Nonoperative Dynamic Treatment of Acute Achilles Tendon Rupture: The Influence of Early Weight-Bearing on Clinical Outcome

A Blinded, Randomized Controlled Trial

Kristoffer Weisskirchner Barfod, PhD, MD, Jesper Bencke, MSc, PhD, Hanne Bloch Lauridsen, MSc, Ilija Ban, MD, Lars Ebskov, MD, and Anders Troelsen, MD, DMSc, PhD

Investigation performed at the Department of Orthopedics, Clinical Orthopedic Research Hvidovre, Copenhagen University Hospital Hvidovre, Hvidovre, Denmark

Background: Dynamic rehabilitation has been suggested to be an important part of nonoperative treatment of acute Achilles tendon rupture that results in functional outcome and rerupture rates comparable with those of operative treatment. However, the optimal role of weight-bearing during early rehabilitation remains unclear. The purpose of this study was to compare immediate weight-bearing with non-weight-bearing in a nonoperative dynamic treatment protocol for Achilles tendon rupture.

Methods: The study was conducted as a blinded, randomized, controlled, parallel superiority trial. Patients eighteen to sixty years of age were eligible for inclusion. Both groups were treated nonoperatively with controlled early motion. The intervention group was allowed full weight-bearing from day one, and the control group was non-weight-bearing for six weeks. The primary outcome was the Achilles tendon Total Rupture Score (ATRS) after one year. Secondary outcomes included heel-rise work, health-related quality of life, and the rerupture rate. Outcome assessors were blinded to the intervention.

Results: Thirty patients were randomized to each group; twenty-nine in the weight-bearing group and twenty-seven in the control group were analyzed. The only significant difference between the groups was better health-related quality of life in the weight-bearing group at twelve months (p = 0.009). The mean ATRS at twelve months was 73 in the weight-bearing group and 74 in the control group (p = 0.81). At twelve months, the total heel-rise work performed by the injured limb relative to that by the uninjured limb was 53% in the weight-bearing group and 58% in the control group (p = 0.37). There were three reruptures in the weight-bearing group and two in the control group (p = 1.0).

Conclusions: The ATRS and heel-rise work results did not differ significantly between the groups. The rerupture rate was 9% overall, and both groups had substantial functional deficits in the injured limb compared with the uninjured limb. Immediate weight-bearing can be recommended as an option in the nonoperative treatment of Achilles tendon rupture.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Nonoperative treatment of acute Achilles tendon rupture is a well-accepted treatment modality used as the standard of care by approximately one-half of hospitals in some regions. Dynamic rehabilitation after nonoperative treatment of Achilles tendon rupture has been suggested to be an important part of treatment that results in functional outcome and...
rerupture rates comparable with those of surgical treatment. However, the optimal nonoperative treatment protocol, particularly the role of weight-bearing during early rehabilitation, remains to be clarified.

The role of controlled early motion has been discussed since the early 1980s. In theory, controlled early motion of tendons leads to improved healing through the release of growth factors, and animal studies have shown a threefold increase in the strength of Achilles tendons with dynamic rehabilitation. Nevertheless, randomized controlled trials have demonstrated no important significant differences between the outcomes of rehabilitation protocols with dynamic mobilization and immobilization. It should be noted, however, that none of those previous studies were noninferiority studies, and as such they were not powered to rule out possible differences.

The role of weight-bearing has been sparsely investigated in the clinical setting. In experimental models, however, it is well documented that mechanical loading improves tendon-healing. Thus, it is reasonable to believe that early loading of the tendon under controlled conditions will have beneficial effects on tendon-healing. Immediate weight-bearing in a nonoperative treatment protocol has been investigated in one randomized controlled trial. The trial provided no evidence for either a functional benefit from immediate weight-bearing or any detrimental effect on outcome parameters. The objective of the present blinded, randomized controlled trial was to compare immediate weight-bearing with normal walking, and no detrimental effect involving other outcome parameters.

### TABLE I Baseline Demographic Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Weight-Bearing Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age* (yr)</td>
<td>41.2 ± 6.4, 41.4 (26.6-51.8), n = 29</td>
<td>39.1 ± 7.5, 39.2 (26.7-56.4), n = 28</td>
</tr>
<tr>
<td>Sex, M/F†</td>
<td>24 (83)/5 (17)</td>
<td>24 (86)/4 (14)</td>
</tr>
<tr>
<td>Height* (cm)</td>
<td>177.1 ± 7.0, 176.7 (163.5-196.7), n = 27</td>
<td>180.0 ± 9.6, 178.1 (161.1-198.7), n = 27</td>
</tr>
<tr>
<td>Weight* (kg)</td>
<td>86.3 ± 13.7, 84.3 (63.2-116.2), n = 27</td>
<td>86.1 ± 13.2, 86.4 (63.7-117.3), n = 27</td>
</tr>
<tr>
<td>Injured side, R/L†</td>
<td>12 (41)/17 (59)</td>
<td>16 (57)/12 (43)</td>
</tr>
<tr>
<td>Dominant side, R/L†</td>
<td>21 (87)/3 (13)</td>
<td>18 (86)/3 (14)</td>
</tr>
<tr>
<td>Smoker, Y/N†</td>
<td>5 (17)/24 (83)</td>
<td>9 (32)/19 (68)</td>
</tr>
<tr>
<td>Work†</td>
<td>Heavy: 8 (28)</td>
<td>5 (18)</td>
</tr>
<tr>
<td></td>
<td>Light but mobile: 10 (34)</td>
<td>5 (18)</td>
</tr>
<tr>
<td></td>
<td>Sedentary: 11 (38)</td>
<td>18 (64)</td>
</tr>
<tr>
<td>Sports* (hr/wk)</td>
<td>4.6 ± 2.4, 4.0 (1.0-10.0), n = 22</td>
<td>5.5 ± 4.1, 5.0 (1.0-18.0), n = 23</td>
</tr>
<tr>
<td>ATRS pre-injury*</td>
<td>98.6 ± 4.0, 100 (79-100), n = 29</td>
<td>98.7 ± 3.4, 100 (84-100), n = 27</td>
</tr>
</tbody>
</table>

*The values are reported as the mean and standard deviation, the median with the minimum and maximum in parentheses, and the number of patients for whom data were available. †The values are reported as the number of patients, with the percentage in parentheses.

### TABLE II Treatment Protocol

- **Weeks 1 and 2**
  - Orthosis with three wedges
  - The orthosis could not be removed at any time
  - Weight-bearing group: weight-bearing allowed, crutches recommended
  - Control group: No weight-bearing

- **Weeks 3 and 4**
  - Orthosis with two wedges
  - Controlled early motion in both groups
  - Weight-bearing group: full weight-bearing
  - Control group: no weight-bearing

- **Weeks 5 and 6**
  - Orthosis with one wedge
  - Controlled early motion in both groups
  - Weight-bearing group: full weight-bearing
  - Control group: no weight-bearing

- **Weeks 7 and 8**
  - Orthosis without wedges
  - Controlled early motion in both groups
  - Weight-bearing group: full weight-bearing
  - Control group: full weight-bearing

- **Weeks 9 to 16**
  - Visit to physiotherapist three times a week.
  - Standardized rehabilitation protocol with room for individualization
non-weight-bearing in a nonoperative treatment protocol for Achilles tendon rupture utilizing controlled early motion. We hypothesized that immediate weight-bearing would lead to better patient-reported and functional outcomes. The primary end point was the Achilles tendon Total Rupture Score (ATRS) at one year.

Materials and Methods
This was a blinded, randomized, controlled superiority trial with participants individually randomized to one of two parallel groups.

Patients (Table I)
Patients referred to the orthopaedic department of Copenhagen University Hospital Hvidovre from April 2011 to March 2012 with an Achilles tendon rupture were assessed for eligibility. The diagnosis was based on a medical history including a clear snapping of the Achilles tendon and a clinical examination showing a palpable gap and a positive calf squeeze test. Sixty patients were included in the trial and were randomly assigned to one of two parallel groups by means of opaque, sealed envelopes. The envelopes were prepared and shuffled by an experienced researcher with no other connection to the trial.

All patients who were eighteen to sixty years of age and were believed to be able to follow the treatment protocol and give written consent in Danish were eligible for inclusion if randomization could be done within four days of the rupture. Three of the patients who presented with an Achilles tendon rupture during the study period were more than sixty years of age, one was unable to follow a non-weight-bearing protocol because of severe obesity, and nine presented later than four days after injury. One additional patient was excluded because of a previous Achilles tendon injury, and one was excluded because of corticosteroid injections within the past six months. No patient was excluded because of an ASA (American Society of Anesthesiologists) score of three or more, a medical history of arterial insufficiency in the legs, or a rupture within 1 cm of the calcaneus. Five of the patients who were eligible declined to participate (Fig. 1). The rupture site was determined by palpation; in case of doubt, ultrasonography was used. The study was approved by the Regional Ethical Review Board. All participants received oral and written information regarding the trial before written consent was obtained.

Treatment (Table II)
Both groups received the same treatment other than weight-bearing. In the emergency department, an ankle orthosis (DJO Nextep Contour 2 Walker) with three 1.5-cm wedges was applied, fixing the ankle in equinus (20° to 30° of plantar flexion). The orthosis was worn for eight weeks, and the ankle was gradually brought to a neutral position by removal of a wedge every second week. The patient was instructed not to remove the orthosis at any time during the first two weeks. After two weeks, the first wedge was removed and controlled early motion was begun; 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 (see Appendix). Gravity plantar flexed the foot, and the patient then actively dorsiflexed the foot to a horizontal position. The patient was instructed to perform a series of twenty-five repetitions of this exercise. During weeks three to six, the orthosis was not to be removed except during the exercises. During the last two weeks of treatment, the orthosis could be removed at night.

**Intervention**

The treatment protocol for the groups differed only in the permission to bear weight. The intervention group was allowed full weight-bearing from day one; crutches were recommended but not obligatory during the first two weeks of treatment. The control group was instructed not to bear weight for the first six weeks of treatment; full weight-bearing was allowed during the last two weeks.

**Subsequent Rehabilitation**

A standardized rehabilitation protocol was followed during weeks nine to sixteen. The patient was trained three times a week by a team of specialized physiotherapists. Recommendations were individualized, but in general cycling was allowed from week ten and jogging from week fourteen. Racquet and contact sports could be resumed after approximately one year, and other types of sports could be resumed after six months.

**End Points**

The primary end point was the ATRS at one year. To our knowledge, the ATRS is the only patient-reported outcome measure validated for use after Achilles tendon rupture. Secondary end points were heel-rise work and height, rerupture, duration of sick leave, and quality of life during treatment. Heel-rise work was measured as described by Silbernagel et al. and Nilsson-Helander et al.\(^2\) A limb symmetry index (LSI) was calculated to compare the two treatment groups with regard to the work and height in the heel-rise test. The LSI was defined as the ratio between the scores of the involved and uninvolved limb, expressed as a percentage (LSI = involved/uninvolved × 100)\(^4\).

The trial was designed in accordance with the CONSORT (Consolidated Standards of Reporting Trials) recommendations, and no changes were made to the design after commencement of the trial. The full trial protocol can be found in the Appendix. The trial was registered at ClinicalTrials.gov (NCT01470833).

### TABLE III ATRS and Heel-Rise Outcomes*

<table>
<thead>
<tr>
<th>Test</th>
<th>Weight-Bearing Group</th>
<th>Control Group</th>
<th>P Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATRS</td>
<td>61.1 ± 18.0, 61 (34-95), n = 28</td>
<td>67.0 ± 21.0, 67 (27-99), n = 27</td>
<td>0.27</td>
</tr>
<tr>
<td>Heel-rise work† (%)</td>
<td>40 ± 15, 42 (1-73), n = 24</td>
<td>36 ± 21, 36 (1-72), n = 24</td>
<td>0.46</td>
</tr>
<tr>
<td>Heel-rise height† (%)</td>
<td>66 ± 21, 67 (1-97), n = 24</td>
<td>58 ± 23, 65 (0-96), n = 24</td>
<td>0.24</td>
</tr>
</tbody>
</table>

*The values are reported as the mean and standard deviation, the median with the minimum and maximum in parentheses, and the number of patients with data. †Mann-Whitney U test. ‡Relative to the uninvolved limb.
Nonoperative Dynamic Treatment of Acute Achilles Tendon Rupture

Source of Funding
Limited grant support for the research was received from DJO Nordic, which had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Results
Thirty patients were randomly assigned to each group (Fig. 1, Table I). One patient in the weight-bearing group discontinued the treatment and was lost to follow-up when he decided to undergo operative treatment at another hospital. Two patients in the control group discontinued the treatment and were lost to follow-up because they could not comply with the non-weight-bearing protocol and did not wish to participate in the follow-up. One patient in each group missed the six-month follow-up visit because they were temporarily working out of the state. Thus, twenty-eight patients in the weight-bearing group and twenty-seven in the control group were included in the six-month analysis; all had been treated in accordance with their original assignment. One patient in the control group did not attend the one-year follow-up visit because he was unsatisfied with the given treatment. Thus, twenty-nine patients in the weight-bearing group and twenty-seven in the control group were included in the one-year analysis; again, all had been treated in accordance with their original assignment.

Patient-Reported Outcome
The ATRS did not differ significantly between the weight-bearing and non-weight-bearing groups at six months of follow-up (mean, 61.1 and 67.0, respectively) or at twelve months (73.4 and 74.4, respectively) (Table III). The ATRS increased significantly from six to twelve months (p < 0.05) in both groups.

The scores on the questionnaire created to measure health-related quality of life during the initial eight weeks of treatment were significantly better in the group that was allowed immediate weight-bearing (p = 0.009) (Table IV).

Functional Assessment
The work and height results on the heel-rise test did not differ significantly between the groups (Table III). The mean LSI (derived by comparing the values with those for the contralateral limb) for the work results was 40% in the weight-bearing group and 36% in the non-weight-bearing group at six months, and the corresponding values at twelve months were 53% and 58% (Table III). The work results increased significantly (p < 0.05) from six to twelve months in both groups.

Rerupture
The overall rate of rerupture was 9% (five of fifty-six) at twelve months of follow-up. Three reruptures were in the weight-bearing group and two were in the non-weight-bearing group (Table IV). The study was inadequately powered to clearly test the hypothesis that the rerupture rate would be equal in the two groups.

Work and Sports
The mean duration of sick leave did not differ significantly between the weight-bearing group (fifty-two days) and the non-weight-bearing group (eighty-one days). Although sporting activities were resumed sooner in the weight-bearing group (after a mean of 143 days) than in the non-weight-bearing group (181 days), the difference did not reach significance. Overall, 16% (eight of fifty-one) had returned to their pre-injury level of sports activity at one year of follow-up (Table IV).

Complications
One patient in the non-weight-bearing group sustained a severe tendon elongation, as assessed with the Matles test. He was unable to perform a single heel rise and had pain from the fat pad under the heel. He underwent operative tendon shortening but continued to have problems at one year of follow-up. No infection or nerve damage was seen in the patients who underwent surgery for re rupture or elongation. No cases of deep venous thrombosis were found.

Discussion
Dynamic rehabilitation has been advocated in a number of studies. However, the optimal nonoperative treatment protocol for Achilles tendon rupture, particularly the role of early weight-bearing during dynamic rehabilitation, remains unclear. We hypothesized that immediate weight-bearing would lead to better patient-reported and functional outcomes. To our knowledge, this is the first randomized controlled trial utilizing validated outcome measures to investigate the role of immediate weight-bearing in a nonoperative dynamic rehabilitation protocol.

Nonoperative treatment has gained increasing popularity during the past decade. A number of meta-analyses comparing operative and nonoperative treatment have shown a significantly lower rate of rerupture and a significantly higher rate of other complications among operatively treated patients. An examination by Soroceanu et al. involving only studies using dynamic rehabilitation revealed no significant difference in the rate of re rupture between operatively and nonoperatively treated patients; the increased risk of other complications in the

<table>
<thead>
<tr>
<th>Weight-Bearing Group</th>
<th>Control Group</th>
<th>P Value†</th>
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<tbody>
<tr>
<td>73.4 ± 16.2, 75 (39-94), n = 29</td>
<td>74.4 ± 17.7, 75 (34-100), n = 27</td>
<td>0.81</td>
</tr>
<tr>
<td>53 ± 20, 53 (10-94), n = 29</td>
<td>58 ± 25, 56 (9-99), n = 25</td>
<td>0.37</td>
</tr>
<tr>
<td>69 ± 17, 70 (26-96), n = 29</td>
<td>72 ± 14, 73 (42-95), n = 25</td>
<td>0.44</td>
</tr>
</tbody>
</table>
operative group was the only significant difference. This corresponds well with the postulate by Twaddle and Poon that "it is possible that controlled early motion is the important factor in optimizing outcomes in patients with Achilles tendon rupture and that surgery makes no difference to the outcome apart from increasing the risk of local infection."

It should be noted, however, that the trials included in the meta-analysis by Soroeceanu et al. differ from those included in the other meta-analyses. Also, we are aware of no high-quality trials that investigated the effect of controlled early motion compared with immobilization in a randomized controlled study design in which the parallel groups differed only in the mobilization regimen. Finally, there is no broadly accepted definition of dynamic rehabilitation. The term has been used to refer to controlled early mobilization in some studies, to controlled early weight-bearing in others, and to a combination of the two in still others. Also, the mobilization methods in the studies varied, with some using a hinged orthosis that allowed continuous movement whereas others used a fixed removable orthosis (as in the present trial).

Immediate weight-bearing increases the force on the Achilles tendon, which could potentially lead to elongation or rerupture of the healing tendon. Use of the orthotic heel lift reduces the force on the Achilles tendon and the resulting strain while allowing for isometric contractions. The role of weight-bearing is of fundamental importance as it influences not only the quality of treatment but also the patient's self-care ability. Two previous randomized controlled trials have investigated the effect of weight-bearing in the treatment of Achilles tendon rupture. Costa et al. considered return to normal activities to be the most important outcome parameter. They found that immediate weight-bearing led to quicker return to normal walking and stair climbing in operatively but not nonoperatively treated patients. Suchak et al. considered quality of life to be the most important outcome parameter. They found that early weight-bearing led to better health-related quality of life during treatment. Neither of these analyses found detrimental effects of early weight-bearing, although they were not designed as non-inferiority studies.

The results of the present study revealed no significant differences in the ATRS or heel-rise work results between the groups. The study was designed to have a power of 0.90 for the ATRS. The ATRS and heel-rise work are measures that have been specifically developed and validated for evaluation after an Achilles tendon rupture. The ATRS includes questions regarding walking, stair climbing, and quality of life. The combination of a patient-reported outcome measure and a functional endurance test has shown good validity and ability to detect changes involving this condition. The ATRS has been formally translated and validated in a Danish population.

Health-related quality of life during the initial eight weeks of treatment appeared to be better in the group allowed immediate weight-bearing. This is in line with the conclusion of Suchak et al. that early weight-bearing provides enhanced quality of life. However, this finding of the present study should be interpreted with caution as health-related quality of life was measured with use of a custom-designed measure with unknown validity and reliability. The differences in the rerupture rate, time to return to work, and time to return to sports were not significant. The question of whether quicker return to work and sports occurs after early weight-bearing (as a result of less muscle atrophy) is intriguing but was not answered in this trial.

Finally, it is worth noting that our overall treatment results, irrespective of group allocation, leave room for improvement. Nine percent of patients sustained a rerupture, patients had a strength deficit of 40% to 50% in the injured limb, and only 16% had returned to their pre-injury level of sports activity at one year of follow-up. Previous studies have shown 30% to 60% return to the same level of sports activity in both operatively and nonoperatively treated patients.

This study has several limitations. First, it was designed as a superiority study intended to show that immediate weight-bearing was superior to non-weight-bearing. Thus, although only minimal differences were found, we cannot claim immediate weight-bearing and non-weight-bearing to be equally effective in the treatment of Achilles tendon rupture. Second, compliance with the allocated treatment regimen was not controlled. Third, the quality-of-life measure used has unknown validity and reliability. Fourth, the power calculation in the present study was based on a standard deviation of 10 points in the ATRS, as reported in the study by Nilsson-Helander et al. However, the actual standard deviation in the present study was 16, which should be taken into consideration when designing future studies utilizing the ATRS as the primary outcome.

The generalizability of the study is good; we aimed to control for all factors other than weight-bearing, and there was no recognized selection bias in the inclusion procedure. The results should be generalizable to a population of otherwise healthy individuals between eighteen and sixty years of age with no use of corticosteroids during the past six months and no medical history of arterial insufficiency in the legs.

In future studies, it would be interesting to investigate the role of controlled early ankle motion in the rehabilitation following nonoperative treatment of Achilles tendon rupture. Controlled early motion has been strongly advocated as an important part of nonoperative dynamic rehabilitation, but to our knowledge no high-quality randomized controlled trial has been forthcoming. It would also be interesting to look further into the influence of tendon length on return to a normal gait pattern as assessed by gait analysis. In a case report utilizing gait analysis, the injured side displayed differences in strength, range of ankle motion, heel rise, and tendon length compared with the uninvolved side at one year after an Achilles tendon rupture.

In conclusion, it seems reasonable to recommend immediate weight-bearing during nonoperative dynamic treatment as a safe treatment modality for Achilles tendon rupture. Our results are consistent with previous findings that immediate weight-bearing does not have a detrimental effect on outcome.

Appendix

Appendices showing the quality-of-life questionnaire and detailing the trial protocol as well as a figure illustrating...
the controlled motion exercise are available with the online version of this article as a data supplement at jbs.org.

Jesper Bencke, MSc, PhD

Krisunner Weisskirchner Barfod, PhD, MD

Nonoperative Dynamic Treatment of Acute Achilles Tendon Rupture

Hanne Bloch Lauridsen, MSc
Ilia Ban, MD
Lars Elskov, MD
Anders Troelsen, MD, DMSc, PhD

Gait Analysis Laboratory (J.B. and H.B.L.), Department of Orthopedics (K.W.B., L.B., L.E., and A.T.), Clinical Orthopedic Research Hvidovre, Copenhagen University Hospital Hvidovre, Køgegård Allé 30, 2650 Hvidovre, Denmark.

E-mail address for K.W. Barfod: kbarfod@dadlnet.dk

References


