

A comparison of interface pressures of three compression bandaging systems used on healthy volunteers

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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's principle) converge in one well designed, easy to apply and wear product, the compression bandage can demonstrate high degree of patient compliance/concordance and thus desired clinical results. The Dual Compression System (DCS) UrgoK2 two layer bandage, which contains two proprietary layers (K Tech and K Press), with printed indicators (PresSure) for application of the correct stretch for each layer, is designed with the 3 C's requirement in mind. This design can lead to continuous levels of consistent pressure on the compressed limb, with obvious potential clinical benefits associated with continuity of the correct therapeutic pressure over weeks. The study described herein focuses on proving that indeed, continuous therapeutic pressure is achievable with UrgoK2 when applied by clinicians used to applying compression wraps. This Continuity factor is very important for clinical success.

Methods:

The study compared interface pressures and human acceptability of three compression systems in a single center over a period of 7 days in a randomized, open, controlled model of testing. Healthy volunteers with intact lower leg skin, 24 in number, were treated by the application of the 2 Layer Bandage UrgoK2, the 4 layer Profore®, or a pure Short Stretch Bandage (SSB), in a single center. Interface pressures were measured at D1, D3 and D7, in supine, sitting and active standing position. The primary objective was a study of loss of pressure over time of the three bandage systems. Secondary objectives included measurement of bandage wearing comfort factors.

Results:

UrgoK2 maintains up to 7 days an effective therapeutic pressure (40 mmHg), regardless the position of the subject, while the short stretch bandage show over 7 days a significant loss of pressure (30% at D3). Regarding safety and comfort, all the evaluated criteria show a greater acceptability of the Dual Compression System in UrgoK2, resulting in better day and night compliance. In contrast, up to 25% of volunteers wearing the 4 layer Profore bandage stopped the test on the third day, which could be explained by a higher than therapeutically recommended, uncomfortable pressure in all positions (see tables). Two-layer bandaging had significantly lower scores than four-layer bandage for the following important patient centric parameters: tightness ($p=0.0003$), pain ($p<0.0001$), sweating ($p=0.0005$), itching ($p=0.01$), and sensation of heat ($p<0.0001$).

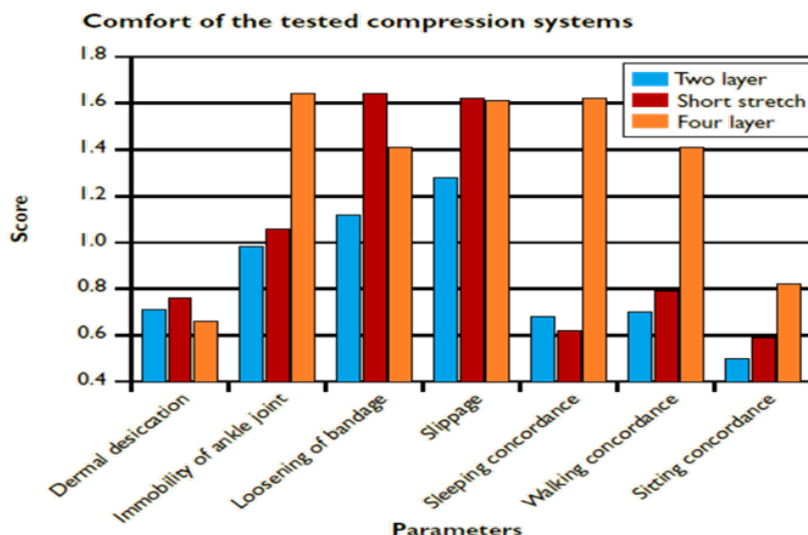
Two-layer bandaging also had significantly better scores than four-layer bandaging for the following additional patient centric parameters: immobility of ankle joint ($p<0.0001$), slippage ($p=0.003$), loosening of bandage ($p=0.0003$), concordance when sleeping ($p<0.0001$), sitting ($p=0.0001$) and walking ($p<0.0001$), again all positive factors in favor of UrgoK2.

Table 1

Maximal working pressure (mmHg)	After application	D3	D7
UrgoK2	61.62	53.6	46.8
Profore	78.97	75.0	69.5
Short Stretch Bandage	71.46	54.35	50.0

Table 2

Position	UrgoK2	Short stretch Bandage	Profore
Supine	47.81	48.47	51.54
Sitting	49.44	47.97	54.02
Active standing	55.81	64.72	62.08
Maximal working pressure	61.62	71.46	78.97

Figure 1

Conclusions:

The continuity of a consistent, comfortable therapeutic pressure level is very important if a multilayer bandaging system is to achieve its clinical goals. This study shows that without sacrificing comfort, or consistency, one can achieve continuous therapeutic pressure over a long period of 7 days. In addition to the the continuity of the therapeutic pressure over time in all positions, it is notable that many comfort factors with the 2 layer bandage are significantly better compared to the 4 layer bandage. The 4 layer bandaging system lacks a stretching guide system similar to the PresSure system in UrgoK2. It is possible that this may lead to application of higher than desired pressure, resulting in an increase in discomfort related factors, which further results in discontinuation and the consequent failure in meeting clinical goals.



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