

## Increased therapy demand and impending loss of previous residence status after proximal femur fractures can be determined by continuous gait analysis – A clinical feasibility study

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### ARTICLE INFO

#### Keywords:

Elderly  
Hip fractures  
Weight-bearing  
Aftercare

### ABSTRACT

Proximal femur fractures account for increased healthcare costs whenever patients are unable to return to their previous state of residence. Studies suggest that patients benefit from early weight-bearing, yet compliance to weight-bearing regimes is poorly investigated. Aim of the study was thus to show the clinical feasibility of a new measurement tool able to determine continuous weight-bearing behavior after intramedullary nail osteosynthesis of intertrochanteric femur fractures, assess the influence of weight-bearing on clinical outcome and determine rehabilitation demand based on early postoperative gait performance.

In an observational study, gait data of 22 patients with intertrochanteric femur fractures were evaluated. During the inpatient stay patients were continuously monitored with a gait analysis insole. Primary outcome was the amount of weight-bearing reached. Short-term functional outcome, as well as return to the previous state of living were evaluated in relation to weight-bearing and activity during the inpatient stay.

With the presented technique continuous gait data of all patients during postoperative mobilization could be obtained. Only 13 patients reached full weight-bearing. The technique was feasible to determine correlations between weight-bearing and outcome, as well as between gait activity and outcome. Significant gait differences between patients able to return to their previous state of living and those who could not were seen.

Dynamic insole measurements are feasible to continuously determine the postoperative gait performance. Their postoperative use showed, that the continuous compliance to permissive weight-bearing after intertrochanteric fractures is low. The presented measurement technique has the potential to identify patients at risk for reduced outcome and impending loss of previous residence status. Further studies will have to investigate the effects of technology assisted “patient at risk” identification and adapted therapy on clinical outcome.

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### Introduction

Hip fractures remain a significant burden of disease for patients worldwide and while incidence rates vary between studies and countries, there is a general trend towards a rise in age-adjusted hip fracture rates [1]. Statistically, more than three quarters of these hip fracture patients are female and over 90 percent are aged over 70 [2]. Given the current demographic development and projected increase of osteoporosis related fractures, a steadily increasing strain on our

health system has to be expected, apart from the high personal burden of disease [3–5]. These costs further increase whenever patients are unable to return to their previous residence due to impaired mobility [3–5]. To improve patients mobility is thus the key influential factor to reduce the high personal and socioeconomic burden of disease [3–5]. Studies suggest that patients benefit from early weight-bearing as this maintains muscle and bone mass and reduces adverse events associated with long immobilization [6]. Discontinuous gait analysis has already been used to describe the intermediate rehabilitation process during proximal femur fracture aftercare in 21 patients and shown that higher initial fracture loading rates are associated with faster rehabilitation [7]. Thus, modern fracture stabilization aims at the possibility of immediate full weight-bearing in elderly patients

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and, as a result of the known benefits of early mobilization, permissive full weight-bearing with walking aids for comfort after cephalomedullary nail osteosynthesis of intertrochanteric femur fractures is recommended at many institutions.

From short-term punctiform measurements it is known, that patient compliance to these weight-bearing recommendations is low regardless of the training method used [8]. This is true especially in an elderly population after lower extremity surgery and has been confirmed by newer continuous gait analysis tools [9]. Due to the scarcity of continuous monitoring tools, until now the true patient adherence to these weight-bearing recommendations has been poorly investigated and the true influence of continuous early weight-bearing behavior on rehabilitation outcome is still unclear. We hypothesize, that employing tools to continuously monitor the postoperative gait performance of patients is feasible in a clinical setting and can determine associations between patient behavior and outcome.

Aim of the current study was thus to provide a first clinical use analysis of a dynamic gait analysis insole and determine the feasibility of its use, as well as its value in determining the association between individual gait performance and outcome.

## Methods

A monocentric, prospective, observational study design was chosen. Inclusion criteria were all patients aged 65 or older with intertrochanteric femur fractures (AO/OTA Type 31-A1 – 31-A3) treated with cephalomedullary nail osteosynthesis between July and November 2016 (Gamma-3 Nail, Stryker GmbH & Co. KG, Duisburg, Germany; PFNA, DePuy Synthes GmbH, Umkirch, Germany). Exclusion criteria were impaired mobility or gait abnormalities before the fracture event, fracture non-union and patients with shoe sizes outside the range of 36–45 (EU). All participating patients, or their legal representatives, consented to the use of their clinical, radiographic and gait results for study purposes. The study was approved by the local ethics committee.

During their inpatient stay (average 11.5 days), all patients were continuously monitored with the OpenGo pedobarography insole (Moticon GmbH, Munich, Germany). The average daily gait and the maximum/average amount of weight-bearing reached were recorded. Full weight-bearing was defined as reaching 100 percent of the body weight on the injured extremity. Immediate postoperative permissive full weight-bearing with walking aids for comfort was allowed under physical therapy supervision. All patients received 30 minutes daily physical therapy instructed training sessions to weight-bear as pain permits during their inpatient stay. Exercises and help during physical therapy training sessions were not further specified and at the therapists discretion. Before discharge, a Mini-Cog dementia status was performed [10] and the preoperative patient mobility assessed with the Parker Mobility Score (PMS) [11]. Clinical controls were performed at 6 weeks and 3 months with the performance oriented mobility assessment (POMA) [12]. Normal distribution was tested with the D'Agostino & Pearson normality test. A correlation analysis between clinical and early gait outcome was performed as Pearsons *r*. Comparative statistics were performed with the Mann Whitney U Test after testing for normal distribution. All statistical tests were performed with Graph Pad Prism 6.0 (GraphPad Software Inc., La Jolla, USA).

## Results

### General patient data

In total 22 patients were included into the study, 16 female, 6 male. The average patient age was 81.6 years (range 65–98 years),

average height 161.1 cm (range 156–186 cm) and average weight 66.9 kg (range 40–93 kg). The average patient discharge to rehabilitation was after 11.5 days (range 5–16 days). The insole was tolerated well by all patients. Analyzable gait data could be obtained on 187 of 253 days representing 74 percent of the entire patient stay. The insole was handled by a study nurse and required no further handling of the staff on the ward. The standard aftercare procedures at our department were not affected by the insole use.

Of the 22 patients, only 13 reached full weight-bearing during their inpatient stay, with a mean maximum weight-bearing reached of 124.7% body weight (range 0–363%) (Fig. 1). With the insole it was possible to determine a moderate correlation between maximum weight-bearing reached ( $r = 0.45$ ,  $p = 0.0363$ ) (Fig. 2a), average weight-bearing ( $r = 0.49$ ,  $p = 0.0211$ ) (Fig. 2b) and activity ( $r = 0.52$ ,  $p = 0.0123$ ) (Fig. 2c) and clinical outcome at the final follow up. No significant correlations between average daily gait activity and age, PMS, or Mini-Cog were seen (Age:  $r = -0.41$ ,  $p = 0.0562$ ; PMS:  $r = 0.27$ ,  $p = 0.2224$ ; Mini-Cog:  $r = 0.29$ ,  $p = 0.1982$ ).

Of the 22 patients analyzed, 15 were able to return to their previous state of living by the 3 month follow up. When dividing the patients into “returners” and “non-returners” the insole was able to determine differences in average weight-bearing during the inpatient stay ( $13.2 \pm 7.7$  vs.  $5.5 \pm 2.7$ ,  $p = 0.007$ ) (Fig. 3a). Maximum weight-bearing ( $143.4 \pm 72.5$  vs.  $84.4 \pm 47.2$ ,  $p = 0.054$ ), and average daily activity ( $52.6 \pm 49.7$  vs.  $33.2 \pm 24.9$ ,  $p = 0.353$ ) showed no significant differences (Fig. 3b, c).

## Discussion

The current study shows a first use scenario of a continuously measuring dynamic gait insole in a clinical setting. It was feasible to determine postoperative weight-bearing and gait based associations to patient outcome in a standard clinical setting.

As the cephalomedullary nail is generally deemed a stable implant, large-scale studies have employed the aftercare concept of permissive full weight-bearing [13]. However, the true continuous compliance to such weight-bearing recommendations is unknown and discontinuous studies suggest that compliance rates are low, especially in elderly patients [14]. Yet, patients benefit from early weight-bearing as it reduces adverse events [6]. With an average postoperative hospital length of stay of 11.5 days in our study, in line with current European literature [15], the main effort of early rehabilitation has to be ensured by the hospital physical therapy staff. In that respect dynamic, continuous monitoring tools can help to determine the true postoperative patient performance that could otherwise only be grossly assessed [9].

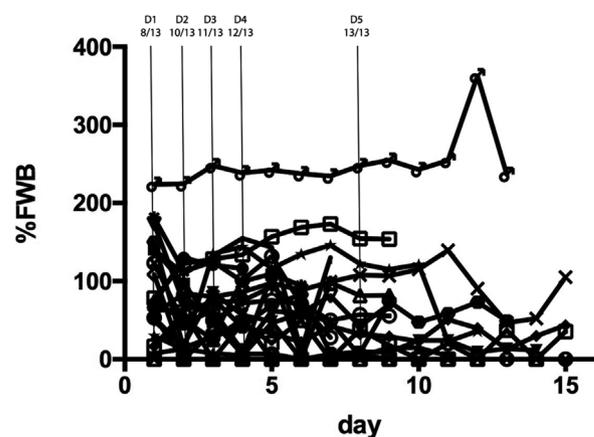
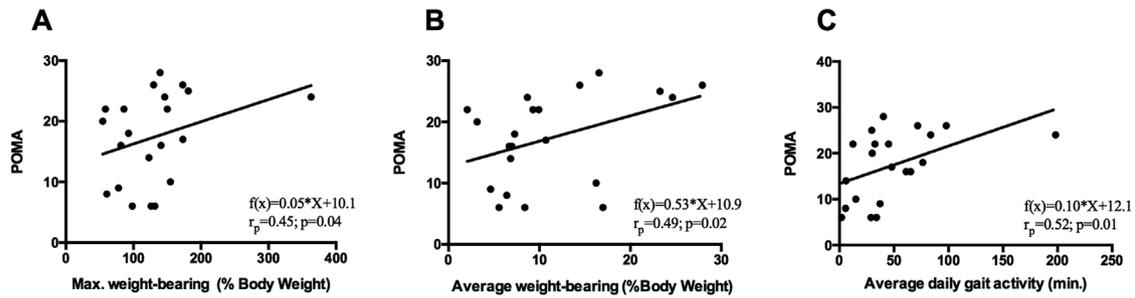
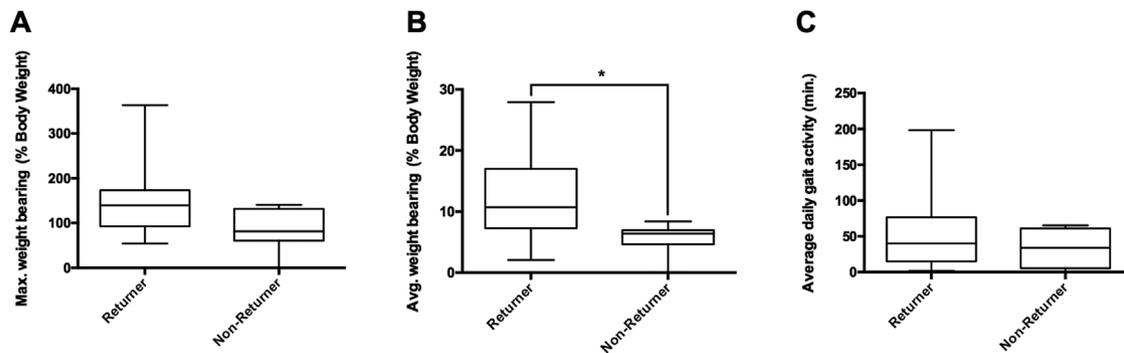


Fig. 1. Per patient daily maximum weight-bearing distribution.



**Fig. 2.** Correlation and linear regression between the POMA Score at the 3 month follow-up and (a) maximum weight-bearing reached during in patient stay, (b) average weight-bearing reached and (c) daily gait activity.



**Fig. 3.** Box Plot of (a) maximum weight-bearing reached during in patient stay, (b) average weight-bearing reached and (c) daily gait activity for patients who would return to their previous state of residence (returner), or not return (non-returner). Boxes show mean, as well as 1<sup>st</sup> and 3<sup>rd</sup> quartile. Whiskers show min. to max. values. \* $<0.05$ .

The presented measurement tool was easily included into our clinical workflow, without additional work required by the nursing, physical therapy, or surgical staff. With this tool, the majority of in hospital gait events could be recorded. The days with missing gait data are most likely due to failed mobilization and activity, however could potentially be a compliance issue resulting from not wearing the insole. Based on the available data, we were able to show that only 60% of the patients reached full weight-bearing during the in patient stay. This further emphasizes that the common clinical and research assumption that patients adhere to permissive full weight-bearing limits might be flawed and stresses the importance of early, continuous monitoring. This has already been suggested by a discontinuous study after intertrochanteric fractures treated with screw osteosynthesis where patients only reached loads of around 60% despite a permissive full weight-bearing aftercare regime [16].

To know the true, continuous gait performance is thus of great importance for general treatment, as well as clinical studies. Discontinuous gait analysis studies have already shown correlations between weight-bearing and outcome in lower extremity fractures [17]. Our results show that the average weight-bearing, as well as the amount of daily gait activity are correlated to the clinical outcome as measured by the POMA score. Higher average weight-bearing and more time spent during gait was associated with improved outcome. This confirms the results of Bakker et al. who were able to show a similar correlation between gait (steps, walking bouts and loading rates) and the POMA outcome score over a period of up to 20 weeks [7], further suggesting the clinical validity of the presented measurement tool. The potential advantage of the continuous gait analysis in our study is that we were able to detect the gait changes during the in-patient stay, allowing for an early adaptation of physical therapy and orthogeriatric treatment [18].

Apart from the personal burden of disease, this fracture is also associated with increased societal costs for the treatment itself, but also whenever a patient is unable to return to their previous living conditions [5,19]. Patients that would not return to their previous state of living in our study showed a significant decrease in average weight-bearing. Also maximum weight-bearing and activity were decreased, albeit statistically not significant. By already identifying individuals at risk during the postoperative inpatient stay, these *low performers* could receive early, targeted orthogeriatric aftercare known to increase rehabilitation success and reduce hospital length of stay [15]. A recent Cochrane review has identified several training methods aimed at increasing patient mobility in an ambulatory setting [4]. During this aftercare, the presented insole could furthermore be used to continuously determine the patients rehabilitation effort and tailor the aftercare to the specific deficits. Even if the insole is just used during the immediate, in-patient aftercare phase patients at risk could be determined early.

#### Limitations

This study had a number of limitations. First, the number of patients in the study was limited, in part due to the restricted availability of prototype insole material. However studies investigating rehabilitation success in a similar timeframe and patient clientele have reported similar participant numbers [7,20,21]. Additionally, two different surgical implants were used for our study. As the available, current literature shows no significant clinical differences between different nail systems this was not further analyzed [22,23]. Furthermore, the gait observation time for the patients differed between participants as a function of their discharge. However we felt that this is the most clinically applicable timepoint to analyze the postoperative performance of patients, giving patients with initial mobility impairment, or

postoperative pain time to adapt and for the future it would provide a thoroughly long base for aftercare recommendations. The follow-up time was short with only 3 months, the socioeconomically relevant endpoint with return to home, however, was already meaningfully different at that time. Ultimately, the patients' compliance in wearing the insole remains unclear. The physical therapy and hospital nursing staff were instructed to check the correct insole placement whenever a patient was mobilized. Regular physical therapy as per our institutional standard was performed. Exercises and helps were at the therapists discretion and not controlled as part of this study.

## Conclusion

Postoperative monitoring of gait performance with the presented technique is not only clinically feasible, but provides the opportunity to determine the actual activity and weight-bearing behavior during aftercare. Based on this feasibility study and pending further analysis, dynamic gait measurements could potentially identify patients at risk for a suboptimal clinical outcome and could trigger specific physical therapy. Further randomized, controlled studies are needed to determine the effect of gait-analysis-based aftercare on the clinical outcome in high-risk patients.

## Conflict of Interest Statement

The research material for this study was provided by the TK System of the AO Foundation. Prof. Tim Pohlemann was Chairman of the TK System of the AO Foundation. Tim Pohlemann and Benedikt Braun served as unpaid advisors to the Moticon GmbH. The study was registered and approved by the local ethics committee (Nr. 249/14).

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