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Fanette Chassagne[a,b,c*], Clothilde Helouin-Desenne[c], Jérome Molimard[a,b], Reynald Convert[c], Pierre Badel[a,b], Pascal Giraux[d-e]

*[a] Inserm, U1059, Saint-Etienne, F-42023, France*

*[b] Mines Saint-Etienne, Saint-Etienne, F-42023, France*

*[c] Thuasne, BP243, 92307 Levallois-Perret cedex, France*

*[d] Department of Physical Medicine and Rehabilitation, Faculty of Medicine, University Jean Monnet, Saint-Etienne, France*

*[e] Université de Lyon, Université Jean Monnet - Saint-Etienne, LIBM, EA 7424, F-42023, SAINT-ETIENNE, France*

[*]Corresponding author. Email: fanette.chassagne@emse.fr

## Abstract

Objective: To investigate the pressure of superimposed bandages and to compare it to the pressure applied by single component bandages

Methods: Six different bandages, composed of one elastic and/or one non-elastic bandages, were applied in a spiral pattern on both legs of 25 patients at risk of venous thrombosis (consecutive to central or peripheral motor deficiency). Pressure was measured at four measurement points on the leg (B1 and C on the medial and lateral sides of the leg) and in three positions: supine, sitting and standing.

Results: The two single bandages applied similar pressure in supine position. Their superimposition showed different pressure levels ($p<0.05$), but similar static stiffness index, depending on the order in which the bandage components were applied on the leg. The highest interface pressure was measured at point B1 on the medial side of the leg. This point also showed the highest pressure increase from supine to standing position.

The pressure applied by the superimposition of two bandages was computed as a linear combination of the pressure applied by each single component (with a constant term set to 0). However, this linear combination did not properly fit the experimental pressure measurements.

Conclusion: The order of bandage application showed a significant impact on interface pressure. However, the poor correlation between the pressure applied by each bandage component and the one resulting from their superimposition underlined the poor understanding of interface pressure generated by the superimposition of compression bandages and should lead to further investigations.

Keywords: Compression bandages, Interface pressure, Multi-layer bandages

## 1 Introduction

Compression therapy remains the cornerstone of severe venous pathologies such as ulcers [1]. This treatment, whose efficacy is admitted [2]–[4], can be performed thanks to stockings or bandages. Bandages are preferred at the early stages of the treatment [5] and/or for the most severe pathologies. Compression bandages can be differentiated, being either *short-stretch* or *long-stretch* [6], with regards to their maximal stretch. Another terminology classifies the bandages with regards to their elastic properties, being either *elastic* or *non-elastic*. The difference in mechanical properties will lead to different behaviors once applied on the leg. Elastic bandages result in lower pressure variation from supine to standing position (and also between resting and working pressure) as they can more easily accommodate the change in leg morphology [7]. On the other hand, the pressure increase induced by non-elastic bandages is much higher. From a clinical point of view this differentiation is possible thanks to the *Static Stiffness Index* (*SSI*), which is the pressure increase, at measurement point B1 (Figure 1 – A), from supine to standing position [8]. This index helps to characterize the behavior of multi-component bandages combining elastic and non-elastic bandages. The superimposition of compression bandages is very common in clinical practice [9] and showed a positive impact on ulcer healing [10], [11]. Multi-layer bandages are often composed of a padding layer (to homogenize the leg geometry), one to two compression layers and possibly a fixation layer (cohesive bandage). Even though the most representative illustration of multi-layer bandages is the so-called 4-layer bandage [12], a large diversity of multi-layer bandages is commercially available [13], [14].

Interface pressure is one of the key parameter of compression treatment. Pressure generated by one single bandage was extensively investigated. The impact of several parameters such as fabric materials [15]–[17] , application technique [18], [19] or body positions [20] was assessed. However, whether there is a direct relationship between the pressure applied by a single bandage and the one applied by the superimposition of bandages remains an open question.

The pressure applied by two-layer bandages composed of short-stretch and long-stretch bandages as well as their *stiffness* (i.e. the pressure increase per 1 centimeter increase in leg circumference [21]) was investigated *in vitro* [22]. This pressure applied by superimposed bandages was then compared with the pressure applied by each component separately. Furthermore, *in vivo* interface pressure measurements were performed to evaluate the *stiffness* of commercially available multi-component bandages [23]. It was also observed that superimposing bandages led to an increase in *Static stiffness Index* even with elastic bandages [24]. However, a study performed with the 4-layer bandage, showed that the pressure resulting from the superimposition of bandages was not the sum of the pressure applied by each single bandages [25].

Consequently, the objective of this study was to investigate the pressure applied by the superimposition of elastic and/or non-elastic compression bandages. These pressures were compared to the pressure applied by each single bandage with the aim to evaluate the possible linear correlation between the pressure applied by single and multi-component bandages. The impact of the order of bandage application was also addressed. Interface pressure measurements were performed in 3 positions to assess the pressure variation and the *Static Stiffness Index* of the bandages.

## 2 Methods

This protocol was approved by the local *Ethical Committee* (CPP Sud-Est I – 2015-34) (NCT02803398).

### 2.1 Population

26 patients (16 women – 10 men; mean age = 48 [19 – 72]) were included in the study, but one left after the first visit for medical reasons unrelated to this study. These patients were at risk of venous thrombosis and were treated with compression therapy (stockings or bandages). This risk was the consequence of walking impairment or very limited walking distance induced by a central or peripheral motor deficiency. They were hospitalized in the Physical Medicine and Rehabilitation Department of the University Hospital of Saint-Etienne, France. To take part in the study, they had to be able to stand for at least 10 min in a standing frame (Figure 1 – B). Patients with venous thrombosis history, venous or arterial ulcer, cutaneous wound on the lower leg, or with any contraindication to compression therapy were not included in the study. Among the 26 patients included in the study, 13 suffered from post-stroke hemiplegia (partial or complete), 3 suffered from paraplegia (consecutive to a trauma (2) or a surgery (1)) and 2 had a cerebellar stroke. The 8 remaining patients were treated for motor deficiency or impaired balance resulting from various pathologies.

### 2.2 Bandages

The pressure applied by two different bandages was investigated in the study: Biflex® 16 (Thuasne) and Rosidal® K (L & R). Both were 10-cm wide bandages but differed in their mechanical properties. Biflex® 16 (B16) is an elastic and long-stretch bandage composed of elastic yarns, whereas Rosidal® K (RK) is a non-elastic and short-stretch bandage only composed of cotton yarns (thus non-elastic yarns). The pressure applied by the different possible combinations of these two bandages was measured, even though these bandages were never associated in regular practice. This resulted in six possible combinations:

- B16: a single Biflex® 16 bandage,
- RK: a single Rosidal® K bandage,
- B16+B16: a Biflex® 16 was applied on top of another Biflex® 16,
- RK+RK: a Rosidal® K was applied on top of another Rosidal® K,
- B16+RK: a Rosidal® K was applied on top of a Biflex® 16,
- RK+B16: a Biflex® 16 was applied on top of a Rosidal® K.

All bandages were applied in a spiral pattern with a 50% overlapping technique (i.e. a 2-layer bandaging technique) by a single experienced operator. Biflex® 16 was applied on the lower limb with a target stretch equal to 1.3 (Equation 1) and Rosidal® K with a maximum stretch, following their manufacturers' recommendations.

$$Stretch = \frac{actual\ bandage\ length\ (L)}{initial\ bandage\ length\ (L_0)} \qquad \textbf{Equation 1}$$

Following the methodology described in a previous study [26], the stretch of the applied bandage was then measured thanks to marks drawn every 10-cm on the non-stretched bandage. The six bandages were applied on the leg in a randomized order.

### 2.3 Interface pressure measurements

Interface pressure measurements were performed at four measurement points: two at the height of measurement point B1 (where the Achille's tendon turns into the gastrocnemius muscle [27]) on the medial and lateral side of the leg and two at the height of measurement point C (at the calf largest circumference [27]) (Figure 1 – A). Four probes were kept in place during the six bandage applications. The pressure was measured thanks to the sensor Picopress ® (MicroLab Elettronica, Ponte S. Nicolo, Italy), which was used in several previous studies [3], [16], [28].

## 2.4 Interface pressure measurements protocol

Pressure measurements were performed on both legs. The first leg on which bandages were applied was randomly selected for each patient. The order in which the six bandages were applied was also randomized and was the same for both patient's legs. All randomizations were performed with the software Matlab®.

The protocol was divided into three visits. The time between two visits could not exceed five days. Informed consents were signed by the patients before their inclusion.

*1st visit*

This visit consisted in the inclusion visit.

*2nd and 3rd visits*

These two visits, which consisted in interface pressure measurements, were identical: the 2nd visit was performed on the first leg and the 3rd visit on the second leg.

First, the patient lied on an examination bed and four sensors were taped on her/his leg. Then the first bandage (selected from the randomization) was applied on the leg. The bandage stretch was measured around measurement points B1 and C after each bandage application and for both bandages in the case of multi-component bandages. Pressure measurement was taken one minute after bandage application. Then the patient sat on the edge of the bed, her/his feet on the ground with a 90° angle between the thigh and the lower leg. Pressure was measured one minute later. Eventually, the patient stood in a standing frame (Figure 1 – B) and the last pressure measurement was taken after waiting for one min. This waiting time was chosen in order to reach a stationary state of leg venous system [29]. Eventually the patient lied on the examination bed and the same protocol was repeated for the 5 remaining bandages.

### 2.5 Statistical analysis

144 pressure values were measured for each patient, hence a total of 3600 pressure values (105 missing values). Bar graphs represent the mean value and 95% confidence interval. The normality of the distribution was tested with the Shapiro-Wilk test. Most of the comparison tests were paired tests. For only two groups, the comparison was performed with the non-parametric Wilcoxon test (or the paired T test with regard to the data distribution) and for more than two groups, with the Friedman test. The Nemenyi post-hoc test was used to test the multiple paired comparisons.

The coefficient of determination $R^2$ was computed as an evaluation of the linear correlation between two samples (the experimental data and the one given by the linear regression for example).

The statistical analysis was performed thanks to XLSTAT and Matlab®.

## 3 Results

### 3.1 Interface pressure measurements

Stretch of the applied bandage was measured in the area of measurement point B1 and C for all bandage applications. Mean stretches, measured at both areas and for all bandages combinations, were equal to $1.347 \pm 0.005$ for the RK and $1.294 \pm 0.005$ for the B16 (whose target stretch was 1.3) (Figure 2). Stretch was higher at measurement point C than at B1.

Pressures applied by the B16 and the RK at measurement point B1 (medial) in supine position were found to be very similar, respectively $25.69 \pm 1.16$ and $25.94 \pm 1.13$ mmHg (Figure 3). Two-component bandages resulted in much higher pressures: $49.64 \pm 1.94$ mmHg for 2B16, $47.98 \pm 2.24$ mmHg for 2RK. The superimposition of two different bandages applied different pressures depending on the order of bandages application ($p<0.05$): $52.38 \pm 2.34$ mmHg for a RK applied on top of a B16 (B16+RK) and $48.10 \pm 1.59$ mmHg for a B16 applied on top of a RK (RK+B16). This difference was statistically significant.

Pressure was measured in three positions, supine then sitting and eventually standing, in a very short time (about five minutes). For all bandages, pressure increased from supine to sitting position and then to sitting to standing position (Figure 4 - A).

The pressure increase at measurement point B1 (medial) from supine to standing position is the so called *Static Stiffness Index* (SSI), which helps to characterize the mechanical properties of the whole bandage [8].

The minimum *SSI* was observed for a single elastic bandage ($4.18 \pm 0.75$ mmHg) (Figure 4 - B). However, the superimposition of two of these bandages resulted in an increased *SSI* ($6.48 \pm 0.82$ mmHg). The maximum *SSI* was obtained for the superimposition of two non-elastic bandages ($13.60 \pm 2.29$ mmHg). As expected, a single non-elastic bandage showed a high *SSI* ($7.35 \pm 1.55$ mmHg). Eventually the two combinations of elastic and non-elastic bandages have similar *SSI*: $9.54 \pm 1.32$ mmHg for B16+RK and $9.98 \pm 1.48$ mmHg for RK+B16.

Interface pressure was measured at four points on the leg: at the height of measurement point B1 and C on the medial and lateral side of the leg (B1 med, B1 lat, C med and C lat). In supine position, all bandages were found to be degressive (i.e. the pressure applied at measurement point B1 (medial) was higher than at point C (medial)), except the RK (Figure 5 – A). For most bandages, pressures on the lateral side of the leg were lower than on the medial side.

The highest interface pressure was always measured at B1 on the medial side of the leg (Figure 5 – A, B, C). This measurement point also showed the largest pressure increase from supine to standing position (Figure 5 – D): $8.52 \pm 0.68$ mmHg for B1 medial, $5.43 \pm 0.65$ mmHg for B1 lateral, $6.42 \pm 0.65$ mmHg for C medial and $3.63 \pm 0.57$ mmHg for C lateral.

### 3.2 Pressure applied by a 2-component bandage with regards to the one applied by each component

Interface pressure applied by the six possible combinations of elastic and non-elastic bandages was measured with the aim to better understand the superimposition of compression bandages. The assumption was made that the pressure applied by the superimposition of two bandages would be a linear combination of the pressure applied by both single bandages (with a constant term set to 0).

The pressure measurements at four locations (height of measurement B1 and C; medial and lateral) on the leg and in supine position were considered for this analysis.

First, the ratio between the pressure applied by the superimposition of two identical bandages and the pressure applied by a single bandage was computed. This ratio was equal to 1.89 for the B16 and 1.80 for the RK (Equation 2 (a) and (b)). However, the coefficient of determination $R^2$ was very low for the RK.

Then the pressure applied by the combination of two different bandages was computed as a linear combination of the pressure applied by both single bandages. By comparing the two equations (Equation 2 (c) and (d)), it can be noticed that the order of bandage application tends to impact interface pressure, despite the low coefficient of determination.

$$P_{2B16} = 1.89\ \ P_{B16}\ (R^2 = 0.48, p < 0.001)\ (a)$$

$$P_{2RK} = 1.80\ \ P_{RK}\ (R^2 = 0.06, p < 0.001)\ (b)$$

$$P_{B16+RK} = 1.31\ \ P_{B16} + 0.67\ \ P_{RK}\ (R^2 = 0.37, p < 0.001)\ (c)$$

$$P_{RK+B16} = 0.91\ \ P_{RK} + 0.92\ \ P_{B16}(R^2 = 0.10, p < 0.001)\ (d)$$

**Equation 2: Pressure applied by multi-component bandages as a linear combination of the pressure applied by a single component bandage; $P_{B16}$ and $P_{RK}$ are the pressures applied by a single B16 and RK, $P_{2B16}$ and $P_{2RK}$ are the pressures applied by the superimposition of two B16 and two RK, $P_{B16+RK}$ was the pressure applied by a RK over a B16 and $P_{RK+B16}$ was the pressure applied by a B16 over a RK**

## 4 Discussion

Interface pressure applied by six different single or multi component bandages was measured at four measurement points on the leg and in three positions. These six bandages, whose *SSI* were evaluated, resulted from the combination of one elastic (B16) and one inelastic (RK) bandage. The pressure varied with the bandage components but also with the order in which the components were applied on the leg. Eventually, the pressure applied by the four multi-component bandages was computed as a linear combination of the pressure applied by the two single component bandages.

### 4.1 Interface pressure measurements

The design of this study was very close to an *in vitro* study by Hirai et al. [22]. The pressure and the *stiffness* (i.e. the pressure increase for a 1 cm leg circumference increase) of different combinations of short and long stretch bandage were measured, as well as the pressure applied by the single bandages. The two single bandages (short-stretch and long-stretch) applied very similar pressure levels (about 30 mmHg) but had very different *stiffnesses*: 4 mmHg for the long-stretch bandage and 17 mmHg for the short-stretch bandage.

However, their observations contradicted the present study. Indeed, for the range of pressure measured in the present study (about 50 mmHg), Hirai *et al.* observed no significant impact of the order of bandage application on *in vitro* interface pressure and *stiffness*. In the present study, B16+RK exerted a higher pressure than RK+B16, even though the pressure applied by B16 and RK were similar. Nonetheless the *SSI* of these two bandages were equal, which was in agreement with the in-vitro study of Hirai *et al.*. In the present study, the difference between the mean pressures applied by B16+RK and RK+B16 is about 4 mmHg. Although it is statistically significant, the clinical meaning of such a difference may be discussed.

This *SSI* is an usual tool for the classification of compression bandages [6]. The *SSI* of inelastic bandages is usually higher than 10 mmHg and the one of elastic bandages is lower. However, it was found here that the *SSI* of RK, which is a non-elastic bandage, was lower than 10 mmHg. This was previously observed for a low-pressure bandaging technique [30]. According to this classification, in the present study, all multi-component bandages composed of at least one non-elastic bandage are inelastic bandages. This result corroborated the fact that adding at least one non-elastic component to the bandage has a pronounced effect on *SSI* [9], [22]. However, the superimposition of bandages (either elastic or non-elastic) increased the *SSI*, which led to think that bandage-to-bandage friction can play a role in the *SSI*. Indeed, by superimposing bandages, the bandage-to-bandage contact surface is highly increased. In standing position, the increase in leg volume is limited by the mechanical resistance of the bandage but also by the friction between the different layers.

Bandage degressivity was assessed thanks to interface pressure at 4 different measurement points (points B1 and C on the medial and lateral side of the leg). Compression bandages are commonly applied on the leg with a constant stretch. The conical shape of the leg (increase circumference from the ankle to the knee) lead to a degressive pressure profile: the pressure decreases from the ankle to the knee. In this study, all bandages were found to be significantly degressive except the RK. This can be explained by the fact that stretch was higher at measurement point C than at point B1 (Figure 2). As a consequence, as it can be noticed in Figure 6, this stretch increase (in green in Figure 6) led to a larger tension increase for the RK than for the B16, respectively 48.3 % and 9.0% of the tension for the mean stretch (in black in Figure 6). The difference in stretch between the two heights on the leg (heights of measurement point B1 and C) led to a much higher increase in tension for the RK than for the B16. For RK, this larger tension increase may compensate the increase in circumference from measurement point B1 to C, hence the fact that the bandage was not degressive. Nonetheless, all the trends observed here about the bandage stretch cannot be generalized as they are the results of only one bandager.

Eventually, measuring the pressure at two heights on the leg and on the medial and lateral sides of the leg showed that the maximum pressure increase from supine to standing position was observed at measurement point B1 which confirmed the relevance of the use of this point for the characterization of the stiffness of the bandage [30]. Also, pressures measured on the medial side of the leg were higher than those measured on the lateral side. This can easily be explained by the anatomy of the leg: the radii of curvature are lower on the medial side than on the lateral side.

### 4.2 Pressure applied by a 2 component bandage with regards to the one applied by each component

The pressure applied by two-component bandages at four measurement points on the leg (in supine position) was computed as a linear combination of the one applied by each single component. However, except for the superimposition of two elastic compression bandages, this linear model did not properly fit the experimental data.

It could have been expected that the pressure applied by a two-component bandage would be the sum of the pressures applied by each single component bandage (according to Laplace's Law). A possible explanation could be the thickness of the bandage [31]. Moreover, the second bandage was applied on a deformed leg shape induced by the application of the first bandage.

For the computation of the pressure applied by two-component bandages, setting the constant term to 0 for the linear model might be a too strong hypothesis. Also, the low correlation between the pressure applied by a two-component bandage, composed of at least one non-elastic bandage, and the one applied by a single component bandage might be due to the mechanical properties of the fabrics. As it can be observed in Figure 6, the stretch variation in between the confidence interval (in red in Figure 6) induced a much larger tension variation for the non-elastic bandage (about 19% of the mean value) than for the elastic bandage (about 4% of the mean value).

Finally, the very low correlation between the pressure applied by each single components and the one resulting from their superimposition highlighted the lack of understanding of the mechanisms involved in bandages superimposition.

### 4.3 Limitations

Pressure measurements were taken in a very short time after bandage application. However pressure tends to vary over time [32] because of various phenomena: such as bandage relaxation [33] (loss of tension over time), reduction of leg edema [34] and bandage slippage on the lower leg. It was chosen to take measurements in a very short time to limit the impact of these phenomena, which are complex to evaluate. Nevertheless, relaxation tests (performed in our laboratory, results not shown here) showed that after 10 minutes, the B16 lost about 7% of its nominal tension (for a stretch equal to 1.30) whereas the RK lost about 22% (for a stretch equal to 1.35). It could be interesting to perform these measurements within a longer period of time to reach a stationary state for bandage materials, although it would hardly be sustainable for the patients. Moreover, these measurements were static measurements. Even though pressure was measured in three positions, this study did not investigate the working pressure of these bandages (i.e. the interface pressure applied while walking).

The two bandages were chosen as representative bandages of elastic and non-elastic bandages, even though they are not routinely combined in usual clinical practice. Thereby measurements of pressure applied by other commercially available multi-component bandages would be of high interest.

Patients included in the study were all at risk of venous thrombosis due to walking impairment. However, the causes of their motor deficiency were very heterogeneous. Some of the pathologies might have had an impact of patients’ muscle pump, which could influence pressure variations in different body positions. In future studies, it would be relevant to assess the venous pumping function of patients’ leg before bandage applications.

## 5 Conclusion

This study consisted in static interface pressure measurements applied by 6 different bandages, all composed of elastic and/or non-elastic bandages. First, it was observed that the components of the bandage but also the order in which they are applied on the leg significantly impact interface pressure. Second, the very low correlation between the pressure applied by multi-component bandages and the one applied by the single-component highlighted the poor understanding of the mechanisms involved in bandages superimposition. Further mechanical studies would be needed to better understand the pressure generation resulting from such superimposition.

Following a similar protocol, it would be clinically relevant to characterize the performance of commercially available multi-component bandages, and also to investigate their dynamic behavior, while walking for instance.

## 6 Conflict of Interest

Thuasne is a compression bandages manufacturer.

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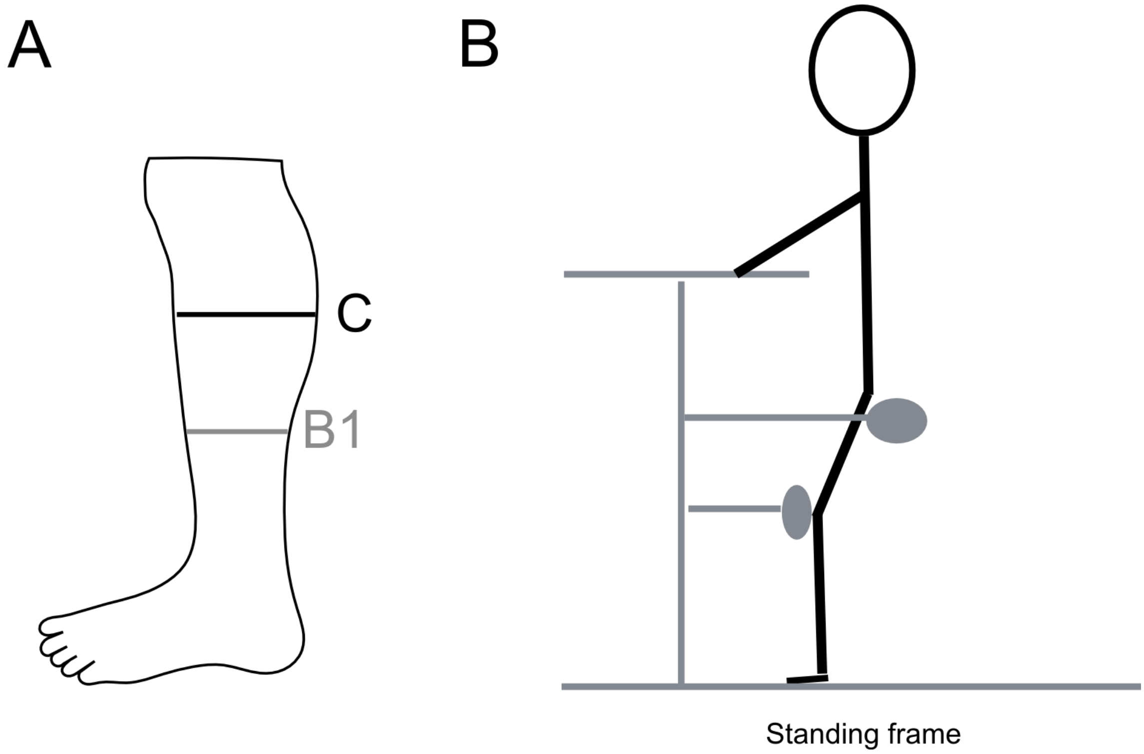


**Figure 1: A – Location of measurement points B1 and C; B - Patient's position in the standing frame**

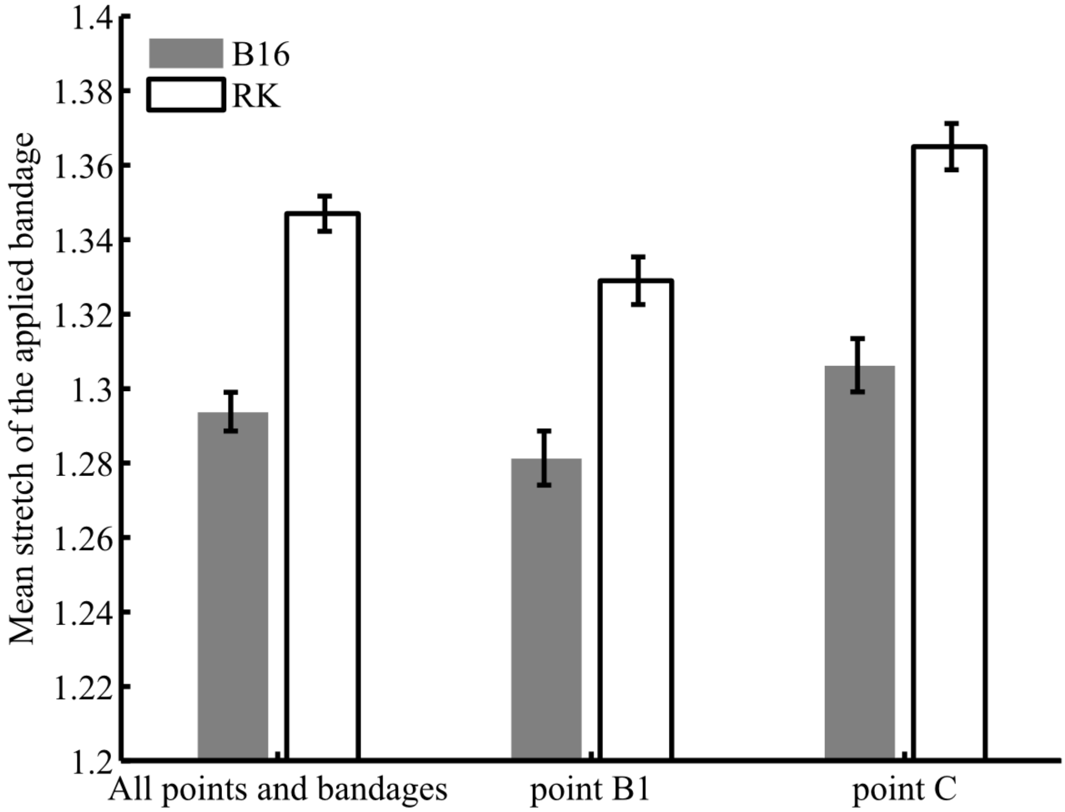


**Figure 2: Stretch of the applied bandages; for all measurement points and bandages; at measurement point B1; at measurement point C;**

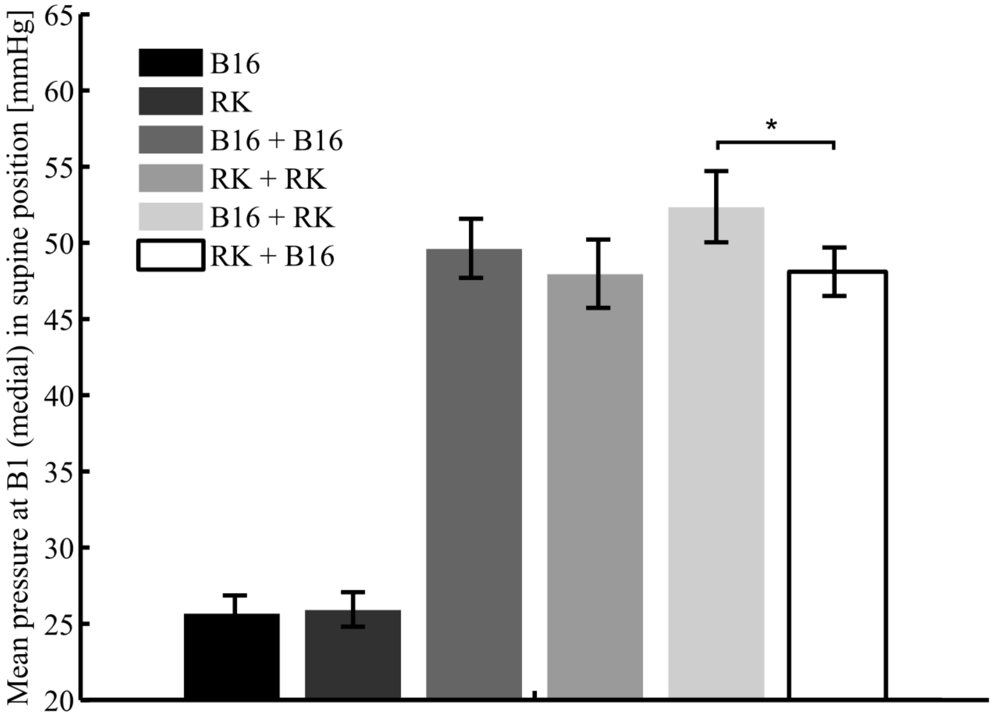


**Figure 3: Mean pressure applied by the 6 different bandages at measurement point B1 (medial) in supine position; * states for significant difference**

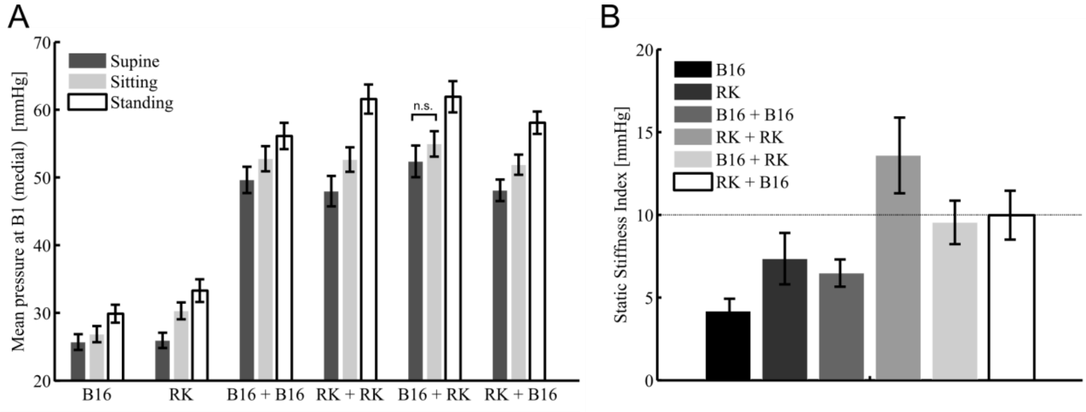


**Figure 4: A - Mean pressures applied by the 6 bandages at measurement point B1 (medial) in supine, sitting and standing positions; n.s. states for non-significant difference; B - Static Stiffness Index for the 6 bandages**

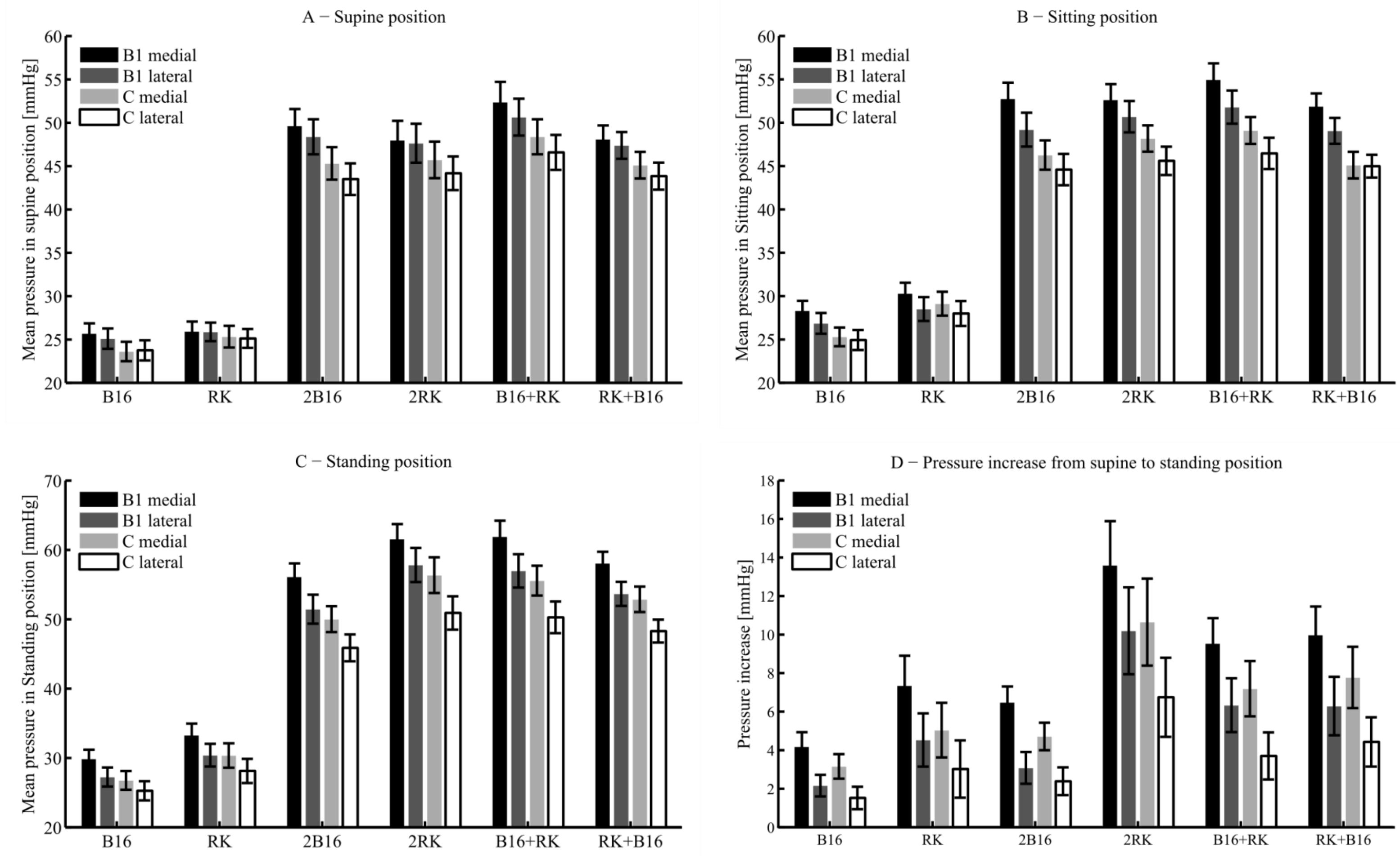


**Figure 5: Mean pressure for the four measurement points and the six bandages in the three positions, supine (A), sitting (B) and standing (C); Pressure increase from supine to standing position for the six bandages and the four measurement points (D)**

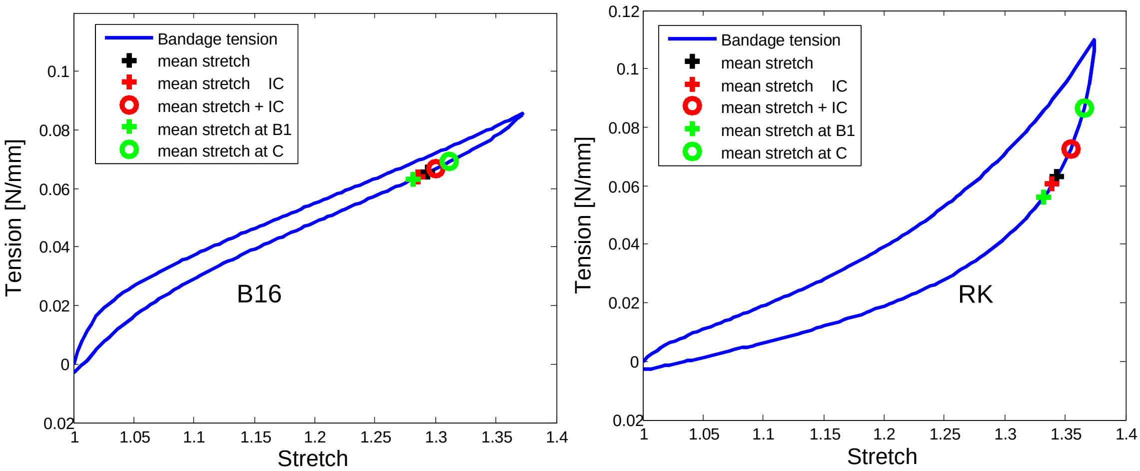


**Figure 6: Tension as a function of the stretch for both bandages B16 and RK**