

A preliminary analysis of gait performance of patients with multiple sclerosis using a sensorized crutch tip

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Abstract: The quality of life and functional mobility of patients with Multiple Sclerosis (MS) can significantly improve with exercise and a rehabilitation therapy adjusted to the needs of each patient. The assessment of gait and functional mobility of patients with MS is usually done based on clinical scales and tests, which have various limitations. This work presents the preliminary results of a clinical study carried out with patients with MS walking with a sensorized crutch tip. This tip allows to define new indicators that can be correlated with the clinical assessment scales and provide further objective and quantitative information to assess gait performance and level of impairment of patients with MS, and characterize their gait patterns. The results suggest that parameters such as the average cycle time and the average percentage of body weight might be useful to evaluate the gait performance and level of disability. Moreover, parameters related with the pitch angle of the crutch allow to determine crutch usage patterns and spot differences between patients with similar functional performance.

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1. INTRODUCTION

Multiple Sclerosis (MS) is one of the main causes of nontraumatic neurologic disability in young adults . With more than 2.3 million people suffering from this disease, MS has a big impact in society [WHO (2006)]. Currently, MS does not have a cure and the treatment focuses on the prevention of new attacks, alleviating the symptoms, and maintaining walking capabilities and motor function. Exercise and physiotherapy have been found to be useful to achieve significant improvements in the quality of life and functional mobility of patients with MS [Henze et al. (2006)]. Evidence has shown that exercise has beneficial effects on balance, mobility, muscle weakness, depression and fatigue [Flachenecker (2015)].

However, in order to achieve the best outcome of the rehabilitation therapy based on exercise, it has to be adapted to the capabilities of each patient [Flachenecker (2015)]. Therefore, it is essential to make an assessment of the functional deficits of each patient. In particular, gait assessment provides important information, as one of the main goals of the therapy is to maintain motor function capabilities.

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Clinical evaluation of each MS patient is a thorough task, in which clinical tests or scales such as the Expanded Disability Status Scale (EDSS), the Multiple Sclerosis Functional Composite (MSFC) or the 10 Meter Walk Test (10MWT) are used to assess gait and functional mobility [Meyer-Moock et al. (2014)]. However, patients with MS usually present high inter-subject variability, even for patients within the same scale values. Moreover, the evaluation of the level of impairment of the patient is usually carried out within a particular day in a clinical setting, and do not consider daily life activities [Bove et al. (2019)].

In order to provide objective, accurate and quantitative data to perform the gait analysis of patients with MS, three main technological approaches have been proposed in the literature: instrumented walkways, Motion Capture Systems and accelerometry.

Instrumented walkways are pressure-sensitive mats such as the GAITRite [McDonough et al. (2001)] or systems based on a transmitter bar and a receiver bar composed of a set of infrared LEDs, such as the OptoGait [Healy et al. (2019)]. These systems are portable, easy to use, accurate and relatively affordable, but they do not provide information about the orientation of the body.

Motion Capture Systems are able to capture the 3D motion of each body segment at high frequencies and accurately [Kim and Eng (2004)]. However, they are expensive,

require a long time for calibration and post-processing and their capture range is usually limited to a few meters [Tunca et al. (2017)].

Finally, accelerometry is based on the use of small motion sensors (usually Inertial Measurement Units-IMUs) to monitor the motion of different body limbs [Tunca et al. (2017)]. This technique is very popular due to the small size and reduced price of wearable sensors. In addition, they allow monitoring in different environments for a long time [Park and Jayaraman (2003)].

In recent years, various researchers have developed prototypes of crutches and canes with integrated motion sensors [Sardini et al. (2015); Tsuda et al. (2012); Wade et al. (2019); Mekki et al. (2017)]. These devices are non-invasive and allow conducting gait monitoring and assessment of gait performance of those patients who require assistive devices for walking. In addition to gait monitoring, some authors have even combined instrumented canes with automatic control to actively assist people who need a walking aid [Wakita et al. (2013)]. However, an objective, quantitative and accurate gait monitoring is essential for a good control.

Different parameters have been defined by each research group focusing on gait monitoring using a crutch or cane. For example, Mekki et al. (2017) proposed the stride time, the pitch angle of the cane and the axial force on the cane as potential parameters to detect and predict the freezing of gait in patients with Parkinson; Wade et al. (2019) showed that both the standard deviation of the angular velocity about the y -axis and the mean roll angle of the cane were significantly associated with the functional gait assessment score, and they might be used to assess fall risk; Simic et al. (2011) used the peak body weight support (BWS) and the BWS impulse to monitor knee adduction moment in patients with osteoarthritis; and Sprint et al. (2016) compared parameters such as the gait cycle and the stance percentage to monitor assisted gait in patients that had suffered a stroke. The selected set of indicators is related to the disease that is analyzed. In fact, no work has proposed specific indicators for patients with MS.

In this work, a preliminary analysis is carried out in patients with MS using a sensorized crutch tip. The tip can be adapted to any crutch or cane, and integrates a set of low-cost sensors that can be used to measure the applied force on the crutch and to estimate the crutch pitch angle. The main contribution of this work is to show the results of using a set of objective and quantitative indicators to assess gait performance and level of impairment of patients with MS, as well as to determine crutch usage patterns.

The rest of the paper is organized as follows: in Section 2, the crutch prototype and the pitch angle estimation algorithm are briefly presented; in Section 3, the experimental setup and the selected parameters are described; in Section 4, the preliminary experimental results and their discussion are explained; and finally, in Section 5, the most relevant conclusions and the lines for future work are presented.

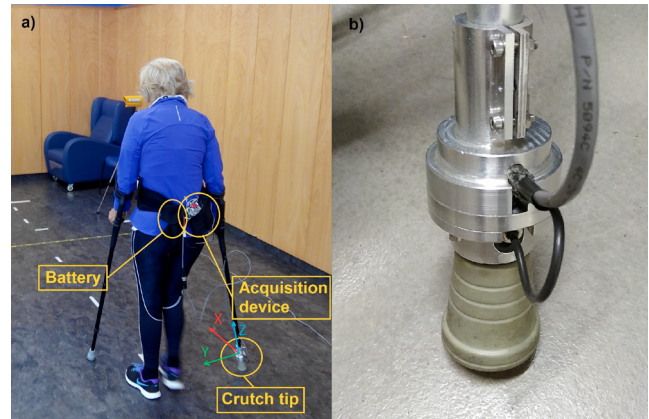


Fig. 1. Prototype of the instrumented crutch tip system.
a) Overview of the system b) Close look at the tip

2. INSTRUMENTED TIP PROTOTYPE

The instrumented tip prototype and its estimation algorithm are detailed in Sesar et al. (2019), where its measurement capability was analyzed and experimentally validated. In this section, for the sake of clarity, a brief summary is presented.

2.1 Structure and Integrated Sensors

The instrumented crutch tip prototype implements a piezoelectric force sensor, a 2-axes inclinometer and a low cost 6 degrees-of-freedom IMU that integrates a 3-axis gyroscope and a 3-axis accelerometer. These sensors are housed in the aluminium structure of the tip (Fig. 1), which also includes a Printed Circuit Board (PCB) with the required electronics for signal conditioning. The tip was designed to be easily adjustable to different standard crutch or cane diameters, while minimizing its weight (240 g) and size (84 mm long and 51 mm diameter).

A cable transmits the signals from these sensors to a data acquisition device, which, together with the battery, is attached to the body trunk with a belt, in order to minimize the weight of the crutch tip. Figure 1 shows a picture of a patient using the developed prototype and the details of the crutch tip. The local reference system of the crutch tip is defined with the z -axis aligned with the longitudinal axis of the crutch rod, the x -axis aligned with the longitudinal axis of the hand grip of the crutch and the y -axis accordingly, in order to create a right-hand reference system.

After applying a pre-load, the crutch tip is able to measure longitudinal forces between 0 and 500 N with an RMS error below 9 N. In addition, it can withstand sudden impacts against the ground and compression forces of up to 1200 N. Moreover, it can measure static inclinations with a non-linearity under 0.8 degrees and angular velocities of up to $\pm 500^\circ/\text{s}$ with a small dynamic error. On the other hand, the acquisition system is designed to capture the force, inclination, angular velocity and linear acceleration data from the internal sensors of the sensorized tip at a sampling rate of 100Hz. These data are stored in the internal memory of the acquisition device and can be downloaded to a computer for processing using WiFi.

2.2 Pitch angle estimation algorithm

While the force sensor provides direct measurement of the body weight applied on the crutch, the motion of the crutch is defined mainly by the amplitude of the angle of the crutch with respect to its frontal plane. This is estimated by measuring the rotation around the y -axis of the crutch (i.e. pitch angle).

However, measuring the pitch angle is not a trivial task. The integrated sensors present some limitations: the measurements of the inclinometer are significantly altered by impacts and nongravitational accelerations [Sardini et al. (2015)], and the gyroscope introduces a drift, which can be high in low cost IMUs [Tsuda et al. (2012)].

In order to overcome these limitations and obtain an accurate estimation of the pitch angle that allows defining the crutch motion, a novel sensor fusion algorithm was proposed and validated in Sesar et al. (2019). In contrast to the algorithms based on the traditional Kalman filter, the angle estimated by this algorithm is not affected by non-gravitational accelerations during the swing phase or by the impacts against the ground. This algorithm combines the force measurement on the z -axis of the crutch; the angular velocity measurement on the y -axis, given by the gyroscope; and the inclination measurement on the y -axis, given by the inclinometer, as shown in Fig. 1. The procedure is briefly summarized in Fig. 2.

The first step is to determine the limits between the stance phase (when the crutch is in contact with the ground) and swing phase (when the crutch is not in contact with the ground) in each cycle of the movement of the crutch. For that purpose, a limit in the force value is used. If the current time instant does not correspond to the end of a stance phase, the algorithm performs a discrete integration of the gyroscope signal u_k with time step T_s (Fig. 2, Step 1), in order to estimate the pitch angle x_k ,

$$x_k = x_{k-1} + \frac{T_s}{2} (u_k + u_{k-1}) \quad (1)$$

If the current time step corresponds to the end of a stance phase, the algorithm corrects the drift of the gyroscope, using the measurements provided by the inclinometer during the last cycle. The inclinometer signal suffers disturbances due to the dynamics of the swing phase and the impacts, but it is more accurate in the middle of the stance phase. For this reason, the algorithm calculates the mean of the inclinometer measurements in the last stance phase and integrates the gyroscope signal from that point (Fig. 2, Step 2), obtaining a corrected x'_k :

$$x'_t = x'_{t-1} + \frac{T_s}{3} (u_{t-1} + u_t + u_{t+1}) \quad (2)$$

$$t = m + 1, m + 2, \dots, k$$

After correcting the gyroscope drift, the algorithm continues integrating the gyroscope signal by applying Eq. 1, until the end of the next stance phase (Fig. 2, Step 3).

This approach assumes that the angular velocities around the global vertical axis are negligible, but it was observed that this assumption is generally acceptable when healthy

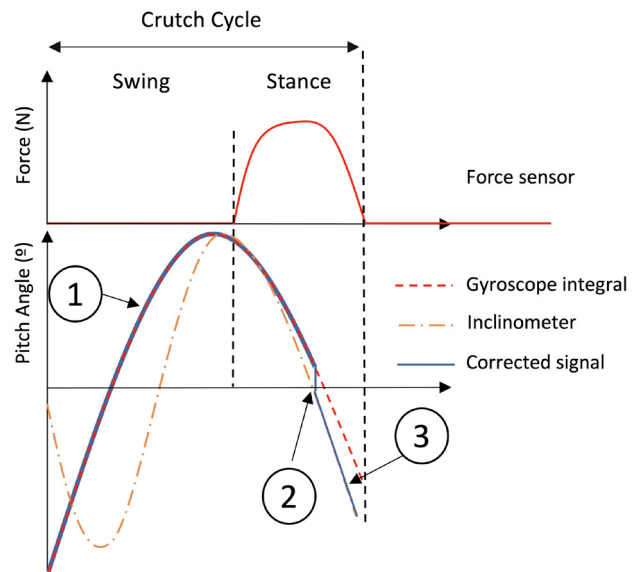


Fig. 2. Simplified interpretation of the Sensor Fusion Algorithm

participants walk with the instrumented crutch following a straight line. In addition, it was observed that the misalignment between the x -axis of the crutch and the sagittal axis of the subjects was small, so the pitch angle of the crutch was similar to the anteroposterior angle (i.e. angle of rotation around the frontal axis of the subject).

3. EXPERIMENTAL SETUP AND METHODS

This section explains the experimental protocol that was followed in the trials with patients with MS. In addition, the data processing procedure and the parameters selected for assessing movement quality are described.

3.1 Trial methodology

The trials with patients with MS were conducted in the facilities of ADEMBI (Multiple Sclerosis Association of Biscay) and approved by the Ethics Committee of Clinical Research of the Basque Country (CEIm) with Approval Code PS2018017.

In order to select the appropriate patients with MS, the Expanded Disability Status Scale (EDSS) was used. The EDSS is a traditional clinical scale used to assess the disability of patients with MS and it ranges from 0 (no disability) to 10 (dead) [Kurtzke (1983)]. The determination of EDSS scores between 4 and 7 heavily depends on aspects of walking ability. This way, patients with a score of 6 or 6.5 need the help of a crutch or cane to walk, but they can walk 100 meters or more. However, patients with a score of 7 or higher are unable to walk more than a few steps, even with assistive devices.

A set of four patients with EDSS scores higher or equal to 6 were selected for this preliminary analysis, whose characteristics are summarized in Table 1. The first column shows the weight of the patients on the day of the experiments, the second presents the EDSS score and the third one indicates the number of crutches used in the trial.

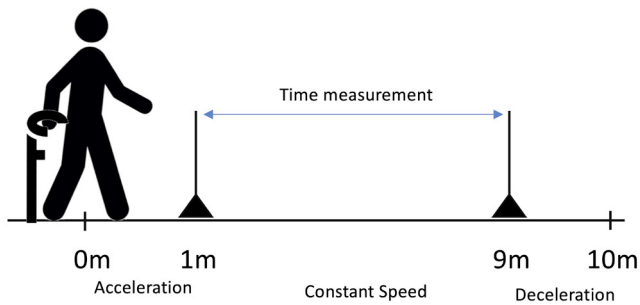


Fig. 3. 10-Meter Walk Test (10MWT) setup

The selected test was the 10-Meter Walk Test (10MWT). This is a standard clinical test frequently used to measure the walking capability of patients. In addition, various studies have shown that it has validity and an excellent reliability in many conditions and with different populations with neuromuscular diseases [Tyson and Connell (2009)].

In order to execute the test, a 10 meter walkway was marked on the floor and a pair of photocells were placed at 1 m and at 9 m from the start line. The photocells were placed at the height of the body trunk and the walking speed was calculated based on the time elapsed between both photocell gates, allowing the first and last meters in the 10 meter walkway for acceleration and deceleration. The experimental setup is summarized in Fig.3.

Prior to the test, the sensorized tip was attached to the assistive device of each patient. Then, patients were asked to stand behind the start line and, when the therapist indicated, walk at their normal and comfortable pace and stop after the 10 meter line. During the test, the average speed was estimated from the times recorded by the photocells, while the sensorized tip captured the force and inclination data. Each patient performed this trial twice, except for patient 4, who was too tired to repeat the experiment due to his condition (EDSS score 7.5). For this case, in which the patient used two crutches, the sensorized tip was attached to the crutch used by the dominant hand.

3.2 Selected indicators

The 10MWT only considers the mean speed in the central interval to evaluate the gait performance. However, other parameters can be defined and calculated based on the information provided by the sensors integrated in the instrumented crutch. The hypothesis behind this work is that these additional parameters might provide further objective and quantitative information about how the subject is using the crutch and what is the level of impairment of the patient.

Table 1. Characteristics of the selected patients with MS

	Weight (Kg)	EDSS	Number of crutches
Patient 1	77.8	6	1 crutch
Patient 2	83.7	6	1 crutch
Patient 3	62.8	6.5	1 crutch
Patient 4	63.3	7.5	2 crutches

The following set of parameters was defined by the authors based on their clinical experience and on the literature review:

- Average speed [Tyson and Connell (2009)]: for this calculation, the time instants at which the body trunk crosses the lines are taken as a reference.
- Number of cycles [Sprint et al. (2016)]: the number of crutch cycles (swing/stance phases) observed in the force sensor signal as per Fig. 2.
- Average of the Maxima of Percentage of the Body Weight (avg max PBW) [Routson et al. (2016); Simic et al. (2011)]: for each crutch cycle, the maximum applied force on the crutch is measured and expressed in percentage with respect to the body weight of each patient. This indicator is the mean of the values associated to all cycles.
- Average Percentage of the Body Weight (avg PBW) [Simic et al. (2011)]: for each crutch stance phase, the average force applied on the crutch is calculated and expressed in percentage with respect to the body weight of each patient. The indicator is the mean of the values associated to all cycles.
- Average of peak to peak time (avg PPT): for each two consecutive cycles, the time from a maximum force value to the next one is calculated, and the average of all these values is computed.
- Average cycle time [Sprint et al. (2016)]: it is the mean of the times between the starts of two consecutive stance phases.
- Average Stance Phase Time (avg SPT) [Mekki et al. (2017)]: for each cycle, the time of the stance phase is measured, and the mean of all cycles is calculated.
- Average Stance Phase Percentage (avg SPP) [Sprint et al. (2016)]: for each cycle, the time of the stance phase is measured and compared with the measured cycle time, calculating the relative percentage of the stance phase with respect with the whole cycle. The mean of all cycles gives the value of this indicator.
- Mean pitch angle at force maximum (avg PAFM): it is the mean of the pitch angles at the time instants corresponding to the maximum value of the force sensor signal at each stance phase. This angle is estimated with the algorithm described in subsection 2.2.
- Mean pitch angle at initial contact (avg PAIC): it is the mean of the pitch angles at the start of the stance phases.
- Mean pitch angle at terminal contact (avg PATC): it is the mean of the pitch angles at the end of the stance phases.
- Mean stance pitch angle (avg SPA) [Wade et al. (2019)]: it is the mean of the pitch angles at all time instants of the crutch stance phase.
- Mean of pitch angle amplitude (avg PAA) [Culmer et al. (2014)]: it is the mean of the differences between the angles at the ends of the stance phases and the angles at the starts of the stance phases.

4. RESULTS AND DISCUSSION

In this section, results from the test defined in the previous section will be detailed and analyzed. Table 2 shows the results obtained from the data recorded with the patients.

Note that for the patients who did the experiment twice, the mean values of the two repetitions are presented.

Table 2. Summary of indicators for patients with MS.

Patient	1	2	3	4
EDSS	6	6	6.5	7.5
Avg. speed (m/s)	0.695	0.646	0.523	0.147
Number of cycles	8	8	8	24
Avg. Max PBW (%)	14.0	13.7	27.6	45.1
Avg. PBW(%)	8.4	8.2	20.4	27.3
Avg. PPT (s)	1.47	1.51	1.82	2.25
Avg. cycle time (s)	1.48	1.53	1.94	2.25
Avg. SPT (s)	0.81	0.87	1.29	1.60
Avg. SPP (%)	54.4	56.6	66.9	71.4
Avg. PAFM (°)	-7.73	-16.22	-3.11	-2.17
Avg. PAIC (°)	-16.37	-21.02	-16.02	-14.52
Avg. PATC (°)	4.91	-3.33	3.17	-3.89
Avg. SPA (°)	-4.71	-14.28	-3.7	-7.82
Avg. PAA (°)	21.27	17.68	19.2	10.63

First, the correlation between the EDSS score and the set of parameters defined in the previous section has been analyzed, which are summarized in Table 3. From the data, it can be observed that those parameters related to the motion speed of the patient, this is the average speed, the number of cycles, the average cycle time and the average peak to peak time (PPT) are highly correlated with the EDSS score. These results suggest that the higher the EDSS score is, the lower will be the functional mobility of the patients and they will walk slower, they will need more steps, and they will need more time to complete each step. In addition, the mean pitch angle amplitude (PAA) is moderately correlated with the EDSS score, which suggests that the angular range of the crutch will be smaller and the steps will be shorter for higher scores.

A second set of indicators related with the load or weight applied on the crutch is highly correlated with the EDSS score: the average of the maxima of PBW and the average PBW during stance phases. This means that the higher the EDSS score is, the greater will be the force applied on the crutch. Note that patient 4 walks with 2 crutches, but only the load applied on one crutch was measured. Hence, even higher values will be expected on these parameters, if a symmetrical crutch load configuration is considered. Moreover, the force will be applied for a longer time in each cycle for higher EDSS scores, since the average SPT and the average SPP are also correlated with the EDSS score.

Table 3. Indicators with best correlation with EDSS score

Indicator	R ²	Indicator	R ²
Avg. Speed	0.8414	Avg. Max. PBW	0.9734
Nr. of cycles	0.8854	Avg. PBW	0.8613
Avg. cycle time	0.91	Avg. SPP	0.7761
Avg. PPT	0.9616	Avg. SPT	0.8859
Avg. PAA	0.6251		

The rest of parameters detailed in subsection 3.2 (the ones related with the values of the pitch angle at initial, maximum and terminal contact points, i.e., PAIC, PAFM and PATC) were not significantly associated with the EDSS, but they provide insightful information about the use of

the crutch and they can reveal differences between patients with the same EDSS score. This might be important to characterize gait and provide further information about the status of the patient.

For instance, looking at the values of mean PAIC and mean PATC in table 2, it can be seen that patient 2 supports on the crutch only when its pitch angle has negative values, while patient 1 starts the stance phase with a negative pitch angle (crutch tip in front of the body) and finishes it with a positive pitch angle (crutch tip behind the body). Consequently, the mean SPA is greater (more negative) for patient 2 than for patient 1. In addition, patient 2 applies its maximum weight at a much bigger pitch angle (when the crutch is more inclined) than patient 1 and the mean PAA for patient 2 is significantly smaller than for patient 1, despite having the same EDSS score. Hence, the estimation of this angle allows to give more information about the particular use each patient gives to the assistive device.

Note that this is a preliminary study to assess gait performance and level of impairment of MS patients using the presented sensorized tip and the proposed parameters. In order to determine the validity and reliability of these parameters, as well as their general correlation with the clinical scales traditionally used to detect changes in the gait performance of the patient, a more exhaustive analysis would be required, including a higher number of patients with a variety of EDSS scores. For example, the F-observed value for the data corresponding to the average of the maxima of PBW is 159.13, but the table of Snedecor's F-test shows that the critical value for 3 degrees of freedom and $p = 0.05$ is 215.71. This means that the probability that the observed correlation was by chance is greater than 5% and the results are not statistically significant. Therefore, the results presented in this paper are not sufficient to generalize and they might be biased due to the small size and limited scope of the sample.

However, the results give interesting insights to continue research in the area of objective gait monitoring and assessment of the level of impairment. In particular, the parameters related to the motion speed, and to the force applied by the crutch are potential candidates to be correlated with the EDSS, while the characterization of the pitch angle allows to determine how the crutch is being used by the patient, and hence, may provide a more detailed analysis of functional mobility.

5. CONCLUSIONS

It is important to make an accurate assessment of the functional mobility difficulties of patients with MS, in order to adjust the therapy to the functional performance of each patient. However, traditional clinical scales have some drawbacks and provide limited information. This work presents the preliminary results of using a sensorized crutch tip to provide additional objective and quantitative information about assisted gait in patients with MS.

From a clinical trial with patients with MS, several potential parameters have been defined, which might be correlated to the EDSS score of the patient, such as the

mean speed, the number of cycles, the mean cycle time, the average PPT, the average of the maxima of PBW, the average PBW and the average SPT. In addition, other indicators related with the pitch angle are not associated with the EDSS, but they might provide useful information to identify various crutch usage patterns, recognise pattern changes during the recovery or detect quantitative differences between patients with similar scores in clinical scales.

The authors will like to point out that these results are preliminary and indicate a starting path for further research. Hence, future work will validate the use of the proposed tip with MS patients, it will involve clinical trials with more patients and healthy participants, it will analyze other parameters defined from sensor data, it will examine correlations with other clinical scales, it will include more complex movements, and it will also conduct prolonged measurements during everyday life activities. In addition, insole pressure sensors will be used for analyzing the distribution of weight on the feet and on the crutch.

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