

# Stride One in Post-Operative Recovery:

## Early Progressive Weight Bearing for Lower-Limb Fractures



It is estimated that in 2019, 436 million people worldwide were living with fractures and associated problems in functioning that could benefit from rehabilitation<sup>1</sup>. The top three anatomical sites of fracture in terms of number of years lived with disability (YLDs) and age-standardized YLD rates are fracture of the lower limb (patella, tibia or fibula, or ankle); pelvis; and hip<sup>2</sup>.

An increase in life expectancy will lead to a concurrent increase in the proportion of elderly individuals in the population, and consequently to a rise in the incidence of hip fractures. The number of hip fractures is expected to increase to about 4.5 million per year worldwide by 2050. Even with successful surgery, the mortality and the risk of permanent disability and dependence remain high in patients with hip fractures. As a result, medical costs associated with the treatment of these patients are increasing.

For these reasons, hip fractures are an increasingly important global public health issue<sup>3</sup>. Hip fractures in older patients are one of the most common injuries; in the USA alone, hip fracture cases represent around 30% of all hospitalized cases<sup>4</sup>.

Progressive weight-bearing after a fracture can be an effective strategy for promoting healing and functional recovery, but its implementation requires careful consideration of individual patient factors and fracture characteristics. Early, controlled weight-bearing can stimulate bone healing and improve functional outcomes, while excessive or premature weight-bearing can delay healing or lead to complications.

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<sup>5,6</sup>.

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# The role of Early and Progressive Weight-Bearing (EPWB)



EPWB can prevent prolonged periods of bedriddenness and reduce the loss of muscle strength within the first postoperative weeks in the fractured limb. This is on average more than 50% compared with the non-fractured limb, especially for those with trochanteric fractures<sup>7,8,9</sup>.

EPWB and mobilization is safe for a variety of fractures such as intra- and peri-articular fractures, femoral, tibial plateau (after internal fixation with subchondral screws and a buttress plate), tibia plafond, ankle, and calcaneal fractures. No increase in complication rate was found compared to usual care with time-contingent weight bearing<sup>10,11,12,13,14,15,16,26</sup>.

In a larger literature study on 4918 elderly patients with a fracture of the hip it was found that postoperative weight-bearing restrictions even led to a significantly greater risk of developing more adverse events compared with those who are encouraged to start bearing weight<sup>17</sup>.

Early (within 2 weeks) weight bearing-exercises after hip and tibial fracture surgery result in significant reduction of non-union, avascular necrosis and mortality over 1 and 3 years<sup>18,19</sup>.

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# The role of Early and Progressive Weight-Bearing (EPWB)



Early weight-bearing after surgery for ankle fracture does not increase the re-operation risk<sup>20</sup> and reduces the risk of deep venous thrombosis<sup>21</sup>.

In terms of infection after open reduction and internal fixation of unstable ankle fractures, no statistically significant difference between the early weight-bearing group and the late weight-bearing group is found<sup>22</sup>.

Several significant **improved health outcomes** have been demonstrated when managing fractures of the lower limb with EPWB compared to late, time-restraint weight bearing, such as better walking speed, mobility, level of daily activities, functional recovery, return to work, and Quality of Life<sup>11,13,14,15,16,21,23,24</sup>.

EPWB **enhances the rehabilitation program** for fractures of the lower limb with a quicker bone healing time, reduced time to full weight bearing (time to full weight bearing from 20 to 15 weeks), higher patient satisfaction, less pain, shorter hospital stays, discharge to home and less discharge to high-level care<sup>13,14,20,21,23,25,26,27</sup>.

EPWB reduces expenses and is cost saving for every improvement in functioning (measured with the Lower Extremity Functional Scale)<sup>13,26</sup>.

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## Current Practice

Several circumstances give rise to a wide range of weight bearing patterns and inconsistent rehabilitation after surgery for peri- or intra-articular fractures of the lower extremity.

Currently, a **lack of standardization** exists regarding EPWB protocols and weight-bearing doses or clinical decision-making used to progress weight bearing<sup>14</sup>. In view of a lack of evidence, many orthopedic and trauma surgeons tend to advise conservatively with regard to weight bearing in rehabilitation after the surgical management of peri- or intra-articular fractures of the lower extremity, and hold on to the prevailing dogmas, i.e. recommending time-contingent progression of weight bearing<sup>28,29</sup>.

A gap exists between the basic **scientific knowledge** concerning the benefit of progressive loading of injured bone and **clinical practice**. This gap presents an opportunity to improve the rehabilitation process through staged and sequential loading for optimal outcomes. Little research has reported on progression of weight bearing and no study details a controlled progression of weight-bearing status. Hence, there is little helpful information for enhancing the rehabilitation professional's clinical decision-making<sup>14</sup>.

Many studies use weight bearing "as tolerated" with signs and symptoms of potential complications (such as pain) as the only clinical benchmark (also called permissive WB)<sup>14</sup>.

The lack of individual feedback on the actual weight bearing status causes great differences in weight bearing when the patient is advised restricted weight bearing<sup>30,31,32</sup>.

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## Current Practice

Studies reported that one third of the patients do not comply with a non- or restricted weight bearing regimen and patients exceed the prescribed amount of partial weight bearing even when self-reported compliance was high<sup>32,33</sup>. Multiple published studies have shown high non-compliance rates with weight-bearing prescriptions<sup>34,35,36</sup>.

A study concluded that partial weight bearing could not accurately be reproduced with any of the weight-bearing techniques that are currently applied, which was supported by previous evidence showing an inability to accurately reproduce partial weight-bearing orders<sup>[4]<sup>21</sup></sup>.

Despite physical therapy training, weight-bearing compliance to recommended limits is low during the post-operative aftercare after ankle, tibial shaft and intertrochanteric femur fractures. Adherence to the partial weight-bearing task even further decreases over time<sup>35</sup>. Only one in 10 patients completely adheres to the set weight bearing limit<sup>38</sup>.

A substantial economic burden has been demonstrated in monetary terms and effect on Quality of Life of patients with peri- and/or intra-articular fractures of the lower extremities managed with non-weight bearing for 6-12 weeks, followed by partial weight bearing with a 25% increase in fracture loading every week during 26 weeks follow-up<sup>39</sup>.

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# The Potential of Real-Time Biofeedback on Weight Bearing Loads



WHO recommends progressive weight-bearing exercises in people with fractures in the lower extremity, including the use of a weight scaling<sup>40</sup>. However, since the ability of patients to produce partial weight bearing is attached to their **ability to reproduce partial weight-bearing orders**<sup>41</sup>, a real-time biofeedback on weight bearing loads is crucial.

There is evidence that feedback or stimulation based on sound or noise is beneficial<sup>42</sup>. Providing the adequate level of weight bearing on the fracture in a timely fashion during early aftercare treatment is essential in the speed towards full mobilization. Both over-loading and under-loading may lead to a prolonged and complicated recovery<sup>43,44,45</sup>.

A smart insole with real-time biofeedback on weight bearing levels has the potential to finetune and fully **accommodate this balance that has to be kept between over-loading and under-loading**.

A smart insole for remote monitoring of the patient's weight-bearing loads and providing real-time feedback for non-compliant weight-bearing demonstrated **high reliability** and excellent agreement with a force plate<sup>46</sup>. Advanced sensor technologies used in a biofeedback system have shown highly accurate measurements, especially in the static situation<sup>47</sup>.

Real-time audio-visual biofeedback significantly enhances compliance with weight-bearing instructions in PWB training (88% compliance in the biofeedback group compared to 19% compliance in group with standard care using a bathroom scale) while reducing the training duration with 25%. Based on these findings, the implementation of biofeedback devices in PWB training is recommended<sup>42,48,49</sup>.

Uncontrolled weight-bearing recommendations should be viewed with caution and carefully considered as fiction. A smart insole is able to determine weight bearing continuously and immediately helps to define real-time patient behavior and establish realistic, individual weight-bearing recommendations<sup>35</sup>.

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# The Potential of Real-Time Biofeedback on Weight Bearing Loads



Control of postoperative pain is a vital part of rehabilitation for ensuring patient safety<sup>41</sup>. Safe and gradual weight-bearing is essential for pain management, restoring strength, balance and mobility, and normalizing walking patterns<sup>50,51</sup>.

The use of biofeedback devices supports weight-bearing instructions. Smart steps and biofeedback devices provide real-time feedback enabling the therapist to determine the level of weight bearing that can be applied for the patient in an accurate way, as well as safely increasing the weight-bearing load<sup>52</sup>.

Measures of loading distribution patterns with a smart insole could inform **EPWB protocols**. Underfoot loading distribution patterns, particularly on the medial surface of the foot, have been demonstrated to predict fracture healing time in people with lower extremity fractures<sup>53</sup>.

Significant differences in time to painless full weight bearing between high and low performers were shown. Early 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<sup>38</sup>.

As fracture care continues to evolve, we expect external weight-bearing monitoring devices to play a key role in **data collection and monitoring** of 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<sup>54</sup>.

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# The Application of Stride One for Selected Health Conditions



Currently, in people with **tibial plateau fracture** managed with ORIF a prolonged non-weight bearing protocol is often prescribed resulting in an increased risk of postoperative knee stiffness, nonunion or malunion, Range of Motion limitations, muscle atrophy and pain. Significant functional improvements such as better walking capacity and pain reduction are seen with early weight-bearing but surgeons and rehabilitation teams need tools for careful weight-bearing management<sup>55,56,57,58</sup>.

Stride One's precise audio feedback ensures safe and controlled progressive loading, critical for fracture healing and preventing re-injury. This may include the reduction of the non-weight bearing period with earlier mobilization based on reliable parameters. Visual feedback on correct movement and loading encourages patients to adhere to weight-bearing protocols, crucial for optimal healing. Real-time gait analysis helps identify and correct abnormal patterns, facilitating a quicker return to a normalized gait.

Currently, in people with **periprosthetic fracture fixation** (in the lower extremity) highly individualized, prolonged NWB/PWB, followed by very gradual progression to full weight-bearing is often required. Refracture can occur in multimorbid patients<sup>59,60</sup>. Extensive gait retraining with assistive devices is needed. This requires complex planning, rapid mobilization, and a precise weight-bearing control.

Stride One's real-time feedback is critical for managing the restricted WB protocols and ensuring safe, gradual loading on the compromised limb. A reduction of NWB periods is possible according to patient characteristics and surgery types. Objective analysis helps correct complex gait deviations and compensatory patterns resulting from prolonged immobilization and altered biomechanics. Objective progress tracking and motivational feedback are invaluable during the very long and challenging recovery periods. By ensuring proper loading and movement, Stride One can help prevent nonunion or malunion, re-fracture, or further implant loosening.

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# The Application of Stride One for Selected Health Conditions



In people with an **Open Reduction Internal Fixation (ORIF)** of the ankle prolonged non-weight bearing is often required but may result in non-healing, challenges with full pain-free Range of Motion, residual ankle pain, strength deficits and impaired proprioception. Surgeons need tools for safe and progressive early mobilization and weight-bearing management<sup>61,62,63</sup>.

Stride One's precise weight-bearing feedback ensures safe and controlled loading, critical for fracture healing and preventing re-injury. This may include the reduction of the non-weight bearing period with earlier mobilization based on reliable parameters. Real-time gait analysis helps identify and correct abnormal patterns, facilitating a quicker return to a normalized gait. Biofeedback-guided balance exercises enhance joint awareness and proprioception. Stride One provides quantitative data on weight-bearing, gait parameters, and functional strength, enabling surgeons to make data-driven decisions on progression and return to activity.

In people managed with **High Tibial Osteotomy (HTO) / Distal Femoral Osteotomy (DFO)** often prolonged NWB/PWB followed by gradual progression is needed, and extensive gait retraining once weight-bearing is allowed. However, malunion or nonunion (1-3%), incomplete correction and a lack of knee Range of Motion (extension) may occur; safe weight-bearing biofeedback training may reduce a prolonged non-weight-bearing period and risk of reoperation<sup>64,45,66</sup>.

Stride One's precise feedback is invaluable for managing the critical NWB/PWB phases and ensuring safe, progressive loading. Real-time gait analysis helps correct complex gait deviations and compensatory patterns developed after prolonged immobilization and new alignment. Long recovery periods benefit greatly from objective progress tracking and motivational feedback.

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# The Application of Stride One for Selected Health Conditions



In **cartilage repair** (e.g. microfracture, Autologous Chondrocyte Implantation (ACI), and Osteochondral Autograft Transfer System (OATS)) strict weight-bearing restrictions are used: safe and progressive weight-bearing is essential for protecting healing tissue from load/shear forces<sup>67</sup>.

Stride One's accurate feedback is crucial for adhering to strict NWB/PWB protocols and ensuring optimal, gradual loading to protect the delicate cartilage repair. By guiding precise loading and movement, Stride One can help prevent re-injury or failure of the cartilage repair.

Biofeedback helps patients perform exercises within safe ranges and with appropriate load, preventing shear forces that could damage the repair. Visual progress and objective data can motivate patients through the often very slow and restrictive early rehabilitation phases.

Stride One provides surgeons with quantitative data on patient compliance with weight-bearing restrictions, crucial for optimal cartilage healing.

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Stride One is a Class I medical device certified under the Medical Device Directive 93/42/EEC. It conforms to applicable EU safety and performance requirements and bears the CE mark. This certification applies solely to the product's current intended use and classification under MDD. Stride One is intended to support post-operative rehabilitation following lower-limb orthopedic procedures. It is not intended to replace clinical judgment, professional physiotherapy, or prescribed rehabilitation protocols. Use should be advised by a healthcare professional. Clinical decisions should be based on the full clinical context, including patient-specific factors and professional expertise. Patient selection, rehabilitation protocols, and monitoring remain the sole responsibility of the treating healthcare provider. The device is currently undergoing further clinical validation. Ceriter makes no claims regarding treatment outcomes or specific levels of efficacy beyond the scope of its certified use.

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