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Orthotic Walking Boots for Patients with Fractures or Ligament Injuries: A Review of Clinical Effectiveness and Cost-Effectiveness

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Authors: Srabani Banerjee, Andrea Ryce

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Context and Policy Issues

Ankle injuries are one of the most common orthopedic injuries in the general population.[1] In a Swedish study it was reported that the annual incidence of ankle fractures in the adult population was 179 per 100,000 persons.[2] In the US, over five million ankle injuries occur annually.[3] In Canadians aged 12 years or older, it was estimated that there were 942,000 activity-limiting ankle or foot injuries per year.[4]

Ankle injuries include sprains and fractures. In ankle fractures, one or more of the bones that make up the ankle joint are broken.[5] The ankle joint is made up of three bones: tibia (shinbone), fibula (smaller bone of the lower leg) and talus (a small bone located between the heel bone [calcaneus] and the tibia and fibula).[5] The ankle bones and joint are held in position by the ligaments.[5] Toddler's fractures were first defined in 1964 by Dunbar et al. as oblique, non-displaced fractures of the distal one-third of the tibia occurring in children aged between nine months and three years; subsequently the term has also been used to include fractures of the proximal and mid-tibia.[6]

Treatments for ankle fractures include surgical and non-surgical options, depending on the type of fracture.[7] Generally, in case of fractures that are stable and undisplaced, non-surgical options are used to immobilize the affected leg with regular radiographic follow-up.[7] Immobilization methods include use of cast (made of plaster of Paris, or other synthetic material), braces, splints, or orthotic walking boots.[7] There appears to be uncertainty around the optimal non-surgical immobilization method for treating fractures.[7]

The purpose of this report is to review the clinical effectiveness and cost-effectiveness of orthotic walking boots for patients with ankle fractures or ligament injuries.

Research Questions

1. What is the clinical effectiveness of orthotic walking boots for patients with fractures or ligament injuries?
2. What is the cost-effectiveness of orthotic walking boots for patients with fractures or ligament injuries?

Key Findings

Evidence was available from three retrospective non-randomized studies. Based on a single low-quality study, treatment with rocker bottom walking boots provided greater clinical effectiveness than treatment with casts for adults with ankle fractures, however the between-group differences were not statistically significant for all of the outcomes investigated. Based on two low quality studies, treatment with controlled ankle motion boots was comparable to treatment with casts in pediatric patients with toddler's fracture in terms of clinical effectiveness outcomes; however, skin complications were observed with the use of casts but not with use of boots. No relevant cost-effectiveness studies were identified.

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including PubMed, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concept was orthotic walking boots. The search was also limited to English language documents published between January 1, 2014 and August 8, 2019.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients of all ages with ankle, tibia, or fibula fractures or ligament injuries
Intervention	Removable orthotic walking boots
Comparator	Non-removable casts or casting
Outcomes	Clinical effectiveness (e.g., patient quality of life, falls, adverse events) Cost-effectiveness
Study Designs	Health technology assessments, systematic reviews/meta-analyses, randomized controlled trials, non-randomized studies, and economic evaluations

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2014.

Critical Appraisal of Individual Studies

The primary studies were critically appraised using the Downs and Black checklist.[8] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 490 citations were identified in the literature search. Following screening of titles and abstracts, 479 citations were excluded and 11 potentially relevant reports from the electronic search were retrieved for full-text review. No potentially relevant publications were retrieved from the grey literature search for full-text review. Of these potentially relevant articles, eight publications were excluded for various reasons, and three publications met the inclusion criteria and were included in this report. These comprised three non-randomized studies.[6,9,10] No relevant systematic reviews, randomized controlled

trials or economic evaluations were identified. Appendix 1 presents the PRISMA[11] flowchart of the study selection.

Summary of Study Characteristics

Characteristics of the selected studies are summarized below, and additional details are provided in Appendix 2, Table 2.

Study Design

The three selected studies[6,9,10] were retrospective, non-randomized studies.

Country of Origin

Two studies[6,10] were conducted in the US and published in 2019 and 2016; and one study[9] was conducted in Japan and published in 2017.

Patient Population

One study[9] involved adult patients who had undergone surgery for an unstable ankle fracture and had the affected ankle immobilized during the post-operative recuperative period. The study included 47 patients with a mean age of 48.5 years, and the proportion of females was 53%. There were dissimilarities between the intervention and control groups; in the intervention group there were more severe cases and older patients compared with the control group.

Two studies[6,10] involved toddlers. One study[10] involved 192 patients with non-displaced spiral tibia fracture or occult fracture; the mean age was 2.04 years, and the proportion of females was 27%. The second study[6] involved 75 patients with radiographic evidence of toddler's fracture; the mean age was 21.3 months, and the proportion of females was 64%.

Interventions and Comparators

The study in adults[9] compared patients treated with a rocker bottom walking boot with those treated with a plaster cast. In the other two studies[6,10] a controlled ankle motion (CAM) boot was compared with a cast or splint, or no immobilization. Of note, in one study,[10] the initial mode of immobilization was changed to a different type in some patients (details in Appendix 2, Table 2) and results were presented according to both initial immobilization and final immobilization. The reasons for the changes were not reported.

Outcomes

Outcomes reported included time duration for improvement,[6,9,10] range of motion (difference with respect to unaffected side),[9] and complications.[6,10]

Summary of Critical Appraisal

The critical appraisal of the included studies is presented below and details are available in Appendix 3, Table 3.

All three selected studies[6,9,10] were retrospective non-randomized studies and were subject to selection bias. In all three studies[6,9,10] the objective was stated; inclusion and exclusion criteria were stated; and the patient characteristics, interventions, and outcomes were described but lacked details. In one study,[9] there was a statistically significant between-group difference with respect to mean age. In two studies[6,9] there appeared to be between-group differences in terms of the number of patients with a particular type or mechanism of

injury; however, whether the differences were statistically significant was not reported. In one study it was unclear if there were differences between the intervention and comparator groups, as the patient characteristics were not presented separately for the groups. In two studies,[6,10] the treatment type was selected based on the judgment of the attending physician, so there may have been systematic differences in patients assigned to different interventions. In one study,[6] data for all outcomes for all patients were not reported, and the extent of impact of the missing data on the findings is unclear. In one study[6] conflicts of interest were not presented, and in two studies[9,10] the authors reported that there were no conflicts of interest. Overall the selected studies appeared to be of low quality.

Summary of Findings

Findings are summarized below and details are available in Appendix 4, Table 4.

Clinical Effectiveness of Orthotic Walking Boots Compared with Casts

Adult patients

One study[9] compared patients treated with rocker bottom walking boots and those treated with casts, and showed that the duration of times to stand unipedal on the affected side after allowing full weight bearing (*P* =0.003) and to walk without crutches (*P* = 0.001) were significantly shorter for patients in the boot group. However, there were no statistically significant differences between groups with respect to range of motion (*P* = 0.842) or time to put full weight on the affected ankle (*P* = 0.732). There was no reporting of adverse effects.

Pediatric patients

In one study[10], the initial immobilization type was later changed at follow up, to a different type for some patients; reasons for changes were not reported. This study showed that return to weight bearing was statistically significantly faster (*P* = 0.04) with patients who were initially immobilized with a boot compared to a short leg cast, however there was no statistically significant difference (*P* = 0.20) between the groups based on final immobilization type. The authors mentioned that the shorter time to weight bearing in patients initially immobilized with boots may not be clinically significant, however the findings suggested that casts did not expedite healing. Note that results for the comparison of boots versus long casts were only presented graphically (i.e., not described in the text, so there are no results to report here). In the second study[6] the duration (days) of immobilization was comparable in both the boot and cast/splint groups; mean (95% confidence interval): 27.0 (23.5 to 30.9) and 27.5 (26.0 to 29.1), respectively.

In one study[10] there were three superficial skin ulcer complications in the group with initial immobilization with cast (out of 136 patients in the cast group); no other complications were reported. In another study,[6] skin breakdown was reported in 26.5% of the patients in the group with a cast or splint, and 0% of the patients in the group with boots.

Cost-Effectiveness of Orthotic Walking Boots

No relevant studies regarding the cost-effectiveness of orthotic walking boots for patients with ankle fractures or ligament injuries were identified, hence a summary of findings cannot be provided.

Limitations

The number of relevant studies identified were few (three studies) and of low quality. All the selected studies were retrospective non-randomized studies. Furthermore, treatment was at the discretion of the attending physician. No information with respect to quality of life or incidence of falls was available. In one study[6] the comparator was mixed (included both cast or splint), and results were not presented separately, hence it was unclear how boots compared specifically with casts.

No relevant cost-effectiveness studies were identified.

Findings need to be interpreted with caution, considering the limitations (such as sparse evidence, and low-quality studies).

Conclusions and Implications for Decision or Policy Making

Three relevant retrospective non-randomized studies,[6,9,10]comparing boots with casts for the treatment of ankle fractures were identified. One study[9] involved adult patients and the remaining two studies[6,10] involved pediatric patients. No relevant cost-effectiveness studies were identified.

There remains uncertainty with respect to the effectiveness of orthotic boots compared with casts for the treatment of patients with ankle fractures or ligament injuries. However, safety issues (skin complications) were reported with use of casts but not with use of boots in two studies involving pediatric patients. Based on a single low quality study,[9] treatment with rocker bottom walking boots provided greater clinical effectiveness than treatment with casts in adults with ankle fractures, however the between-group differences were not statistically significant for all of the outcomes investigated. Based on two low quality studies,[6,10] treatment with controlled ankle motion boots was comparable to treatment with casts in pediatric patients with toddler's fracture, in terms of clinical effectiveness outcomes; however, skin complications were observed with the use of casts but not with use of boots.

Well-designed, prospective studies are needed to determine which immobilization technique offers the most benefit for treating ankle fractures and ligament injuries.

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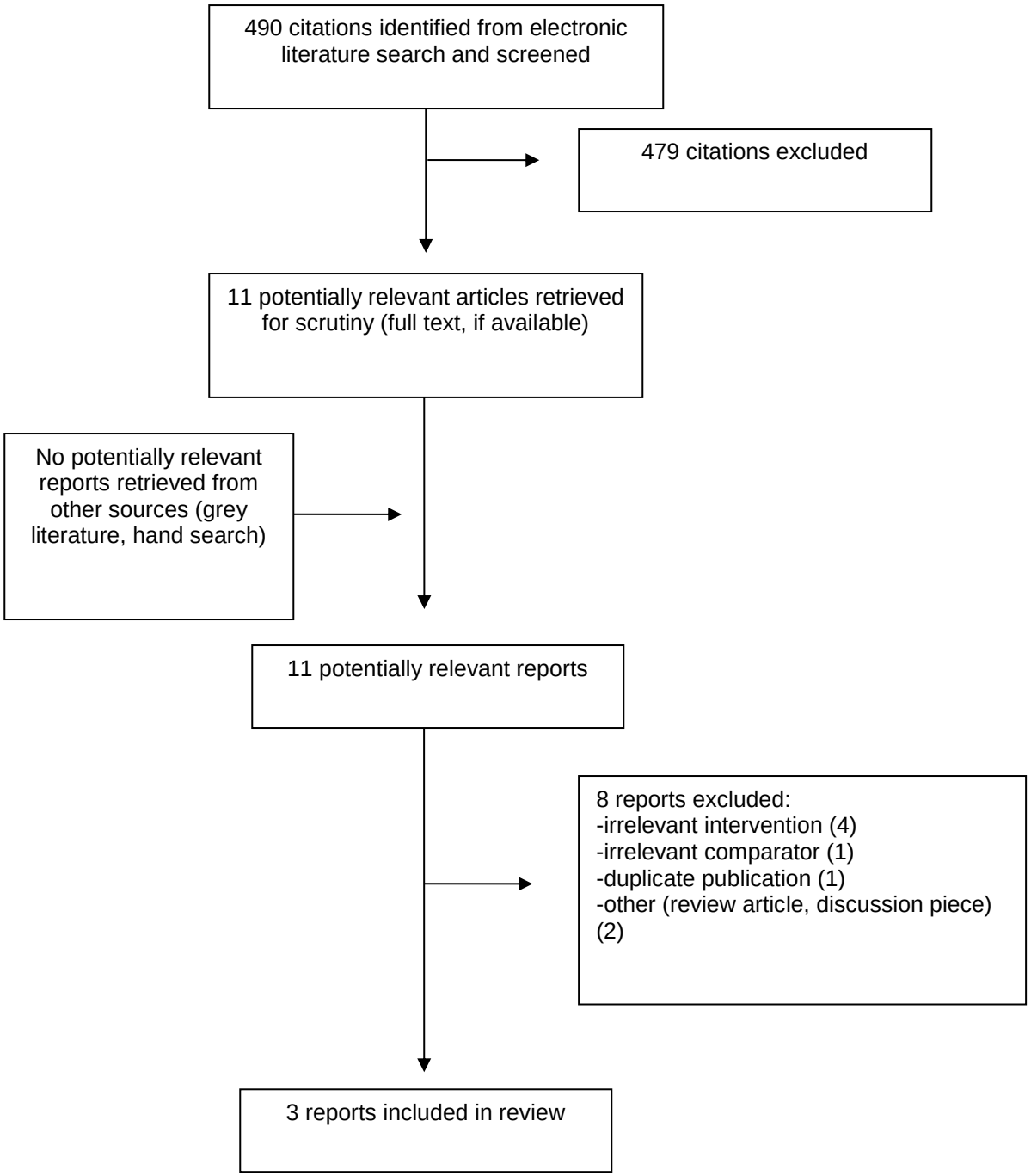
Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table 2: Characteristics of Included Primary Clinical Studies

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
Bauer,[10] 2019, US	3 year retrospective chart review The patients initially presented to the emergency department, orthopedic clinic or pediatrician at the investigators' hospital; or to the emergency department or pediatrician at a different hospital. All these patients were followed up at the orthopedic clinic.	Pediatric patients with isolated, non-displaced spiral tibia fractures with intact fibula, or those without the appearance of any injury (negative radiograph) in order not to miss occult fractures. N = 192 (patients with initial immobilization type: 53 with long leg cast, 83 with short leg cast, 46 with boot, 3 with long leg splint and 7 with none) Age (mean [95% CI]) (year): 2.04 (1.94 to 2.14) % Female: 27%	CAM walker boots (intervention of interest) compared with long leg cast, short leg cast, long leg splint, and none (i.e., no immobilization) Initial immobilization was with long leg cast in 53 patients, short leg cast in 83 patients, and boot in 46 patients. Twenty-three patients with the long leg cast and 28 patients with the short leg cast changed to boot after a mean duration of 10.9 days and 13.5 days respectively. Also, 19 patients with the long leg cast and 2 patients with the boot changed to the short leg cast after a mean duration of 8.7 days and 10.5 days respectively. Reasons for change were not presented. This resulted in final immobilization with the long cast, short leg cast, and boot in 11, 77, and 97 patients respectively Ten different physicians treated the children. The immobilization type and duration were based on the clinical judgement of the attending physician. Generally, decision to discontinue	Time duration to return to weight bearing, and complications Duration of follow up: not explicitly stated (results reported up to 6 weeks)

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
			immobilization was based on the patient's ability to weight-bear in the clinic or by the family's report.	
Amaha,[9] 2017, Japan	Retrospective study - review of medical records of patients who underwent surgery for ankle fracture at a single hospital in Japan, between January 2008 and October 2014	Adult patients who had undergone surgery for an unstable ankle fracture. The surgical procedure entailed an open reduction and an internal fixation. N = 47 (22 in WB group, and 25 in PC group) Age (mean ± SD) (years): 53.9 ± 11.9 for WB, and 43.8 ± 16.1 for PC (*P* = 0.026). % Female: 50% in WB, 56% in PC.	Walking boot (WB) with a rocker bottom design (Bledsoe walking boot) compared to plaster cast (PC). WB had an adjustable heel lift, which allowed the user to change the ankle position to facilitate walking with a post-operative swollen ankle.	Time duration for improvement at various stages; ROM; loss of reduction; non-union. Duration of follow-up at least 6 weeks
Schuh,[6] 2016, US	Retrospective study of patients in the age range of 9 months to 3 years presenting at the pediatric emergency department at Seattle's children's hospital between January 1, 2008 to December 31, 2012.	Pediatric patients with radiographic evidence of toddler's fracture N = 75 (18 with CAM boots, 50 with cast or splint, and 7 with no immobilization) Age (month) (mean ± SD): 11 ± 61.1, in boot group; 34 ± 68.0 in the cast/splint group; and 3 ± 42.9 in the immobilization group. % Female: 32% in boot group, 39% in the cast/splint group, and 57% in the immobilization group.	CAM boots (intervention of interest) compared with cast or splint or with no immobilization. Method of immobilization used was at the discretion of the treatment provider.	Duration of immobilization, number of follow-up orthopedic visits, change in therapy at follow-up, number of repeat radiographs, return to emergency department after initial treatment, and complications. Duration of follow-up: not reported

CAM = controlled ankle motion; PC = plaster cast; ROM = range of motion; SD = standard deviation; WB = walking boot.

Appendix 3: Critical Appraisal of Included Publications

Table 3: Strengths and Limitations of Clinical Studies using Downs and Black checklist[8]

Strengths	Limitations
Bauer,[10] 2019, US	
• The objective was clearly stated • The inclusion and exclusion criteria were stated • Patient characteristics, intervention and outcomes were described. Descriptions of the interventions lacked details. • Sample size calculation was conducted, and the study had sufficient power to detect a difference between groups • *P* values were reported for the results • The authors mentioned that there were no conflicts of interest	• Not a randomized controlled trial. This was a retrospective review of medical records. Characteristics of the different groups were not presented separately hence it was unclear if there were any were dissimilarities between the intervention and control groups. • Of the 192 patients in the study, weight bearing information was available for 184 patients at final follow up. The remaining 8 patients did not have weight bearing information for various reasons
Amaha,[9] 2017, Japan	
• The objective was clearly stated • The inclusion and exclusion criteria were stated • Patient characteristics, intervention and outcomes were described. • All patients selected were analyzed • *P* values were reported for the results • The authors mentioned that there were no conflicts of interest	• Not a randomized controlled trial. This was a retrospective review of medical records. There were dissimilarities between the intervention and control groups with respect to mean age of the patients and severity of injury. • There was no evidence of a sample size calculation
Schuh,[6] 2016, US	
• The objective was clearly stated • The inclusion and exclusion criteria were stated • Patient characteristics, intervention and outcomes were described. Descriptions of the interventions lacked details • *P* values were reported for the results	• Not a randomized controlled trial. This was a retrospective review of medical records. *P* values for between-group differences in patient characteristics were not presented, hence it unclear if there were differences between groups. • There was no evidence of a sample size calculation • All outcomes for all selected patients were not documented in the medical records; the analyses were based on the data available. • Conflicts of interest were not presented

Appendix 4: Main Study Findings and Authors' Conclusions

Table 4: Summary of Findings of Included Primary Clinical Studies

Main Study Findings	Authors' Conclusion
Bauer,[10] 2019, US	
Outcomes in pediatric patients (9 months to 4 years) with ankle fractures (Note: Initial immobilization was with long leg cast in 53 patients, short leg cast in 83 patients, and boot in 46 patients. Twenty-three patients with the long leg cast and 28 patients with the short leg cast changed to boot after a mean duration of 10.9 days and 13.5 days respectively. Also, 19 patients with the long leg cast and 2 patients with the boot changed to the short leg cast after a mean duration of 8.7 days and 10.5 days respectively. Reasons for change were not presented. This resulted in final immobilization with the long cast, short leg cast, and boot in 11, 77, and 97 patients respectively) Return to weight bearing (weeks): 2.5 for the group with initial immobilization with boot and 2.8 for the group with initial immobilization with short leg cast, *P* = 0.04. Note that results for the comparison of boots versus long casts were only presented graphically (i.e., not described in the text, so there are no results to report here). There was no statistically significant difference in time to weight-bear based on final type of immobilization (*P* = 0.20). Adverse effects: There were 3 superficial skin ulcer complications in the group with initial immobilization using cast. No other complications were reported.	"This study, to our knowledge, represents the largest cohort of toddler's fractures in the literature. The findings demonstrate the inherent stability of the fracture and therefore successful treatment no matter the immobilization type used, without aid by follow-up radiographs. We recommend immobilization based on family and physician agreement, although the use of a boot may speed weightbearing and avoid cast sores." (p. 316-317)
Amaha,[9] 2017, Japan	
Outcomes in adult patients with ankle fracture who underwent surgery, and then were prescribed either a walking boot (WB) or plaster cast (PC). Time duration after which the patients were allowed to put full weight on affected side (mean ± SD) (weeks): 5.5 ± 0.9 with WB, 5.8 ± 1.5 with PC; *P* = 0.732. Time duration for the patient to stand unipedal on the affected side after allowing full weight bearing (mean ± SD) (weeks): 1.4 ± 1.7 with WB, 3.1 ± 2.2 with PC; *P* = 0.003 Time duration for the patient to walk without crutches (mean ± SD) (weeks): 2.6 ± 1.8 with WB, 4.5 ± 2.3 with PC; *P* = 0.001 ROM of ankle (within-patient differences between the affected and unaffected sides), (mean ± SD) (weeks): 5 ± 3.8 with WB, 5.2 ± 2.8 with PC; *P* = 0.842 Loss of reduction: none in both groups Nonunion: none in both groups	"The WB treatment results in faster functional recovery, allowing the patients to return to normal activities at a faster rate." (p.13)
Schuh,[6] 2016, US	
Outcomes in pediatric patients (9 months to 3 years) with toddler's fracture Duration of immobilization (mean [95% CI]) (days): 27.0 (23.5 to 30.9) for WB group, 27.5 (26.0 to 29.1) for CS group, and 4.1 (2.8 to 5.9) NM group; *P* < 0.001 (based on available data i.e., data from 8, 43, and 7 patients in WB, CS, and NM	"This study demonstrates the wide variation in management of toddler's fractures while highlighting the potential harm done by unnecessary splinting and casting. The incidence of skin breakdown related to

Main Study Findings	Authors' Conclusion
groups respectively). Some patients in the NM group who were followed up at an orthopedic clinic were subsequently immobilized. Number of orthopedic follow-up visits (mean [95% CI]): 1.2 (0.8 to 1.9) for WB group, 1.3 (1.0 to 1.6) for CS group, and 0.9 (0.3 to 1.9) for NM group; *P* < 0.001. Change (%) in therapy at follow-up (mean [95% CI]): 27.3 (6.0 to 61.0) for WB group, 10.4 (3.5 to 22.7) for CS group, and 50.0 (6.8 to 93.2) for NM group; *P* = 0.04 (based on available data i.e., data from 8, 43, and 7 patients in WB, CS, and NM groups respectively). Number of repeat radiographs (mean [95% CI]): 0.5 (0.2 to 0.9) for WB group, 2.1 (1.7 to 2.5) for CS group, and 0.4 (0.1 to 1.3) for NM group; *P* < 0.001. Return to emergency department after initial treatment (%) (mean [95% CI]): 0 (0 to 18.5) for WB group, 8.0 (2.2 to 19.2) for CS group, and 14.3 (0.4 to 57.9) for NM group; *P* = 0.3. Skin breakdown (%) (mean [95% CI]): 0 (0 to 28.5) for WB group, 26.5 (15.0 to 41.1) for CS group, and 0 (0 to 60.2) for NM group; *P* = 0.1 (based on available data i.e., data from 11, 49, and 4 patients in WB, CS, and NM groups respectively). None of the patients who were not immobilized, and 9.6% of the patients who were immobilized at their initial visit, returned for concerns with pain. Note: Results pertain to the "initial treatment" group (initially there were 18, 50, and 7 patients in WB, CS, and NM groups respectively) Also, data for all outcomes were not recorded for all patients and analyses were based on available data.	splinting and casting was a concerning finding." (p.4 of 6)

CI = confidence interval; CS = cast or splint; NM = no mobilization; PC = plaster cast; ROM = range of motion; SD = standard deviation; WB = walking boot.