

# CADTH RAPID RESPONSE REPORT: SUMMARY WITH CRITICAL APPRAISAL

# External Supports for the Treatment of Ankle Sprain: A Review of Clinical Effectiveness

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## **Abbreviations**

AMSTAR A Measurement Tool to Assess systematic Reviews

NSAIDS Non-steroidal anti-inflammatory drugs

PRICE Protection, rest, ice, compression, and elevation

PRISMA Preferred Reporting Items for Systematic Reviews and Meta-

Analyses

RCT Randomized controlled trial

RICE Rest, ice, compression, and elevation

SR Systematic review VAS Visual analog scale

# **Context and Policy Issues**

In Canada, 35% of injuries are related to sport or exercise.<sup>1</sup> Ankle injuries (sprain or strain) are among the most common types of injury (51%) presenting to the primary care offices and emergency departments.<sup>1</sup> There are three types of ankle sprain, the location of which is determined by the mechanism of injury: lateral ankle sprain (most common), medial ankle sprain, and syndesmotic sprain (high ankle sprain).<sup>2</sup> Ankle sprain is classified based on clinical signs and functional loss, as follows: grade 1 (mild stretching of a ligament without any instability), grade 2 (more severe injury involving incomplete tear of a ligament with slight instability), and grade 3 (complete tear of a ligament and instability).<sup>2</sup>

The immediate goal for treatment of ankle sprain is to reduce pain and swelling. The RICE (rest, ice, compression, elevation) approach has been commonly used in the first two to three days following injury, although evidence on the effectiveness of RICE alone is still lacking.<sup>2</sup> Non-steroidal anti-inflammatory drugs (NSAIDs) can be used to reduce pain. However, the use of NSAIDs may delay the natural healing process due to their inflammatory suppression mechanism.<sup>3</sup> Other modes of non-pharmacological treatment of ankle sprain, depending on the severity of the injury, include immobilization, exercise, manual mobilization, and functional rehabilitation.<sup>2</sup> External ankle supports used in immobilization treatments include bandages, tapes, stockings, and different types of braces.<sup>2</sup> In more severe cases, the ankle is normally immobilized with a plaster cast or splint for a few days.<sup>4</sup> Given the wide variety of types of external ankle supports, there is a need to find out their clinical effectiveness for the treatment of ankle sprain.

The aim of this report is to review the evidence regarding the clinical effectiveness of external supports for the treatment of individuals with ankle sprain.

# **Research Question**

What is the clinical effectiveness of external supports for the treatment of individuals with ankle sprain?



# **Key Findings**

This review included one systematic review and two primary studies (one randomized controlled trial and one cohort study) regarding the clinical effectiveness of external supports for the treatment of individuals with ankle sprain. The external supports identified in this review were stockings, elastic bandages, cohesive tape, lace-up ankle supports, semi-rigid ankle supports or posterior rigid supports, and short-leg casts.

Based the findings of the systematic review, stockings were found to be significantly more effective in improving pain, swelling, functional outcomes, and range of motion compared to bandages. However, stockings showed no significant difference in pain and swelling, but had a significantly shorter period of return to sport activities compared with placebo. The systematic review found no significant differences between taping and other external supports (such as soft braces, semi-rigid braces and lace-up braces) with regards to pain, swelling, function, range of motion, patient satisfaction, and return to sports or work. There were also no significant differences between semi-rigid or posterior rigid supports compared to tape or bandages with regards to pain, range of motion, function, or return to sports or work. There was some evidence that semi-rigid or posterior rigid supports had significantly higher patient satisfaction than tape or bandages. Reported complications associated with bandages and Air-cast brace were suspected deep vein thrombosis and suspected pulmonary embolism, with Bledsoe boots were associated with cellulitis, and taping was associated with dermatitis, skin blister, bullae formation or skin abnormalities; however, the incidence rates of these complications were unclear.

The included randomized controlled trial found that the addition of kinesiotape to acupuncture did not significantly improve pain, swelling, quality of life, or number of recurrent ankle sprains. The included cohort study also found no significant differences between cohesive taping and short-leg casts in terms of swelling and function.

Taken together, stockings may be a better treatment option among different external supports for functional treatment for acute ankle sprains. Treatment with bandages, tape and semi-rigid or posterior rigid supports may be associated with some complications, however the risk of these complications was unclear.

# **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 concepts were ankle sprain and ankle support devices. No filters were applied to limit the retrieval by study type. The search was also limited to English language documents published between January 1, 2015 and April 2, 2020.



#### 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 any age) with ankle sprain of any grade   |
|---------------|--|
| Intervention  | External supports (e.g., ankle braces, support bandages, ankle tape, walking boots)  |
| Comparator    | Pharmacotherapy (e.g., ibuprofen, acetaminophen, opioids); non-pharmacological treatments (e.g., external supports, immobilization, RICE method, alternative exercises); surgery; no treatment (i.e., no exercise); any combination of the listed comparators (e.g., pharmacotherapy and exercise) |
| Outcomes      | Clinical effectiveness (e.g., ankle function [e.g., Karlsson ankle function scale score], pain, quality of life, time to return to activities, risk for re-injuries)   |
| Study Designs | Health technology assessments, systematic reviews, randomized controlled trials, and non-randomized studies  |

RICE = rest, ice, compression, and elevation.

## **Exclusion Criteria**

Studies were excluded if they did not meet the selection criteria in Table 1 or if they were published prior to 2015. The identified primary studies that were captured in the included systematic reviews (SR) were excluded.

## Critical Appraisal of Individual Studies

The included SRs were critically appraised by one reviewer using the A MeaSurement Tool to Assess systematic Reviews version 2 (AMSTAR 2) checklist.<sup>5</sup> The critical appraisal checklist of Downs and Black was used to assess the quality of the included randomized controlled trial (RCT) and non-randomized study.<sup>6</sup> Summary scores were not calculated for the included studies; rather, the strengths and limitations were described narratively.

# **Summary of Evidence**

# Quantity of Research Available

A total of 461 citations were identified in the literature search. Following screening of titles and abstracts, 455 citations were excluded and six potentially relevant reports from the electronic search were retrieved for full-text review. One potentially relevant publication was retrieved from the grey literature search. Of the seven potentially relevant articles, four publications were excluded for various reasons, while three publications met the inclusion criteria and were included in this report. These comprised one SR and two primary studies (one RCT and one cohort study). Appendix 1 presents the PRISMA flowchart<sup>7</sup> of the study selection.

# Summary of Study Characteristics

The detailed characteristics of the included SR<sup>8</sup> (Table 2) and two primary studies<sup>9,10</sup> (Table 3) are presented in Appendix 2.



#### Study Design

The included SR $^8$  selected RCTs and quasi-experimental studies, which were identified from searches of multiple databases from September 2007 to September 2017. The PEDro scale (a 10-point scale) was used to assess the methodological quality of included studies. Studies with a score of  $\geq$  6 were considered as high quality. Those with score < 6 were considered as low quality.

One included primary study<sup>9</sup> was multicentre, assessor-blinded, parallel 1:1 RCT. The required sample size was calculated a priori. Data were analyzed using the per-protocol approach. Another included primary study<sup>10</sup> was a cohort study with no sample size calculation.

## Country of Origin

The included SR was conducted by authors from UK.<sup>8</sup> The included primary studies were conducted by authors from Republic of Korea<sup>9</sup> and Turkey.<sup>10</sup>

#### Patient Population

The SR<sup>8</sup> included studies involving adult patients with acute ankle sprains of mild (grade 1), moderate (grade 2) and severe (grade 3). The mean age of patients was not reported.

The RCT<sup>9</sup> included adult patients with acute lateral ankle sprain recruited from three hospitals, with mean age of 39 years. Patients had grade 1 (54%) and grade 2 (46%) lateral ankle sprain.

The cohort study<sup>10</sup> included patients with acute ankle sprains recruited from the emergency and orthopedic clinics. The mean age was 28.61 years, ranging from 11 to 52 years. Patients were diagnosed with grade 1 and grade 2 ankle sprain, but the proportion of patients with each grade of severity was not reported.

## Interventions and Comparators

The SR<sup>8</sup> included 10 studies (nine RCTs and one non-RCT) comparing the effectiveness of different external supports for acute ankle sprains. They were grouped as 1) elastic bandages, stockings or external assistance with elastic-sock-like material to support the ankle joint, 2) all types of adhesive or elastic tapes to support the ankle joint, 3) lace-up ankle supports or other external assistance made up of soft canvas-like or nylon materials, and 4) semi-rigid ankle supports, posterior rigid supports or other external assistances made up of firm thermo plastic elements. The actual interventions in the included studies in the SR were phase-adapted semi-rigid orthosis (Malleo TriStep), non phase-adapted semi-rigid orthosis (Aircast Air-stirrup), compression stockings, below knee casts, Bledsoe boots, tubular bandages, Aircast braces, soft braces (Push med ankle brace), tape, semi-rigid braces, plaster of Paris, walking boots, and lace-up braces. Five out of 10 studies reported the duration of the treatment periods, which varied from three to seven weeks.

The RCT<sup>9</sup> compared kinesiotape plus acupuncture with acupuncture alone. Patients were treated once daily, five days per week, for one week. Follow-up periods were at week 1 (after the single week of treatment) and at week 5 (four weeks after completion of treatment) for outcomes such as pain, edema, function and quality of life. The number of recurrent ankle sprains was quantified at weeks 5, 9, 13 and 27.



The cohort study<sup>10</sup> compared cohesive taping with short-leg casts. All patients were advised to apply a standard therapy regimen including rest, ice, elevation and anti-inflammatory drugs. Weight-bearing was prohibited during the first 10 days, weight-bearing with control was allowed during the next 10 days, and full weight-bearing was allowed after 20 days of treatment. Treatment was completed at the end of 40 days. Outcomes were evaluated at day 1, day 10 and day 100.

#### Outcomes

The outcomes considered in the SR<sup>8</sup> were pain, swelling, functions, ankle mobility or range of motion, complications and side effects, return to sports or work, and other outcomes (i.e., duration of crutches use, stair climbing, using analgesic medications, benefit score, and patient satisfaction). Pain was assessed using a visual analog scale (VAS), a 10-cm straight line marked at each end with the anchor labels "no pain" and "pain as bad as it could be". Scores were recorded in millimeters (range from 0 to 100 mm). Functions were assessed with Foot and Ankle Outcome score (FAOS), American Orthopedic Foot and Ankle Society's (AOFAS) Ankle Hind Foot scale, questionnaires for ankle dorsiflexion comparing with sound leg, Karlsson scoring scale, or Tegner activity scale. The FAOS evaluates symptoms and functional limitation, and consists of five subscales: pain (9 items), other symptoms (7 items), activities of daily living (17 items), sports and recreational activities (5 items) and foot- and ankle-related quality of life (4 items); the subscales are scored using a Likert response format, with higher scores indicating higher levels of function. The AOFAS (100 points total) evaluates pain (40 points; 0 = severe, almost always present, and 40 = none), function (50 points; 6 categories; 0 = severe limitation, and highest point of each category = no limitation), and alignment (10 points; 0 = poor, and 10 = good). The Karlsson scoring scale (100-point scale) consists of 8 subscales, which are pain (20 points; 20 = none, 0 = constant), swelling (10 points; 10 = none, 0 = constant), instability (25 points; 25 = none, 0 = constant), stiffness (5 points; 5 = none, 0 = marked), stair climbing (10 points; 10 = no problems, 0 = impossible), running (10 points; 10 = no problems, 0 = impossible), work activities (15 points; 15 = same as pre-injury, 0 = severe impaired), and support (5 points; 5 = none, 0 = ankle support during daily activity). The Tegner activity scale has 11 levels of activities of daily living, recreation, and competitive sports, where 0 represents disability, and a score of 10 represents national and international elite competitive sports.

The included RCT<sup>9</sup> assessed symptoms and function using FAOS, edema, quality of life using the European Quality of life Five Dimension-Five Level Scale (EQ-5D-5L), and number of recurrent ankle sprains. The EQ-5D assesses health-related quality of life, and defines health in terms of five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). EQ-5D-5L is a new version of EQ-5D that includes five levels of severity in each of the existing five EQ-5D dimensions.

The included cohort study<sup>10</sup> assessed pain and function using AOFAS, and edema.

#### Summary of Critical Appraisal

The detailed quality assessments of the included SR<sup>8</sup> (Table 4) and primary studies<sup>9,10</sup> (Table 5) are presented in Appendix 3.

The authors of the SR<sup>8</sup> provided appropriate research questions, explanations for selection of the study designs for inclusion in the review, and used comprehensive literature search strategies. The authors described the included studies in adequate detail and used the



PEDro scale (a 10-point scale) to assess the quality of the included studies. This SR used a narrative approach to summarize the findings. The risk of bias in individual studies was accounted for when interpreting and discussing the results. The authors provided satisfactory explanations for any heterogeneity observed in the results.

In terms of limitations, the authors of the SR<sup>8</sup> did not provide explicit statements that protocols had been established prior to the conduct of the review. It was unclear if study selection and data extraction were performed in duplicate, as this was not reported. The authors did not provide lists of excluded studies or report the sources of funding for the included studies. Conflicts of interest and financial disclosures were not declared in the review. Although all studies included in the SR were clinical trials, blinding of the physicians or patients was not possible due to nature of the interventions. Thus, there might be some risk of selection bias (i.e., clinicians or participants choosing the interventions) in those trials. Side effects of the interventions were described in the SR, but the incidence rates of some side effects were not reported.

The authors of the RCT<sup>9</sup> clearly described the objective of the study, the main outcomes to be measured, the interventions of interest and the main findings of the study. The study provided estimates of the random variability in the data for the main outcomes (i.e., standard deviations), and reported the actual probability values for all outcomes. The study did not report on adverse events. In terms of external validity, the study aimed to recruit participants from the entire population, as it recruited patients via local newspapers, the internet, and posters in communities and hospitals. However, the study participants may not represent the entire population from which they were recruited since they were from only three hospitals. The staff, places and facilities where the patients were treated may not be representative of the treatment the majority of patients receive. In term of internal validity (assessing general bias), it was not possible to blind the study participants to the interventions, but the outcome assessors were blinded. No retrospective unplanned subgroup analyses were reported, appropriate statistical tests were used to assess the main outcomes, all patients were followed up with the same length of time, the discontinuation rates were low (10% in the intervention group and 3% in the control group, although reasons for drop-out were not provided), and the outcomes were measured using reliable and valid methods. In terms of internal validity (assessing selection bias), patients from the intervention and control groups were probably recruited from the same population and during the same period of time. Whether there was allocation concealment during assignment of participants to groups was not described. Although the efficacy was assessed and reported using per-protocol analysis, the authors stated that both full set analysis and per-protocol analysis were not different. A sample size calculation was performed a priori, and enough participants were enrolled to have sufficient power to detect a clinically important effect with a statistical power of 0.8.

The authors of the cohort study<sup>10</sup> clearly described the objective, the main outcomes to be measured, and the main findings of the study. The study provided estimates of the random variability in the data for the main outcomes (i.e., standard deviations), but did not report the actual probability values for the main outcome. The characteristics of the included patients were not clearly described, especially the proportion of patients with disease severity (i.e., grade 1 or grade 2) was not reported. The list of principle confounders was not provided. It was unclear how patients were selected into each treatment group. The study did not report on adverse events or the number of patients lost to follow-up. In term of external validity, it was unclear if the recruited participants were representative of the entire population, and it was unclear if the patients who participated in the study were representative of the



population from which they were recruited. Patients were recruited from emergency and orthopedic clinics, which may not be representative of treatment the majority of patients receive. In term of internal validity (assessing general bias), outcome assessors were not blinded, there were no retrospective unplanned subgroup analysis reported, all patients had same length of follow-up, and the outcomes were measured using reliable and valid methods. Compliance with the interventions was not reported. The study had high risk of selection bias, as it was unclear if patients in the taping and short-leg cast groups were recruited from the same population, there was no randomization to intervention groups, there was no adjustment for confounding in the analyses, patients lost to follow-up were not reported and taken into account, and a sample size calculation was not performed.

# Summary of Findings

The main findings and authors' conclusions of the SR,<sup>8</sup> (Table 6), RCT<sup>9</sup> and cohort study<sup>10</sup> (Table 7), are presented in Appendix 4.

Clinical Effectiveness of External Supports

## Pain

- The SR<sup>8</sup> included four high-quality RCTs assessing the efficacy of stockings and bandages with respect to pain. One RCT found that stockings were significantly more effective than bandages in reducing pain (P < 0.001), but another RCT showed no significant difference in pain between stocking and placebo groups. One RCT showed that bandages were significantly less effective in reducing pain compared to below-knee casts (P < 0.05), and were not significantly different compared to Air-cast braces and Bledsoe boots at 4 weeks and 12 weeks of follow-up. However, there were no significant differences between all groups at 9 months. One RCT showed that bandages significantly reduced pain compared to Plaster of Paris at six weeks follow-up.</p>
- The SR<sup>8</sup> included two low-quality studies (one RCT and one cohort study) assessing the efficacy of taping treatment with respect to pain. One low quality cohort study found no significant difference between tape and soft braces (Push med brace) for pain at one-year follow-up. One low quality RCT found no significant difference in pain among tape, semi-rigid brace and lace-up brace groups.
- The SR<sup>8</sup> included one high-quality RCT and two low-quality RCTs comparing the efficacy between different interventions (Air-cast braces and Bledsoe boots; Air-cast braces, immobilization, and walking boot; tape, semi-rigid ankle supports, and lace-up supports) in terms of pain. The results showed no significant differences in pain between interventions.
- The included RCT<sup>9</sup> found that the addition of kinesiotape to acupuncture did not significantly reduce pain compared to acupuncture alone.

#### **Swelling**

 The SR<sup>8</sup> included two high-quality RCTs assessing the efficacy of stockings in reducing swelling. One RCT found that stockings significantly reduced swelling



- compared to bandages (P < 0.001). Another RCT found no significant difference in swelling between stockings and placebo.
- The SR<sup>8</sup> included one low-quality cohort study, which found no significant difference between tape and soft braces (Push med ankle brace) on swelling at one-year follow-up. The SR did not find any trial evaluating swelling following treatment with semi-ankle supports, posterior rigid supports or thermoplastic assistance.
- The included RCT<sup>9</sup> found no significant difference between the combination of kinesiotape plus acupuncture and acupuncture alone in terms of degree of edema.
- The included cohort study<sup>10</sup> found no significant difference between cohesive taping and short-leg casts in terms of edema improvement after 10 days followup.

# Functions including quality of life

- The SR<sup>8</sup> included four high-quality RCTs investigating the efficacy of bandages, Air-cast braces, below-knee casts, Bledsoe boots, and stockings in terms of functional outcomes. Two RCTs found that bandages were significantly less effective than Air-cast braces and below-knee casts, and were not significantly different compared to Bledsoe boots. There was no significant difference across all groups at nine months follow-up. One RCT found that bandages were significantly more effective than Plaster of Paris at week 6 (P < 0.001), while another RCT showed that stockings had significantly higher functional outcome scores compared to bandages at week 4 (P =0.002) and week 8 (P < 0.001).</p>
- The SR<sup>8</sup> included one high-quality RCT and two low-quality studies (one RCT and cohort study) examining the efficacy of taping treatments in terms of functional outcome. One low-quality cohort study found no significant difference between tape and soft braces (Push med brace) in functional outcomes at one-year follow-up, while one high-quality RCT found no significant difference in Karlsson scores between tape and semi-rigid braces. One low-quality RCT found no significant differences in overall functional outcomes among tape, semi-rigid braces and lace-up braces.
- The SR<sup>8</sup> included four high-quality RCTs and two low-quality RCTs investigating functional outcomes in semi-rigid ankle supports, posterior rigid supports or thermoplastic external assistance. Two high-quality RCTs found no significant difference in functional outcomes among Air-cast braces, Bledsoe boots, below-knee casts and bandages at nine months follow-up. One high-quality RCT did not find any significant difference in functional outcomes between two types of semi-rigid braces (Malleo TriStep and Aircast Air-stirrup), while another high-quality RCT found no significant difference between semi-rigid braces and tape. One low-quality RCT showed that semi-rigid braces had significantly higher functional scores than immobilization boots at week 3 (P = 0.0348) and week 6 (P = 0.027), but no significant difference at week 12. Another low-quality RCT found no significant difference in functional scores among semi-rigid braces, lace-up braces and tape.



- The included RCT<sup>9</sup> found no significant difference between the combination of kinesiotape plus acupuncture and acupuncture alone in terms of quality of life and functional outcomes.
- The included cohort study<sup>10</sup> found no significant difference between cohesive and short-leg casts in terms of function after 10 days and 100 days follow-up.

## Ankle mobility and range of motion

- The SR<sup>8</sup> included one high-quality RCT, which found that stockings resulted in greater range of motion compared to bandages after eight weeks of treatment (P < 0.001).</li>
- The SR<sup>8</sup> included one high-quality RCT, which found no significant difference in both active and passive range of motion between tape and semi-rigid braces at week 4 and week 12 follow-up.

# Complications and side effects

- The SR<sup>8</sup> included two high-quality RCTs assessing the complications associated with bandages, Air-cast braces, Bledsoe boots, and below-knee casts. One RCT found two out of 144 patients in the bandage group had suspected deep vein thrombosis or pulmonary embolism. Air-cast braces were associated cellulitis (one out of 149 patients), suspected deep vein thrombosis or pulmonary embolism (one out of 149 patients). One out of 119 patients of below-knee cast group had suspected deep vein thrombosis or pulmonary embolism. Cellulitis (one out of 149 patients) was also reported in Bledsoe boot group. Another high-quality RCT also reported the presence of deep vein thrombosis (in the Air-cast, bandage, and below-knee cast groups), pulmonary embolism (in the Air-cast and bandage groups), and cellulitis (in the Air-cast and Bledsoe boot groups); however, incidence rate was not reported in the SR.
- The SR<sup>8</sup> included one high-quality RCT and two low-quality studies (one RCT and cohort study) examining the incidence of complications and side-effects in patients treated with soft braces, tape and semi-rigid braces. One low-quality cohort study found that tape and soft braces (Push med brace) were associated with skin irritation and that 52% and 39% discontinued treatment, respectively. The rate of ankle re-injury was 14% and 17% in the tape group and the soft brace (Push med brace), respectively, at one-year follow-up. One high-quality RCT found that tape had a significantly higher rate of complications (dermatitis, bullae formation or skin abnormalities) compared to semi-rigid braces (P < 0.001). One low-quality RCT found that two out of 66 patients in the tape group had skin blisters and had to switch to the semi-rigid brace treatment.</p>

# Return to sports or work

- The SR<sup>8</sup> included one high-quality RCT, which found that the period of returning to sport activities among patients receiving stocking treatment was significantly shorter than among those receiving placebo. Another high-quality RCT found no significant difference between those treated with stockings and bandages in time to return to work.
- The SR<sup>8</sup> included one low-quality RCT, showing no significant difference in return to sports or work among tape, semi-rigid brace and lace-up brace groups.



#### Other outcomes

- The SR<sup>8</sup> included two high-quality RCTs investigating other outcomes (duration of crutches use, stair climbing, using analgesic medications, or benefit score) in those treated with stockings and bandages. One RCT found that the duration of crutches use was significantly shorter in the stocking group than in the bandage group (P = 0.003); however, there were no significant differences between groups in stair climbing, or using analgesic medications. One RCT showed that those treated with bandages had a lower benefit score than those treated with below-knee casts, Air-cast, and Bledsoe boots, but statistical comparisons were not provided.
- The SR<sup>8</sup> included one high-quality RCT, which showed that patients in the semirigid brace group had higher satisfaction than those in taping group (P < 0.001).</li>
- The SR<sup>8</sup> included two high-quality RCTs assessing patient satisfaction among different interventions (Air-cast brace, Bledsoe boot and bandage; semi-rigid brace and tape). One RCT showed that patients who were treated with Air-cast braces and Bledsoe boots had higher satisfaction than those treated with bandages, but statistical comparison was not reported. One RCT showed that those treated with semi-rigid braces had higher patient satisfaction than those treated with tape (P < 0.0001).</p>

#### Recurrence of ankle sprains

 The included RCT<sup>9</sup> found no significant difference between the combination of kinesiotape plus acupuncture and acupuncture alone in terms of the number of recurrent ankle sprains.

#### Limitations

There was no evidence on the effectiveness of external supports compared to pharmacotherapy, surgery, or exercise in combination with pharmacotherapy or surgery, for the treatment of ankle sprains. The population in the included studies consisted mainly adult patients; thus, the findings cannot be generalized to other populations. Due to few trials per comparison and wide heterogeneity in terms of patient demographics and study characteristics of the included trials in the SR, meta-analysis was not possible to obtain point estimates of the main outcome measures. Therefore, the evidence obtained in this review was based solely on narrative review of the findings that came from limited number of trials, and therefore the findings should be cautiously interpreted.

# **Conclusions and Implications for Decision or Policy Making**

This review included one SR<sup>8</sup> and two primary studies (one RCT<sup>9</sup> and one cohort study<sup>10</sup>) regarding the clinical effectiveness of external supports for the treatment of individuals with ankle sprain. The external supports identified in this review were stockings, bandages, cohesive tape, lace-up ankle supports, semi-rigid ankle supports or posterior rigid supports, and short-leg casts.

Based the findings of the SR,<sup>8</sup> stockings were found to be significantly more effective in improving pain, swelling, functional outcomes, and range of motion compared to bandages. However, compared with placebo, stockings showed no significant difference in pain and swelling, and had a significantly shorter period of return to sport activities. Complications



identified in the treatment with bandage were suspected deep vein thrombosis and pulmonary embolism, but importantly the incidence rates of these complications were not reported.

The SR<sup>8</sup> found no significant differences between taping treatment and other external supports such as soft braces (Push med brace), semi-rigid braces and lace-up braces with regards to pain, swelling, function, range of motion, patient satisfaction, and return to sports or work. The included RCT<sup>9</sup> found that the addition of kinesiotape to acupuncture did not significantly improve pain, swelling, quality of life or number of recurrent ankle sprains. The included cohort study<sup>10</sup> also found no significant differences between cohesive taping and short-leg casts in terms of swelling and function. Complications associated with taping treatment were dermatitis, skin blister, bullae formation or skin abnormalities, but incidence rates were not reported.

Based the findings of the SR,<sup>8</sup> there were no significant differences between semi-rigid or posterior rigid supports and tape or bandages with regards to pain, range of motion, function, or return to sports or work. There was some evidence that patients treated with semi-rigid or posterior rigid supports had significantly higher "benefit score" than those treated with tape or bandages. Complications associated with Bledsoe boot was cellulitis, and with Air-cast brace were skin complications, suspected deep vein thrombosis and suspected pulmonary embolism, but incidence rates were not reported.

Taken together, these findings suggest that stockings may be an effective external support treatment option for the treatment of acute ankle sprains. Treatment with bandages, tape, and semi-rigid or posterior rigid supports may be associated with some complications, however the incidence rates were unclear so the risk of having a complication is unknown. Further well-controlled studies are needed to identify the type of external supports that are effective for the treatment of ankle sprains with different grades of severity.

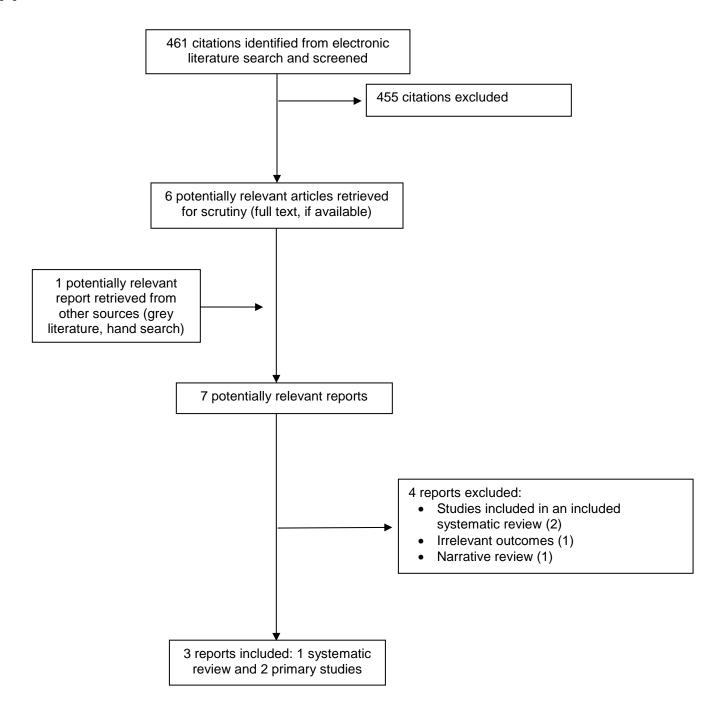


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# **Appendix 1: Selection of Included Studies**





# **Appendix 2: Characteristics of Included Publications**

**Table 2: Characteristics of Included Systematic Reviews** 

| First Author, Publication Year, Country, Funding        | Objectives, Types and<br>Numbers of Primary<br>Studies Included, Quality<br>Assessment Tool,<br>Databases and Search<br>Date   | Patient<br>Characteristics   | Interventions and comparators  | Outcomes   |
|---|--|--|--|--|
| Kyaw et al., 2019 <sup>8</sup> UK Funding: Not reported | Objective: To review the clinical effectiveness of different functional treatments for acute ankle sprains  10 studies (9 RCTs and 1 non-randomized trial)  Quality assessment: PEDro scale (range 0 to 10; scoring ≥ 6 considered as high quality)  Databases: PubMed Central, MEDLINE via OVID and Cochrane library  Search period: September 2007 to September 2017 | Adults with acute ankle sprain  Age: Not reported  Diagnosis: Grade 1, 2 and 3 | Elastic bandages, stockings or external assistance with elastic-sock-like material to support ankle joint. All types of adhesive or elastic tapes to support ankle joint. Lace-up ankle support or other external assistance made up of soft canvas-like or nylon materials. Semi-rigid ankle support, posterior rigid support or other external assistances made up of firm thermo plastic elements.  The actual interventions in the included studies were phase-adapted semi-rigid orthosis (Malleo TriStep), non phase-adapted semi-rigid orthosis (Aircast Airstirrup), compression stockings, below knee casts, Bledsoe boots, tubular bandages, Aircast braces, soft braces (Push med ankle brace), taping, tape (Coumans bandage), semi-rigid braces, plaster of Paris, walking boots, and lace-up braces  Treatment period: 5 of 10 included studies reported treatment periods ranging | Pain <sup>a</sup> Swelling Functions <sup>b</sup> Ankle mobility or range of motion <sup>c</sup> Complications and side effects Return to sports or work <sup>c</sup> Patient satisfaction |



| First Author,<br>Publication Year,<br>Country, Funding | Objectives, Types and<br>Numbers of Primary<br>Studies Included, Quality<br>Assessment Tool,<br>Databases and Search<br>Date | Patient<br>Characteristics | Interventions and comparators   | Outcomes |
|--|--|----------------------------|---|----------|
|  |  |                            | from 3 to 7 weeks. The other studies did not report treatment period. |          |

RCTs = randomized controlled trials.

**Table 3: Characteristics of Included Primary Studies** 

| First Author,<br>Publication Year,<br>Country, Funding                                   | Study Design and Analysis   | Patient<br>Characteristics   | Interventions  | Comparators             | Outcomes   |
|--|---|--|--|-------------------------|--|
| Shin et al., 2020 <sup>9</sup> Republic of Korea Funding: Ministry of Health and Welfare | Multicentre,<br>assessor blinded,<br>parallel 1:1, RCT<br>Sample size<br>calculation: Yes<br>ITT: No (per-<br>protocol analyses)<br>Statistical<br>analysis:<br>Appropriate | Adult patients with acute lateral ankle sprain recruited from three hospitals  Mean age: 39 years  % female: 66  Diagnosis: Grade 1 (54%), grade 2 (46%)  Average days since injury: 3.5 | Kenesiotape plus acupuncture; AcuKT (n = 30)  Treatment period: once daily, 5 days per week for 1 week.  Follow-up period: Week 1, week 5 for pain, edema, function and quality of life Week 5, 9, 13 and 27 for number of recurrent ankle sprains | Acupuncture (n = 30)    | Primary outcome Pain (visual analog score [VAS])a  Secondary outcomes Symptoms and Function (Foot and Ankle Outcome score [FAOS])b Edema European Quality of life Five Dimension-Five Level Scale (EQ-5D-5L) scoresc Number of recurrent ankle sprains |
| Uslu et al., 2015 <sup>10</sup><br>Turkey  | Cohort study Sample size calculation: No  | Patients with acute low-type ankle sprains recruited from  | Cohesive taping (n = 32)   | Short-leg cast (n = 27) | Edema<br>Pain and function using<br>AOFAS <sup>d</sup>   |

<sup>&</sup>lt;sup>a</sup> Pain was assessed with visual analog scale (VAS).

<sup>&</sup>lt;sup>b</sup> Functions were assessed with Foot and Ankle Outcome score (FAOS), American Orthopedic Foot and Ankle Society's (AOFAS) Ankle Hind Foot scale, questionnaires for ankle dorsiflexion comparing with sound leg, Karlsson scoring scale, or Tegner activity scale.

<sup>&</sup>lt;sup>c</sup> Mobility, recovery of normal occupation and impact of treatment was assessed using SF-12 questionnaires.



| First Author,<br>Publication Year,<br>Country, Funding | Study Design<br>and Analysis            | Patient<br>Characteristics   | Interventions  | Comparators                                   | Outcomes |
|--|---|--|--|---|----------|
| Funding: Not reported                                  | Statistical<br>analysis:<br>Appropriate | emergency and orthopedic clinics  Mean age: 28.61 years (range 11 to 52 years)  Diagnosis: Grade 1 and 2. Proportion not reported  Average days since injury: Not reported | Standard therapy: rest, anti-inflammatory drugs First 10 days: no weigh Next 10 days: controller allowed After 20 days: Full weigh Treatment completion: | t-bearing d weight-bearing ht-bearing allowed |          |

AOFAS = American Orthopedic Foot and Ankle Society's (AOFAS) Ankle Hind Foot scale; EQ-5D-5L = European Quality of life Five Dimension-Five Level Scale; FAOS = Foot and Ankle Outcome score; RCT = randomized controlled trial; VAS = visual analog scale.

a VAS is a 10-cm straight line marked at each end with the anchor labels "no pain" and "pain as bad as it could be". Scores were recorded in millimeters (range from 0 to 100 mm).

<sup>&</sup>lt;sup>b</sup> FAOS evaluates symptoms and functional limitations; consists of five subscales: pain (9 items), other symptoms (7 items), activities of daily living (17 items), sports and recreational activities (5 items), and foot- and ankle-related quality of life (4 items); the subscales are scored using a Likert response format, with higher scores indicating higher levels of function.

<sup>&</sup>lt;sup>c</sup> EQ-5D assesses health-related quality of life; health is defined in terms of five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). EQ-5D-5L is a new version of EQ-5D that includes five levels of severity in each of the existing five EQ-5D dimensions.

<sup>&</sup>lt;sup>d</sup> AOFAS (100 points total) evaluates pain (40 points; 0 = severe, almost always present and 40 = none), function (50 points; 6 categories; 0 = severe limitation, and highest point of each category = no limitation), and alignment (10 points; 0 = poor, and 10 = good).



# **Appendix 3: Critical Appraisal of Included Publications**

# **Table 4: Quality Assessment of Systematic Review**

| AMSTAR 2 Checklist <sup>5</sup>  | Kyaw et al., 2019 <sup>8</sup> |
|--|--------------------------------|
| 1. Did the research questions and inclusion criteria for the review include the components of PICO?  | Yes                            |
| 2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol? | No                             |
| 3. Did the review authors explain their selection of the study designs for inclusion in the review?  | Yes                            |
| 4. Did the review authors use a comprehensive literature search strategy?  | Yes                            |
| 5. Did the review authors perform study selection in duplicate?  | Unclear                        |
| 6. Did the review authors perform data extraction in duplicate?  | Unclear                        |
| 7. Did the review authors provide a list of excluded studies and justify the exclusions?   | No                             |
| 8. Did the review authors describe the included studies in adequate detail?  | Yes                            |
| 9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?  | Yes                            |
| 10. Did the review authors report on the sources of funding for the studies included in the review?  | No                             |
| 11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?  | NA                             |
| 12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?                               | NA                             |
| 13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?  | Yes                            |
| 14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity<br>observed in the results of the review?  | Yes                            |
| 15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?         | NA                             |
| 16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?  | No                             |

AMSTAR = Assessing the Methodological Quality of Systematic Reviews; NA = not applicable; PICO = Population, Intervention, Comparator, and Outcome; RoB = risk of bias.



Table 5: Quality Assessment of RCT and non-RCT

| Downs and Black Critical Appraisal Checklist <sup>6</sup>   | Shin et al., 2020 <sup>9</sup>  | Uslu et al., 2015 <sup>10</sup>  |
|---|---|--|
| Reporting   |   |  |
| 1. Is the hypothesis/aim/objective of the study clearly described?  | Yes   | Yes  |
| 2. Are the main outcomes to be measured clearly described in the Introduction or Methods section?   | Yes   | Yes  |
| 3. Are the characteristics of the patients included in the study clearly described?   | Yes   | Partial yes (proportion of grading not reported)                             |
| 4. Are the interventions of interest clearly described?   | Yes   | Yes  |
| 5. Are the distributions of principal confounders in each group of subjects to be compared clearly described?   | NA  | No (list of principle confounders not provided)                              |
| 6. Are the main findings of the study clearly described?  | Yes   | Yes  |
| 7. Does the study provide estimates of the random variability in the data for the main outcomes?  | Yes (SD provided)   | Yes (SD provided)  |
| 8. Have all important adverse events that may be a consequence of the intervention being reported?  | No  | No   |
| 9. Have the characteristics of patients lost to follow-up been described?   | NA  | Unclear  |
| 10. Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?  | Yes   | No   |
| External validity   |   |  |
| 11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited?   | Yes (publicized via local,<br>newspapers, internet and<br>posters in communities and<br>hospitals | Unclear  |
| 12. Were the subjects who were prepared to participate representative of the entire population from which they were recruited?  | Unclear (recruited from 3 hospitals)  | Unclear  |
| 13. Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of the patients receive?   | Probably not (patients were recruited only from hospitals)  | Probably not (patients were recruited from emergency and orthopedic clinics) |
| Internal validity – bias  |   |  |
| 14. Was an attempt made to blind study subjects to the intervention they have received?   | NA  | NA   |
| 15. Was an attempt made to blind those measuring the main outcomes of the intervention?   | Yes   | No   |
| 16. If any of the results of the study were based on "data dredging", was this made clear?  | Yes (no retrospective unplanned subgroup analyses were reported)                                  | Yes (no retrospective unplanned subgroup analyses were reported)             |
| 17. In trials and cohort studies, so the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls? | Yes (same length of follow-up for all patients)   | Yes (same length of follow-<br>up for all patients)                          |



| Downs and Black Critical Appraisal Checklist <sup>6</sup>  | Shin et al., 2020 <sup>9</sup>  | Uslu et al., 2015 <sup>10</sup>   |
|--|---|---|
| 18. Were the statistical tests used to assess the main outcomes appropriate?   | Yes   | Yes   |
| 19. Was compliance with the intervention/s reliable?   | Yes   | Unclear   |
| 20. Were the main outcome measures used accurate (valid and reliable)?   | Yes   | Yes   |
| Internal validity – confounding (selection bias)   |   |   |
| 21. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?       | Probably yes (from 3 hospitals)   | Unclear   |
| 22. Were study subjects in different intervention groups (trial and cohort studies) or were the cases and controls (case-controls studies) recruited over the same period of time? | Yes   | Yes   |
| 23. Were study subjects randomized to intervention groups?   | Yes   | No  |
| 24. Was the randomized intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?                                  | Unclear   | NA  |
| 25. Was the adequate adjustment for confounding in the analyses from which the main findings were drawn?   | NA (no significant differences in the baseline between groups)  | No  |
| 26. Were losses of patients to follow-up taken into account?   | No (per protocol analyses; but<br>the authors stated that they<br>were not different from the full<br>analysis set) | Unclear   |
| 27. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?                  | Yes   | Unclear   |
| 28. Other concerns   | Complications and side effects were not reported. Limited to grade 1 and 2 injury only.                             | Complications and side effects were not reported. Potential lack of homogeneous control due to imbalance in injury severity between groups. Limited to grade 1 and 2 injury only. |

 ${\sf NA = not \ applicable; \ RCT = randomized \ controlled} \ \overline{\sf trial; \ SD = standard \ deviation.}$ 



# **Appendix 4: Main Study Findings and Authors' Conclusions**

# **Table 6: Summary of Findings of Systematic Reviews**

|              | Main Study Findings  | Author's Conclusions   |
|--------------|--|--|
|              | Kyaw et al., 2019 <sup>8</sup>   |  |
|              | bandages, stockings and all external assistance with elastic sock-like als (5 high-quality RCTs; assessed by the authors)  | "The semi-rigid or posterior rigid support group or stocking were the most effective functional interventions for acute ankle sprain treatment." (pp1) |
|              | One RCT showed no difference in pain at rest and during walking between stocking and placebo groups.   | (,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,  |
| _            | One RCT showed that Tubigrip bandages significantly reduced pain compared to Plaster of Paris at six weeks follow-up (P < 0.001), but there was no significant difference at week 4 (P = $0.403$ )   |  |
| -            | One RCT showed that below-knee casts were significantly more effective than tubular bandages (P < 0.05), but tubular bandages were not significantly different from Air-cast braces and Bledsoe boots in pain management at 4 and 12 weeks. There were no significant differences in all groups at 9 months.   |  |
| -            | One RCT showed that stockings were significantly more effective than Tubigrip bandages at all follow-up time points (P $<$ 0.001)  |  |
| Swellin<br>– | ng:  One RCT did not find any significant difference in swelling management between stocking and placebo groups during follow-ups.   |  |
| -            | One RCT found that elastic stockings significantly reduced swelling compared to Tubigrip bandages ( $P < 0.001$ ).   |  |
| Function—    | One RCT compared 4 groups (Below-knee cast versus Bledsoe boot versus Tubular bandage versus Aircast)  At week 4: The below-knee cast was significantly more effective than the tubular bandage in two FAOS subscales (pain and QOL) and SF12 physical function  At week 4: There was no significant difference between the tubular bandage and the Air-cast brace.  At week 12: The below knee cast was significantly more effective than the tubular bandage in four FAOS subscales (pain, activities of daily livings, sport activities and QOL).  At week 12: The Air-cast brace was significantly more effective than tubular bandage in FAOS subscale QOL and SF12 mental function.  At week 12: There was no significant difference between tubular bandage and Bledsoe boot. |  |
| -            | One RCT compared 3 groups (Tubigrip bandage versus Below-knee cast versus Air-cast brace)  At 3 months: Below knee cast was significantly more effective than Tubigrip in overall ankle function (FAOS), specifically in subscales of pain, symptoms and activities of daily living.  At 3 months: The Air-cast brace was significantly more effective than Tubigrip in FAOS.  |  |



| Main Study Findings  | Author's Conclusions |
|--|----------------------|
| <ul> <li>At 9 months: There were no significant differences in all groups.</li> <li>No significant difference between Bledsoe boot and Tubigrip at each follow-up.</li> </ul>  |                      |
| <ul> <li>One RCT showed no significant difference in Karlsson score between<br/>Tubigrip bandage and Plaster of Paris in week 2 (P = 0.759), but Tubigrip<br/>bandage had significantly higher score than Plaster of Paris in week 6 (P &lt; 0.001)</li> </ul>   |                      |
| <ul> <li>One RCT showed that those treated with elastic stockings had significantly higher functional outcome scores compared to Tubigrip in AOFAS and SF12 v2 score at week 4 (P = 0.002) and week 8 (P &lt; 0.001).</li> </ul>   |                      |
| Ankle mobility or range of motion  One RCT found that elastic stocking use resulted in significantly greater range of motion than Tubigrip bandage by 8 weeks (79° versus 56°; P < 0.001).   |                      |
| Complications and side effects  One RCT found two out of 144 patients with suspected deep vein thrombosis or pulmonary embolism in tubular bandage treatment group.  |                      |
| <ul> <li>One RCT found deep vein thrombosis or pulmonary embolism in Tubigrip<br/>treatment group. Incidence rates were not reported.</li> </ul>   |                      |
| Return to sports or work  One RCT found that the time period to return to sport activities was significantly shorter in the stocking group compared to the placebo group.  |                      |
| Other outcomes  One RCT found that the duration of crutches use was significantly shorter in the stocking group than the Tubigrip group (P = 0.003). There were no significant differences between groups for stair climbing (P = 0.242), using analgesic medications, (P = 0.297) or return to work (P = 0.11). |                      |
| <ul> <li>One RCT showed that patients treated with tubular bandages had a lower<br/>benefit score than those treated with the below-knee cast, Air-cast and<br/>Bledsoe boot, but statistical comparison was not provided.</li> </ul>  |                      |
| All types of adhesives and elastic tapes to support ankle joint (One high-quality [RCT] and two low-quality [RCT, cohort] studies; assessed by the authors)  |                      |
| Pain:  One low-quality cohort study found no significant difference between those treated with tape or soft brace (Push med brace) in pain at one-year follow-up (P = 0.707).  |                      |
| <ul> <li>One low-quality RCT found no significant difference in pain among tape,<br/>semi-rigid brace, and lace-up brace groups.</li> </ul>  |                      |
| Swelling:  One low-quality cohort study found no significant difference between tape and soft brace (Push med brace) groups in swelling at one-year follow-up (P = 0.820).   |                      |



|         | Main Study Findings   | Author's Conclusions |
|---------|---|----------------------|
| Functio | ons:  |                      |
| _       | One low-quality cohort study found no significant difference between tape and soft brace (Push med brace) groups in functional outcomes at one-year follow-up ( $P = 0.850$ ).  |                      |
| -       | One high-quality RCT found no significant difference in the Karlsson score between patients treated with tape or semi-rigid brace ( $P = 0.4$ ).  |                      |
| _       | One low-quality RCT found no significant differences in the Karlsson score, Tegner activity scale, or FAOS in tape, semi-rigid brace and lace-up brace groups. However, the lace-up supports had significantly higher FAOS subscale (Function in sports) at 6 months ( $P = 0.02$ ) compared to semi-rigid braces.  |                      |
| Ankle n | nobility and range of motion:   |                      |
| _       | One high-quality RCT found no significant difference in both active and passive range of motion between tape and semi-rigid brace groups at week 4 and week 12 follow-ups.  |                      |
| Compli  | cations and side effects:   |                      |
| -       | One low-quality cohort study showed that 52% in the tape group and 39% in the soft brace (Push med brace) did not complete the 4 weeks of treatment due to skin irritation. The rate of ankle re-injury was 14% and 17% in the tape group and the soft brace (Push med brace), respectively, at one-year follow-up. |                      |
| _       | One high-quality RCT found that those treated with tape had a significantly higher complication rate compared to those treated with semi-rigid braces (59.1% versus 14.6%; P < 0.001). The complications included dermatitis, bullae formation or skin abnormalities.   |                      |
| _       | One low-quality RCT found that two patients out of 66 from the tape group had skin blisters and had to switch to semi-rigid brace.  |                      |
| Patient | satisfaction:   |                      |
| -       | One high-quality RCT found that patients in the semi-rigid brace group had higher satisfaction than those in the tape group ( $P < 0.001$ ). Patient satisfaction in the tape group decreased significantly from week 1 to week 5 ( $P < 0.05$ ).   |                      |
| Return  | to sports or work:  |                      |
| -       | One low-quality RCT found no significant difference in time to return to sports or work among three groups (tape, semi-rigid brace and lace-up brace).  |                      |
| made ι  | igid ankle support, posterior rigid support or other external assistance up of firm thermoplastic elements (Four high quality RCTs and two low RCTs; assessed by the authors)   |                      |
| Pain:   |   |                      |
| _       | One high-quality RCT showed no significant difference in pain between Air-  |                      |
| -       | cast brace and Bledsoe boot groups at 4 and 12 weeks.  One low-quality RCT reported no significant difference in pain between Aircast brace and immobilization walking boot groups.  One low-quality RCT found no significant difference in pain among semi-rigid brace, lace-up brace, and tape groups.            |                      |



| Main Study Findings  | Author's Conclusions |
|--|----------------------|
| Swelling:  |                      |
| <ul> <li>No trial evaluated this outcome.</li> </ul>   |                      |
| Functions:   |                      |
| <ul> <li>One high-quality RCT did not find any significant difference in FAOS and<br/>AOFAS scores between groups treated with two types of semi-rigid braces<br/>(Malleo TriStep and Aircast Air-stirrup).</li> </ul>   |                      |
| <ul> <li>Two high-quality RCTs found no significant difference in FAOS and SF 12<br/>mental scores among Aircast, Bledsoe boot, below-knee cast, and tubular<br/>bandage groups at 9 months.</li> </ul>  |                      |
| <ul> <li>One high-quality RCT found no significant difference in Karlsson score<br/>between semi-rigid brace and tape groups.</li> </ul>   |                      |
| <ul> <li>One low-quality RCT found that patients treated with semi-rigid braces had<br/>significantly higher AOFAS functional score compared to those treated with<br/>immobilized boots at week 3 (P = 0.0348) and week 6 (P = 0.027), but no<br/>significant difference at week 12.</li> </ul> |                      |
| <ul> <li>One low-quality RCT found no significant difference in Karlsson score and<br/>Tanger score among semi-rigid brace, lace-up brace, and tape groups.</li> </ul>   |                      |
| Ankle mobility and range of motion:  |                      |
| <ul> <li>One high-quality RCT did not find any significant difference in both active<br/>and passive range of motion between patients treated with semi-rigid brace<br/>or tape at 5 and 13-week follow-ups.</li> </ul>  |                      |
| Complications and side effects:  |                      |
| <ul> <li>Two high-quality RCTs found Aircast brace was associated with cellulitis,<br/>suspected deep vein thrombosis and pulmonary embolism. Cellulitis also<br/>occurred in Bledsoe boot. Proportions of affected patients were not reported.</li> </ul>                                       |                      |
| Return to sports or works:   |                      |
| <ul> <li>One low-quality RCT found no significant difference in time to return to sports<br/>or work among semi-rigid brace, lace-up brace, and tape groups.</li> </ul>  |                      |
| Patient satisfaction:  |                      |
| <ul> <li>One high-quality RCT showed that Aircast braces and Bledsoe boots had<br/>higher beneficial effects than bandages, but statistical comparisons were not<br/>reported.</li> </ul>  |                      |
| <ul> <li>One high quality RCT showed that patients treated with semi-rigid braces<br/>had significantly higher satisfaction than those treated with tape (P &lt;<br/>0.0001).</li> </ul>   |                      |

AOFAS = American Orthopedic Foot and Ankle Society's Ankle Hind Foot scale; FAOS = Foot and Ankle Outcome score; QOL = quality of life; RCTs = randomized controlled trial; SF 12 v2 = Short Form 12 items (version 2) Health Survey.



**Table 7: Summary of Findings of Included Primary Studies** 

| Main Study Findings  | Author's Conclusions  |
|--|---|
| Shin et al., 2020 <sup>9</sup>   |   |
| Kinesiotape plus acupuncture (AcuKT) (n = 27) versus Acupuncture (n = 29)  | "The results indicate that AcuKT did not show a positive add-on   |
| Pain (VAS score): No significant difference between groups (P = 0.774).  | effect of KT with acupuncture in terms of pain reduction, edema,  |
| <b>Degree of edema:</b> No significant difference between groups (P = 0. 662).   | recovery of function, activities of daily living, quality of life or                                      |
| Quality of life (total EQ-5D-5L): No significant difference between groups (P = 0.698). Function (FAOS: total, symptom/rigidity, ache, function everyday life, features sports/leisure, quality of life): No significant difference between groups (P > 0.05). | relapse of ALAS." <sup>9</sup> (pp1)  |
| Number of recurrent ankle sprains: No significant difference between groups (P = 0.268)  |   |
| Uslu et al., 2015 <sup>10</sup>  |   |
| Cohesive taping (n = 32) versus short-leg cast (n = 27)  | "Each treatment method was effective in decreasing edema  |
| Edema:  - At baseline (on first day after trauma): 1.57 ± 0.94 cm versus 1.55 ± 1.02 cm; P = 0.75  | and increasing functional scores<br>of the ankle. At the beginning of<br>treatment, not only the level of |
| – At day 10: $0.67 \pm 0.53$ cm versus $1.11 \pm 0.78$ cm; improvement from baseline, but no significant difference between groups   | edema but also the initial functional scores of the ankle and examination are important                   |
| Function (total AOFAS):  | in making decisions regarding   |
| <ul> <li>At baseline (on first day after trauma): 61.84 ± 18.47 versus 37.07 ± 21.93; P &lt; 0.01</li> <li>At day 10: 79.25 ± 12.67 versus 59.37 ± 18.58; improvement from baseline, but no significant difference between groups</li> </ul>                   | the optimal treatment option." <sup>10</sup> (pp307)  |
| <ul> <li>At day 100: 94.22 ± 6.22 versus 93.33 ± 7.33; improvement from baseline, but no significant difference between groups</li> </ul>  |   |

ALAS = acute lateral ankle sprain; AOFAS = American Orthopedic Foot and Ankle Society's Ankle Hind Foot scale; EQ-5D-5L = European Quality of life Five Dimension-Five Level Scale; VAS = visual analog scale.