Consecutive patients with a confirmed rupture of at least one of the lateral ligaments of the ankle were randomly assigned to receive either operative or functional treatment. They were evaluated at a median of 8 years (6 to 11).

In total, 370 patients were included. Follow-up was available for 317 (86%). Fewer patients allocated to operative treatment reported residual pain compared with those who had been allocated to functional treatment (16% versus 25%, RR 0.64, CI 0.41 to 1.0). Fewer surgically-treated patients reported symptoms of giving way (20% versus 32%, RR 0.62, CI 0.42 to 0.92) and recurrent sprains (22% versus 34%, RR 0.66, CI 0.45 to 0.94). The anterior drawer test was less frequently positive in surgically-treated patients (30% versus 54%, RR 0.54, CI 0.41 to 0.72). The median Povacz score was significantly higher in the operative group (26 versus 22, p < 0.001).

Compared with functional treatment, operative treatment gives a better long-term outcome in terms of residual pain, recurrent sprains and stability.

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Acute injuries of the ankle are the most common type of injury seen by general practitioners and emergency departments. They involve about 25% of all injuries of the musculoskeletal system with over 20 000 cases occurring in the USA each day. Inversion trauma constitutes a large percentage of these injuries. In about 10% to 15% of all inversion injuries, there is rupture of the lateral ligaments of the ankle with involvement of the anterior talofibular ligament. In order to assist in the precise diagnosis, various diagnostic methods are available which are more or less invasive. Diagnosis by means of delayed examination has a high sensitivity and specificity. This procedure has been proposed as the diagnostic strategy of choice in a recent editorial by Klenerman.

In spite of its frequency, the selection of treatment for damage to the lateral ligaments remains controversial. Two publications in the 1980s reported better results with functional treatment compared with operative treatment. Yet a recent meta-analysis concluded that operative treatment leads to better short- and mid-term results with regard to ‘giving way’ and residual pain. There are few studies reporting the long-term outcome and they usually involve only small numbers of patients. Munk, Holm-Christensen and Lind compared three different methods of treatment in 79 patients with a mean follow-up of 11 years. They found no differences and concluded that non-operative treatment was adequate.

Our aim was to provide the evidence for the choice between operative or functional treatment as the initial strategy, followed by after-treatment with either tape or an elastic bandage. For this purpose we conducted a randomised, prospective trial. We began with the hypothesis that operative treatment would lead to less residual pain and giving way, compared with functional treatment.

Patients and Methods

All the patients were initially seen between March 1988 and March 1991 in the emergency department and referred to the outpatient clinic after four to seven days. They were between 18 and 45 years of age with a painful ankle caused by an indirect supination injury. Those who presented within 48 hours of injury were eligible. Patients with pre-existing instability of the affected ankle were excluded as well as those who lived too far from the hospital for adequate follow-up. Informed consent was obtained before each patient underwent arthrography within 48 hours of the injury. Standard anteroposterior and lateral radiographs...
were taken to exclude a fracture and any patient with a fracture was excluded. After five to seven days, delayed physical examination was performed by the principal investigator (CNVD), who was blinded as to the initial history, physical examination and arthrography. Patients were included in the study if they showed a positive delayed physical examination or a leak of contrast on the arthrogram, indicating a disruption of at least one of the fibular collateral ligaments.

The Tegner score was used to describe and compare activity levels. Although it was originally developed for knee injuries, we found it to be very useful for assessing the function of other joints in the lower limb. The Tegner activity scale ranges from 0 to 10, where 0 represents sick leave or disability due to knee (ankle) symptoms and 10 ability to participate in competitive sports such as soccer, football and rugby at national and international levels. The median Tegner activity level before injury was 7 (1 to 9) for both the injured and contralateral sides, and if there was a marked difference on the affected side with that on the non-injured side. The ADT was measured with a goniometer. Stability was tested by comparing the manual anterior drawer test (ADT) on the affected side with that on the non-injured side. The ADT was graded positive if there was a marked difference between the injured and contralateral sides, and if there was consensus between two investigators. The ankle was also palpated for tenderness.

The primary outcome measures were residual pain and giving way. Pain was scored as present if the patient reported pain in the affected ankle or when tenderness was elicited during physical examination. The outcome of treatment using one of the following descriptions: excellent, good, fair, or poor.

The physical examination was carried out by experienced clinicians (ACMP, RK, KB) who did not know whether the patient had received tape or elastic bandaging. Because of the presence of a surgical scar, blinding for operative or functional treatment was not possible. The range of movement was measured with a goniometer. Stability was tested by comparing the manual anterior drawer test (ADT) on the affected side with that on the non-injured side. The ADT was graded positive if there was a marked difference between the injured and contralateral sides, and if there was consensus between two investigators. The ankle was also palpated for tenderness.

Patients were reviewed at one, two and six weeks and at three and six months after the injury. After at least six years a standardised follow-up examination was performed, at which an extensive history was recorded on a standard scoring form. Physical examination of both ankles was performed and standard anteroposterior and lateral radiographs of both ankles were taken. The clinical history addressed a number of variables, including residual complaints of pain or swelling, interference with daily activities, a feeling of instability and giving way. The use of supportive bandaging during sports or daily activities and recurrent sprains were noted. The intervals between injury and resumption of work and sport were calculated using information provided at the earliest point of follow-up. All patients were asked to grade the outcome of treatment using one of the following descriptions: excellent, good, fair, or poor.

Statistical analysis. All outcomes were analysed according to the intention-to-treat principle. In order to express the long-term effectiveness of operative compared with functional treatment, relative risks were calculated with corresponding 95% confidence intervals (CI). The relative risk (RR) expresses the proportion of patients with complaints related to the treatment strategy under evaluation. For example, an RR of 0.80 for residual pain means that the proportion

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**Table I.** Details of the patients included in the study

<table>
<thead>
<tr>
<th>Operation</th>
<th>Functional</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>181</td>
<td>189</td>
</tr>
<tr>
<td>Male:female</td>
<td>133:48</td>
<td>125:64</td>
</tr>
<tr>
<td>Median age in years (range)</td>
<td>26 (17 to 40)</td>
<td>27 (17 to 45)</td>
</tr>
<tr>
<td>Left/right ankle</td>
<td>96/85</td>
<td>103/86</td>
</tr>
<tr>
<td>Single/multiple lesion</td>
<td>92/76</td>
<td>110/79</td>
</tr>
<tr>
<td>No lesion during operation</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>Median Tegner score</td>
<td>7 (1 to 9)</td>
<td>7 (1 to 9)</td>
</tr>
<tr>
<td>Radiographic grade &gt; 0 (%)</td>
<td>20</td>
<td>15</td>
</tr>
</tbody>
</table>

*a*based on the 317 patients who returned for follow-up

**Table II.** Scoring system for degenerative changes of the ankle (van Dijk et al20)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal joint or subchondral sclerosis</td>
</tr>
<tr>
<td>I</td>
<td>Osteophytes without narrowing of the joint space</td>
</tr>
<tr>
<td>II</td>
<td>Narrowing of the joint space with or without osteophytes</td>
</tr>
<tr>
<td>III</td>
<td>(Sub)total disappearance or deformation of the joint space</td>
</tr>
</tbody>
</table>
of patients with pain is only 80% in the operative treatment group compared with the proportion in the functional treatment group. CI around the RR were calculated using the asymptotic approximation on the log scale.\(^21\) We also used conventional statistical tests to compare the outcome in both groups. The chi-squared test was used for dichotomous variables and the Mann-Whitney test for all ordinal variables. Two-sided \(p\) values of less than 0.05 were considered to indicate statistical significance. All data were analysed using the SPSS (Chicago, Illinois) data analysis program.

A power analysis was performed to estimate the sample size needed for this study. We predicted that up to 30% of the patients would have symptoms of giving way at follow-up. Using a continuity corrected chi-squared test and setting two-sided alpha at 0.05, we had to include at least 174 patients in each group to obtain a power of 90% in detecting a reduction of 50% after operative treatment.

### Results

The initial study group comprised 515 patients of which 388 consenting patients had a positive delayed physical examination four to seven days after injury or a leak of contrast on arthrography, indicating a disruption of at least one of the fibular collateral ligaments. Of these 70% were men. The median age of the included patients was 27 years (17 to 45). In 52% of the patients the right ankle was involved. Of the 388 patients, 185 were allocated to the operative group and 203 to the functional treatment group. Thirteen patients were excluded from those treated operatively because they had only a capsular lesion at operation. They were kept under review following the intention-to-treat principle. One patient had a superficial wound necrosis after surgery probably due to a haematoma. Further surgery was performed to excise a necrotic margin of skin after which it healed satisfactorily. There were no late complications which could be attributed to the surgery. In six patients an osteochondral defect of the dome of the talus was found laterally. In four patients a lesion of the distal anterior syndesmosis and in two a lesion of the deltoid ligament were found (Table III).

### Table III. Concomitant injuries in each treatment group

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Operation</th>
<th>Functional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peroneal tendon luxation</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Syndesmosis rupture</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>Deltoid rupture</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Talar dome defects</td>
<td>6</td>
<td>-</td>
</tr>
</tbody>
</table>

### Table IV. Details of patients lost to follow-up

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Operation (n = 23)</th>
<th>Functional (n = 30)</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male:female</td>
<td>16:7</td>
<td>21:9</td>
<td>0.889</td>
</tr>
<tr>
<td>Median age in years (range)</td>
<td>26 (17 to 31)</td>
<td>25 (18 to 38)</td>
<td>0.426*</td>
</tr>
<tr>
<td>Left/right ankle</td>
<td>8/15</td>
<td>14/16</td>
<td>0.522</td>
</tr>
<tr>
<td>Single/multiple lesion</td>
<td>13/10</td>
<td>14/16</td>
<td>0.645</td>
</tr>
<tr>
<td>Median length of follow-up in weeks (range)</td>
<td>24 (0 to 24)</td>
<td>24 (0 to 24)</td>
<td>0.923*</td>
</tr>
<tr>
<td>No lesion at operation</td>
<td>3</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Median Tegner score</td>
<td>6 (2 to 9)</td>
<td>6 (1 to 9)</td>
<td>0.713</td>
</tr>
</tbody>
</table>

*\(^*\)Mann-Whitney test

*1. Non-compliance (n = 3); high operating risk (n = 2)
*2. Non-compliance (n = 1)

†1. Not responding to written attest (n = 7); not retraceable (n = 7); deceased (n = 1); emigrated (n = 6).
†2. Not responding to written attest (n = 18); non-co-operative (n = 6); not retraceable (n = 3); deceased (n = 1); emigrated (n = 3); captivity (n = 1)

Flow chart for the patients.
We reviewed 312 patients for the long-term follow-up examination. Another five refused to attend and were visited at their homes and 53 patients were lost to follow-up. No important differences were found for the baseline characteristics of these patients (Table IV). For 36 of these patients a standardised six-month follow-up was available. We compared these results with those available at six months for patients who were seen for long-term follow-up and found no significant differences.

Of the 317 patients who returned for follow-up, 159 had received operative and 158 functional treatment (Fig. 1). The median follow-up was 8 years (6 to 11).

The selection of functional treatment did not lead to significant differences in any of the outcome measures used and they are reported as a single group. Table V contains a summary of the findings at long-term follow-up for both groups. Fewer patients allocated to operative treatment reported residual pain compared with those who had functional treatment (16% v 25%, RR 0.64, 95% CI 0.41 to 1.0). Surgically-treated patients also reported fewer symptoms of giving way (20% v 32%, RR 0.62, 95% CI 0.42 to 0.92) and fewer recurrent sprains (22% v 34%, RR 0.66, 95% CI 0.45 to 0.94). No differences were seen for swelling of the ankle (14% v 14%, RR 1.0, 95% CI 0.58 to 1.73). Most patients in both groups rated the subjective outcome of treatment as good or excellent. Of the 294 patients, 241 (78%) of both groups who actively participated in sports at the time of injury, had resumed their sporting activities.

In both groups approximately 38% of patients had tenderness of an area of the ankle. The anterior drawer test was less often positive in surgically treated patients (30% v 54%, RR 0.55, 95% CI 0.41 to 0.72).

In the surgically-treated group, 85% of patients had an excellent or a good Povacz score and 14% a poor one.
compared with 75% and 25%, respectively, in the group which had functional treatment. The median Povacz score was 26 points in the operative group compared with 22 points in the functional group (p < 0.001). There was a significant difference in the outcome as measured using the Good score in favour of operative treatment (Mann-Whitney test statistic 6.4, p = 0.01). The median Tegner score at follow-up was 7 (1 to 9) for the operative group compared with 6 (1 to 9) for the functional treatment group (p = 0.215).

In total 310 patients had radiographic examination; five were seen for follow-up at home where no radiographs could be taken. One patient refused radiographic examination, one patient was pregnant at the time of follow-up and in 12 the radiographs taken at the initial trauma could not be retrieved. Therefore the radiographs of 298 patients were available for evaluation.

The median increase in the radiographic score between the day of injury and at the time of follow-up did not differ significantly between the operative and functional groups (p = 0.703; Table VI). In the functional group more patients had an increase of one point (40% v 32%), whereas in the operative group more patients had an increase in the radiographic score of two points (15% v 4%). In the functional group three (2%) patients had an increase of three points.

**Discussion**

We found operative treatment led to a better long-term outcome. Significantly fewer patients allocated to operative treatment experienced residual pain and giving way and there were fewer positive results on the anterior drawer test and significantly better Povacz scores.

Limitations of the present study include the suboptimal randomisation design used and the numbers lost to follow-up. 14,22,23 In our study, based on the week of presentation in the emergency department, concealment of allocation was not guaranteed. 24 As patients were aware of the type of treatment which they had received, we could not exclude selective recall bias. To minimise the potential for bias, we used a standardised procedure for the history and physical examination. Both were performed by a small number of trained investigators. Since the differences in outcome are quite substantial, we do not think that they are attributable to bias. The 13 patients treated operatively who demonstrated only a capsular lesion at operation, remained in the study. An analysis without these patients did not alter the results.

Persistent pain after a severe ankle injury has been described before. 15,25 In our study, 20% of the patients reported some pain during daily activities. During physical examination, tenderness was elicited in 38%, of whom 53% had pain on the medial side of the ankle, the mechanism of which was studied by van Dijk et al in 1997. 25 The natural history of ruptures of the lateral ligaments has not been studied by van Dijk et al in 1997. 25 The natural history of ruptures of the lateral ligaments has been described. In a meta-analysis we found a minimal treatment strategy 6,26-28 to lead to a greater number of persistent symptoms. 14 Chronic instability of the ankle, either mechanical or functional, is a symptom which occurs frequently after an ankle sprain (10% to 20%). 29 Mechanical instability from laxity or elongation of a ruptured ligament can be demonstrated by a positive anterior drawer test or talar tilt, both on physical examination and stress radiography. 5,30 In our study, 42% of the patients had an abnormal anterior drawer sign, but less did so after operative treatment (Table V). Functional instability or giving way is a feeling of uncertainty in the ankle, which can occur with or without actual mechanical instability and is attributed to a proprioceptive deficit. 30,31 It is reported in 15% to 60% of patients after a lesion of the lateral ligament of the ankle. 32 In our study 25% of the patients still experienced giving way, six to 11 years after treatment. During the initial assessment, we found tenderness over the anterior syndesmosis in 40% of patients with a rupture of the lateral ligament. 5,10 At long-term follow-up these patients showed results similar to those of other patients and, furthermore, there was no correlation between patients with tenderness over the syndesmosis soon after injury and those with tenderness in that area at follow-up.

The results of our trial concur with the outcome of a recent meta-analysis. 14 Although the long-term prognosis for rupture of the lateral ligaments has been reported to be favourable for most patients, 18 we found only one study which evaluated the long-term outcome. Munk, Holm-Christensen and Lind 15 reported the results of 79 patients with a mean follow-up of 11 years which showed no differences between the various treatment groups. The study of Povacz et al 18 reported the results of a two-year follow-up with 146 patients randomised between operative and functional treatment. They found no significant differences between the groups. In a meta-analysis we found physical rehabilitation to be of significant importance to the outcome of surgery. In fact prolonged splintage (six weeks in a cast) as used in the trial by Povacz et al gave the least favourable results.

Despite the statistically significant superiority of operative over functional treatment, there are a number of reasons for questioning the use of operative treatment as the treatment of choice. First, delayed operative reconstruction of the injured ligaments has been reported to generate similar results compared with acute repair, even many years after initial injury. 32,33 Secondly, some studies presenting a favourable outcome for operative treatment, report the results of the senior author’s own cases. 5,17,34,35 The decision to operate on every patient with a lesion of the ligaments of the ankle will increase the number of patients referred for surgery and impose an unacceptable strain on the available capacity of operating theatres. Operative treatment is also associated with much higher costs. 33,36 In addition, operative treatment enhances the risk of complications such as infection, failure of wound healing, dystrophy,
nerve damage, etc and leads to a longer period away from work and sports.

In summary, we found operative treatment led to better results at the short- and long-term follow-up. We believe that operative treatment for lateral ligament ruptures can be adopted in selected cases when higher functional demands are required.

Primary repair of the ligament with a reconstruction of the normal anatomy offers some resistance to the extra stresses imposed by activities such as sports at a competitive level. If operative treatment is rejected or not available, taping is a good alternative.

No benefits in any form have been received from a commercial party related directly or indirectly to the subject of this article.

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