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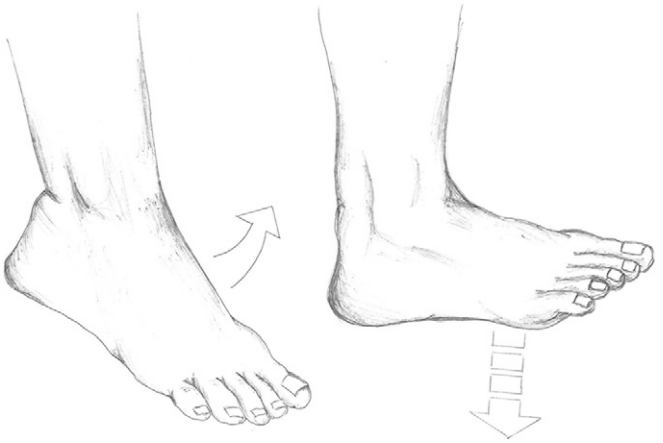

Fig. E-1

Controlled early motion. Both groups performed controlled early motion of the ankle joint during weeks three to eight. The patient was instructed to remove the orthosis at least five times a day while sitting on the edge of a table with both legs hanging down. Gravity plantar flexed the foot, whereupon the patient actively dorsiflexed the foot to a horizontal position. The patient was instructed to perform a series of twenty-five repetitions.

## Quality-of-Life Questionnaire

The following questions concern limitations due to the treatment as an average over the eight-week treatment period:

1. Did you feel limited in your daily activities (e.g., shopping, cooking, using the restroom) due to the treatment?

| Very Much | | | | | | | | | | | Not at All |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

2. Did you feel limited in your work due to the treatment?

| Very Much | | | | | | | | | | | Not at All |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

3. Did you feel limited in your social life (e.g., going to the movies and meeting with friends) due to the treatment?

| Very Much | | | | | | | | | | | Not at All |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

4. Did the treatment affect your mood?

| Very Much | | | | | | | | | | | Not at All |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

5. What was your average pain level?

| Very Much | | | | | | | | | | | Not at All |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

## Trial Protocol

Acute Achilles tendon rupture is relatively frequent (eleven to thirty-seven per 100,000 per year). There are great social benefits in optimizing treatment and shortening recovery.

There is no consensus regarding the best treatment of acute Achilles tendon rupture. Surgical treatment has traditionally been considered superior, but more recent studies have shown evidence that nonoperative treatment with early dynamic rehabilitation yields the same functional outcome with fewer side effects.

Nonoperative treatment traditionally involves non-weight-bearing for six weeks. This is not evidence-based but rather due to tradition. It has been well documented that mechanical loading improves tendon-healing in general and has no detrimental effect on the healing of surgically treated Achilles tendons.

The objective of this randomized study was to compare early weight-bearing with non-weight-bearing following nonoperative treatment of acute Achilles tendon rupture.

### *Background*

Acute Achilles tendon rupture is potentially debilitating. The age distribution of patients is bimodal, with a maximum incidence resulting from sports-related injuries around forty years of age followed by a second and smaller peak in the incidence at fifty to sixty years of age resulting from non-sports-related injuries[28-30]. The condition costs millions of dollars in treatment and lost earnings.

There is no consensus regarding the best treatment of acute Achilles tendon rupture. It is the authors' belief that the decision between nonoperative and operative treatment differs between orthopaedic surgical departments and individual orthopaedic surgeons.

Surgery is traditionally considered superior to conservative treatment because of a lower risk of rerupture of the Achilles tendon, despite the fact that surgery has a significantly increased risk of serious side effects such as deep infection[23]. The preference for operative treatment is based on studies comparing surgical treatment followed by early dynamization with nonoperative treatment without dynamization. However, recent studies have shown increasing evidence that nonoperative treatment with early dynamization of the ankle yields the same functional outcome as operative treatment without significantly increased risk of rerupture[3,4]. The same studies have shown that the overall complication rate is higher with surgery than with nonoperative treatment. The surgical complications include infection, nerve damage, adhesion, contracture, and cosmetic problems.

Pajala et al. assessed the outcomes of patients who developed a rerupture or a deep wound infection. They concluded that the outcome after rerupture without a complicating infection was satisfactory, whereas the outcome after a deep wound infection was devastating[31]. The risk of a debilitating complication is thus greater with surgery than with conservative treatment.

Although nonoperative treatment traditionally involves non-weight-bearing for six weeks, Suchak et al. showed that early weight-bearing after surgical treatment of Achilles tendon rupture improves health-related quality of life in the period after surgery and has no negative effect on tendon-healing[16].

It is well documented that mechanical loading improves tendon-healing[12]. Thus, it is reasonable to believe that early loading of the tendon under controlled conditions will have a beneficial effect on tendon-healing.

### *Objectives of the Study*

The primary objective of this randomized study was to compare early weight-bearing with non-weight-bearing following nonoperative treatment of acute Achilles tendon rupture. All patients were treated with dynamic rehabilitation in a DJO Walker orthosis. Functional outcome was self-assessed with use of the ATRS and the heel-rise work test.

Secondary objectives were to investigate the differences between the groups with regard to rerupture, time to return to work, and time to return to sports.

### *Method and Subjects*

This randomized clinical trial was approved by the medical ethic committee. Patients who were allowed to bear weight from day one were compared with patients who were not allowed to bear weight during the first six weeks of treatment. The orthosis used is equipped with a pressure sensor that detects when the patient bears weight on the foot.

**Time Course**

The study was planned for a two-year period. Recruitment of patients started on April 1, 2011; it was expected to be completed in 2011 but had to be extended to March 2012. The follow-up period was one year.

**Population**

Patients treated for acute Achilles tendon rupture at Copenhagen University Hospital Hvidovre were eligible for the study. Patients who fulfilled the inclusion criteria but did not wish to participate were treated according to the standard regimen (nonoperatively, without early controlled movement of the ankle joint).

**Inclusion Procedure**

After primary treatment in the emergency room, patients were attended to in the orthopaedic outpatient clinic. The patients were examined by an investigator or another authorized person in the research group, who assessed whether the patient met the inclusion criteria. If so, the patient was verbally informed of the study as well as provided with written information. The patient was given the opportunity, on an informed basis and without any pressure, to decide whether he or she wished to participate in the trial. The patient was informed of his or her right to twenty-four hours of reflection. If the patient chose to participate, the investigator left the room and the randomization was conducted by the project nurse, who also gave instructions regarding the treatment plan (for weeks three to eight).

**Number of Patients**

The study was designed to include thirty patients in each group (total, sixty patients). The sample size calculation was based on a clinically relevant difference of 10 points in the ATRS, a standard deviation of 10 points, and a power of 0.90 (two-sided). Twenty-two patients were required in each group, and thirty were to be included in each group because of the risk of drop-out.

**Inclusion Criteria**

The inclusion criteria were (1) an age of eighteen to sixty years, (2) ability to speak and understand Danish, (3) ability to give informed consent, (4) ability to follow a regimen with a removable ankle orthosis, (5) ability to determine that the rupture occurred within the past four days, and (6) ability to attend the follow-up appointments.

**Exclusion Criteria**

The inclusion criteria were (1) terminal illness, (2) a previous Achilles tendon rupture, (3) previous surgery on the Achilles tendon, (4) treatment with fluoroquinolones during the past six months, (5) tendinosis treated with a tablet or injection containing corticosteroids within the past six months, (6) a diagnosis of arterial insufficiency in the leg, (7) absence of a palpable pulse in the foot, (8) severe medical illness as indicated by an ASA score of >2, and (9) a distance of <1 cm from the calcaneus to the rupture.

*Treatment*

In the emergency room, the ankle orthosis (DJO Walker) was applied with the foot in 20° to 30° of plantar flexion. The orthosis was worn for eight weeks, gradually bringing the foot to 0°. Dynamic rehabilitation of the ankle joint was begun on day fifteen.

The overall protocol was as follows:

Weeks one and two: The orthosis, with three wedges, must be worn twenty-four hours a day, and cannot be removed for bathing or at night.

Weeks three and four: Dynamic rehabilitation is performed. The boot, with two wedges, cannot be removed at night.

Weeks five and six: Dynamic rehabilitation is performed. The boot, with one wedge, cannot be removed at night.

Weeks seven and eight: Dynamic rehabilitation is performed. The boot, with no wedges, can be removed at night.

**Group Allowed Early Weight-Bearing**

The weight-bearing protocol was as follows:

Weeks one and two: Weight-bearing is allowed as tolerated. Crutches are recommended.

Weeks three and four: Full weight-bearing is allowed.

Weeks five to eight: Full weight-bearing is allowed. Use of crutches should be avoided.

**Group Not Allowed Early Weight-Bearing**

The weight-bearing protocol was as follows:

Weeks one to six: No weight-bearing is allowed. Crutches are obligatory.

Weeks seven and eight: Full weight-bearing is allowed.

**Dynamic Rehabilitation**

The dynamic rehabilitation protocol was as follows:

Beginning on day fifteen, patients in both groups must perform ankle exercises. A minimum of five times a day, the patient must remove the orthosis, sit on a table with the legs hanging freely over the edge, and perform twenty-five repetitions of active dorsiflexion and passive plantar flexion.

**Verification of Compliance with Weight-Bearing Restrictions**

All DJO Walkers used in the study were equipped with an integrated pressure sensor that detects when load is applied in the boot.

**Subsequent Rehabilitation**

After eight weeks the patient is seen in the outpatient clinic. He or she is instructed in the rehabilitation regimen by a physiotherapist. Rehabilitation is designed as a home exercise program with emphasis on movement, stability, coordination, and strength.

The protocol was as follows:

Week ten: Cycling was begun.

Week fourteen: Slow, controlled jogging was begun.

Weeks twenty-six to fifty-two: Sports can be resumed. Badminton, tennis, and squash as well as contact sports are not recommended before weeks forty to fifty-two.

Week fifty-two: No restrictions.

*End Points*

The primary end point was the ATRS, which is a patient-reported, validated scoring tool developed for assessment of symptoms and physical activity after treatment for acute Achilles tendon rupture.

The secondary end points were (1) the biomechanical test results, (2) work on the heel-rise test, (3) height on the heel-rise test, (4) occurrence of a rerupture, (5) the time to return to work, and (6) the time to return to sports.