Superabsorbent charcoal dressing versus silver foam dressing in wound area reduction: a randomised controlled trial

Aim: This study aimed to compare the effect of a novel sterile polyacrylate wound pad with activated carbon cloth treatment with a standard non-adhesive hydrocellular foam dressing with silver in reducing wound area.
Method: A multicentre randomised controlled open-label wound-dressing trial was conducted in two wound care outpatient clinics in western Switzerland from November 2018 to March 2020.
Results: A total of 77 successive patients were randomised to receive either a sterile polyacrylate wound pad with activated carbon cloth treatment (n=38) or the standard non-adhesive hydrocellular foam dressing with silver (n=39). Reduction in wound area was the primary outcome, whereas the application period of the dressing, odour, maceration and pain were the secondary outcomes. Wound area was measured at baseline and during each wound dressing change until the dressings were no longer indicated. Wound area reduced faster in the intervention group than in the control group (0.45cm^2 per day vs. 0.2cm^2 per day), although the application period was longer in the intervention group compared with the control group (9.5 days vs. 8.1 days). Maceration reduction was more pronounced in the intervention group (-2.07cm^2) than in the control group (-0.71cm^2). Odour, pain and infection were similar in both groups.
Conclusion: Sterile polyacrylate wound pad dressings with activated carbon cloth reduced the wound area, as well as the maceration area, faster than the non-adhesive hydrocellular foam dressing with silver.
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diabetes • dressing • foam dressing • infection • maceration • odour • pain • superabsorbent dressing • ulcer • wound • wound area reduction • wound care • wound dressing • wound healing

Hard-to-heal wounds are common but often neglected, not only at the level of the individual and family but also at the level of society as a whole.[1] Hard-to-heal wounds are those in which the normal healing process has been interrupted once or multiple times in the phases of haemostasis, inflammation, proliferation and maturation.[2] They affect a large segment of the population,[3] with mixed aetiology wounds having a prevalence of 2.21 per 1000.[4] The annual cost of care for patients with hard-to-heal wounds is estimated to be £8.3 billion in the UK.[5]

The care of hard-to-heal wounds is complex and targets the management of risk factors and protective factors associated with wound size reduction and recurrence. Evidence has shown an association between wound area reduction and best-practice wound care,[6] which is defined by integrating individual clinical expertise with the best available external clinical evidence from systematic research.[7] Wound dressings are part of best-practice wound care. A retrospective cohort study including 24 patients with venous leg ulcers (VLUs) in which different wound dressings were used reported a wound size reduction varying from 0.1–1cm^2 per week, with a mean wound size reduction of 0.415cm^2 (standard deviation (SD): 0.383) per week.[8] In a prospective multicentre study including patients with a diabetic foot ulcer (DFU), Sheehan et al.[9] investigated the wound area reduction using a collagen wound dressing versus a regular gauze dressing. They reported a wound size reduction within 4 weeks of 1.5cm^2 in the collagen group versus 0.8cm^2 in the gauze group ($p<0.02$). The healing rate is mostly associated with the management of bacteria, among other factors that cause wound odour—the wound dressing used and its ability to absorb wound exudate.[10] Bacteria responsible for wound odour include anaerobes and aerobes.[10,11] Malodorous molecules produced by bacteria include a range of volatile metabolites, such as cadaverine, putrescine, sulfur and short-chain fatty acids.[10] Cadaverine and putrescine have an intense acidic smell and can have a profoundly negative impact on the quality of life of the patient and their carers,

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causing feelings of guilt and/or repulsion, and frequently leading to social isolation and depression.[12,13]

Wound exudate supports the healing process in all wounds. In the healing process, exudate is particularly noticeable during the inflammatory and proliferative phases, providing nutrients as an energy source for metabolising cells. Additionally, the moisture level in the local wound environment is regulated by exudate.[14] Evidence has shown that wound contraction can be described by an exponential curve, but many factors can influence wound healing, including initial size, depth, age of subject, wound duration, patient comorbidities and medications.[15–17] However, overproduction of exudate, its presence in the wrong place or incorrect exudate composition affect the healing process adversely.[18] To manage odour and exudate, different dressings are used in clinical practice. The most frequently used in odour management are charcoal- and silver-based dressings.[13] The mode of action and the method of application differ between these types of dressings. Dressings with a charcoal layer need to remain dry to be effective in adsorbing volatile malodorous compounds. Therefore, they are applied as an outer layer, with no direct contact with the wound.[13] Superabsorbent dressings or negative-pressure wound therapy (NPWT) devices are used to absorb excess exudate.[19]

There is no evidence that a superabsorbent dressing with an active charcoal layer is more effective than standard non-adhesive hydrocellular foam dressing with silver in reducing the area of hard-to-heal wounds. Therefore, in this study, we compared wound area reduction brought about by two wound dressings frequently used in clinical practice (Curea P1 Duo Active (Curea Medical GmbH, Germany) vs. Allevyn Ag+ (Smith+Nephew, UK)), and clinically indicated application period, as well as wound odour, infection, maceration and pain.

Method

Study design, setting and ethics

The methods used in this trial were previously described fully in the study protocol.[20] Briefly, this was a multicentre, prospective, randomised, controlled, open-label wound dressing trial in two outpatient wound clinics in the Canton of Geneva. The study was approved by the ethics committee of the Canton of Geneva (2018-01589) and was registered with ClinicalTrials.gov (NCT03596112).

Study population

Ninety consecutive patients, who were admitted to the wound care outpatient clinic in the Canton of Geneva between November 2018 and March 2020, were screened for this trial. Inclusion criteria were:

- An existing hard-to-heal exuding wound for at least 3 months on the lower limb
- Wound surface area 2–12cm^2
- Age over 18 years
- Proficiency in the French language.

Participants who did not provide valid informed consent were excluded. Participants were followed up for 14 days.

Randomisation and blinding

Patients who met the inclusion criteria were randomly allocated to either the intervention group, which received wound care with a polyacrylate wound pad with the activated carbon cloth, or the control group, which received wound care with non-adhesive hydrocellular foam dressing with silver. Randomisation was managed as described previously.[20] Owing to the appearance of the wound dressings, the participants and nurses could not be blinded to treatment allocation. However, the evaluating investigators, investigators who traced the ulcers and the study coordinator were all blinded to the treatment groups.

Test material

Two wound dressings that are indicated for hard-to-heal and low-to-heavy exuding wounds, as well as for infected or vulnerable-to-infection wounds, were used for this trial. Product A is a hydrophilic, double-spun, bonded, non-woven dressing composed of polypropylene, web treatment and additives (pigments). It has an air-formed, non-woven composite of pulp (cellulose) and cross-linked acrylate polymer with a knitted activated carbon cloth (Curea P1 Duo Active). Polyacrylate wound dressings/pads are a relatively recent addition to the clinician's toolbox. These dressings are highly effective for exudate management, as their substantial absorbency and fluid retention can be adjusted to the need. They also have the ability to sequestrate and inhibit bacteria and matrix metalloproteinases (MMPs) in their core. The specific polyacrylate dressing in this study also contains a layer of activated carbon. As activated carbon is commonly used for the decontamination of wounds in the inflammatory stage, this specific novel combination of polyacrylate and activated carbon warranted a comparison against silver-containing dressings, which are widely used for the same indication.

Product B is an absorbent hydrocellular foam pad with silver held between a highly permeable outer top film and a non-adherent wound contact layer that will not stick to the wound itself (Allevyn Ag+).

Sample size

Initially, the sample size required to answer the hypothesis was calculated based on data from the literature assuming an average wound area of 3.0cm^2 at baseline and 1.5cm^2 at 12 weeks for the control group and 1.2cm^2 for the intervention group (20% difference in wound area between the groups).[20] No separate pilot study was conducted; instead, the data of the first six participants were used to check whether the assumptions about wound area reduction and application time held true for this study population. Based on the results, the hypothesis was revised and

the required sample size was re-estimated. Using an alpha value of 0.05 and a power of 0.9, the sample size obtained was 37 per group. PASS 12 software (NCSS, US) was used for these calculations.[21]

Data collection, outcomes and analysis

Data collection and outcomes

A different trained study nurse collected the data for each group. The nurse performed data entry using electronic support (EvaSys software, EvaSys GmbH, Germany) and measured wound areas using a 3D wound imaging device.[22] The collected data included demographic information, wound aetiology, health-related characteristics and the secondary outcomes: application period, wound odour, infection, maceration and pain. The application period was defined as the period from the start of treatment until the absorbent dressing was not clinically indicated. All other secondary outcomes were measured as described previously.[20] Wound size, wound odour, maceration, infection and pain were recorded at the start of treatment and at the end of the dressing application period. All participants were followed up every 2–3 days. The research team oversaw the nurses' practice.

Statistical analysis

Descriptive analysis was used for sociodemographic and clinical variables; relative and absolute frequencies were used for continuous and categorical variables. Between-group and within-group comparisons were performed using unpaired and paired t-tests, respectively. The Mann–Whitney U-test was used for nonhomogeneous distribution of variance. SPSS V.2521 (IBM Corporation, US) was used for data entry and analysis.

Table 1. Demographic characteristics of study participants overall and by study group

	All participants (n=77)		Intervention group (n=38)		Control group (n=39)	
Characteristic	**n**	**%**	**n**	**%**	**n**	**%**
Gender						
Male	34	44.2	17	44.7	17	43.6
Female	43	55.8	21	55.3	22	56.4
Mean age in years (SD)	77.5 (12.6)		78.6 (14.0)		76.3 (11.0)	
Male (n=34)	76.2 (13.5)		77.9 (16.3)		74.5 (10.1)	
Female (n=43)	78.5 (11.9)		79.2 (12.2)		77.7 (11.7)	
Marital status						
Single	7	9.1	1	2.6	6	15.4
Married	41	53.2	20	52.6	21	53.8
Divorced	12	15.6	1	2.6	11	28.2
Widowed	7	22.1	16	42.1	1	2.6
Highest education level						
Compulsory	25	32.5	10	26.3	15	38.5
High school	1	1.3	1	2.6	0	0
Vocational	44	57.1	25	65.8	19	48.7
University degree	7	9.1	2	5.3	5	12.8
Profession						
Retired	62	80.5	29	76.3	33	84.6
Invalid pension	14	18.2	8	21.0	6	15.4
Other	1	1.3	1	2.6	0	0
Income in CHF						
<25,000	41	53.2	18	47.4	23	59.0
25,000–100,000	36	46.8	20	52.6	16	41.0

CHF—Swiss francs; SD—standard deviation

Results

Of the 90 patients who fulfilled the inclusion criteria, 77 consented to participate in the study (intervention group=38, control group=39), resulting in a participation rate of 85.6%.

Demographic characteristics of the study population

Of the 77 participants, the majority (55.8%) were female, retired (80.5%), had an education level of vocational training (57.1%) and were married (53.2%) (Table 1). The mean age of all participants was 77.5 years (SD: 12.6), ranging from 50 years to 94 years. The mean age of male participants at 76.2 years (SD: 13.5) was lower than that of the female participants, at 78.5 years (SD: 11.9). Two-thirds of the participants had at least vocational training or a university education, and over 80% were retired; just over half lived on an income of less than 25,000 Swiss francs per year and were married. Apart from marital status, there were no relevant differences in the observed characteristics between the intervention and control groups.

Health-related characteristics of study population

The most common type of wound in both groups was VLU (n=56; 72.7%), followed by DFU (n=13; 16.9%), while the most common comorbidities were chronic venous insufficiency (CVI) and diabetes mellitus (DM), with frequencies of 75.3% and 22%, respectively. The participants' mean BMI was 26.0 (SD: 3.5), ranging between 18.4 and 39.3. Two-thirds (n=53; 68.8%) of the participants reported themselves as non-smokers. All smokers stated that they smoked one or fewer packets per day.

The distribution of participants in the groups according to the health-related variables is shown in Table 2. There were no between-group differences with regard to smoking status and BMI, although there were more participants with VLU and CVI in the control group and more participants with DFUs and DM in the intervention group.

Wound area reduction and application period

The mean relative wound area at the start of the study was 4.31cm^2 (SD: 1.25) in the intervention group and 4.81cm^2 (SD: 1.59) in the control group; at the end of the study, these values were 2.36cm^2 (SD: 0.86) and 4.05cm^2 (SD: 1.48), respectively. The absolute mean wound area reduction in the intervention group was

Table 2. Health related characteristics of study population overall and by study group

	All participants (n=77)		Intervention group (n=38)		Control group (n=39)	
Wound type						
VLU	56	72.7	21	55.3	35	89.8
DFU	13	16.9	11	28.9	2	5.1
ALU	1	1.3	1	2.6	0	0
Mixed LU	7	9.1	5	13.2	2	5.1
Comorbidities						
CVD	58	75.3	23	60.5	35	89.7
DM	17	22.0	13	34.2	4	10.3
PAOD	2	2.7	2	5.3	0	0
BMI (kg/m^2)	26.0 (SD: 3.54)	p=0.68, Δ=0.32, 95% CI: [-1.24:1.89]	26.2 (SD: 4.1)	p=0.72, Δ=0.45, 95% CI: [-2.15:3.06]	25.2 (SD: 5.1)	p=0.85, Δ=0.19, 95% CI: [-1.78:2.16]
Male (n=34)	26.2 (SD: 2.60)		26.5 (SD: 2.85)		25.9 (SD: 2.38)	
Female (n=42)	25.9 (SD: 4.17)		26.0 (SD: 4.93)		25.7 (SD: 3.39)	
Smoking status						
Non-smoker	53	68.8	29	76.3	24	61.5
Smoker	24	31.2	9	23.7	15	38.5

ALU—arterial leg ulcer; BMI—body mass index; CI—confidence interval; CVD—cardiovascular disease; DFU—diabetic foot ulcer; DM—diabetes mellitus; LU—leg ulcer; PAOD—peripheral arterial occlusive disease; SD—standard deviation; VLU–venous leg ulcer

1.96cm^2 or 43.9%, while that in the control group was 0.76cm^2 or 14.1%. The differences within and between the groups are relevant and statistically significant (Table 3). The median application periods for the two dressings were different (7 days (interquartile range (IQR): 4–10) for the intervention group and 4 days (IQR: 3–7) for the control group). Overall, the wound area reduction was twice as high in the intervention group as in the control group (0.45cm^2/day of application vs. 0.2cm^2/day of application). However, this difference, although clinically relevant, is not statistically significant due to the variability. The relative wound area reduction in the intervention group was 9.2% per day (SD: 11.75) versus 3.99% in the control group (SD: 6.25). The wound area reduction differed between genders: it was greater in men (0.31cm^2/day) than in women (0.21cm^2/day). This difference was also observed in the percentage/day value, where the difference in men was 7.36% but only 0.21% in women. The between-group differences in the wound area reduction were clinically relevant. Smoking or wound area at the study start was not found to be associated with wound area reduction.

Wound odour

At the start of the study, 54 of the 77 participants (70.1%) had wound odour, with an average odour strength of 26.1 (SD: 14.4) on the visual analogue scale (VAS) from 0 to 100. Wound odour was absent for all participants at the second data collection point.

Infection

Wound infection was present in only three participants at the start of the study, and all these cases were resolved during treatment.

Maceration

Wound maceration was present in 75.3% (n=58) of the participants at baseline, with an average maceration size of 3.85cm^2 in the intervention group and 2.68cm^2 in the control group (p=0.008). At the end of the study, the maceration size was very similar in the two groups, at 1.93cm^2 and 2.0cm^2, respectively. However, the reduction in maceration was more pronounced in the intervention group (-2.07cm^2) than in the control group (-0.71cm^2).

Pain

Pain was present in 94.8% of the participants, and equally distributed in both study groups. The pain strength was higher in the control group at the start of the study, but it was similar between the groups at the end of the study.

Discussion

This multicentre, prospective, randomised controlled open-label trial involving 77 participants was designed to compare wound area reduction brought about by using a sterile polyacrylate wound pad with activated carbon cloth dressing and a standard non-adhesive hydrocellular foam dressing with silver. The study population was comparable to those of other studies on hard-to-heal wounds. In this study, the two groups were similar with regard to age, gender, body mass index (BMI) and smoking status. However, the distribution of the wound types and comorbidities within the groups was not similar. The initial wound area in the control group was 0.5cm^2 larger than in the intervention group. These initial data were similar to those in other studies using wound area reduction as an outcome.[9–24] In the

Table 3. Wound area reduction and application period between two time points (T0 and T1)

	All participants (n=77)	Intervention group (n=38)	Control group (n=39)	Differences
Wound area reduction between T0 and T1 (%)	28.8 (SD: 22.7; 95% CI: [23.7:34.0])	43.9 (SD: 16.7; 95% CI: [38.4:49.4])	14.1 (SD: 17.6; 95% CI: [8.4:19.8])	P<0.001, Δ=29.8, 95% CI: [22.0:37.6]
Wound area reduction between T0 and T1 (cm^2)	-1.35 (SD: 1.20)	-1.96 (SD: 1.10)	-0.76 (SD: 0.995)	p<0.001, Δ=-1.19, 95% CI: [-1.68:-0.72]
Application period between T0 and T1 (days)	8.81 (SD: 9.5)	9.51 (SD: 9.12)	8.13 (SD: 9.91)	p=0.53, Δ=1.39, 95% CI: [-2.94:5.71]

CI—confidence interval; SD—standard deviation

present study, the hard-to-heal wounds healed significantly better (e.g., faster wound area reduction), and there was a significant reduction in maceration in wounds treated with a sterile polyacrylate wound pad with activated carbon cloth dressing. This may be because the absorbency level of the superabsorbent dressing is at least twice as high as that of the foam dressings.[25]

Wound area reduction is the most commonly used outcome in wound care studies.[26] The present results demonstrated a faster wound area reduction of 43.9% in the intervention group within 9.51 days of application period compared with the control group, which showed a 14.1% wound area reduction in an application period of 8.13 days. The application period was a maximum of 10 days, which is shorter than that in other studies. This is because the dressings were no longer clinically indicated beyond this time, due to increased exudate production. The literature showed that a wound area reduction of 53% was achieved within 6 months when different superabsorbent dressings were applied.[27] A 3D wound imaging device was used in the present study to measure the wound area.[22] This method is more accurate than those used in other studies.

Containment of wound odour is a challenge in wound management. Charcoal-containing dressings are the most commonly used, followed by silver-based dressings.[28] In the present study, wound odour was not detected in either the charcoal or silver dressing group at the second data collection point. The prevention and management of maceration is also an important aspect of wound management.[2] Evidence has demonstrated a relationship between maceration and wound healing.[29] Leakage is a sign of failure of the dressing to contain the wound exudate and can lead to maceration. In the present study, use of the sterile polyacrylate wound pad with activated carbon cloth dressing led to a reduction in maceration of 2.07cm^2, compared with the 0.71cm^2 reduction achieved using the standard non-adhesive hydrocellular foam dressing with a silver pad. Again, less maceration has a positive impact on wound healing.

Limitations

This study has some limitations, including the between-group difference in wound area at baseline. Further, the maximum application period was only 10 days, and the odour measurement relied on clinical judgement, which is subjective.

Conclusion

The findings of the present study may indicate that, clinically, hard-to-heal wounds similar to those of the patients enrolled in this study and that are managed with a sterile polyacrylate wound pad with activated carbon cloth pad are likely to heal faster and show less maceration than those treated with a standard non-adhesive hydrocellular foam dressing with silver. JWC

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Reflective questions

- What is the purpose of using odour adsorbent wound dressings for hard-to-heal wounds?
- What could be the causes of exudate in hard-to-heal wounds?
- How relevant is wound area reduction in clinical practice?

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