Efficacy of two compression systems in the management of VLUs: results of a European RCT

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Message:

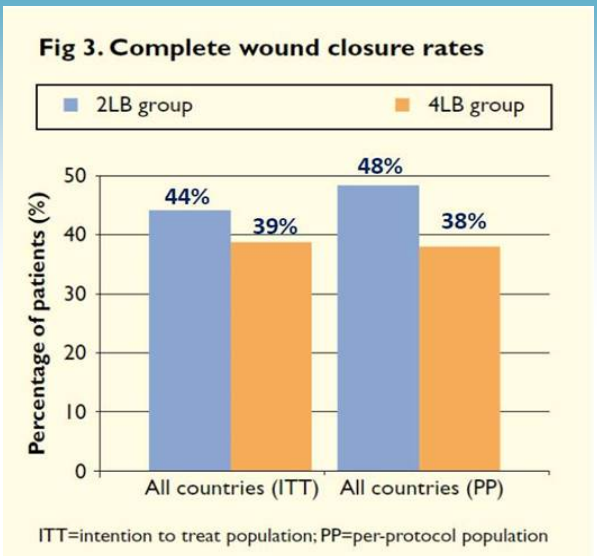
A well designed multilayered compression system must provide **Consistent** levels of therapeutic compression, **Continuously** (day and night), with a high degree of **Comfort**. When these three elements (the three C' principle) converge in one well designed, easy to apply and wear 2 layered bandage product, the clinical results may well be equivalent to results from more inconvenient, bulky, and uncomfortable standard of care 4 layer bandages. This was proven in a large randomized controlled study. The study additionally proves that nurses prefer to apply the 2 layer bandage. The 2 layer bandage features printed stretch indicators that allow consistent application of therapeutic pressure which impacts clinical results.

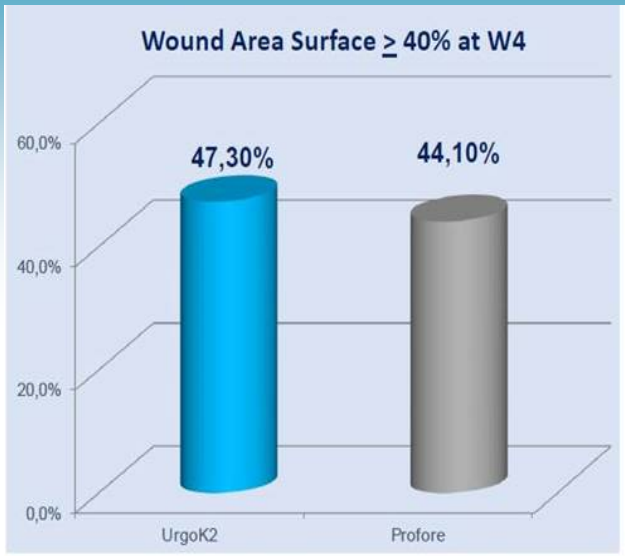
Methods:

This was a European multicentred open label randomized controlled trial (trial named ODYSSEY) conducted in 2 parallel groups which consisted of the two layer Dual Compression System* (Urgo K2) and a Four Layer Compression System** (Profore). The wound closure rates of venous leg ulcers at 12 weeks was the primary outcome objective. Secondary objectives included measurement of clinician preference in terms of ease of application. A total of 186 patients were included spread between 37 active sites, 3 countries, with 93 patients in each study arm, over a total period of 18 months.

Results:

Despite having only two layers, the UrgoK2 delivered non inferior clinical results compared to the more complicated 4 layered Profore. Percent wound closure was higher in the mean in the UrgoK2 group in all three countries, showing a consistency in results. There was no difference in wound surface reduction in the two groups over time. Pain severity scores tended to be higher with the 4 layer bandage with no statistical difference noted. Importantly, a statistically significant difference was found ($p = 0.035$) in clinician acceptability, with 62.0% of the UrgoK2 applications scoring "very easy" versus 46.7% of the Profore group.





ITT (Intent to Treat analysis) is a preferred method for clinical study arms comparison. It includes all patients in the study, even those who dropped off and is therefore more "real life". PP stands for "per protocol" and includes only those patients who completed the study in totality. In this case, both types of analysis show the 2LB is as good as the 4 LB in clinical efficacy.

Conclusion:

In keeping with the principles of 3 C's (Consistency, Continuity, and Comfort) and keeping in mind the fact that "a wound never sleeps", the two layer engineered bandage with one layer providing compression during ambulation, and the other providing compression at night or non ambulation, produces equivalent clinical results compared to a far more bulky, less easy and time consuming to apply 4 layer commonly used bandage system. No compromise in clinical efficacy is required in moving to a more convenient and clinician/patient acceptable 2 layer bandaging system because such a multilayer bandaging system is just as efficacious as a 4 layer complex bandaging system.

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