

# Wound cleansing efficacy of two cellulose-based dressings

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## Abstract

**Aims:** The objective of this prospective randomised comparative study was to assess the effects of two different cellulose-based dressings and their influence on venous leg ulcer cleansing and debridement over a four-week observation period. **Methods:** After ethics committee approval was obtained, both in and outpatients at the trial centres were recruited to the study after giving written informed consent. Forty patients (n=20/20) were included on an intention to treat basis. **Results:** Forty patients completed the study (n=20/n=20) and were included in the analysis. The ulcers in the study group (SG) showed a 43.53% reduction in wound area, whereas the ulcers in the control group (CG) had a 17.94% reduction. The reduction of yellow tissue was significantly larger in the SG ( $t=0.020$  at day 7 and  $t=0.45$  at day 14; 75.2% at baseline, 16.5% at 28 days) than in the CG (80.2% at baseline, 34.5% at 28 days). Pain reduction was faster and better in the SG (visual analogue scale [VAS] 1.30) at 28 days than in the CG (VAS 3.20). **Conclusions:** Both cellulose-based dressings were found to be successful in wound cleansing. Pain reduction was faster and better in the SG, contributing to an improved quality of life. **Conflict of interest:** This study was supported by Lohmann & Rauscher GmbH.

## KEY WORDS

Wound cleansing  
Debridement  
Fibrin layer  
Cellulose-based dressings

In European countries, 1–2 % of the total population suffer from venous leg ulcers (Stacey et al, 2002). The causal therapy consists of compression bandaging on the one hand, and traditional surgery for varicose veins (including sclera-therapy) on the other. Compression is considered the mainstay of treatment for venous leg ulcers (Partsch et al 1999; Stacey et al, 2002). This may be supplemented by primary dressings that promote a moist wound healing environment. A range of topical products are available, but there is little comparative

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evidence on their effectiveness, i.e. there is no strong basis for disproving the validity of a multimodal treatment approach.

Many patients with venous leg ulcers are frail and present with complex issues, such as impaired control of the peripheral

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circulation and tissue oxygenation, defective remodelling of the extracellular matrix, failure to re-epithelialise, and prolonged inflammation (Margolis et al, 2000). Specific risk factors have been identified in this patient group, such as:

- ▶▶ Advanced age
- ▶▶ Venous insufficiency
- ▶▶ Low mobility
- ▶▶ Diabetes mellitus and/or other chronic conditions, eczema, exuding dermatitis, comorbidities, etc.

Persistent of open wounds result in prolonged treatment for both inpatients and outpatients.

With venous leg ulcers, the primary goals of therapy consist of reducing oedema, wound bed preparation (WBP) and exudate management (Falanga, 2000; Margolis et al, 2000; Vogt et al, 2007). Ineffective exudate and oedema management can be due to inadequate compression therapy, or the presence of infection (Falanga, 2000; Margolis et al, 2000). It is debated as to whether venous leg ulcers should be regarded as contaminated or not (Falanga, 2000).

Any open skin lesion is a potential invasion site for microorganisms. Adequate exudate management is needed to prevent secondary infection, while simultaneously following the principles of moist wound healing management, which include keeping the wound moist but not too wet and avoiding maceration while controlling exudate (Vogt et al, 2007).

A prospective randomised comparative study was designed by the authors to assess the effects of two different cellulose-based dressings and their influence on leg ulcer cleansing and debridement.

## Materials

The following cellulose-based dressings were evaluated: Suprasorb® X (bio-cellulose wound dressing, Lohmann &

**Table 1**

Patient details at baseline

Start of treatment	SG (n=20)	CG (n=20)	Details
Female/male	n=20 (f =10/m=10)	n=20 (f=12/m=8)	N=40/22 female and 18 male
Mean age (years)	66.4 (±7.97) maximum 79/ minimum 51	65.25 (± 8.31) maximum 76/ minimum 42	
Mean wound area (mm <sup>2</sup> )	548.58 (±893.5) maximum 2744.16/ minimum 45.53	629.9 (±992.5) maximum 4254.03/ minimum 43.05	
Mean necrosis (%)	45.53 629.9 (±992.5) Max. 4254.03/Min. 43.05 Mean necrosis (%) 3.36 (± 12.61)	4.2 (± 9.13)	
Mean yellow (%)	75.2(± 31.9)	80.17(± 13.8)	
Mean granulation (%)	21.44 (± 28.5)	15.61(± 13.9)	

Rauscher) for the study group (SG) and Aquacel® (Hydrofiber dressing, Convatec) for the control group (CG). The biocellulose wound dressing is hydrophilic, and has the ability both to donate and absorb moisture depending on the condition of the wound bed (Alvarez et al, 2004). It is synthesised by *Acetobacter xylinum*, and processed into a matrix material that is biocompatible (Alvarez et al, 2004). The biocellulose dressing is a moist cellulose dressing, whereas the Hydrofiber is a dry cellulose dressing.

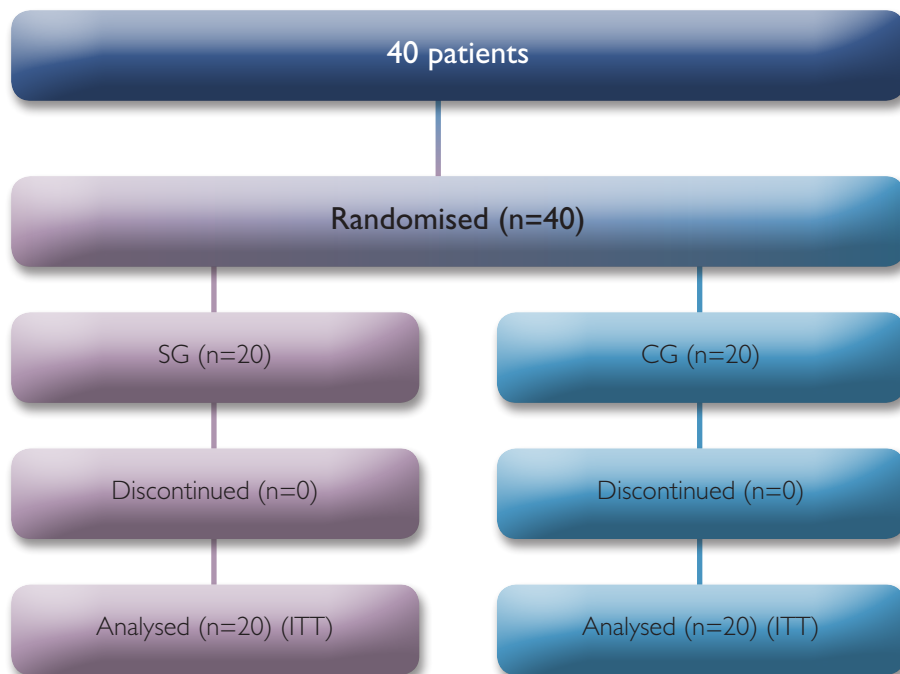
Various studies have been published on the use of the Hydrofiber dressing for exudate management and wound cleansing (Foster and Moore 1997; Cohn et al, 2004; Abuzakuk et al, 2006; Ravenscroft et al, 2006). Alvarez et al (2004) looked at the efficacy of debridement and reduction of fibrin layers in the wound bed, when applying the biocellulose dressing compared to a moist wound healing (MWH) dressing.

**Study design**

For the randomised, controlled clinical study, eligible patients between the ages of 18 and 90 were randomly assigned to receive either the biocellulose dressing (SG) or the Hydrofiber dressing (CG). Patients in both the SG and CG received compression treatment with short-stretch compression bandages and a foam under-padding layer (Rosidal® system, Lohmann & Rauscher). Forty in and outpatients at the trial centres (n=20/20) were included in the study on an intention to treat basis.

The observation period was four weeks, typically the period described in the literature to achieve complete (autolytic) cleansing/debridement (Alvarez et al, 2004). To enrol the patient the target ulcer had to be secondary to chronic venous insufficiency (having the signs of venous disease), with the wound bed containing fibrin coatings and/or slough. Ulcer aetiology was assessed before entry into the trial using ankle brachial pressure index (ABPI), Duplex sonography and digital photoplethysmography (DPPG).

Patients were entered into the study after Institutional Review Board (IRB) informed consent was obtained. They were assigned treatment according to a computer generated randomisation



**Notes:**

- SG = study group (hydrobalance dressing), CG = control group (Hydrofiber dressing)
- Depending on the exudate levels, dressings in the SG and CG were covered with either a film or foam dressing.

**Figure 1. Consort patient flow diagram.**

Table 2

Evolution of wound size during the study period

Evolution of wound size	SG (n=20)					CG (n=20)					Details
	Day 0	Day 7	Day 14	Day 21	Day 28	Day 0	Day 7	Day 14	Day 21	Day 28	
Mean wound size mm <sup>2</sup> (SD)	548.58 (±870.9)	514.21 (±827.7)	383.51 (± 649.2)	358.87 (± 584.5)	309.8 (±508.6)	630.36 (±976.2)	599.90 (±906.3)	581.28 (±878.3)	552.23 (±864.8)	517.28 (±808.4)	
	Mean	SD	STD error	t	Sig (2 tailed)	mean	SD	Std error	T	Sig (2 tailed)	
Total reduction	238.78	580.69	129.85	1.84	0.082	113.08	170.06	38.02	2.97	0.008	Paired sample tests
% reduction					43.53%					17.94%	

## Notes:

- ▶ An outlying observation, or outlier, is one that appears to deviate markedly from other members of the sample in which it occurs. Outliers can occur by chance in any distribution (Ramaswamy et al, 2000). To avoid an error therefore the tests were repeated discarding the outlier in the CG and the largest ulcer in the SG
- ▶ By chance in the CG, there was one outlier (an ulcer size at baseline of 4254.03mm<sup>2</sup> reduced to 3591.21mm<sup>2</sup> at 28 days). This one outlier had an ulcer size at baseline that was much larger compared to the other patients. When repeating the tests discarding the outlier in the CG and the largest ulcer in the SG (2744.16 mm<sup>2</sup> at baseline, reduced to 231.32mm<sup>2</sup> at 28 days), the total mean reduction in ulcer size was NS (CG t = 0.657. SG t= 0.345)

schedule. Patients with bilateral ulceration were randomised to one treatment only. The reference limb was taken as the one with the largest total area of ulceration.

### Dressing regimen

Saline was used to cleanse the wound before applying the assigned treatment. Where applicable, the peri-wound skin was protected with a zinc cream. No other means (antimicrobial agents, enzymes, etc), or methods of cleansing (jets, high-powered rinsing, etc) were allowed during the study.

For both groups, dressing changes took place at the discretion of the clinician, which was on average at two-day intervals. Depending on the amount of exudate present in both groups, a film (Suprasorb® F) or a foam dressing (Suprasorb® P) was selected and applied by the clinician as a secondary dressing.

### Ulcer area and progression

To assess progress of the wound bed over the four-week treatment period, the change in percentage of fibrin and granulation tissue present at visit day 0 (start) versus day 28 (end) was compared between both groups. This was done by photographing the wounds on a weekly basis using a high resolution digital camera

on days 0 (baseline), 7, 14 and 28 ± 1 day. Photographs were analysed by the same trained clinician using a digital tool (Wound Healing Analyzing Tool [WHAT]), which assessed wound size and the development of the wound bed (Wild et al, 2008). The assessor was blinded to the treatment given.

With the biocellulose dressing, changes to the wound edges may occur, such as a whitish coating on the peri-wound skin in the area that is covered with the dressing. These could be misinterpreted as maceration by less experienced clinicians (Mustafi and Schmitz, 2008), especially when performing visual assessment only. However, this discolouration can easily be removed by gentle wiping with a moist swab. Underneath, the epidermis is intact and appears to be soft and more delicate compared to the patient's normal skin (so called 'wipe' or 'wave' effect) (Mustafi and Schmitz, 2008). Therefore, photographs for assessment were taken after dressing removal and cleansing with saline, before the next dressing was applied. Accurate assessment of the wound bed and peri-wound skin condition was thus achieved by using visual assessment, and analysis of digital photographs by a trained clinician with specific software.

For pain analysis at dressing changes, a 10-point visual analogue scale (VAS) was used at day 7, day 14 and 28 ± 1 day (Vewers and Lowe, 1990). Patients were asked to put a stroke on a 10cm line at dressing changes to indicate the degree of pain they experienced, with 0cm indicating the least pain and 10cm the most.

### Statistical analysis

Statistical evaluation was performed using Statistical Package for the Social Sciences (SPSS 16.0). Appropriate tests were carried out at the 5% significance level, with repeated measures analyses of variance (ANOVA). The confidence interval (CI) was 95%. Where appropriate, a student t-test was used to determine significance.

## Results

### Patient characteristics

A total of 40 patients (22 females and 18 males) completed the four-week study period (SG, n=20 [10 female, 10 male], CG, n=20 [12 female, 8 male]) *Figure 1*.

The groups were comparable at baseline in terms of age. The patients in the SG had a mean age of 66.4 years (SD±7.97, range 79–51), and 65.25 years in the CG (SD±8.31, range 76–42).

**Table 3**

Evolution of wound bed condition during the study period

Wound bed condition	SG (n=20)			CG (n=20)		
	Necrosis % (SD)	Yellow % (SD)	Granulation % (SD)	Necrosis % (SD)	Yellow % (SD)	Granulation % (SD)
Baseline	3.37 (±12.3)	75.2 (±13.8)	21.4 (±27.8)	7.52 (±16.1)	80.2(±13.8)	16.15(±15.2)
Day 7	0.5 (±0.56)	65.3 (±27.2)	33.15 (±27.6)	3.50 (±8.4)	75.2 (±12.8)	21.28 (±13.3)
Day 14	0.40 (±0.49)	42.3 (±21.4)	57.29 (±21.32)	2.11 (±2.95)	56.83 (±9.3)	41.06 (±9.66)
Day 21	0.20 (±0.29)	32.3 (±18.66)	67.50 (±18.72)	0.90 (±1.33)	45.4 (±9.07)	53.70 (±9.27)
Day 28	0.15 (±0.29)	16.5 (±11.62)	83.41 (±11.70)	0.3 (±0.57)	34.5 (±7.69)	65.20 (±7.69)

Note:

▶▶ The percentage of necrosis (black), yellow tissue (slough and fibrin) and granulation tissue present at baseline, at day 7, day 14, day 21 and day 28 is shown in Table 3.

**Table 3a**

Reduction of yellow tissue during the study period

Yellow % Reduction	SG (n=20)			CG (n=20)		
	Mean	SD (std error mean)	t (2 tailed)	Mean	SD (std error mean)	t (2 tailed)
Day 7	9,85	5,59 (1.25)	0.000*	4,96	2,72 (0.61)	0.000
Day 14	32,89	16,67 (3.73)	0.000**	23,34	9,84 (2.20)	0.000
Day 21	42,90	20,12 (4.50)	0.000	34,77	10,68 (2.39)	0.000
Day 28	58,75	26,46 (5.92)	0.000	45,67	10,95 (2.45)	0.000

Note:

▶▶ When comparing the reduction of % of yellow tissue between the SG and the CG the reduction of yellow tissue was significantly faster in the SG at day 7 (t=0.020)\* and at day 14 (t=0.45)\*\*

**Table 4**

Evolution of pain (VAS) at dressing changes during the study period

Pain at dressing changes	SG	CG
	VAS (10-point scale)	VAS (10-point scale)
Day 7	2.25 (± 1.06) max 5 min 1	3.73 (± 1.26) max 6, min 1
Day 14	2.70 (± 0.86) max 4 min 1	5.25 (± 1.37) max 8, min 2
Day 28	1.30 (± 0.47) max 2, min 1	3.20 (± 1.20) max 5 min 1

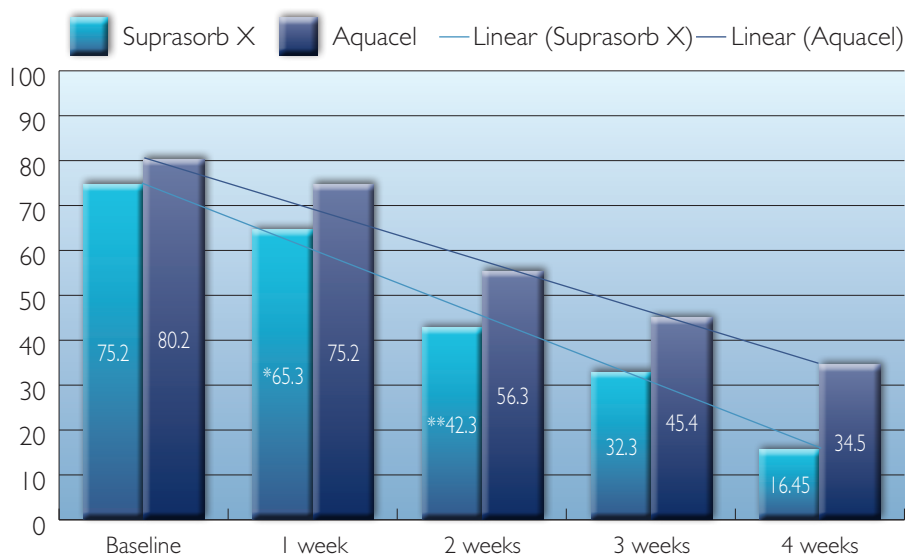
The mean ulcer area for the CG (629.9mm<sup>2</sup>, SD±992.5) was larger than in the SG, due to one outlier who had an ulcer size at baseline of 4254.03mm<sup>2</sup>. The mean ulcer area in the SG at baseline was 630.36mm<sup>2</sup> (SD±976.2), and the

largest ulcer in the SG was 2744.16mm<sup>2</sup> (Table 1).

The total mean reduction in ulcer size was larger in the SG (43.53%, t=0.082) compared with the CG (17.94%, 0.008).

However, when comparing the reduction in ulcer size between the SG and the CG, no statistically significant difference (NSS) was shown. When repeating the tests discarding the outlier in the CG and the largest ulcer in the SG, the results remained NSS (CG t=0.657 versus SG t=0.345).

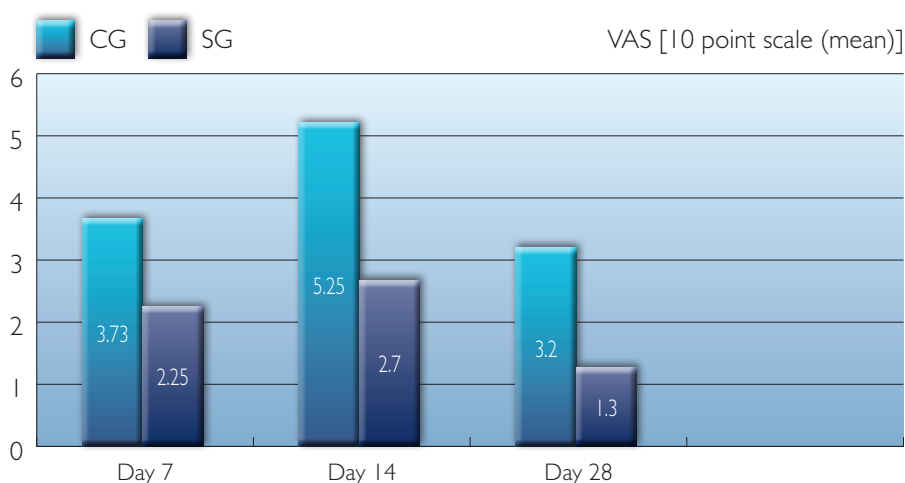
At baseline in the SG, 75.2% yellow tissue was present, which reduced to 65.3% in one week. Although a reduction in yellow tissue (cleansing effect) was shown in both groups, the reduction was significantly larger in the SG at day 7 (t=0.020) and at day 14, when the amount of yellow tissue was 42.3% (t=0.45). For the SG, this was 32.3% after three weeks and 16.45% after four weeks.



**Notes:**

The % reduction of yellow tissue comparing the SG and the CG was significantly better for the SG at day 7 ( $t=0.020$ )\* and at day 14 ( $t=0.45$ )\*\*.

**Figure 2: Wound bed evolution, reduction of yellow (fluid necrosis and fibrin) tissue comparing SG and CG.**



**Figure 3: Evolution of wound pain (VAS) upon dressing changes during the study period.**

In the CG, less reduction of yellow tissue was observed. At the start there was 80.2% yellow tissue present. This reduced to 75.2% after one week, 56.3% after two weeks, and 45.4% after three weeks. At week four the yellow tissue present in the wound bed had reduced to 34.5%.

The daily reduction of yellow tissue in the SG was 2.098%, compared with 1.63% in the CG (Tables 3, 3a and Figure 2).

In the SG the pain score (VAS, 0–10) during dressing changes at 28 days was 1.30 (SD±0.47) (range 2–1), while in the CG this was 3.20 (SD ± 1.20) (range 5–1). (Table 4 and Figure 3).

**Discussion**

The correct choice of secondary dressing is essential. A film dressing in combination with, for example, the cellulose-based dressing, is a good choice as absorbent dressings may dry out the wound bed. When the wound bed becomes too dry an accumulation of viscous exudate is left underneath the dressing, inhibiting wound healing (Alvarez et al, 2004). This can be controlled with appropriate intervals between dressing changes, or using the Hydrofiber dressing. Additional moistening with saline appears to be essential for dry wounds (Abuzakuk et al, 2006). For moderate exuding wounds, foam dressings may be a better option as they manage

exudate better in moderately exuding wounds (Alvarez et al, 2004).

Contrary to the CG, in the SG less experienced clinicians misinterpreted the white rubbery aspect of the peri-wound skin as maceration. After cleansing the epidermis was intact, however, it was softer and more sensitive than normal skin (so-called 'wipe effect'). This was also observed in a study by Mustafi and Schmitz (2008). For the present study, the authors therefore had one trained clinician to assess and analyse the photographs.

The cooling effect of the biocellulose dressing was reported to be particularly comfortable by patients, this was similar to findings in a previously published study (Alvarez et al, 2004).

Whenever there is evidence of critical colonisation, topical antimicrobial agents should be introduced, e.g. by switching to a biocellulose dressing + polyhexamethylene biguanide (PHMB) or the Hydrofiber dressing + Ag.

With regard to the interpretation of 'wound bed coatings', a clear definition of terms is needed. In German-speaking countries, any type of wound bed coating is commonly, but falsely, referred to as 'fibrin'. Fibrin is defined as a collagenous structure, generally associated with progress in the wound healing processes (Midwood et al, 2004; Nguyen et al, 2009).

In Anglo-American wound healing jargon, however, a clear distinction is made between 'slough' and 'fibrin'. The term 'slough' is used for a conglomeration of coagulated wound exudate, debris and liquid necrosis. However, due to their identical colour spectrum (yellow), accurate assessment is difficult to accomplish with the naked eye, and digital analysis requires validation by an experienced wound treatment specialist, as was performed in this study (Stremitzer et al, 2007; Wild et al, 2008). In this context, the dimensions of the surface area appear to be a useful parameter for assessment. If the surface area becomes smaller, as the yellow coating increases, it is most likely to be fibrin. Morphologically, fibrin can be identified as a thin, delicate film on top of the granulation tissue. In macro-photography,



## Key points

- ▶ Many patients with venous leg ulcers are frail and present with complex issues.
- ▶ Persistent of open wounds result in prolonged treatment for both inpatients and outpatients.
- ▶ This prospective randomised comparative study was designed by the authors to assess the effects of two different cellulose-based dressings and their influence on leg ulcer cleansing and debridement.
- ▶ Both cellulose-based dressings used in this study demonstrated cleansing/debridement properties over the four-week observation period.
- ▶ Accurate assessment of the wound bed is essential to demonstrate such results.
- ▶ A digital measurement and analysis system of wounds based on colour segmentation was found to be useful in this study, with the results being confirmed by an experienced clinician.

these differences at the tissue level are clearly discernible. The accurate differential diagnosis should be included in the interpretation of the data.

Pain reduction is one of the most important outcomes for patients. Reduction of pain medication, a good night's sleep and faster healing times are reasons for changing treatment regimens. Costs should summarise all the factors (time to ulcer closure, aspects of quality of life, clinicians' time, cost of materials, medication, e.g. for pain or antibiotics).

## Limitations

Further studies are required with a larger number of patients (at least 350 patients per group) to demonstrate the differences

in clinical efficacy between the two cellulose-based dressings used in this study. Additionally, patients could be followed up to ulcer healing, or a 24-week study period to assess the effect of ulcer cleansing on healing (Margolis et al, 2000).

## Conclusions

Both cellulose-based dressings used in this study demonstrated cleansing/debridement properties over the four-week observation period. In the SG, a greater and faster reduction of yellow tissue in the wound bed was seen compared to the CG. Accurate assessment of the wound bed is essential to demonstrate such results. A digital measurement and analysis system of wounds based on colour segmentation was found to be useful in this study, with the results being confirmed by an experienced clinician.

Due to the large number of patients with venous leg ulcers, it is important to establish validated treatment regimens based on the results of prospective, randomised trials. However, due to financial and practical restraints, such data is more likely to be found with outcome studies. **WUK**

*Aquacel® and Aquacel® Ag are products of Convatec. Suprasorb® X, Suprasorb® X+PHMB, Suprasorb® P, Suprasorb® F and Rosidal® system are products of Lohmann & Rauscher.*

*The sponsors had no role in the design and conduct of the study, in the collection, analysis, and interpretation of data, or in the preparation of the manuscript, review, or approval of the manuscript.*

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