Paper Tape Prevents Foot Blisters: A Randomized Prevention Trial Assessing Paper Tape in Endurance Distances II (Pre-TAPED II)

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Objective: To determine whether paper tape prevents foot blisters in multistage ultramarathon runners.

Design: Multisite prospective randomized trial.

Setting: The 2014 250-km (155-mile) 6-stage RacingThePlanet ultramarathons in Jordan, Gobi, Madagascar, and Atacama Deserts.

Participants: One hundred twenty-eight participants were enrolled: 19 (15%) from the Jordan, 35 (27%) from Gobi, 21 (16%) from Madagascar, and 53 (41%) from the Atacama Desert. The mean age was 39.3 years (22-63) and body mass index was 24.2 kg/m^2 (17.4-35.1), with 31 (22.5%) females.

Interventions: Paper tape was applied to a randomly selected foot before the race, either to participants' blister-prone areas or randomly selected location if there was no blister history, with untaped areas of the same foot used as the control.

Main Outcome Measures: Development of a blister anywhere on the study foot.

Results: One hundred six (83%) participants developed 117 blisters, with treatment success in 98 (77%) runners. Paper tape reduced blisters by 40% ($P < 0.01$, 95% confidence interval, 28-52) with a number needed to treat of 1.31. Most of the study participants had 1 blister (78%), with most common locations on the toes (n = 58, 50%) and heel (n = 27, 23%), with 94 (80%) blisters occurring by the end of stage 2. Treatment success was associated with earlier stages [odds ratio (OR), 74.9, $P < 0.01$] and time spent running (OR, 0.66, $P = 0.01$).

Conclusion: Paper tape was found to prevent both the incidence and frequency of foot blisters in runners.

Key Words: blisters, feet, ultramarathon, runners, injury prevention, paper tape

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INTRODUCTION

Friction foot blisters are one of the most common injuries encountered in hikers, runners, and endurance athletes.[1] Although most are of minor medical significance, they can impair concentration, decrease athletic performance and enjoyment, and be potentially debilitating. Blister rates in the outdoor community range from 54% of backpackers to 64% of long-distance hikers.[2,3] Blister incidence in marathons has been reported as high as 39%[4] and 76% to 100% in multistage ultramarathon runners.[5,6] Foot blisters have been the most commonly reported injury in adventure racing[7] and are the most common factor that adversely affects performance in single-stage ultramarathon finishers.[8] Foot care accounts for 20% of all medical visits in marathons[9–12] and up to 76% of medical visits in multistage ultramarathons.[13,14] In addition to sports and outdoor recreationalists, blister prevention is a problem in both training and active duty military personnel. Studies report blister rates of 48% to 65% after short marches[15,16] in 57% of trainees[17] and 33% during a 12-month period of deployment.[18] Furthermore, 84% of cellulitis in military recruits was caused by blisters, with an average loss of 8 training days per case.[19] Sixteen percent to 22% of those affected with blisters received temporary duty restrictions, which may impact troop readiness.[20] There is currently no proven efficacious technique for blister prevention.

Blister injury arises from friction between the skin and another object.[21–23] The skin surface is subjected to normal forces (F_n), the perpendicular force or "force of contact," and tangential shear forces.[24] When an external force is applied at

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The preventive taping techniques studied are promoted in Dr Lipman's book, "The Wilderness First Aid Handbook" and app: www.wildernessaid.com. The other authors report no conflicts of interest.

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the skin interface, small irregularities create an opposing frictional force (F_f), which prevents sliding across the skin.[23,25] The magnitude of a frictional force is defined by the formula: $F_f = \mu \times F_n$, where μ is the coefficient of friction or ratio of shear force to normal force.[25] When external forces exceed the opposing frictional force, movement occurs at the skin surface interface and shear stress extends horizontally between the skin layers.[26] Repeated sliding at a friction point causes exfoliation of the stratum corneum with development of erythema and a sensation of warmth, the "hot spot."[23,24] Continued friction causes delamination between the cells of the stratum spinosum, and a cleft forms that then fills with a low-protein transudate resulting in a blister.[21,24,27,28]

Despite extensive studies on the impact of shear forces on blister development, there has been scant research on the efficacy of various blister prevention modalities (eg, powders, antiperspirants, lubricants, tapes, or adhesive pads). In our previous blister prevention study in multistage ultramarathon runners (Pre-TAPED), we found that paper tape applied to the majority of common blister-prone areas of one foot compared with the other untaped foot was not efficacious.[6] As paper tape was well tolerated and 84% of the study participants would choose to use it again for blister prevention, we believed that the study's methodology limited insight into the reduced shear-stress area under the tape itself compared with the surrounding skin, and subsequently may have underestimated the effectiveness of paper tape. Therefore, we wanted to investigate the individual's blister-sensitive areas with focal preventive taping. The objective of this study was to examine whether paper tape could prevent hot spots and blisters on specific blister-prone areas in multistage ultramarathon runners.

FIGURE 1. Example of a pretaped foot.

METHODS

Setting and Selection of Participants

This randomized, prospective cohort trial was undertaken during the 2014 RacingThePlanet 250-km (155-mile), 6-stage, ultramarathon foot races through the Gobi Desert in China, Atacama Desert of Chile, Jordan, and Madagascar Deserts. These races had 4 consecutive 25 mile (40 km) days, a combined fifth and sixth day of 50 miles (80 km), and finished with a 5 to 6 mile (10 km) day. Participants carried their own equipment for the duration of the race, including a minimum of 2000 calories per day and were offered 1.5 L of water per 6 to 7 miles (10-12 km). As each race had similar distances and logistical demands, the cohorts were combined for analysis. Approval was obtained from the institutional review boards of Stanford University School of Medicine and Resurrection Medical Center. ClinicalTrials.gov identifier: NCT01945112.

Research Design

All English-understanding race competitors were provided the opportunity to enroll at race registration the day before the race start, and informed consent was obtained before completing a demographics questionnaire. 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 an intervention foot randomized by coin toss (with the opposite foot not studied). Paper tape was applied by medical staff trained in application procedures described by study manual and on-site researcher the evening before the first day of racing. The intervention foot was dried and brushed clean of residual grit, then covered with 2.5-cm (1-inch) 3M

TABLE 1. Demographic Data

Variable	Mean	Range	SD
Age, yrs	39.3	22-63	8.3
Height, cm	175.1	144-201	9.1
Weight, kg	74.5	44-105	12.9
BMI, kg/m^{-2}	24.2	17-35	3.0
Pack weight	10.3	6-25	2.4
Geographic area			
North America	37		
South America	5		
Asia*	16		
Africa	3		
Oceana*	18		
Europe	48		
Russia/Eurasia	2		

N = 128, 31 (24%) females.
*1 participant from both Asia and Oceana; Oceana = Australia and New Zealand.

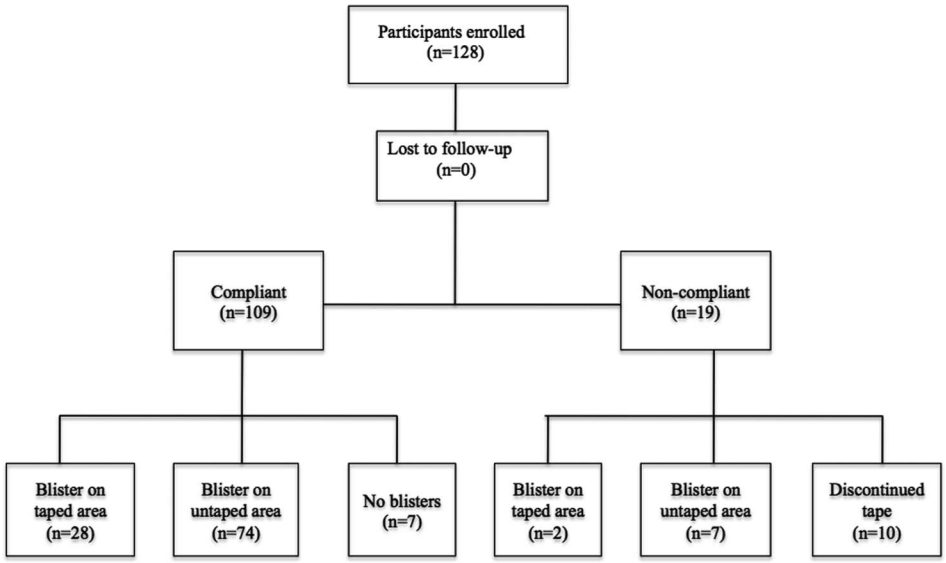

FIGURE 2. CONSORT study diagram.

Micropore™ paper tape (3M, St Paul, Minnesota) at the participant's blister-prone area(s) (directed application). If the study participant was not susceptible to blisters, 1 randomly selected area was chosen (undirected application) based on the most common blister locations: a toe, instep (head of the first metatarsal), outstep (head of the fifth metatarsal), or the heel (calcaneal tuberosity).[5,6] Toes were taped with a 1.3- to 2.5-cm (0.5- to 1-inch)-wide longitudinal strip of tape applied along the dorsum and plantar aspects that covered 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 first and fifth metatarsal heads were taped with a 5.1-cm (2-inch)-wide strip perpendicular to the foot axis, and the heel was taped with a 5.1-cm (2-inch)-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 tape at any time on the course or at the 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") anywhere on the randomly chosen foot, with the uncovered portion of the same foot serving as the control. When the study end point was reached, an exit questionnaire was completed.

Statistical Analysis

The sample size was calculated to achieve 80% power ($\alpha = 0.05$, 2-tailed test). Based on our previous work with paper tape in similar races, we assumed that a single foot would have a blister rate of at least 35%.[6] A total of 82 participants were required to detect a significant difference, defined a priori as a reduction in blister incidence of 25%. Outcome measures were analyzed by the χ^2 test and independent samples *t* test, with independent predictors of the number of blisters analyzed by analysis of variance and logistic regression for treatment success (defined as no blister development underneath the paper tape). Time-adjusted incidence [incidence density rate (IDR)] of the outcome measure was calculated by stage times of blister occurrence, and participants' performance was analyzed per quintile of finishers (eg, >10%, >10%-25%, >25%-50%, >50%-75%, >75%). $P < 0.05$ was considered significant. All analysis was done with R statistical computation software version 3.1.1.

RESULTS

One hundred twenty-eight participants were enrolled, with 19 (15%) participants from the Jordan, 35 (27%) from Gobi, 21 (16%) from Madagascar, and 53 (41%) from the Atacama Desert. Table 1 describes the characteristics of the study cohort, and the participant flow diagram is shown in Figure 2. For all study participants, there were a total of 240 applications of paper tape (Table 2), with a total of 117 blisters that occurred in the locations described in Table 3, most commonly on the toes. The majority of participants developed 1 blister (Table 4), with 94 (80%) of all blisters occurring by the end of stage 2 (Figure 3).

TABLE 2. Paper Tape Application Sites

	Toe, n = 135 (%)	Heel, n = 35 (%)	Instep, n = 46 (%)	Outstep, n = 14 (%)	Ball, n = 7 (%)	Sole, n = 3 (%)
Right foot	85 (63)	23 (66)	30 (65)	10 (71)	4 (57)	1 (33)
Average applications per subject	1.09	0.29	0.38	0.13	0.05	0.01
Left foot	50 (37)	12 (34)	16 (35)	4 (29)	3 (43)	2 (67)
Average applications per subject	1	0.24	0.32	0.08	0.06	0.04

TABLE 3. Blister Locations

	No Blister, n = 23 (%)	Toe, n = 58 (%)	Heel, n = 27 (%)	Instep, n = 15 (%)	Outstep, n = 1 (%)	Ball, n = 10 (%)	Sole, n = 3 (%)
Right foot	15 (65)	37 (64)	18 (67)	10 (67)	0	4 (40)	2 (67)
Average/subject	0.19	0.47	0.23	0.13	0	0.05	0.03
Left foot	8 (35)	21 (36)	9 (33)	5 (33)	1 (100)	6 (60)	1 (33)
Average/subject	0.16	0.42	0.18	0.1	0.02	0.12	0.02

There was no statistical significance when comparing equivalent sites of either feet ($P = 0.93$), an additional area that developed blisters on the left foot only was "under foot" (n = 3, 6%).

A total of 109 (85%) participants were compliant with the study protocol, with 6 reasons for noncompliance found in 19 participants; the most common being lack of adhesion (n = 10, 53%). In those compliant with the protocol, there were 97 blisters (89%), 28 (26%) blisters under the paper tape, and 74 (68%) on the untaped areas. Blisters occurred at uncovered areas rather than underneath the paper tape in 81 (74%) runners. The blister incidence and treatment success per race location is described in Table 5. Intent-to-treat analysis of the 128 enrolled participants found that 106 (83%) developed blisters, with treatment success in 98 (77%) runners. Paper tape had an absolute reduction of blister incidence of 40%, with a number needed to treat of 1.31. There was similar statistical significance observed in both the protocol compliant and noncompliant groups (Table 6). Of the 97 (89%) who had directed application of paper tape, there were 89 (92%) blisters, a treatment success in 70 (72%), with a statistically significant reduction in blister incidence in the taped versus untaped area [$P < 0.01$, 95% confidence interval (CI), 27-55].

Exploratory logistic regression modeling showed that the stage of race was the best predictor of treatment success [odds ratio (OR), 74.9, $P \leq 0.01$, 95% CI, 4.7-3277.7], followed by time spent racing (OR, 0.66, $P = 0.01$, 95% CI, 0.5-0.9) (Figure 4) and opposite dominant handedness (relative to which foot was taped) (OR, 3.7, $P = 0.05$, 95% CI, 1.1-15.2). Variables that were not statistically associated with treatment success included height, age, sex, weight, pack weight, body mass index (BMI), and race performance.

Multiple linear regression and analysis of variance were used to test correlation between the number of blisters and BMI, performance, pack weight, age, and race stage. Stage of race was most strongly correlated ($P < 0.01$, $R^2 = 0.17$). Normalizing for time spent racing, analysis of variance of the number of blisters per hour shows the strongest relationship for race location ($P < 0.01$, $R^2 = 0.19$) and whether tape was reapplied ($P < 0.01$, $R^2 = 0.07$). Factors that did not have a significant association with the number of blisters included age, weight, sex, BMI, use of Injinji socks (San Diego, CA), and pack weight.

TABLE 4. Number of Blisters

	0 Blister (%)	1 Blister (%)	2 Blisters (%)	3 Blisters (%)
Compliant	13 (12)	85 (78)	9 (8)	2 (2)
Overall	25 (20)	91 (71)	10 (8)	2 (1)

DISCUSSION

We found that paper tape had a robust protective effect on blister formation on runners' feet in multistage ultramarathons. Paper tape is an inexpensive, readily available, and easy-to-apply intervention that prevented blisters in approximately 3-quarters of the people who applied it. This study was the first to show that a simple adhesive tape can prevent foot blisters.

Blisters may lead to pain and inability to complete a race, with 6% to 16% of nonfinishers of ultraendurance events citing blisters as the primary reason for withdrawing.[7,13] These rates of nonfinishers due to blisters may be an underestimation because the pain associated with blisters may lead to a modified gait, which can exacerbate underlying injuries.[5,29] Runners citing sprains or muscle injuries as reasons for withdrawal may in fact have blisters that are worsening these injuries. Military trainees with blisters were found to have a higher incidence of overuse injuries, particularly to their knees and ankles,[17,19] and those with blisters were 50% more likely to experience additional injuries.[21]

Prospective studies on blister reduction often examined strategies to decrease friction between the skin and other objects,[21,23,30] because the magnitude of the F_f is the major factor found to contribute to blister formation.[24] Despite over 40 years of clinical trials on blisters, multiple interventions have not provided a solution to this "enemy of the feet." Petroleum jelly was found to increase friction and subsequent blister formation an hour after application.[24] Application of an emollient combined with antiperspirant was not shown to reduce blister incidence,[31] another attempt with antiperspirant alone was more successful,[15] but the excessive irritation in the majority of study subjects has discouraged use except in cases of hyperhidrosis.[15,32,33] A comparison of common blister prevention bandages (eg, Band-Aid, Moleskin, New-Skin, Compeed, Tegaderm) and a proprietary adhesive bandage Blist-O-Ban (Seaberg Company Inc, Newport, OR) found the lowest coefficient of friction in the adhesive pad[34]; however, paper tape was not included for comparison. Paper tape has a lower profile than that of most of these commercially available products, with the added advantage of affordability and ease of application to the toes and intertriginous areas. There was high user satisfaction of paper tape in this study, with 81% of compliant study participants who "agreed" or "strongly agreed" (on a 5-point Likert scale) to use paper tape for blister prevention in the future.

Previous ultramarathon studies have found that the most common location for blisters is the toes, accounting for

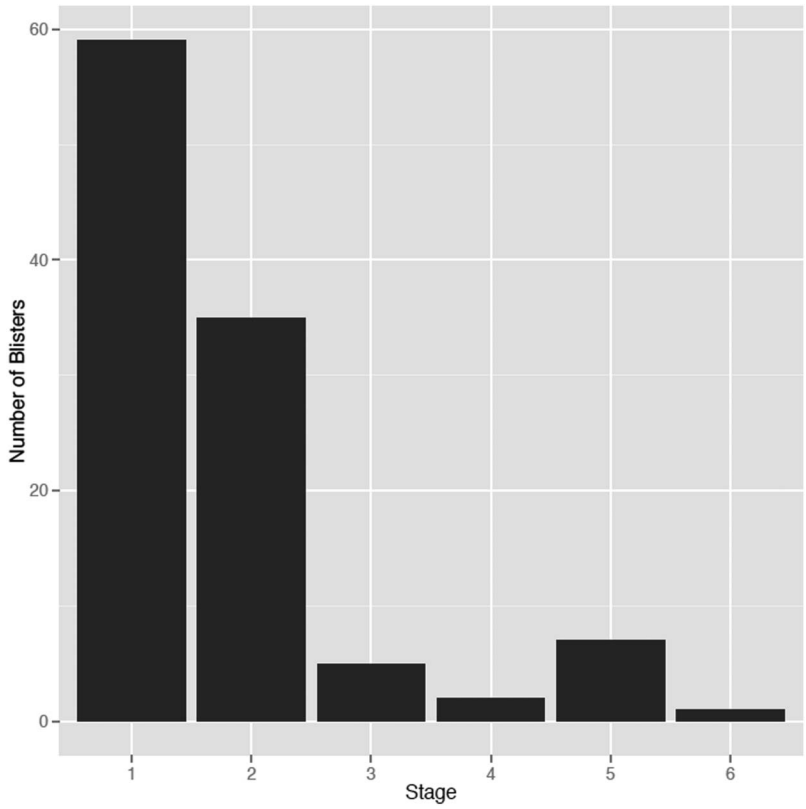

FIGURE 3. Number of blisters per stage of race.

52% to 65% of encountered blisters.[5,6] This locational trend was confirmed in this study with toes representing 56% of pretaped areas, and 50% of blisters occurring on the toes. Increased blister rates on the toes may be due to the greater contact time of this area of the plantar surface, with blister-prone individuals found to have significantly increased pressure and magnitudes of shear stress.[35] Paper tape is uniquely suited to protect these blister-prone areas as its soft surface minimizes abrasion and friction blister development to the neighboring toes.[36]

Contrary to the findings of our smaller previous study,[6] there was no correlation with blisters and Injinji socks, likely because those who wore these toe-separated socks did not get blisters at that location, so chose not to directly apply paper tape to the toes. Injinji socks are popular among ultraendurance runners, used by 45% (n = 49) of our compliant study participants Although we did not see significant correlation with toe blisters and Injinjis, it seems reasonable to avoid the use of paper tape on the toes with Injinji socks.

Feet of ultramarathon runners are exposed to heat, moisture, and repetitive activity for extended periods of time.

TABLE 5. Incidence of Blisters Per Race Location

Location	N	Total Incidence (%)	Treatment Success (%)
Jordan	19	10 (53)	17 (90)
Gobi	35	29 (83)	22 (63)
Madagascar	21	21 (100)	14 (67)
Atacama	53	46 (87)	45 (85)

The number of times a frictional stress is applied has been shown to increase blister rates.[24] By analysis of IDR, we found that those who developed a blister under the tape (treatment failure) encountered it early in the race, whereas those who had treatment success had blisters developing appreciably later in the race in the noncovered locations. Figure 4 supports the efficacy of paper tape for blister prevention. This intervention likely minimized the shear stress at the blister vulnerable areas, as these areas have been found to have a 50% increase in shear time integral values compared with nonblistered sites.[35]

Of the compliant participants, there were 47 people (43%) who reapplied tape a total of 121 times. The need for tape reapplication was associated with an increased number of blisters, although not with treatment success or failure. It stands to reason that race locations (such as Madagascar and the Gobi) with wetter courses may have led to treatment failure by poor tape adhesion as seen by the lowest success rates. These wet conditions are also more apt to contribute to increased blister formation, represented by the greater number of blisters encountered. Repetitive rubbing on moist skin produces higher F_f than on dry or very wet skin.[21,23,27] Wetter environments likely increased the need for frequent reapplications, possibly minimizing the overall benefit of paper tape. Although the most common reason for protocol noncompliance was the lack of tape adhesion, there is a benefit of the weak adhesive qualities of paper tape in that it minimizes the possibility of unroofing a blister upon its removal. The intact superficial epidermal cells of the stratum corneum and stratum granulosum form the blister's "roof." In blister

TABLE 6. Blister Incidence

	N	Taped Area (%)	Untaped Area (%)	Total Incidence (%)	Treatment Success (%)	*P*	Blister Reduction 95% CI	IDR	NNT
Compliant	109	28 (26)	74 (68)	97 (89)	81 (74)	<0.01	29%-55%	7.6	1.35
Overall	128	30 (23)	81 (63)	106 (83)	98 (77)	<0.01	28%-52%	5.4	1.31

NNT, number needed to treat.

prevention and treatment, the maintenance of the roof's integrity optimizes healing rates,[28] which highlights the utility of paper tape for dermatologic maintenance.

There are multiple variables at play over a 155-mile 6-stage ultramarathon that may have an effect on blister incidence and the success of a prophylactic. There was wide variation in treatment success between the study sites, which may be a reflection of these factors, but interrace conclusions are limited by combination of the cohort for study power. Interrace data were combined for the analysis as each race had similar design, length, and logistical demands; as the environmental and race conditions varied between the study locations, this assumption may have led to disparate results. However, our cohort grouping was similar to multiple studies that have combined athletes from different races for analysis.[6,8,38]

The Pre-TAPED II study methodology examined the areas at highest risk for blister development unique to each runner on 1 randomly assigned foot. The study participants directed 92% of the taped areas. Although the larger surface area of the foot that was untaped may have biased the results toward a positive study outcome, the historical predilection of blister development in these taped areas offered greatest protection and thus provided us maximal insight into intervention efficacy.[39]

Participants were not blinded to outcomes, as the end-of-study data collection was by self-reported questionnaire. This was logistically unavoidable. Although all study participants were requested to avoid taping the study foot, we could not standardize other foot care interventions that could possibly have led to unknown variables affecting outcomes.

CONCLUSIONS

We demonstrated than an inexpensive and easy-to-apply adhesive tape prevented foot blisters in runners. Foot care represents a substantial burden on medical teams at these races, and blisters cause significant discomfort to athletes,

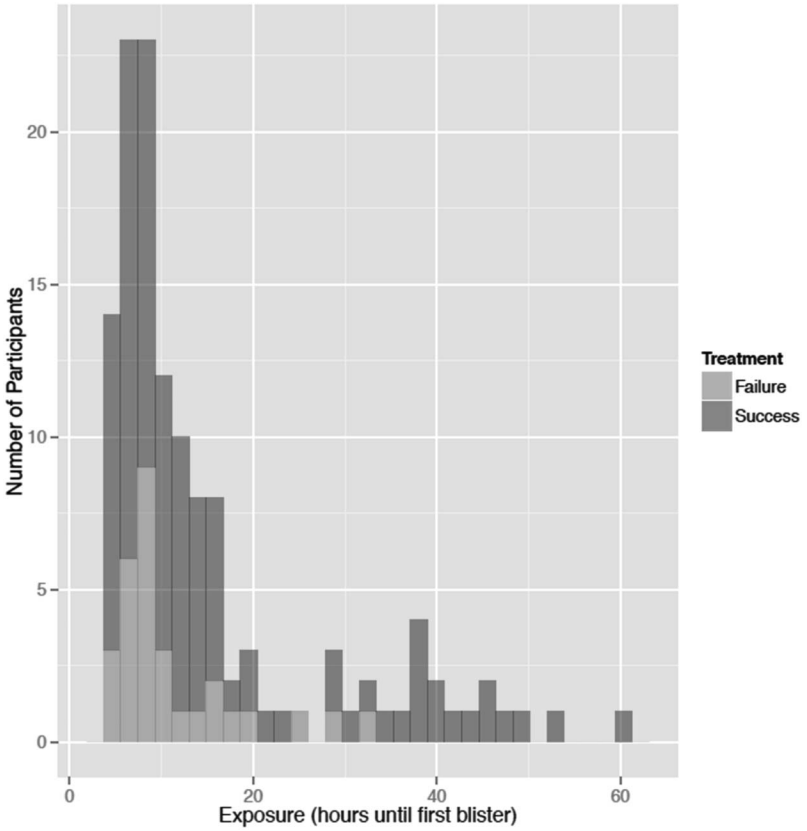

FIGURE 4. Treatment success versus time spent racing.

which may negatively impact race performance. This simple pretaping technique of blister-sensitive areas may substantially improve utilization and enjoyment of the outdoors by minimizing both the number and occurrence of friction foot blisters.

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