



Functional treatment for acute ankle sprains: Softcast wrap versus MOK-cast. A prospective randomized single-center trial

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ABSTRACT

Background: The outcome of a removable (MOK-cast) versus a non-removable polyester wrap for acute lateral ankle ligament injury is unknown.

Methods: Patients with grade II–III lateral ankle ligament injuries were randomized between treatment with a MOK-cast and a wrap. Primary outcome is the Karlsson score for function. Secondary outcomes are patient satisfaction and pain at 4 months follow-up.

Results: Randomisation resulted in 53 and 54 patients per arm. Four month follow up was completed by 92% (n = 100). The mean Karlsson score improved from 20 to 87 (p < 0.01) in the wrap group and 20 to 90 (p < 0.01) in the MOK-cast group. In the MOK-cast group treatment satisfaction was higher (8.2 vs 7.8 p 0.04). Reported pain was higher in the first thirty days after injury (p < 0.01).

Conclusions: Both wrap and MOK-cast are effective functional treatment options in acute lateral ankle ligament injury. MOK-cast is associated with increased patient satisfaction but higher VAS pain scores. Level of evidence: I.

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1. Introduction

Acute lateral ankle sprains are the single most common sports injury accounting for 2–6% of overall emergency department presentations [1,2]. Roughly half of all acute ankle sprains are due to exercise and they account for 19–23% of all sports injuries [2]. Approximately 600,000 acute ankle sprains occur in the Netherlands every year [3]. The estimated total annual cost to society adds up to 600 million Euro in the Netherlands alone [1].

Despite the high incidence of this injury, there seems to be no single commonly applied treatment. Definitive conclusions on the most effective treatment, both clinically and in costs are hampered by the variety of treatments and outcome measures used [1]. Functional treatment of acute ankle sprains has been advocated and widely accepted as effective and safe [1,2,4]. The use of lace-up ankle support wherein the semi-rigid support is removable and adjustable, is wide-spread and gaining acceptance in daily practice,

yet definitive proof of its safety, let alone superiority seems lacking. In short-term follow-up studies lace-up ankle support only seem to perform superior with regards to its effects on swelling [1].

The aim of this study was to determine the outcome of two functional treatment regimes after moderate and severe acute lateral ankle ligament injuries. The reference treatment is a semi-rigid polyester wrap for three weeks (Delta-Cast[®] Conformable, BSN Medical S.A. Leuven, Belgium). The soft-cast wrap is widely accepted as semi-rigid treatment which is considered to be a functional treatment [1,5]. A thinly applied polyester cast allows movement in the dorsal-plantar plane, yet restricting movement in other directions. This is in contrast to immobilisation with plaster cast which is a more rigid form of immobilisation. To accurately compare the wrap with its adjustable and removable counterpart, the MOK-cast [5] was chosen as experimental treatment. The MOK-cast uses the same materials and provides comparable restrictions, yet is made removable and adjustable with a set of Velcro fixtures. It can and should in fact be worn in the patient's own footwear. The MOK-cast offers an adjustable and theoretically thereby a more functional treatment for the patient, yet retaining the same material properties of the wrap. With the MOK-cast being

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removable and adjustable, patient can be offered a treatment in which they are more in control plus the advantage of saving the patient and physician an extra visit to the outpatient clinic.

This study was designed to gain insight into the functional outcome of a removable semi-rigid ankle support (MOK-cast) compared to the soft-cast wrap. Secondary interests were pain and patient satisfaction.

2. Methods

The study was performed at the Spaarne gasthuis Hospital in Hoofddorp, the Netherlands. In the period between July 2009 and July 2010, all patients between 18–70 years of age presenting to the emergency department with an acute lateral ankle sprain suspicion grade II–III [7,8] were screened for eligibility. Presentation within 24 h of trauma was required and patients needed to be able to exercise at their own desired level before the trauma without additional ankle support. Patients with avulsion fractures of the distal fibula were treated as ligament injuries. Exclusion criteria included a history of ankle sprains with persistent giving way complaints, grade I lateral ankle sprains and an ankle fracture. Patients with bilateral ankle sprains, previous ankle ligament surgery, multi-trauma patients, other fractures, neuromuscular disorders of the lower extremities, active rheumatoid arthritis, alcoholism, serious psychiatric and neurological illness were also excluded from this study. All patients received RICE therapy for the first five to seven days with relative rest with crutches, cooling, a pressure bandage and elevation, yet were advised to try gradually loading the affected ankle when possible. Demographics were obtained and subjects filled out a questionnaire on daily activities, general health and sporting activities.

Five to seven days after the initial trauma, a delayed physical examination was performed, to establish the level of injury. The physical examination was performed as described by van Dijk [6] and the classification proposed by Bergfeld et al. [7,8] was used to assess the severity of the ankle sprain. A grade I injury involves a stretching or partial tear of the lateral ligament complex, almost always the anterior talofibular ligament (ATFL). Patients without haemorrhage, tenderness or instability of the ankle, were excluded from this study. A grade II injury involves a torn ATFL with an intact calcaneofibular ligament (CFL), some ligament instability, persistent swelling, pain and haemorrhage. A grade III injury involves a complete tear of the lateral ligament complex as evident by marked ligament instability, diffuse swelling and haemorrhage. Differentiation between grade II and III levels is neither reliable, nor has it any implication for treatment or prognosis [9,10].

After ascertaining the level of injury, patients with grade II and III injuries were asked to participate in the study. Randomization was performed by sealed brown envelopes (using a 1:1 allocation ratio). Both groups were treated with the same semi rigid polyester for three weeks. The wrap (Fig. 1A) was further modified to form the MOK-cast (Fig. 1B), following the principles of ‘focused rigidity’,

Table 1
Karlsson scoring scale [10].

| Category | Degree | Score |
|------------------------|--|-------|
| Pain | None | 20 |
| | During exercise | 15 |
| | Walking on uneven surface | 10 |
| | Walking on even surface | 5 |
| | Constant (severe) | 0 |
| Swelling | None | 10 |
| | After exercise | 5 |
| | Constant | 0 |
| Subjective Instability | None | 15 |
| | Walking on uneven surface | 10 |
| | Walking on even surface | 5 |
| | Constant (severe, ankle support required) | 0 |
| Stiffness | None | 5 |
| | Moderate (In the morning or after exercise) | 2 |
| | Marked (Constant) | 0 |
| Stair climbing | No problem | 10 |
| | Impaired (instability) | 5 |
| | Impossible | 0 |
| Running | No problem | 10 |
| | Impaired | 5 |
| | Impossible | 0 |
| Work activities | Same as before injury | 15 |
| | Same work, less sport, normal daily activities | 10 |
| | Light work, no sports, normal daily activities | 5 |
| | Severely impaired work, decreased daily activities | 0 |
| Ankle support | None | 5 |
| | Support during exercise | 2 |
| | Ankle support during daily activities | 0 |

making it adjustable and removable. All patients in the MOK-cast group received the same written instructions.

Follow-up was at four weeks, two months and four months after trauma. The primary outcome measure was the ankle function measured with the modified Karlsson scoring scale (KSS) [11]. The modified KSS gives a score from 0 to 90 on perceived function of the ankle and foot, divided over eight topics relevant to daily function (1;10) (Table 1). The modified KSS 4 months after trauma was the primary endpoint.

Secondary outcome measures were pain relief and patient satisfaction. Subjects were asked to record a daily pain rating (1–10) for the first 30 days of treatment. The minimal clinically important difference was set at 1 point on the VAS scale as previous reported by Kelly [12]. Furthermore during each visit subjects were asked to score (1–10) their satisfaction, both on overall treatment and on perceived result.

2.1. Sample size

A sample size analysis was performed based on a difference of 10 points in functional outcome (Karlsson Score) between the two groups, at four months follow-up. Using a power of 90%, a difference of 10 in Karlsson score at four months, and a standard

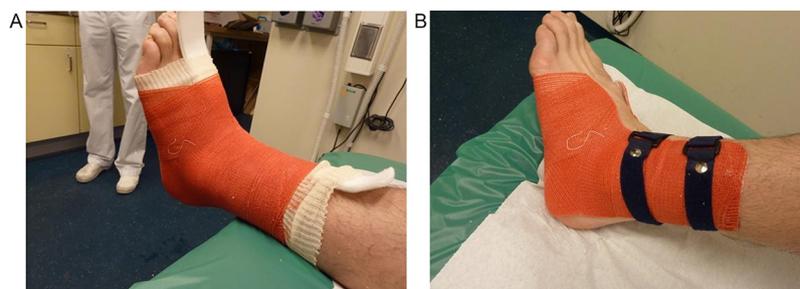


Fig. 1. (A) Semi-rigid polyester wrap, (B) MOK-cast with a set of Velcro fixtures.

deviation of 15, it was estimated that 49 patients per group were required. It was assumed that 10% of the patients would drop out and, consequently, we aimed to include 54 patients per group.

2.2. Statistical analysis

Analysis of the data was performed by use of SPSS version 20 (IBM Corp, Armonk, NY, USA) with the obtained data. Patient's baseline characteristics (gender, age, BMI, number of sports activities, KSS, Anterior Drawer test and initial treatment at the

A&E department) were described and compared between the treatment groups. A multivariate analysis was performed on all mentioned patient characteristics in relation to functional outcome to identify possible predictors. Analyses were performed on an intention-to-treat basis. Continuous data are presented as means (with SD) when normally distributed; otherwise, the medians (with ranges) are reported. Categorical data are presented as frequencies (with proportions). Due to skewed distributions of the KSS and VAS pain scores, the differences between the treatment groups were separately analysed at each

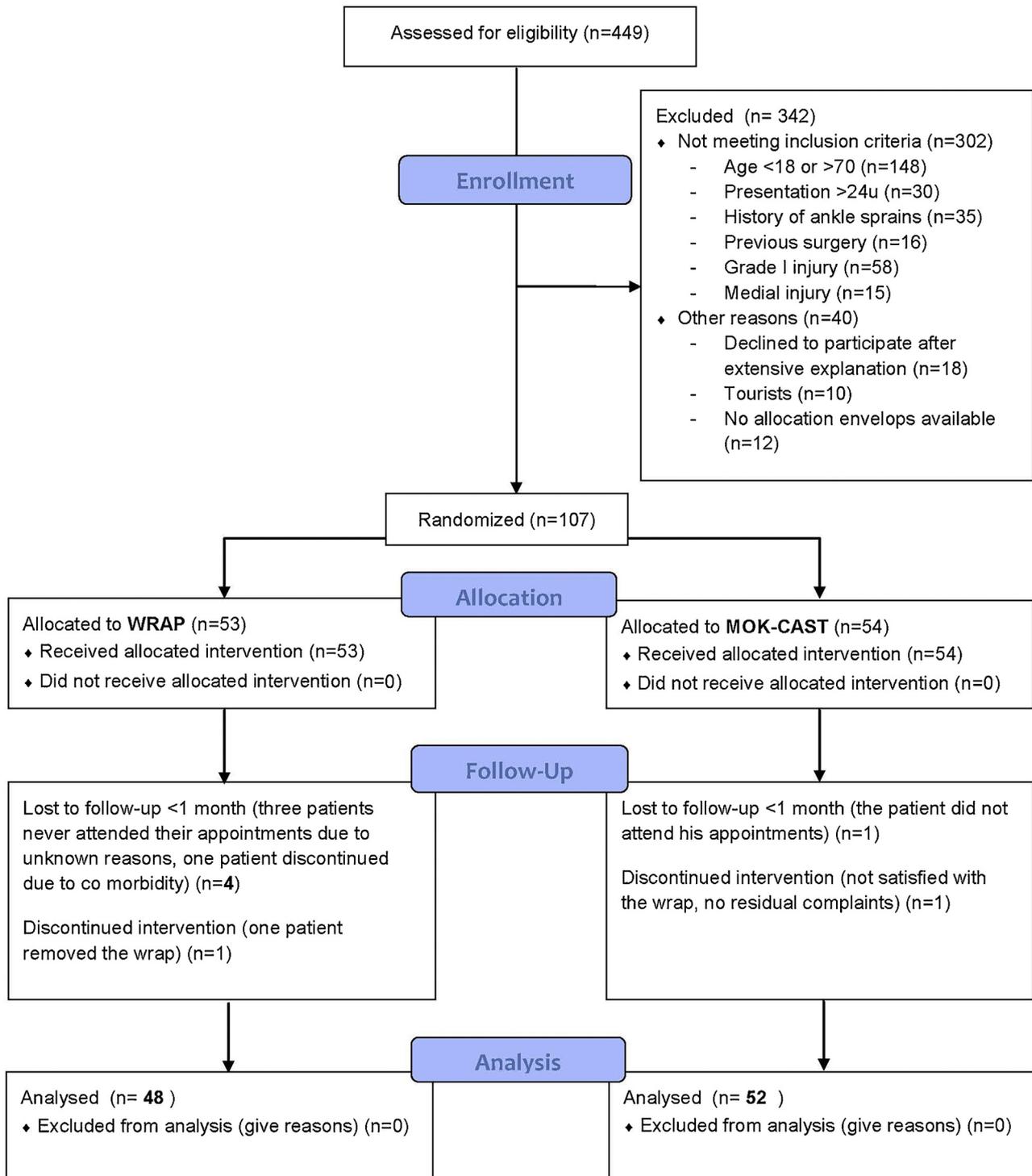


Fig. 2. CONSORT flow diagram.

time point by use of the Mann–Whitney *U* test. Significance level was adjusted for multiplicity and set at 0.0125 (0.05/4). In an additional analysis, both the KSS and VAS pain scores were analysed as ‘change from baseline’ (CFB) values by use of the Mann–Whitney *U* test. The normally distributed satisfaction scores were analysed by use of Linear Mixed Model analysis to estimate longitudinal change in satisfaction (with treatment and with result) as a function of time, and the mean difference between the two treatment groups. A *p*-value of <0.05 was considered statistically significant.

3. Results

A total of 107 patients were randomized of which 53 patients in the wrap group and 54 patients in the MOK-cast group. The CONSORT flow diagram that illustrates the progress of the patients is provided in Fig. 2. Three patients were lost due to non-compliance and four patients were lost to follow-up, all within the first month of follow-up. One hundred patients completed the follow-up of at least 4 months, of which 52 were males and 48 were females. Forty-eight patients were analysed in the wrap group and 52 patients in the MOK-cast group. Ethical approval (document no. NL28085.029.09 and METC no. 2009.147) was obtained at the ethical committee of the VU University Medical Center.

Table 2 presents data of both groups on age, sex, body mass index (BMI), level of sporting activity, KSS-score, reported pain at the start of treatment and primary treatment applied at the emergency department. No significant differences were observed between groups on all baseline variables.

The functional outcome (KSS-score) during each follow-up measurement demonstrated a steady progression and no significant differences in scores between treatment groups were detected as shown in Table 3. The mean KSS score improved from 20 to 87 ($p < 0.01$) and from 20 to 90 ($p < 0.01$) for the wrap and MOK-cast group respectively (Table 3). No significant difference was seen in the additional analysis using the CFB-values as seen in Table 4.

For the wrap and MOKcast respectively, 39 and 40 subjects returned data on their pain scores for the first 30 days after trauma. The VAS Pain scores were comparable at baseline. From day 10 onwards, a small but significant difference was seen in reported pain between groups in favour of the wrap. The CFB values analysis did not show the same significant differences, possibly due to the small absolute values.

Despite the small difference in reported pain, treatment satisfaction scores were generally high in both groups, wherein a significant difference was seen after four months follow-up in favour of the MOK-cast. Patients generally reported hygiene and flexibility of treatment as the main issues for a high satisfaction scores. Trouble removing and reapplying the cast, discomfort from sharp edges and insufficient instructions how to optimize the adjustable and removable aspects of the MOK-cast to improve comfort, were mentioned by some patients as negative aspects of the MOK-cast-treatment.

Reported outcome satisfaction scores were generally high in both groups and did not differ significantly between groups.

Of all patient characteristics, only age seemed negatively correlated to functional outcome at 4 months ($p = 0.022$). No correlations with functional outcome were observed for BMI, sporting activity, gender or apparent severity of initial sprain.

Two patients developed Complex Regional Pain Syndrome (CRPS) Type 1. The nature of the condition makes exact analysis into the origin of this complication complex and open to discussion. However after careful analysis of these cases we concluded that one patient in the wrap group most probably developed CRPS due to inadequate application of the wrap at start of treatment. A second patient in the MOK-cast-group developed CRPS only after she fell down a flight of stairs six weeks after her initial ankle sprain. She suffered an additional trauma without evidence of new ankle ligament injury of the afflicted ankle and unfortunately developed CRPS in the following weeks. Disregarding any one or both of the mentioned patients, data on patient satisfaction were still significantly in favour of the MOK-cast. Differences between functional scores during follow-up remained insignificant.

Table 2
Patient and treatment characteristics.

| | Wrap (N=53) | MOKcast (N=54) | <i>p</i> -Value | Total (N=107) |
|-------------------------------------|-------------|----------------|-------------------|---------------|
| Gender | | | | |
| Male (%) | 30 (57) | 26 (48) | 0.41 ^a | 56 (52) |
| Female (%) | 23 (43) | 28 (52) | | 51 (48) |
| Age (years) | | | | |
| Median (range) | 35 (19–62) | 35 (19–67) | 0.77 ^b | 35 (19–67) |
| BMI (kg/cm ²) | | | | |
| Median (range) | 25 (22–38) | 26 (20–44) | 0.78 ^b | 25 (20–44) |
| KSS-score at baseline | | | | |
| Median (range) | 20 (0–62) | 20 (0–70) | 0.84 ^b | 20 (0–70) |
| Number of sport activities per week | | | | |
| Median (range) | 1 (0–4) | 2 (0–12) | 0.98 ^b | 2 (0–12) |
| Anterior Drawer Test at baseline | | | | |
| Negative (%) | 38 (72%) | 42(78%) | 0.49 ^a | 80 (75) |
| Positive (%) | 15 (28%) | 12 (22%) | | 27 (25) |
| Treatment at A&E department | | | | |
| Pressure bandage(%) | 49 (92) | 48 (89) | 0.72 ^c | 96 (90) |
| Below-knee cast (%) | 5 (8) | 6 (11) | | 11 (10) |

^a Chi-square.

^b Mann–Whitney *U* Test.

^c Fisher exact.

Table 3
Karlsson score, VAS for pain and satisfaction scores at all time points .

| | Wrap N = 53 | MOKcast N = 54 | p-Value |
|---|----------------|-------------------|--------------------|
| KSS at baseline median (range) | 20 (0–62) | 20 (0–70) | 0.84 ^a |
| KSS at 4 weeks | 57 (17–85) | 57 (7–90) | 0.37 ^a |
| KSS at 2 months | 80 (22–90) | 78.5 (27–90) | 0.55 ^a |
| KSS at 4 months | 87 (42–90) | 90 (35–90) | 0.64 ^a |
| VAS after initial trauma median (range) | 7 (1–10) | 7 (2–10) | 0.73 ^a |
| VAS at day 5 | 3 (1–8) | 5 (1–9) | 0.10 ^a |
| VAS at day 10 | 3 (1–9) | 5 (1–9) | 0.09 ^a |
| VAS at day 15 | 2 (1–8) | 3 (1–9) | <0.01 ^a |
| VAS at day 20 | 1 (1–8) | 2 (1–10) | <0.01 ^a |
| VAS at day 25 | 1 (1–7) | 2 (1–9) | 0.03 ^a |
| VAS at day 30 | 1 (1–7) | 1 (1–7) | 0.01 ^a |
| Treatment satisfaction at 4 weeks mean (SD) | 7.7 (0.9) | 8.1 (1.2) | |
| Treatment satisfaction at 2 months | 7.9 (1.0) | 8.1 (1.4) | |
| Treatment satisfaction at 4 months | 7.8 (1.0) | 8.2 (1.1) | 0.04 ^b |
| Result satisfaction at 4 weeks mean (SD) | 7.5 (1.2) | 7.7 (1.5) | |
| Result satisfaction at 2 months | 7.6 (1.4) | 8.1 (1.4) | |
| Result satisfaction at 4 months | 8.0 (1.1) | 8.4 (1.1) | 0.17 ^c |

^a Mann–Whitney *U* test.

^b Linear Mixed Model analysis: mean difference between MOK and wrap 0.38 (95%CI: 0.02–0.75), for satisfaction of the treatment ($p=0.04$), influence of time was not statistically significant ($p=0.99$).

^c Linear Mixed Model analysis: mean difference between MOK and wrap is not significant for satisfaction of the result ($p=0.17$), influence of time is significant ($p=0.001$), mean incline of 0.04 (95%CI: 0.02–0.07) points a week.

Table 4
Change from baseline (CFB) values for KSS and VAS.

| | Wrap N = 48 | MOKcast N = 52 | p-value |
|----------------------------------|----------------|-------------------|-------------------|
| KSS at 4 weeks median (range) | 32.5 (–8:62) | 37 (–5:85) | 0.41 ^a |
| KSS at 2 months | 50 (5:80) | 53 (5:90) | 0.99 ^a |
| KSS at 4 months | 66 (7:90) | 63 (20:90) | 0.92 ^a |
| VAS at day 5 median (range) | –2 (–8:3) | –2 (–8:2) | 0.59 ^a |
| VAS at day 10 | –3 (–8:4) | –2 (–8:2) | 0.70 ^a |
| VAS at day 15 | –4 (–8:0) | –3 (–8:1) | 0.42 ^a |
| VAS at day 20 | –5 (–9:0) | –4 (–8:0) | 0.40 ^a |
| VAS at day 25 | –5 (–9:0) | –5 (–8:1) | 0.72 ^a |
| VAS at day 30 | –6 (–8:0) | –5.5 (–8:–1) | 0.91 ^a |

^a p-Values by Mann–Whitney *U* test.

4. Discussion

The most important finding of this prospective, randomised trial is that both a MOK-cast and a softcast wrap are effective functional treatment options for acute lateral ankle ligament injury.

There was no difference in functional outcome four months after treatment. Since most ankle sprains have a good to excellent functional outcome after 1-year, irrespective of the functional therapy they receive, achieving optimization in the short, – to midterm is especially relevant [9]. Functional treatment is favoured over immobilization treatment and is considered the optimal treatment in patients with acute lateral ankle ligament injury [1,4]. However, there is an ongoing debate if there is a type of functional support that is superior over another [4,13,14]. The purpose of this study was to determine whether there is a difference in outcome between a removable and non-removable semi-rigid brace for acute lateral ankle ligament injury. As material and shape of the support were kept as similar as possible, the study was designed to measure the effect of removability and

adjustability. By making the wrap removable and adjustable patients have the potential benefit of tightening the brace during treatment as the swelling reduces which could improve the stability. A second advantage could be the improved hygiene and thereby comfort when compared to a non-removable brace. The final advantage is the option to remove the brace by themselves after a period of three weeks, which saves the patient an extra visit to the outpatient clinic. Overall the patient is given more control over their own treatment. However there are disadvantages in making the wrap adjustable and removable since the reported pain was higher in the MOK-cast group. The finishing of the MOK-cast as well as the instructions on its use might be improved and, although comfort and satisfaction might be improved by compliance, we have no evidence to suggest it would further influence functional outcome. Despite the higher reported pain in the MOK-cast group during treatment, patients tend to be more satisfied with a removable and adjustable ankle support. This is in line with the accepted trend in daily practice towards a more personalised and functional treatment of ankle sprains.

The patients were followed for four months. Although longer follow-up might be suggested [1], the effect of follow-up beyond four months seems to have little effect on the outcome [14,15]. Four months after treatment, most of the patients have returned to near optimal functional scores. Therefore, it is unlikely that a longer follow-up will lead to better reported results. However there have been studies that report on residual disabling signs and symptoms after ankle sprains in the long term [16]. Due to the relative short period of follow-up, this study does not provide data on these possible residual symptoms. The goal of this paper was to report on the treatment of acute ankle instability as described in the Cochrane by de Vries et al. [17]. Outcomes were assessed using patient reported outcome measures, as is common practice in most trials of similar interventions [11,18,19].

The strengths of the current randomized trial are that it was initiated after a proper sample size calculation and the fact that the primary and secondary endpoints were measured with patient reported outcome measures. In contrast to other trials, grade I ankle sprains were not included because these injuries do not need a supportive treatment. Despite including just short of the objected

108 subjects, drop-out was low and sample size remained sufficient. A limitation of the study is that the providers and patients were not blinded to assignment after allocation because we were unable to conceal the specific support the patients were wearing. Therefore the four week follow-up did not occur in a blinded setting. This is in contrast to the two and four month follow-up, after removal of the support, when the observer was blinded for the assigned treatment.

In accordance to findings of van Rijn et al. [3] that functional outcome is independent of severity of the initial sprain, no correlation was found between this variable and any of our outcome measures. Furthermore, of the patient characteristics, age was the only variable that had a correlation to functional outcome. This effect is similar for both groups and no subgroup could be identified which would benefit from either treatment. Patient preference might therefore become the most important factor in the decision on type of semi rigid ankle brace.

5. Conclusion

Both the wrap and the MOK-cast are effective functional treatment options in acute lateral ankle ligament injury. Patient preference seems to be in favour of a removable form of functional treatment even though this results in less pain reduction. More attention for patient comfort and adequate instruction is necessary for further improvement of patient satisfaction. Further studies should focus on a functional, comfortable and cost-effective type of removable and adjustable treatment for acute ankle sprains.

Conflict of interest

This author, their immediate family, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article.

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