

Validation of Partial Weight-Bearing estimator using instrumented crutches

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1. INTRODUCTION

Incremental weight-bearing is common during post-surgery gait rehabilitation minimize implant failures and enhance healing of the soft tissue. The Partial Weight-Bearing (PWB) method involves gradually increasing the weight load on the limb over time, a process that is tailored to each patient based on the severity of their injury and the clinician's discretion. [1], [2]. Walking aids, such as crutches, can help reduce instability and they are typically prescribed to support weight-bearing on the affected weak lower extremity [3]. In the course of rehabilitation, physiotherapists typically offer prompt feedback to patients on their posture, load, and step sequence, based on their perception and experience. Consequently, the outcome is contingent on the therapist's proficiency, and the patient's progress is assessed subjectively by the therapist [4]. Multiple studies have indicated that patients generally fail to comply adequately with lower extremity partial weight-bearing protocols [5]–[8]. To verify compliance with the rehabilitation goals, force platforms and motion capture systems are commonly used to extract kinematics and kinetics information of the gait also when performed with walking aids. Even if gait laboratories could perform highly accurate measurements [9], some limitations must be considered in clinical applications: they are expensive to set up and operate [10]; patients may need to travel to a specialized gait laboratory, and this can be challenging for individuals who have limited mobility; the controlled environment of the laboratory may be a rough simulation of a patient's real-life walking patterns; and the test takes place over a relatively short period of time [11]. Recently, numerous wearable technologies have emerged with the objective of facilitating gait analysis in non-laboratory settings. Several instrumented insoles are employed to gather data during daily activities, and while many of these devices allow for real-time data acquisition, they generally require preliminary calibration to ensure accurate measurement of forces [10], [12], [13], [14], [15]. Several research groups have created instrumented crutches because they allow the estimation of the patient's performance during walking and provide feedback to improve rehabilitation [14]–[20]. In [15], [16] vibratory and audio feedback was added to inform the user of overloading or underloading, and in [21], patients showed higher compliance to the rehabilitation goals when audio feedback was provided.

In this paper, we provide a preliminary methodological validation of an estimator of the partial weight-bearing of the lower limbs during a walk with instrumented crutches. The estimate was provided by a pair of instrumented crutches to measure the ground reaction forces along their principal axis, and the forces were acquired and processed in real-time [16]–[18], [23], [24]. The system is validated on six healthy subjects, and since the estimation of the load on the lower limbs during partial weight-bearing is affected by dynamics factors ignored by the model, the tests were performed varying the walking cadence and the load on the crutches. Two force platforms by BTS were used to collect the reference values of the leg load. Since neurological conditions, orthopedic problems, and medical conditions could lead to alterations in gait behaviour [22], this preliminary validation aimed to promote future investigations to confirm and reinforce the method by expanding the sample size and including impairments.

2. MATERIAL AND METHODS

2.1. Experimental Set-Up

The instrumented crutches, shown in Figure 1, measure the force exerted along their principal axis and the crutch's orientation during assisted walking. They are a new version of the previously developed instrumented crutches [17], [18], [20][21], [26]. A Raspberry PI 3 B+ controls the data acquisition from the strain gauge bridges fixed close to the tip, and the crutch's orientation is obtained by an inertial measurement unit. Data are shared wirelessly in a ROS network [23], and a PC under the same network collects them. The force is measured at 60 Hz in a range from 0 to 600 N with 6 N of measurement

uncertainty ($P = 95\%$) [17]. The total mass of a single crutch, including the acquisition board and the power unit attached close to the handle, is about 1 kg.

In addition to the instrumented crutches, the experimental configuration comprised two force plates from BTS Bioengineering, which were utilized to gauge the ground reaction force of each foot. Furthermore, a marker-based motion capture system from Vicon Motion Systems, comprising eight cameras, was deployed to capture the subject's kinematics. The sampling frequencies were different for the three systems: the force plates acquired data at 1 kHz, the motion-capture system acquired data at 100 Hz, and the crutches acquired data at 60 Hz, so a resampling procedure was required before starting data processing. The Vicon Full Body Plug-In Gait model was used for the placement of the markers on the subject's body [24].

A custom-made trigger box was used for data synchronization between the motion capture system, the force platforms, and the instrumented crutches [25]. The internal clock of the trigger box was synchronized with the same NTP server as that used for the instrumented crutches, and when it received a starting trigger from the mocap system, it published its timestamp through the ROS network. The published timestamp was then associated with the first sample of the motion capture system and the force plates. The crutches were already synchronized with the NTP server, and they saved their timestamp labels.

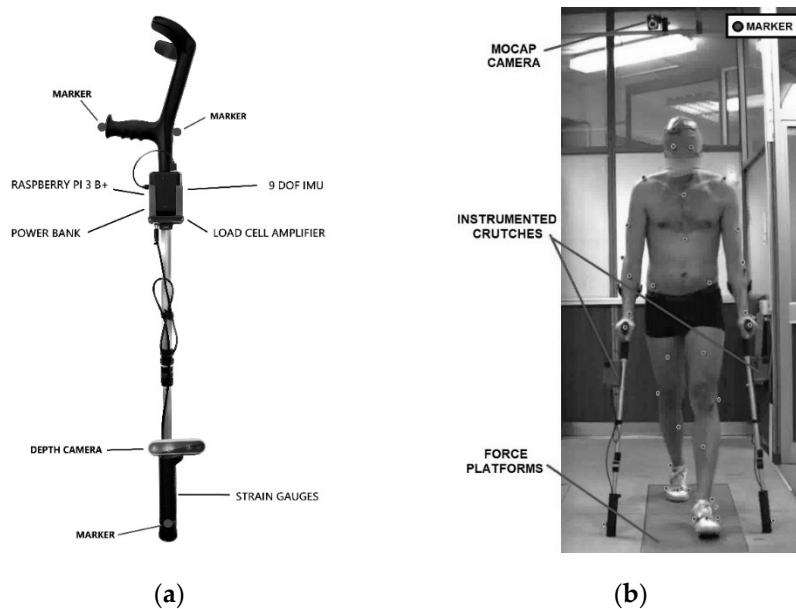


Figure 1. (a) Instrumented crutches and marker placement; (b) subject walking with instrumented crutches during validation. Red dots highlight the visible markers from the frontal point of view.

2.2. Experimental Protocol

As the model that determined the PWB from crutches' forces disregarded the impact of gait dynamics, the protocol incorporated three distinct pacing conditions for walking, namely normal or preferred rhythm, as well as slow and fast cadence rhythms. A metronome was employed to assist subjects in maintaining a pace of either 50 or 90 steps per minute, with the aim of encompassing reasonable cadence ranges for walking with crutches [26], [27]. Subjects were asked to walk using the 2-point contralateral pattern, and then the tests were repeated with the 3-point partial weight-bearing (3-point PWB) walking pattern [28]. Finally, in order to achieve weight-bearing values on the lower limbs that are consistent with those typically prescribed by clinicians, the subjects were required to load 20% or 40% of their body weight onto the crutch. In this way, during the 2-point contralateral pattern, the PWB

should range between 60–80%BW, and during the 3-point PWB pattern, it should range between 20–60%BW. Prior to the tests, the subjects underwent a training session lasting approximately 10 minutes to familiarize themselves with walking patterns, cadences, and crutch loads.

The experimental protocol was applied to 6 subjects, 5 male and 1 female with a weight of 78 ± 12 kg, a height of 1.77 ± 0.03 m, and an age of 38 ± 12 years old (mean \pm STD). Since at this stage, we were interested in the validation of the proposed approach and not in clinical validation, we performed the tests on healthy subjects only. The study was conducted in accordance with the Declaration of Helsinki, and informed consent was obtained from all subjects involved.

2.3. Partial Weight-Bearing Estimation and Validation

Since during assisted walking, the external forces applied to the subject are the ground reaction forces on the feet and on the crutches, the authors believed that the load supported by the user's lower limbs could be approximated by subtracting the left crutch force (LCF) and the right crutch force (RCF) from the total subject body's weight (BW), which is the sum of the instrumented crutches' weight and the user's weight. The load is then normalized and expressed as a percentage of the total subject's weight:

$$PWB = \frac{TW - LCF - RCF}{BW} \quad (1)$$

The reference values are obtained from the sum of the left platform force (LPF) and the right platform force (RPF), normalized by the total subject's weight:

$$\widehat{PWB} = \frac{LPF + RPF}{BW} \quad (2)$$

The difference between the two values is considered the error:

$$ERROR = PWB - \widehat{PWB} \quad (3)$$

The error was calculated during the steps on the force platforms when all the external forces were known, and the validation intervals were obtained from the gait events recorded by the motion capture. The valid interval started after the last toe-off event outside the force platforms, shown in Figure 2a, and it ended at the first heel contact outside the force platforms, as shown in Figure 2c. The gait cycle was then divided into single and double support; Figure 2b shows the double support phase starting from the first heel contact on the force plate and ending at the next toe-off. Figure 2d shows the PWB estimated by the instrumented crutches compared with the reference during the gait cycle. The root-mean-square error (RMSE) was used to measure the difference between the values predicted by the estimator and the values observed. The mean error (ME) was used to measure the systematic bias since the RMSE included both stochastic and systematic errors.

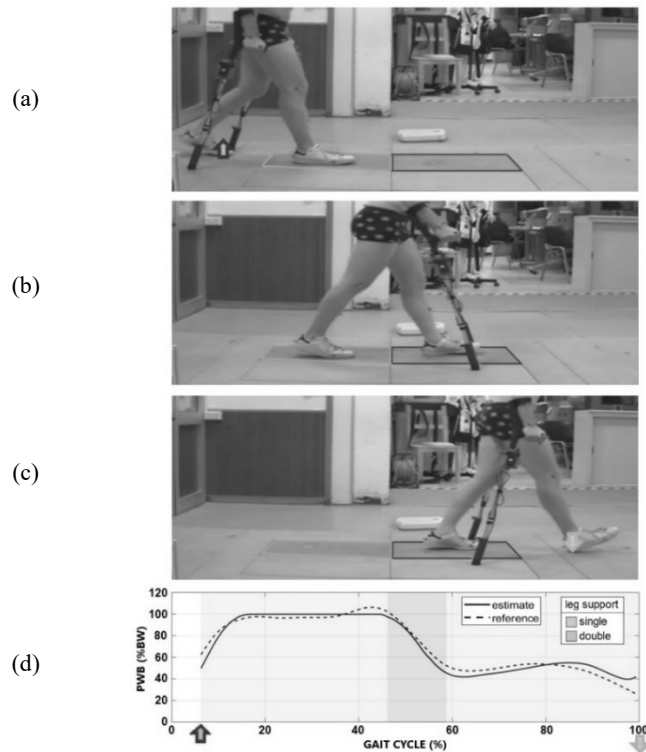


Figure 2. (a) The gait event at the start of the interval for the validation of the PWB. The single support phase of the right leg started from this event until the next left foot's heel contact. (b) The double leg support phase with all external forces measured.

The Guide to the Expression of Uncertainty in Measurement is applied to the PWB estimate with all the parameters used in the analytical formula of the measurand, along with their associated uncertainties. The following parameters are used in the analytical formula of the measurand:

1. The subject's body mass: since the crutches could be used in clinics or domestic environments where body mass is measured with domestic scales, the associated uncertainty is obtained from [33] that analysed the mean and standard deviation of domestic scales. The standard uncertainty is equal to 1.1 kg.
2. The crutch load: the crutches are calibrated using force plates and the standard uncertainty obtained is 3 N.
3. The crutch mass: each instrumented crutch weighs 0.950 kg. A standard uncertainty of 0.05 kg is considered due to manufacturing differences.

The standard uncertainty is calculated by combining all the individual sources of uncertainty using the law of propagation of uncertainty once all the parameters and their associated uncertainties are identified. The uncertainty propagation is then repeated for some of the possible combinations of the subject's body mass (40, 80, and 120 kg) and the crutches' loads (2.5, 12.5, 20.0, 37.5, and 47.5 %BW). As shown in Figure 3a, lower values of PWB have higher standard uncertainty and it also depends on the subject's body mass. Both the subject's body mass and the crutch load increase their uncertainty magnification [29] with lower values of PWB, as reported in Figure 3b, while the percentage contribution of the body mass is predominant, as shown in Figure 3c. When the load on the crutches is lower, which means higher PWB values, the contribution of the crutch load uncertainty increases up to 50% for both crutches measurements.

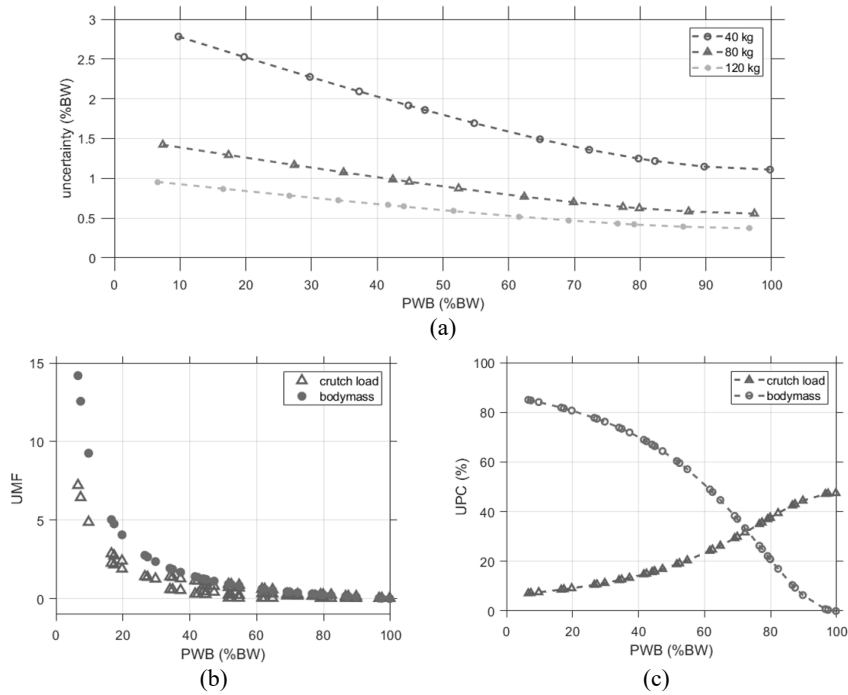


Figure 3. a) Uncertainty of the PWB estimate with respect to the PWB value. b) Uncertainty Magnification Factor of the subject's body mass and the crutch force measurement. c) Uncertainty Percentage Contribution of the subject's body mass and the crutch force measurement.

3. RESULTS AND DISCUSSION

A sensitivity analysis was performed using ANOVA outcomes in Tables 2 and 3 indicating that the error was markedly affected by both cadence and leg support. A faster walking speed resulted in a greater contribution to inertia, and double-leg support encompassing the toe-off and heel contact phases generated greater accelerations than the midstance phases. When the cadence was about 90 steps/min, the RMSEs reached more than twice the value reached walking at 50 steps/min in all the parameter combinations, as shown in Figure 4. Moreover, the double-support condition was more affected by a high systematic error than the single support, as highlighted by the boxplots in Figure 5. The highest RMSE value is observed during double-support walking at a speed of 90 steps/min, and this can be explained by the contribution of the mean error in this combination, indicating a systematic bias in the measurement. Hence, it can be inferred that real-time measurements are comparatively more reliable at lower walking cadences and speeds, which are commonly observed during the initial stages of rehabilitation. Typically, assisted walking with crutches involves cadence values of around [26], [27]. The PWB's reference, estimate, and error are shown with respect to the time on the left and with respect to the gait cycle on the right in Figure 6. The data are compared during the 3-point PWB gait pattern and the cadence on the left and the crutch load on the right; moreover, the double-leg support is shown in the background. In the three-point PWB gait pattern, the PWB estimation during the single support of the unaffected limb was not useful for rehabilitation purposes, and the crutches were lifted from the ground most of the time with saturation at 100%BW of the prediction. As shown in Figure 6, the unaffected limb single-support was in the interval before the double support for the three-point PWB pattern, and the errors reached the highest positive values. If only the affected limb single-support interval was considered during three-point PWB walking in all the other conditions, the RMSE was about 6.8%BW and the ME was 1.3%BW, and as shown by the boxplots in Figure 7, the RMSE was not influenced by the crutch load but only by the cadence.

Table 1. ANOVA of the PWB's RMSE.

Parameter	Sum of Squares	Degrees of Freedom	Mean Squares	F	p-Value
Cadence	4242	1	4242	264	<0.05
Crutch load	345	1	345	21	<0.05
Pattern	13	1	13	1	0.36
Subject	860	5	172	11	<0.05
Support	811	1	811	50	<0.05
Error	4113	256	16		
Total	10,624	265			

Table 2. ANOVA of the PWB's ME.

Parameter	Sum of Squares	Degrees of Freedom	Mean Squares	F	p-Value
Cadence	1346	1	1346	46	<0.05
Crutch load	361	1	361	12	<0.05
Pattern	37	1	37	1	0.26
Subject	1336	5	267	9	<0.05
Support	10,177	1	10,177	348	<0.05
Error	7471	256	29		
Total	20,961	265			

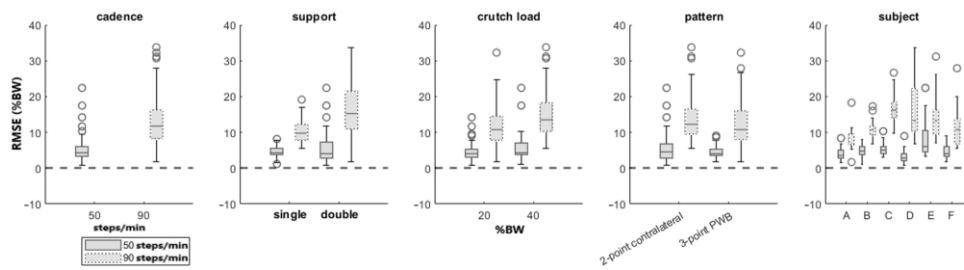


Figure 4. Boxplots of the PWB's RMSE.

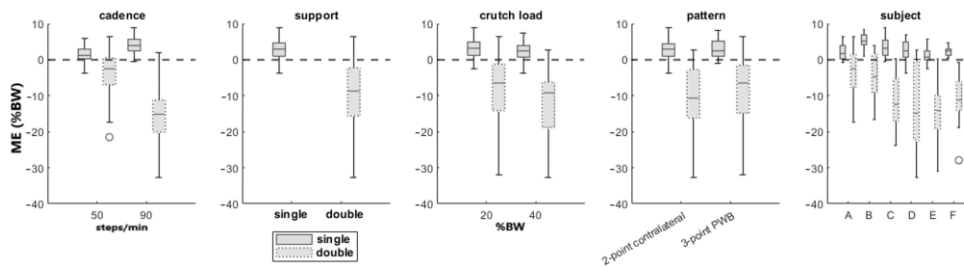


Figure 5. Boxplots of the PWB's ME.

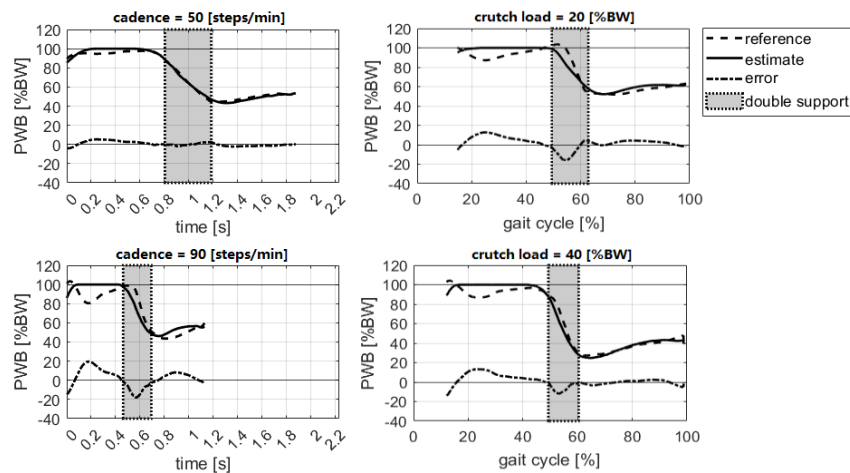


Figure 6. Comparison between the mean of the estimated PWB and the reference of the 3-point PWB walking pattern test. The effect of the cadence is shown on the left while the effect of the crutch load is shown on the right side.

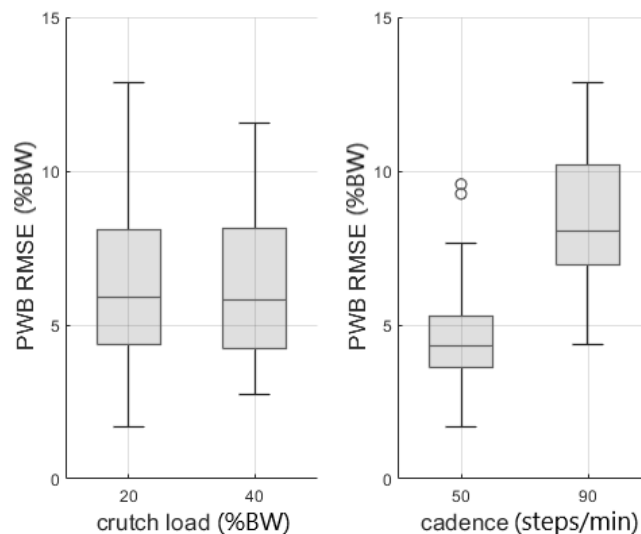


Figure 7. PWB's RMSE boxplots in the single-support phase of the affected limb.

4. CONCLUSIONS

The primary objective of this study was to conduct a preliminary methodological investigation on the effectiveness of using instrumented crutches to estimate load on the legs. Although the inclusion of a larger sample size with a more balanced distribution of genders could have produced more generalizable outcomes, this preliminary study yielded promising results that established the validity and efficacy of the load estimator system. Future studies should encompass a larger participant cohort and ensure adequate gender representation to validate and reinforce the preliminary findings. In addition, it is advised that future investigations should encompass diverse walking conditions, such as different speed ranges, inclines, and terrain types, to validate the accuracy and effectiveness of the load estimator system. Based on the outcomes obtained, it can be inferred that cadence has a more pronounced effect on the PWB estimation and therefore necessitates further investigation.

Conversely, the crutch load could be either self-selected by the subject or indicated by the therapist, as it has a comparatively lesser impact. Additionally, it is recommended to test the estimator with various impairments, as deviations in gait patterns may alter the predictions.

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