Patient Safety Issue: Controlled ankle motion boots are widely used to manage foot and ankle conditions; however, as they are easily removed and designed for ambulation, their use in non-weightbearing periods is questionable. The goal of this study was to determine patient compliance with non-weightbearing restrictions while using controlled ankle motion boots after foot/ankle surgery.

Non-Weightbearing In CAM Boots After Foot/Ankle Fracture Fixation: Are Patients Compliant?

Amos Z. Dai[1], MD; Michelle Regan[1], PA-C; Megan C. Paulus[1], MD[1]

[1]Department of Orthopaedics and Rehabilitation, Stony Brook University

ABSTRACT

Background: The controlled ankle motion (CAM) boot has become an integral part of the management of both operative and nonoperative foot and ankle conditions. Similar to casts, CAM boots are used to immobilize the foot and ankle after injury or surgery. However, unlike casts, CAM boots can be readily removed for showering and range of motion (ROM) exercises. While CAM boots are well-designed for ambulation and are frequently utilized in early weightbearing (WB) and early ROM protocols, their usage in non-weightbearing (NWB) protocols is less clear.

Purpose: The purpose of the current study is to determine the patient compliance rate with NWB restriction in a CAM boot after foot/ankle surgery.

Methods: Patients who underwent foot and ankle surgery by a single surgeon and were instructed to be NWB in a CAM boot at two weeks postoperative were enrolled in this study at their six-week postoperative clinic visit. They were given an anonymous questionnaire asking about their level of compliance with the prescribed NWB restriction. The main question of interest asked, *"Since you started wearing the CAM boot, how many times have you put any weight on the injured leg while standing or walking?"* to which subjects could respond with never, a few times, or frequently. This was termed 'stated non-compliance' and the responses were graded as -0, 1, or 2, respectively. If their stated noncompliance was greater than grade 0, they were asked to provide reason(s). Photos of the CAM boot sole and the heel portion was visually inspected for wear and graded as 0, 1, or 2, depending on whether there was a low, medium or high level of wear, respectively. This was termed 'wear noncompliance'. For any given patient, 'final noncompliance' was defined as the higher grade between stated and wear noncompliance. Moderate compliance rate was defined as percentage of patients with a final noncompliance of 0 or 1. Strict compliance rate was defined as the percentage of patients with a final noncompliance grade of 0. Of the 35 patients eligible for the study, 97% responded to the survey. 65% (22/34) of patients were female with a mean age of 54.8 years.

Results: The moderate compliance was determined to be 91% and strict compliance rate was 29%. There was 53% agreement between stated noncompliance and wear noncompliance. Both cases of grade 2 stated noncompliance were also classified as grade 2 wear noncompliance. In the remaining 16 patients in which stated and wear noncompliance were not in agreement, 12 patients reported grade 1 stated noncompliance but their wear noncompliance was grade 0. The most commonly reported reason for noncompliance was that they tripped and needed to put weight on the operative leg to avoid falling. All three cases of grade 2 final noncompliance reported 'no pain' as one of their reasons for noncompliance.

Conclusion: In a postoperative foot and ankle patient population, NWB restriction in a CAM boot yields a moderate compliance rate of 91% and strict compliance rate of 29%. CAM boots may be sufficient for more stable fixation constructs such as most ankle fractures. However, surgeries requiring strict NWB compliance such as joint depression type calcaneus fracture and pilon open reduction internal fixation may be more reliably served with casting. Assessment of CAM boot wear pattern can be used to grossly estimate patient compliance and is especially useful for identifying higher levels of noncompliance.

Introduction

Postoperative management of surgically treated ankle fractures remains a matter of ongoing debate[14]. Proponents of non-weightbearing (NWB) and immobilization after unstable ankle fractures note that reducing forces at the fracture site is important for preventing secondary fracture displacement and hardware failure. Therefore, the traditional recommendation is for patients to be placed into a postoperative splint or cast and remain NWB or up to 8 weeks[17]. However, recent clinical[1,6,8] and biomechanical[16] studies have shown that immediate weightbearing after stable fixation of ankle fractures does not lead to increased fracture displacement and may even hasten recovery and return to work[5].

The controlled ankle motion (CAM) boot has become an integral part in the management of both operative and nonoperative foot and ankle conditions. Similar to casts, CAM boots are used to immobilize the foot and ankle after injury or surgery. However, unlike casts, CAM boots can be readily removed for showering and range of motion (ROM) exercises. In addition, they have adjustable straps and some have a pneumatic air feature which allows the boot to conform to postinjury/postoperative swelling. Sometimes called "CAM walkers", these boots also have a rocker bot-

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tom design that allow for efficient ambulation while minimizing sagittal plane motion[1].

While CAM boots are well-designed for ambulation and are frequently utilized in early weightbearing (WB) and early ROM protocols, their usage in NWB protocols is less clear. Compliance is a concern when patients are told not to walk in a boot that was designed for walking. Chiodo et al. found the patient noncompliance rate to be high (27.5%) with postoperative NWB restriction in short leg casts[4]. We hypothesize that the noncompliance rate to be is even higher for CAM boots. The purpose of the current study is to determine the patient compliance rate with NWB restriction in a CAM boot after foot/ankle surgery.

Materials and Methods

Prior approval for this study was obtained from the institutional review board. Patients who underwent foot or ankle surgery by a single fellowship-trained orthopedic foot and ankle surgeon were screened for the study. Inclusion criteria included age ≥ 18 and a unilateral foot or ankle procedure that required a period of NWB in a CAM boot starting at 2 weeks postoperatively. CAM Boots (AIRCAST AirSelect, Dallas, TX) (Figure 1) were fitted and dispensed by the certified athletic trainer in our clinic. All patients were permitted to remove the CAM boot twice a day, once for ROM exercises and once for showering. Otherwise, patients were instructed to wear the boot at all times, including while sleeping. Patients who were instead placed into casts at 2 weeks postoperative were excluded. Patients were also excluded if they suffered an open fracture, were non-ambulatory at baseline, or received a CAM boot other than the model dispensed in our clinic. All patients were made NWB in a short leg plaster splint for the first 2 weeks postoperative to allow for wound healing.

Figure 1: AIRCAST AirSelect Controlled Ankle Motion (CAM) Boot. Red square indicates the region that was analyzed to estimate non-weightbearing noncompliance.

All eligible patients were approached with the study at their 6-week postoperative visit, after the period of NWB (or potential WB) has occurred. Informed consent was obtained from all patients that were included in the study. Patients were administered a 6-item survey (Figure 2) that included the following:

- Age
- Sex
- Patient's own recollection of prescribed WB status
- Frequency they put any amount of weight on the injured leg
- If applicable, why the patient put weight in the injured leg
- Preference for a boot or cast

Cam Boot Survey

1. Age: _____
2. Sex: _____
3. What were you told your weight bearing status was? (Choose one)
   - ○ No weight bearing
   - ○ Toe touch weightbearing
   - ○ Partial weightbearing
     - ▪ __%
     - ▪ Was not specified
   - ○ Weightbearing as tolerated
   - ○ Don't remember
   - ○ Was not told
4. Since you started wearing the CAM boot, how many times have you put any weight on the injured leg while standing or walking (Choose one)
   - ○ Never
   - ○ A few times
   - ○ Frequently
5. Why did you put weight on this leg (Check all that apply)
   - ○ I only did it a few times by accident because I forgot I wasn't supposed to
   - ○ I was not told I couldn't put any weight on it
   - ○ I wasn't feeling any pain
   - ○ I tripped and needed to in order to avoid falling
   - ○ Not Applicable, I haven't put any weight on this leg
   - ○ Other, please explain _____
6. If you had this surgery again, would you prefer a boot or a cast /splint?

PLEASE PLACE QUESTIONS IN THE PROVIDED ENVELOPE AND SEAL IT

Figure 2: Survey administered to subjects at 6-week postoperative visit to assess patient reported non-weightbearing noncompliance.

Patients were instructed to place their surveys into an unmarked envelope and envelopes were then stored in a locked box. They were assured that the attending surgeon would not have access to these surveys and that participation/nonparticipation and responses would not affect their care in any fashion. A total of 39 patients were eligible for the study from April 2021 to May 2022. Four patients were excluded because they had received a CAM boot model that was different from the standard boot prescribed in our clinic. One out of the remaining 35 patients declined to participate. The final response rate for the study was 97% (34/35). 65% (22/34) of patients were female with a mean age of 54.8 years.

In addition, a photograph of the sole of the CAM boot was taken in order to assess noncompliance based on amount of wear ('wear noncompliance') and compare to self-reported compliance ('stated noncompliance'). Photographs of patients' CAM boots were de-identified and were graded by a single senior orthopedic resident and was based on the amount of wear in the heel portion of the boot sole, specifically in the engraved letters "SOFT-STRIKE" (Figure 1). Figure 3 shows the noncompliance grading scale with respect to survey response and to heel wear pattern. When there was disagreement between the stated noncompliance and the wear noncompliance, the higher compliance grade was selected as the 'final compliance'. For example, for a given patient, if wear noncompliance was 1 and stated noncompliance was 2, the final noncompliance was recorded as 2. For purposes of this study, we defined moderate compliance as the percentage of subjects with a final noncompliance of grade 0 or 1. Strict compliance was the percentage of subjects with a final noncompliance of grade 0.

Grade	Stated Noncompliance	Wear Noncompliance
0	“never”	Minimal wear
1	“a few times”	Faded but legible
2	“frequently”	Barely legible or illegible

Figure 3 Noncompliance grading system. Stated noncompliance is based on patients’ response to the question, “Since you started wearing the CAM boot, how many times have you put any weight on the injured leg while standing or walking?”. Wear noncompliance is based on the appearance of the letters “SOFTSTRIKE” in the heel portion of the CAM boot at 6 weeks postop.

Consideration was given to placement of a pressure-sensitive film in the CAM boot at 2 weeks postoperative, as described by Chiodo et al.[4], but this would require informing the patient that they were being monitored. This would introduce a significant Hawthorne effect, even if patients are not specifically informed that their weightbearing was being monitored. Hence, we chose to enroll patients at 6 weeks and assess compliance via self-reported survey and amount of wear on the boot retrospectively.

Results

For stated noncompliance, 38% of patients reported “never” bearing weight (grade 0 on noncompliance scale), 56% reported “a few times” (grade 1), and 6% reported “frequently” (grade 2). For wear noncompliance, 65% of patients were grade 0, 26% were grade 1 and 9% were grade 2. See Figure 4 for examples of each grade. Table 1 shows results of stated and wear noncompliance grading.

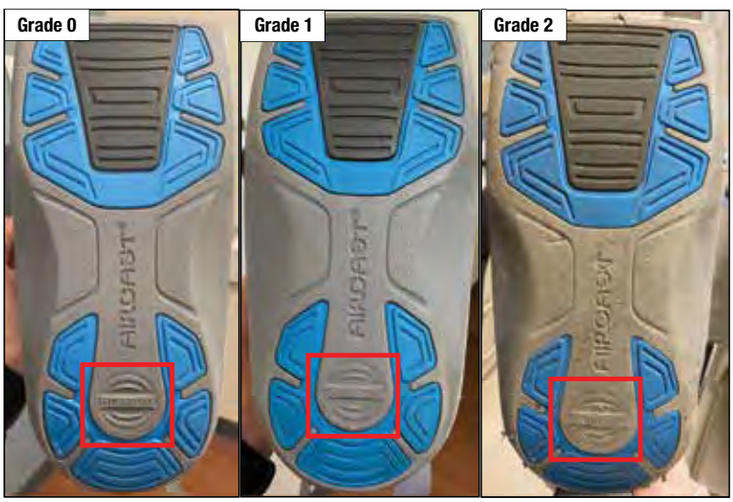

Figure 4 Examples of each noncompliance grade, based on the wear pattern in the heel portion (red squares) of the controlled ankle motion (CAM) boot.

Patient ID	WB Status Recall	Boot/Cast Preference	Stated Non-compliance	Wear Non-nompliance	Final Non-compliance	Reason for Noncompliance
1	NWB	Boot	2	1	2	No pain
2	NWB	NR	1	0	1	Forgot, Tripped
3	NWB	Boot	1	0	1	Balance
4	NWB	Boot	1	0	1	No response
5	NWB	Boot	1	1	1	Tripped
6	NWB	NR	0	1	1	N/A
7	NWB	NR	1	0	1	Balance
8	NWB	Boot	1	0	1	Tripped
9	NWB	NR	0	0	0	N/A
10	NWB	Boot	1	1	1	Forgot
11	NWB	Boot	1	0	1	Balance
12	NWB	Boot	0	0	0	N/A
13	NWB	Boot	1	2	2	Forgot, No pain, Tripped
14	NWB	Boot	0	0	0	N/A
15	NWB	Boot	1	0	1	Tripped
16	NWB	Boot	0	0	0	N/A
17	NWB	Boot	1	1	1	No pain
18	NWB	Boot	1	0	1	Forgot
19	NWB	Boot	2	2	2	No pain
20	NWB	Boot	1	0	1	Forgot
21	NWB	NR	1	1	1	NR
22	NWB	Boot	1	1	1	Forgot
23	NWB	Boot	1	0	1	Tripped
24	NWB	NR	0	0	0	N/A
25	NWB	Boot	0	1	1	N/A
26	NWB	Boot	0	0	0	N/A
27	NWB	Boot	0	0	0	N/A
28	NWB	Boot	1	0	1	Tripped
29	NWB	Boot	1	0	1	Tripped
30	NWB	Boot	0	0	0	N/A
31	NWB	Boot	0	1	1	N/A
32	NWB	NR	0	0	0	N/A
33	NWB	Boot	1	1	1	Tripped
34	NWB	Boot	0	0	0	N/A

Table 1: NWB in CAM boot survey and wear analysis results. WB status recall refers to what weightbearing status patients remember being told at their previous visit. Stated noncompliance and wear noncompliance grading system is shown in Figure 3. Final noncompliance takes the higher of the two noncompliance grades (stated vs wear noncompliance). Reason for noncompliance was asked of all patients who reported at least Grade 1 stated noncompliance. Refer to Figure 2 for full survey. NWB = non-weightbearing. NR = no response. N/A = not applicable.

Overall there was 53% agreement between stated noncompliance and wear noncompliance. Both cases of grade 2 stated noncompliance were also classified as grade 2

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wear noncompliance. In the remaining 16 patients where stated and wear noncompliance were not in agreement, 12 patients reported grade 1 stated noncompliance but their wear noncompliance was grade 0. Three patients reported grade 0 stated noncompliance but wear noncompliance was grade 1. There was one patient who reported grade 0 stated noncompliance but wear noncompliance was grade 1. There were no patients who had grade 1 stated noncompliance with grade 0 wear noncompliance. Interestingly, there were no patients in which stated and wear noncompliance differed by more than a single grade. In cases of disagreement between stated and wear noncompliance, the higher grade was assumed to be the truer of the two and taken as the final noncompliance. The final noncompliance results are as follows: 29% grade 0, 62% grade 1, and 9% grade 2. Moderate compliance rate = (10+21)/34 x 100% = 91%. Strict compliance rate = 10/34 x 100% = 29%.

Of the 21 patients who reported at least some degree of noncompliance (stated noncompliance grades 1 and 2), the most common reason for noncompliance was that they tripped and needed to bear weight to avoid falling (9 patients). The second most common reason was "I only did a few times because I forgot I wasn't supposed to" (6 patients). See Table 1 for all reported reasons for noncompliance. All three patients with a final noncompliance grade of 2 reported "no pain" as one of their reasons for noncompliance. 100% (34/34) of patients correctly recalled that they were given a NWB restriction at the previous office visit. 100% of patients who responded to question 6 on the survey preferred a CAM boot to a splint/cast.

Discussion

In a population of post-surgical patients who were given a NWB restriction in a CAM boot following orthopedic foot or ankle surgery, the moderate compliance was determined to be 91% and strict compliance rate was 29%. To our knowledge, this is the first study to evaluate patient compliance with NWB in CAM boots.

Chiodo et al. examined a cohort of 51 patients made NWB in a short leg cast and found a compliance rate of 72.5% (reported noncompliance rate of 27.5)[2]. Although their study used an objective measure of compliance (pressure sensitive film), their patients were aware of being monitored. A significant Hawthorne effect likely exists in that study, even despite attempts to minimize it by not explicitly informing patients that their weightbearing was being monitored. On the other hand, many compliance studies are limited by their reliance on patient reported compliance rates and it has been shown that patients tend to overestimate their level of compliance[10,11,15]. Our study addresses this shortcoming by including an analysis of CAM boot wear pattern.

Overall there was a 53% agreement between stated and wear noncompliance. Of the 16 cases of disagreement, the vast majority (12) were cases in which stated noncompliance grade (grade 1) was higher than wear noncompliance (grade 0). Meanwhile, both cases of high stated noncompliance (grade 2) were also classified as grade 2 wear noncompliance. This suggests that visual inspection of the heel portion of the CAM boot may be used to identify gross noncompliance but may have difficulty distinguishing between patients who are strictly compliant (grade 0) vs those who are noncompliant on occasion (grade 1). Interestingly, all three patients with a final noncompliance grade of 2 reported "no pain" as one of their reasons for noncompliance, while "I tripped" and "I forgot" were the most common reasons in the grade 1 group. All patients correctly recalled that they were prescribed NWB. These results suggest that the noncompliance grade 2 patients may knowingly disregard their NWB restriction when their pain has resolved while grade 1 patients are noncompliant accidently and infrequently.

Postoperative NWB is prescribed for several foot and ankle injuries. However, likely not all of them truly necessitate strict NWB. For example, no significant fracture displacement, no hardware failure, and no new fractures occurred in a cadaveric model of early weightbearing in unstable ankle fracture after open reduction and internal fixation[16]. This has also been shown in clinical studies[1] and in fact, immediate postoperative weightbearing (IWB) resulted in an earlier return to work compared with traditional protocols[5]. This remains a controversial topic amongst orthopedic traumatologists and foot and ankle surgeons[14]. In our study, moderate compliance rate, which we define as the proportion of patients with grade 0 or grade 1 noncompliance, was 91%. Therefore, we believe the CAM boot to be sufficient for NWB protocol following ankle fracture fixation.

In contrast, strict NWB has been advocated following distal tibia pilon fracture fixation[3], triple arthrodesis[13], as well as for nonoperative treatment of certain 5th metatarsal base fractures[7] and navicular stress fractures[9,12]. Intra-articular calcaneus fractures and osteochondral lesions of the talus fit in this category as well. Strict compliance in our study, which we define as the proportion of patients in with grade 0 noncompliance, was 29%. Hence, for injuries requiring strict NWB, strong consideration should be given to short leg casting as opposed to CAM boot.

This study has several limitations that should be noted. First, there was no direct comparison group (e.g., short leg casts) in our study. We assume that patients will be more compliant with short leg casts than with CAM boots due to its removability and design. However, if they majority of noncompliant patients are noncompliant because they tripped and did so accidently, theoretically patients would also be noncompliant in a short leg cast. Second, we included "all-comers" that were made NWB in a CAM boot at 2 weeks postop, regardless of type of injury. This included ankle fractures, Lisfranc injuries, pilon fractures, calcaneus fracture, osteochondral lesions of the talus. These injuries have different pain profiles and varying proportions of this injuries relative to the entire cohort may have affected compliance rates (i.e., longer the pain persisted, the longer the patient is expected to be compliant). In this study we introduce a method of assessing NWB compliance via inspection of the CAM boot heel. Inter- and intra-observer reliability of this method has yet to be determined and should be an area of future study. Another limitation is that we tested this method on one specific model of CAM boot that has letters engraved in the heel region. Not all CAM boots have this design and therefore some may not be amenable to this visual inspection method.

This study has several strengths as well. High response rate (97%) indicates that our study has a low nonresponse bias. Also, we believe there to be no Hawthorne effect as we chose to consent patients to the study after the period of interest (week 3-6) was over. Finally, we introduced a new objective method of evaluating CAM boot noncompliance based on the amount of wear at the heel. We believe surgeons can also use this method to assess compliance with weightbearing as tolerated protocols for injuries that encourage weightbearing. In fact, by counseling patients that we are able to assess their compliance at the time the CAM boot is dispensed, we can use the Hawthorne effect to our advantage to discourage noncompliance.

Conclusion

In a postoperative foot and ankle patient population, NWB restriction in a CAM boot yields a moderate compliance rate of 91% and strict compliance rate of 29%. CAM boots may be sufficient for more stable fixation constructs such as most ankle fractures. However, surgeries requiring strict NWB compliance such as joint depression type calcaneus fracture and pilon open reduction internal fixation may be more reliably served with casting. Assessment of CAM boot wear pattern can be used to grossly estimate patient compliance and is especially useful for identifying higher levels of noncompliance.

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