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High plantar force loading after Achilles tendon rupture repair with early functional mobilization

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23 Abstract

24 **Background:** Mechanical loading is essential for tendon healing and may explain variability 25 in patient outcome after Achilles tendon rupture (ATR) repair. However, there is no 26 consensus regarding the optimal postoperative regime, and the actual amount of loading 27 during orthosis immobilization is unknown. 28 Purpose: The primary aim of this study was to assess the number of steps and the amount of 29 loading in a weight bearing orthosis during the first six weeks post-surgical ATR repair. A 30 secondary purpose was to investigate if the amount of loading was correlated to fear of 31 movement or/and pain. 32 **Study Design:** Case series; Level of evidence, 4. 33 Methods: Thirty-four patients, mean (SD) age 38.8 (8.7) years, with ATR repair were 34 included. Early functional mobilization was allowed postoperatively in an orthosis with adjustable ankle range of motion. During the first two weeks postoperatively, patient-reported 35 36 loading and pain were assessed using visual analogue scale and step counts with a pedometer. 37 At the two- and six-weeks follow-up, a mobile force sensor was used for measuring plantar 38 force loading, and Tampa scale of Kinesiophobia questionnaire was used to examine fear of 39 movement. 40 **Results:** Between the first and second week a significant increase in the daily average number 41 of steps taken (2025-2753, p<0.001) as well as increase in self-reported loading (20-53%, 42 p<0.001) was observed. Patient self-reported loading was significantly associated with the 43 plantar force measurement (rho=0.719, p<0.001). At six weeks loading was 88.2% on the 44 injured vs. uninjured limb. Fear of movement was neither correlated to pedometer data, 45 subjective loading, pain, nor to force data. Patients with less pain during activity, however, reported significantly higher subjective load and were taking more steps (p < 0.05). 46

Conclusions: This is the first study to demonstrate the actual loading patterns during postoperative functional mobilization in surgically repaired ATR patients. The quick improvements in loading magnitude and frequency observed may reflect improved tendon loading essential for healing. Pain rather than fear of movement was associated with the high variability in loading parameters. The data of this study may be used to improve ATR rehabilitation protocols for future studies. **Key words:** Early functional mobilization, loading, step counts, fear of movement What is known about the subject: Mechanical loading plays an important role for tendon healing. Early weight bearing has demonstrated improvement in patients' symptoms, function and satisfaction, but the actual loading in these protocols is mostly unknown. Therefore, no consensus regarding the optimal postoperative regime can be established. What this study adds to existing knowledge: This study establishes the actual loading pattern, in both magnitude and frequency and their associated factors, during direct postoperative functional mobilization in surgically repaired ATR patients. The early loading pattern depends on postoperative pain rather than fear of movement.

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Achilles tendon rupture (ATR) is a common injury with a high variability in patient outcome, ^{2,20–23} which may depend on differences in mechanical loading. ^{27,31} Thus, immediate weight bearing after an Achilles tendon rupture is suggested to provide beneficial mechanical loading for healing of the Achilles tendon. ^{3,7,11,12,15,24} The optimal loading protocol, however, is not known. Although early weight bearing has resulted in greater improvement in symptoms, function and patient satisfaction in surgically treated ATR patients, ¹³ different postoperative protocols have been used, 8 making comparisons between studies difficult. Even the natural course of loading, i.e how much the patient actually loads in an orthosis after ATR surgery, is not known. To evaluate different early weight bearing protocols, the actual cumulative amount of loading should first be assessed. Thus, both the frequency (steps taken per day) as well as the magnitude of load on the injured leg must be registered daily during the orthosis mobilization. Today, mobile plantar force sensors, pedometers and self-reported diaries are available for assessments of frequency, magnitude and pattern of loading. Even though ATR-patients use the same weight bearing protocol, large variations in outcomes have been found. ^{20,23} Thus, the factors regulating loading behavior are not fully known. Fear of movement has been suggested as a confounding factor influencing the outcome.²¹ Therefore, it is of great interest to evaluate if fear of movement and/or pain are related to the amount of loading early after ATR surgery. The primary purpose of this study was to assess the number of steps as well as the amount of loading in a weight bearing orthosis during the first six weeks post-surgical ATR repair. A

secondary aim was to investigate if loading was correlated to fear of movement and pain. We hypothesized that direct weight bearing after ATR repair would result in an improved and more symmetrical loading pattern during the early immobilization period. Furthermore, we hypothesized that patients with a low degree of fear of movement would load their injured side to a greater degree compared to patients with a high degree of fear of movement.

Materials and Methods

Study design

This study is a prospective cohort study of a subgroup of patients included in a larger prospective randomized controlled trial. Ethical approval was obtained from the Regional Ethical Review Committee in Stockholm, Sweden (Dnr: 2013/1791-31/3). The study was additionally registered on clinicaltrials.gov (trial number NCT02318472).

Patients

Eligible for inclusion in the randomized controlled trial were patients between 18 – 75 years with an acute unilateral Achilles tendon rupture if surgery was performed within one week after the injury. The exclusion criteria to participate in the randomized trial was; current anticoagulation treatment (including high dose acetylsalicylic acid), known kidney failure, heart failure with pitting edema, thrombophlebitis, thromboembolic event during the previous three months, known malignancy, hemophilia, pregnancy, other surgery during the previous month, inability to follow instructions and planned follow-up at another hospital. All participants received oral and written information about the study procedure and provided written informed consent prior to surgery. Patients were randomized postoperatively using consecutively-numbered sealed envelopes opened after surgery. A non-stratified block

randomization was used assigning the patient to either direct postoperative early functional mobilization or immobilization and non-weight bearing.

To meet the purpose of this study, which was to assess loading and pedometer data, only patient cases randomized to early functional mobilization were included in the present study. An additional inclusion criterion was that the pair of insoles for force measurements needed to fit in the patient's own shoes. Two patients could not be included due to technical errors with the equipment. Between September 2016 and January 2018, a total of 34 patients meeting the inclusion criteria were consecutively included in this study. Written consent was collected from all patients at study inclusion.

Surgical procedure

A standardized surgical procedure was performed, using the modified Kessler suture technique, on an outpatient basis as described earlier. ¹⁰ The surgical procedures were performed by orthopedic surgeons from one university hospital.

Postoperative regime

The early functional mobilization was initiated directly postoperatively. An orthosis (VACO®ped, OPED Gmbh, Germany) with adjustable range of motion of the ankle was used. During the first two postoperative weeks, 15 to 30 degrees of plantar flexion was allowed with a rocker sole. At two weeks postoperatively, this was increased to 5 to 30 degrees of plantar flexion for the remaining four weeks. Full weight bearing with crutches and plantar flexion exercises were allowed directly after application of the orthosis. Non-weight bearing plantar flexion exercises without the orthosis was recommended to be performed daily for one hour during the first two weeks. The patients were informed to weight bear as

tolerated and that loading their injured leg directly in the orthosis was safe. For the remaining four weeks in the orthosis, patients could take the orthosis off when not walking and perform plantar flexion exercises several times per day.

Self-reported diary

At home, from the day after surgery, patients completed a self-reported diary on estimated daily weight bearing load, number of steps/day with a pedometer for the first two weeks and pain on a visual analogue scale (VAS) for the first week. Patients estimated their daily loading on a VAS scale, ranging from 0 (non-weight bearing) to 100 (full weight bearing without crutches). For analysis, the scale was converted to percent. The 2-week follow-up varied between days 10–16 postoperatively. Patients received a pedometer (Yamax SW 200/LS2000, Yamax Corporation, Japan) to register the number of steps/day. The pedometer was worn at the hip. The Yamax SW-200 has been used as a gold standard pedometer in earlier validation studies ²⁸ and has shown to hold good validity (r=0.80-0.90) in a healthy population. ^{4,18} Pain was registered on a VAS scale ranging from 0 (no pain) to 100 (worst imaginable pain) for the first week, both during rest and during activity.

Follow-up evaluations

Patient-reported outcome measures (PROM)

Tampa scale of Kinesiophobia (TSK-SV) ¹⁶ and Physical Activity Scale (PAS) ²⁵ were completed at two and six weeks postoperatively prior to the gait evaluation. TSK-SV is comprised of 17 items and evaluates fear of movement and pain on a 4-point Likert scale with scoring alternatives ranging from "strongly disagree" to "strongly agree." The scale ranges from 17 to 68, a total sum is calculated, and a high score indicates a high degree of kinesiophobia. Kinesiophobia has been defined as present when the value is more than 37 in

170 patients with low back pain. ¹⁶ PAS was used to evaluate the patient physical activity before 171 the injury and was completed at the 2-week follow-up. It is scored from 1 (no physical 172 activity) to 6 (heavy physical exercise several times/week). ²⁵ 173 174 Plantar force loading 175 A mobile force sensor, the Loadsol® insoles (Novel GmbH, Munich, Germany) was used for 176 measuring plantar force loading. The insoles were connected through Bluetooth to an iPod 177 touch device and were calibrated to body weight before use. The measurement was done with 178 the insoles in the patient's normal shoe on the healthy side and in the orthosis on the injured 179 side. The patients were instructed to walk in a flat corridor in the orthosis at a self-selected 180 speed for three minutes. Crutches were allowed if needed. The orthosis is provided with a 181 wedged sole externally, so make the insoles lie flat in the orthosis. 182 183 For plantar force measurements three patients were excluded due to technical errors and two 184 patients were measured only at one occasion. Pedometer assessment was missing from one 185 patient. For analysis of force data, the maximal force (peak force) in Newton, the average 186 peak force over three minutes walking in Newton, stance phase (single and double support) in 187 % of the total gait cycle and the cadence (step frequency) was recorded and used for analysis. 188 The insoles have been tested for validity and reliability in healthy during walking, running and hopping. 9 189 190 191 Patient characteristics in relation to outcome measures 192 In order to assess whether the outcome data (self-reported loading, pedometer data, TSK-SV, 193 PAS, plantar force loading) were correlated to patient characteristics (age, gender, BMI,

nicotine usage) these variables were analyzed statistically with correlation analyses. The

195 analyses demonstrated no significant correlations between patient characteristics and outcome 196 data (p>0.05). 197 198 **Statistics** 199 Data were processed in the Loadpad Analysis® software and Microsoft Excel. 200 Descriptive data were reported as mean, median, standard deviation and frequency. 201 Nonparametric statistics were used for ordinal data and for data that were not normally 202 distributed. Wilcoxon signed ranked test was used to compare differences between injured 203 and uninjured side and for differences between follow-up occasions. Spearman's rank 204 correlation was used to analyze relationship between patient-reported outcomes and gait 205 parameters as well as understanding the relationship between self-reported subjective load to 206 plantar force measurement. The Limb symmetry index (LSI) was used to compare differences 207 in loading between the two- and six-week follow-up. The LSI value was defined as the ratio 208 between the injured limb and the uninjured limb, expressed as a percentage (LSI, 209 injured/uninjured x100). All data were analyzed in SPSS (IBM SPSS, Version 25.0. Armonk, 210 NY, USA). The level of significance was p<0.05 for all analyses. 211 Results 212 213 **Patients** 214 In total, 34 patients who had sustained an acute Achilles tendon rupture were enrolled (Table 215 1). 216 217 218

220	Table 1	. Demograp	hic	data	n = 34
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Age (years) mean (SD)	38.8 (8.7)
Gender (M/F) n (%)	28/6 (82/18)
Height (cm) mean (SD)	177.7 (8.3)
Weight (kg) mean (SD)	81.0 (10.8)
BMI (kg/m²) mean (SD)	25.6 (2.7)
Nicotine (smoker/snuff/no) n (%)	0/8/26 (0/23/77)
Injured side (L/R) n (%)	17/17 (50/50)
PAS before injury median (range)	5 (2-6)

PAS= Physical Activity Scale, BMI= Body mass index

Pedometer data

Patients significantly increased the daily average number of steps taken between week one and two (p<0.001). The number of steps taken daily was, median (range), during week one 2025 (174 - 14687) and during week two 2753 (305 - 13085) (Figure 1).

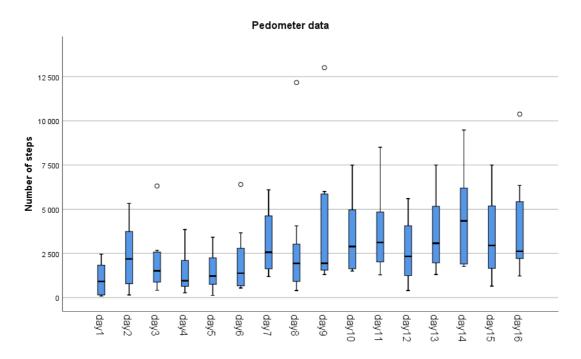


Figure 1. Boxplot of daily step counts during the first two weeks postoperatively

Self-reported loading

There was a significant increase in the average patient-reported loading between week one and two (p<0.001). The patient-reported loading was, median (min-max), during week one 20 (5-90) % and during week two 52.5 (20-100) % (Figure 2).

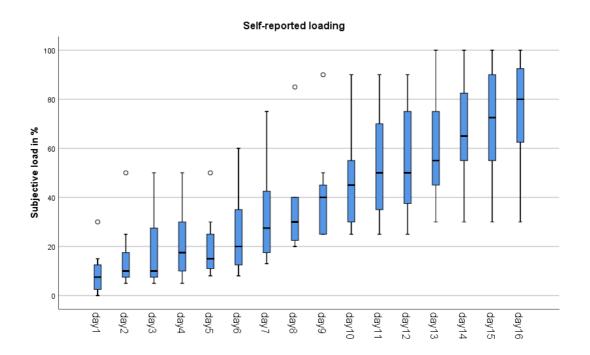


Figure 2. Boxplot of daily self-reported loading during the first two weeks.

Self-reported pain

Self-reported pain assessment, VAS 0-100, during both activity and at rest decreased significantly during the first postoperative week (p<0.001). Pain, mean (SD), was day one during activity 74 (21) and at rest 57 (24). Pain at day seven was during activity 27 (20) and at rest 15 (13) (Figures 3-4).

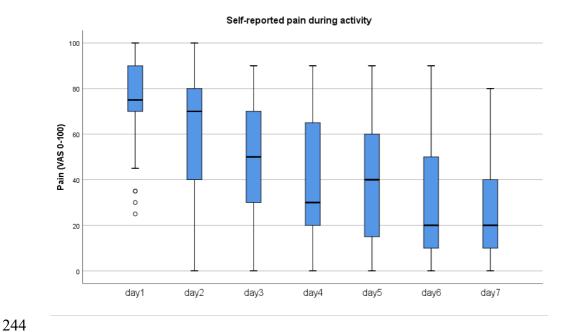


Figure 3. Boxplot of self-reported pain (VAS 0-100) during activity week one.

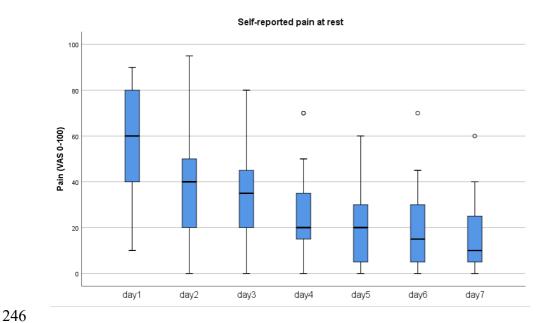


Figure 4. Boxplot of self-reported pain (VAS 0-100) at rest week one.

Patient-reported fear of movement did not change significantly between two, mean 35.5 (SD 7.0), and six weeks, mean 34.2 (SD 7.9). At two weeks 13/34 (38.2 %) reported a score >37,

which represents a high degree of fear of movement.

Patient-reported fear of movement

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Plantar force

There were, at both two and six weeks, significantly lower plantar force load and less stance time on the injured-compared to the uninjured limb (p<0.001) (Table 2). The limb symmetry index (LSI) of both maximum force and average peak force increased significantly from twoto six weeks (Table 2). In addition, the stance time was more symmetrical at six weeks and cadence was increased (Table 2).

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Table 2. Plantar force assessment with the Loadsol® insoles

	2 weeks (n=31)	6 weeks (n=32)
Max force, N		
injured, mean (SD)	705.5 (288.3)*	968.3 (226.3)*
uninjured, mean (SD)	1167.7 (251.7)*	1114.1 (329.0)*
LSI max force, % mean (SD)	62.8 (28.5) ^b	88.2 (11.8) ^b
Average peak force, N		
injured, mean (SD)	514.2 (285.0)*	858.6 (200.3)*
uninjured, mean (SD)	986.9 (159.0)*	989.4 (312.2)*
LSI average peak force, % mean (SD)	53.6 (31.5) ^b	88.2 (11.5) ^b
Stance time, %		
injured, mean (SD)	65.6 (9.7)*	68.2 (6.3)*
uninjured, mean (SD)	77.7 (5.4)*	74.7 (5.5)*
Cadence, steps/min		
mean (SD)	79.6 (14.6) ^b	94.9 (9.0) ^b

N=Newton, LSI= limb symmetry index (injured/uninjured*100)

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Correlations between patient-reported outcome and pedometer data

Patients reporting higher subjective loading were taking more steps per day during both the first- (rho=0.599, p<0.001) (Figure 5) and second postoperative week (rho=0.383, p=0.030). Patients with less pain during activity the first postoperative week reported a higher subjective load (rho=-0.354--0.483, p=0.043-0.004) and were taking more steps (rho=-0.366-0.453,

²⁶³ * significant side differences (P<0.001) 264

^b significant differences between test occasions (P<0.001)

p= 0.036-0.008). Patients experiencing more pain at rest the first two postoperative days reported lower subjective loading (rho= -0.374--0.418, p= 0.016-0.032).

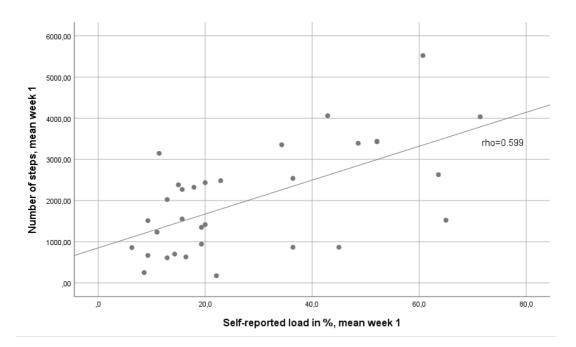


Figure 5. Correlation between self-reported loading and pedometer data week one.

Fear of movement was in these patients neither correlated to pedometer data, subjective loading data, pain, nor to force data (rho= -0.204-0.116, p=0.271-0.998).

Relationship between patient-reported subjective loading and force data

Patient self-reported loading was significantly associated to the force measurement, LSI average peak force, assessed at two weeks (rho= 0.719, p<0.001) (Figure 6). At 2-weeks self-reported loading on the injured leg was 52.5 (20 - 100) % and LSI average peak force was 53.6 (31.5) %.

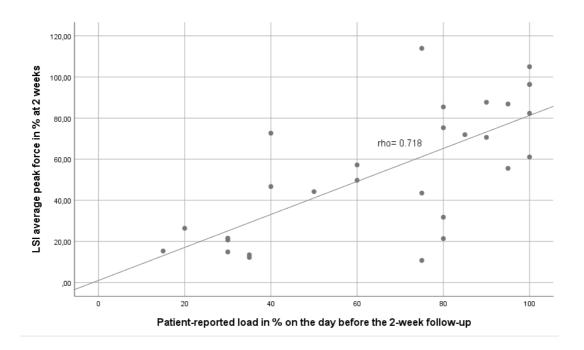


Figure 6. Relationship between self-reported and objectively measured load at the 2-week follow-up

Discussion

The results of this study demonstrate for the first time the combined objective and subjective data of the frequency, magnitude and pattern of loading after acute Achilles tendon rupture repair. During the two first postoperative weeks with functional mobilization ATR patients increase the number of steps and the loading of the injured limb up to around 50% of normal values. Between weeks two and six post-surgery, loading of the injured-compared to the intact leg increased from 50% up to around 90%. Contrary to our hypothesis, this loading pattern did not relate to the patient-reported fear of movement, but rather to the experience of pain.

The most important finding of this study was the demonstration of a high combined increase in loading frequency as well as loading magnitude up to two weeks post ATR surgery using functional mobilization. The observed increase in loading frequency up to the second

postoperative week, with around 2700 steps taken daily would seem to represent around 50% of the normal number of steps taken daily in an aged matched population (around 5400 steps).¹ The number of daily steps taken after ATR have been shown essential for the tendon healing process ²⁷ as well as for general health condition.¹

The minimum recommendation of daily number of steps in healthy adults is suggested to be 3000, 5 times a week, in line with the recommendation of 30 min moderate intensity walking per day. ^{17,30} There was a wide variation in number of steps per day but on a group level, patients in this study were almost able to reach the minimum health recommendations in terms of walking already at two weeks postoperatively. Thus, we can conclude that direct weight bearing post ATR surgery in a functional orthosis allows for early increased loading frequency.

The observation at two weeks post-surgery that the number of daily steps taken were 50% of normal was paralleled with the finding that patients loaded 50% on the injured compared to their intact limb. This observation would seem to reflect the finding that the recovery of loading frequency and the recovery of loading magnitude are correlated to each other. The loading magnitude, i.e. early tensional load, is crucial for improving the mechanical properties of the healing Achilles tendon.^{27,31} The optimal combination of loading magnitude and loading frequency for tendon healing and patient recovery, however, is unknown.

Earlier studies on early weight bearing protocols demonstrating earlier return to sporting activity, better subjective patient outcomes ¹⁹ and improved health-related quality of life ²⁹ have not provided detailed reports of loading both magnitude and frequency. Therefore, to optimize the postoperative regime of ATR we suggest that future studies provide data of both magnitude and frequency of loading, similarly as performed in this study.

The second main finding of this study was the significant increase in the magnitude of loading from the second up to the sixth postoperative week. Thus, the observed increased loading from 50% up to around 90% on the injured- compared to the intact leg may reflect vital tensional loading on the healing Achilles tendon, which is important for achieving improved patient-reported outcome. These specific data can also be used by health care personnel, who want to provide their ATR patients with information about weight bearing in an orthosis postoperatively.

The finding at two weeks, that the magnitude of loading was around 50% was supported not only from the self-reported loading assessment but also from the plantar force measurements, may have clinical implications. Thus, the observation of a significant relationship between the subjective and objective loading measurements suggests that the patient-reported assessments may be a good estimation of loading. Since objective measurement devices of loading parameters are rarely available in the clinic patient assessments may be used instead.

steps and reported higher load on their injured leg suggest that the patient's experience of pain is one of the determining factors for both loading frequency and loading magnitude.

Therefore, patient information and pain control post-surgery may be important factors in regulating loading- frequency and magnitude, and thereby possibly also patient-reported outcome.

The finding in our study showing that patients with less activity-related pain, walked more

Contrary to our hypothesis, step counts did not relate to patient fear of movement, but rather to pain. This finding would seem to be in contrast with the findings of Olsson et al ²¹, who

assessed fear of movement 12 weeks after ATR and found that fear of movement was correlated with physical activity, patient-reported symptoms, and general health. In the present study, however, there were no relationships between fear of movement and pain or loading parameters. A possible explanation for this discrepancy between studies are different time points of assessment. The perception and willingness to be active when out of the boot and returning to activity may not be relevant while still in the boot. Moreover, most patients in this study did not experience pain at two weeks postoperatively, which is one of the main factors in the pain-related fear of movement/injury survey.

There are some potential limitations in this study. Three-dimensional gait analysis is the golden standard to objectively assess forces during gait. Though, this method is expensive and not usually available for clinical use. Also, this method is not suitable when wearing an orthosis due to the difficulty of marker placement on bony landmarks. Different types of insoles have shown good reliability and validity in both healthy and patients ^{5,6,14} and wireless insoles may be a useful tool for evaluate forces during gait. Sandberg et al ²⁶ used an insole device to measure plantar flexion moments and found that patients after ATR repair was not activating the calf muscles during gait in an orthosis. ²⁶ A possible limitation in the present study is that the used measures of plantar load might not be directly translated into load on the Achilles tendon and further, we do not know if the patients loading activated the triceps surae muscles.

Another limitation is that the pedometer (Yamax SW-200) used, has been suggested to be less accurate at slower gait speeds ¹⁸, which may cause a possible underestimation of steps during the first week, as patients are not walking in their normal gait speed with crutches. In the study by Sandberg et al, ²⁶ they found that walking speed was reduced four weeks

postoperative after ATR repair but seemed to have normalized at seven weeks postoperatively. We did not assess gait speed, however at the six weeks follow-up, patients were walking more symmetrical and with a higher cadence than at two weeks.

Despite these potential limitations, this is the first study to quantify cumulative tendon load using a combination of laboratory and field-based tools. Since tendon healing and patient recovery is affected by magnitude and frequency of loading, the total amount of weight bearing steps during the early rehabilitation phase may account for the variation in recovery of the patients.

Clinical Relevance

Mobile plantar force sensors are a feasible technology to objectively quantify loading early after surgery in patients with Achilles tendon rupture. Reliable and practical methods to assess the actual loading during mobilization are of importance for future studies determining the effect of the rehabilitation protocols on outcome in this patient population. The patients' subjective assessment of weight bearing, however, seems as a practical and easy method for weight bearing estimation when more objective measurements are lacking.

Conclusions

This study demonstrated relatively high plantar forces in surgically treated ATR patients already at two weeks postoperatively when treated with early functional mobilization in a dynamic orthosis. There was a significant increase in plantar forces between two and six weeks, with the patients loading around 90% on the injured compared to the healthy side. Pain, rather than fear of movement, was associated with both loading frequency and magnitude.

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