

The use of a novel dual compression system (DCS) in lower limb skin improvement while also managing edema and venous leg ulcer : analysis of results from a large observational study

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INTRODUCTION

- The use of compression in the management of the venous reflux condition is highly recommended.
- The Dual Compression System (DCS) that combines long and short stretch bandages that provide compression.
- DCS is designed to confidently apply consistent therapeutic pressure (30-50 mm Hg) via visual indicators.
- It is also known that patients with venous reflux conditions frequently suffer from skin problems in the lower limb.
- An analysis of skin improvement from this real-life study is presented.

METHODS

- The clinical data from a large prospective, multicentre, observational study treated with the DCS in outpatient settings or during home visits for a maximum duration of six weeks (4 clinician visits maximum) was obtained for this study.
- For this work, all clinical data related to skin condition were extracted and analysed from the original study.
- The primary outcome was the improvement of the skin by the final visit.
- The condition of the skin was assessed on a five-point scale where one was ('healthy') to five ('severely damaged').
- Additional outcome measures included other standard measures such as wound healing rate, wound healing progression, local tolerability and acceptance of the compression therapy.
- The McNemar test was used to determine if patients changed from an Altered state (Skin condition score of 2 to 5) to Healthy state, or vice versa, randomly or not.
- A p value <0.05 was considered statistically significant.

RESULTS

- A total of 702 patients were followed for an average of 27 (SD 17) days and two follow-up visits were performed at day 7 (+/-5) and 15 (+/- 10).
- At baseline, the condition of the skin was rated as healthy (score: 1) in 9.5%, damaged (score 2, 3 or 4) in 60.3%, severely damaged (score 5) in 5.6% patients. (Table 1)
- The physician's final assessment found the skin condition compared with the initial visit was 'improved' in 73.9% patients, 'unchanged' in 20.2% patients and 'deteriorated' in 0.4% patients. (Table 1)
- At the 1st follow-up visit, 195 (36.9%) with a baseline score of 2 to 5 already showed an improvement of their skin condition. (Table 2)
- In particular, 19 patients (3.2%) moved from Altered to Healthy skin condition. (Table 3)
- At the 2nd follow-up visit, 339 (72.2%) with a baseline score of 2 to 5 showed an improvement of their skin condition. (Table 2)
- In particular, 106 patients (20.3%) moved from Altered to Healthy skin condition. (Table 5)
- Patient acceptance rates were high with "very well" or "well" tolerated and "very well" or "well" accepted by >95% of patients.
- At the final visit, 30.9% of wounds had healed, 61.8% had improved, 66.7% limb oedema resolved, and 44.2% reported improvement in ankle mobility.

Table 1. Change in Skin Condition from Baseline Visit to Final Visit

Parameter	Total (n = 702)
Skin condition at baseline (N, %)	
1 - Healthy	67 (9.5)
2	217 (30.9)
3	206 (29.3)
4	88 (12.5)
5 – Severely Damage	39 (5.6)
Missing	85 (12.1)
Skin evolution at final visit	
Improved	519 (73.9)
Unchanged	142 (20.2)
Worsened	3 (0.4)
Missing	38 (5.4)

Table 2. Skin Condition at 1st Follow-up Visit According to Condition at Baseline

Parameter	Skin Condition at Baseline					
	1 (n = 67)	2 (n = 217)	3 (n = 206)	4 (n = 88)	5 (n = 39)	Total (n = 617)
Skin condition 1st visit	61	202	200	88	38	589
1 - Healthy	56 (91.8)	17 (8.4)	2 (1.0)	0	0	75 (12.7)
2	5 (8.2)	176 (87.1)	95 (47.5)	6 (6.8)	0	282 (47.9)
3	0	8 (4.0)	100 (50.0)	55 (62.5)	3 (7.9)	166 (28.2)
4	0	1 (0.5)	3 (1.5)	27 (30.7)	17 (43.6)	28 (5.4)
5 – Severely Damage	0	0	1 (0.6)	1 (1.2)	1 (2.6)	3 (0.6)
Missing	6	15	6	0	1	28

Column percentages are presented in parentheses.

Table 3. Skin Condition at 1st Follow-up Visit According to Skin Condition at Baseline (N = 702)

Parameter	Skin Condition at Baseline		p-value
	Healthy (n = 67)	Altered (n = 550)	
Skin condition 1st visit, N	61	528	0.0066
Healthy	56 (9.5)	19 (3.2)	
Altered	5 (0.9)	509 (86.4)	
Missing	6	22	

McNemar test compared patients who changed health states. Patients who remain in the same health state at both visits are not considered.

Table 4. Skin Condition at 2nd Follow-up Visit According to Condition at Baseline

Parameter	Skin Condition at Baseline					
	1 (n = 67)	2 (n = 217)	3 (n = 206)	4 (n = 88)	5 (n = 39)	Total (n = 617)
Skin condition 2nd visit	54	168	178	84	39	523
1 - Healthy	50 (92.6)	82 (48.8)	22 (12.4)	2 (2.4)	0	156 (29.8)
2	4 (7.4)	80 (47.6)	123 (69.1)	38 (45.2)	4 (10.3)	249 (47.6)
3	0	6 (3.6)	30 (16.9)	34 (40.5)	17 (43.6)	87 (16.6)
4	0	0	2 (1.1)	9 (10.7)	17 (43.6)	28 (5.4)
5 – Severely Damaged	0	0	1 (0.6)	1 (1.2)	1 (2.6)	3 (0.6)
Missing	13	49	28	4	0	94

Column percentages are presented in parentheses.

Table 5. Skin Condition at 2nd Follow-up Visit According to Skin Condition at Baseline (N = 702)

Parameter	Skin Condition at Baseline		p-value
	Healthy (n = 67)	Altered (n = 550)	
Skin condition 2nd visit, N	54	469	<0.0001
Healthy	50 (9.6)	106 (20.3)	
Altered	4 (0.8)	363 (69.4)	
Missing	13	81	

McNemar test compared patients who changed health states. Patients who remain in the same health state at both visits are not considered.

LIMITATIONS

- The primary study did not include a comparator of other multi-layer bandage systems. However, the efficacy of DCS has been established in several studies.

CONCLUSION

- Concurrent with improvement in the venous reflux condition and wound healing/edema reduction, skin quality improvement was observed in a large and rigorous study on patients with venous ulcers and or edema.
- Comparative studies in this regard are suggested.

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