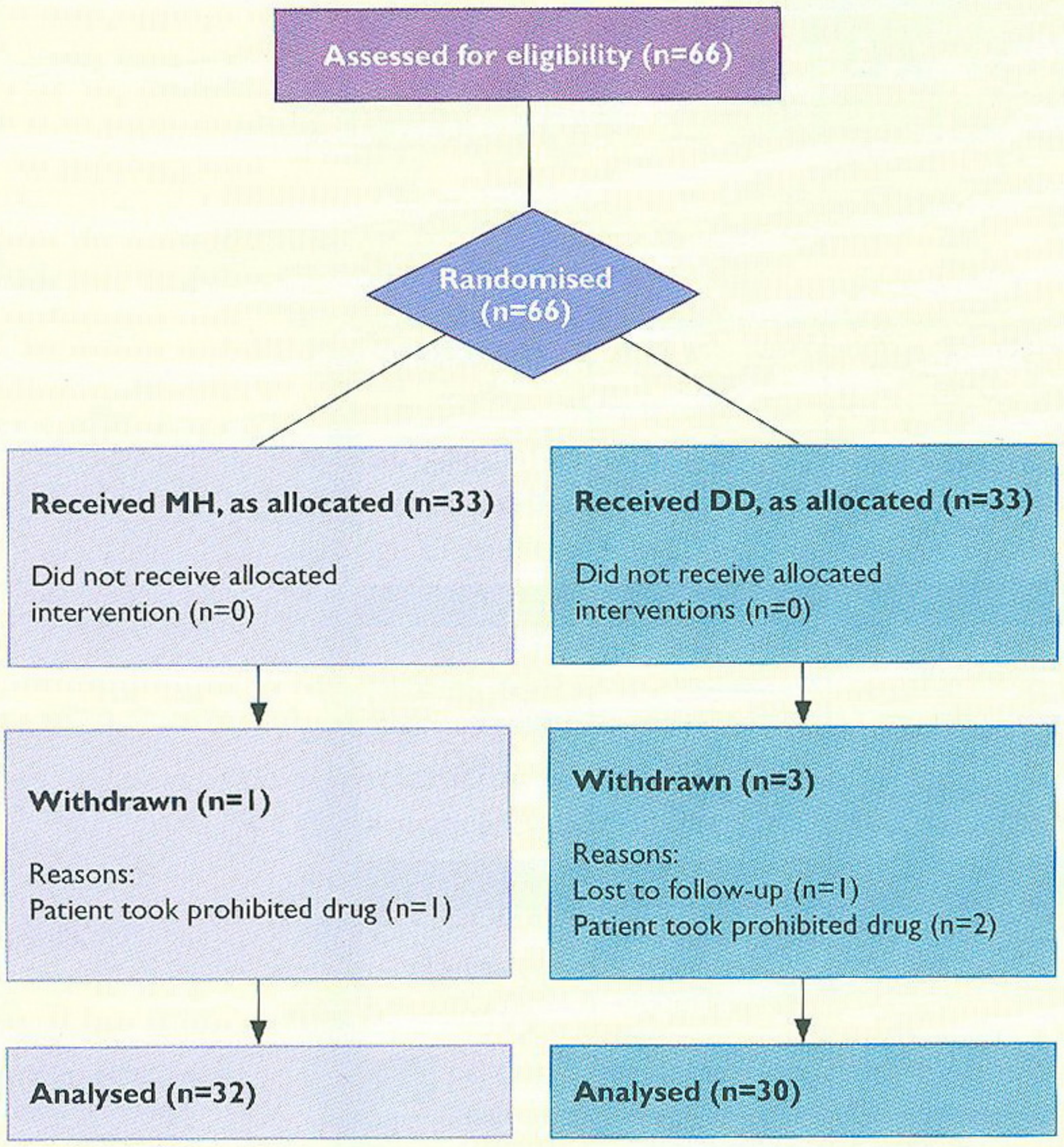

Table 1. Characteristics of the participants at baseline

Variable	MH (n=33)	DD (n=33)
Age (years)*	33.9 ± 13.4	38.2 ± 11.3
Gender (male/female)	7/26	9/24
Height (cm)*	163.1 ± 8.3	163.1 ± 6.9
Weight (kg)*	59.1 ± 9.6	58.9 ± 11.2
Disease history (n)	10 (30%)	11 (33%)
Medication (n)	13 (39%)	12 (36%)
Tissue type (%)*		
• Necrotic tissue	0.61 ± 3.48	0.61 ± 2.42
• Crust	1.52 ± 8.70	0.61 ± 3.48
• Fibrous tissue	2.42 ± 10.01	0.00 ± 0.00
• Granulation tissue	76.52 ± 39.85	81.21 ± 37.48
• Epidermal tissue	18.94 ± 36.35	17.58 ± 37.42
• Other	0.00 ± 0.00	0.00 ± 0.00

* Results presented as mean ± standard deviation

Exclusion criteria consisted of:

- History of hypersensitivity or related symptoms to the materials used in the study
- Wound that has significant depth, or shows signs of severe skin infection (cellulitis, abscess, ulcer, furuncle [boil])
- Secondary infection or perforation due to bites or stings by an animal, human or insect
- In need of a surgical intervention for treatment
- Skin infection due to bacteria, virus or infection of a bacterial origin
- Other various conditions that the investigating clinician found inappropriate for enrolment.

Interventions

For patients who met the inclusion criteria, informed consent was obtained from the patient before randomisation. Patients were randomly assigned to receive wound coverage with either Medifoam H (MH) or DuoDERM (DD) following simple randomisation procedures (computerised random numbers), achieved using opaque envelopes.

All wounds were treated according to normal departmental practice and sutures were given, where appropriate. An initial wound assessment was undertaken and MH or DD was applied (day 1). Dressings were changed when clinically indicated using the appropriate aseptic technique and applied for 7 days. Evaluation of wounds and dressings were done on days 3 and 7, and the patients were then followed for 1 week (day 14).

Patients were blinded to dressing allocation; however, total blinding was not possible among investigators, as there was a slight visual difference between the two dressings.

Wound assessments

The investigator who performed initial wound assessment and applied the dressing material performed serial wound assessment on days 3 and 7. Wound assessment included efficacy parameters: the amount of exudate, wound infection rate and wound healing rate. These parameters were recorded qualitatively, as 'none', 'mild', 'moderate' or 'severe' for exudate and wound infection, and as 'improved', 'no change' or 'worsened' for wound healing, based on the investigator's clinical judgement.

The investigator also performed clinical evaluation to assess wound condition by the percentage of necrotic tissue, crust, fibrous tissue, granulation tissue, and epithelial tissue present at the wound bed, based on subjective, clinical judgement.

Dressing performance assessments

All patients filled in an evaluation form at the end of their hospital visit (day 14). The form asked patients to report their subjective experience of itching, burning, leakage of exudates, pain and discomfort during

Table 2. Amount of exudate

	MH (n=33)	DD (n=33)	p-value*
Baseline (n)			
• None	3 (9.1%)	3 (9.1%)	
• Mild	7 (21%)	5 (15%)	
• Moderate	21 (64%)	25 (76%)	
• Severe	2 (6.1%)	0 (0.0%)	0.5494
Day 3 (n)			
• None	2 (6.1%)	3 (9.1%)	
• Mild	19 (58%)	16 (48%)	
• Moderate	12 (36%)	14 (42%)	
• Severe	0 (0.0%)	0 (0.0%)	0.7479
Day 7 (n)			
• None	27 (82%)	22 (67%)	
• Mild	5 (15%)	9 (27%)	
• Moderate	1 (3.0%)	2 (6.1%)	
• Severe	0 (0.0%)	2 (6.1%)	0.4193
improved (n)†	27 (82%)	22 (67%)	

* Fisher's exact test;
† 95% confidence interval: –5.6%; 35.9%

use of dressing, pain at dressing removal, and dressing adherence. The results were recorded as 'none', 'minimal', 'moderate' or 'severe'.

In addition, pain was assessed initially and on days 3 and 7 on a 10-point visual analogue scale (VAS) where 0 represents no pain and 10 unbearable pain.

Sample size

A sample size of 33 patients in either group was determined using a two-sided 5% significance level and 80% power, given an anticipated dropout rate of 20%.

Statistical analyses

Treatment differences for qualitative variables such as amount of exudate, wound infection rate and wound healing rate, were analysed using Fisher's exact test or the Chi-squared test. Treatment differences for quantitative variables (percentage of tissue type or pain score) were analysed using the Wilcoxon rank sum test. Results were considered significant for $p<0.05$. All analyses were conducted using SPSS software.

Results

A total of 66 patients were enrolled in the study. Thirty-three patients (seven males, 26 females) were randomly selected to receive MH; the other 33 patients (nine males, 24 females) received DD. One patient in the DD group missed the day 3 evaluation and so was excluded. One patient in the MH group and two patients at DD group took prohibited medications and were excluded (Fig 1).

The study population included participants ranging from 21–71 years of age, with a mean age of 33.9±13.4 years and 33.2±11.3 years, in the MH and DD groups, respectively. Table 1 shows participants' baseline characteristics; most variables were comparable in the two groups. The most common wound aetiology was post laser treatment (n=25 and n=24 in MH and DD groups, respectively), followed by laceration and suture wounds (n=6 and n=5 in MH and DD groups, respectively; Fig 2) and the most injury location was the face (n=20 and n=22 in the MH and DD groups, respectively; Fig 3).

Wound assessments

The amount of exudate improved in both groups, with 82% (n=27) in MH group and 67% (n=22) in the DD group recording an improvement in exudate level, with no statistical differences between groups (Table 2). Wound infection rate and the wound healing rate are summarised in Table 3 and Table 4.

Fig 2. Range of wound aetiologies included in the study

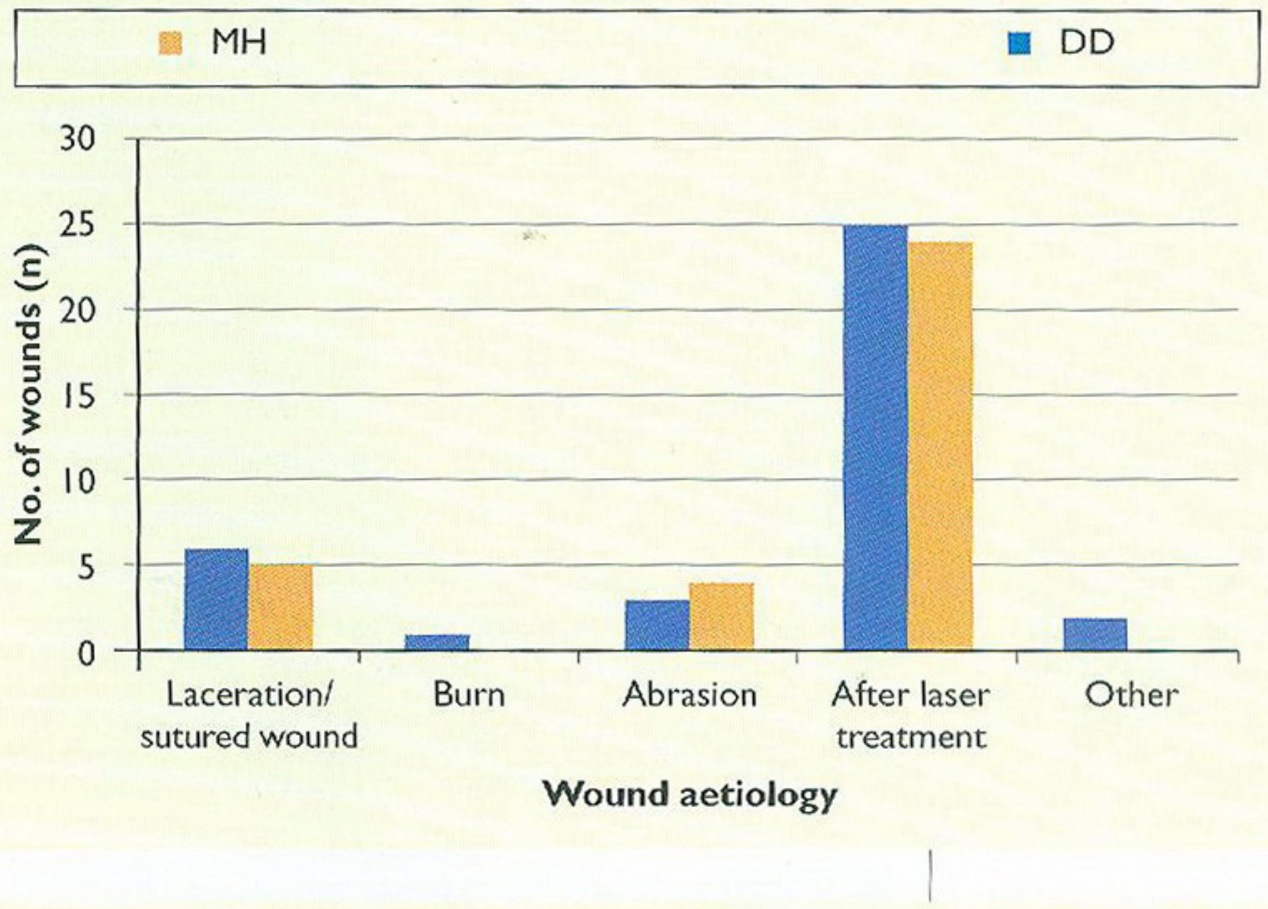

Fig 3. Range of wound locations included in the study

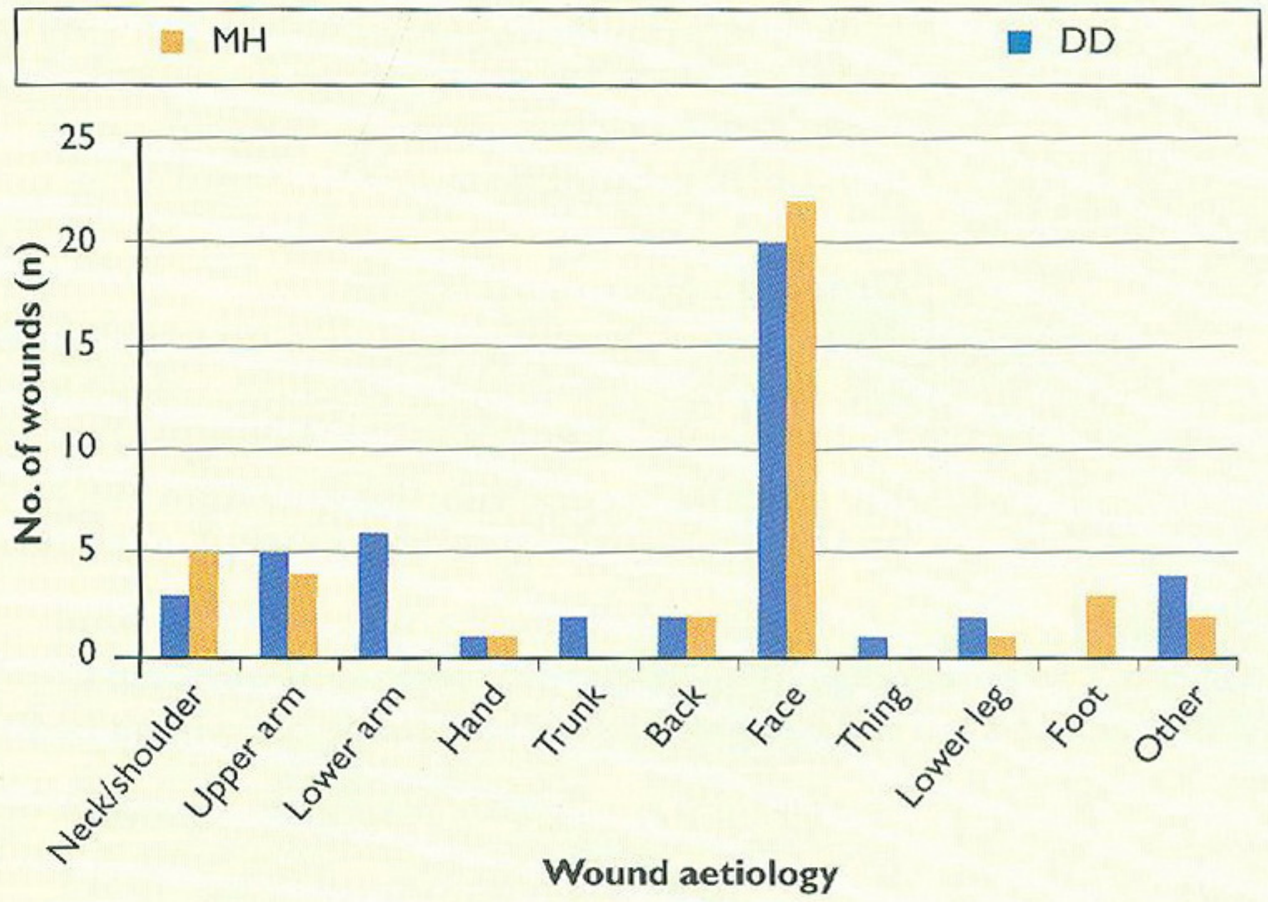

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Table 3. Wound infection

	MH (n=33)	DD (n=33)	p-value*
Baseline			
• None	30 (91%)	32 (97%)	
• Mild	3 (9.1%)	1 (3.0%)	
• Moderate	0 (0.0%)	0 (0.0%)	
• Severe	0 (0.0%)	0 (0.0%)	0.6132
Day 3			
• None	31 (94%)	31 (94%)	
• Mild	2 (6.1%)	1 (3.0%)	
• Moderate	0 (0.0%)	1 (3.0%)	
• Severe	0 (0.0%)	0 (0.0%)	1.0000
Day 7			
• None	32 (97%)	31 (94%)	
• Mild	1 (3.0%)	1 (3.0%)	
• Moderate	0 (0.0%)	0 (0.0%)	
• Severe	0 (0.0%)	1 (3.0%)	1.0000

* Fisher's exact test;

Clinical evaluation of wound condition is summarised in Table 5. There were no statistical differences between the two groups for any category of wound assessment at any time during the study.

Dressing performance assessments

There were no significant differences in burning, leakage of exudates, pain or discomfort experienced by the patients during use of dressing, pain at dressing removal, or dressing adherence between two groups. During dressing use, some patients in the MH group reported an increase in mild itching compared with participants in the DD group.

Throughout wound management, patients in MH group reported a lower mean VAS score (1.0±1.7) than those in the DD group (1.2±1.4); however, the difference between mean VAS scores between the two groups at day 3 and day 7 were not significant (Table 6).

Table 4. Wound healing rate

	MH (n=33)	DD (n=33)	p-value
Day 3			
• Improved	25 (76%)	23 (74%)	
• No change	8 (24%)	8 (26%)	
• Worse	0 (0.0%)	0 (0.0%)	0.8852*
Day 7			
• Improved	31 (94%)	29 (94%)	
• No change	2 (6.1%)	2 (6.5%)	
• Worse	0 (0.0%)	0 (0.0%)	1.0000†

* Chi-square test; † Fisher's exact test

Table 5. The percentage of necrotic tissue, crust, fibrous tissue, granulation tissue and epithelial tissue present at the wound bed

	MH (n=33)	DD (n=33)	p-value*
Day 3			
• Necrotic tissue (%)	0.0±0.0	0.0±0.0	—
• Crust (%)	0.3±1.7	0.7±2.5	0.5328
• Fibrous tissue (%)	0.0±0.0	0.0±0.0	—
• Granulation tissue (%)	58.3±33.0	55.3±36.0	0.8334
• Epidermal tissue (%)	41.4±33.3	44.0±36.6	0.9083
• Other (%)	0.0±0.0	0.0±0.0	—
Day 7			
• Necrotic tissue (%)	0.0±0.0	0.0±0.0	—
• Crust (%)	0.0±0.0	1.1±5.4	0.1475
• Fibrous tissue (%)	0.0±0.0	0.0±0.0	—
• Granulation tissue (%)	5.0±17.7	3.6±10.3	0.4002
• Epidermal tissue (%)	95.0±17.7	95.3±11.7	0.2571
• Other (%)	0.0±0.0	0.0±0.0	—

Results presented as mean ± standard deviation;
*Wilcoxon rank sum test

Discussion

The use of adhesive hydrocolloid dressings is now widespread; these materials offer the advantages of occlusion, reduced frequency for dressing change and better adsorption.[2–6] Most dressings that employ a closed technique may protect the wound from contamination by exogenous bacteria, and they may also foster an exchange of oxygen and water vapour. Hydrocolloid dressings simplify wound management and prevent crusting because they efficiently drain exudates.[2,7,8]

In this study a new hydrocolloid dressing, MH, was compared with a traditional hydrocolloid dressing, DD. No significant differences were observed between the dressings in a range of wound situations. MH is a biocomposite wound dressing consisting of a semi-permeable polyurethane film protection layer, a hydrocolloid absorption layer, and a wound contact layer. Polyurethane film is semi-permeable and controls evaporation. The hydrocolloid layer absorbs exudates and protects the wound. The wound contact layer improves adhesion and promotes occlusion, offering the optimum environment for moist wound healing. DD is an occlusive hydrocolloid dressing, and has been shown to be efficacious in the management of donor sites and superficial burns. Both MH and DD provide an alternative method to daily care while providing an effective barrier that produces an environment that is conducive to healing.

In a study of these types of superficial wounds, it is difficult to demonstrate that one material is superior

to another in terms of wound healing. This is because, based on clinical experience, these types of wounds tend to heal in 5–10 days, depending on the site, if there are no adverse factors affecting wound healing. Our primary concern was to ensure that the dressings did not have any adverse effects on wound healing, and our results clearly demonstrate that there were no problems with healing. All the wounds showed epithelialisation and progress towards healing within 7 days (Table 4).

Overall, wound characteristics and other assessments show similarity between the two groups. Wound assessment demonstrated no evidence for any difference in exudate control, wound healing, or infection with use of the MH dressing compared with the DD dressing. We found a mild itching sensation associated with MH use, but there were no significant differences between the two groups in pain, burning or discomfort during dressing use.

Table 6. Comparison of mean visual analogue scale (VAS) scores between the two groups

	MH (n=27)	DD (n=26)	p-value*
Baseline	1.0 ± 1.7	1.2 ± 1.4	—
Day 3			
• Mean	0.3 ± 0.6	0.3 ± 0.7	—
• Difference vs baseline	–0.7 ± 0.4	–0.9 ± 1.0	0.0587
Day 7			
• Mean	0.0 ± 0.0	0.1 ± 0.3	—
• Difference vs baseline	–1.0 ± 1.7	–1.2 ± 1.4	0.2613

*Wilcoxon rank sum test

Conclusion

There are a variety of dressings available for wound management, with no single dressing is considered to be the best. The search for an optimal wound care method and dressing is ongoing. When selecting a new dressing, clinicians need to consider a patient's acceptability of the dressing material and other available products that are comparable. We conducted this study to compare MH with a more commonly used dressing, DD. The data collected from this gave no evidence for any difference in efficacy between the two dressings, suggesting MH as a suitable alternative to DD for acute wound management. ■