

Characteristic changes of the stance-phase plantar pressure curve when walking uphill and downhill - implications for long-term monitoring of gait patterns via insoles for smart healthcare

Christian Wolff, Patrick Steinheimer, Elke Warmerdam, Tim Dahmen, Philipp Slusallek, Christian Schlinkmann, Fei Chen, Marcel Orth, Tim Pohlemann, Bergita Ganse

Submitted to: Journal of Medical Internet Research
on: January 24, 2023

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript..... 5

Supplementary Files..... 21

 Figures 22

 Figure 1..... 23

 Figure 2..... 24

 Figure 3..... 25

 Multimedia Appendixes 26

 Multimedia Appendix 0..... 27

 TOC/Feature image for homepages 28

 TOC/Feature image for homepage 0..... 29

Characteristic changes of the stance-phase plantar pressure curve when walking uphill and downhill – implications for long-term monitoring of gait patterns via insoles for smart healthcare

Christian Wolff¹ MSc; Patrick Steinheimer² MSc; Elke Warmerdam³ MSc, PhD; Tim Dahmen¹ MSc, PhD; Philipp Slusallek¹ MSc, PhD; Christian Schlinkmann¹ MSc; Fei Chen¹ MSc; Marcel Orth² MD, PhD; Tim Pohlemann² MD, PhD; Bergita Ganse^{3,2} MD, PhD

¹German Research Center for Artificial Intelligence (DFKI) Saarbrücken DE

²Department of Trauma, Hand and Reconstructive Surgery Departments and Institutes of Surgery Saarland University Homburg DE

³Chair of Innovative Implant Development (Fracture Healing) Departments and Institutes of Surgery Saarland University Homburg/Saar DE

Corresponding Author:

Bergita Ganse MD, PhD

Chair of Innovative Implant Development (Fracture Healing)

Departments and Institutes of Surgery

Saarland University

Kirrberger Str. 1

Building 57

Homburg/Saar

DE

Abstract

Background: Monitoring of gait patterns via insoles is popular to study behavior and activity in the daily life of people and throughout the rehabilitation process of patients. Live data analyses may improve personalized prevention and treatment regimen, as well as rehabilitation. The M-shaped plantar pressure curve during the stance phase is mainly defined by the loading and unloading slope, two maxima, one minimum, as well as the force during defined periods. When monitoring gait continuously, walking uphill or downhill could affect this curve in characteristic ways.

Objective: For walking on a slope, typical changes in the stance phase curve measured by insoles were hypothesized.

Methods: Forty healthy participants of both sexes were fitted with individually calibrated insoles with 16 pressure sensors each and a recording frequency of 100 Hz. Participants walked on a treadmill at 4 km/h for one minute in each of the following slopes: -20, -15, -10, -5, 0, 5, 10, 15 and 20 %. Raw data were exported for analyses. A custom-developed data platform was used for data processing and parameter calculation.

Results: An ANOVA analysis with the gait parameters as dependent and slope as independent variables revealed significant changes for the following parameters of the stance phase curve: the mean force during loading and unloading, the two maxima and the minimum, as well as the loading and unloading slope (all $P < .001$).

Conclusions: Results indicate that a simultaneous increase in loading slope, the first maximum and the mean loading force combined with a decrease in the mean unloading force, the second maximum, and the unloading slope indicates downhill walking. The opposite indicates uphill walking. The minimum has its peak at horizontal walking and values drop when walking uphill and downhill alike. It is therefore not a suitable parameter to distinguish between uphill and downhill walking. While patient-related factors, such as anthropometrics, injury or disease shape the stance phase curve on a longer-term scale, walking on slopes leads to temporary and characteristic short-term changes in the curve trajectory. Clinical Trial: The study is registered in the German Clinical Trials Register (DRKS-ID: DRKS00025108)

(JMIR Preprints 24/01/2023:44948)

DOI: <https://doi.org/10.2196/preprints.44948>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

Please make my preprint PDF available to anyone at any time (recommended).

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

✓ **No, I do not wish to publish my submitted manuscript as a preprint.**

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain v

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <http://www.jmir.org/preprint/44948>

Original Manuscript

Original Paper

Characteristic changes of the stance-phase plantar pressure curve when walking uphill and downhill – implications for long-term monitoring of gait patterns via insoles for smart healthcare

Abstract

Background: Monitoring of gait patterns by insoles is popular to study behavior and activity in the daily life of people and throughout the rehabilitation process of patients. Live data analyses may improve personalized prevention and treatment regimen, as well as rehabilitation. The M-shaped plantar pressure curve during the stance phase is mainly defined by the loading and unloading slope, two maxima, one minimum, as well as the force during defined periods. When monitoring gait continuously, walking uphill or downhill could affect this curve in characteristic ways.

Objectives: For walking on a slope, typical changes in the stance phase curve measured by insoles were hypothesized.

Methods: Forty healthy participants of both sexes were fitted with individually calibrated insoles with 16 pressure sensors each and a recording frequency of 100 Hz. Participants walked on a treadmill at 4 km/h for one minute in each of the following slopes: -20, -15, -10, -5, 0, 5, 10, 15, and 20 %. Raw data were exported for analyses. A custom-developed data platform was used for data processing and parameter calculation, including step detection, data transformation, and normalization for time by natural cubic spline interpolation and force (proportion of body weight). To identify the time-axis positions of the desired maxima and minimum among the available extremum candidates in each step, a gaussian filter was applied ($\text{Sigma} = 3$, kernel size 7). Inconclusive extremum candidates were further processed by screening for time plausibility, max/min-pool filtering, and monotony. Several parameters that describe the curve trajectory were computed for each step. Normal distribution of data was tested by the Kolmogorov-Smirnov and Shapiro-Wilk tests.

Results: Data were normally distributed. An ANOVA analysis with the gait parameters as dependent and slope as independent variables revealed significant changes related to the slope for the following parameters of the stance phase curve: the mean force during loading and unloading, the two maxima and the minimum, as well as the loading and unloading slope (all $P < .001$). A simultaneous increase in loading slope, the first maximum and the mean loading force combined with a decrease in the mean unloading force, the second maximum, and the unloading slope is characteristic for downhill walking. The opposite represents uphill walking. The minimum had its peak at horizontal walking and values dropped when walking uphill and downhill alike. It is therefore not a suitable parameter to distinguish between uphill and downhill walking.

Conclusions: While patient-related factors, such as anthropometrics, injury or disease shape the stance phase curve on a longer-term scale, walking on slopes leads to temporary and characteristic short-term changes in the curve trajectory.

Trial Registration: The study is registered in the German Clinical Trials Register (DRKS-ID: DRKS00025108)

Keywords: movement analysis; ground reaction forces; wearables; slope; gait analysis; rehabilitation; postoperative treatment; sensors; personalized medicine; digital health;

pedography; baropedography

Introduction

Long-term monitoring of gait patterns and plantar-pressure distributions via insoles are increasingly popular ways to study behavior and activity in the field and in the everyday life of people and patients, including healing, personalized prevention, and treatment or disease progression [1-3]. In recent years, the usability of instrumented insoles for gait analyses has increased. A number of technical issues could be resolved, including calibration, hysteresis and drift, durability, usability, limited energy supply and battery life, data storage capacity, and the restriction to low sample frequencies associated with higher error rates, i.e., when force peaks are missed [3-5]. The usability of instrumented insoles is currently still limited by difficulties in data analysis. Advanced algorithms and tools are needed and currently developed to be able to draw meaningful conclusions from such insole gait data [6,7]. When analyzing long-term field data and developing smart healthcare innovations, automated data annotation is desirable to determine and quantify the activities a person has conducted. Ideally, the activity type can be determined algorithmically from the plantar pressure data alone.

Characteristic gait changes have been reported for walking on slopes, such as changes in the contribution of the ankle joint to leg work [8]. In addition, uphill walking on a treadmill increases hip and knee flexion angles during the stance phase, as well as the forward tilt of the thorax [9]. Furthermore, a decrease in dorsiflexion was observed during downhill walking at initial contact, in midstance and during the second half of the swing phase [9]. During uphill walking with increasing inclination, more positive joint work was identified for the ankle and hip joint, while negative joint work increased during downhill walking [10]. Older individuals were shown to have a disproportionate recruitment of hip muscles and smaller increases in activity of the medial gastrocnemius muscle with steeper uphill slopes than younger adults, resulting in difficulty to walk on steep slopes [11].

The M-shaped curve of ground reaction forces or plantar pressure during the stance phase is mainly defined by the loading and unloading slope, two maxima, one minimum, as well as the force during defined periods [12]. When monitoring gait continuously via insoles, walking uphill or downhill in a slope could affect the gait cycle curve in characteristic ways. If these typical changes were known, one could correct for such confounders when analyzing insole data. We hypothesized that walking on a slope generates typical changes in the plantar pressure stance phase curve that vary between uphill and downhill walking.

Methods

The study is part of the project Smart Implants 2.0 – Weight-bearing and Gait Observation for Early Monitoring of Fracture Healing and Individualized Therapy after Trauma, funded by the Werner Siemens Foundation. It was registered in the German Clinical Trials Register (DRKS-ID: DRKS00025108). Ethical approval was obtained from the IRB of Saarland Medical Board (Ärztekammer des Saarlandes, Germany, application number 30/21).

Data collection

Inclusion criteria were the ability to walk on a treadmill, and age 18 years and older. Exclusion criteria were age under 18 years, use of walking aids, inability to give consent, pregnancy, immobility, and previous injury of the lower legs or pelvis. The aim was to collect data from healthy volunteers.

The healthy participants of both sexes (none of them identified as diverse) were fitted with individually calibrated OpenGO insoles (Moticon GmbH, Munich, Germany) with 16 pressure sensors in each insole to be used in regular running shoes. Calibration to the individual body weight was conducted using the Moticon OpenGO app by letting the participants walk and shift their body weight in a standardized way. The insole size was selected to fit the individual participant's shoe size. Measurements were conducted with a recording frequency of 100 Hz in the record mode of the device. Raw data were exported for analyses. The participants walked on a treadmill at 4 km/h (Mercury, HP Cosmos, Nussdorf-Traunstein, Germany) for one minute while insole data were collected with three-minute breaks for recovery. Recordings were obtained for slopes of -20, -15, -10, -5, 0, 5, 10, 15, and 20 %. The participants were asked to walk for one minute straight, and recording was only commenced when the walking was already in progress to avoid bias by including altered steps upon gait initiation.

Data processing

The pressure readings of the force sensors in the insole device yield a weighted sum as a total vertical ground reaction force reading. To compute the force, every summand is weighted by its sensor area and a respective scaling factor accounting for the sensor's surrounding area, as well as gaps between sensors that depend on the insole size. This process is conducted by the Moticon software as an automated processing step before file export. Insole data were exported as described previously [13,14]. A custom-developed data platform was then used for further processing and parameter calculation, in which step detection was conducted as follows. The stance phases were identified and extracted from the time series data by considering any activity with consecutive force readings above 30 N. A tolerance of up to three missing values was implemented to account for possible recording issues. Any activity with a duration of less than 300ms or more than 2000 ms was discarded. Both the force and time axes were normalized. Force readings were transformed from Newton to proportion of body weight of the respective participant. Of note, as plantar pressure was measured instead of weight, due to acceleration, values regularly exceeded the body weight for peak load bearing instances. Normalizing the time axis was more complex, as the lack of a fixed cadence resulted in varying step lengths and thus differing numbers of true measurement points for each step. Therefore, a natural cubic spline interpolation was conducted on the original raw data. Based on the resulting curve for each stance phase, 100 equidistant samples were taken, resulting in an interpolated force measurement point for every 1% of overall stance phase length. This approach accounted for the lower recording frequency and higher sensor noise inherent to the insoles when compared with other gait measuring devices, such as sensor-equipped treadmills or force plates. Parameters that describe the trajectory of the stance phase curve are usually based on or derived from the characteristic local extrema, i.e., the first and second force peak and the local minimum in-between force peaks. These maxima and the minimum are used as parameters themselves to describe the curve trajectory [13]. Sensor jitter may lead to the existence of multiple ambiguous candidates for the named extrema. As a solution to this, a gaussian filter was applied to the original raw data in a repetition of the normalization process. The applied filtering strategy (Sigma = 3, kernel size 7) was chosen to prioritize elimination of extrema ambiguity at the expense of signal precision. This can result in overcorrection in areas with a higher signal volatility, mostly at the start and end of the stance phase. Hence, to avoid loss of high-frequency detail, the filtered and normalized curve was not used for parameter analysis, but only to determine unambiguous time-axis positions (indices) for the extremum candidates. These indices were then re-applied to the non-filtered, normalized data to identify the corresponding plantar pressure measurement closest to the original raw data. In case the use of the filtered data still led to inconclusive extremum candidates, the following additional

detection strategies were applied in the named order: 1. Time plausibility: Extremum candidates occurring within the first or last 10 indices (first/last 10 % of overall time span) were eliminated, 2. Max/Min-pool filtering: Should multiple extremum candidates occur within a pool size of 5 indices (equals to 5 % of overall time span), the candidate with the highest/lowest force value was chosen. 3. Monotony-check: In case of multiple remaining extremum candidates, candidates where the curve did not display a strict monotonous decrease or increase in both directions within 5 indices each were eliminated. 4. Monotony grace: In case the monotony check had eliminated too many candidates (less than 2 maximum candidates or less than 1 minimum candidate remaining), the eliminated candidates were re-instated in descending order of their highest achieved monotony distance until the target number of candidates was reached.

After applying these strategies, every stance activity that remained with an irregular amount of unambiguous extremum candidates was removed from the dataset. In total, 585 load bearing events were excluded as not fitting the strict parameter definitions.

Parameters

For each participant, across the minute of walking all stance phase curves were extracted. The parameters illustrated in Figure 1 were calculated for each stance phase and used to analyze changes in the trajectory of the stance phase curve. To do so, data from both feet were pooled. The curve is mainly described by two maxima and a minimum in between the maxima, Fz2 (the first maximum), Fz3 (the minimum) and Fz4 (the second maximum). The mean force over the entire stance phase is referred to as $F_{\text{mean}_{\text{stance}}}$. The mean force between the start of loading-phase and Fz2 is $F_{\text{mean}_{\text{load}}}$. The mean force between Fz2 and Fz4 is $F_{\text{mean}_{\text{mid}}}$. The mean force between Fz4 and the end of the unloading-phase is $F_{\text{mean}_{\text{unload}}}$. All these parameters have the unit percent body weight. In addition, the loading and unloading slope have the units percent body weight or percent stance phase duration. The loading slope was computed as the slope of the line defined by the start of the loading phase and the first force reading equal or higher than 80% of Fz2. The unloading slope was calculated as the slope of the line defined by the first force reading in the unloading phase below 80% of Fz4 and the end of the stance phase event.

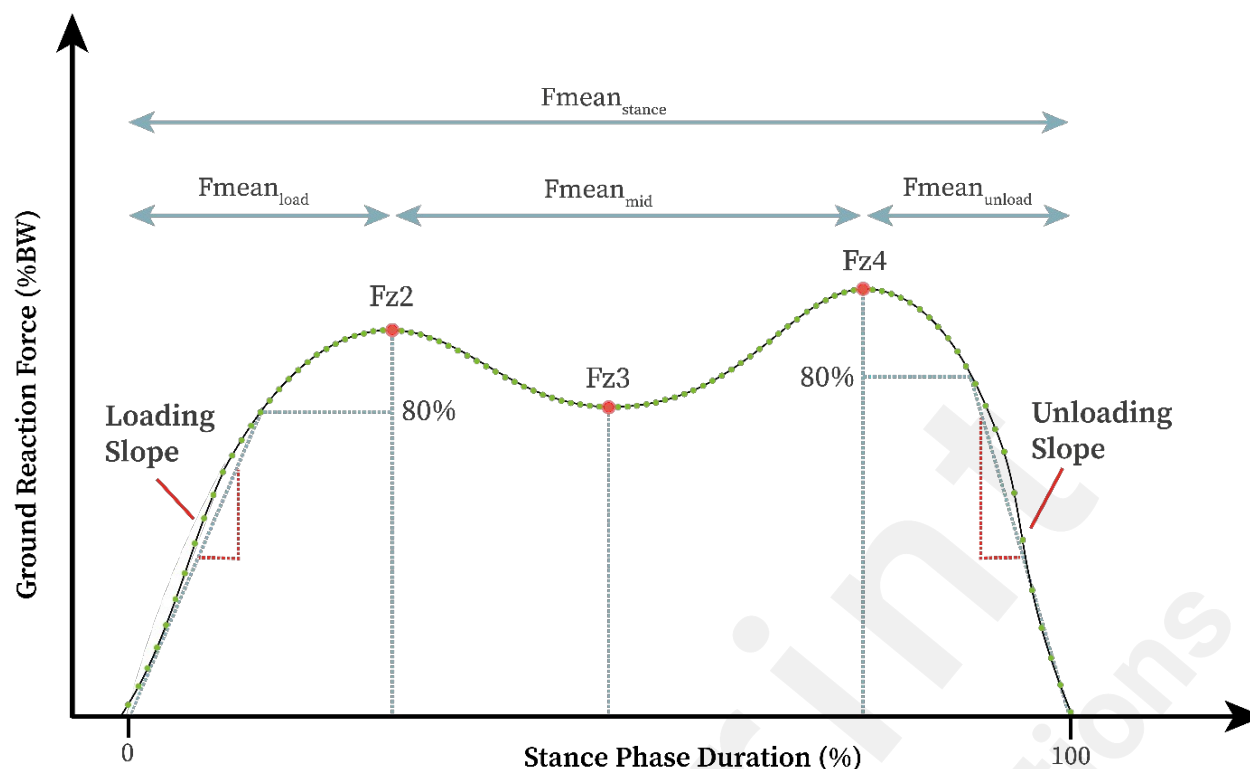


Figure 1. Depiction of the analyzed parameters of the stance phase

Statistical analyses

Statistical tests were executed with IBM SPSS Statistics version 29 (IBM SPSS Statistics, Armonk, NY, United States). Significance was defined as $P < .05$. The normal distribution of data was tested by the Kolmogorov-Smirnov and Shapiro-Wilk tests. A linear regression analysis of variance (ANOVA) was conducted for each of the gait parameters as the dependent variable, with the slope (-20 to 20 %) as independent variable. Mean values and standard deviations (SD) are reported. Linear regression slopes are reported for comparability and to allow for correction, even though for some of the parameters other, but differing regression types yielded higher R^2 values. The sample size of 40 was an estimate based on what is common in the field, and taking into account the aim to measure a very diverse group of volunteers. An a-priori sample size calculation was not conducted due to lack of comparable data.

Results

Measurements were taken from 40 healthy participants (19 women and 21 men) with an average age of 43.90 ± 17.30 years (range 18 to 87). Participant characteristics are summarized in Table 1. Data were successfully recorded for all of the participants and slope levels, resulting in a complete data set (Multimedia Appendix 1).

Table 1: Participant characteristics.

	Total	Women	Men
N	40	19	21
Mean age \pm SD [years]	43.90 ± 17.30	$39.05 \pm$	$48.29 \pm$

		14.65	18.64
Mean height \pm SD [cm]	174.43 \pm 11.24	165.79 \pm 6.05	182.24 \pm 8.85
Mean weight \pm SD [kg]	80.40 \pm 26.85	66.22 \pm 16.15	93.24 \pm 28.40
Mean BMI \pm SD [kg/m ²]	23.04 \pm 6.83	20.15 \pm 5.06	25.65 \pm 7.28

Data were normally distributed. Figure 2 visualizes the differences between the analyzed slope values on the stance phase curve. Figure 3 shows the normalized changes in the analyzed parameters with the slope of the treadmill. The ANOVA analysis revealed significant changes with the slope for $F_{\text{mean}_{\text{load}}}$, $F_{\text{mean}_{\text{unload}}}$, $Fz2$, $Fz3$, $Fz4$, loading and unloading slope (all $P < .001$). There was no significant correlation of the slope with $F_{\text{mean}_{\text{stance}}}$ ($P = .980$) and $F_{\text{mean}_{\text{mid}}}$ ($P = .125$). Other than the other parameters with significant changes related to slope, $Fz3$ had its peak at horizontal walking and values dropped when walking uphill and downhill alike. Thus, a simultaneous and short-term increase in loading slope and $F_{\text{mean}_{\text{load}}}$ combined with a decrease in $F_{\text{mean}_{\text{unload}}}$, $Fz2$, $Fz4$ and the unloading slope indicates downhill walking, while the opposite indicates uphill walking. $Fz3$ is not a suitable parameter to distinguish between uphill and downhill walking, as its value decreases both when walking uphill as well as downhill. Mean values and the SD of the analyzed parameters for each treadmill slope level in absolute values are displayed in Table 2. Table 3 indicates the linear regression slopes and R^2 -values for each of the curves shown in Figure 3.

Discussion

Principal results

The present study identified characteristic changes when walking with an uphill or downhill slope in insole plantar pressure data of healthy participants. The most pronounced changes with treadmill slope were found in the loading slope of the curve. A typical combination of changes in several parameters was reported that defines uphill and downhill walking and may be used for annotation and correction when analysing such data. These changes in the trajectory of the force curve with different surface slopes relative to the force vector of Earth's gravity are related to changes in plantar load distribution. When walking downhill, the first maximum was found to be higher compared to when walking uphill, which is caused by the more pronounced force transfer through the heel of the foot, followed by a lower second maximum due to the even lower surface at push off.

While patient-related factors, such as curve characteristics related to body size, muscle power, degenerative disease etc., would remain constant throughout an insole measurement, fatigue-related changes [15] may increasingly appear and then stay toward the later stages of a recording of a walking bout. Also, age, body height, body weight, body mass index and handgrip strength were shown to cause characteristic changes in the plantar pressure force curve, that would usually only change on a long-term scale [16]. In contrast, as shown in the present data set, walking on slopes leads to temporary and characteristic changes in specific properties of the stance-phase curve. Changes over time in the identified parameters should thus be considered and correctly interpreted when studying long-term field gait data collected via insoles. To analyse the healing process, i.e., after an injury, slow changes in parameters would be expected and a trend towards what is considered normal over several weeks [17]. Short-term changes over minutes or hours would thus not be explainable by the healing progress and should have a different cause. In addition, asymmetry between the legs should slowly decrease throughout healing [18]. When walking on a slope, asymmetry could also be affected, if the

injury causes increasing problems such as pain when walking uphill or downhill. It is also recommendable to identify the characteristics of walking with walking aids, such as crutches, to be able to classify the nature of the observed changes and the treatment stage better.

Limitations

Effects of walking speed were not analysed in the present study, even though it is known that lower extremity joint loading is affected by varying step length and cadence during graded uphill and downhill walking [19]. These parameters, however, do not seem to be necessary to successfully annotate gait data obtained by insoles. For participant or patient convenience, it would be desirable if insoles did not need to be combined with further devices or wearables. The present data suggest that at least the identification of walking on slopes does not require further sensors. It is also known that kinematic, kinetic and electromyographic parameters differ between treadmill walking and overground gait, while spatiotemporal, kinematic, kinetic, electromyographic and energy consumption outcome measures are largely comparable [20]. Another limitation of the study is that the parameters analysed here can only be used when a regular gait curve is present. If this is not the case, other methods need to be applied, i.e., machine-learning for step detection and segmentation or the analysis of further parameters, possibly slopes and averages, or differences between individual sensors [21]. Differences between the 16 sensors embedded in each insole were not analysed in the present study and could be assessed in the future, e.g., to distinguish between ground types (gravel, sand etc.). Another limitation is that the present characteristic changes that were assessed in healthy participants may differ for patients with gait disorders, depending on their disease or injury type. It will therefore be important to collect longitudinal data on different slopes from patients with defined diseases and injuries throughout the healing process or throughout different disease stages. These studies would serve to identify if the reported findings are valid also for patients, and for which patient groups this is true.

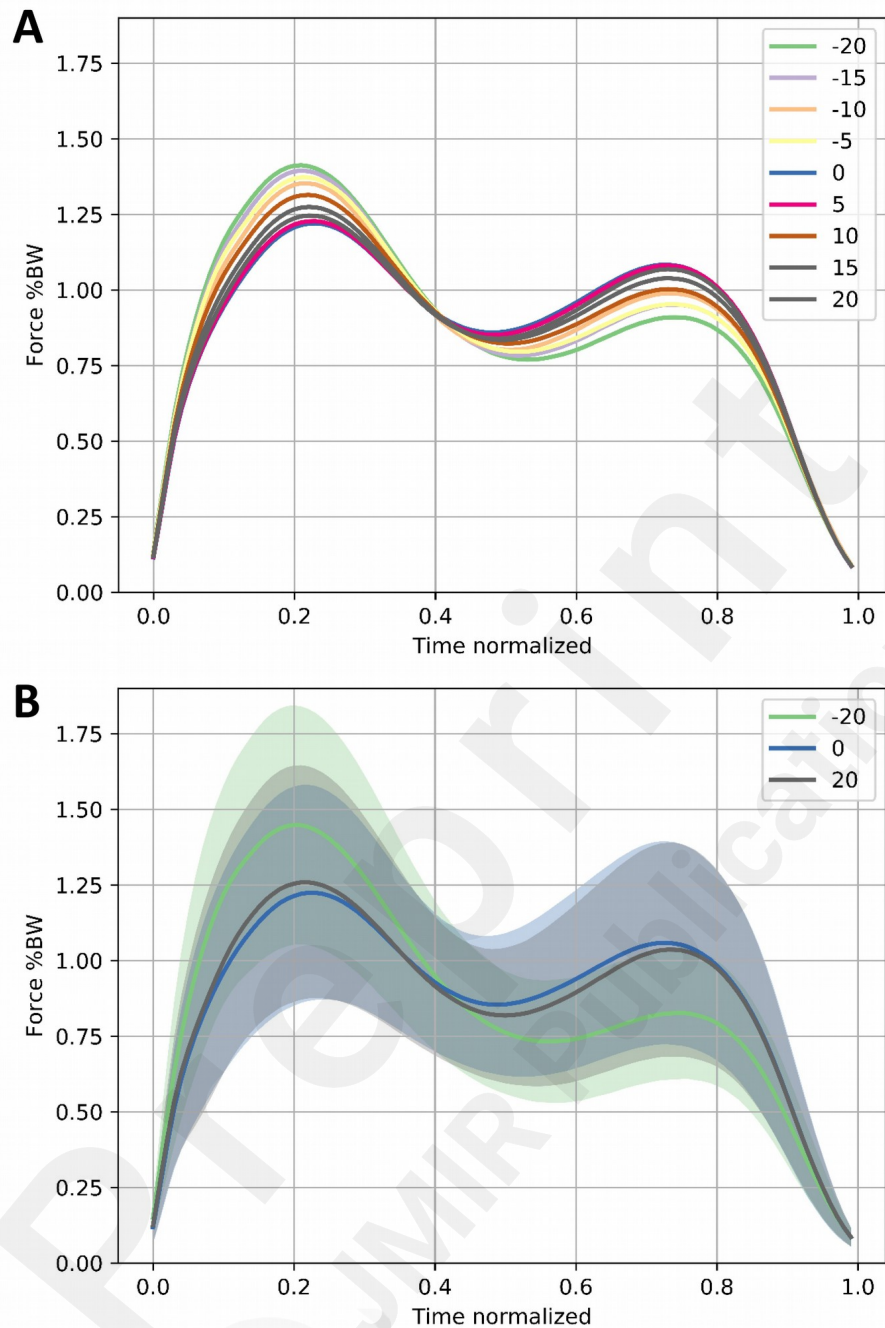


Figure 2. A: The mean trajectories of the stance phase curve for each of the analyzed slope levels. B: The mean trajectories and the 95 % confidence interval for -20, 0 and 20 %.

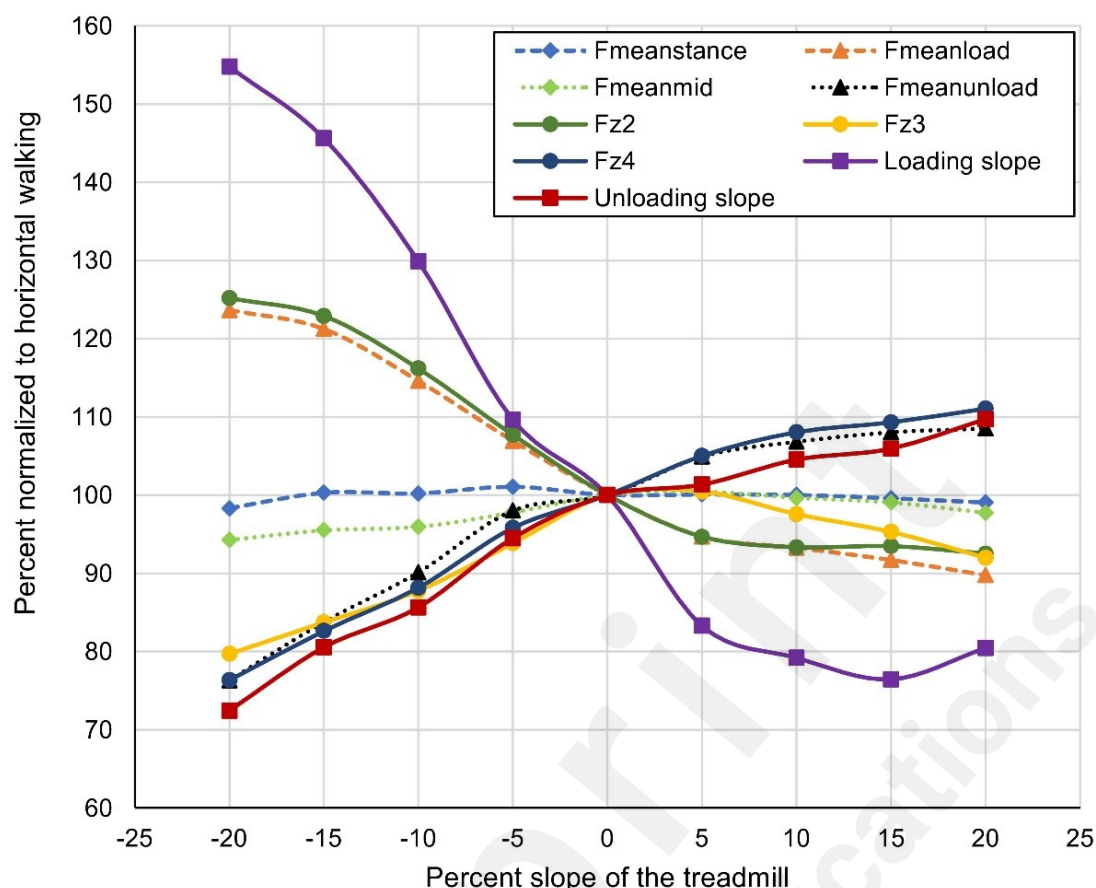


Figure 3. For each slope level, the mean value of each parameter is shown in percent of horizontal walking (all values averaged over all participants)

Table 2: Mean values and SD of the analyzed parameters for each slope level (absolute values)

	-20	-15	-10	-5	0	5	10	15	20
Fmean _{stance} [% body weight]	0.88 ± 0.21	0.90 ± 0.21	0.90 ± 0.21	0.91 ± 0.21	0.90 ± 0.21	0.90 ± 0.21	0.90 ± 0.21	0.89 ± 0.20	0.89 ± 0.20
Fmean _{load} [% body weight]	1.06 ± 0.30	1.04 ± 0.28	0.98 ± 0.26	0.91 ± 0.23	0.86 ± 0.21	0.81 ± 0.20	0.80 ± 0.20	0.78 ± 0.19	0.77 ± 0.18
Fmean _{mid} [% body weight]	0.97 ± 0.24	0.99 ± 0.23	0.99 ± 0.23	1.01 ± 0.23	1.03 ± 0.25	1.04 ± 0.25	1.03 ± 0.25	1.02 ± 0.25	1.01 ± 0.24
Fmean _{unload} [% body weight]	0.55 ± 0.14	0.61 ± 0.14	0.65 ± 0.16	0.71 ± 0.16	0.72 ± 0.17	0.76 ± 0.18	0.77 ± 0.18	0.78 ± 0.18	0.79 ± 0.18
Fz2 [% body weight]	1.50 ± 0.39	1.48 ± 0.38	1.39 ± 0.36	1.29 ± 0.33	1.20 ± 0.30	1.14 ± 0.29	1.12 ± 0.29	1.12 ± 0.29	1.11 ± 0.29
Fz3 [% body weight]	0.70 ± 0.20	0.74 ± 0.19	0.77 ± 0.18	0.83 ± 0.19	0.88 ± 0.22	0.88 ± 0.21	0.86 ± 0.21	0.84 ± 0.22	0.81 ± 0.19
Fz4 [% body weight]	0.88 ± 0.24	0.96 ± 0.24	1.02 ± 0.26	1.11 ± 0.28	1.16 ± 0.32	1.22 ± 0.33	1.25 ± 0.33	1.26 ± 0.34	1.29 ± 0.35

Loading slope [% body weight / % stance phase duration]	11.00 ± 4.58	10.35 ± 4.01	9.23 ± 3.58	7.79 ± 2.99	7.10 ± 2.91	5.92 ± 2.11	5.63 ± 2.07	5.43 ± 1.85	5.71 ± 2.07
Unloading slope [% body weight / % stance phase duration]	-5.30 ± 1.66	-5.89 ± 1.87	-6.26 ± 2.10	-6.91 ± 2.34	-7.31 ± 2.71	-7.41 ± 2.64	-7.65 ± 2.79	-7.75 ± 2.92	-8.02 ± 3.02

Table 3: Linear regression slopes and R²-values for each of the curves shown in Figure 3.

	Linear regression slope [%]	R ²
Fmean _{stance} [% body weight]	-0.002	0.001
Fmean _{load} [% body weight]	0.930	0.943
Fmean _{mid} [% body weight]	0.116	0.527
Fmean _{unload} [% body weight]	0.807	0.909
Fz2 [% body weight]	-0.926	0.907
Fz3 [% body weight]	0.367	0.483
Fz4 [% body weight]	0.894	0.952
Loading slope [% body weight / % stance phase duration]	-2.109	0.910
Unloading slope [% body weight / % stance phase duration]	0.900	0.935

Use of wearables in patients

The insole technology and present data may be valuable in real-world settings when investigating changes in mechanical properties during walking, i.e., in occupational health research, sport and exercise science, for urban planning, and to plan inclusive architecture. For instance, the global average slope of urban areas is about 3.70° [22]. Wearables such as pressure insoles are increasingly used to study gait and movement, as well as for fall detection, fall classification and fall risk assessment in the daily life of patients, and furthermore for lifestyle and health monitoring [1,3,23-27]. Long-term monitoring, especially if combined with additional sensors, may produce large amounts of data that require advanced strategies for analyses. Apart from regression statistics, among the options is the use of machine learning algorithms trained with annotated data for pattern recognition [24,26]. For longer-term monitoring of patients, it would be desirable if such algorithms were trained to identify various key activities of the daily life that might indicate the level of healing progress. For example, when a patient with a tibial fracture is capable of cycling again, this is likely an indication for advances in the healing process. It would also be of interest to identify risky behaviour, possibly leading to excessive forces, and to warn the patient by giving, e.g., an audible or haptic warning signal. To guarantee meaningful data interpretation, machine learning may be combined with conventional regression-based analyses, such as the ones proposed in the present paper to best tackle data complexity. Furthermore, prediction algorithms could be implemented for falls and diseases that enable for more refined individual recommendations. Ideally, such interventions would be based on live data analyses. Limitations in computing power of small wearable devices can increasingly be mitigated by both algorithmic optimization techniques in machine learning, such as dimensionality reduction, reservoir computing and network pruning, as well as hardware innovations [27,28]. In the near future, such advances will likely allow real-time feedback based on data from various sources combined [29,30]. Alternatively, extracting decision-making systems (symbolic artificial intelligence), such as threshold-based methods, might offer an immediate route to real-time feedback.

Sensors in orthoses and implants

Apart from insoles, very similar data might be collected from mechanical sensors embedded in orthoses [31] or implants [32]. Potentially, walking on a slope in these recordings changes the data in similar ways as described here. It would be highly desirable, if patients did not need to use separate wearables such as insoles anymore, but if orthoses and implants had sensors embedded, not only to monitor healing progress, but also to identify healing problems or complications and the need for surgical revision [33]. If similar load data could be collected by sensors in artificial hip or knee joints, or potentially even by plates or nails that stabilize bone fractures, recovery regimen could be monitored continuously and advice given in a timely manner [34]. Alarms could go off if forces exceeded certain thresholds or if live pattern analyses revealed unfavourable patterns known to be associated with exceeding forces or problems. As these developments seem to have a high potential with regard to rehabilitation and postoperative treatment, data analyses of insole data should be further studied and ideally, details such as algorithms and characteristics should be published to enable for the further development and widespread application of the named interventions.

Conclusion

Characteristic changes in the plantar-pressure stance phase curve were identified which reflect uphill and downhill walking. Automated annotation and continuous analyses of gait data via wearables could enable improved rehabilitation and feedback systems for prevention and treatment. A combination of traditional regression statistics embedded in heuristics combined with artificial intelligence methods may yield the best results.

Acknowledgements

The Werner Siemens Foundation (project Smart Implants 2.0) funded this work. The authors would like to acknowledge the help of the study nurses Aynur Gökten and Jacqueline Orth during the measurements, as well as the help of Lisa-Marie Jost in designing figure 1.

Conflicts of interest

TP is President and Board Member of the AO-Foundation, Switzerland, and Extended Board Member of the German Society of Orthopedic Trauma Surgery (DGU), the German Society of Orthopedic Surgery and Traumatology (DGOU), and the German Society of Surgery (DGCH). TP is also the speaker of the Medical Advisory Board of the German Ministry of Defence. The other authors do not have a conflict of interest.

Author's contributions

CW contributed the data processing platform, data analysis, methods and figure 2. PS conducted the measurements. BG contributed the idea, ran the statistical analyses, interpreted the data, made the tables, drafted, submitted, and revised the manuscript. TD, CS and FC took part in the data platform implementation. EW, TD, PS, CS, FC, MO and TP helped with data interpretation. All authors have contributed to manuscript drafting and revision, read, and approved the submitted version of the manuscript.

Abbreviations

ANOVA: Analysis of variance

DRKS: German Clinical Trials Register

Fz2: The first maximum

Fz3: The minimum

Fz4: The second maximum

IRB: Institutional Review Board

Fmean_{stance}: The mean force over the entire stance phase

Fmean_{load}: The mean force between the start of loading-phase and Fz2

Fmean_{mid}: The mean force between Fz2 and Fz4

Fmean_{unload}: The mean force between Fz4 and the end of the unloading-phase

SD: Standard deviation

Multimedia Appendix 1

Data set

References

1. Braun BJ, Veith NT, Rollmann M, Orth M, Fritz T, Herath SC, Holstein JH, Pohlemann T. Weight-bearing recommendations after operative fracture treatment-fact or fiction? Gait results with and feasibility of a dynamic, continuous pedobarography insole. *Int Orthop*. 2017; 41(8):1507-1512. doi: 10.1007/s00264-017-3481-7.
2. Ramirez-Bautista JA, Huerta-Ruelas JA, Chaparro-Cardenas SL, Hernandez-Zavala A. A Review in Detection and Monitoring Gait Disorders Using In-Shoe Plantar Measurement

- Systems. *IEEE Rev Biomed Eng.* 2017; 10:299-309. doi: 10.1109/RBME.2017.2747402.
3. Subramaniam S, Majumder S, Faisal AI, Deen MJ. Insole-Based Systems for Health Monitoring: Current Solutions and Research Challenges. *Sensors (Basel)*. 2022a; 22(2):438. doi: 10.3390/s22020438.
 4. Elstüb LJ, Grohowski LM, Wolf DN, Owen MK, Noehren B, Zelik KE. Effect of pressure insole sampling frequency on insole-measured peak force accuracy during running. *J Biomech.* 2022; 145:111387. doi: 10.1016/j.jbiomech.2022.111387.
 5. North K, Kubiak EN, Hitchcock RW. Sensor packaging design for continuous underfoot load monitoring. *Biomed Microdevices.* 2012; 14(1):217-24. doi: 10.1007/s10544-011-9599-2.
 6. Anderson W, Choffin Z, Jeong N, Callihan M, Jeong S, Sazonov E. Empirical Study on Human Movement Classification Using Insole Footwear Sensor System and Machine Learning. *Sensors (Basel)*. 2022; 22(7):2743. doi: 10.3390/s22072743.
 7. Chatzaki C, Skaramagkas V, Kefalopoulou Z, Tachos N, Kostikis N, Kanellos F, Triantafyllou E, Chroni E, Fotiadis DI, Tsiknakis M. Can Gait Features Help in Differentiating Parkinson's Disease Medication States and Severity Levels? A Machine Learning Approach. *Sensors (Basel)*. 2022; 22(24):9937. doi: 10.3390/s22249937.
 8. Montgomery JR, Grabowski AM. The contributions of ankle, knee and hip joint work to individual leg work change during uphill and downhill walking over a range of speeds. *R Soc Open Sci.* 2018; 5(8):180550. doi: 10.1098/rsos.180550.
 9. Strutzenberger G, Leutgeb L, Claußen L, Schwameder H. Gait on slopes: Differences in temporo-spatial, kinematic and kinetic gait parameters between walking on a ramp and on a treadmill. *Gait Posture.* 2022; 91:73-78. doi: 10.1016/j.gaitpost.2021.09.196.
 10. Alexander N, Strutzenberger G, Ameshofer LM, Schwameder H. Lower limb joint work and joint work contribution during downhill and uphill walking at different inclinations. *J Biomech.* 2017; 61:75-80. doi: 10.1016/j.jbiomech.2017.07.001.
 11. Franz JR, Kram R. How does age affect leg muscle activity/coactivity during uphill and downhill walking? *Gait Posture.* 2013; 37(3):378-84. doi: 10.1016/j.gaitpost.2012.08.004.
 12. Larsen AH, Puggaard L, Härmäläinen U, Aagaard P. Comparison of ground reaction forces and antagonist muscle coactivation during stair walking with ageing. *J Electromyogr Kinesiol.* 2008; 18(4):568-80. doi: 10.1016/j.jelekin.2006.12.008.
 13. Braun BJ, Veith NT, Hell R, Döbele S, Roland M, Rollmann M, Holstein J, Pohlemann T. Validation and reliability testing of a new, fully integrated gait analysis insole. *J Foot Ankle Res.* 2015; 8:54. doi: 10.1186/s13047-015-0111-8.
 14. Stöggl T, Martinier A. Validation of Moticon's OpenGo sensor insoles during gait, jumps, balance and cross-country skiing specific imitation movements. *J Sports Sci.* 2017; 35(2):196-206. doi: 10.1080/02640414.2016.1161205.
 15. Chardon M, Barbieri FA, Penedo T, Santos PCR, Vuillerme N. The effects of experimentally-induced fatigue on gait parameters during obstacle crossing: A systematic review. *Neurosci Biobehav Rev.* 2022; 142:104854. doi: 10.1016/j.neubiorev.2022.104854.
 16. Wolff C, Steinheimer P, Warmerdam E, Dahmen T, Slusallek P, Schlinkmann C, Chen F, Orth M, Pohlemann T, Ganse B. Effects of age, body height, body weight, body mass index and handgrip strength on the trajectory of the plantar pressure stance-phase curve of the gait cycle. *Front Bioeng Biotechnol.* 2023; 11:1110099. doi: 10.3389/fbioe.2023.1110099.
 17. Agres AN, Alves SA, Höntzsch D, El Attal R, Pohlemann T, Schaser KD, Joeris A, Hess D, Duda GN. Improved weight bearing during gait at 6 weeks post-surgery with an angle

- stable locking system after distal tibial fracture. *Gait Posture*. 2024; 107:169-176. doi: 10.1016/j.gaitpost.2023.09.013.
18. Rosenbaum D, Macri F, Lupselo FS, Preis OC. Gait and function as tools for the assessment of fracture repair - the role of movement analysis for the assessment of fracture healing. *Injury*. 2014; 45 Suppl 2:S39-43. doi: 10.1016/j.injury.2014.04.007.
 19. Schwameder H, Lindenhofner E, Müller E. Effect of walking speed on lower extremity joint loading in graded ramp walking. *Sports Biomech*. 2005; 4(2):227-43. doi: 10.1080/14763140508522865.
 20. Semaan MB, Wallard L, Ruiz V, Gillet C, Leteneur S, Simoneau-Buessinger E. Is treadmill walking biomechanically comparable to overground walking? A systematic review. *Gait Posture*. 2022; 92:249-257. doi: 10.1016/j.gaitpost.2021.11.009.
 21. Blades S, Marriott H, Hundza S, Honert EC, Stellingwerff T, Klimstra M. Evaluation of Different Pressure-Based Foot Contact Event Detection Algorithms across Different Slopes and Speeds. *Sensors (Basel)*. 2023; 23(5):2736. doi: 10.3390/s23052736.
 22. Shi K, Liu G, Zhou L, Cui Y, Liu S, Wu Y. Satellite remote sensing data reveal increased slope climbing of urban land expansion worldwide. *Landscape and Urban Planning* 2023; 235:104755. Doi: 10.1016/j.landurbplan.2023.104755
 23. Cates B, Sim T, Heo H, Kim B, Kim H, Mun J. A novel detection model and its optimal features to classify falls from low- and high-acceleration activities of daily life using an insole sensor system. *Sensors*. 2018; 18:1227. doi: 10.3390/s18041227
 24. Kraus M, Saller MM, Baumbach SF, Neuerburg C, Stumpf UC, Böcker W, Keppler AM. Prediction of Physical Frailty in Orthogeriatric Patients Using Sensor Insole-Based Gait Analysis and Machine Learning Algorithms: Cross-sectional Study. *JMIR Med Inform*. 2022; 10(1):e32724. doi: 10.2196/32724.
 25. Subramaniam S, Faisal AI, Deen MJ. Wearable Sensor Systems for Fall Risk Assessment: A Review. *Front Digit Health*. 2022b; 4:921506. doi: 10.3389/fdgth.2022.921506.
 26. Harris EJ, Khoo IH, Demircan E. A Survey of Human Gait-Based Artificial Intelligence Applications. *Front Robot AI*. 2022; 8:749274. doi: 10.3389/frobt.2021.749274.
 27. Hou CKJ, Behdinan K. Dimensionality Reduction in Surrogate Modeling: A Review of Combined Methods. *Data Sci Eng*. 2022; 7(4):402-427. doi: 10.1007/s41019-022-00193-5.
 28. Tanaka G, Yamane T, Héroux JB, Nakane R, Kanazawa N, Takeda S, Numata H, Nakano D, Hirose A. Recent advances in physical reservoir computing: A review. *Neural Netw*. 2019; 115:100-123. doi: 10.1016/j.neunet.2019.03.005.
 29. Chiasson-Poirier L, Younesian H, Turcot K, Sylvestre J. Detecting Gait Events from Accelerations Using Reservoir Computing. *Sensors (Basel)*. 2022; 22(19):7180. doi: 10.3390/s22197180.
 30. Zhang Q, Jin T, Cai J, Xu L, He T, Wang T, Tian Y, Li L, Peng Y, Lee C. Wearable Triboelectric Sensors Enabled Gait Analysis and Waist Motion Capture for IoT-Based Smart Healthcare Applications. *Adv Sci (Weinh)*. 2022; 9(4):e2103694. doi: 10.1002/advs.202103694.
 31. Moreira L, Figueiredo J, Cerqueira J, Santos CP. A Review on Locomotion Mode Recognition and Prediction When Using Active Orthoses and Exoskeletons. *Sensors (Basel)*. 2022; 22(19):7109. doi: 10.3390/s22197109.
 32. Alves SA, Polzehl J, Brisson NM, Bender A, Agres AN, Damm P, Duda GN. Ground reaction forces and external hip joint moments predict in vivo hip contact forces during gait. *J Biomech*. 2022 Apr;135:111037. doi: 10.1016/j.jbiomech.2022.111037.
 33. Warmerdam E, Orth M, Pohlemann T, Ganse B. Gait Analysis to Monitor Fracture Healing of the Lower Leg. *Bioengineering (Basel)*. 2023; 10(2):255. doi:

10.3390/bioengineering10020255.

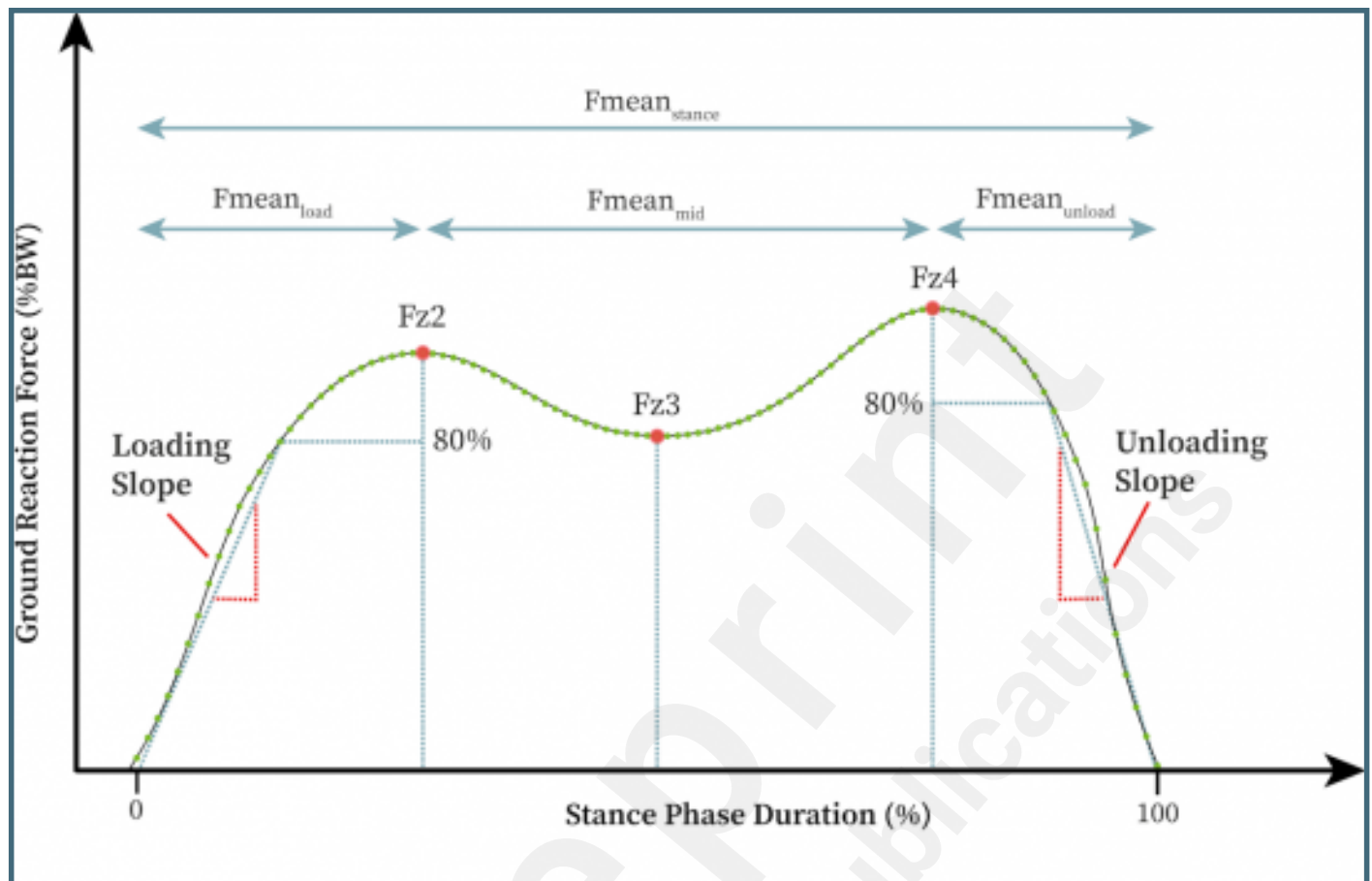
34. Ganse B, Orth M, Roland M, Diebels S, Motzki P, Seelecke S, Kirsch SM, Welsch F, Andres A, Wickert K, Braun BJ, Pohlemann T. Concepts and clinical aspects of active implants for the treatment of bone fractures. *Acta Biomater.* 2022; 146:1-9. doi: 10.1016/j.actbio.2022.05.001.



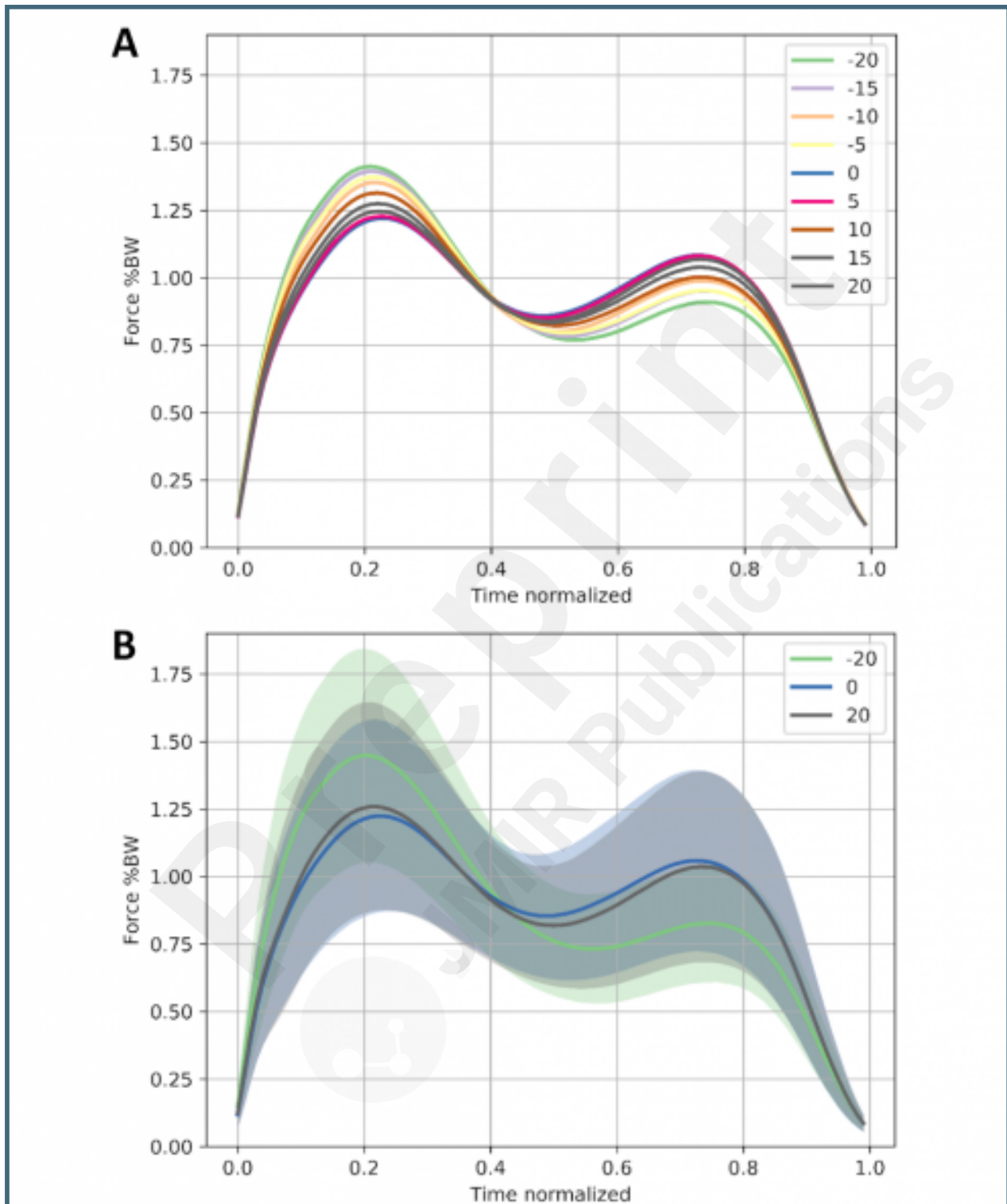
Supplementary Files

Figures

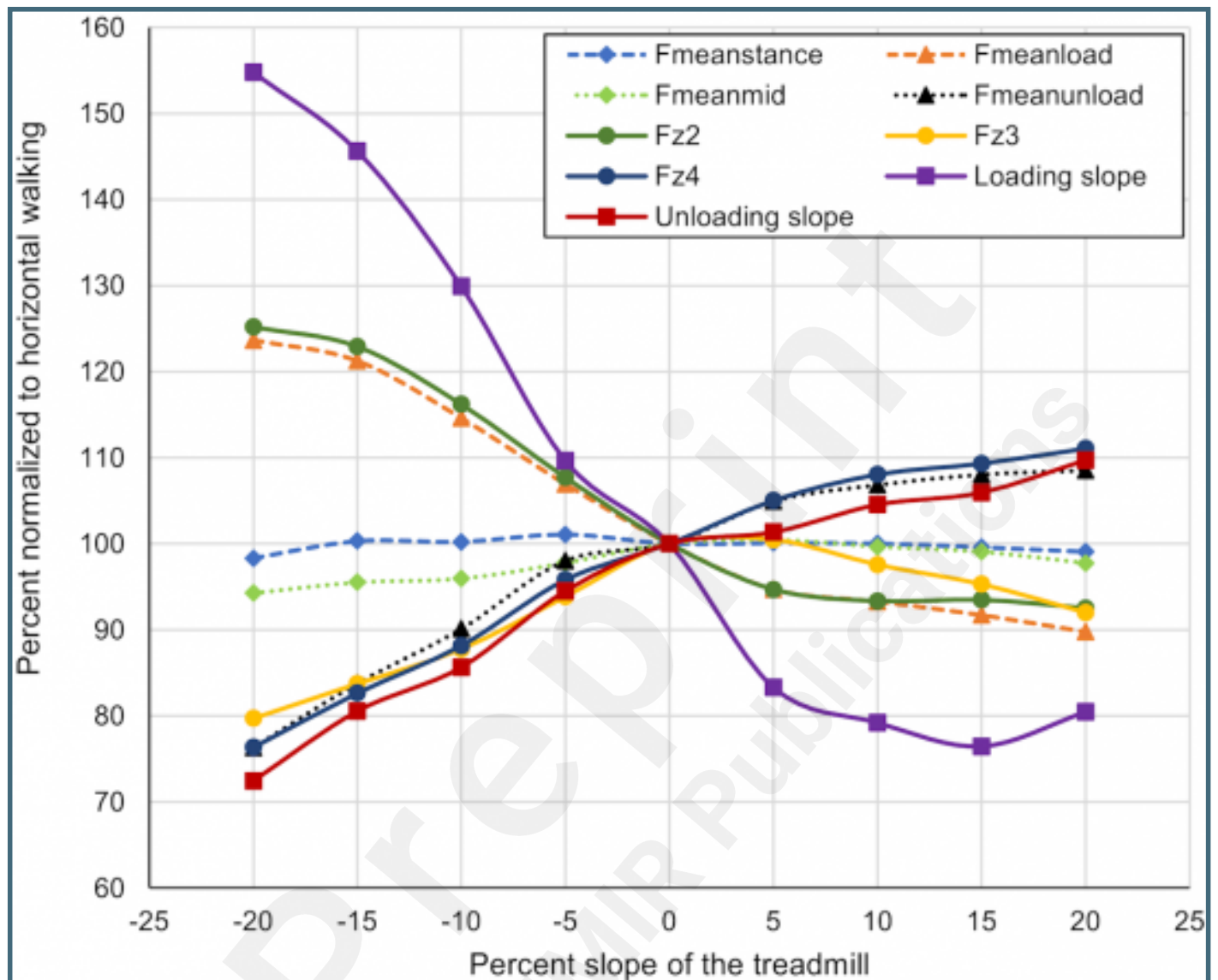
Depiction of the analyzed parameters of the stance phase.



A: The mean trajectories of the stance phase curve for each of the analyzed slope levels. B: The mean trajectories and the 95 % confidence interval for -20, 0 and 20 %.



For each slope level, the mean value of each parameter is shown in percent of horizontal walking (all values averaged over all participants).



Multimedia Appendixes

Data file.

URL: <http://asset.jmir.pub/assets/e4455acd95c94f1981ec2da5bfdb4f77.xlsx>



TOC/Feature image for homepages

Untitled.

