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A novel tool for continuous fracture aftercare – Clinical feasibility and first results of a new telemetric gait analysis insole

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ABSTRACT

Weight bearing after lower extremity fractures still remains a highly controversial issue. Even in ankle fractures, the most common lower extremity injury no standard aftercare protocol has been established. Average non weight bearing times range from 0 to 7 weeks, with standardised, radiological healing controls at fixed time intervals. Recent literature calls for patient-adapted aftercare protocols based on individual fracture and load scenarios. We show the clinical feasibility and first results of a new, insole embedded gait analysis tool for continuous monitoring of gait, load and activity.

Ten patients were monitored with a new, independent gait analysis insole for up to 3 months postoperatively. Strict 20 kg partial weight bearing was ordered for 6 weeks. Overall activity, load spectrum, ground reaction forces, clinical scoring and general health data were recorded and correlated. Statistical analysis with power analysis, *t*-test and Spearman correlation was performed.

Only one patient completely adhered to the set weight bearing limit. Average time in minutes over the limit was 374 min. Based on the parameters load, activity, gait time over 20 kg weight bearing and maximum ground reaction force high and low performers were defined after 3 weeks. Significant difference in time to painless full weight bearing between high and low performers was shown. Correlation analysis revealed a significant correlation between weight bearing and clinical scoring as well as pain (American Orthopaedic Foot and Ankle Society (AOFAS) Score $r_s = 0.74$; Olerud–Molander Score $r_s = 0.93$; VAS pain $r_s = -0.95$).

Early, continuous gait analysis is able to define aftercare performers with significant differences in time to full painless weight bearing where clinical or radiographic controls could not. Patient compliance to standardised weight bearing limits and protocols is low. Highly individual rehabilitation patterns were seen in all patients. Aftercare protocols should be adjusted to real-time patient conditions, rather than fixed intervals and limits. With a real-time measuring device high performers could be identified and influenced towards optimal healing conditions early, while low performers are recognised and missing healing influences could be corrected according to patient condition.

Introduction

Recent estimations show that 100,000 fractures in the United States go on to become a non-union every year [1]. The lower extremity non-union rate is stagnating at up to 10% [2,3]. Standard aftercare procedures in trauma surgery however have not changed in principle and have been based on radiographic controls since its introduction [4]. Especially in ankle fractures, the most common lower extremity fracture, clear aftercare standards have not been established [5]. A recent survey has shown that non weight bearing times after ankle fractures are still not agreed upon by orthopaedic surgeons [6]. These times range from 0 [7] to an average of 7 weeks [6]. Weight bearing limits based on standardised controls and X-ray are furthermore limited by the restricted correlation of radiographs and fracture stiffness [8,9]. The current review literature thus calls for new patient centred weight bearing recommendations and individualised aftercare protocols [5].

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To define new aftercare recommendations conventional clinical and radiographic controls are unfeasible due to their limited inter- and intraobserver reliability [10] and overall weak biomechanical correlation [8,9]. To incorporate individual biomechanical and activity boundary conditions into the aftercare process few specialised research tools to investigate fracture healing locally have been introduced [11,12]. These are however limited to certain fracture entities, invasive and restricted by their experimental character and necessary in-patient visits. To recruit larger patient numbers gait is a useful tool to monitor fracture healing [13]. Several studies have shown a preliminary correlation of gait and healing at several fixed time points after lower extremity fractures [14,15]. Bone healing however is a continuous process and influenced in real-time by the surrounding biomechanical environment [16]. To detect the influence of weight bearing on fracture healing early continuous measurements of the biomechanical influences are needed. Together with the AO Foundation and Moticon GmbH we developed a new tool to measure gait, load and activity continuously and independently for over 4 weeks after lower extremity fractures.

The aim of the current study was to use this new tool in a first clinical trial testing its ability to monitor healing over the course of up to 3 months, define a preliminary aftercare performance grading and investigate the effect of early patient performance on healing.

Patients and methods

Patients

A prospective, controlled study design was chosen. Ten consecutively consenting patients with ankle fractures (Weber B type; no syndesmotic rupture) were included into the study. Exclusion criteria were impaired mobility, or gait abnormalities before the fracture event, patients with multiple injuries, patients below the age of 18 and patients with shoe sizes outside the range of 37–46 (EU). All patients were treated with our standard aftercare protocol: Immediate postoperative weight bearing with a 20 kg limit for 6 weeks in a controlled ankle motion boot was allowed. After 6 weeks physical therapy supervised increase to full weight bearing as tolerated was ordered. All patients received a minimum of 5 physical therapy instructed weight bearing measurements and were instructed to control their weight bearing at least weekly on a bathroom scale during the first 6 weeks. Radiographic controls were performed at 6 weeks and 3 months. Clinical controls and patient questioning were performed at 3, 6 weeks and 3 months with the EQ5D, VAS (visual analogue scale) pain, American Orthopaedic Foot and Ankle Society (AOFAS) and Olerud–Molander score. The patients' activity, gait and load characteristics were recorded with the OpenGo insole (Moticon GmbH, Munich, Germany) for up to 3 months. The study was approved by the local ethics committee.

Gait analysis sensor

All patients were monitored for 3 months after surgery with the OpenGo insole (Moticon GmbH, Munich). The insole incorporates 13 capacitive pressure sensors, a 3D accelerometer and a temperature sensor, measuring peak pressures, pressure distribution, acceleration, motion sequences, gait patterns and temperature. It operates completely wireless. Data is stored on a flash drive. The insole can be placed in any shoe and shoes can be changed at random during the study due to an automated zeroing system (Fig. 1).

Fig. 1. Standard right OpenGo insole (Moticon GmbH, Munich). Artificial leather cover. 13 capacitive pressure sensors, accelerometer and thermometer. (a) View from above. (b) View from below. The round opening for a regular 3,7V Li-ion battery can be seen (red arrow). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

Defining high and low performers

Based on the load integral (kg/h), activity (minutes), maximum load (kg) and gait time over 20 kg (minutes) patients were defined into either high performers or low performers at 3 weeks post surgery (Fig. 2a and b). Low performers were defined as performing below 40% in 3 or more of the four categories, the rest was deemed a high performer.

Data analysis

The gait data was analyzed with the Beaker software (build 01.01.14; Moticon GmbH, Munich, Germany). Mean and standard deviation of the time to full painless weight bearing and VAS pain was compared between previously defined high and low performers with the unpaired Student's *t*-test. Correlation between the different clinical scoring systems and the total weight bearing ability was calculated as Spearman's *r*. All statistical tests above were performed with Graph Pad Prism 5.0 (GraphPad Software Inc., La Jolla, USA). A priori power analysis was performed with G*power [17]. Based on our previous clinical results a difference of 10 days for time to painless full weight bearing between groups was presumed. Effect size was set at $d = 2.5$, α error probability at 0.05 and power above 0.9. This revealed a necessary patient number of 8 with a power of 0.93. $P < 0.05$ was defined as statistically significant.

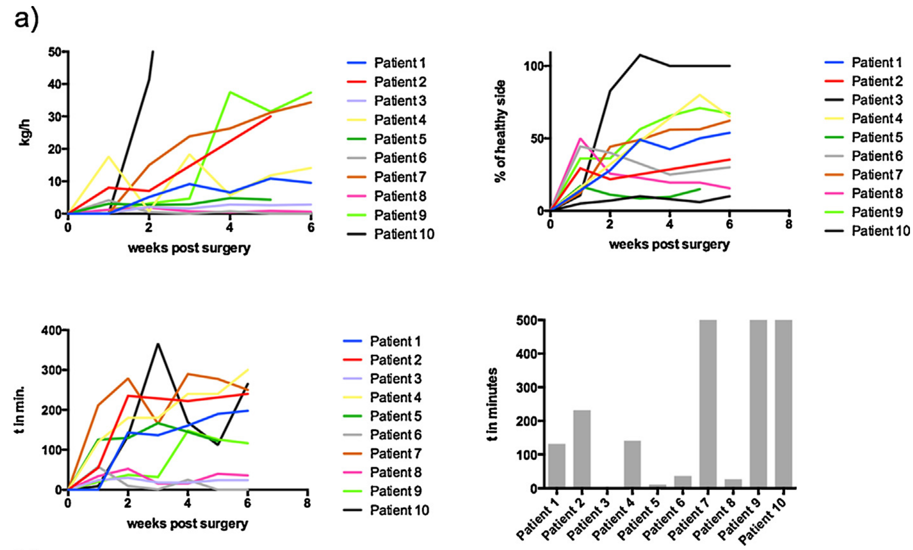
Results

General health data

The average patient age was 53.3 years. Three fractures were on the right side and seven on the left. All patients had no previously reported gait disorder or any systemic disease interfering with fracture healing. The longest continuously recorded insole data without external measures was 4 weeks and 5 days.

High and low performers

In all 6 patients were high and 4 low performers. No significant difference was seen between both groups in age (high vs. low performers; 56.7 ± 3.4 vs. 48.3 ± 12.3; $p = 0.16$), weight (78.8 ± 13.2 vs. 79.5 ± 12.1; $p = 0.94$) and height (171.0 ± 11.5 vs. 169.0 ± 5.3;



b)

Patient 1: Above average integral, force, activity, events = high performer
Patient 2: Above average integral, force, activity, events = high performer
Patient 3: Below average integral, force, activity, events = low performer
Patient 4: Above average integral, force, activity, events = high performer
Patient 5: Below average integral, force, events; high activity = low performer
Patient 6: Below average integral, activity; average events, force = low performer
Patient 7: Above average integral, force, activity, events = high performer
Patient 8: Below average integral, activity; average events, force = low performer
Patient 9: Above average integral, force, activity, events = high performer
Patient 10: Above average integral, force, activity, events = high performer

Fig. 2. (a) Gait analysis of each patient during the first 6 weeks. Top left: Average ground reaction force integral (kg/h). Top right: Highest weekly weight bearing amount for every patient in percent of the healthy contralateral side. Bottom left: Overall gait activity with the injured foot in minutes per week. Bottom right: Ground reaction force over the 20 kg weight bearing limit in minutes over 6 weeks. (b) Definition of patient aftercare performance levels.

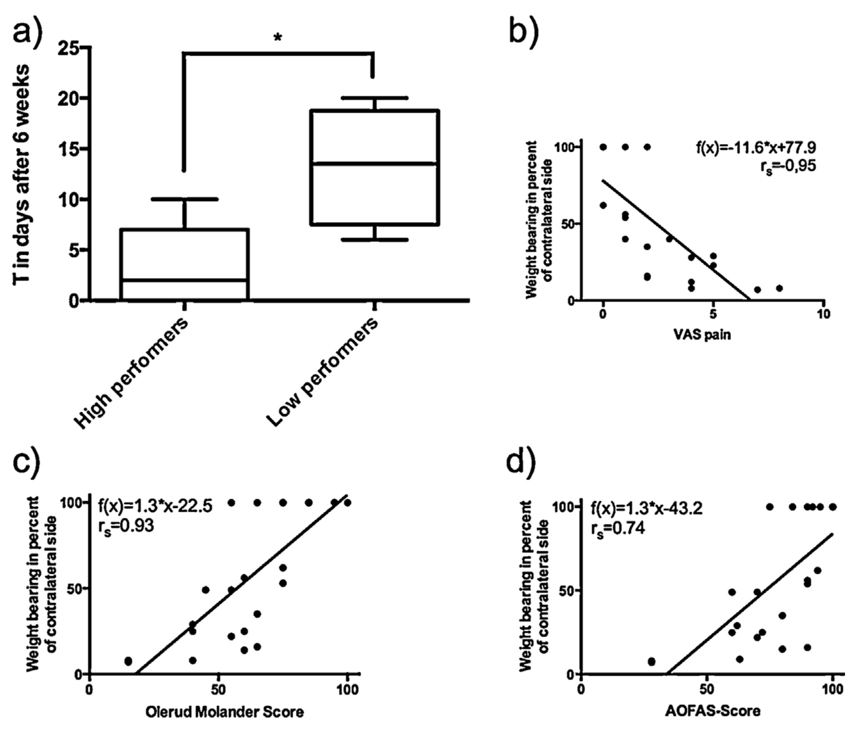


Fig. 3. (a) Box Plot of time to full painless weight bearing in days after 6 weeks for high and low performers. High performers: 3.3 ± 4.1; low performers: 13.3 ± 5.9, $p = 0.01$. Boxes show mean, as well as 1st and 3rd quartile. Whiskers show min. to max. values. *<0.05. (b) Correlation between the VAS pain score and ability to bear weight over 3 months. $r_s = 0.95$; $p = 0.001$. (c) Correlation between the Olerud–Molander Score and ability to bear weight over 3 months. $r_s = 0.93$; $p = 0.004$. (d) Correlation between the AOFAS Score and ability to bear weight over 3 months. $r_s = 0.74$; $p = 0.003$.

$p = 0.76$). At the time of definition no significant difference between VAS pain (3.2 ± 1.9 vs. 4.7 ± 1.7; $p = 0.22$) and clinical scoring between high and low performers (Olerud–Molander Score: 46.7 ± 8.8 vs. 37.5 ± 16.6; $p = 0.28$; AOFAS Score: 67.0 ± 11.9 vs. 55.3 ± 18.6; $p = 0.25$) was seen.

Correlations and time to full weight bearing

The previously defined high performers reached time to full weight bearing after 6 weeks significantly earlier than the low performers (3.3 ± 4.1 vs. 13.3 ± 5.9; $p = 0.01$) (Fig. 3a). Strong correlation was seen between VAS pain and weight bearing ($r_s = -0.95$; $p = 0.001$), between the Olerud–Molander Score and weight bearing ($r_s = 0.93$; $p = 0.004$) and between the AOFAS Score and weight bearing at 3 months ($r_s = 0.74$; $p = 0.003$) (Fig. 3b–d). All patients ultimately reached full weight bearing by week 9. At three months no significant difference between high and low performers in pain level (0.2 ± 0.4 vs. 0.5 ± 1.0; $p = 0.48$) and clinical scoring (Olerud–Molander Score: 89.0 ± 10.0 vs. 80.0 ± 5.0; p= 0.15; AOFAS Score: 93.7 ± 8.0 vs. 85.3 ± 4.7; p = 0.23) was seen. Radiographic controls showed no secondary dislocation, no implant loosening and no visible fracture line in all fibula cortices at 3 months. All patients reached age appropriate normal EQ5D satisfaction values at the 3 months follow up, no statistical difference between high and low performers was seen (0.94 ± 0.1 vs. 0.84 ± 0.2; $p = 0.17$).

Discussion

The socioeconomic impact of delayed fracture union is high [18]. As the most common type of lower extremity injury [19] and with a rising incidence, especially in the elderly [20] ankle fractures contribute substantially to the increasing medical costs. High total surgical [21] and direct aftercare costs are reported [22] and add to the even higher indirect treatment costs. Review of literature suggests that these costs could be reduced by earlier active mobilisation aftercare protocols [5]. A standard for aftercare however does not exist and new studies investigating the amount of beneficial weight bearing are needed [6].

With the current study we introduce the first gait analysis insole for continuous fracture aftercare with an independent running time of over 4 weeks. Without interfering with our traditional aftercare protocol patients were monitored for up to 3 months after surgery until painless full weight bearing was reached. Based on different key characteristics of gait and load spectrum aftercare performers for ankle fractures were defined for the first time. Despite the low sample size a significant difference in time to full weight bearing was predicted as soon as 3 weeks after surgery between high and low performers.

Full weight bearing after lower extremity fractures has been identified as a predictor of biomechanical fracture stability and thus healing [15]. Several studies have shown an association between gait and severity of fracture, and proven the predictive effect of gait on fracture healing [14,23]. All these conventional gait analysis tools have the disadvantage of detecting the healing event fairly late, in part due to their discontinuous measuring and low resolution [13]. The high resolution and continuous sensing capability of the insole system was able to detect statistically relevant performance levels already 3 weeks after surgery. Initially the difference in performance at 3 weeks was not defined by pain or clinical scoring since no significant difference was shown at this time point. During the continued course of healing a clear negative correlation between pain and weight bearing was seen. This shows that low performers have higher pain levels and thus continued low performance. With the standard aftercare protocol these patients would have been detected earliest at the 6 week clinical or radiographic follow up, where physical therapy controlled increase in weight bearing would have been recommended.

All patients ultimately reached full painless weight bearing. The previously defined low performers took more time to reach painless, unassisted full weight bearing and thus slower return to normal activity. However, at 3 months patients' quality of life and clinical outcome as shown by the EQ5D and clinical scoring were not significantly different between high and low performers. This shows another advantage of the insoles continuous measuring capability. With regular clinical controls and X-ray at standard intervals performance groups could not have been defined and differences would probably not have been noticed.

The earlier prediction of the healing course could be used during physical therapy aftercare to identify low performers and increase their activity and load according to their abilities and condition early on. Current physical therapy weight bearing control is based on different techniques, the most prominent being knowledge of results, concurrent feedback and the standard bathroom scale technique [24]. All of these however have a poor long term retention and patient general compliance to fixed weight bearing protocols is low [25]. This is confirmed by our results showing that patients performed well above the set weight bearing limits. The amount of over performance during the early course of fracture healing was however associated with better results and obviously no adverse consequences. This shows the need for individualised aftercare protocols based on patient constitution rather than fixed protocols. With the current tool the individual performance after lower extremity fractures can be reliably monitored. The postoperative treatment could be adjusted through a real-time feedback capability to increase performance of low performers before painful delays in weight bearing increase occur.

Limitations

Ankle fracture aftercare is controversially handled and few articles about immediate full weight bearing without adverse consequences already exist [7]. Ankle fractures were chosen since sufficient patient numbers with standardised fracture entities can be recruited and adverse consequences of low compliance to weight bearing recommendations are not to be expected [5,7]. They are however limited by missing specific radiographic scores for bone healing and generally have good healing outcomes. In our series all patients healed well and no secondary dislocations were seen. The difference between high and low performers was purely clinical and temporary during the early course of healing. However this served as a proof of concept, that meaningful differences between patients can be observed early in the healing course, where standard clinical, radiological and score based aftercare would not be able to detect any differences. Further studies are needed with fracture entities that allow radiographic correlation of gait parameters and bone healing, i.e. tibia fractures through the RUST score [26], to define the general early predictive effect of gait analysis on long term healing or non union development also in other lower extremity fractures. Despite sufficient power to show statistical significance the overall patient number was low due to the use of limited quantities of prototype testing material.

Conclusion

The insole is clinically feasible to measure gait differences during the extended aftercare of lower extremity fractures. Different, patient specific and highly individual rehabilitation gait characteristics were observed. Despite the low sample size and individual gait profiles we were able to define aftercare performance groups and detect meaningful differences in ankle fracture patients through early continuous gait analysis. Continuous measurements of patient gait and load characteristics could be used to increase activity and load spectrum according to the individual patient constitution. New classification systems based on patient constitution and performance level could help to detect delayed healing early and could be used to influence healing courses positively.

Conflict of interest

The insole material for this study was provided by the AO Foundation. Prof. Tim Pohlemann is chairman of the AO TK System of the AO Foundation. There is no further commercial relationship that may lead to a conflict of interest.

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