

LEG ULCERS TREATED WITH COLLAGEN ALGINATE DRESSING LED TO WOUND SIZE REDUCTION & IMPROVEMENT IN QUALITY OF LIFE OF PATIENTS

Alisha Oropallo, MD^{1,2,3}, Amit Rao, MD¹, Sally Kaplan, RN¹, Farisha Baksh, BS¹, and Christina Del Pin, MD^{1,2}

¹Northwell Health System, Department of Surgery, Comprehensive Wound Care Healing and Hyperbarics, Lake Success, NY 11042; ²Donald & Barbara Zucker School of Medicine at Hofstra/Northwell, Hempstead, NY 11550;

³Northwell Health System, Department of Surgery, North Shore University Hospital, Manhasset, NY 11030

Aim

Chronic venous ulcers (VLU) are a major problem affecting the quality of life (QoL) of patients. This prospective observational study is evaluating the role of the native collagen alginate dressing* in the wound healing of VLU under compression under daily clinical practice. The impact on wound pain influencing the patients' QoL was evaluated, too.

Method

Between 06/2021 and 06/2022 299 patients were studied, of whom 60 were enrolled and 50 participated the study. Patients with VLU more than 6 weeks old were followed for 28 days (initial visit and final visit, 3 follow-up visits). Wound size was measured using wound assessment software. Wound pain was assessed using a 11-visual analog scale (VAS 0 to 10) before dressing change. Wound-QoL questionnaire¹ is completed at the first and last study visit.

Results

Variable	Treatment group
Number of participants	50
Age, years	
Mean ± SD	68.7 ± 14.6
Sex, n (%)	
Male	29 (58.0%)
Female	21 (42.0%)
ABPI (mean ± SD)	1.11 ± 0.11
Median (range)	1.1 (0.8-1.3)
Wound type (n)	
Ulcus cruris venosum	50 (100%)
Wound age	
6 w. ≤ wound age ≤ 12 w.	14 (28%)
12 w. ≤ wound age ≤ 6 m	17 (34%)
6 m ≤ wound age ≤ 12 m	19 (38%)

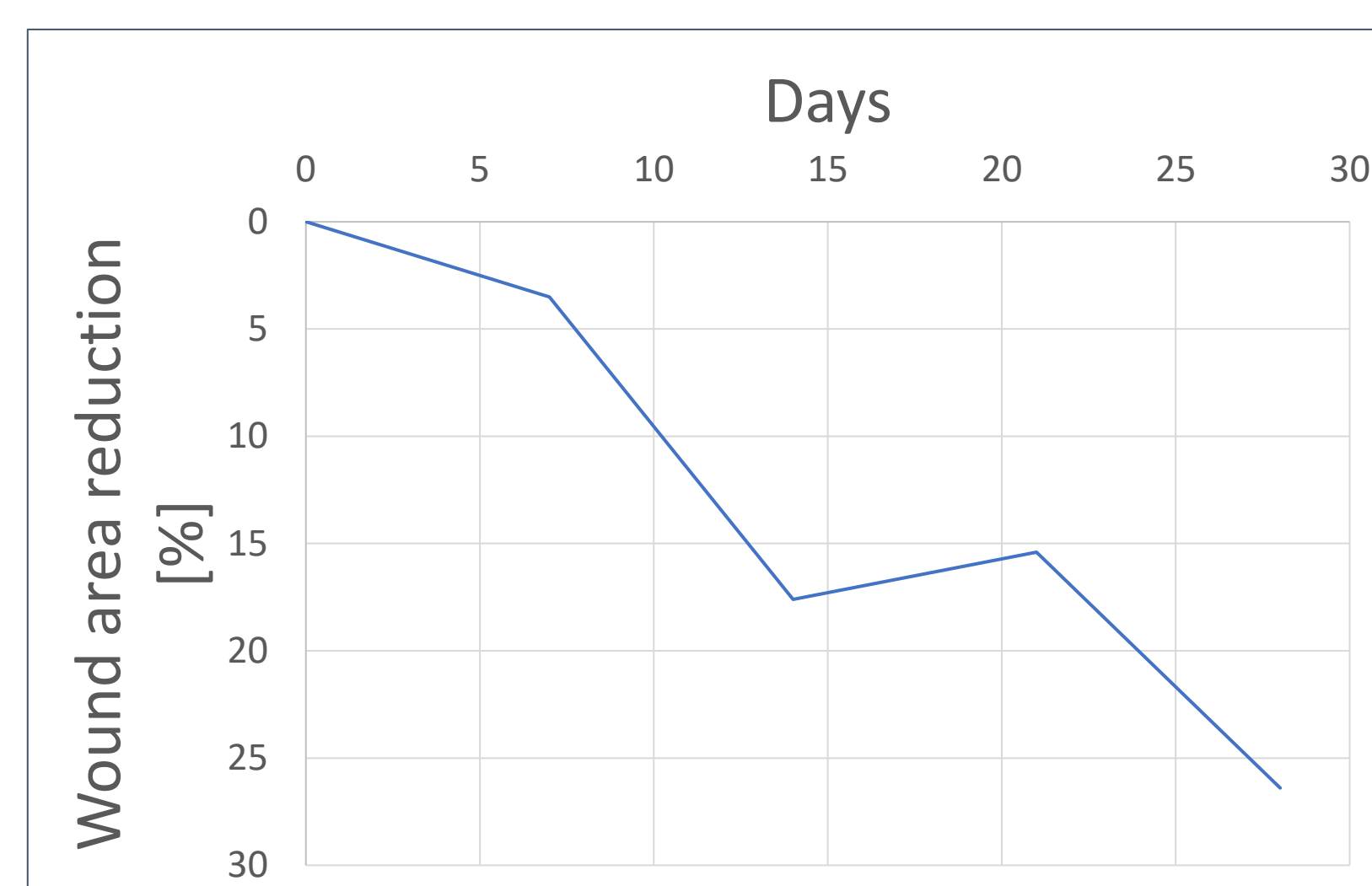


Fig. 1 shows the time course of the the mean wound size reduction(%). A significant reduction of the wound size at visit 5 compared to baseline.

	N	Me an	SD	Min	Max	Lower 95 % CL	Upper 95 % CL	t-test p-value
Reduction V1-V5	46	5.1	7.8	-15.5	23.0	2.8	7.4	<.0001
Reduction V1-V4	46	3.2	10.3	-46.1	21.6	0.2	6.3	0.0393
Reduction V1-V3	49	3.9	8.6	-23.6	32.1	1.5	6.4	0.0025
Reduction V1-V2	50	1.0	9.2	-30.0	36.9	-1.6	3.6	0.4601

Tab. 2 shows the time course of the mean wound size (%). A significant reduction of the wound area at visit 5 compared to baseline (N=46, mean ±SD 5.1±7.8cm², *p*<0.001) was documented.

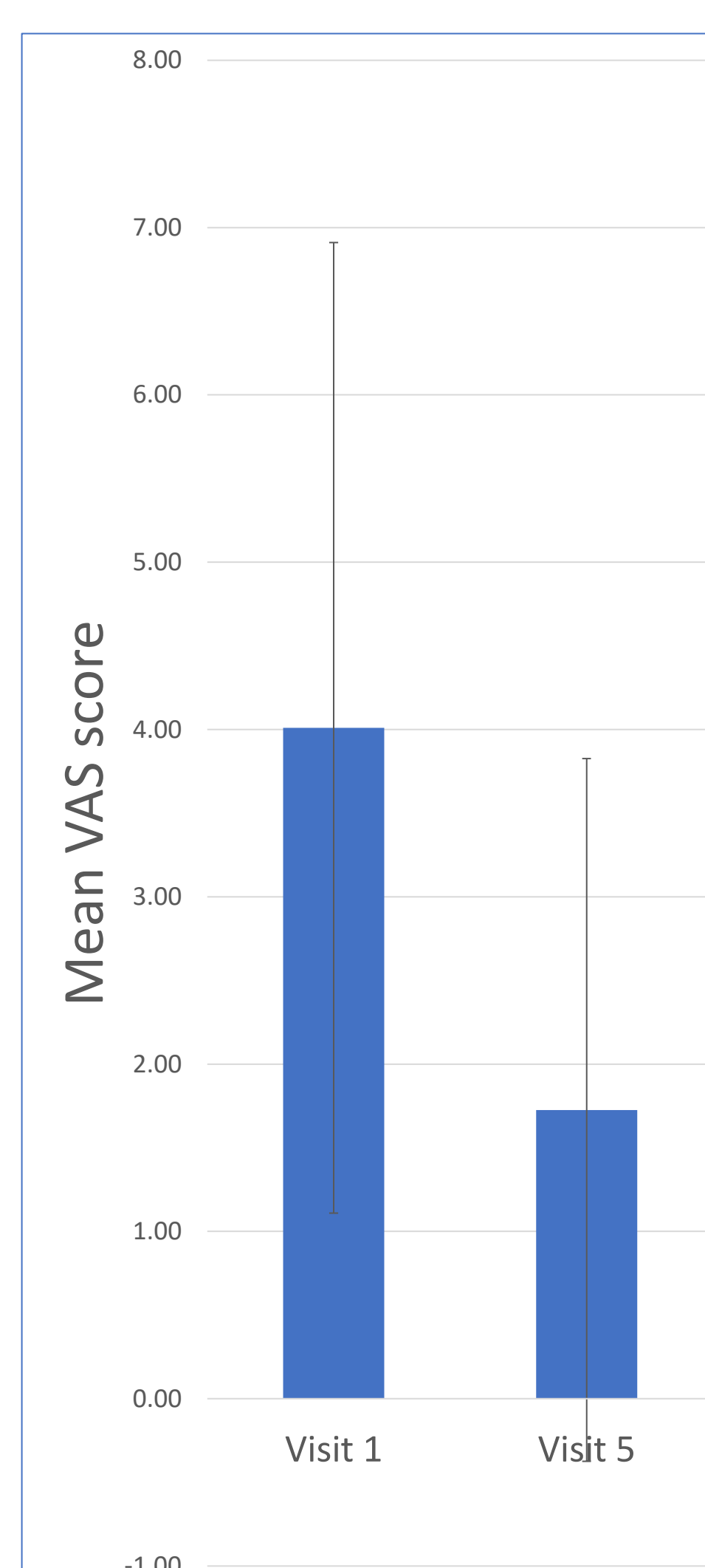


Fig. 2: Pain score was significantly reduced at visit 5 compared to baseline (N=47, mean ±SD 2.3±2.4, *p*<0.001).

One exemplary cases show transition of the stagnating VLUs to healing wounds, as well as a reduction of pain symptoms and an improvement of total QoL. An 84-year-old female with history of chronic venous insufficiency presented with VLU for 1 month duration. **No adverse events occurred.**

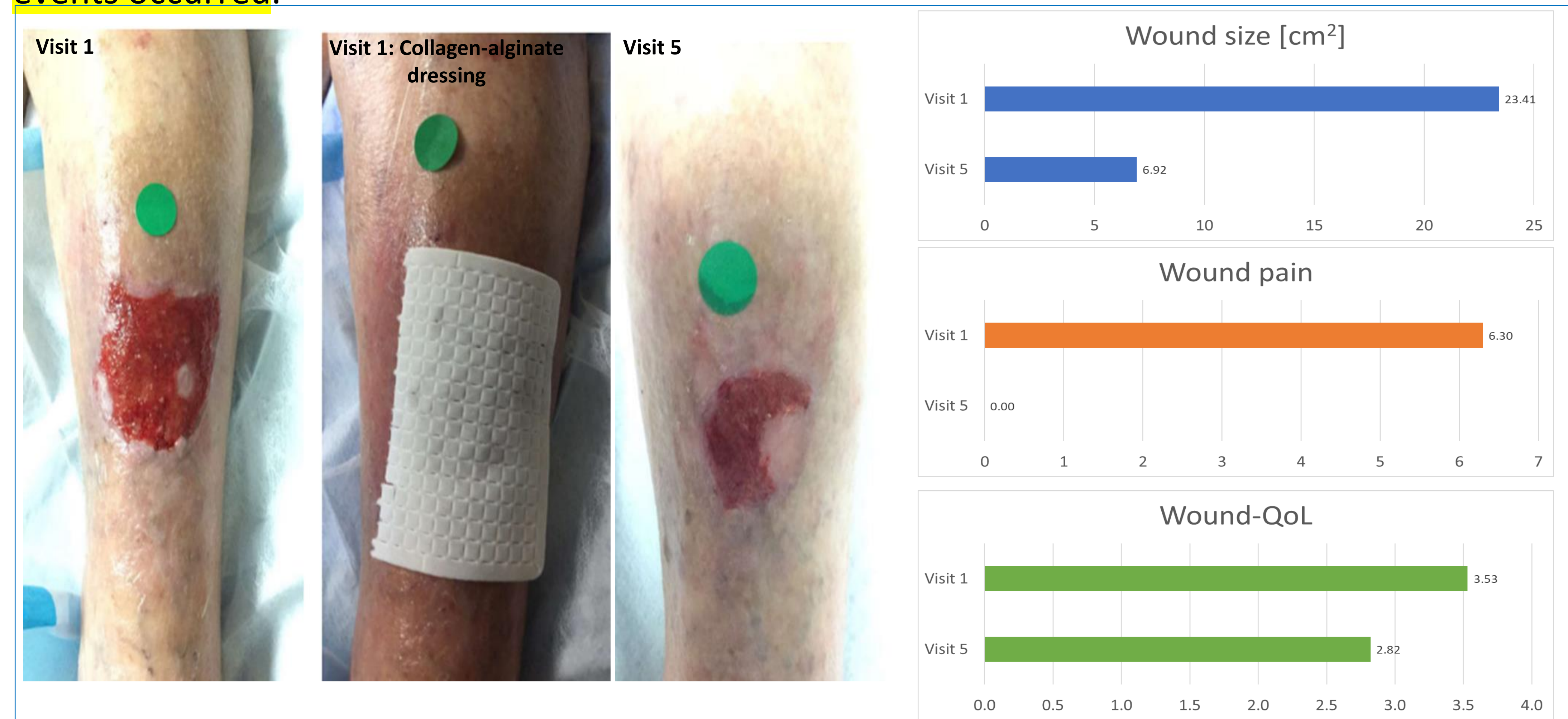


Fig. 3: One case of a 39% reduction in wound size after the 4-week collagen-alginate dressing treatment. The patient reported a 100% reduction in pain symptoms and 51% improvement in wound-QoL global score.

Tab. 1: Demographics of the patients

Conclusion

The study demonstrates the effectiveness of the collagen-alginate dressing to significantly decrease the wound area, reduce pain and improve total QoL in VLU patients. Further studies involving RCT or multi-institutional trials may demonstrate further efficacy of the product.

*Cutimed® Epiona®, BSN medical GmbH

Study funded by BSN medical GmbH.

¹ Augustin M, Conde Montero E, Zander N, Baade K, Herberger K, Debus ES, Diener H, Neubert T, Blome C. Validity and feasibility of the wound-QoL questionnaire on health-related quality of life in chronic wounds. Wound Repair Regen. 2017 Sep;25(5):852-857. Epub 2017 Nov 2.