A Prospective, Randomized Clinical Investigation of the Treatment of First-Time Ankle Sprains

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Am. J. Sports Med. 2006; 34; 1401 originally published online Jun 26, 2006;
DOI: 10.1177/0363546506288676

Winner of the 1999 O'Donoghue Award

A Prospective, Randomized Clinical Investigation of the Treatment of First-Time Ankle Sprains

Bruce D. Beynnon,*† PhD, Per A. Renström,‡ MD, PhD, Larry Haugh,† PhD, Benjamin S. Uh,† MD, and Howard Barker,† MD
From the †Department of Orthopaedics & Rehabilitation, McClure Musculoskeletal Research Center, University of Vermont, Burlington, Vermont, and the ‡Department of Orthopaedics, Sports Medicine & Arthroscopy, Karolinska Institute, Stockholm, Sweden

Background: Acute ankle ligament sprains are treated with the use of controlled mobilization with protection provided by external support (eg, functional treatment); however, there is little information regarding the best type of external support to use.

Hypothesis: There is no difference between elastic wrapping, bracing, bracing combined with elastic wrapping, and casting for treatment of acute, first-time ankle ligament sprains in terms of the time a patient requires to return to normal function.

Study Design: Randomized controlled clinical trial; Level of evidence, 1.

Methods: Patients suffering their first ligament injury were stratified by the severity of the sprain (grades I, II, or III) and then randomized to undergo functional treatment with different types of external supports. The patients completed daily logs until they returned to normal function and were followed up at 6 months.

Results: Treatment of grade I sprains with the Air-Stirrup brace combined with an elastic wrap returned subjects to normal walking and stair climbing in half the time required for those treated with the Air-Stirrup brace alone and in half the time required for those treated with an elastic wrap alone. Treatment of grade II sprains with the Air-Stirrup brace combined with the elastic wrap allowed patients to return to normal walking and stair climbing in the shortest time interval. Treatment of grade III sprains with the Air-Stirrup brace or a walking cast for 10 days followed by bracing returned subjects to normal walking and stair climbing in the same time intervals. The 6-month follow-up of each sprain severity group revealed no difference between the treatments for frequency of reinjury, ankle motion, and function.

Conclusion: Treatment of first-time grade I and II ankle ligament sprains with the Air-Stirrup brace combined with an elastic wrap provides earlier return to preinjury function compared to use of the Air-Stirrup brace alone, an elastic wrap alone, or a walking cast for 10 days.

Keywords: ankle injuries; ligament injuries; sprains; rehabilitation

Ankle ligament injuries are the most common injuries in sports and physical activity. In the United States alone, there is 1 inversion injury of the ankle per 10 000 persons per day,[9,39,51] resulting in an estimated 23 000 sprains per day. It has been estimated that ankle sprains compose approximately one quarter of all musculoskeletal injuries[27] and that subjects with ankle sprains constitute 7% to 10% of all cases examined at emergency departments of hospitals in Scandinavia.[55] The natural history of ankle ligament sprains is not completely understood, and therefore the exact disability rate associated with this injury is unknown; however, it is thought to be of considerable magnitude.[45]

The management of ankle sprains includes a wide variety of treatment modalities and many different rehabilitation techniques. The current consensus of what is known about the efficacy of the different approaches used to treat these debilitating injuries has come from a series of meta-analyses that have compiled data from published investigations that were based on the highest level of scientific evidence: randomized controlled trials. In the first meta-analysis, Kerkhoffs et al[28] reported that there was "insufficient

*Address correspondence to Bruce D. Beynnon, PhD, Department of Orthopaedics & Rehabilitation, McClure Musculoskeletal Research Center, University of Vermont, Burlington, VT 05405-0084 (e-mail: bruce.beynnon@uvm.edu).

Presented at the 25th annual meeting of the AOSSM, Traverse City, Michigan, June 1999.

No potential conflict of interest declared.

The American Journal of Sports Medicine, Vol. 34, No. 9
DOI: 10.1177/0363546506288676

evidence available from randomized controlled trials to determine the relative effectiveness of surgical and nonsurgical treatment for acute injuries of the lateral ligament complex of the ankle." The second established that immobilization of the ankle with a cast delayed a patient's return to work and sports and was associated with increased swelling compared with controlled mobilization with the use of protection provided by external support (referred to as functional treatment).[29] There was no difference between the treatments with regard to reinjury rates, ankle motion, and pain. The third meta-analysis focused on functional treatment and revealed inconsistency of reported follow-up intervals and a wide variety of treatments in the randomized trials available at the time.[30] Consequently, it was impossible for the authors to make definitive conclusions about the most effective functional treatment.

Our review of original investigations revealed that many different approaches have been used to treat ankle ligament injuries, and although the treatment has typically been matched with the severity of injury, a majority of studies have included subjects who suffered their first injury combined with those who suffered repeated injuries of this kind. This is a concern because depending on the type of ankle ligament injury that is suffered and the subsequent healing response, the outcome of a first-time ankle injury may be different than the outcome of repeated ankle injuries. Many uncontrolled, nonrandomized studies of grade II sprains have advocated primary repair of torn ankle ligaments, citing satisfactory subjective results and mechanically stable ankles[§]; however, an equal number of studies have reported similar satisfactory results after functional treatment.[1,14,20-23,36,40] Treatment of grade III lateral ankle ligament sprains has also generated much controversy in the literature, although in this case, some prospective, randomized clinical trials have been conducted.[‖] Treatment with operative repair and cast, immobilization with a cast alone, or early functional treatment has resulted in a 1-year prognosis that was excellent or good for most patients.[10,17,19,35,41,52,54] Functional treatment provided the quickest recovery to full range of motion and return to work and physical activity, and it did not compromise the mechanical stability of the joint when healing was complete.

The literature, current opinion, and practice patterns all support functional treatment rather than surgical repair of acute grade I, II, and III tears of the lateral ankle ligaments. There is, however, little information regarding the best type of functional treatment for these severe injuries. The objective of this prospective, randomized trial was to compare treatment with early, controlled mobilization with different types of external support (functional treatment) for subjects who had sustained their first grade I and II sprain of the lateral ankle ligaments and to compare functional treatment versus immobilization for subjects who suffered their first severe grade III sprain. The primary hypothesis was that no difference exists between elastic wrapping, bracing, bracing combined with elastic wrapping, and casting treatments of first-time ankle sprains in time to return to normal, or preinjury, activity level. The secondary hypotheses were that no difference exists between these same treatments in the time to return to full weightbearing, experience no pain during weightbearing, achieve full capability in function at normal activities of daily living, return to full capability in work or school activity, and return to full capability at usual athletic and recreational physical activity. A 6-month follow-up was completed to evaluate the tertiary hypothesis that no difference exists between the treatments in terms of patient function, reinjury rates, and ankle motion.

METHODS

This prospective clinical study of acute ankle sprains was designed to compare different treatments of grade I, II, and III sprains of the lateral ankle ligaments. The study was approved by our universities' committees on human research, and all subjects provided informed consent before participation.

Inclusion/Exclusion Criteria

This was a community-based study of first-time ankle sprains in skeletally mature subjects who did not have congenital deformity or degenerative conditions. Between April 1993 and June 1998, all subjects who had sustained an ankle injury and visited the emergency departments of our 2 university-affiliated hospitals, had visited the university's student health center, or were university athletes who had consulted trainers at the university were invited to participate in this study. Subjects were included only if they presented to our clinic within 72 hours after the initial ankle trauma. They were excluded if they had experienced or exhibited any of the following conditions: had a previous sprain of either ankle; had abnormal gait before injury; had a previous fracture in either ankle within the past 12 months; showed radiographic evidence of a fracture at the time of presentation; showed radiographic evidence of a syndesmosis injury, burns, lacerations, or puncture wounds; had open tibial epiphyses; were younger than 16 years or older than 65 years; were pregnant or planning on becoming pregnant; had chronic illnesses, metabolic disease, or neurologic disease; or were unwilling to adhere to the prescribed treatment program.

Classification of Ankle Injury

Within 72 hours after the initial ankle trauma, subjects visited our sports medicine clinic for classification of ankle injury. Classification of ankle injury severity is challenging because there are several grading systems available that vary with the number of ligaments involved and the severity of injury. We chose to use the classification system described by Bergfeld et al.[6] A grade I injury includes a partial tear of the lateral ligament complex. A grade II injury involves decreased motion and some loss of function, a torn anterior talofibular ligament with an intact calcaneofibular ligament, some ligamentous instability (eg, positive anterior drawer and negative talar tilt results), swelling and

[§]References 3, 8, 24, 34, 44, 48, 50, 51, 53.
[‖]References 10, 12, 16, 17, 19, 32, 35, 41, 43, 46, 52, 54.

hemorrhage, and point tenderness. A grade III injury involves almost total loss of function, diffuse swelling and hemorrhage, extreme point tenderness, disruption of the ankle capsule, and a complete tear of the lateral ligament complex as evidenced by marked ligamentous instability (eg, positive anterior drawer and talar tilt test results). To validate the grading system, 2 examiners examined and graded the first 20 patients in a single blinded fashion; the results were identical.

Randomization and Treatment

Subjects were then randomized to a treatment group according to the grade of the ankle sprain, sex, and age. Treating clinicians and subjects were blinded to the randomization process, and the assigned treatment was concealed within an envelope before allocation. A block randomization procedure was used so that the treatment schedule was arranged in blocks, with each block containing each treatment once. For example, there were 4 treatment methods for grade II ankle sprains. Because we had 4 treatment methods and planned to test a total of 80 subjects with this injury, there were 20 blocks. The first block contained a random ordering of the 4 treatment methods, the second block contained an independent random ordering of the 4 conditions, and so on. Each random sequence of the 4 treatments obtained from a table of random numbers composed a separate block.

Patients with a grade I ankle sprain were treated with an elastic wrap (Ace), Air-Stirrup ankle brace (Aircast, Inc, Summit, NJ), or an Air-Stirrup ankle brace combined with an elastic wrap (Figure 1). Those with a grade II sprain were treated with an elastic wrap, Air-Stirrup ankle brace, Air-Stirrup ankle brace combined with an elastic wrap, or a fiberglass walking cast worn for 10 days followed by the use of an elastic wrap. Subjects with a grade III ankle sprain were randomized to treatment with either the Air-Stirrup ankle brace or a fiberglass walking cast worn for 10 days followed by the use of an elastic wrap.

Figure 1. View of the Air-Stirrup brace combined with the elastic wrap.

Rehabilitation Program

Other than the before-mentioned treatment options, all subjects underwent the same care administered by the same clinicians at the same clinic. All subjects followed the same standardized home rehabilitation program that was provided through written instructions and oral directions. Rehabilitation involved 3 phases. Phase 1 occurred during the first week after the baseline visit. During this time, subjects were instructed to use crutches as needed, perform swelling control with ice (eg, administer ice for 15-20 minutes, every 3-4 hours, for 72 hours after injury), and elevate the injured ankle above heart level for 15 minutes every 3 to 4 hours during the first 72 hours after injury. Range of motion exercises were performed, including passive range of motion, Achilles tendon stretching, and ankle circles. Subjects were allowed to begin with toe curl, ankle inversion, and ankle eversion exercises with a towel and progress to swimming, walking, and riding a stationary bike when they felt comfortable doing so. During phase 2, subjects initiated contrast treatments (eg, alternate use of heat, followed by cold), and strength training progressed to isometric eversion, inversion, and dorsiflexion and plantarflexion exercises. This was followed by dynamic exercises (heel and toe raises) and then single- and double-leg balance training. Once the subject had completed phases 1 and 2, was pain free, and obtained full range of motion, the subject progressed to phase 3. This involved agility drills (eg, directional walking, jumping-hopping, and running activities), sport-specific drills, balance-board training, and elastic resistance training with a Thera-Band. After the subjects' strength had returned to normal, they continued with balance exercises and gradual return to sports.

Primary and Secondary Outcome Measures: Baseline Through Day 21 or Until the Patient Healed

At the baseline visit, subjects were given a daily log and instructed how to use it at home. The log contained questions that the subjects answered by indicating their responses on a visual analog scale. Each day, the subjects indicated their status with regard to return to walking a minimum of 1 block and climbing a minimum of 1 flight of stairs in the same way they did before ankle injury, placing

full weight on the ankle without a limp (primary outcome). They also documented their status with regard to tolerating full weightbearing, experiencing no pain during weightbearing, achieving full capability in function of normal activities of daily living, returning to full capability in work or school activity, and returning to full capability at usual athletic and recreational physical activity (secondary outcomes).

Thus, for each ankle sprain group (grades I, II, and III), the log allowed us to measure the primary outcome (ie, the time required to return to walking a minimum of 1 block and climbing a minimum of 1 flight of stairs as was done before ankle injury, placing full weight on the ankle without a limp) and secondary outcomes (ie, the time required for subjects to return to full weightbearing, experience no pain during full weightbearing, obtain full capability in function at normal activities of daily living, return to full capability in work or school activity, and return to full capability at usual athletic or recreational physical activity). These primary and secondary outcomes were evaluated with the daily log for 21 consecutive days after the baseline visit, and if necessary, this continued until the subjects could walk and climb stairs as they did before the initial injury.

Patient Function and Ankle Motion: Tertiary Outcomes Obtained at 6-Month Follow-Ups

Patient function and ankle motion were evaluated at the baseline and 6-month follow-up visits. Measures included demographic data, history of present ankle sprain (or reinjury at the 6-month follow-up), and Karlsson's functional scoring scale (an evaluation of pain, disability, and activity limitation).[26] Plantarflexion and dorsiflexion motion of the normal and injured ankles was evaluated with a handheld goniometer at the baseline and 6-month follow-up visits. Dorsiflexion motion was evaluated relative to the neutral position with the subject actively dorsiflexing the ankle and establishing the limit of motion, whereas plantarflexion motion was measured relative to the same neutral position with subject actively plantar flexing the ankle to establish the limit of motion.

At the 6-month follow-up, the single-legged hop and toe raise tests were performed. For the single-legged hop, subjects were instructed to jump and land as far as they felt comfortable on their noninjured legs. Two jumps were attempted and the mean recorded. This was repeated on the injured leg. Next, subjects stood on an inclined board and were instructed to perform toe raises by bearing weight on their toes and elevating their heels to a maximum height. This was done individually on the injured and uninjured ankles during 15-second intervals. The number of toe raises was recorded for injured and uninjured limbs.

Statistical Analyses

A power analysis was performed to estimate the sample size necessary to test our primary hypothesis, and this showed that 20 subjects were required for each treatment group. Thus, our initial goal was to recruit a total of 180 subjects: 60 subjects with grade I sprains, 80 with grade II sprains, and 40 with grade III sprains.

An intent-to-treat analysis was used. For the primary outcome of time required to return to normal (preinjury) activity (ie, walking and stair climbing), we viewed the statistical tests of our hypotheses in a "survival analysis" mode. Because it was possible that normal function was never achieved by a select subset of the treated subjects, analysis of the data at the 6-month follow-up took into account the percentage of subjects not completely cured. In addition, there were censored data because of subjects' noncompliance with the study protocol or the fact that some subjects moved away from the geographic area in which our study was conducted. These data were handled by log-rank and other parametric likelihood methods. Event-time distributions were estimated and displayed nonparametrically by the Kaplan-Meier method. Differences between treatment groups were tested nonparametrically by log-rank tests. Alternative nonparametric tests were done to confirm that the conclusions were robust to the methods used. Secondary outcomes were analyzed in a similar manner. Karlsson's functional scoring scale, ankle motion, and single-legged hop and toe raise tests were treated as continuous data. Treatment group comparisons were performed with analysis of variance and post hoc testing, although nonparametric rank tests were also performed to check that the conclusions were robust to the data distribution assumptions.

RESULTS

Between April 1993 and June 1998, 1310 patients with ankle sprains were invited to participate. Two hundred twelve of these patients experienced their first ankle sprain, satisfied the inclusion criteria, and provided consent to participate. This group comprised 64 (30%) grade I sprains, 116 (55%) grade II sprains, and 32 (15%) grade III sprains. A total of 172 subjects (81% of those initially enrolled) completed the baseline and primary/secondary outcome measures (ie, the baseline and daily log outcomes). Of these, 52 were grade I sprains (81% of subjects initially enrolled), 93 (80%) were grade II sprains, and 27 (84%) were grade III sprains. One hundred thirty subjects (61%) completed the baseline, primary/secondary outcome response and tertiary outcomes obtained at the 6-month follow-up. These subjects were distributed as follows: 44 (69%) had grade I sprains, 68 (59%) had grade II sprains, and 18 (56%) had grade III sprains.

The randomization procedure created a homogeneous sample of subjects. Subjects were of similar age, body mass index, sex, and activity levels between treatments for each ankle sprain severity group (Tables 1 and 2). Subjects suffering a grade I sprain were competing in sports (34%), at home (47%), at work (15%), or participating in some other activity (5%) when the injury occurred. Similarly, subjects suffering a grade II sprain were participating in sports (39%), at home (40%), at work (17%), involved in an auto accident (1%), or taking part in some other activity (3%) at the time of injury. Those suffering a grade III sprain were

TABLE 1
Age of Subjects Entered Into Study by Treatment Within a Grade

	I			II				III	
Age	Elastic Wrap	Air-Stirrup Ankle Brace	Air-Stirrup Ankle Brace With Wrap	Elastic Wrap	Air-Stirrup Ankle Brace	Air-Stirrup Ankle Brace With Wrap	Cast	Air-Stirrup Ankle Brace	Cast
Age, y									
Mean	29.6	27.3	31.2	29.3	31.2	31	31.9	25.5	27.5
Median	28	22	26	28	28	28	32	26	26
SD	10.2	10.1	13.4	8.4	11.5	9.3	8.2	5.5	7.8
Range	17-58	16-47	16-61	19-45	16-59	17-58	20-47	17-33	17-46
Analysis of variance/*P*	.5446			.8194				.4528	

taking part in sports (71%), at home (26%), or working (3%) at the time of injury.

The position of the ankle when the injury occurred was reported to be predominantly inversion for all ankle sprain severity groups. Subjects experiencing a grade I ankle sprain exhibited tenderness over the anterior talofibular, calcaneofibular, and anterior tibiofibular ligaments 89%, 34%, and 16% of the time, correspondingly (Table 3). For grade II sprains, these values were 96%, 59%, and 42%, respectively, whereas for grade III sprains, the distribution was 97%, 90%, and 69%, respectively.

Primary Outcome Measure

Subjects with a grade I ankle sprain who received the Air-Stirrup brace combined with the elastic wrap treatment required a mean of 4.62 days to return to normal walking and 5.46 days for normal stair climbing; for the elastic wrap, these values were 11.16 and 12.05 days, respectively; whereas for the Air-Stirrup brace alone, they were 10.33 and 11.43 days, respectively (Table 4). Treatment with the Air-Stirrup brace combined with the elastic wrap returned subjects to normal walking and stair climbing in less than half the time required for those treated with the Air-Stirrup brace alone ($P = .0008$ and .003, respectively) and in half the time required for those treated with the elastic wrap ($P = .004$ and .008, correspondingly). In contrast, there was no difference between treatment with an elastic wrap and Air-Stirrup brace in time to return to normal walking ($P = .84$) and stair climbing ($P = .98$).

Subjects who suffered a grade II ankle sprain and received the Air-Stirrup brace combined with the elastic wrap required 10.1 days to return to normal walking and 11.72 days for normal stair climbing (Table 4). These respective time intervals were 11.67 and 13.38 days for the elastic wrap treatment, 13.38 and 16.38 days for the Air-Stirrup ankle brace treatment, and 24.12 and 27.94 days for the cast treatment. The most dramatic effect was observed for patients treated with the Air-Stirrup brace combined with the elastic wrap; these subjects returned to normal walking ($P = .0001$) and stair climbing ($P = .0001$) in 40% of the time required for those treated with casting. Similar findings were observed for comparisons between the Air-Stirrup brace and casting, as well as the elastic wrap treatment and casting.

Patients suffering a grade III ankle sprain had no difference between treatment with the Air-Stirrup brace and cast immobilization for 10 days followed by the use of an elastic wrap in time required to return to normal walking ($P = .918$) and stair climbing ($P = .802$). Subjects treated with the Air-Stirrup brace required 18.56 days to return to normal walking and 18.31 days to return to normal stair climbing. For the cast treatment group, these values were 19 days and 21.08 days, respectively.

Secondary Outcome Measures

Among the subjects who sustained a grade I ankle sprain, there was no difference in time to return to walking with full weightbearing for treatment with the elastic wrap, Air-Stirrup brace, or Air-Stirrup brace combined with the elastic wrap ($P = .8331$) (Table 4). There was a strong trend for treatment with the Air-Stirrup brace combined with the elastic wrap ($P = .0621$) and the elastic wrap ($P = .0521$) to provide full weightbearing without pain within a shorter time interval than with the Air-Stirrup brace treatment (Table 4). The time required for subjects to become fully capable in function at work or school and regain full capability during normal activities of daily living was similar between the elastic wrap, Air-Stirrup brace, and Air-Stirrup brace combined with the elastic wrap treatments ($P = .7326$ and .567, respectively). In contrast, treatment with the Air-Stirrup brace combined with the elastic wrap resulted in an earlier return to full capability at athletics and recreational activity than treatment with the Air-Stirrup brace alone ($P = .0101$).

Grade II ankle sprains treated with the elastic wrap, the Air-Stirrup brace, and the Air-Stirrup brace combined with the elastic wrap required similar time intervals to return to walking with full weightbearing ($P = .1853$) (Table 4). There was a trend for pain-free weightbearing to occur sooner in

TABLE 2
Activity Level of Subjects at Work/School by Treatment Within Grade

	I						II								III			
	Elastic Wrap		Air-Stirrup Ankle Brace		Air-Stirrup Ankle Brace With Wrap		Elastic Wrap		Air-Stirrup Ankle Brace		Air-Stirrup Ankle Brace With Wrap		Cast		Air-Stirrup Ankle Brace		Cast	
Activity Level	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Sedentary (often sitting)	2	17	1	11	2	22	3	21	4	22	7	23	3	21	2	20	2	17
Semisedentary (some to moderate sitting)	5	42	3	33	1	11	6	43	4	22	5	17	3	21	2	20	1	8
Light labor[a]	1	8	3	33	4	44	3	21	2	11	2	7	1	7	1	10	3	25
Moderate labor[a]	3	25	1	11	2	22	1	7	6	33	14	47	2	14	4	40	3	25
Heavy labor[a]	1	8	1	11	0	0	1	7	2	11	2	7	5	36	1	10	3	25
χ^2 P	.630						.109										.678	

[a]Only subjects who worked were asked this question.

TABLE 3
The Number and Percentage of Subjects Within Each Treatment Grade Who Had Tenderness in the Lateral Locations of the Injured Ankles at Baseline[a]

	Grade I		Grade II		Grade III	
Location of Tenderness	n	%	n	%	n	%
Fibula	3	5	13	11	1	3
Posterior tibiofibular ligament	0	0	1	0.8	0	0
Posterior talofibular ligament	0	0	12	10	4	12
Superior peroneus retinaculum	1	2	4	4	1	3
Calcaneus	0	0	0	0	0	0
Inferior peroneal retinacula	0	0	0	0	0	0
Calcaneofibular ligament	22	34	68	59	29	90
Peroneal muscle tendons	1	2	0	0	0	0
Anterior talofibular ligament	57	89	111	96	31	97
Talus	0	0	0	0	0	0
Anterior tibiofibular ligament	10	16	49	42	22	69
Tibia	0	0	0	0	0	0

[a]Subjects typically had pain at multiple locations.

TABLE 4
Primary and Secondary Outcomes by Grade and Treatment[a]

	I			II				III	
Outcome	Elastic Wrap	Air-Stirrup Ankle Brace	Air-Stirrup Ankle Brace With Wrap	Elastic Wrap	Air-Stirrup Ankle Brace	Air-Stirrup Ankle Brace With Wrap	Cast	Air-Stirrup Ankle Brace	Cast
Primary outcomes									
No. of days required to return to:									
1. Normal (preinjury) walking	11.16	10.33	4.62	11.67	13.38	10.10	24.12	18.56	19
2. Normal (preinjury) stair climbing	12.05	11.43	5.46	13.38	16.38	11.72	27.94	18.31	21.08
Secondary outcomes									
No. of days required to:									
3. Return to full weightbearing during walking	5.83	7.10	5.62	7.3	10.13	8.59	9.56	16.56	11.08
4. Experience no pain during weightbearing	6.67	9.9	6.31	9.8	12.48	9.21	13.62	17.5	16.17
5. Attain full capability in normal daily activities	7.61	9.3	7.54	9.05	12.03	12.28	19.72	20.07	17.86
6. Attain full capability in work or school	6.67	5.88	7.25	8.74	11	9.3	13.93	19.56	16.82
7. Attain full capability in usual athletic or recreational physical activity	11.72	14.07	7.92	14.89	19.42	17.12	19.73	20.8	20

[a]Values are means.

subjects treated with the elastic wrap and Air-Stirrup brace combined with the elastic wrap than among those treated with casting. The time necessary for subjects to be fully capable of function at work or school, regain full capability during normal activities of daily living, and return to athletic and recreational activity was significantly longer for subjects treated with casting than for those treated with the elastic wrap ($P < .0009$ for all comparisons) (Table 4). A comparison of casting and the Air-Stirrup brace combined with the elastic wrap treatment revealed a similar trend.

TABLE 5
Data From the 6-Month Follow-Up[a]

	I			II				III	
Outcome	Elastic Wrap	Air-Stirrup Ankle Brace	Air-Stirrup Ankle Brace With Wrap	Elastic Wrap	Air-Stirrup Ankle Brace	Air-Stirrup Ankle Brace With Wrap	Cast	Air-Stirrup Ankle Brace	Cast
Karlsson's scale									
Mean	95.1	93.8	95.5	92.2	92.9	96.8	88.76	94.1	89
SD	7.4	8.9	9.7	8.5	10.9	6.2	15.10	9.4	11.8
Overall comparison (*P*)		.88			.19			.373	
Difference in number of toe raises between injured and uninjured ankles									
Mean	–0.5	–0.4	–0.3	–1.6	–0.8	–0.7	–0.7	–0.2	–0.6
SD	1.7	2.1	3.3	4.5	2.3	2.4	1.6	2.6	1.7
Overall comparison (*P*)		.96			.806			.713	
Difference in jumping distance between injured and uninjured ankles, cm									
Mean	–1.78	–6.3	0	0.76	4.1	0.13	0.0	2.79	–5.84
SD	13.7	12.7	3.81	8.6	8.96	9.65	8.64	9.9	13.46
Overall comparison (*P*)		.399			.487			.154	

[a]Included are Karlsson's functional scoring scale, the difference in the number of toe raises performed in a 15-second time interval between injured and uninjured limbs, and the difference in jumping distance between injured and uninjured legs.

For the subjects who suffered grade III sprains, there was no difference in time required to return to walking with full weightbearing between the Air-Stirrup brace and cast treatments. Likewise, there was no difference between the treatments in time to return to pain-free weightbearing, full function at work or school, and full capability during normal activities of daily living and athletic or recreational activity.

Tertiary Outcome Measures: 6-Month Follow-Up

The 6-month follow-up of the subjects who suffered grade I ankle sprains revealed no differences between treatments for Karlsson's functional scoring scale (Table 5), jumping distances between injured and uninjured ankles (Table 5), the number of toe raises subjects performed between injured and uninjured ankles (Table 5), and dorsiflexion and plantarflexion motion of the ankle (Table 6). Likewise, the 6-month follow-up of the subjects who suffered grade II and III ankle sprains revealed no differences between the treatments for Karlsson's functional scoring scale (Table 5), jumping distances between injured and uninjured ankles (Table 5), the number of toe raises between injured and uninjured ankles (Table 5), and dorsiflexion and plantarflexion motion of the ankle (Table 6).

For each ankle sprain grade, there was no difference in the frequency of reinjury between the treatments ($P = .244$, .923, and .527 for grade I, II, and III ankle sprains, correspondingly).

DISCUSSION

This community-based investigation of skeletally mature subjects was designed to determine the therapeutic efficacy of different treatments of first-time ankle sprains. Treatments were matched with the severity of injury. For mild and moderate ankle sprains (grades I and II), a selection of functional treatments that permitted immediate controlled mobilization with different types of protection was compared, whereas for the more severe grade III sprains, functional treatment was compared with short-term immobilization followed by the use of an elastic wrap. The findings from this study support the use of the Air-Stirrup brace combined with an elastic wrap for the treatment of grade I and II ankle sprains. Treatment of grade I ankle sprains with an Air-Stirrup brace combined with an elastic wrap returned patients to normal (preinjury) walking and stair climbing in less than half the time required for subjects treated with either an Air-Stirrup brace alone or an elastic wrap alone (the mean decrease was 6 days). Likewise, treatment of grade II sprains with the Air-Stirrup brace combined with an elastic wrap returned subjects to normal walking and stair climbing in half the time required for subjects treated with immobilization for 10 days (the mean decrease was 16 days). Similar observations, although somewhat less dramatic, were made for the Air-Stirrup brace and elastic wrap combination compared with the Air-Stirrup brace alone and the elastic wrap alone. In contrast to what was found for grade I and II sprains,

TABLE 6
Difference in Dorsiflexion and Plantarflexion Motion of the Ankle Between the Uninjured Leg at Baseline and the Injured Leg at 6 Months by Grade and Treatment

	I			II				III	
Motion	Elastic Wrap	Air-Stirrup Ankle Brace	Air-Stirrup Ankle Brace With Wrap	Elastic Wrap	Air-Stirrup Ankle Brace	Air-Stirrup Ankle Brace With Wrap	Cast	Air-Stirrup Ankle Brace	Cast
Dorsiflexion, deg									
Mean difference	–2.0	–0.8	–3.5	0.2	2.6	0.9	1.1	2.2	6.8
SD	7.0	8.8	3.2	6.9	5.7	7.3	7.8	6.0	13.5
Overall comparison (*P*)		.6835			.7984			.3681	
Plantar flexion, deg									
Mean difference	0.22	–2.83	10.5	1.24	5.93	2.55	–0.53	–1.7	–1.7
SD	11.92	16.41	8	12.55	18.98	12.48	14.85	6.65	9
Overall comparison (*P*)		.0881			.6680			.9958	

treatment of grade III sprains with either the Air-Stirrup brace or casting for 10 days followed by use of an elastic wrap produced comparable outcomes. Subjects in these 2 treatment groups required the same length of time to return to preinjury walking and stair climbing. It may be that treatment of these severe grade III sprains with the Air-Stirrup brace combined with an elastic wrap provides a subject with a quicker return to preinjury activity, as was observed for the subjects who suffered grade I and II sprains; unfortunately, this treatment was not included for this group because we anticipated a limited number of subjects with severe grade III ankle sprains would be available for study.

Before designing this investigation, we realized that most patients (75%-100%) who suffer a sprain of the lateral ligaments of the ankle have a 1-year outcome that is excellent or good and completely acceptable to the patients irrespective of the therapy they receive (eg, surgical repair and cast, casting alone, or early controlled mobilization with the use of external support); however, the short- and intermediate-term outcome was unclear.[25] We also realized that a majority of investigations included subjects who suffered their first injury combined with subjects who suffered repeated ankle injuries and had associated sequela, making it difficult to determine the severity and extent of the injury that was studied. Therefore, the objective of our investigation was to determine the short-term outcome of first-time grade I, II, and III ankle sprains and identify the best means of providing early controlled mobilization with the goal of returning patients to their preinjury activity levels. It is important for us to point out that the primary hypothesis of our study and the corresponding outcomes were dissimilar to those used in previous investigations because we chose to evaluate a short-term outcome that challenged the injured ankle and was essential to all potential study subjects: the time required to return to preinjury activity (quantified as walking a minimum of 1 block and climbing a minimum of 1 flight of stairs in the same way they did before ankle injury, placing full weight on the ankle without a limp). The rationale for this was based on the realization that it would not be appropriate to evaluate a primary hypothesis based on the time to return to preinjury activity in specific athletic events or the time to return to work because only a portion of the participants in our community-based study took part in athletics on a daily basis and were either students who did not work or individuals who were not employed. Consequently, comparisons between the findings from our study and those of prior reports in the literature must be done carefully because of differences in the patient populations studied, types of injuries studied, time points when the data were collected, and the experimental designs that were used to test the primary hypothesis.

After ankle ligament trauma, the time required to regain full capability at work, school, and recreational activity is an important consideration for the injured subject and important for society in terms of the economic impact. We found that subjects who suffered grade II ankle sprains and were treated with the functional approach that included either the elastic wrap or the Air-Stirrup ankle brace combined with an elastic wrap required significantly less time (on average, 5 days) to attain full capability at work or school compared with those treated with immobilization followed by the use of an elastic wrap. Kerkhoffs et al[29] reported a meta-analysis that reached the same conclusion. For these same subjects who suffered grade II sprains, we found the time required to return to full capability in athletic or recreational activity was faster (on average, 5 days) for treatment with either the elastic wrap or Air-Stirrup brace combined with the elastic wrap compared with casting. Again, Kerkhoffs et al[29] reported similar findings. In contrast, for the subjects who suffered the more serious grade III sprains, we did not find a difference in time required to regain full capability in work, school, and athletic and recreational activity between functional treatment with the Air-Stirrup ankle brace and casting for 10 days followed by the use of an elastic wrap. Raemy and Jacob[47] performed a prospective study of 30 confirmed grade III ankle ligament injuries treated with an Air-Stirrup brace, and in 28 cases in which recovery was sufficient, the mean work disability was 17 days. As well, we found the time required for a subject to regain full capability at work or school was 19.5 days for subjects with grade III sprains who were treated with the Air-Stirrup brace.

Fritschy et al[18] conducted a 28-month study of 1400 patients with ankle sprains. Of the 259 cases treated with a pneumatic splint, 114 showed lateral instability of more than 10 (range, 10 -30) and would fit our criteria for a grade III sprain. In this study, the mean time off from work was 17 days, which is similar to our finding of 19.5 days for subjects with grade III sprains treated with the Air-Stirrup brace.

The incidence of reinjury is an important concern after ankle ligament trauma that is thought to be related to mechanical instability of the ankle and should be evaluated at follow-up intervals of 6 months and more. At the 6-month follow-up, we observed no difference in the frequency of reinjury for treatment of grade I ankle sprains between the different external supports that were studied (eg, elastic wrap, Air-Stirrup ankle brace, Air-Stirrup ankle brace combined with an elastic wrap). Likewise, there was no difference in the frequency of reinjury for treatment of grade II sprains between the before-mentioned external supports and cast immobilization for 10 days followed by the use of an elastic wrap. As well, there was no difference in the frequency of reinjury for treatment of grade III ankle sprains between the Air-Stirrup ankle brace and cast immobilization for 10 days followed by the use of an elastic wrap. Prior studies of similar treatments have reported corresponding findings at follow-up intervals of 6 months or more.[¶]

For all sprain severity groups, the type of treatment appeared to have no effect on function as measured by jumping distances and the number of toe raises that subjects performed at the 6-month follow-up. These findings indicate that all treatments were comparable in terms of restoration of function by the 6-month follow-up.

Restricted mobility of the ankle, particularly in dorsiflexion, is one explanation for persistent problems after ankle ligament trauma.[4,5] For all ankle sprain severity groups, we observed no difference in dorsiflexion or plantarflexion range of motion between treatments at the 6-month follow-up. Previous investigations of similar treatments have presented equivalent findings at common follow-up intervals.[7,11,42] Although not statistically significant, the subjects who suffered a grade III ankle sprain and were treated with casting for 10 days followed by the use of an elastic wrap had a 7 dorsiflexion deficit when compared with the contralateral normal side, whereas treatment of grade III sprains with the Air-Stirrup brace produced a 2 dorsiflexion deficit. A larger sample size may have established a statistically significant difference between these treatments.

Immobilization with the use of either plaster or fiberglass casts has been the routine ankle sprain treatment in most emergency departments. Immobilization of the ankle provides protection, decreases swelling, and minimizes pain; however, it carries with it the disadvantages of muscle atrophy, a decrease in total collagen mass of the ankle ligaments,[2,31,32] and a reduction of the structural properties of all ankle ligaments. Broström[10] and Lindstrand[38] included plaster cast immobilization as a treatment group in their studies and showed that after 1 year, the results were similar to those of surgery and functional treatment. However, it is currently not known how much time is required for patients to rehabilitate after this kind of treatment. Other investigations that have studied immobilization have demonstrated similar results.[35,41,52,54] Konradsen et al[33] performed a prospective, randomized study of 80 patients with grade III lateral ankle ligament ruptures who were treated with either early mobilization in an Air-Stirrup brace or immobilization with the use of a plaster walking cast. The patient population was similar to our study in that only subjects with first-time inversion injuries were included. Patients were evaluated at 7 weeks, 3 months, and 1 year after injury. Those treated with early mobilization achieved full ankle motion and returned to work and sport earlier than did those treated with immobilization, although there was no effect of treatment on ankle stability at the 1-year follow-up. In contrast, we found that treatment with the Air-Stirrup brace versus casting had no effect on the short-term outcome for patients with grade III ankle sprains. One explanation for the different findings between these studies is that we used casting for only 10 days followed by the use of an elastic wrap, whereas Konradsen et al treated subjects with immobilization for 1 week with a crural plaster slab without weightbearing followed by the use of a short plaster cast for 5 weeks. The longer period of immobilization may have delayed return to work and sport and limited motion.

When this study was designed, a concerted effort was made to minimize potential sources of confounding and bias. Before initiating our investigation, we recognized that it would be important to match the treatments with the severity of injury, and therefore we established the capability to diagnose an ankle sprain (grade I, II, or III) in a reliable manner. We also recognized that a history of ankle injury(ies) has an effect on outcome, and therefore the entry criteria were carefully selected and clearly defined at the onset of the study to identify skeletally mature subjects who suffered their first ankle sprains. This allowed us to accurately assign a subject to an ankle sprain severity group and avoid the potential confounding that may have been introduced by studying subjects with prior ankle injuries that had an unknown magnitude of prior damage to the soft tissues that span the ankle and may have healed incompletely or had subsequent sequela. The randomization process was adequately concealed from the treating physicians and study participants before allocation with the use of sealed envelopes, and for each ankle sprain grade, the randomization scheme created treatment groups with similar baseline characteristics (Tables 1, 2, and 3). One weakness of the study was that the treatment providers and study participants were not blinded to assignment status after allocation because we were unable to conceal the specific external support the subject was wearing. However, the primary and secondary outcomes were recorded by the patient via the daily logs outside of the clinical setting, and therefore blinding of the physician to the treatments may have had little influence on the measurement of these outcomes. It was not possible to blind subjects to the treatments they received, and the effect this had on outcome remains unclear. The study was controlled, and except for the specific treatments within each ankle

[¶]References 10, 11, 13, 15, 17, 31, 33, 35, 37, 42, 49, 52, 54.

sprain grade that were studied, the subjects received the same standardized rehabilitation program and regular monitoring of compliance with rehabilitation. The primary and secondary hypotheses were relevant to all study participants, and the duration of the surveillance was clinically appropriate to collect the primary and secondary outcomes because subjects recorded their status on a daily basis from the time of injury until they returned to walking and stair climbing in the same manner they did before the index injury. This allowed us to obtain an accurate measurement of the time (number of days) to return to normal preinjury status rather than relying on predetermined follow-up intervals to collect these data when subjects may not have recalled the exact point in time that they returned to the normal condition. For each ankle sprain severity grade, the primary and secondary outcome measures were obtained from an adequate proportion of those enrolled (at least 80% were followed); however, a smaller proportion of subjects participated in the 6-month follow-up. Capturing a larger proportion of those enrolled at the 6-month follow-up may have produced statistically significant findings for some of the tertiary comparisons. For example, analyzing a larger proportion of those enrolled with grade III sprains at the 6-month follow-up may have demonstrated that immobilization produced a significant decrease of dorsiflexion range of motion compared to the Air-Stirrup brace treatment. The final strength of our investigation was the use of an intent-to-treat analysis that included the outcomes of the patients who withdrew and completed only a portion of the study in the analysis.

In summary, treatment of first-time grade I and II sprains of the lateral ligaments of the ankle with the Air-Stirrup brace combined with an elastic wrap provided earlier return to preinjury function compared with treatment with the Air-Stirrup brace alone, an elastic wrap alone, or a walking cast for 10 days followed by the use of an elastic wrap. Treatment of first-time grade III sprains with the Air-Stirrup brace returned subjects to preinjury function in the same time interval compared with treatment with a walking cast for 10 days followed by the use of an elastic wrap. After 6 months of healing, all treatments produced comparable outcomes in terms of clinical testing, activity level, functional status, and patient satisfaction. Efforts are currently under way to perform a similar randomized controlled trial in subjects who have suffered repeated ankle injuries.

ACKNOWLEDGMENT

The authors gratefully acknowledge support for this investigation from Aircast Inc.

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