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Weight-Bearing Monitoring Devices in Lower Extremity Fractures: A Scoping Review

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Background: Orthopaedic surgeons commonly prescribe weight-bearing parameters for their patients for a variety of reasons. Weight-bearing may be limited in order to control the healing environment, but advancing a patient's weight-bearing status is preferably done as quickly as possible to maximize functional recovery. However, it is entirely unclear to what extent these prescriptions are followed in practice. The purpose of this scoping review is to identify and compare non-invasive devices used for the measurement of weight-bearing following lower extremity fractures.

Methods: Database searches of MEDLINE, EMBASE and the Cochrane Central Register of Controlled Trials (CENTRAL) were completed to identify relevant studies. Titles were screened for relevance, and abstracts were screened against the eligibility criteria. We identified studies that investigated the use of external force, pedal pressure, or activity monitoring devices used in adults after lower extremity fractures and excluded studies involving compartment pressure measurement.

Findings: Sixty-two studies met the inclusion criteria. About 39% of studies used an insole-type device, which could be worn in a shoe or integrated into a removable boot. Other device types included step count or activity monitors (52%), force plates (18%), pressure film (2%) and external pedobarography systems (27%).

Interpretation: We found that different monitors offered varying types of measurements and are suitable for a variety of applications. Therefore, selecting the ideal device depends on the metric of interest. Further high-quality prospective studies utilizing device monitoring are needed to validate the theory that early weight-bearing is beneficial and safe for patients with lower extremity fractures.

Keywords: trauma, fracture, lower extremity, weight-bearing, monitoring

Introduction

Orthopaedic surgeons commonly prescribe weight-bearing parameters for their patients for a variety of reasons. The AO Foundation recommends periods of non-weight-bearing or limited weight-bearing for the majority of lower extremity peri-articular fracture patterns.¹ Weight-bearing may be limited in order to modulate the strain environment of a fracture as it heals, to protect soft tissues or to ensure construct safety. However, advancing a patient's weight-bearing status is preferably done as quickly as possible in order to minimize tissue atrophy and disuse osteopenia and maximize functional recovery.^{2,3} These conflicting priorities are an ongoing focus in the literature.

Multiple studies have explored the relationship between load bearing and fracture recovery on a theoretical level. In an in-vitro computer modelling study by Claes et al found that while increased fracture distance was associated with reduced stability, interfragmentary motion was well tolerated at lower fracture distances.⁴ Using a finite element model, Bailon-Plaza and van der Muelen showed that both fracture site stimulation and increase in ambulatory moments within limits resulted in accelerated healing.⁵ Theoretical models support ambulation as a catalyst in early healing of a fracture.

Comparative studies support the safety of early post-operative weight-bearing in a variety of fracture types. A study by Graham showed that accelerated weight-bearing is safe and effective in surgically treated hip fracture patients at 1 and 3 year follow ups.⁶ Similarly, a Cochrane review by Lin et al showed that patients in early and delayed weight-bearing groups have similar activity levels and complication rates following surgical fixation of ankle fractures.⁷ These studies

are limited in that no measure of participants' weight-bearing behavior was utilized. This significantly limits the conclusions that can be drawn since the only discrete difference between the comparative groups is the investigators' instructions, not necessarily the patient's behavior. However, comparative studies using current load sensing technology have been proposed. Kalmet et al have suggested a comparison of "permissive weight bearing" and traditional non-weight-bearing outcomes in pelvic, acetabular and lower extremity peri-articular fractures, and plan to use an electronic insole to monitor weight-bearing activity.⁸

It remains unclear to what extent weight-bearing prescriptions are followed in practice. Multiple published studies have shown high non-compliance rates. In a study of 51 lower extremity fracture patients with non-weight-bearing instructions, Chiodo et al found that 27.5% of patients exceeded loading limits over the 3-month study duration.⁹ Similarly, Braun et al showed that 53% of patients were unable to comply with weight-bearing prescriptions post-operatively in multiple lower extremity fracture types.¹⁰ Dabke et al found similar results during crutch assisted weight-bearing in a lab setting.¹¹

Given high rates of non-compliance following lower extremity fracture, accurate methods of weight-bearing monitoring are critical to ensure the integrity of future studies. The purpose of this scoping review was to identify and compare non-invasive devices used for the measurement of weight-bearing following lower extremity fractures.

Materials and Methods

Database searches of MEDLINE, EMBASE and the Cochrane Central Register of Controlled Trials (CENTRAL) were completed to identify relevant studies. Searches of MEDLINE and EMBASE databases were completed on and were inclusive to September 6th, 2023, with the CENTRAL database search completed on March 27th, 2025 and inclusive to December 31st, 2023. Our eligibility criteria included studies that used non-invasive force, plantar pressure, or activity monitoring devices in adults after lower extremity fractures. We specifically excluded studies involving compartment pressure measurement. The review protocol was developed with the assistance of a medical librarian and finalized prior to being implemented, however was not formally registered. An example of the search terms used is included in Table 1, with full database specific search terms included in <u>Appendix 1</u>.

Titles were screened for relevance and abstracts were screened against the eligibility criteria. Title, abstract and full text screening was completed by two independent reviewers (JR, AW). An additional search of clinicaltrials.gov, the WHO International Clinical Trial Registry Platform (ICTRP), Networked Digital Library of Theses and Dissertations (NDLTD), Dissertations and Theses Global and Grey Matters was completed to identify unpublished literature. Any theses or dissertations meeting eligibility criteria were screened for relevant published sub-studies. Reference lists of all studies meeting inclusion criteria after full text review were reviewed to identify additional relevant literature. Results were documented in a pre-defined charting form. A PRISMA diagram outlining the review process is shown in Figure 1.

Results

Device types were identified and separated into 5 groups for further analysis (Table 2). Some studies used more than one method of measurement, and devices were included in multiple categories as necessary. About 39% of studies used an insole-type device, which could be worn in a shoe or integrated into a removable boot. Other device types included step count or activity monitors (52%), force plates (18%), pressure film (2%) and external pedobarography systems (27%).

I	(((pressure or force or load or weight) adj I (measure* or estimat* or quantif* or computat* or evaluat*)) or ((step or pace or tread or footstep or footfall or stride or tramp) adj I (count* or sum* or total or tally or calculat* or computat*))).mp.
2	(exp Lower Extremity/ and exp Fractures, Bone/) or exp Femoral Fractures/ or exp Hip Fractures/ or exp Tibial Fractures/ or exp Fibula Fractures/ or exp Ankle Fractures/
3	I and 2
4	(1 and 2) not (compartment* or (compartment* adj1 syndrome)).mp.

Table I MEDLINE Database Search Terms

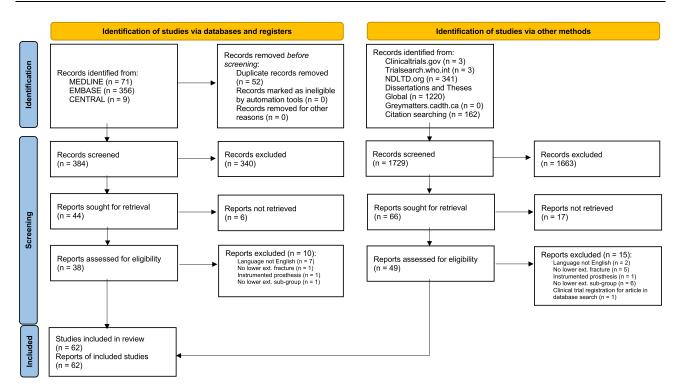


Figure I PRISMA diagram. Adapted from Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n71. under the CC BY 4.0 license.

Relevant metrics for each identified device were collected from available manufacturer data (Table 3). In the case that manufacturer data was not publicly available, manufacturers and study authors were contacted to request missing information. Relevant information from review studies and cited background work were used when manufacturer data were unavailable, and we were unable to contact study authors.

About 47% of devices were found to be suitable for remote monitoring or tracking based on available information. Data storage capacity ranged from hours to multiple months. Storage capacity metrics were not included for all force plate, pressure plate and pedobarographic systems.

Discussion

The purpose of this scoping review was to identify and compare non-invasive devices used for monitoring lower extremity weight-bearing activity after fracture. Device suitability for monitoring applications is reviewed below for each group.

Force Plate

A force plate can be a versatile tool for weight-bearing monitoring and can be used in different capacities depending on the metric of interest. Of the devices identified, all were able to collect force data in a lab setting. Early studies by Pratt et al^{20} and

Device Туре	Studies Using Device Type		
Insole	24		
Step count or activity monitor	32		
Force plate	11		
Pressure film	I		
External pedobarography	17		

Table 2 Weight-Bearing Monitoring Device Sub-Categories

Table 3 Device Metrics

Device/Model		Туре	Force	Pressure	Step Count	Remote Tracking	Data Storage	Study	Source
Force plate	Bertec	Force plate	Yes	No	No	No	N/A	Dabke et al, ¹¹ Bozkurt et al ¹²	Dabke et al, ¹¹ Bozkurt et al ¹²
Force plate	Kistler	Force plate	Yes	No	No	No	N/A	Joslin et al, ¹³ Catani et al, ¹⁴ Kitaoka et al ¹⁵	Joslin et al, ¹³ Catani et al, ¹⁴ Kitaoka et al ¹⁵
Force plate	NS	Force plate	Yes	No	No	No	N/A	Kershaw et al ¹⁶	Kershaw et al ¹⁶
Force plate	NS	Force plate	Yes	No	No	No	N/A	van Hoeve et al ¹⁷	van Hoeve et al ¹⁷
Force plate	NS	Force plate	Yes	No	No	No	N/A	Wardlaw et al ¹⁸	Wardlaw et al ¹⁸
Force plate	AMTI	Force plate	Yes	No	No	No	N/A	Mittlmeier et al ¹⁹	Mittlmeier et al ¹⁹
Force plate	Custom	Force plate	Yes	No	No	No	N/A	Pratt et al ²⁰	Pratt et al, ²⁰ Pratt et al ²¹
RehaWalk Treadmill	Zebris	Multiple	Yes	Yes	No	No	N/A	Mendel et al ²²	Zebris ²³ *
EMED	Novel	External pedobarography	Yes	Yes	No	No	N/A	Durr et al, ²⁴ Mehlhorn et al, ²⁵ Çolak et al, ²⁶ Kosters et al, ²⁷ Jansen et al, ²⁸ Jansen et al, ²⁹ Hirschmuller et al, ³⁰ Becker et al, ³¹ Rosenbaum et al, ³² Mittlmeier et al, ³³ Mittlmeier et al ¹⁹	Novel ³⁴ *
Footscan	Materialise (RSscan)	External pedobarography	No	Yes	No	No	N/A	Genc et al, ³⁵ Zielinski et al, ³⁶ Schepers et al, ³⁷ Schepers et al ³⁸	Materialise ³⁹ *
FootWork	Podoactivia	External pedobarography	Yes	Yes	No	No	N/A	Jordan-Palomar et al ⁴⁰	Jordan-Palomar et al, ⁴⁰ Alfaro-Santafé et al ⁴¹
Dynamic optical pedobarograph	NS	External pedobarography	No	Yes	No	No	N/A	Davies et al ⁴²	Davies et al ⁴²
GANGAS	Medilogic	Insole	No	Yes	No	No	N/A	Besch et al, ⁴³ Follak & Merk ⁴⁴	Mediologic ⁴⁵ *
Pedar	Novel	Insole	Yes	Yes	Yes	No	N/A	Hunt et al, ⁴⁶ Hetsroni et al, ⁴⁷ Kuschnaroff Contreras et al, ⁴⁸ Vasarhelyi et al ⁴⁹	Novel ⁵⁰ *, Novel ⁵¹ *
F-scan	Tekscan	Insole	Yes	Yes	Yes	Yes	2h**	Koval et al, ⁵² Teng et al, ⁵³ Kuschnaroff Contreras et al ⁵⁴	Tekscan ⁵⁵ *
SensiStep/FeetB@ck	Evalan	Insole	Yes	No	Yes	Yes	24h	Raaben et al, ⁵⁶ Bakker et al ⁵⁷	Bakker et al, ⁵⁷ Evalan ⁵⁸ *
Custom	Custom	Insole	Yes	No	Yes	Yes	>24h**	Aranzulla et al ⁵⁹	Aranzulla et al ⁵⁹
SmartStep	Andante	Insole	Yes	No	Yes	Yes	NS	Hershko et al ⁶⁰	Isakov, ⁶¹ VirtualPoint ⁶² +
OpenGO	Moticon	Insole	Yes	Yes	Yes	Yes	~I-32h‡	Braun et al, ¹⁰ Braun et al ⁶³	Moticon ⁶⁴ *
ReGO	Moticon	Insole	Yes	Yes	Yes	No	N/A	Eickhoff et al ⁶⁵	Moticon ⁶⁶ *
Advanced Tibial Load Analysis System (ATLAS)	Custom	Insole	Yes	No	Yes	Yes	3m	North et al, ⁶⁷ Lajevardi-Khosh et al, ⁶⁸ Lajevardi-Khosh et al, ⁶⁹ Lajevardi-Khosh et al, ⁷⁰ North et al ⁷¹	North et al, ⁷² Lajevardi-Khosh et al ⁷⁰
ParoTec	Paromed	Insole	No	Yes	No	No	NS	Dudkiewicz et al ⁷³	Paromed ⁷⁴ *, Paromed ⁷⁵ *
Fscan	Footlabs	Insole	Yes	Yes	No	NS	NS	Kinner et al ⁷⁶	Kinner et al ⁷⁶
NS	Penny andGiles	Insole	No	Yes	No	NS	NS	Follak & Merk ⁴⁴	Follak & Merk ⁴⁴
Pressure Sensitive Film	FujiFilm	Pressure film	Yes	Yes	No	No	N/A	Chiodo et al ⁹	FujiFilm ⁷⁷ *
Alta HR	Fitbit	Activity monitor	No	No	Yes	Yes	7d^	Reppas-Rindlisbacher et al ⁷⁸	FitBit ⁷⁹
Charge 4	Fitbit	Activity monitor	No	No	Yes	Yes	7d^	Hewage et al ⁸⁰	FitBit ⁸¹
NS	Fitbit	Activity monitor	No	No	Yes	Yes	NS	Mendel et al ²²	Mendel et al ²²

StepWatch3	Modus Health	Activity monitor	No	No	Yes	Yes	>2m	Reider et al, ⁸² Kosters et al ²⁷	Cyma Tech ⁸³
Actibelt RCT2	Trium	Activity monitor	No	No	Yes	Yes	75d	Mueller et al ⁸⁴	Daumer (e-mail communication, March 9 th , 2024)
Flex	Fitbit	Activity monitor	No	No	Yes	Yes	7d^	Schmal et al ⁸⁵	FitBit ⁸⁶
Shine	Misfit	Activity monitor	No	No	Yes	Yes	30d^	Schmal et al ⁸⁵	Misfit ⁸⁷
AX3	Axivity	Activity monitor	No	No	Yes	Yes	21d‡	Schmal et al, ⁸⁵ Armitage et al ⁸⁸	Axivity ⁸⁹ *
NS	ActiGraph	Activity monitor	No	No	Yes	Yes	180d	Resnick et al ⁹⁰	ActiGraph ⁹¹ ++
ActivPAL professional	PAL	Activity monitor	No	No	Yes	Yes	NS	Taraldsen et al, ⁹² Taraldsen et al, ⁹³ Taraldsen et al ⁹⁴	PAL ⁹⁵
PAM AM300	Pam Coach	Activity monitor	No	No	Yes	Yes	64d	Pol et al ⁹⁶	Pam Coach ⁹⁷

*Model information available from the manufacturer at the time of source access was cited. **Limited by battery life. +Device information from the manufacturer was not available online, therefore was obtained from the alternate source listed. ‡Variable depending on specified measurement frequency. ^Activity data stored on the device without sync. ++Specifications given for ActiGraph wGT3X-BT model. **Abbreviation**: NS: not specified or information not available after contacting authors/manufacturers. Wardlaw et al¹⁸ measured limb loading using a force plate and oscillograph paired with an instrumented cast system and were able to calculate fracture stiffness. Kershaw et al¹⁶ and Joslin et al¹³ used force plate systems to demonstrate an increase in longitudinal weight-bearing activity with fracture healing, in addition to fracture stiffness measurements. Other studies used force plates paired with video analysis, goniometers and/or electromyography to assess joint and muscle forces during gait.^{12,14,15,17,19} None of the identified systems were found to be suitable for ambulatory use and therefore would require interval assessment and extrapolation of loading behaviour to the home environment.

External Pedobarography

These systems allow for the measurement of underfoot pressure distribution through an instrumented mat or pressure plate. For example, the Novel EMED measures underfoot pressure distribution during standing or with movement,³⁴ with functionality demonstrated in multiple studies.^{19,24–33} Pedobarography devices can also be coupled with traditional gait analysis techniques, such as force, video and strength testing, to provide an additional metric to assess patient function and recovery.^{19,25,27,30,33,36,40} Some models of the Materialise Footscan allow researchers to synchronize gait analysis with pressure data acquisition through an integrated system.³⁹ A unique treadmill based system is demonstrated by Mendel et al²² in a mobility study of sacral fracture patients. The Zebris RehaWalk allows for collection of pressure distribution and step count, in addition to force data, while providing visual feedback to the patient.²³ As with force plate systems, these devices are generally not suitable for ambulatory use and require monitoring by an experienced research team during data collection.

Insole Monitoring

These devices allow researchers to collect force, pressure and step count data through an instrumented insole in the patient's shoe. Based on the available information, most of the devices in this category are capable of collecting force and step count data simultaneously.^{50,51,55,57–59,61,62,64,66,70,72} The Novel Pedar, Tekscan F-scan and Moticon OpenGo/ReGO systems also have the additional benefit of providing pressure distribution data.^{50,51,55,64,66} Some devices are optimized for ambulatory monitoring. For example, the ATLAS is a multi-sensor system integrated into the sole of a CAM walking boot and is designed for continuous monitoring for up to 3 months.⁷² The Moticon OpenGO has been used in multiple studies of lower extremity weight-bearing post-fracture^{10,63} and allows for continuous monitoring on the order of days using the "SmartRecording mode" (depending on the measurement frequency setting, Figure 2).⁶⁴ In contrast, the Tekscan F-scan and Evalan SensiStep have an ambulatory capability limited to less than 1 day by battery or storage capacity,^{55,58} making them less than ideal for home monitoring applications. In general, insole systems with the ability to collect a range of gait data, including force, pressure distribution and step count over weeks to months, are ideally suited for ambulatory monitoring applications. These devices allow a range of gait data to be collected while minimizing intervention by both the patient and research team.

Step Count/Activity Monitors

All of the identified activity monitors had ambulatory monitoring capabilities that ranged in their storage capacity from 7 to 180 days depending on the device (Daumer, e-mail communication, March 9th, 2024).^{79,81,83,86,87,89,91,97} Popular consumer wearables produced by FitBit are capable of monitoring step count data for up to 7 days without syncing.^{79,81,86} Some other devices marketed towards research applications, such as the Cyma Tech StepWatch, Trium ActiBelt, ActiGraph wGT3X-BT and Pam Coach AM300, are capable of collecting activity data for multiple months (Daumer, e-mail communication, March 9th, 2024).^{83,91,97} While relatively simple to implement and easy to use, an inherent limitation of these devices is their inability to collect load or pressure distribution data. However, when taken as a proxy for load bearing activity step count remains a valuable source of information for patient mobility and functional status.

Pressure Sensitive Film

Chiodo et al⁹ placed a pressure sensitive film in the casts of lower extremity fracture patients to assess compliance with non-weight-bearing restrictions. The Fujifilm material allows for assessment of pressure distribution via the proprietary software once removed.⁷⁷ While simple to implement, this approach has multiple limitations. A pressure threshold must



Figure 2 Moticon OpenGo Insole (Color). Used with permission from moticon.com.

be set to differentiate compliance versus non-compliance. As well, data is lost when a previously measured value is exceeded, therefore, information on the frequency of load bearing events cannot be assessed over time. While a reasonable approach for assessing if a patient has been 100% compliant with non-weight-bearing restrictions, this material is not ideal for following the loading behaviours of patients with partial weight-bearing restrictions over time.

Study Limitations

While this scoping review identified a variety of non-invasive devices used to monitor activity or load bearing in patients with lower extremity fractures, there are some limitations to the study. Our database search included a focused search through MEDLINE, EMBASE and CENTRAL. An expanded search of other databases specializing in medical and biomechanical literature may identify additional studies and devices that are not captured in this study. As well, many studies included limited or incomplete information on the monitoring device used, and in some cases did not report manufacturer information. However, we attempted to provide a comprehensive overview by obtaining missing data from published device documentation, manufacturer specifications, user and product manuals when available, and contacting manufacturers with information requests as necessary.

We also note that the included studies are heterogeneous in their choice of device and fracture types studied, resulting in varying endpoints of interest. Nevertheless, we chose to focus on the capabilities of each device to demonstrate possible indications for use in future research (ie measurement type, ability to facilitate remote tracking, and data storage capacity). Thus, this scoping review may serve as a guide for future studies to focus on specific device indications, related complications and the effect on treatment outcomes.

Conclusions

In this scoping review, a variety of approaches and devices used for weight-bearing and activity monitoring for patients with lower extremity fractures were found in the literature. We found that different monitors offered varying types of measurements and are suitable for a variety of applications. Therefore, selecting the ideal device depends on the metric of

interest. If detailed gait analysis is necessary, devices such as the Zebris RehaWalk, Novel Pedar/EMED and Tekscan F-scan provide many sensing elements to collect pressure distribution data with a high degree of resolution.^{23,34,50,51,55} Increased resolution does come at the cost of higher data and storage requirements. With reduced number of sensors, the ATLAS and Moticon OpenGO devices require less data storage, which improves ambulatory monitoring capacity.^{64,72} Some activity monitors also have the benefit of reduced storage requirements given simplified data metrics^{83,91} but rely on the assumption that step count correlates with the degree of lower extremity loading. Pressure sensitive films may be suitable for monitoring of non-weight-bearing compliance but are limited in providing time course data.⁹

As fracture care continues to evolve, we expect external weight-bearing monitoring devices to play a key role in data collection and monitoring patient compliance. With reduced costs and increasing system resolution over time, the accessibility of these devices should improve. Once the ideal parameters for weight-bearing following lower extremity fracture are elucidated, there may be a role for such devices to provide real-time feedback to the patient on their compliance. In the interim, the systems currently available on the market provide an array of options for researchers to choose from in monitoring loading post-lower extremity fracture. Further high-quality prospective studies utilizing device monitoring are needed to validate the theory that early weight-bearing is beneficial and safe for patients with lower extremity fractures.^{2,3,7}

Ethics Approval and Informed Consent

Not required as based on previously published data and does not include novel data on humans (individuals, samples or data) or animals.

Consent for Publication

The authors confirm that the details of any images, videos, recordings, etc. can be published, and that the person(s) providing consent have been shown the article contents to be published. We will provide copies of signed consent forms to the journal editorial office if requested.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors have no financial or non-financial competing interests to report, including but not limited to employment with the study sponsor, stock holdings or options, patents, royalties, personal fees, holding a board position, or any political, religious, or academic interest relevant to the published content.

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