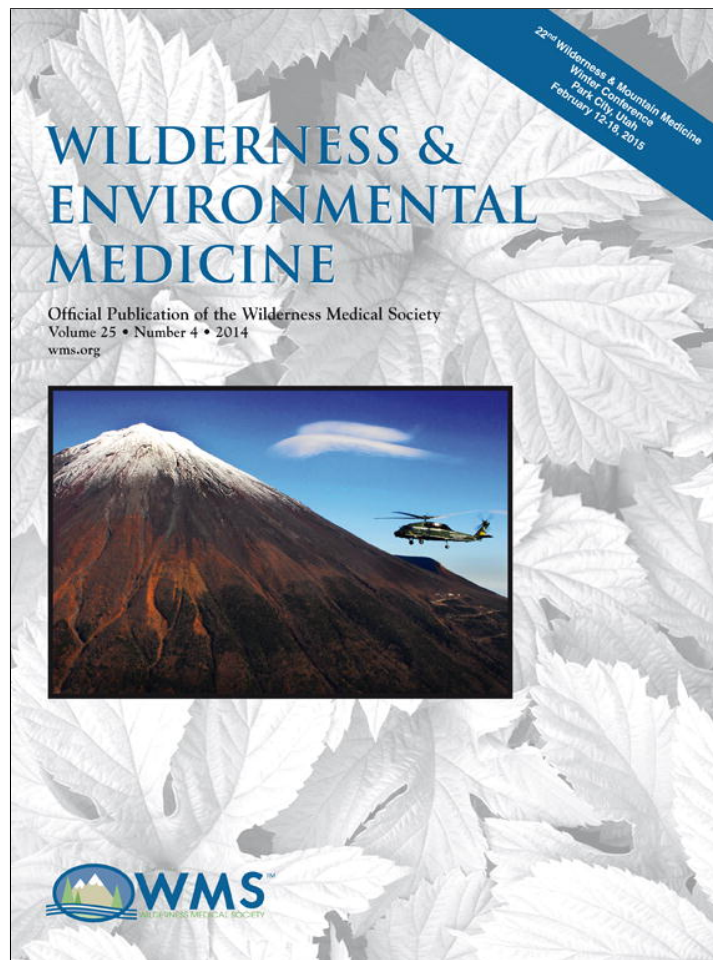


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BRIEF REPORT

## A Prospective Randomized Blister Prevention Trial Assessing Paper Tape in Endurance Distances (Pre-TAPED)

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**Objective.**—Friction foot blisters are a common injury occurring in up to 39% of marathoners, the most common injury in adventure racing, and represent more than 70% of medical visits in multi-stage ultramarathons. The goal of the study was to determine whether paper tape could prevent foot blisters in ultramarathon runners.

**Methods.**—This prospective randomized trial was undertaken during RacingThePlanet 155-mile (250-km), 7-day self-supported ultramarathons in China, Australia, Egypt, Chile, and Nepal in 2010 and 2011. Paper tape was applied prerace to one randomly selected foot, with the untreated foot acting as the own control. The study end point was development of a hot spot or blister on any location of either foot.

**Results.**—One hundred thirty-six participants were enrolled with 90 (66%) having completed data for analysis. There were 36% women, with a mean age of  $40 \pm 9.4$  years (range, 25–40 years) and pack weight of  $11 \pm 1.8$  kg (range, 8–16 kg). All participants developed blisters, with 89% occurring by day 2 and 59% located on the toes. No protective effect was observed by the intervention (47 versus 35; 52% versus 39%;  $P = .22$ ), with fewer blisters occurring around the tape on the experimental foot than under the tape (23 vs 31; 25.6% versus 34.4%), yet 84% of study participants when queried would choose paper tape for blister prevention in the future.

**Conclusions.**—Although paper tape was not found to be significantly protective against blisters, the intervention was well tolerated with high user satisfaction.

*Key words:* blisters, ultramarathon, multistage, feet, prevention, paper tape

### Introduction

Friction foot blisters are one of the most common injuries encountered in hikers, runners, and endurance athletes.<sup>1</sup> Incidence of blisters in marathons have been as high as 39%,<sup>2</sup> and are the most commonly reported injury in adventure racing.<sup>3</sup> In multi-stage ultramarathons, foot care represented 74% of medical visits,<sup>4</sup>

and blister incidence in the military has been reported in more than 30% of active-duty soldiers.<sup>5</sup> Furthermore, 84% of cellulitis in military recruits was determined to be caused by a blister,<sup>6</sup> and those with blisters were found to be 50% more likely to experience additional injuries.<sup>7</sup> Although most blisters in both the tactical and outdoor communities are of minor medical significance, they can impair concentration, decrease athletic performance and enjoyment, and be potentially debilitating.

The etiology of blister formation is multifactorial in nature. Friction and resultant shear stress cause delamination between the epidermal layers of the stratum granulosum and stratum spinosum.<sup>8</sup> This shearing

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causes a cleft that then fills with fluid with a characteristic bullae leading to a friction blister. Prevention of hot spots and blisters by minimizing friction is the premise for most treatments, with a myriad of commercially available adhesive products. Most evidence suggesting effectiveness is anecdotal, and products that have proven efficacy such as Blist-O-Ban (Seaberg Company Inc, Newport, OR)<sup>9</sup> are relatively expensive, limiting its use in certain populations. The purpose of this study was to determine whether application of paper tape was an effective blister prevention method in competitors in multistage ultramarathon foot races.

## Methods

This study was a randomized, prospective cohort trial in RacingThePlanet 150-mile (250-km), 6-stage, ultramarathon foot races through diverse wilderness terrain. These races had 4 sequential 25-mile (40-km) days, a combined fifth and sixth day of 50 miles (80 km), and finishing with a 10-mile (16-km) day. Participants carried all their own equipment for the duration of the race, including a minimum of 2000 cal/day, and offered 1.5 L of water per 6 to 7 miles (10–12 km). Study participants were entrants in the Gobi Desert, China (2010), Kimberly, Australia (2010), Sahara, Egypt (2010, 2011), Atacama, Chile (2011), and Pokhara, Nepal (2011) races. Approval was obtained from institutional review boards at Stanford University School of Medicine, University of Washington Medical Center, and University of California Davis School of Medicine. A description of the trial can be found at ClinicalTrials.gov (identifier: NCT01120808).

All English-speaking race competitors were given the opportunity to enroll at race registration the day before race start, where informed consent was obtained and a questionnaire completed with demographics, equipment, and training data. Exclusion criteria were any blister or hot spot on either foot at the time of enrollment or an allergy to paper tape. Each participant had a foot for the intervention method randomly assigned by coin toss, with their other foot serving as a control. The evening before the first day of racing, 3M Micropore (St. Paul, MN) paper tape was applied by medical staff, who were trained by the study coordinator and study manual in the application procedures. The intervention foot was dried and brushed clean of residual grit, then covered with paper tape at preselected blister-prone areas: the toes (dorsum and plantar distal phalanx), instep (head of 1st metatarsal), outstep (head of 5th metatarsal), and the heel (at the calcaneal tuberosity). All 5 toes had a 0.5- to 1-inch (1.3- to 2.5-cm) wide longitudinal strip of tape applied along the dorsum and plantar aspects of each toe



**Figure 1.** Example of pre-taped foot.

covering the distal phalanx and nail bed. Another piece of tape was applied circumferentially around each toe at the distal phalanx, with the cut ends of the tape located on the dorsum of the toe. The width of the tape size depended on adequate coverage based on a subject's toe size. The 1st and 5th metatarsal heads were taped with 2-inch (5.1-cm) wide strips perpendicular to the foot axis, and the heel was taped with a 2-inch (5.1-cm) wide horizontal piece of paper tape covering the calcaneal tuberosity (Figure 1). Tape corners were smoothed flat. After the initial application of tape, either the participant or medical personnel could reapply at any time on the course or at the camp medical tent as necessary for the duration of the study. The study end point was the development of a hot spot or blister (described as "blister") on either foot. At the time of study end, an exit questionnaire was completed.

Sample size was calculated to achieve 80% power ( $\alpha = 0.05$ , 2-tailed test), assuming the incidence of blisters at 35%; 82 total participants were required to detect a significant difference, defined a priori as a reduction in blister incidence of 25%. Outcome measures were analyzed by  $\chi^2$  test and independent samples *t* test. A probability value of less than .05 was considered significant. All analysis was by SPSS software (SPSS version 19.0, Somers, NY).

## Results

One hundred thirty-six participants were enrolled, with 90 (66%) completing data collection and included for intent-to-treat analysis (Figure 2). Participant demographics and training characteristics are described in Table 1. As all the events had approximately equal distances, caloric, and logistical demands, the study participants were combined into a single cohort for analysis. All participants' feet developed blisters (100%) without a statistically significant effect by the intervention (47 vs 35; 52.2% vs 38.8%;  $P = .22$ ), with

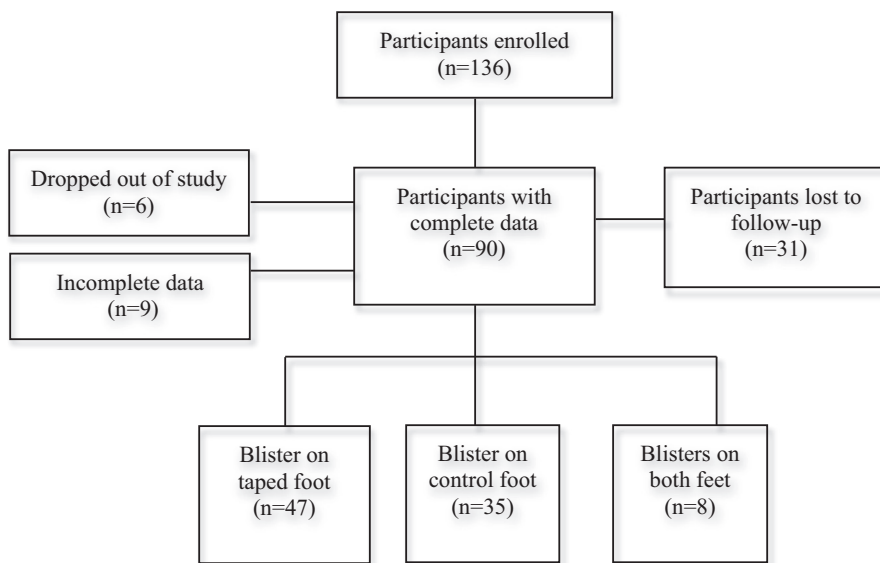


Figure 2. Participant flow chart.

fewer blisters occurring around the tape on the experimental foot than under the tape (23 vs 31; 25.6% vs 34.4%). The most common location to have a blister was on the toe (Table 2), with the majority of blisters occurring on the first 2 days of the race (Table 3). Tape was reapplied on 75 (83%) of participants' feet, in 70 cases (93.3%) by the runners themselves.

Table 4 shows variables associated with blister development. Hand dominance was associated with a significant decrease in blisters when the ipsilateral foot was taped. Factors found to significantly increase blisters on the experimental foot included lower pack weight to body weight ratio and use of Injinji (San Diego, CA) style toe socks, with 40 (44%) of the study participants wearing Injinji socks. The usual blister prevention methods used by the study participants included

lubrication (22.2%), tape (13.3%), a nonspecified intervention (0.02%), or nothing at all (62.2%). When queried at trial completion, the majority of the athletes would choose to use paper tape for blister prophylaxis in the future (84% vs 16%).

Discussion

This was the first trial to examine blister prevention in a multi-stage ultramarathon, as well as the largest study to date that evaluated an adhesive's effects on blistered feet. Paper tape was not found to be an efficacious blister prophylactic and may have increased blisters, especially when used with Injinji socks. As 84% of the study participants would use paper tape for blister prevention in the future, we suspect that the intervention reduced friction directly below the application site, but methodological limitations may have underestimated intervention efficacy.

The toes accounted for 52% of blisters, and 66% of all blisters were encountered on day 1 of the 6-stage race, with 89% of blisters by the end of day 2. This information could prove helpful to running enthusiasts who, if choosing to pretape, apply the tape at the beginning of the race. Also, those wearing Injinji socks should consider avoiding toe taping as the separated toe coverings may have compounded friction (rather than minimizing it) and led to the observed increase of blister formation with paper tape. Furthermore, the high incidence of tape reapplication (anecdotally caused by water crossings) lends this intervention to drier environments, and the readers should prepare for reapplications while crossing endurance distances.

Table 1. Demographics of study participants

	N	Mean	Range	SD
Age (y)	90	39.7	25–64	9.4
Height (cm)	88	173.5	147–195	8.5
Weight (kg)	87	72.3	46–108	11.8
BMI (kg/m <sup>2</sup> ) <sup>a</sup>	86	24.0	17.3–32.9	3.0
Pack weight (kg)	90	10.7	8–16	1.8
Prior marathons	89	4.3	0–50	7.7
Prior staged ultramarathons	89	1.4	0–20	2.9
Prior continuous ultramarathons	88	0.8	0–20	2.5
Run training (km/wk)	90	43.7	0–120	26.0
Walk training (km/wk)	90	20.9	0–150	27.9

<sup>a</sup> 1 participant did not record height, 1 did not have height and weight, and 2 were missing weight only. BMI, body mass index.

**Table 2.** Blister location

	Study participants (%)	Blisters (N)	Toe (%)	Web space (%)	Heel (%)	Instep (%)	Outstep (%)	Other (%)
Taped foot <sup>a</sup>	47 (52.2)	50	27 (54.0)	0	14 (28.0)	3 (6.0)	3 (6.0)	3 (6.0)
Control foot <sup>b</sup>	35 (38.8)	37	16 (43.2)	6 (16.2)	4 (10.8)	5 (13.5)	0	6 (16.2)
Both feet	8 (8.8)	16	11 (68.7)	0	5 (31.3)	0	0	0
Total	90	103	54 (52.4)	6 (5.8)	23 (22.3)	8 (7.8)	3 (2.9)	9 (8.7)

<sup>a</sup> 3 participants with 2 blisters.

<sup>b</sup> 1 participant with 3 blisters.

The association of lower pack weight to body weight ratio with increased blister formation with paper tape is somewhat counterintuitive, as it has been assumed that increased normal force would increase friction and subsequent blister formation. The lower pack weight ratio may have resulted in faster run times and subsequent shearing forces; however, additional studies are needed to further elucidate this relationship. An increased training distance average did not affect blister development, although our sample size is likely somewhat skewed owing to the nature of the participants in ultramarathons. Also, the age of running shoes worn by participants did not appear to statistically worsen the chances of blister formation, with shoes ranging from brand new and less than 1 month old, whereas others were beyond 5 months. Newer shoes are assumed to

have less flexibility and potentially create more areas of friction, although many ultrarunners frequently compete in shoes a ½ to a full size larger than normal to accommodate anticipated swelling. There are multiple variables at play in an ultramarathon that affect race success, failure, and blister occurrence—further studies are needed to explore the relationships between the above predictors and outcome variables to optimize the multi-stage ultramarathon experience.

**Limitations**

Our study methodology taped the majority of common blister sites on one randomly assigned foot, based on the notion that larger coverage would provide greater protection and allow us maximal insight into intervention

**Table 3.** Day of blister occurrence

	N	Day 1 (%)	Day 2 (%)	Day 3 (%)	Day 4 (%)	Day 5 (%)	Day 6 (%)
Taped foot	47	30 (63.8)	10 (21.3)	4 (8.5)	1 (2.1)	1 (2.1)	1 (2.1)
Control foot	35	21 (60.0)	11 (31.4)	3 (8.6)	0	0	0
Both feet	8	8 (100)	0	0	0	0	0
Total	90	59 (65.6)	21 (23.3)	7 (7.8)	1 (1.1)	1 (1.1)	1 (1.1)

**Table 4.** Variables associated with blister development

Variable	Experimental foot with blister (SD)	Experimental foot without blister (SD)	P value	95% CI
Ipsilateral hand dominance	29%	32%	< .001	— <sup>a</sup>
Lower pack weight to body weight ratio	0.15 (0.03)	0.16 (0.03)	.03	0.001–0.031
Injinji	34%	27%	.02	— <sup>a</sup>
Average weekly training (km)	42.2 (26.9)	46.1 (24.6)	.48	–7.23 to 15.2
Pack weight (kg)	10.6 (1.82)	10.9 (± 1.88)	.53	–0.544 to 1.05
Shoe age	New = 14% 1–2 mo = 40% > 5 mo = 8%	New = 13% 1–2 mo = 18% > 5 mo = 7%	.32	— <sup>a</sup>

<sup>a</sup>  $\chi^2$  test for dichotomous outcomes.

efficacy. However, comparison of a control foot against an experimental foot denied us an external benchmark and limited our ability to assign quartiles or analyze subgroups. One of the subgroups of interest was the area under the paper tape, where injury-inducing shear stress would likely be most reduced. Although these covered locations did not have a lower incidence of injury, further study comparing the area under the paper tape compared with the area around the tape could provide a more accurate indication of intervention success or failure.

Participants were not blinded to outcomes; as the end-of-study data collection was by self-reported questionnaire, it was logistically unavoidable. Although all study participants were requested to avoid taping the control foot, we could not standardize other foot-care measures such as lubrication or powders, possibly leading to unknown variables affecting outcomes. Although each race studied was similar in duration and distance, unique environmental factors such as humidity, river crossings, or sand dunes may have affected the paper tape and subsequent blister formation that was not accounted for.

### Conclusion

This study shows that paper tape is an inexpensive and easy-to-apply blister prophylactic that, although not significantly protective, was found to have high user satisfaction. Further paper tape trials should compare blisters occurring under the tape with blisters on the rest of the uncovered foot for improved evaluation of treatment efficacy.

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