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Weight-bearing recommendations after operative fracture treatment—fact or fiction? Gait results with and feasibility of a dynamic, continuous pedobarography insole

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Abstract

Purpose Rehabilitation after lower-extremity fractures is based on the physicians' recommendation for non-, partial-, or full weight-bearing. Clinical studies rely on this assumption, but continuous compliance or objective loading rates are unknown. The purpose of this study was to determine the compliance to weight-bearing recommendations by introducing a novel, pedobarography system continuously registering postoperative ground forces into ankle, tibial shaft and proximal femur fracture aftercare and test its feasibility for this purpose.

Methods In this prospective, observational study, a continuously measuring pedobarography insole was placed in the patients shoe during the immediate post-operative aftercare after ankle, tibial shaft and intertrochanteric femur fractures. Weight-bearing was ordered as per the institutional standard and controlled by physical therapy. The insole was retrieved after a maximum of six weeks (28 days [range 5–42 days]). Non-compliance was defined as a failure to maintain, or reach the ordered weight-bearing within 30%.

Results Overall 30 patients were included in the study. Fourteen (47%) of the patients were compliant to the weight-bearing recommendations. Within two weeks after surgery patients deviated from the recommendation by over 50%. Sex, age and weight did not influence the performance ($p > 0.05$). Ankle fracture patients (partial weight-bearing) showed a significantly increased deviation from the recommendation ($p = 0.01$).

Conclusions Our study results show that, despite physical therapy training, weight-bearing compliance to recommended limits was low. Adherence to the partial weight-bearing task was further decreased over time. Uncontrolled weight-bearing recommendations should thus be viewed with caution and carefully considered as fiction. The presented insole is feasible to determine weight bearing continuously, could immediately help define real-time patient behaviour and establish realistic, individual weight-bearing recommendations.

Keywords Weight-bearing · Compliance · Pedobarography · Gait analysis

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Introduction

Studies investigating the patient behaviour after operative and non-operative treatments of various lower extremity pathologies commonly recommend a weight-bearing level after the initial treatment [1]. These physician weight-bearing recommendations are a key component of controlling physical therapy with respect to fracture loading and activity in clinical and research settings [2, 3]. Generally prolonged non weight-bearing is associated with delayed healing and worse outcome after fractures, while excess of weight-bearing is associated with loss of reduction and slower healing [4, 5]. However, most of these studies do not control the actual weight-bearing achieved and thus rely exclusively on patient compliance. From short-term punctiform measurements it is known that patient compliance to weight-bearing restrictions is limited regardless of the training method used. Training relying on the knowledge of results technique is inaccurate with respect to short-term weight-bearing limits, but able to increase the

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retention effect of learned limits, while the concurrent feedback technique offers a good short-term learning effect, but the retention of the learned limits is low [6, 7]. The most commonly employed training method is simply using a household weight-scale. While this method is highly available it shows neither good short-term learning effects, nor a good retention of the learned limits [8]. Furthermore, these studies were performed as discontinuous compliance measures in part with healthy participants. No studies on continuous compliance over several weeks exist.

To measure the continuous compliance to weight-bearing protocols and allow real-time physical therapy influence on aftercare performance, a new gait analysis insole with continuous measuring capability over several weeks was developed in cooperation with Moticon (Moticon GmbH; Munich, Germany) and the AO Foundation (Arbeitsgemeinschaft Osteosynthesefragen, Davos, Switzerland). It measures the kinetic and temporospatial gait parameters of every step over a battery lifetime of up to four weeks without necessary external hardware. Real-time, wireless feedback to the physical therapist and patient can be given at any time.

The purpose of this study was to continuously determine the postoperative weight-bearing compliance to standard aftercare recommendations of patients with various lower extremity injuries with a new, objective measurement insole and determine its feasibility.

Methods

The study was designed as a prospective, observational study. Thirty consenting patients with operatively-treated ankle fractures type Weber B (plate and screw osteosynthesis), tibial shaft fractures (non angular stable intramedullary nail osteosynthesis) and intertrochanteric femur fractures (cephalomedullary nail osteosynthesis) were included and treated with our standard aftercare protocol (Table 1). Exclusion criteria were previously existing gait disorders, or impaired mobility before the fracture event, patients with multiple injuries, patients below the legal age of 18 and patients with shoe sizes outside the range of 36–45 (EU). For ankle fractures post-operative partial weight-bearing with a 20-kg weight limit was ordered for six weeks along with a controlled ankle motion boot, while for tibial shaft and intertrochanteric fractures immediate full weight-bearing with walking aids for comfort was ordered. All partial weight-bearing patients received at least five physical therapy instructed weight-bearing measurements with the standard weight-scale instruction technique during their inpatient stay and were instructed to control their weight-bearing with a bathroom scale and receive physical therapy at least twice weekly after discharge. The permissive full weight-bearing group received at least five physical therapy instructed training sessions on proper three and four point crutch walking as pain permits during their inpatient stay. Patients were followed up at three- and six-week intervals. During the aftercare phase an insole consisting of 13 capacitive pressure sensors, a 3D accelerometer and a temperature sensor was placed in the patients shoe on both sides (OpenGO, Moticon GmbH; Munich, Germany) (Fig. 1) [9]. Peak pressure, resulting forces, average daily gait time and average daily gait time outside the recommended limits were measured continuously and read out at the clinical follow-ups. Weight-bearing compliance was calculated as percent weight-bearing reached with the injured leg during the stance phase of gait. Compliance was defined as being within 30% of the ordered limit. Influences of sex, age and weight on weight-bearing compliance were determined as Pearson correlation coefficients. Compliance differences between the fracture types were compared as ANOVA with a Tukey post test. Parameters between the partial and permissive full weight-bearing group were compared with the Student's t-test. Statistical analysis was performed with Prism 6.0 (Graphpad Software Inc., La Jolla, CA, USA). $P < 0.05$ was defined as statistically significant. Informed consent was obtained from all individual participants included in the study. The study was approved by the local ethics committee.

Results

Overall 30 patients were included in the study. The average age was 61.2 years (range 18–92 years), 15 patients were female and

Table 1 Aftercare protocols for partial (ankle fracture) and full weight bearing (tibial shaft, intertrochanteric fractures)

Parameter	Partial weight-bearing group	Full weight-bearing group
Weight bearing recommendation	20 kg weight-bearing with CAM boot and crutches	Permissive full weight-bearing, crutches for comfort
Physical therapy as inpatient	Minimum of five sessions with weight-scale instruction technique	Minimum of five sessions teaching 3- and 4- point crutch-assisted walking as comfort permits
Physical therapy after discharge	Minimum of twice weekly, weight-scale instruction technique for six weeks	Minimum of twice weekly instruction of 3- and 4-point crutch-assisted walking as comfort permits

Fig. 1 OpenGO Insole (Moticon GmbH; Munich, Germany)

the average weight was 73.2 kg (range 56–95 kg). Twelve ankle fractures, six tibial shaft fractures and 12 intertrochanteric fractures were included. The patients wore the insoles for an average of 28 days immediately post-operative (range 5–42 days).

Within the study period 14 patients reached the recommended weight-bearing limit, giving a compliance rate of 47% (Table 2). Within two weeks after the surgical fracture, stabilization deviation from the trained weight-bearing limit was 52.5%. Sex ($r_p = -0.22$; $p = 0.24$), age ($r_p = -0.06$; $p = 0.75$) and weight ($r_p = 0.07$; $p = 0.73$) all showed no significant compliance difference. A significant compliance difference was seen between ankle fractures and tibial shaft fractures (mean difference 210.3%; $p = 0.03$) and between ankle and intertrochanteric fractures (mean difference 206.1%; $p = 0.01$) (Fig. 2). No cases of implant failure were observed. One delayed-union occurred in a patient with a tibial shaft fracture staying below the recommended full weight-bearing limit during the first 46 days of the aftercare process.

Grouping the patients as either partial or full weight-bearing showed that, for the partial weight-bearing group, compliance decreased over time, while for the full weight-bearing group compliance increased (Table 3). Overall there was a significant difference between the compliance (partial: 294.8% vs. full: 86.9%; $p < 0.0001$) and weight (partial: 80.2 kg vs. full: 68.9%; $p = 0.01$) between partial and full weight-bearing patients. Partial weight-bearing patients spent an average of 136.1 minutes daily during gait, permissive full weight-bearing patients 59.7 minutes.

Discussion

Despite the general scientific knowledge that healing is multifactorial, individual, gender-specific and based on parameters related to fracture pattern, fixation methods as well as mechanical loading and activity levels [10, 11], modern concepts of surgical stabilization and aftercare are based on traditional, highly standardized protocols. It is general orthopaedic practice to advise patients to adhere to certain weight-bearing protocols with the belief that the correct amount of fracture loading through gait will benefit healing, while over-, or under-loading could result in either non-union, or implant failure [12]. However, already teaching a patient a weight-bearing skill is known to be quite challenging [13]. Even newer techniques employing biofeedback that have shown a better learning effect are not sufficiently tested for a short, six-week aftercare process [14]. Especially the most commonly-used practice of controlling weight-bearing with a household scale is highly unreliable even in short-term measurements [8]. Further complicating the compliance issue is that long-term, truly continuous compliance measurements after lower extremity fractures simply do not exist. Yet we seem to gladly rely on prescribing weight-bearing limits that are most likely not maintained during our everyday clinical practice and, even worse, we rely on it for clinical studies without truly controlling it. As a result weight-bearing recommendations for even common fracture entities, such as ankle fractures, can vary drastically between treating physicians [15].

To determine the overall compliance to either full-, or partial weight-bearing regimes we focused our study on three common orthopaedic trauma entities with ankle, tibial shaft and intertrochanteric femur fractures [16]. The rate of compliance in our study, regardless of the fracture entity and weight-bearing limit, was low with just over 47%. Despite the low rate of compliance no implant failures and only one fracture-delayed union occurred in a patient with a tibial shaft fracture and low compliance. This indicates that despite our standard aftercare techniques patients could adjust their weight-bearing limits independently without endangering their healing result. Study protocols relying on patient compliance to maintain certain levels of weight-bearing thus should control their weight-bearing either continuously or repeatedly in rapid succession. Our results show that this is particularly important for partial weight-bearing regimes, as the compliance was lower during this task. Self-sufficient patient weight-bearing management regimes have thus been advocated for these fractures as long as the fracture/osteosynthesis construct is deemed biomechanically stable [17]. Successful application of this has been shown by Firoozabadi et al. who managed a subgroup of mainly B type, post-operatively stable ankle fracture patients with weight-bearing as tolerated without associated adverse

Table 2 Patient characteristics sorted by fracture type

Fracture type	Number of fractures	Avg. age in years (range)	Avg. weight (range)	Overall compliance (patients)
Ankle	12	52.7 (36–80)	80.2 kg (59–95)	3/12
Tibial shaft	6	40.2 (18–58)	72.5 kg (65–83)	3/6
Intertrochanteric	12	80.3 (65–93)	68 kg (55–92)	7/12

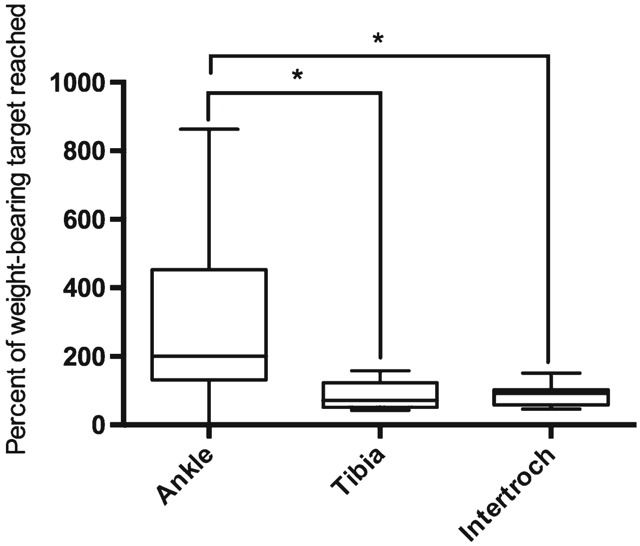

Fig. 2 Box plots show the deviation from the recommended weight-bearing limit (100%) for all three fracture types included in the study. *Boxes* show median, as well as 1st and 3rd quartiles, Tukey whiskers. *$p < 0.05$

consequences [18]. Completely unsupervised weight-bearing, however, bears the risk of secondary fracture dislocation due to extensive overloading of the fracture depending on its type [19]. As seen in our study the only healing complication occurred in a non-compliant tibial shaft fracture patient. Whether or not this can be attributed to non-compliance alone is questionable. The aim of this study was not to address the clinical effects of weight-bearing compliance, but rather to determine the accuracy of such recommendations trained with one of the most common instruction tools worldwide [20]. The delayed-union occurrence in a non-compliant patient does, however, show the weakness of studies investigating healing delays when not controlling for patient compliance continuously.

As shown with this study, to monitor weight-bearing for these purposes is feasible with the presented insole especially in elderly patients. This is of particular importance, as the benefit of early weight-bearing and overall activity after trauma in the elderly has already been shown [21]. In these patients the insole could be immediately used to monitor and increase fracture-loading rates, known to expedite rehabilitation [22], and limit the high costs of unsuccessful reintegration into the patients previous state of residence. In tibial fractures allowing and profiting from early full weight-bearing, the presented insole could be used to guide the patient in reaching the desired rates of fracture loading early on, as continuous fracture loading with the correct frequency has been shown to increase healing rates in tibial shaft fractures [23]. Furthermore, the insole could be used as a healing monitor as studies have shown a direct correlation between weight bearing in tibial fractures and fracture stiffness [24], as well as correlations between weight bearing and non-union development [25]. Associations between gait analysis and clinical improvements in the intermediate-term aftercare phase after tibial plateau fractures have also been described [26].

In our study, the partial weight-bearing skill resulted in the worst compliance, despite the relatively younger average age. Even though the mean weight in the partial weight-bearing group was significantly higher, no correlation between patient weight and compliance to weight-bearing could be seen. This worse compliance for the partial-weight bearing training has been previously shown in a study with patients after total hip arthroplasty and trochanteric osteotomy by Hurkmans et al. [27]. Lower weight-bearing target loads decreased compliance, especially in an older patient clientele. Furthermore, they were able to show that compliance decreased after hospital discharge in the home environment. This trend can be confirmed with our results as the compliance decreased after the first two weeks. This highlights the importance of new, continuously measuring gait analysis tools especially in patients that need controlled weight-bearing in highly unstable osteosynthetic constructs. Other studies have already tested the compliance of patients with different injuries around the foot in their home environment somewhat continuously, for example, Chiodo et al. placed a pressure sensitive film

Table 3 Group characteristics for partial and full weight-bearing

Characteristic	Partial weight-bearing	Permissive full weight-bearing
Number of patients	12	18
Sex		
Male	8	8
Female	4	10
Mean age (range)	52.7 years (22–80)	66.9 years (18–93)
Mean weight (range)	80.2 kg (59–95)*	68.9 kg (55–92)*
Mean overall compliance (range)	294.8% (0–862.5)*	86.9% (42.9–158)*
Number of compliant patients after 2 weeks	5/12	9/18
Number of compliant patients overall	3/12	10/18
Avg. daily activity min. (range)	136.1 (15.7–245.5)	59.7 (2–173)
Avg. daily activity in compliance min. (range)	15.7 (0–94)	58.9 (1.9–173)

The asterisks marks significantly different values in the cast of patients with different foot injuries for an average of 24 days [28]. They were able to show a 27.5% non-compliance rate to a non-weight bearing recommendation. However, they only placed a pressure sensitive film under the patients' heels potentially missing force data from the mid- and forefoot. Furthermore, while this technique can be applied for an extended period of time, is not time sensitive. At the readout it cannot be measured how often and at what time point a certain pressure has been exerted. Thus, the continuous measurement ability can be an advantage of the presented insole. As seen in our results the partial weight-bearing patients spent considerably more time during gait than permissive full weight-bearing patients did. This is owed in part due to the overall higher age of the permissive full weight-bearing group (intertrochanteric femur fractures) and thus lower activity and slower gait speed [29]. With the continuous monitoring function, it cannot only be determined by how much the weight-bearing recommendation is exceeded, but also how often and for how long. The full weight-bearing patients spent almost all of their time below the recommended full weight-bearing limit. This is understandable, as also during physiological gait only a small fraction of the gait cycle is spent at, or above the body weight. Interestingly, the partial weight-bearing patients spent a considerable time of over 10% above the recommended limit. This could be explained by the increased time spent during gait, giving them more time to exceed the lower recommendation. Clinical consequences were not seen. To account for this in future studies the introduced insole in our article has a live view, therapy mode, wherein the current and past load characteristics can be displayed to the physical therapist to ensure that individual loading limits are held. Real-time feedback to the patient concerning the current fracture load is possible through a mobile application. Especially through haptic feedback, this could improve patient compliance [30]. With the insole acting as a constant reminder of the current load situation (concurrent feedback) and weekly physical therapy during the early aftercare phase evaluating the load and patient performance (knowledge of results) the benefits of two proven aftercare principles could be continuously combined for the first time.

Limitations

The present study did not investigate detailed clinical effects of weight-bearing compliance. It is meant as a first attempt to continuously monitor compliance in a diverse patient clientele and determine the value and feasibility of this new aftercare tool in an everyday clinical setting. It did not focus on a single, homogeneous clinical problem, but rather on three common fractures and the overall patient weight-bearing behaviour after different operative treatments. The results are generally limited by our low sample size, explained by the use of limited quantities of prototype material. The Hawthorne effect may have influenced the study as participants were informed that their weight-bearing was monitored as part of the study consent. To limit the effects only the regular follow-up intervals also used in non-study patients were employed. Ultimately the patients' compliance in wearing the insole still remains unclear. Whether or not the insole was worn for all gait events outside the hospital is unclear. However, assuming that the weight-bearing compliance is the same with the insole worn or not, the results of the study would not be influenced by this. This compliance issue is seen in the high range of days, that the insole was worn by the patients, owing in part to patients returning their insoles early as they were released from the hospital to an outside clinic and one insole not recording past day five. These patients were still included in the study as at least five days of continuous, significant gait activity was provided. Although possible, this was merely an observational study, and feedback was not given to the patients, as that was not within our ethical approval at that time.

Conclusions

Compliance to standard aftercare weight-bearing recommendations is low. Uncontrolled weight-bearing recommendations should thus be viewed with great caution and carefully considered as fiction. New tools to continuously monitor and define aftercare weight-bearing limits are needed. The presented insole is feasible to determine continuous weight-bearing compliance to various lower extremity injuries during the postoperative aftercare phase for clinical and research purposes. With the insole two prominent concepts to increase post-operative compliance to weight bearing restrictions with concurrent feedback and knowledge of results could be continuously combined. Further interventional studies can now be performed to determine the therapeutic value of this aftercare tool and define new, realistic weight-bearing standards.

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Compliance with ethical standards

Conflict of interest The insole material for this study was provided by the AO Foundation TK System. Prof. Tim Pohlemann, senior author of this study, is chairman of the TK System of the AO Foundation.

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