Management of venous or mixed leg ulcers at sloughy stage with a new highly negatively charged fiber dressing* that supports the debridement of slough: results of a comparative multicenter randomized controlled trial.

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INTRODUCTION

This study In this study, the negatively charged fiber technology engineered fiber dressing was tested on sloughy venous/mixed etiology leg ulcers at their sloughy stage, in comparison to the traditional Hydrofiber ®** technology based on carboxymethyl cellulose.

METHODS

- RCT (37 centers), on patients presenting with venous or predominantly venous, mixed etiology leg ulcers at their sloughy stage (with more than 70% of the wound bed covered with sloughy tissue at baseline).
- Study over a 6-week period and assessed weekly.
- The primary metric was the relative reduction of the wound surface area after the 6-week treatment period.
- Other important, secondary endpoints were
  - relative reduction of sloughy tissue
  - percentage of patients presenting with a debrided wound
  - debridement status at the end of study

RESULTS

- Altogether, 159 patients (Table 1) were randomized to either the negatively charged dressing (n=83) or Hydrofiber (n=76) dressings. The patient groups were well balanced.
- Compression therapy was administered to both groups and after a median 42-day treatment period.

Primary metric:
The percentage of relative reduction of the wound surface area was very similar (-36.9% vs -35.4% for the negatively charged dressing and Hydrofiber respectively).

Important Secondary Metrics:
- When considering the secondary criteria at week 6, the relative reduction of sloughy/ necrotic tissue was significantly higher for the negatively charged dressing than the Hydrofiber group (-65.3% vs -42,6%; p=0.013).
- The percentage of debrided wounds at the end of the study was also significantly higher in the negatively charged dressing group (52.5% vs 35.1%; p=0.033). A wound is considered debrided, for this study, when its surface area is covered by less than 30% of sloughy tissue at any given clinical evaluation.

Other important findings:
- Dressings used per week 4.0±1.77 and 4.4±1.84 for the negatively charged dressing and Hydrofiber: Similar
- Ease of application and conformability of negative charged dressing and Hydrofiber were very similar Table 2.
- They were predominantly covered with gauze or a pad in more than 66% of the dressing treatments.
- Negative charged dressing was very easy to remove (63.9% vs. 47.2%), doubtless due to its non-adher¬ence to the wound bed (63.6% vs. 36.2%). There was also less bleeding and less dressing fragmenta¬tion with the new charged dressing.
- The Global Performance Scores (Fig 1) showed that the acceptability parameters evaluated by the physicians (patient comfort, tolerance of peri-wound skin, pain on removal, etc.) were significantly in favor of the negative charged dressing group (p<0.05) in six of the nine parameters tested.
- Peri-wound skin had substantially improved with the negative charged dressing, but not with Hydrofiber.
- Removal characteristics of the two dressings (Table 3): trend in favor of the negative charged group seen, noted 'very easy' in about 64% of patients, compared to 47% with Hydrofiber.
- No bleeding in 88% and 71% of treatments for the negative charged dressing and Hydrofiber, respectively.
- Non-adherence to the wound bed noted for > 63% of the negative charged dressing changes, for Hydrofiber non adherence only at 36%.

CONCLUSION

This RCT confirmed that the new negatively charged dressing has similar wound healing efficacy and safety compared to the Hydrofiber. However, the new dressing also showed better support of debridement of slough properties than Hydrofiber in the management of venous leg ulcers at the sloughy stage. There are other important patient centric benefits that were noted and some of these differences were statistically significant. The new negatively charged dressing therefore represents a promising therapeutic option for the painless management of sloughy wounds.

Table 1. Baseline VLU characteristics

	Treatment group		
	Negative Dressing n=83	Hydrofiber n=76	p
Ulcer surface area (cm²)			
mean ± SD	10.77 ± 11.13	12.66 ± 15.18	0.37
[min; max]	[2.17; 73.41]	[0.89; 86.36]	
median	7.56	6.61	
Ulcer duration (months)			
mean ±(SD	12.74 ± 9.67	15.57 ± 11.43	0.24
[min; max]	[3; 36]	[3; 36]	
median	10	12	
Recurrency n(%)	45 (54.2%)	32 (42.1%)	0.09
Wound Bed aspect (%)			
- Sloughy tissue			
mean ± SD	82.75 ± 10.84	80.65 ± 10.11	0.21
[min; max]	[70; 100]	[70; 100]	
median	80.0	80.0	
- Granulation tissue			
mean ± SD	17.25 ± 10.84	19.34 ± 10.11	0.21
[min; max]	[0; 30]	[0; 30]	
median	20.0	20.0	
Peri-lesional skin condition n (%)			
- Healthy	16 (19.3%)	26 (34.2%)	0.033

Fig 1. Each parameter value (score from 0 (very poor) to 4 (very good)) of the Global Performance Score

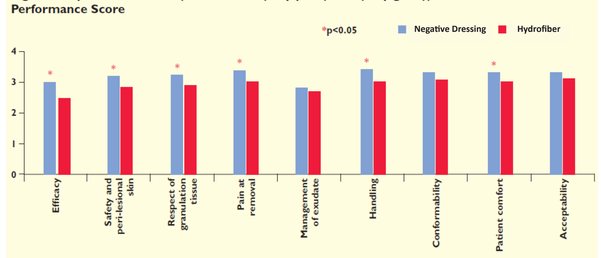

Table 2. Characteristics of study dressings application

Application parameters for the study dressings		Treatment group: Negative Dressing n	Negative Dressing %	Hydrofiber n	Hydrofiber %
Ease of dressing application	Very easy	669	70.0%	592	66.0%
	Easy	285	29.8%	300	33.4%
	Difficult	2	0.2%	4	0.4%
	Very difficult	-	-	1	0.1%
	Total	956	100%	897	100%
Conformability during dressing application	Very good	623	65.6%	501	56.5%
	Good	295	31.1%	366	41.3%
	Poor	9	0.9%	15	1.7%
	Very poor	22	2.3%	5	0.6%
	Total	949	100%	887	100%
Type of secondary dressing	None	59	6.3%	6	0.7%
	Gauze/pad	623	66.7%	655	71.6%
	Hydrocellular	63	6.7%	115	12.6%
	Other	190	20.3%	139	15.2%
	Total	935	100%	915	100%

Table 3. Characteristics of study dressings removal

Removal parameters for the study dressings		Treatment group: Negative Dressing n	Negative Dressing %	Hydrofiber n	Hydrofiber %
Ease of removal	Very easy	624	63.9%	439	47.2%
	Easy	337	34.5%	429	46.1%
	Difficult	14	1.4%	56	6.0%
	Very difficult	1	0.1%	6	0.6%
	Total	976	100.0%	930	100.0%
Pain on removal	None	638	66.0%	576	62.0%
	Minor	150	15.5%	208	22.4%
	Moderate	111	11.5%	108	11.6%
	Marked	68	7.0%	37	4.0%
	Total	967	100.0%	929	100.0%
Bleeding on removal	None	850	88.0%	655	71.1%
	Minor	90	9.3%	183	19.9%
	Moderate	25	2.6%	70	7.6%
	Marked	1	0.1%	13	1.4%
	Total	966	100.0%	921	100.0%
Dressing adherence on removal	None	617	63.3%	336	36.2%
	Minor	266	27.3%	316	34.0%
	Moderate	85	8.7%	222	23.9%
	Marked	6	0.6%	55	5.9%
	Total	974	100.0%	929	100.0%
Dressing fragmentation on removal	None	832	86.0%	696	77.1%
	Minor	102	10.5%	134	14.8%
	Moderate	33	3.4%	68	7.5%
	Marked	-	-	5	0.6%
	Total	967	100.0%	903	100.0%

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