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Effect of Leg Length–Evening Device on Perceived Balance in Patients Wearing a Controlled Ankle Motion Boot

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Abstract

Background: Patients are often made weightbearing as tolerated (WBAT) in a controlled ankle motion (CAM) boot for the management of various foot and ankle conditions. The CAM boot causes a leg length discrepancy (LLD) between the booted (longer) and contralateral (shorter) lower extremities. This discrepancy can potentially cause balance problems, undue strain on joints, and discomfort in patients. We hypothesized that a leg length–evening orthotic placed on the plantar aspect of the contralateral shoe improves balance among patients who are WBAT in a CAM boot.

Methods: Patients made WBAT in a CAM boot were randomized to either the leg length–evening orthotic intervention group or to a control group in which patients wore a normal shoe of their choice. Patients were followed for 2 weeks and asked a series of questions pertaining to balance and pain experienced at their knees, hips, and back. Balance was the primary outcome and was scored from 0 (no difficulty with balance) to 10 (great difficulty with balance). Of 107 subjects enrolled and randomized, 95 (88.8%) completed the study, satisfying the a priori sample size requirement of 94 patients. There were no differences in baseline characteristics between groups ($P > .05$ for each).

Results: Intervention patients reported less difficulty with balance than control patients (intention-to-treat analysis: 2.0 ± 1.5 vs 3.2 ± 1.8, $P = .001$; as-treated analysis: 2.1 ± 1.7 vs 3.0 ± 1.7, $P = .009$). Intervention and control patients did not differ with respect to pain experienced at their knees, hips, or back, or in a composite total pain score ($P > .05$ for each).

Conclusion: This multicenter randomized controlled trial found that adding a limb length–evening orthotic to the plantar aspect of the contralateral shoe in a patient that is WBAT in a CAM boot improved patient-reported self-assessment of balance. The trial was powered to identify a difference in the primary outcome measure of balance and may have been insufficiently powered to identify differences in knee, hip, back, or total pain.

Level of Evidence: Level II, prospective comparative study.

Keywords: weightbearing as tolerated (WBAT), controlled ankle motion (CAM) boot, orthotic, leg-length discrepancy, balance, pain

Introduction

Controlled ankle motion (CAM) boots are used in the management of various foot and ankle conditions, including ankle fractures,[14] syndesmotic injuries,[17] lateral ankle sprains,[15] and plantar fasciitis.[6] The goal of weightbearing as tolerated (WBAT) in a CAM boot is to safely enable the patient to ambulate in as normal a fashion as possible with the limb protected and immobilized.[25] Unfortunately, the unilateral use of a CAM boot can result in an effective leg

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length discrepancy (LLD) between the booted (longer) and nonbooted (shorter) extremities. LLDs have been linked to balance difficulties and hip, knee, and back pain.[2,11,23] Lengthening the shorter limb with a shoe lift in uninjured patients with an LLD can normalize symmetry, relieve pain, and improve gait.[3]

Given the frequency with which CAM boots are prescribed, as well as the evidence that the resulting LLD can lead to balance difficulties and pain, orthotics have been developed to effectively lengthen the contralateral nonbooted extremity. These orthotics attach to the plantar aspect of the patient's normal contralateral shoe, resulting in more equal effective limb lengths.

This study is a randomized controlled trial to evaluate the efficacy of such a limb length–evening orthotic. We hypothesized that the orthotic would improve a patient's perceived balance over the first 2 weeks of being made WBAT in a CAM boot (primary hypothesis) and that it would also reduce falls and other lower extremity joint and back pain (secondary hypotheses).

Methods

Institutional Review Board approval was obtained and the study was registered on clinicaltrials.gov prior to study initiation. Patients were enrolled between July 2018 and August 2019 at 3 different institutions by 5 fellowship-trained orthopedic foot and ankle surgeons. Inclusion criteria were (1) age greater than 18 years and (2) undergoing treatment for a foot and ankle condition having just been made WBAT in a CAM boot, with a plan to continue the boot for at least 2 weeks. Exclusion criteria were (1) unwilling to participate; (2) incarcerated, incapacitated, or otherwise unable to provide appropriate informed consent; and (3) non-English-speaking. Eligible patients were consented after being newly progressed to WBAT in a CAM boot by their respective surgeon. Patients were randomized to either the intervention group (those who received the orthotic) or the control group (those who did not receive the orthotic). A random number generator provided by "www.sealedenvelope.com" was used to create individual 1:1 block-randomization tables for each institution. Random block sizes of 4, 6, 8, and 10 were used for each institution in order to ensure similar group sizes while preserving the unpredictability of the randomization.

Patients randomized to the intervention group were given the orthotic free of charge and encouraged to wear it on the plantar aspect of the contralateral limb for the duration of 2 weeks. The particular orthotic used was the EvenUp (OPED GmbH, Valley/Oberlaindern, Germany) which had 2 different height options from which the patient was able to choose to subjectively maximize limb length–evening effect. Patients in the control group were told simply to wear a contralateral shoe of their choice. At the end of 2 weeks, both groups were contacted by a research assistant and asked a series of questions regarding their balance, pain, and orthotic use (Appendix A). Patients were asked to score their balance and pain over the 2-week period using 10-point visual analog scales, where 0 was defined as "no difficulty with balance" or "no pain" and 10 was defined as "great difficulty with balance" or "severe pain." Pain was assessed at the knees, hip, and back, and a composite total pain score was calculated by taking the sum of these 3. Patients were also asked for their total number of trips and falls during the 2-week period, as well as their average estimated number of feet walked each day. In addition to the outcome questions, patients were asked questions regarding compliance. Patients in the intervention group were asked what proportion of the time when walking they used the limb length–evening orthotic. Patients answering <50% of the time were considered to have crossed over from the intervention to the control group. Patients in the control group were asked whether they had purchased and used a limb length–evening orthotic on their own. Patients answering yes to this question were considered to have crossed over from the control to the intervention group.

To determine the number of patients to be enrolled in the study, an a priori sample size calculation was conducted. Ten patients who were newly made WBAT in a CAM boot were contacted at the end of the 2-week period and asked to rate their balance over the 2-week period on a scale of 0 to 10, as defined above. The mean ($\pm$ SD) response was 3.7 $\pm$ 3.1. Internal a priori discussions determined that a 2-point difference in balance score would be clinically significant. Using these values, and allowing for a type 1 error rate of 0.05, sample size calculation suggested that 94 patients were required to have 80% power to detect a 2-point difference in the balance score between groups. This a priori sample size calculation was submitted in detail along with our original institutional review board application and was not altered during the study period.

Statistical analyses were conducted in Stata, version 16.0 (College Station, TX). Both intention-to-treat and as-treated analyses were conducted for all comparisons. *t* tests (for continuous variables), Pearson chi-squared tests (for categorical variables with expected cell counts $\geq$5), and Fisher exact tests (for categorical variables with expected cell counts <5) were used to compare baseline demographics. Balance (primary outcome), pain, the numbers of trips and falls, and the number of feet walked per day were compared using the Wilcoxon rank-sum test (equivalent to the Mann-Whitney *U* test), as these were considered to be non-normally distributed variables. The level of significance was set at $P < .05$.

Of the 112 patients initially invited to participate in the study, 5 were excluded (3 declined to participate and 2 were non-English speakers). This left 107 patients (95.5% of invited patients) for enrollment and randomization. Of these, 5 from the intervention group and 7 from the control group were lost to follow-up, leaving 95 patients. Enrollment continued until 94 patients had achieved complete follow-up, although 1 extra patient was inadvertently enrolled, for the

Table 1. Baseline Characteristics.

	Intention-to-Treat			As-Treated		
	Control (n=46)	Intervention (n=49)	*P* Value	Control (n=50)	Intervention (n=45)	*P* Value
Age, y, mean ± SD	47.0 ± 2.5	48.8 ± 2.33	.60	46.7 ± 16.3	49.2 ± 16.4	.46
Male sex, n (%)	18 (39.1)	17 (34.7)	.65	21 (42.0)	14 (31.1)	.27
BMI, mean ± SD	30.7 ± 1.6	29.9 ± 1.0	.67	29.1 ± 7.9	31.5 ± 6.7	.22
Condition, n (%)			.21			.50
Malleolar fracture	10 (21.7)	9 (18.4)		9 (18.0)	10 (22.2)	
Foot fracture	8 (17.4)	9 (18.4)		9 (18.0)	8 (17.8)	
Ankle sprain	8 (17.4)	6 (12.2)		7 (14.0)	7 (15.6)	
Tibiotalar arthritis	1 (2.2)	8 (16.3)		2 (4.0)	7 (15.6)	
PTTD	4 (8.7)	3 (6.1)		4 (8.0)	3 (6.7)	
Acute Achilles tendon rupture	4 (8.7)	0 (0.0)		4 (8.0)	0 (0.0)	
Hindfoot arthritis	1 (2.2)	2 (4.1)		1 (2.0)	2 (4.4)	
Midfoot arthritis	2 (4.3)	1 (2.0)		2 (4.0)	1 (2.2)	
Peroneal pathology	1 (2.2)	2 (4.1)		3 (6.0)	0 (0.0)	
Ankle impingement	1 (2.2)	2 (4.1)		2 (4.0)	1 (2.2)	
Ankle instability	0 (0.0)	2 (4.1)		1 (2.0)	1 (2.2)	
Foot sprain	2 (4.3)	0 (0.0)		1 (2.0)	1 (2.2)	
Other[a]	4 (8.7)	5 (10.2)		5 (10.0)	4 (8.9)	
Condition is tibiotalar or above[b]	26 (56.5)	28 (57.1)	.95	27 (54.0)	27 (60.0)	.56
Postoperative,[c] n (%)	19 (41.3)	17 (34.7)	.51	21 (42.0)	15 (33.3)	.39

Abbreviations: BMI, body mass index; PTTD, posterior tibial tendon dysfunction.
[a]Accessory navicular, ankle extensor tendonitis, chronic Achilles pathology, gout, hallux rigidus, osteochondral lesion of the talus, plantar fasciitis, tibial shaft fracture, or webspace neuroma.
[b]Condition was predominantly at or proximal to the tibiotalar joint (vs predominantly distal to the tibiotalar joint).
[c]Patient was being managed in a CAM boot following surgery, vs being managed in a CAM boot as part of nonoperative treatment.

total enrollment of 95 patients included in the final analysis. For the intention-to-treat analysis, 49 patients were analyzed as intervention and 46 were analyzed as control. Seven patients randomized to the control group purchased their own orthotic and were considered to have crossed over from the control to the intervention group. Eleven patients randomized to the intervention group reported <50% usage of the orthotic and were considered to have crossed over from the intervention to the control group. Hence, for the as-treated analysis, 45 patients were analyzed as intervention and 50 patients were analyzed as control. In both analyses, baseline characteristics including age, gender, body mass index, condition predominantly above (vs below) the tibiotalar joint, and postoperative (vs nonoperative), did not differ between groups ($P > .05$ for each in both intention-to-treat and as-treated analyses; Table 1).

Of note, the diagnosis requiring management with a CAM boot was a malleolar fracture (20.0% of patients), foot fracture (17.9%), ankle sprain (14.7%), tibiotalar arthritis (9.5%), posterior tibial tendon dysfunction (7.4%), acute Achilles tendon rupture (4.2%), hindfoot arthritis (3.2%), midfoot arthritis (3.2%), peroneal pathology (3.2%), ankle impingement (3.2%), ankle instability (2.1%), foot sprain (2.1%), accessory navicular (1.1%), ankle extensor tendonitis (1.1%), chronic Achilles pathology (1.1%), gout (1.1%), hallux rigidus (1.1%), osteochondral lesion of the talus (1.1%), plantar fasciitis (1.1%), tibial shaft fracture (1.1%), and webspace neuroma (1.1%) (Table 1).

Also of note, operative and nonoperative rehabilitation protocols for Achilles tendon ruptures varied between surgeons, and all initially included a period of non–weight bearing with gradual progression toward WBAT in a CAM boot. Patients were eligible for enrollment in the trial at the time when they first became WBAT in a CAM boot.

Results

Intention-to-Treat Analysis

In the intention-to-treat analysis, intervention patients reported less difficulty with balance than control patients (2.0 ± 1.5 vs 3.2 ± 1.8, $P = .001$). Intervention and control patients did not differ with respect to pain experienced at their knees, hips, back, or a composite total pain score ($P = .166$, $P = .420$, $P = .472$, $P = .119$, respectively; Table 2). Additionally, intervention and control patients did not differ with respect to number of trips ($P = .221$) or falls ($P = .442$). Finally, intervention and control patients did not differ with respect to number of feet walked per day ($P = .614$).

As-Treated Analysis

In the as-treated analysis, intervention patients reported less difficulty with balance than control patients (2.1 ± 1.7 vs 3.0 ± 1.7, $P = .009$). Intervention and control patients did not differ with respect to pain experienced at their knees, hips, back, or a composite total pain score ($P = .330$,

Table 2. Study Outcomes.

	Intention-to-Treat			As-Treated		
	Control, Mean ± SD (n=46)	Intervention, Mean ± SD (n=49)	*P* Value	Control, Mean ± SD (n=50)	Intervention, Mean ± SD (n=45)	*P* Value
Difficulty with balance (0-10) [a]	3.2 ± 1.8	2.0 ± 1.5	.001	3.0 ± 1.7	2.1 ± 1.7	.009
Trips (count)	2.1 ± 2.7	1.6 ± 2.7	.22	1.7 ± 2.7	2.0 ± 2.7	.71
Falls (count)	0.1 ± 0.3	0.1 ± 0.5	.44	0.0 ± 0.2	0.2 ± 0.6	.31
Knee pain (0-10)	1.9 ± 2.7	1.1 ± 2.1	.17	1.7 ± 2.5	1.2 ± 2.3	.33
Hip pain (0-10)	1.8 ± 2.7	1.2 ± 2.1	.42	1.8 ± 2.6	1.2 ± 2.2	.33
Back pain (0-10)	1.7 ± 2.6	1.2 ± 2.2	.47	1.4 ± 2.4	1.5 ± 2.4	.90
Composite pain (0-30)[b]	5.4 ± 5.8	3.5 ± 4.8	.12	4.9 ± 5.6	3.9 ± 5.1	.36
Feet walked per day (count)	3063.6 ± 4263.1	3493.4 ± 4017.7	.61	3732.5 ± 4685.6	2788.4 ± 3371.4	.48

[a]0 is defined as "no difficulty with balance," whereas 10 is defined as "great difficulty with balance." This was the study's primary outcome, and the outcome for which the a priori sample size calculation was conducted.
[b]Composite pain is simply the sum of knee, hip, and back pain.

$P = .326$, $P = .904$, $P = .355$, respectively; Table 2). Additionally, intervention and control patients did not differ with respect to number of trips ($P = .707$) or falls ($P = .305$). Finally, intervention and control patients did not differ with respect to number of feet walked per day ($P = .483$).

Discussion

The use of a CAM boot for an orthopedic foot and ankle condition results in an LLD between the booted and nonbooted extremities.[12,24] LLDs can negatively impact patients' balance and cause pain in other joints and the low back.[2,11] Thus, limb-lengthening orthotics have been developed that attach to the plantar aspect of the contralateral shoe, lengthening the contralateral limb, and reducing the discrepancy between the effective lengths of the limbs. These types of orthotics have become popular items in many durable medical equipment stores, and it has become common in some settings for patients to purchase one at the time they are newly made WBAT in a CAM boot.

The present study randomized 95 patients newly made WBAT in a CAM boot to receive or not receive the limb length–evening orthotic. In both intention-to-treat and as-treated analyses, patients in the intervention group had statistically significant improvements in self-reported balance, suggesting improved balance with use of the orthotic.

The results of this study should be interpreted in the context of prior research surrounding LLDs, gait, and balance. Azizan et al[1] conducted the most thorough examination of how an LLD impacts balance during ambulation. These authors enrolled 18 healthy volunteers and evaluated measures of balance under various walking conditions. They tested patients both with and without a simulated LLD, and documented alterations in ground reaction forces, center of pressure, and center of mass. They concluded that a greater LLD leads to greater postural instability (greater imbalance) and that normalizing the LLD can potentially lead to improved balance. Similarly, studies conducted by Park et al[22] and Maeda et al[18] also concluded that an LLD shifts the body's center of mass, which negatively impacts body stability and balance.

Similarly, a study conducted by Goodworth et al[11] recruited 12 healthy volunteers to determine how a walking boot impacts balance and whether the correction of the LLD caused by a walking boot improves balance. The subjects performed various balance tests while wearing just a walking boot or a walking boot with a heel lift on the contralateral foot. The results of the study showed increased body motion and tilt in the subjects who wore the walking boot both while static and while ambulating. The heel lift decreased body motion and tilt in the subjects while static; however, body motion was similar between the walking boot and the walking boot plus the heel lift groups while ambulating. The authors concluded that the walking boot increased body motion leading to balance problems under all conditions. Other authors have had similar results.[19]

In the present study, despite the improvements in self-reported balance scores, there were no statistical differences between groups in other balance-related study outcomes, including number of reported trips or number of reported falls. The study was not powered to detect these rare outcomes. With means of only 2 trips and less than 1 fall per patient during the 2-week period, a far greater sample size would be required to evaluate these adverse events.

Having an LLD causes compensatory mechanical changes to the lower limbs for the purpose of maintaining proper balance.[9,13,16] In the knees, an LLD causes increased ground-reaction forces in both the shorter and longer limbs, and this has been documented to contribute to knee pain in the short term and even arthritis in the long term.[3] In the hips, an LLD causes the hip joint on the longer limb to be in a varus position, causing the femoral head to have decreased load-bearing surface.[7] The spine shows an asymmetric lateral-bending motion in patients with an LLD, which has been hypothesized to result in back pain both from degenerative and muscular causes.[16] Results of the present study

showed no differences in knee, hip, or back pain. However, several other studies have shown the opposite. A cross-sectional study conducted by Golightly et al[10] showed that individuals with an LLD had more knee and hip symptoms compared with those without an LLD, even when controlling for variables such as radiographic osteoarthritis and history of knee and hip problems. Other studies have also reported increased knee and hip symptoms in patients with an LLD,[5,9,20] and a study conducted by Giles and Taylor[8] observed back pain to be more common in those with an LLD of more than 10 mm.

In this context, we hypothesized that patients using the limb length–evening orthotic might have decreased large joint and spine pain compared with patients who did not use the orthotic. Although we were unable to demonstrate any statistical differences between groups, there was a trend toward decreased total pain with orthotic use, most notable in the intention-to-treat analysis. It is possible that the study was underpowered to evaluate for these secondary outcomes. Hip, knee, and back pain vary widely between patients at baseline, resulting in large sample sizes required to appropriately power such tests. Hip, knee, and back pain also have many different causes, with back pain known to be particularly multifactorial,[4] and so any impact of the CAM boot may simply be diluted. Moreover, although an LLD clearly influences spine alignment, it is well documented that many individuals compensate for this discrepancy without having back pain[21]; hence, the CAM boot may not have created enough pain to require correcting with the orthotic. Finally, Ready et al[23] assessed joint pain during the initiation of wearing a CAM boot, finding an upward trend of secondary joint pain starting at 2 weeks of CAM boot wear. As the present study stopped data collection at 2 weeks, patients may not have been followed long enough to capture development of clinically significant back pain.

The present study has several strengths. An a priori sample size calculation was conducted for the primary outcome (balance) and the required sample size achieved. The present study is the most direct to evaluate the utility of this increasingly popular type of orthotic and does provide surgeons with some evidence to substantiate its recent popularity among patients.

The present study also has several limitations. First, the study's primary and secondary outcomes were driven primarily by patient response; because we were unable to blind patients to their study group assignment, patient responses and study results were predisposed to information bias including differential misclassification and recall bias. Second, the assessment of balance was very subjective, in that it was patient-reported and retrospective. Ideally, there would have been a more objective way to measure this factor. Third, there was a high degree of crossover between groups. To correct for this, both intention-to-treat and as-treated analyses were conducted. These analyses produced similar results, diminishing the concerns that crossover biased our conclusions. Nevertheless, the crossover is a significant limitation. As a result, the study is better categorized as a level 2 than a level 1 study. Fourth, many patients wear a boot for as long as 6 weeks. It would have been interesting to see if there would have been greater difference if the study had been extended longer than the 2-week follow-up. Additionally, the study was likely underpowered to detect differences in its secondary outcomes, including trips, falls, and the various assessments of pain.

In conclusion, the present study demonstrates that subjective patient-reported self-assessment of balance improved with the use of a leveling device, but no other differences were seen between groups. Future studies might similarly randomize patients to receive or not receive a device, but might strive for more objective and longer-term measurements of balance and other outcomes. This finding supports the use of limb length–evening orthotics during immobilization for orthopedic foot and ankle conditions.

Ethics Approval

Ethical approval for this study was obtained from Rush University Medical Center Institutional Review Board (ORA 18012208).

Declaration of Conflicting Interests

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Appendix A. Two-Week Follow-up Questionnaire

For all patients, regarding the last 2 weeks:

- On a scale of 0 to 10, where 10 is great difficulty with balance and 0 is no difficulty with balance, how would you say your balance has been when walking?
- How many times have you tripped or stumbled?
- How many times have you fallen to the ground?
- On a scale of 0 to 10, where 0 is no pain and 10 is severe pain, how much pain were you having in your knees?
- On a scale of 0 to 10, where 0 is no pain and 10 is severe pain, how much pain were you having in your hips?
- On a scale of 0 to 10, where 0 is no pain and 10 is severe pain, how much pain were you having in your back/spine?
- How many feet per day did you walk?

For patients in the control group, to assess compliance, regarding the last 2 weeks:

- Did you go out and get a leg length–evening orthotic on your own?

For patients in the experimental group, to assess compliance, regarding the last 2 weeks:

- When you were wearing the CAM walking boot, what percent of the time were you wearing the leg length–evening orthotic?