

# First aid treatment for friction blisters: “walking into the right direction?”

Janssen L, Allard NAE, ten Haaf DSM, Romburgh CPP van, Eijsvogels TMH, Hopman MTE

Author list:

Lando Janssen, MD \*

Neeltje AE Allard, MD \*

Dominique SM ten Haaf, MSc \*

Cees PP van Romburgh, MA †

Thijs MH Eijsvogels, PhD \*#

Maria TM Hopman, MD, PhD \*

\* Radboud University Nijmegen Medical Centre (RUNMC), Department of Physiology, Nijmegen, the Netherlands

† The Netherlands Red Cross, The Hague, the Netherlands

# Research Institute for Sport and Exercise Sciences, Liverpool John Moores University, Liverpool, United Kingdom.

Corresponding author:

Lando Janssen, MD

Department of Physiology (286)

Radboud University Nijmegen Medical Center (RUNMC)

Geert Grooteplein Zuid 30, 6525 GA Nijmegen

The Netherlands

Fax number: 0031243540535

Telephone number: 0031614552947

Email: Lando.Janssen@Radboudumc.nl

No author has conflict of interest related to this work.

## Acknowledgments

We recognize the International Nijmegen 4DM Organization and The Netherlands Red Cross for their assistance. We especially thank Han Pelster and Henk Lulf of the Netherlands Red Cross for their contributions during the 4DM. We would like to thank dr. Joseph Hamati for his critical reading of this paper and valuable comments for improving the manuscript

Word count abstract: 250

Word count manuscript: 2968

## Abstract

*Objective:* Blisters are common foot injuries during and after prolonged walking. However, the best treatment remains unclear. The aim of the study was to compare the effect of two different friction blister treatment regimens, wide area fixation dressing versus adhesive tape.

*Design:* A prospective observational cohort study.

*Setting:* The 2015 Nijmegen Four Days Marches in the Netherlands.

*Participants:* A total of 2907 participants ( $45 \pm 16$  yrs., 52% men) were included and received 4131 blister treatments.

*Interventions:* Blisters were treated with either a wide area fixation dressing or adhesive tape.

Main outcome measures: Time of treatment application was our primary outcome. In addition, effectiveness and satisfaction were evaluated in a subgroup ( $n=254$ ). During a one month follow-up period, blister healing, infection and the need for additional medical treatment were assessed in the subgroup.

*Results:* Time of treatment application was lower (41.5 min;  $SD=21.6$  min) in the wide area fixation dressing group compared to the adhesive tape group (43.4 min;  $SD=25.5$  min;  $p=0.02$ ). Furthermore, the wide area fixation dressing group demonstrated a significantly higher drop-out rate (11.7% *versus* 4.0%,  $p=0.048$ ), delayed blister healing (51.9% *versus* 35.3%,  $p=0.02$ ) and a trend towards lower satisfaction ( $p=0.054$ ) when compared to the adhesive tape group.

*Conclusions:* Wide area fixation dressing decreased time of treatment application by 2 minutes (4.5%) when compared to adhesive tape. However, due to lower effectiveness and a trend towards lower satisfaction, we do not recommend the use of wide area fixation dressing over adhesive tape, in routine first aid treatment for friction blisters.

*Keywords:* exercise, walking, acute care, foot injuries, treatment outcome

## **Introduction**

Friction blisters frequently occur during prolonged exercise and often result in exercise cessation(1). These intraepidermal blisters are the result of trauma-induced separation within the epidermis (2, 3). Although the majority of friction blisters remain uncomplicated,

infections can occur (4, 5) with the risk of developing cellulitis or sepsis (6, 7). Furthermore, in an attempt to avoid walking on the painful blisters an antalgic gait pattern occurs which may lead to other exercise-related injuries, such as overuse injuries of the knee (8). Blister treatment aims to reduce pain, facilitate healing of the skin and neutralize infection, and prevent blister recurrence.

During the annual Nijmegen Four Day Marches (4DM), the world's largest multi-day walking event with daily distances ranging from 30-50 km, the need for treatment of friction blisters is very high. In prior years of the 4DM, the number of participants requiring at least a single blister treatment varied between 4000 and 5000, accounting for ~10% of the total number of walkers (9). Ever since 1954, blister treatment during the 4DM has been performed using adhesive tape, however evidence for this treatment is based on only one study (5). Though taping has been found to be an effective treatment (5), it is time consuming which can lead to long waiting lines and disruption of the walking rhythm of the participants. Anecdotal evidence suggests that the use of wide area fixation dressing may decrease time of treatment application by approximately 10%. However, its effectiveness in the treatment of friction blisters is unknown.

To date, only limited research has been conducted to examine different treatment regimens for friction blisters (4, 5). Most studies that examined friction blisters have been performed within the military (2, 6, 8) or in athletes (1, 10), with a high homogeneity for age and physical activity levels and with a primary focus on prevention of blisters. Consequently, the purpose of the current study was to prospectively compare the efficacy of fixation dressing versus adhesive tape in first aid treatment of friction blisters. These two methods of treatment were evaluated based upon time of treatment application, effectiveness, and

material satisfaction in a large group of participants of the 4DM. We hypothesize that treatment with fixation dressing will lead to a reduction in time of treatment application since it can be applied in one piece whereas adhesive tape has to be applied in an overlapping manner (Figure 1). In addition, we expect to find no differences in effectiveness and satisfaction between the treatments. To the best of our knowledge, this is the first study to include a follow-up period to evaluate blister healing when comparing treatments with different blister-covering materials.

## **Methods**

We performed an observational study during the 99<sup>th</sup> 4DM. Participants who walked either 30, 40 or 50 km per day and required blister treatment at treatment centers of the Red Cross were eligible to participate.. Time of treatment application was assessed in the whole study cohort (Figure 2). Subsequently, a subgroup of participants ( $\geq 18$  years) was approached for assessment of treatment effectiveness and satisfaction (Figure 2) via telephone interviews and online questionnaires. Participants who dropped out before they received blister treatment were excluded in subgroup analyses. Written informed consent was obtained from each participant prior to enrollment. This study was conducted in line with the Declaration of Helsinki.

### **Time of treatment application**

Participants' badges containing a unique walking number were scanned at the beginning and at the end of the blister treatment in order to evaluate time of treatment application. For each treatment, caregivers filled out a blister registration form with information on the number and localization of blisters and the type of blister treatment. All these forms were scanned into a database at the end of the day. Treatments from 5 to 180 minutes were

eligible for data analysis; treatments outside this range were deemed unrepresentative of typical blister treatment and excluded.

### Demographics

Two members (LJ and NA) of the research team randomly recruited a subgroup of walkers for participation in the follow-up study. They managed to include 254 participants for the follow-up measurements. One of the research members included only walkers who were treated with fixation dressing, whereas the other included only walkers in the adhesive tape group. Both members included approximately the same number of walkers, resulting in a subgroup treatment ratio of near 1:1. The subgroup was asked to fill out a questionnaire during their treatment containing items regarding demographic characteristics, medical history, foot and shoe type, training, treatment preference, pain intensity score on a 0-10 numeric rating scale and the use of over-the-counter analgesics.

### Assessment of treatment effectiveness

The subgroup was contacted by telephone at the end of the day of enrollment (follow-up 1) to obtain pain intensity scores after treatment and drop-out rate. In order to determine the effect of type of blister treatment on experienced pain, we compared the pre- to post-treatment change ( $\Delta$ ) in pain intensity score between fixation dressing and adhesive tape on each walking day. All included subjects were contacted by telephone again at the end of the 4DM to assess drop-out rate (follow-up 2). One month after the 4DM subjects were invited to complete an online questionnaire (follow-up 3) to evaluate blister healing, the occurrence of infection and the need for additional medical blister treatment. Blister healing was classified into two groups: rapid healing ( $<2$  weeks) and delayed healing ( $\geq 2$  weeks).

178

### 179 Assessment of satisfaction

180 Treatment satisfaction was assessed at the end of enrollment day (follow-up 1), at the end  
181 of the 4DM (follow-up 2) and one month after the 4DM (follow-up 3) using a 5 point Likert  
182 scale (1=very satisfied, 2=satisfied, 3=neutral, 4=dissatisfied, and 5=very dissatisfied). The  
183 average satisfaction score was calculated over the 3 follow-up measurements. To compare  
184 differences in satisfaction between both treatment methods, we pooled very  
185 satisfied/satisfied and very dissatisfied/dissatisfied scores.

186

### 187 Treatment

188 All participants of the 4DM with blisters requiring professional treatment were treated with  
189 either fixation dressing (Fixomull Stretch, BSN medical GmbH & Co KG, Hamburg, Germany)  
190 or adhesive tape (Leukoplast, BSN medical GmbH & Co KG, Hamburg, Germany). The fixation  
191 dressing is a stretchable, non-woven dressing, which can be applied in one piece, whereas  
192 the high tensile strength adhesive tape is applied in several overlapping strips (Figure 1).  
193 Both materials are suitable for use on the entire foot, including heel, forefoot and toes. The  
194 costs for fixation dressing and adhesive tape are similar (approximately \$1,90/€1,80 per  
195 foot). The treatment materials were applied by volunteers of the Netherlands Red Cross.  
196 Although the level of expertise differed between the volunteers ranging from basic to  
197 advanced, all volunteers finished a blister treatment training and were found qualified by  
198 instructors to apply either fixation dressing or adhesive tape. Participants were randomly  
199 allocated to a caregiver using standard treatment with adhesive tape or fixation dressing  
200 without any pre-selection. Since adhesive tape is the standard blister treatment during the  
201 4DM, more volunteers were trained to apply adhesive tape when compared to fixation

202 dressing, resulting in a ratio of 3:1 between the treatment groups. Prior to applying the  
203 fixation dressing or adhesive tape, pre-treatment was carried out by degreasing, disinfecting,  
204 lancing and draining all blisters.

## 206 Statistical analysis

207 To evaluate the effectiveness and satisfaction of both treatment methods, all subjects who  
208 completed at least one of the follow-up measurements were included. Student's t-tests and  
209 Wilcoxon rank sum test were performed to compare data between the adhesive tape and  
210 fixation dressing group for continuous variables when data was normally and non-  
211 parametrically distributed, respectively. For comparison of categorical variables Pearson  $\chi^2$   
212 test was used or Fisher's exact test if observations were <10. All data analyses were  
213 performed with Statistical Package for the Social Sciences (IBM SPSS Statistics for Windows,  
214 Version 22.0, IBM Corp., Armonk, New York). Statistical significance was set at a P value  
215 <0.05.

## 217 **Results**

### 218 Time of treatment application

219 A total of 2907 participants (45±16 yrs., 52% men) were included in the study and they  
220 received 4131 blister treatments with fixation dressing (n=984) or adhesive tape (n=3147),  
221 accounting for 97.1% of all treatments performed with fixation dressing and adhesive tape  
222 during the 4DM (122 treatments excluded due to invalid treatment application times).  
223 Average time of treatment application in the fixation dressing group was lower (41.5 min;  
224 SD=21.6 min) compared to the adhesive tape group (43.4 min; SD=25.5 min; p=0.02; Figure

3). In addition, time of treatment application was calculated for the different parts of the foot (toes, forefoot and heel) separately. Time of treatment application for toe blisters was not different between the fixation dressing and adhesive tape group (34.1 min; SD=16.8 min vs. 35.2 min; SD=22.0 min, respectively;  $p=0.52$ ). For forefoot and heel blisters, time of treatment application was lower in the fixation dressing group compared to the adhesive tape group (27.1 min; SD=13.8 min vs. 32.9 min; SD= 23.2 min;  $p=0.001$  and 27.0 min; SD=11.4 min vs. 32.0 min; SD=18.4 min;  $p<0.001$ , respectively).

### Follow-up measurements

A subgroup of 254 subjects (8.7% of total study population; Figure 2) was included to assess effectiveness and satisfaction. Within this subgroup, the average age ( $p=0.62$ ), gender ( $p=0.95$ ) and walking distance ( $p=0.08$ ) were comparable to the overall study population. Furthermore, age, gender and BMI did not differ across the fixation dressing ( $n=118$ ) and adhesive tape group ( $n=136$ ; Table 1). Foot disorders such as pes planus/pes cavus and toe joint deformities were reported in 18% of the fixation dressing group and 17% of the adhesive tape group. Mean training distance in the previous year was 571 km (SD=568 km) in the fixation dressing group and 631 km (SD=663 km) in the adhesive tape group and did not differ ( $p=0.46$ ). The majority of the subjects wore walking shoes that were broken in (84% and 83% in the fixation dressing group and adhesive tape group, respectively). Furthermore, no differences were found between the groups in the number of blisters (3.1; SD=2.0; Table 1) and the prevalence of denuded and blood blisters. Loss to follow-up ranged from 11% to 39% and did not differ between the fixation dressing and adhesive tape group.

### *Pain score and drop-out*

A similar decrease in pain intensity score was observed in the fixation dressing versus the adhesive tape group (-0.80; SD=2.08 *versus* -0.56; SD=2.68; Table 2). No differences were found between the fixation dressing and adhesive tape group in the proportion of subjects that used over-the-counter analgesics during the 4DM (32.8% *versus* 40.2%;  $p=0.24$ ). A significantly higher drop-out rate in the 4DM was observed in the fixation dressing group as compared to the adhesive tape group (11.7% *versus* 4.0%, respectively,  $p=0.048$ ).

### *Blister healing, infection, additional medical treatment*

Delayed healing was reported more frequently in the fixation dressing group (51.9%) as compared to the adhesive tape group (35.3%;  $p=0.02$ ; Figure 4). The number of subjects in which blisters were complicated by an infection was similar in the fixation dressing and adhesive tape group (11.1% *versus* 16.5%, respectively). Furthermore, no difference was found between the fixation dressing and adhesive tape group in the number of subjects who required additional medical blister treatment (6.5% *versus* 11.8%, respectively).

### *Satisfaction*

In the fixation dressing group 75.4% and 14.6% were (very) satisfied and (very) dissatisfied with the material, respectively, versus 85.3% and 4.9% in the adhesive tape group ( $p=0.054$ ; Figure 5). Subjects who were treated on multiple walking days and received treatment with both fixation dressing and adhesive tape ( $N=67$ ) were also asked to indicate a preference for either material. A total of 60 subjects (90%) reported a preference, with 48.3% in favor of fixation dressing and 51.7% in favor of adhesive tape ( $p=0.80$ ).

271

## 272 **Discussion**

273 The aim of the present study was to compare fixation dressing and adhesive tape in the  
274 treatment for friction blisters with a specific emphasis on time of treatment application,  
275 effectiveness, and satisfaction. The major findings were that treatment with fixation dressing  
276 resulted in: 1) a significant time reduction, 2) higher drop-out rates and delayed blister  
277 healing, 3) no differences in pain intensity score, infection and additional medical treatments  
278 and 4) a trend towards lower satisfaction as compared to treatment with adhesive tape.  
279 These findings indicate that treatment with fixation dressing is inferior to adhesive tape in  
280 treating friction blisters.

281

### 282 Time of treatment application

283 Treatment of friction blisters with fixation dressing led to an average time savings of 2  
284 minutes per treatment when compared to treatment with adhesive tape.. Although this  
285 reduction in time of treatment application (4.5%) may seem small for an individual  
286 treatment, it may actually result in a substantial decrease in waiting time during walking  
287 events where a large number of treatments are given simultaneously (11). Furthermore,  
288 when interpreting time of treatment application we need to take into account that the vast  
289 majority of the subjects in our study had multiple blisters. Moreover, we measured the total  
290 time of treatment application, including inspection, pre-treatment (i.e. degreasing,  
291 disinfecting, lancing and draining) and applying covering material (fixation dressing or  
292 adhesive tape). To the best of our knowledge, there are no other published studies reporting  
293 time of treatment application of friction blisters or similar skin defects that could be utilized  
294 for comparison. In this study a reduction in time of treatment application was achieved by

intervening in the last stage of the treatment, i.e. applying covering material. Additional studies are required to examine whether further time savings may be achieved by shortening other treatment stages, such as the pre-treatment.

#### Treatment effectiveness

During the 4DM we found a significantly higher drop-out rate in the fixation dressing group and no differences in pain intensity scores between the groups. Since no differences in potential confounders were found between the adhesive tape and fixation dressing group at baseline (i.e. age, gender, medical history, foot disorders, training distance, use of over-the-counter analgesics, shoe type and number and type of blisters), the higher drop-out rate appears to be the direct consequence of the use of fixation dressing. By including a follow-up period of one month, we were able to detect delayed blister healing in the fixation dressing group with no difference in either the infection rate or the need of additional medical treatments compared to the adhesive tape group. A study by Roos and van Setten (5) is the only published literature that previously examined effectiveness of blister treatment. They measured effectiveness of adhesive tape compared to gauze (during the 4DM of 1953) by assessing infection, blister recurrence and newly formed blisters 24 hours post treatment. They concluded that the adhesive tape group was superior in all measures; however, since no follow-up period was included the study was unable to evaluate blister healing, delayed infection, and the need for additional medical treatment. This might explain the difference in infection rate after treatment with adhesive tape, which was 0.3% according to Roos and van Setten and 16.5% in our study. Recently, Lipman et al. (10) found that the use of tape in prevention of friction blisters led to a significant reduction in blister formation of 40%. However, as this study focused on a different exercise duration and intensity, these results

may not be extrapolated to participants of long distance walking marches. When all factors are accounted for, adhesive tape has shown to be the most effective way to treat friction blisters.

### Satisfaction

Assessment of treatment satisfaction is especially relevant, since positive associations between satisfaction and clinical outcomes have been found across a wide range of diseases and symptoms, including pain perception (12). This is the first study, to our knowledge, to report satisfaction with blister covering material. We found a trend of higher satisfaction in the adhesive tape group in comparison to the fixation dressing group ( $p=0.054$ ). Although treatment time for adhesive tape was longer, follow-up data revealed a better outcome over time. This may have contributed to the higher satisfaction in the adhesive tape group versus the fixation dressing group.

### Clinical relevance

The reduction in time of treatment application with fixation dressing is relevant for large groups during marching events and, to a lesser extent, for individual treatments. Due to the increasing popularity of long-distance walking events over the last decades (13), rapid and effective treatment for friction blisters is necessary and our study provides novel information on two treatment strategies. Although our data demonstrates that treatment with fixation dressing is a time-saving method for friction blisters, we also found a significantly higher drop-out rate and delayed blister healing in the fixation dressing group. These findings strongly suggest a preference for the use of adhesive tape as a first aid treatment for friction blisters.

343

344 Limitations

345 The strengths of this study include the large population, its unique and prospective study  
346 design and the one month follow-up period. Despite these strengths, a number of limitations  
347 should also be taken into account. We observed the optimal blister treatment for walking  
348 exercise only, so our results may not be applicable to other types of (endurance) exercise  
349 (i.e. running). Furthermore, the self-reported nature of our effectiveness measurements may  
350 lead to recall bias. However, previous studies have demonstrated reasonable agreement  
351 between self- and medical record report of medical conditions (14-16). Furthermore,  
352 anonymity was ensured by asking subjects to only fill out their walking number instead of  
353 identifying information and thus social desirability bias was reduced. Loss to follow-up was  
354 modest (11-39%) (17), and equal in the fixation dressing and adhesive tape group. Therefore,  
355 this did not impact our findings.

356

357 Conclusion

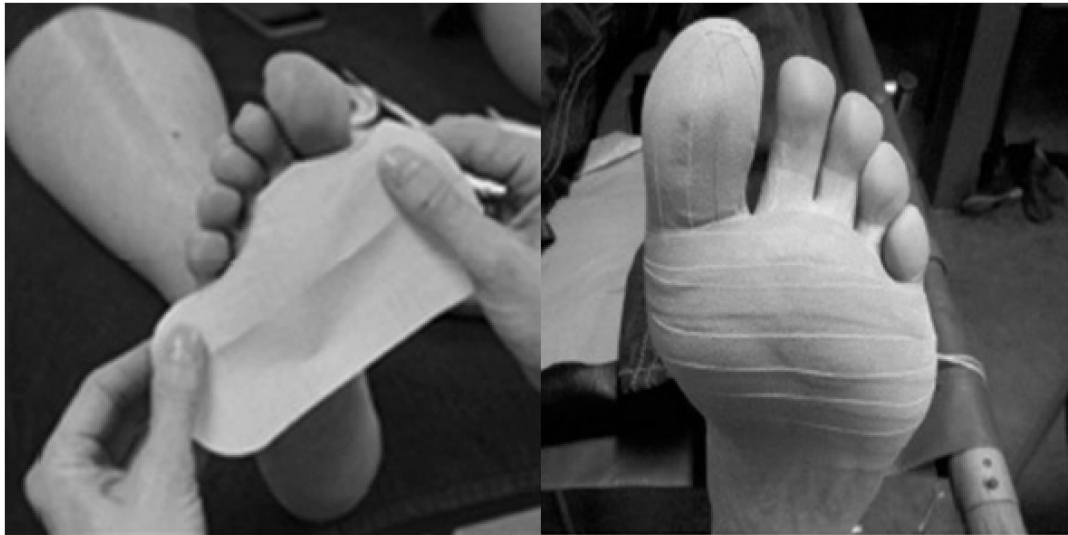
358 Treatment with fixation dressing leads to a small but significant reduction in time of  
359 treatment application. Nevertheless, a higher drop-out rate and delayed blister healing (>2  
360 weeks) were observed in the fixation dressing group in comparison with the adhesive tape  
361 group. Furthermore, a trend towards lower satisfaction was observed in the fixation dressing  
362 group. Consequently, despite the significant time savings, we do not recommend the use of  
363 fixation dressing in routine first aid treatment for friction blisters. In conclusion, our data  
364 supports the use of adhesive tape as the treatment of choice for friction blisters sustained  
365 from (prolonged) walking exercise.

366

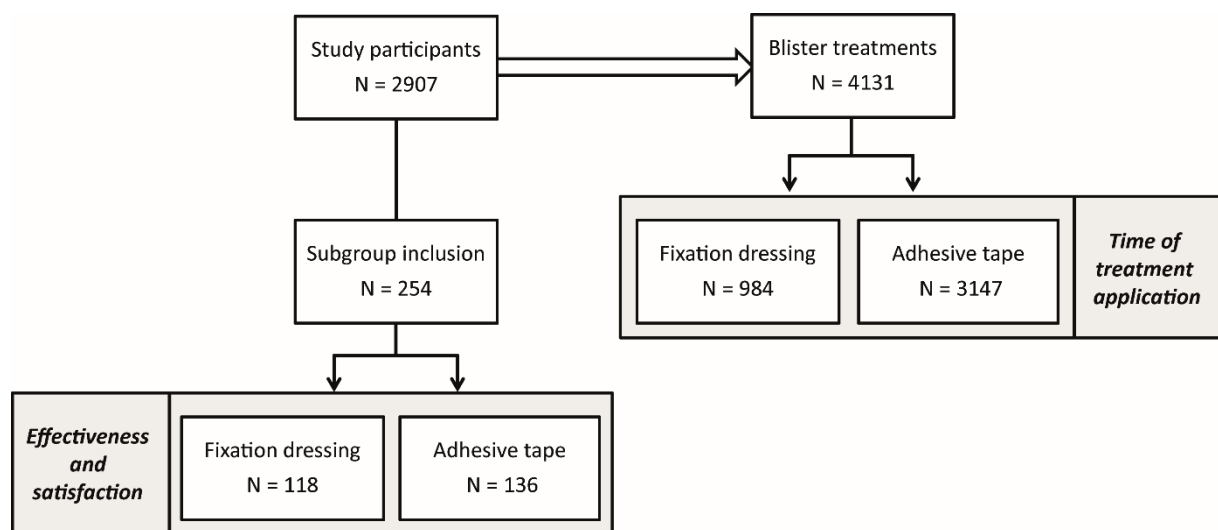
## References

1. Brennan FH, Jr. Managing blisters in competitive athletes. Current sports medicine reports. 2002;1(6):319-22.
2. Knapik JJ, Reynolds KL, Duplantis KL, et al. Friction blisters. Pathophysiology, prevention and treatment. Sports Med. 1995;20(3):136-47.
3. Naylor PFD. EXPERIMENTAL FRICTION BLISTERS. British Journal of Dermatology. 1955;67(10):327-42.
4. Cortese TA, Jr., Fukuyama K, Epstein W, et al. Treatment of friction blisters. An experimental study. Archives of dermatology. 1968;97(6):717-21.
5. Roos J, Setten van PH. De behandeling van wandelblaren. Dutch Journal of Medicine. 1954;98:1988-92.
6. Hoeffler DF. Friction blisters and cellulitis in a navy recruit population. Military medicine. 1975;140(5):333-7.
7. Taylor CM, Riordan FA, Graham C. New football boots and toxic shock syndrome. Bmj. 2006;332(7554):1376-8.
8. Van Tiggelen D, Wickes S, Coorevits P, et al. Sock systems to prevent foot blisters and the impact on overuse injuries of the knee joint. Military medicine. 2009;174(2):183-9.
9. RedCross. Rode Kruis behandelde 12.000 blaren Vierdaagse: The Netherlands Red Cross; 2014 [cited 2014 19-07-2014]. Available from: [http://www.rodekruis.nl/actueel/nieuws/rode-kruis-behandelde-12000-blaren-vierdaagse?gclid=CjwKEAju\\_7y4BRDykp3Hjqyt\\_y0SJACome3TLuQ90LLLa2qGu8k9weWzC5ETWkzXnohe7n\\_InqMbthoCzOrw\\_wcB](http://www.rodekruis.nl/actueel/nieuws/rode-kruis-behandelde-12000-blaren-vierdaagse?gclid=CjwKEAju_7y4BRDykp3Hjqyt_y0SJACome3TLuQ90LLLa2qGu8k9weWzC5ETWkzXnohe7n_InqMbthoCzOrw_wcB).

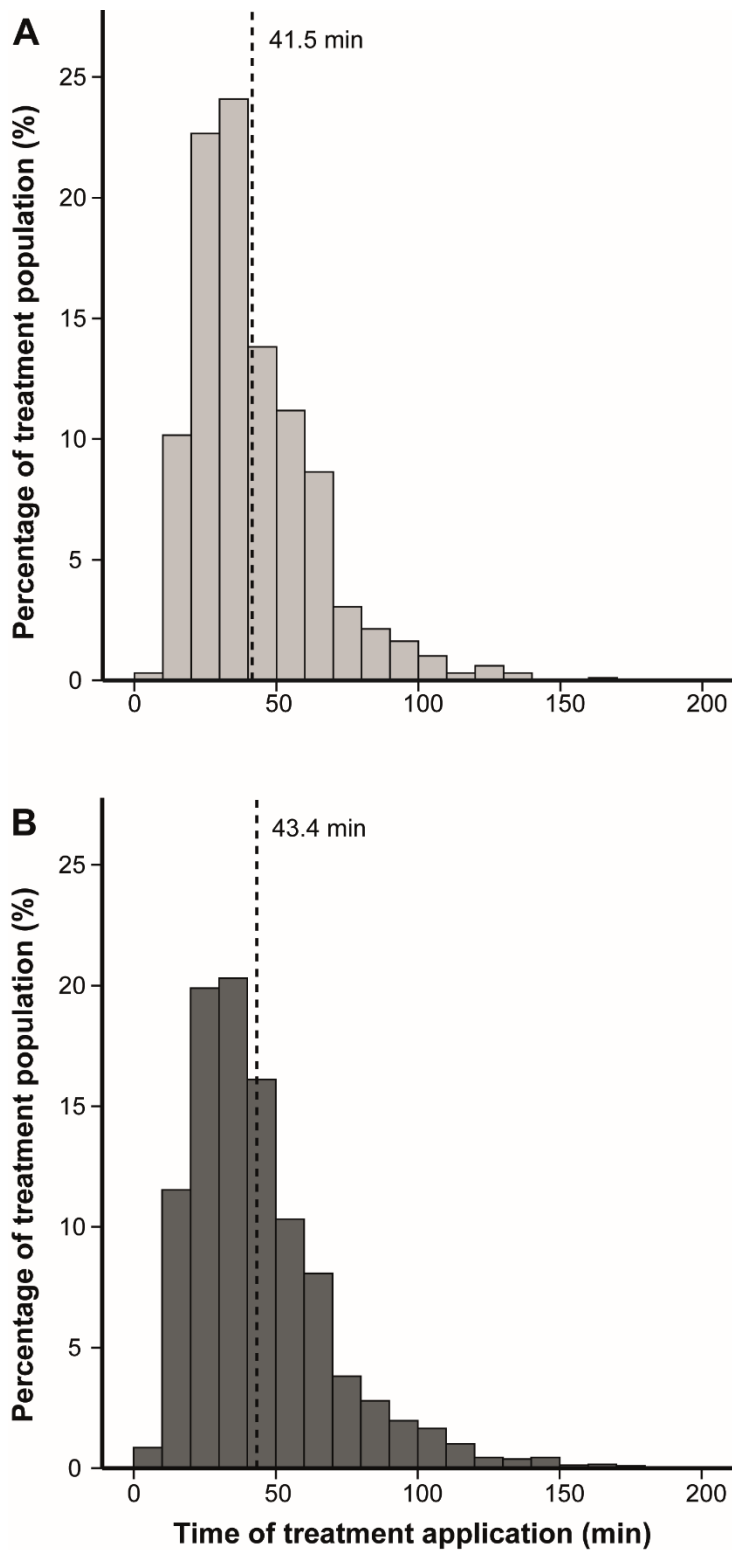
10. Lipman GS, Sharp LJ, Christensen M, et al. Paper Tape Prevents Foot Blisters: A Randomized Prevention Trial Assessing Paper Tape in Endurance Distances II (Pre-TAPED II). *Clinical journal of sport medicine : official journal of the Canadian Academy of Sport Medicine*. 2016.
11. Wiler JL, Bolandifar E, Griffey RT, et al. An emergency department patient flow model based on queueing theory principles. *Academic emergency medicine : official journal of the Society for Academic Emergency Medicine*. 2013;20(9):939-46.
12. Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open*. 2013;3(1).
13. Eijsvogels T. Physiological demands of prolonged exercise: Science of the Nijmegen Four Days Marches: Radboud University Nijmegen Medical Centre; 2011.
14. Okura Y, Urban LH, Mahoney DW, et al. Agreement between self-report questionnaires and medical record data was substantial for diabetes, hypertension, myocardial infarction and stroke but not for heart failure. *Journal of clinical epidemiology*. 2004;57(10):1096-103.
15. Bush TL, Miller SR, Golden AL, et al. Self-report and medical record report agreement of selected medical conditions in the elderly. *American journal of public health*. 1989;79(11):1554-6.
16. Hansen H, Schafer I, Schon G, et al. Agreement between self-reported and general practitioner-reported chronic conditions among multimorbid patients in primary care - results of the MultiCare Cohort Study. *BMC family practice*. 2014;15:39.
17. Kristman V, Manno M, Cote P. Loss to follow-up in cohort studies: how much is too much? *European journal of epidemiology*. 2004;19(8):751-60.



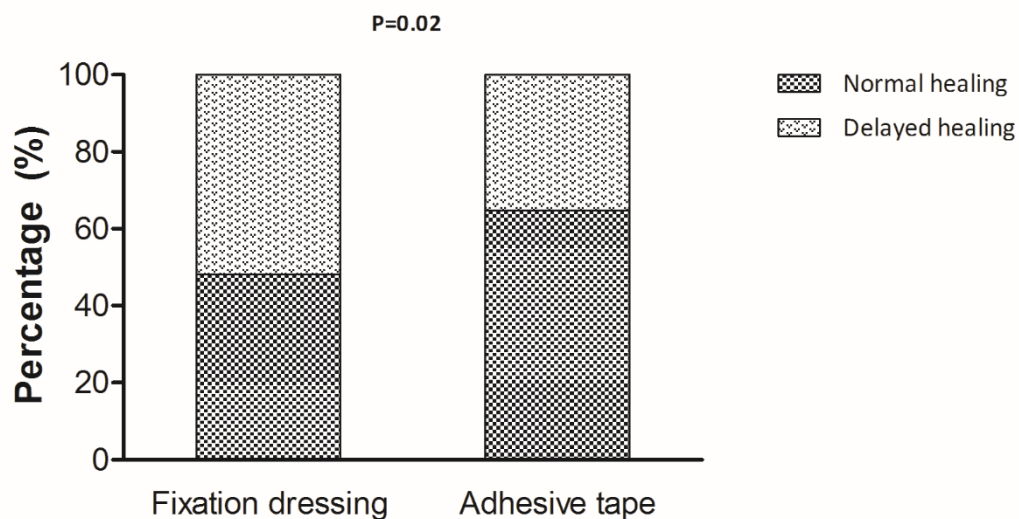
**Figure 1.** An example of the two types of blister treatment that were assessed in the present study: fixation dressing (left) versus adhesive tape (right).



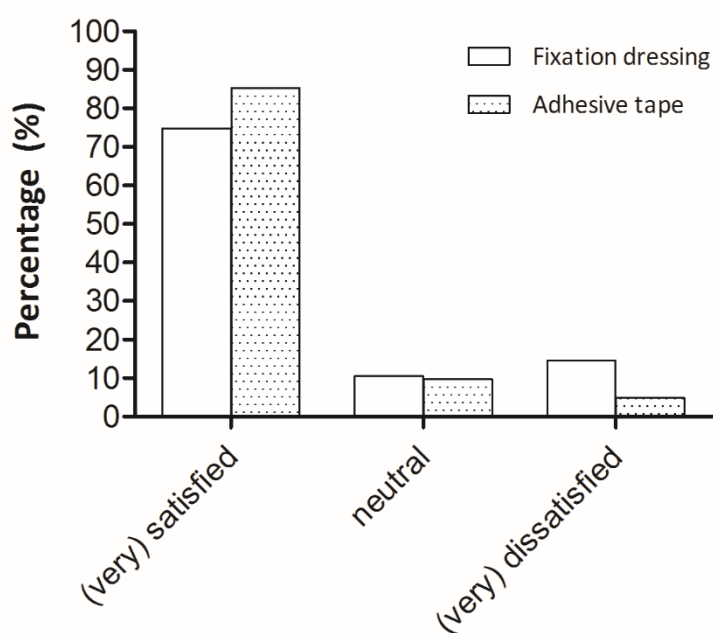
**Figure 2.** Flow chart of the study population and measurements performed. In short, time of treatment application was assessed in 2907 participants with 4131 friction blisters. Furthermore, the effectiveness and satisfaction of the treatment were assessed in 254 participants during 3 follow-up measurements: 1) after the day of inclusion, 2) after finishing the Four Days Marches, and 3) one month after finishing the Four Days Marches.



**Figure 3.** Percentage distribution of the time of treatment application of (A) fixation dressing ( $n=984$ ) and (B) adhesive tape ( $n=3147$ ). The dashed lines represent the average time of treatment application of fixation dressing (41.5 min) and adhesive tape (43.4 min) and show a significant time saving of 2 minutes (4.5%;  $p=0.02$ ).



**Figure 4.** Delayed healing ( $\geq 2$  weeks) was reported significantly more often in the fixation dressing group as compared to the tape group (52% versus 35%, respectively,  $p=0.02$ ).



**Figure 5.** A trend towards lower satisfaction was found in the fixation dressing group as compared to the adhesive tape group; 75.4% in the fixation dressing group was (very) satisfied with the material versus 85.3% in the adhesive tape group, whereas 14.6% and 4.9%

442     *were (very) dissatisfied with the material in the fixation dressing and adhesive tape group,*  
443     *respectively ( $p=0.054$ ).*

444

**Table 1. Subject characteristics**

Characteristics	Fixation dressing (n=136)	Tape (n=118)	P-value
Age, years	43 (14)	45 (14)	0.38
Male gender	55.9%	54.2%	0.79
Caucasian	96.3%	96.6%	0.36
BMI, kg/m <sup>2</sup>	25.1 (3.2)	25.4 (3.7)	0.45
Medical history			
Diabetes	8.8%	3.6%	0.10
Hypertension	8.9%	4.6%	0.16
Dyslipidemia	5.7%	4.0%	0.54
Current smoker	18.1%	15.9%	0.62
Foot disorders			
Pes planus/pes cavus	13.6%	12.5%	0.80
Toe Joint Deformities	4.8%	4.5%	0.90
Training distance, km	571 (568)	631 (663)	0.46
Use of over-the-counter analgesics	32.8%	40.2%	0.24
Type of shoes			0.67
Walking shoes, broken into	84.3%	83.2%	
Walking shoes, new	5.5%	7.1%	
Running shoes	3.9%	4.4%	
Sneakers	2.4%	3.5%	
Walking distance during 4DM			0.48
30 km/day	5.9%	9.3%	
40 km/day	52.2%	46.6%	
50 km/day	41.9%	44.1%	
Blisters			
Number of blisters	3.1 (2.0)	3.1 (1.9)	0.98
Presence of denuded blisters	15.4%	21.2%	0.24
Presence of blood blisters	11.0%	5.1%	0.90

Values are presented as means (SD) or as percentages, indicated by %. There were no significant differences between the fixation dressing and the tape group.

**Table 2. Time of treatment application and effectiveness of fixation dressing and adhesive tape**

<u>Variable</u>	<u>Fixation dressing</u>	<u>Adhesive tape</u>	<u>P-value</u>
Treatment duration, min (SD)	41.5 (21.6)	43.4 (25.5)	0.02*
Δ pain score (SD)	-0.80 (2.08)	-0.56 (2.68)	0.53
Drop out, %	11.7	4.0	0.048*
Delayed healing, %	51.9	35.3	0.02*
Infection, %	11.1	16.5	0.28
Additional medical treatment, %	6.5	11.8	0.20
Satisfied with material, %	75	85.3	0.054

\* Statistically significant difference