Superior Healing Outcomes with an Advanced Wound Care Dressing vs. Standard of Care in Hard-to-Heal Venous Leg Ulcers: Results from a Multinational Randomized Controlled Trial

Stefania Beraldo[1], Matthias Schneider[1], Frau Simona Drews[1], **Cristin Taylor**[2], Beate Hanson[2]
[1]DRK-Krankenhaus Mölln-Ratzeburg GmbH, Ratzeburg, Germany; [2]Convatec Ltd, Deeside, UK

Introduction

- Venous leg ulcers (VLUs) represent one of the most prevalent types of hard-to-heal wounds and currently affect a global population of over 143 million patients, posing a significant burden on healthcare systems worldwide[1]
- Despite the plethora of dressings and advanced therapies available for VLUs, treatment decisions remain a significant challenge due to the limited evidence on comparative effectiveness of different dressings
- There is increasing evidence to suggest that biofilm—microorganisms encased in a matrix of extracellular polymeric substances—is implicated in hard-to-heal wounds[2,3]
- A carboxymethylcellulose fiber dressing containing ionic silver and antibiofilm agents, ethylenediaminetetraacetic acid and benzethonium chloride (hereinafter referred to as CISEB*) was developed to address biofilm in hard-to-heal wounds.
- This multicenter randomized controlled trial (RCT) evaluated the performance of CISEB versus a dialkylcarbamoyl chloride-coated dressing (DACC†) in the treatment of VLUs

Objective

To compare the effectiveness and safety of CISEB versus DACC in hard-to-heal VLUs

Methods

- Randomized, controlled trial (ClinicalTrials.gov NCT05892341) conducted across 20 investigational sites in Colombia, Germany, and the United Kingdom
- Eligible patients (**Table 1**) were randomized 1:1 to receive either CISEB or DACC in accordance with their instructions for use
- Patients were treated with therapeutic compression at 30–40 mmHg and the study dressing for a minimum of 2 and up to 4 weeks
  - At week 2, continuation of the study dressing or transition to long-term management with the standard of care was at the discretion of the investigator
  - VLUs that did not heal within 4 weeks were managed with the standard of care for up to 12 weeks, or until the wound had healed or the dressing was no longer clinically indicated
- Study endpoints are shown in **Table 2**
- This study was conducted in compliance with the Declaration of Helsinki and International Conference on Harmonization guidelines for Good Clinical Practice
- All patients provided written informed consent

Table 1. Inclusion and exclusion criteria

Inclusion	Exclusion
• ≥18 years of age • Venous insufficiency per CEAP classification C6 • ≥1 hard-to-heal VLU suitable for treatment with the study dressings • VLU present for ≥2 months and ≤18 months • Able and willing to give informed consent • Tolerance to compression therapy for VLUs (40 mmHg) • Wound size of 1–100 cm^2 • Ankle-brachial pressure index of 0.8–1.3	• Known hypersensitivities or allergies to the dressing materials • Recent or active cancer treatment • Severe malnutrition • Malignant wounds • Systematic infection treated with antibiotics • Uncontrolled diabetes with an HbA1c ≥ 10 • Certain chronic diseases that impair wound healing

Table 2. Study endpoints

Primary	Secondary	
Complete wound closure at week 12 (100% wound surface epithelialization)	Percent change in wound area (week 4 & 12)	Satisfactory clinical progress (40% wound area reduction at week 4)
Exploratory	**Safety**	
Time to complete wound closure	Adverse events	Dressing-related adverse events

Discussion

- Management of VLUs with CISEB was associated with a statistically significant increased rate of complete wound closure at week 12 (primary endpoint; **Figure 1**) compared to DACC, as well as a faster time to complete wound closure (**Figure 4**)
- A significant decrease in mean wound area (**Figure 2**) and a significant increase in percentage of VLUs with satisfactory clinical progress (**Figure 3**) with CISEB were also observed
- CISEB had a favorable safety profile with a lower incidence of adverse events compared to DACC (**Table 5**)
- The data suggests that an active antimicrobial dressing with surfactants is more effective than a bacteriostatic dressing in the treatment of VLUs and that CISEB should be considered as a standard of care for hard-to-heal VLUs
- This is the first published data for CISEB from a RCT setting, significantly adding to evidence base and potentially shifting the standard of care for VLUs

Conclusion

Management of hard-to-heal VLUs with CISEB was associated with superior healing outcomes compared to DAAC, including a 35% increased likelihood of complete wound closure and a faster time to healing, and a favorable safety profile

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2. Metcalf DG & Bowler PG. *Burns Trauma*. 2013;1(1):5-12.
3. Malone M et al. *J Wound Care*. 2017;26(1):20-25.

*Aquacel Ag+ Extra †Cutimed Sorbact

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Results

Table 3. Demographics

	CISEB (*n* = 100)	DACC (*n* = 103)
Country, n (%)		
Colombia	59 (59.0)	59 (57.3)
Germany	21 (21.0)	22 (21.4)
United Kingdom	20 (20.0)	22 (21.4)
Age, years		
Mean (SD)	67.2 (13.3)	66.8 (13.1)
Median	68	66
Q1, Q3	58, 77	59, 75
Min, Max	38, 91	36, 95
Female, n (%)	71 (71.0)	56 (54.4)
BMI, kg/m^2	n = 99	n = 99
Mean (SD)	31.8 (8.3)	30.1 (6.1)
Median	30.1	28.7
Min, max	16.4, 65.6	15.0, 48.4

Table 4. Baseline wound characteristics

	CISEB (*n* = 100)	DACC (n = 103)
Baseline wound area (cm^2)	n = 107	n = 110
Mean (SD)	10.2 (12.6)	17.3 (22.3)
Median	5.8	8.1
Range (min, max)	0.2, 80.0	0.3, 100.0
Tissue type evaluation, n (%)	n = 92	n = 94
Eschar	6 (6.5)	9 (9.6)
Slough/fibrin	68 (73.9)	75 (79.8)
Healthy granulation	77 (83.7)	83 (88.3)
Unhealthy granulation	5 (5.4)	4 (4.3)
Epithelial	14 (15.2)	11 (11.7)
Other tissue	0	4 (4.3)
Exudate volume, n (%)	n = 92	n = 94
High	3 (3.3)	7 (7.5)
Medium	31 (33.7)	27 (28.7)
Low	56 (60.9)	56 (59.6)
None	2 (2.2)	4 (4.3)
Wound infection, n (%)	n = 92	n = 94
No	86 (93.5)	94 (100.0)
Yes	6 (6.5)	0

Figure 1. Complete wound closure

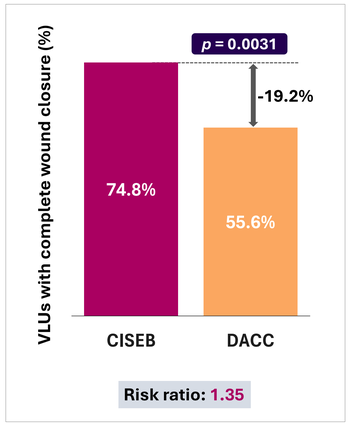

Figure 2. Wound area reduction

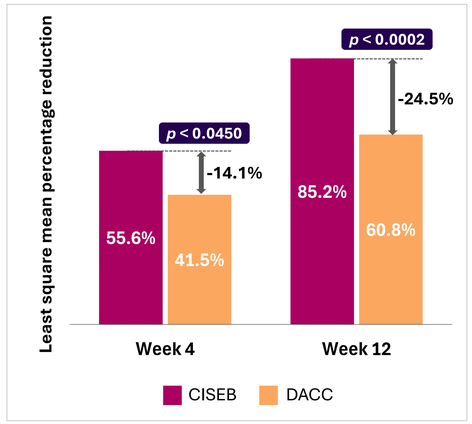

Figure 3. Satisfactory clinical progress

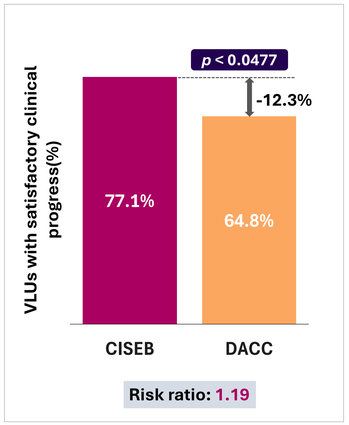

Figure 4. Median time to complete wound closure

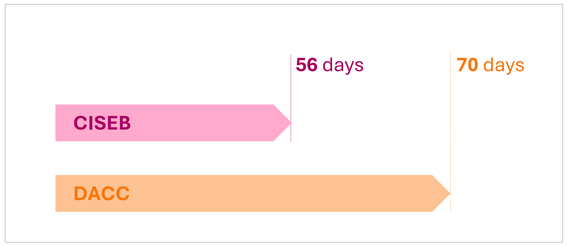

Table 5. Adverse events

	CISEB	DACC
Patients with AEs	5%	18%
Total AEs	11	27
Dressing-related AEs	1 (ulcer bleeding)	4 (all infection)

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