MANAGEMENT OF CHRONIC VENOUS INSUFFICIENCY WITH A NEW DUAL COMPRESSION SYSTEM; RESULTS OF A REAL LIFE STUDY IN 702 PATIENTS

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BACKGROUND

Definitive and therapeutic management of patients with chronic venous insufficiency (CVI) or venous disease is best achieved via the application of compression therapy. A study was conducted to evaluate the safety and efficacy of an engineered multicomponent (2 layer) compression system also called the Dual Compression System (DCS) in an unselected population of patients with chronic venous insufficiency conditions in a real life scenario in over a hundred wound centers.

METHODS

A prospective, multicenter, observational study with a two layer bandage compression system (UrgoK2, Laboratoires Urgo, France) was conducted in 103 wound centers in Germany. Main outcomes included wound healing rate, wound healing progression, assessment of oedema and ankle mobility, local tolerability and acceptance of the compression therapy by the patients.

RESULTS

A total of 702 outpatients with venous leg ulcers (VLU) and/or with lower limb edema due to CVI were treated with the DCS two layer UrgoK2 system for a mean duration of 27±17 days with up to four home/clinic visits (including one baseline and one final visit) with assessment by clinician assessment at each visit.

30.9% of wounds had healed by the final visit, and 61.8% had improved in wound size. 66.7% of patients has resolution of edema, and 44.2% patients reported improvement in ankle mobility. Skin condition improvement was seen in 73.9% of patients and pain level analysis showed that substantial reduction of pain was achieved, both in number of patients reporting pain and in pain

intensity. In line with previous research, the DCS Compression therapy was 'very well' or 'well' tolerated and 'very well' or 'well' accepted by >95% of patients. These positive outcomes were in line with the general opinion of physicians on the evaluated compression bandages, which were judged 'very useful' or 'useful' for >96.6% of patients. The pattern of results was similar whether the patients had VLU, or just limb edema without ulceration. Figures 1-8 describe the information that illustrate the results from the study as described here.

FIGURE 1

Performance of the multicomponent compression system, compared with previous experience with other compression systems, according to the physicians' point of view, stratified by ankle-brachial pressure index level (n=702)

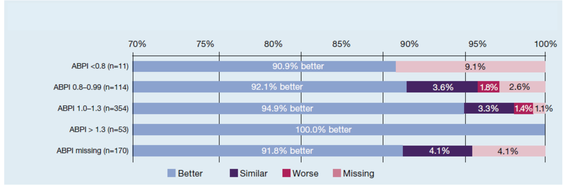


FIGURE 2

Patient discomfort parameters reported at each visit (patients completing all four visits, n=622)

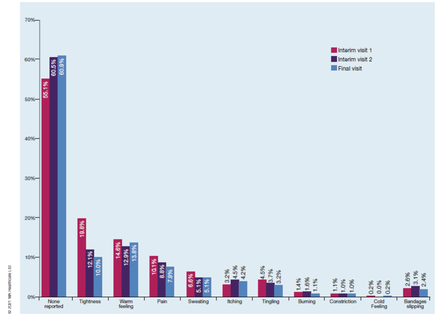


FIGURE 3

Wound healing rate and wound healing progression with the evaluated compression system (n=622)

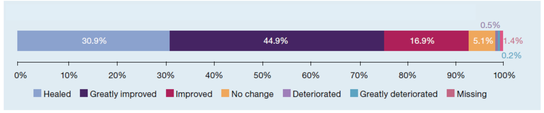


FIGURE 4

Proportion of patients with oedema throughout the study period (patients completing all four visits n=622)

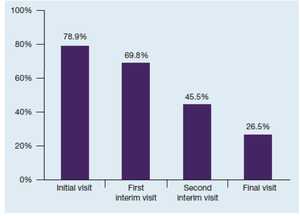
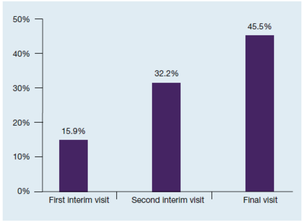


FIGURE 5

Proportion of patients with improved ankle mobility under the multicomponent compression therapy (patients with a 'moderate' or 'poor' ankle mobility at the baseline visit and who had both interim visits completed, n=264)



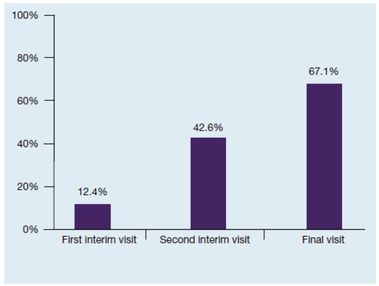
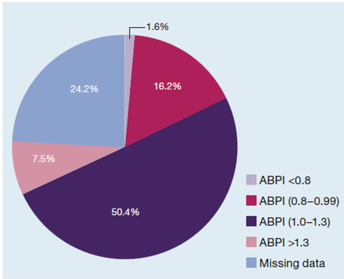


FIGURE 6

Proportion of patients with resolved oedema under the multicomponent compression therapy (patients with oedema at baseline visit and with all four visits completed, n=491)

FIGURE 7

Patient distribution according to their ankle-brachial pressure (ABPI) value (n=702)



Systems	n	%
Medical compression stockings	303	(43.2)
Class 3 (34–46mmHg)	5/303	(1.7)
Class 2 (23–32mmHg)	278/303	(91.7)
Class 1 (18–21mmHg)	18/303	(5.9)
Missing data	2/303	(0.7)
Two-short-stretch bandage system	161	(22.9)
One-short-stretch bandage	130	(18.5)
Two-long-stretch bandage system	4	(0.6)
One-long-stretch bandage	32	(4.6)
Zinc paste bandages	61	(8.7)
Multicomponent bandage system	29	(4.1)

FIGURE 8

Previous compression systems used by the patients (multiple answers possible) (n=702)

CONCLUSION

Previous clinical studies, including randomized clinical trials, under very controlled conditions and the use of defined selection criteria have shown that the UrgoK2 system provides the critical 3C's of compression: Continuity, Consistency, and Comfort, and also that the product is efficacious and effective. This study shows that under real life situations outside a formal clinical study environment, product benefits and safety profiles are high. Analysis of non selected patient data documented in this large observational study of non-selected patients receiving compression therapy over a six week period on average proves that the product efficacy proved in previous RCTs, is accompanied by high product effectiveness is real life.

Also confirmed is the performance and patient/clinician acceptability of the system, regardless of the wound/non wound status of the patients at study initiation. For patients with ulcers or without ulcers, the condition of CVI is well managed, by this first line intervention using compression bandages that are engineered with advanced material and fabric technologies.

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