Laser therapy has enjoyed increasing popularity over the past few years. Various publications have shown spectacular effects of this therapy (1, 2, 3, 4, 8, 12). Closer examination of these effects shows that they can be reduced to analgesia and biostimulation, with a threshold stimulus required for these two effects to be virtually identical (1, 4, 8, 19, 20). Low energy infrared photons accumulate in the cell, or in a molecule, until a sufficient energy level is reached to allow a reaction to take place. This 'non-thermal catalysing effect' is supposed to be unique to infrared and red laser light. In this way, stimulation of the cell's metabolism, and an accelerated resumption of normal activities by the cell could be specifically achieved (1, 5, 9, 11, 19, 20). Histopathological studies (4, 9, 11, 15, 19, 20) have shown that it is especially fibrocytes and macrophages which show increased activity. Thus the tissues are more rapidly cleared of pain transmitters, oedema is resorbed, and the tissues recover. Vasodilatory agents are also said to disappear, reducing the inflammation (4). In addition, it has been reported that the stimulus threshold of axons may be raised by the action of red and infrared laser light (4).

This general explanation provides arguments for the use of lasers in pain point treatments, with the aim of influencing the microclimate near a pain point in such a way that the stimulus threshold is raised (4, 6, 18, 19). It has been suggested that the Helium-Neon laser, with its largely superficial action is especially effective for certain skin disorders (1, 4, 5, 11, 18, 19), while infrared and red laser light is supposed to be particularly effective for deeper structures (1, 3, 4, 6, 9, 10, 17, 18, 19). A study of the literature yields few clues for an adequate formulation of parameters for laser therapy. It has been suggested to use daily treatments with a low pulse frequency and a short duration for acute lesions, and high pulse frequency, long duration treatment a few days apart for chronic disorders (1, 3, 4, 6, 11, 18, 19). But usually it is impossible to derive a complete formulation of parameters from the available literature. Such a formulation is completely absent from the studies by Poldi (13), Scardigno (1) and Canata et al. (3), while De Cuyper (4, 5) mentions only the number of treatments and the average duration of treatment per cm² as parameters. The type of laser used, which has consequences for the degree of penetration of the treatment, is often not indicated.

The reason for undertaking the present effect study on laser therapy was the lack of valid data on effects and effectiveness of laser therapy. This lack is reflected especially in the incomplete formulation of parameters, the absence of sufficient information on the effect of laser therapy on acute soft tissue injuries, and the attribution of possible effects to laser therapy on the basis of insufficiently valid arguments.

The aim of the study was to access the effectiveness of laser therapy in treating a soft tissue injury by means of a randomized, double-blind intervention trial (26), thus giving laser therapy a 'fair chance' to prove itself. For the soft tissue injury in this study we chose ankle sprains. This type of injury is often encountered in the physiotherapist's practice, and its treatment with laser light can easily be standardized. Furthermore, Poldi (13), Canata (3) and De Cuyper (5) have reported favourable results of treating ankle sprains, albeit on the basis of very little research. The use of laser therapy in the treatment of ankle sprains aims at a reduction of the pain and swelling which occur in the acute phase, and in the long run at recovery of the affected ligaments. The present paper limits itself to the assessment of pain scores and impairment of sports participation. Other items assessed in the study, such as restrictions in ADL functions, impairment of social contacts and degree of satisfaction, have been reported on elsewhere (24).

Patients and methods

During a continuous period of 15 weeks, patients with ankle sprains in a medium-sized general hospital were examined in the emergency unit by the physician in attendance. The standardized examination consisted of an anamnesis, visual inspection, manual examination, X-rays, and X-ray stress test. These tests may lead to one of the following diagnoses (24, 36):

- First or second degree ligament injury: these patients were enrolled in the study;
- Third degree ligament injury: surgical treatment;

Since operations on the ankle result in a more complicated situation, which is difficult to standardize, these cases were not included in the study. The population of patients with first or second degree ligament injuries was subjected to a further selection procedure. Only those patients who were present at injuries to the ligamentum calcaneofibulare laterale, or to the ligamentum calcaneofibulare laterale, which were not the result of congenital weakness of the ligaments, and which were less than 48 hours old. The subjects thus
selected were randomized into three groups, all following the standard treatment.

This treatment was as follows. The subjects had their ankle taped up with a pressure bandage for three days, and were instructed to keep the ankle in a high position and not to walk on it. If after three days the swelling had decreased sufficiently to allow a dorsal flexion of at least 90 degrees, a standardized Coumans taping was applied (24). Two weeks later, the patient was given a new standardized Coumans taping. If after two more weeks the physician and physiotherapist found stability and performance of the ankle satisfactory on examination, the treatment was stopped.

As mentioned earlier, the study population consisted of three groups. Group 1 was the laser treatment group, group 2 the placebo group, and group 3 the control group. To facilitate the laser treatment (30), a standardized window was made in the taping (24) in groups 1 and 2. The laser treatment was given as an additional treatment, complementing the standard procedure. All subjects in groups 1 and 2 assumed they were receiving laser therapy, since the laser gun, which had been fitted with a placebo option by the Enraf Nonius company, was constructed in such a way that neither the patient nor the therapist could see whether a laser or placebo treatment was being administered (24). It should be noted that the laser beam could be neither seen nor felt, and that it could only be established after the experiment which setting of the machine actually corresponded to a working laser beam. Groups 1 and 2 were treated with the laser machine at a fixed time each morning. Treatment was given between 8.00 and 9.00 each morning, including weekends, each time in the same room, at constant temperature, humidity and lighting conditions. The treatment was always given by the same therapists, with the patient always in the same position.

Standardization of the laser treatment implied the following. The pain point was identified and marked before starting the treatment and/or opening the window in the patient's Coumans taping. After local cleaning of the skin with alcohol, a switch on the laser gun was set in position 1 or 2. These positions corresponded to the two study groups. Subsequently, the laser probe was held vertically above the pain point, at a distance of 1 cm. next, the laser was switched on. It switched itself off after 180 seconds, which meant the end of the treatment. After treatment, the foot was taped up with a pressure bandage again, or, if the Coumans taping had already been applied, the window was taped up again according to standard procedure (24).

In all, ten laser treatments were administered, the first of which took place within 48 hours after the ankle sprain. This represented the first treatment in the series, which continued with treatments on the 2nd, 3rd, 4th, 5th, 7th, 9th, 11th, 14th, and 17th days (24). The soft laser used in the study was the endo-laser 465, equipped with an infrared probe with a wavelength of 780 nm, and a placebo option. The parameters used were: a treatment time of 180 seconds, a pulse energy of 5 mW and a pulse frequency of 80 Hz. Pulse time was 0.3 msec, at a beam diameter of 1 mm and a skin-probe distance of 1 cm. From the moment of randomization, all three groups, i.e. the laser, placebo and control groups, were asked to fill in a score form for the duration of the study, at a fixed time each day (see Appendix 1). In practice, this meant that subjects filled in a form early in the morning (e.g. at breakfast), recording their experiences of the previous day and night. Data were analysed using statistical tests for small populations. The data presented in the present paper were analysed by means of Student's t test.

Results

All persons who were enrolled for the study and satisfied the requirements (N=38) cooperated. The description of the study population in Table 1 shows that the groups may be regarded as comparable in sex, age and compliance.

Table 2 shows the complaint scores for the three study groups before the start of the experiment. Since there were slight differences in scores between the study groups, effects of treatment are always expressed as percentages of decrease in the scores with respect to the original score for that group.

After 5 days, the average decrease in pain scores during the day was found to be larger for the laser group than for both the placebo group and the control group. Table 2 also shows that there was no significant difference in complaint scores between the placebo group and the control group. After seventeen days, there was only a (slight) significant difference between the laser group and the placebo group.

Table 4 reveals that the average decrease (in %) in pain scores at night also reached a peak after five days. Again, the differences between the groups had practically disappeared after seventeen days. Since all responders were actively engaged in sports, impairment of sports participation could be used as a measure of the effect of treatment. Average decreases (in %) in impairment of sports participation after five and seventeen days are shown in Table 5. After five days, there was a significantly larger decrease in impairment of sports participation in the laser group as compared to the placebo group, but the difference in decrease between the laser and control groups was far less obvious. After seventeen days, the average decrease in impairment of sports participation was still found to be largest in the laser therapy group, but the placebo group also showed a relatively large decrease in complaint scores compared to the control group.

Table 1. Study population

<table>
<thead>
<tr>
<th></th>
<th>Laser</th>
<th>Placebo</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>12</td>
<td>11</td>
<td>15</td>
</tr>
<tr>
<td>Men</td>
<td>67%</td>
<td>64%</td>
<td>67%</td>
</tr>
<tr>
<td>Mean age</td>
<td>26</td>
<td>27</td>
<td>26</td>
</tr>
<tr>
<td>Compliance</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 2. Mean complaint scores before treatment

<table>
<thead>
<tr>
<th></th>
<th>Laser</th>
<th>Placebo</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>daytime</td>
<td>3.9</td>
<td>3.5</td>
<td>3.7</td>
</tr>
<tr>
<td>nighttime</td>
<td>3.9</td>
<td>3.5</td>
<td>4.1</td>
</tr>
<tr>
<td>Impairment of sports participation</td>
<td>9.0</td>
<td>9.8</td>
<td>9.7</td>
</tr>
</tbody>
</table>

A score of 10 corresponds to maximum complaints
A score of 0 corresponds to zero complaints

Table 3. Mean decrease (in %) in pain scores during the day

<table>
<thead>
<tr>
<th></th>
<th>After 5 days</th>
<th>After 17 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser</td>
<td>Placebo</td>
<td>Control</td>
</tr>
<tr>
<td>71%</td>
<td>48%</td>
<td></td>
</tr>
<tr>
<td>71%</td>
<td>48%</td>
<td></td>
</tr>
<tr>
<td>n.s.</td>
<td>53%</td>
<td></td>
</tr>
</tbody>
</table>

n.s. = not significant
Complaint Scoring Form

Name: ___________________________  Group: ___________________________
Date of birth: _____________________  Date: ___________________________
Occupation: _________________________
Sport/hobby: ________________________

Give a mark for each of the items, and indicate this on the scales.
Mark 10 means maximum score; mark 1 means minimum or no score.

Pain: 10 means maximum pain; 1 means no pain

At night: 1 2 3 4 5 6 7 8 9 10
Daytime: 1 2 3 4 5 6 7 8 9 10

Daily activities: to what extent are you hampered in your daily activities by your injury?
10 means maximum impairment
0 means no impairment

Work: 1 2 3 4 5 6 7 8 9 10
Housework: 1 2 3 4 5 6 7 8 9 10
Sports: 1 2 3 4 5 6 7 8 9 10

To what extent does your injury affect your social contacts with relatives, friends and others?

Social: 1 2 3 4 5 6 7 8 9 10

Are you satisfied with the therapy?
10 means utterly dissatisfied
0 means completely satisfied

Satisfaction: 1 2 3 4 5 6 7 8 9 10

Discussion

The study population in the clinical trial reported here was small, hence there is the possibility that a relevant effect of laser therapy has not been revealed. However, a lack of power does not necessarily mean that the findings of a study are meaningless (25). The aim of the present study was to investigate whether laser therapy had any demonstrable effects in complaints which lend themselves relatively well to treatment. Hence a generalisation of the findings to other complaints and/or patients was of secondary importance in this case.

Complaint scores in this study were assessed by means of V.A.S. (Visual Analog Scale). These scales seemed most appropriate for our purposes. This is, of course, debatable. However, studies by Revill et al. (33) have shown that on the basis of these scales, subjects can provide very precise information on the pain they have experienced over the past 24 hours. Several other studies have also preferred this relatively simple method of scoring (30, 32, 34, 35). Arguments against the use of V.A.S. scales include the contention that unidimensional scales can never convey the complexity of the pain experience. It is of course well known that pain has clear emotional and affective components. Subjects might also use these scales to express the various components of their discomfort. We have tried to prevent this by dividing up the pain experience into a daytime and a nighttime sections, and by bringing in the affective and emotional components elsewhere on the scoring form (see Appendix 1).

The pain score measurements show the effect of laser treatment to be most pronounced in the short term. After seventeen days, i.e. at the end of the experiment, the subjects in the laser therapy group still showed a larger decrease in complaint scores, but the difference had almost disappeared. Thus, laser treatment especially seems to accelerate recovery. The differences in the average decrease in pain scores for daytime and nighttime after five days is not easy to explain. A possible explanation might be that the injured foot is not in use during the night, thus causing less pain. It was also found that after five days the laser therapy group is almost free of pain at night, while the other groups still feel pain. This seems to be a clear effect of laser therapy.

As regards the impairment of sports participation, the laser group also appeared to do slightly better than the other groups, although the effect was much less pronounced than for the decrease in pain scores. Impairment of sports participation was assessed by means of V.A.S. scales as well. These scales are reasonably reliable in measuring pain scores, but it is not clear whether they are equally reliable in assessing the degree of impairment of sports participation. Perhaps the use of a dichotomous varia-

Appendix 1

After 5 days  After 17 days

<table>
<thead>
<tr>
<th></th>
<th>Laser</th>
<th>Placebo</th>
<th>Control</th>
<th>p-value</th>
<th>Laser</th>
<th>Placebo</th>
<th>Control</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 5 days</td>
<td>98%</td>
<td>76%</td>
<td></td>
<td>&lt;0.005</td>
<td>97%</td>
<td>95%</td>
<td></td>
<td>n.s.</td>
</tr>
<tr>
<td>After 17 days</td>
<td>98%</td>
<td>60%</td>
<td>&lt;0.005</td>
<td>97%</td>
<td>94%</td>
<td>94%</td>
<td>n.s.</td>
<td></td>
</tr>
</tbody>
</table>

Table 4. Mean decrease (in %) in pain scores during the night

<table>
<thead>
<tr>
<th></th>
<th>Laser</th>
<th>Placebo</th>
<th>Control</th>
<th>p-value</th>
<th>Laser</th>
<th>Placebo</th>
<th>Control</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 5 days</td>
<td>8%</td>
<td>0%</td>
<td></td>
<td>&lt;0.05</td>
<td>42%</td>
<td>37%</td>
<td></td>
<td>n.s.</td>
</tr>
<tr>
<td>After 17 days</td>
<td>8%</td>
<td>4%</td>
<td>n.s.</td>
<td>42%</td>
<td>18%</td>
<td>18%</td>
<td>&lt;0.025</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

Table 5. Mean decrease (in %) in impairment of sports participation
ble would have been more appropriate here after all.

Another possible explanation for the less pronounced differences in impairment of sports participation could be that patients would in general not actively engage in sports within five days after rupture of an ankle ligament. But after seventeen days, some engagement in sports activities is found to be possible. In other words, five days after the start of the therapy may be too brief a period for assessing impairment of sports participation. Another difficult fact to explain is that, after seventeen days, there was hardly any difference between the laser and placebo groups in the impairment of sports participation. It is hard to see why there should be a placebo effect with regard to impairment of sports participation, but none with regard to pain experience. This is probably a chance finding.

Another point of discussion is the need for a window in the taping. Some physiotherapists still apply laser therapy through an intact taping. Previous studies have shown this to be impossible. Even one layer of taping reduces the penetrative energy of low and medium frequency lasers by as much as 70%, and with each subsequent layer the energy decreases quadratically. Bearing in mind that a Coumans taping can easily consist of five or six layers, it will be clear that any effect of laser therapy will thereby be reduced practically to zero. Hence in our opinion a window in the taping is an absolute necessity for laser treatment.

The window we made over the pain point, with a diameter of 1 cm, was found not to affect the quality of the taping (24).

Finally it must be observed that a laser therapy in accordance with our criteria is highly time-consuming, and hence rather expensive. The duration of each treatment is short, but the patient has to come in for treatment frequently. It may be questioned whether the balance of costs and gains for such therapy would be positive. There may, however, be an economic advantage if laser therapy means that some patients can go back to work (sports) sooner.

**Conclusion**

In patients with an acute ankle sprain, laser therapy, applied in accordance with our criteria, results in a more rapid reduction of pain levels, especially at night. A more rapid return to work (sports) also appears possible. However, this will have to be tested in a further study.

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