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1 **Superimposition of elastic and non-elastic compression bandages**

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13 **Abstract**

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

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

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

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

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

36

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

38 1 Introduction

39 Compression therapy remains the cornerstone of severe venous pathologies such as
40 ulcers [1]. This treatment, whose efficacy is admitted [2]–[4], can be performed thanks
41 to stockings or bandages. Bandages are preferred at the early stages of the treatment
42 [5] and/or for the most severe pathologies. Compression bandages can be
43 differentiated, being either *short-stretch* or *long-stretch* [6], with regards to their
44 maximal stretch. Another terminology classifies the bandages with regards to their
45 elastic properties, being either *elastic* or *non-elastic*. The difference in mechanical
46 properties will lead to different behaviors once applied on the leg. Elastic bandages
47 result in lower pressure variation from supine to standing position (and also between
48 resting and working pressure) as they can more easily accommodate the change in leg
49 morphology [7]. On the other hand, the pressure increase induced by non-elastic
50 bandages is much higher. From a clinical point of view this differentiation is possible
51 thanks to the *Static Stiffness Index (SSI)*, which is the pressure increase, at
52 measurement point B1 (Figure 1 – A), from supine to standing position [8]. This index
53 helps to characterize the behavior of multi-component bandages combining elastic
54 and non-elastic bandages. The superimposition of compression bandages is very
55 common in clinical practice [9] and showed a positive impact on ulcer healing [10],
56 [11]. Multi-layer bandages are often composed of a padding layer (to homogenize the
57 leg geometry), one to two compression layers and possibly a fixation layer (cohesive
58 bandage). Even though the most representative illustration of multi-layer bandages is
59 the so-called 4-layer bandage [12], a large diversity of multi-layer bandages is
60 commercially available [13], [14].

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

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

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

85 2 Methods

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

88 2.1 Population

89 26 patients (16 women – 10 men; mean age = 48 [19 – 72]) were included in the study,
90 but one left after the first visit for medical reasons unrelated to this study. These
91 patients were at risk of venous thrombosis and were treated with compression
92 therapy (stockings or bandages). This risk was the consequence of walking impairment
93 or very limited walking distance induced by a central or peripheral motor deficiency.
94 They were hospitalized in the Physical Medicine and Rehabilitation Department of the
95 University Hospital of Saint-Etienne, France. To take part in the study, they had to be
96 able to stand for at least 10 min in a standing frame (Figure 1 – B). Patients with
97 venous thrombosis history, venous or arterial ulcer, cutaneous wound on the lower
98 leg, or with any contraindication to compression therapy were not included in the
99 study. Among the 26 patients included in the study, 13 suffered from post-stroke
100 hemiplegia (partial or complete), 3 suffered from paraplegia (consecutive to a trauma
101 (2) or a surgery (1)) and 2 had a cerebellar stroke. The 8 remaining patients were
102 treated for motor deficiency or impaired balance resulting from various pathologies.

103 2.2 Bandages

104 The pressure applied by two different bandages was investigated in the study: Biflex®
105 16 (Thuasne) and Rosidal® K (L & R). Both were 10-cm wide bandages but differed in
106 their mechanical properties. Biflex® 16 (B16) is an elastic and long-stretch bandage
107 composed of elastic yarns, whereas Rosidal® K (RK) is a non-elastic and short-stretch

108 bandage only composed of cotton yarns (thus non-elastic yarns). The pressure applied
109 by the different possible combinations of these two bandages was measured, even
110 though these bandages were never associated in regular practice. This resulted in six
111 possible combinations:

- 112 - B16: a single Biflex® 16 bandage,
- 113 - RK: a single Rosidal® K bandage,
- 114 - B16+B16: a Biflex® 16 was applied on top of another Biflex® 16,
- 115 - RK+RK: a Rosidal® K was applied on top of another Rosidal® K,
- 116 - B16+RK: a Rosidal® K was applied on top of a Biflex® 16,
- 117 - RK+B16: a Biflex® 16 was applied on top of a Rosidal® K.

118 All bandages were applied in a spiral pattern with a 50% overlapping technique (i.e. a
119 2-layer bandaging technique) by a single experienced operator. Biflex® 16 was applied
120 on the lower limb with a target stretch equal to 1.3 (Equation 1) and Rosidal® K with a
121 maximum stretch, following their manufacturers' recommendations.

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

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

125 2.3 Interface pressure measurements

126 Interface pressure measurements were performed at four measurement points: two at
127 the height of measurement point B1 (where the Achille's tendon turns into the
128 gastrocnemius muscle [27]) on the medial and lateral side of the leg and two at the

129 height of measurement point C (at the calf largest circumference [27]) (Figure 1 – A).
130 Four probes were kept in place during the six bandage applications. The pressure was
131 measured thanks to the sensor Picopress[®] (MicroLab Elettronica, Ponte S. Nicolo,
132 Italy), which was used in several previous studies [3], [16], [28].

133 2.4 Interface pressure measurements protocol

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

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

141 1st visit

142 This visit consisted in the inclusion visit.

143 2nd and 3rd visits

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

146 First, the patient lied on an examination bed and four sensors were taped on her/his
147 leg. Then the first bandage (selected from the randomization) was applied on the leg.

148 The bandage stretch was measured around measurement points B1 and C after each
149 bandage application and for both bandages in the case of multi-component bandages.

150 Pressure measurement was taken one minute after bandage application. Then the
151 patient sat on the edge of the bed, her/his feet on the ground with a 90° angle

152 between the thigh and the lower leg. Pressure was measured one minute later.
153 Eventually, the patient stood in a standing frame (Figure 1 – B) and the last pressure
154 measurement was taken after waiting for one min. This waiting time was chosen in
155 order to reach a stationary state of leg venous system [29]. Eventually the patient lied
156 on the examination bed and the same protocol was repeated for the 5 remaining
157 bandages.

158 2.5 Statistical analysis

159 144 pressure values were measured for each patient, hence a total of 3600 pressure
160 values (105 missing values). Bar graphs represent the mean value and 95% confidence
161 interval. The normality of the distribution was tested with the Shapiro-Wilk test. Most
162 of the comparison tests were paired tests. For only two groups, the comparison was
163 performed with the non-parametric Wilcoxon test (or the paired T test with regard to
164 the data distribution) and for more than two groups, with the Friedman test. The
165 Nemenyi post-hoc test was used to test the multiple paired comparisons.

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

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

170 3 Results

171 3.1 Interface pressure measurements

172 Stretch of the applied bandage was measured in the area of measurement point B1
173 and C for all bandage applications. Mean stretches, measured at both areas and for all

174 bandages combinations, were equal to 1.347 ± 0.005 for the RK and 1.294 ± 0.005
175 for the B16 (whose target stretch was 1.3) (Figure 2). Stretch was higher at
176 measurement point C than at B1.

177 Pressures applied by the B16 and the RK at measurement point B1 (medial) in supine
178 position were found to be very similar, respectively 25.69 ± 1.16 and 25.94 ± 1.13
179 mmHg (Figure 3). Two-component bandages resulted in much higher pressures:
180 49.64 ± 1.94 mmHg for 2B16, 47.98 ± 2.24 mmHg for 2RK. The superimposition of
181 two different bandages applied different pressures depending on the order of
182 bandages application ($p < 0.05$): 52.38 ± 2.34 mmHg for a RK applied on top of a B16
183 (B16+RK) and 48.10 ± 1.59 mmHg for a B16 applied on top of a RK (RK+B16). This
184 difference was statistically significant.

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

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

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

198

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

205 The highest interface pressure was always measured at B1 on the medial side of the
206 leg (Figure 5 – A, B, C). This measurement point also showed the largest pressure
207 increase from supine to standing position (Figure 5 – D): 8.52 ± 0.68 mmHg for B1
208 medial, 5.43 ± 0.65 mmHg for B1 lateral, 6.42 ± 0.65 mmHg for C medial and
209 3.63 ± 0.57 mmHg for C lateral.

210 3.2 Pressure applied by a 2-component bandage with regards to the one applied 211 by each component

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

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

219 First, the ratio between the pressure applied by the superimposition of two identical
220 bandages and the pressure applied by a single bandage was computed. This ratio was

221 equal to 1.89 for the B16 and 1.80 for the RK (Equation 2 (a) and (b)). However, the
 222 coefficient of determination R^2 was very low for the RK.
 223 Then the pressure applied by the combination of two different bandages was
 224 computed as a linear combination of the pressure applied by both single bandages. By
 225 comparing the two equations (Equation 2 (c) and (d)), it can be noticed that the order
 226 of bandage application tends to impact interface pressure, despite the low coefficient
 227 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

228 4 Discussion

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

237 4.1 Interface pressure measurements

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

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

254 This *SSI* is an usual tool for the classification of compression bandages [6]. The *SSI* of
255 inelastic bandages is usually higher than 10 mmHg and the one of elastic bandages is
256 lower. However, it was found here that the *SSI* of RK, which is a non-elastic bandage,
257 was lower than 10 mmHg. This was previously observed for a low-pressure bandaging
258 technique [30]. According to this classification, in the present study, all multi-
259 component bandages composed of at least one non-elastic bandage are inelastic
260 bandages. This result corroborated the fact that adding at least one non-elastic

261 component to the bandage has a pronounced effect on *SSI* [9], [22]. However, the
262 superimposition of bandages (either elastic or non-elastic) increased the *SSI*, which led
263 to think that bandage-to-bandage friction can play a role in the *SSI*. Indeed, by
264 superimposing bandages, the bandage-to-bandage contact surface is highly increased.
265 In standing position, the increase in leg volume is limited by the mechanical resistance
266 of the bandage but also by the friction between the different layers.

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

283 Eventually, measuring the pressure at two heights on the leg and on the medial and
284 lateral sides of the leg showed that the maximum pressure increase from supine to

285 standing position was observed at measurement point B1 which confirmed the
286 relevance of the use of this point for the characterization of the stiffness of the
287 bandage [30]. Also, pressures measured on the medial side of the leg were higher than
288 those measured on the lateral side. This can easily be explained by the anatomy of the
289 leg: the radii of curvature are lower on the medial side than on the lateral side.

290 4.2 Pressure applied by a 2 component bandage with regards to the one applied 291 by each component

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

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

301 For the computation of the pressure applied by two-component bandages, setting the
302 constant term to 0 for the linear model might be a too strong hypothesis. Also, the low
303 correlation between the pressure applied by a two-component bandage, composed of
304 at least one non-elastic bandage, and the one applied by a single component bandage
305 might be due to the mechanical properties of the fabrics. As it can be observed in
306 Figure 6, the stretch variation in between the confidence interval (in red in Figure 6)

307 induced a much larger tension variation for the non-elastic bandage (about 19% of the
308 mean value) than for the elastic bandage (about 4% of the mean value).
309 Finally, the very low correlation between the pressure applied by each single
310 components and the one resulting from their superimposition highlighted the lack of
311 understanding of the mechanisms involved in bandages superimposition.

312 4.3 Limitations

313 Pressure measurements were taken in a very short time after bandage application.
314 However pressure tends to vary over time [32] because of various phenomena: such as
315 bandage relaxation [33] (loss of tension over time), reduction of leg edema [34] and
316 bandage slippage on the lower leg. It was chosen to take measurements in a very short
317 time to limit the impact of these phenomena, which are complex to evaluate.
318 Nevertheless, relaxation tests (performed in our laboratory, results not shown here)
319 showed that after 10 minutes, the B16 lost about 7% of its nominal tension (for a
320 stretch equal to 1.30) whereas the RK lost about 22% (for a stretch equal to 1.35). It
321 could be interesting to perform these measurements within a longer period of time to
322 reach a stationary state for bandage materials, although it would hardly be sustainable
323 for the patients. Moreover, these measurements were static measurements. Even
324 though pressure was measured in three positions, this study did not investigate the
325 working pressure of these bandages (i.e. the interface pressure applied while walking).
326 The two bandages were chosen as representative bandages of elastic and non-elastic
327 bandages, even though they are not routinely combined in usual clinical practice.
328 Thereby measurements of pressure applied by other commercially available multi-
329 component bandages would be of high interest.

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

336 **5 Conclusion**

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

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

348 **6 Conflict of Interest**

349 Thuasne is a compression bandages manufacturer.

350

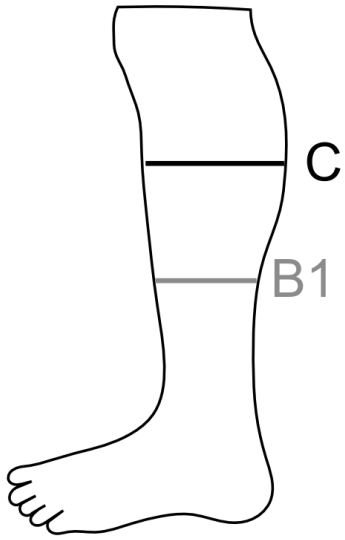
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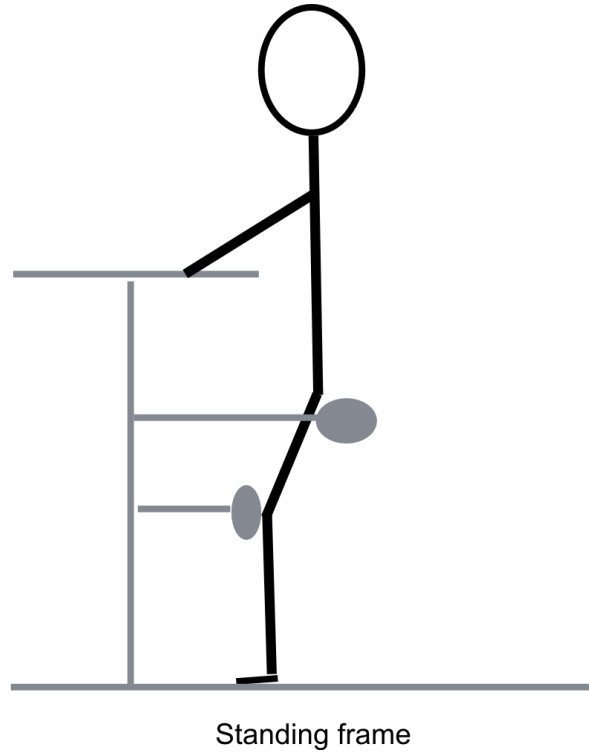
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A



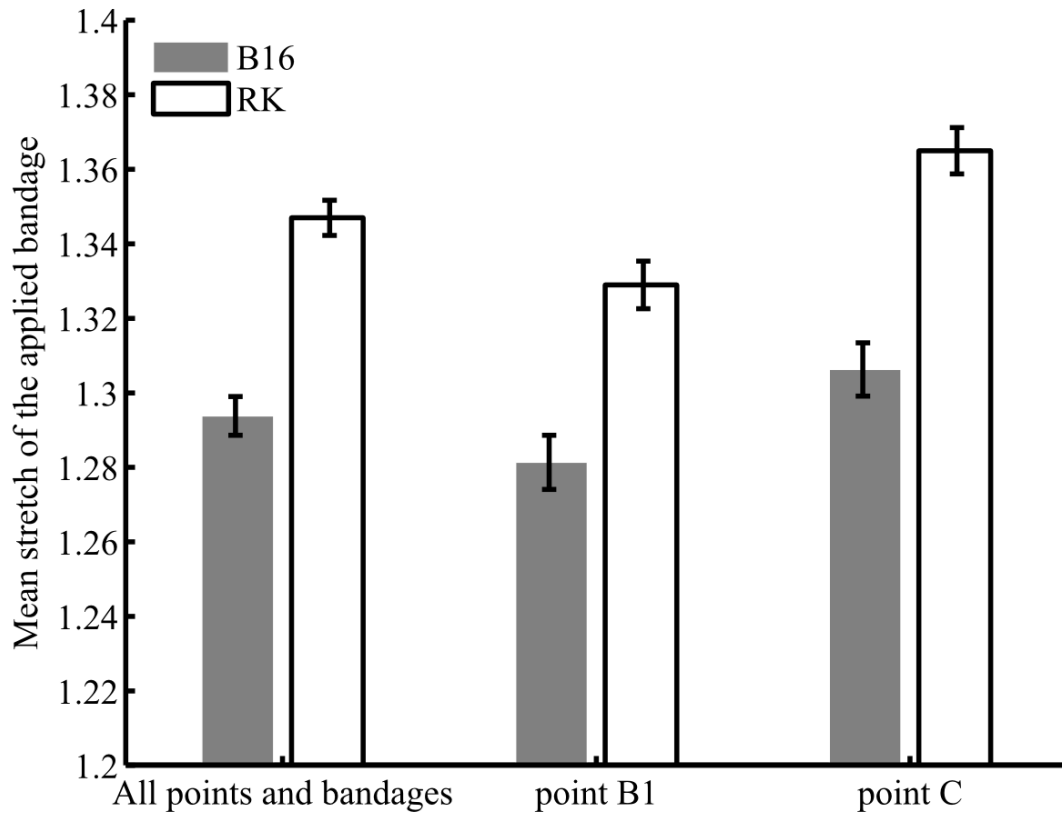
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Figure 1: A – Location of measurement points B1 and C; B - Patient's position in the standing frame

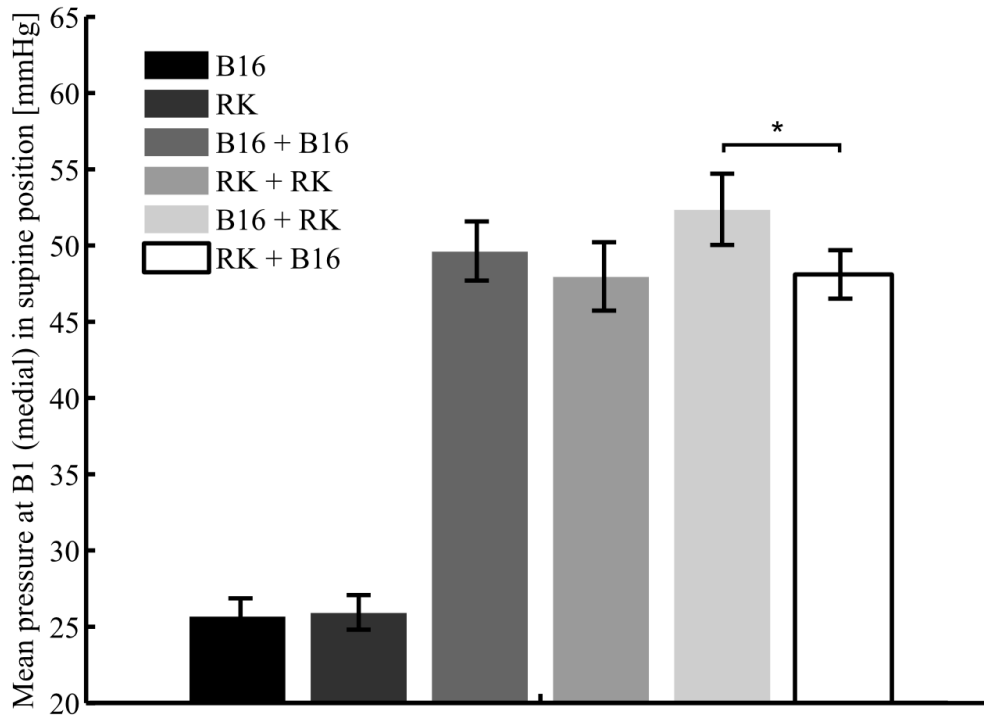


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460 **Figure 2: Stretch of the applied bandages; for all measurement points and bandages; at measurement point B1;**

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at measurement point C;



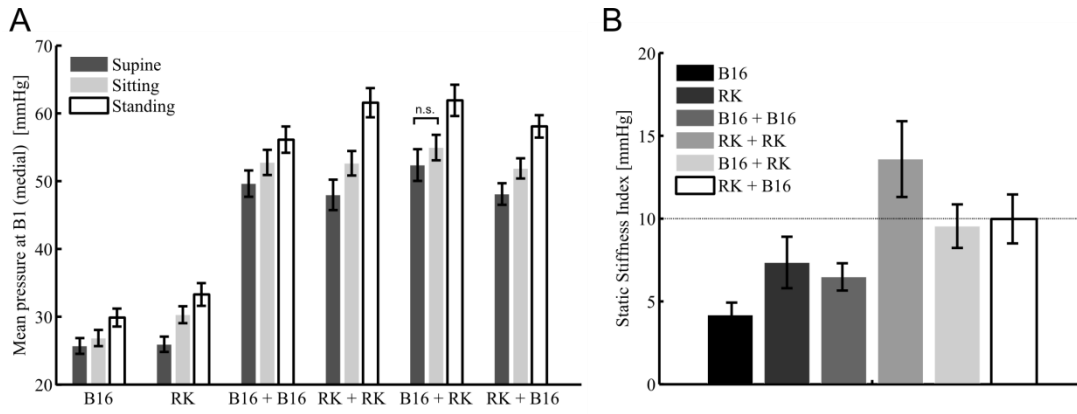
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Figure 3: Mean pressure applied by the 6 different bandages at measurement point B1 (medial) in supine position; * states for significant difference

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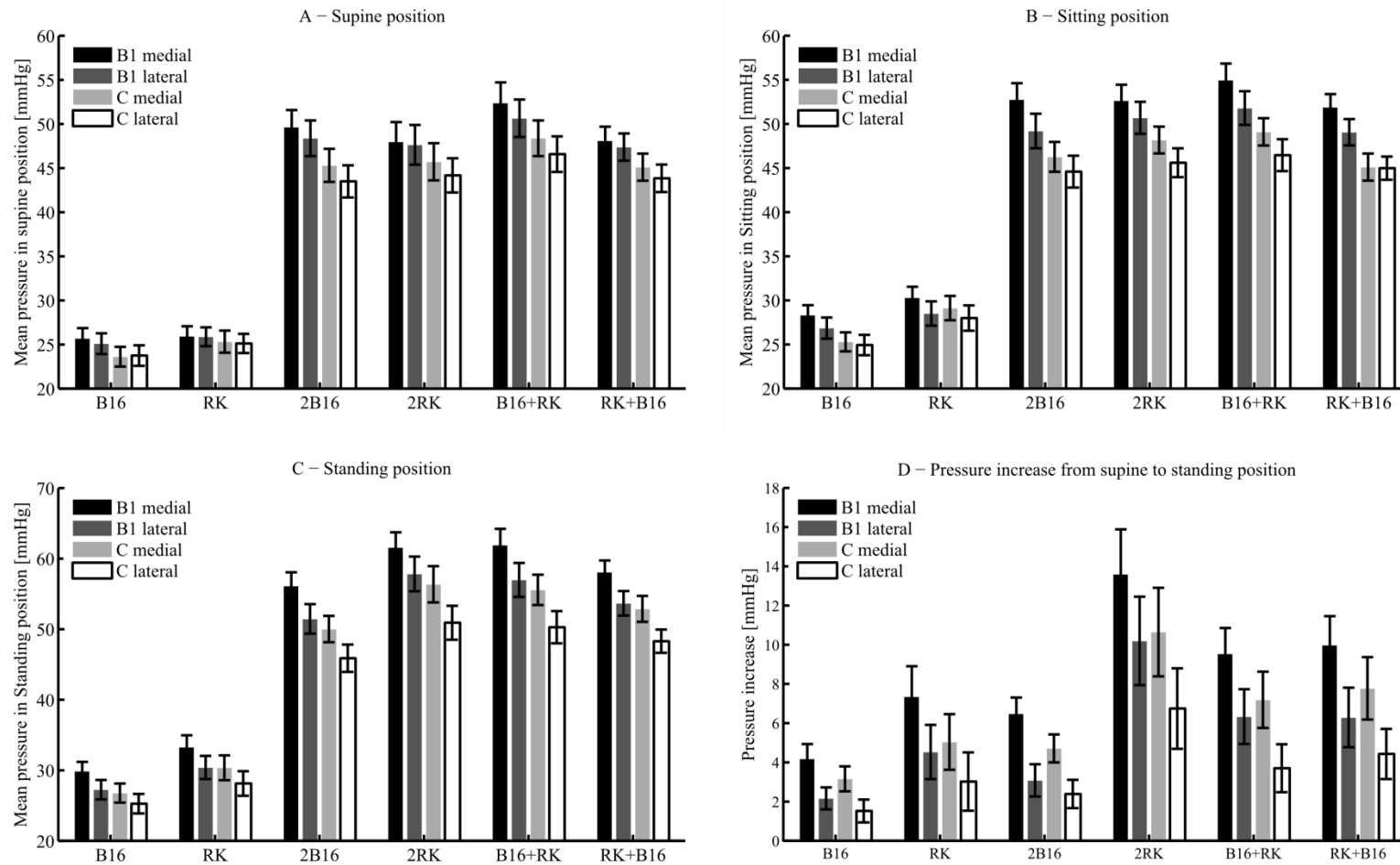


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Figure 4: A - Mean pressures applied by the 6 bandages at measurement point B1 (medial) in supine, sitting and standing positions; n.s. states for non-significant difference; B - Static Stiffness Index for the 6 bandages

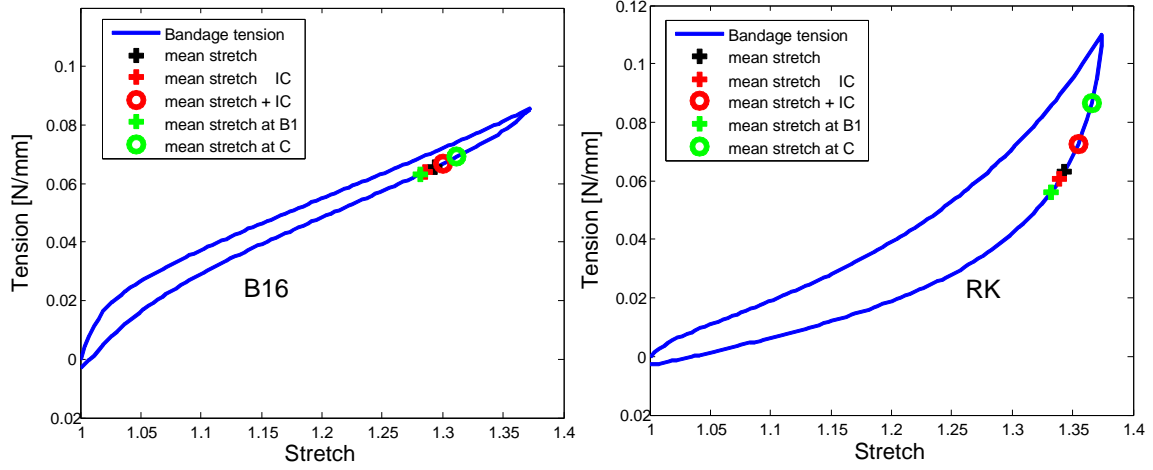


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Figure 5: Mean pressure for the four measurement points and the six bandages in the three positions, supine (A), sitting (B) and standing (C); Pressure increase from supine to standing position for the six bandages and the four measurement points (D)

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

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