



Original article

## Definition of the proper placement point for balance assessment with accelerometers in older women

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### ABSTRACT

**Objective:** To compare the behavior of the spinal levels for the accelerometric analysis and thus to define a proper placement point.

**Method:** Using three triaxial accelerometers (in dorsal and in lumbar regions) and a video camera, of 66 older women through one leg balance and standing tests with open and closed eyes, in static and dynamic conditions and gait repeated three times each trial.

**Results:** The accelerometer located in L5 explain the 88% and the 73% of the results obtained with the accelerometers located in the dorsal region and L4, respectively. The results have also showed a high correlation between the age and the average acceleration for dynamic one leg balance. Furthermore, an increase of the acceleration vector in the course of the trials (except in normal gait) was observed.

**Conclusions:** Although, the accelerometric data obtained in L4 and L5 have often been used arbitrarily for balance evaluation, actually there are differences in the records that made. Therefore, choosing the L4 not only reduces the kinematics information provided by the accelerometers but also simplifies the process of evaluation and analysis.

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## Definición del punto de colocación adecuado, para la evaluación del equilibrio con acelerómetros, en mujeres mayores

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### RESUMEN

**Palabras clave:**

Acelerómetro  
Valoración del equilibrio  
Centro de gravedad  
Antropometría  
Personas mayores

**Objetivo:** Comparar el comportamiento de los diferentes niveles de la columna vertebral para el análisis acelerométrico y así definir el punto de colocación adecuado de los mismos.

**Método:** Usando 3 acelerómetros triaxiales (uno en zona dorsal y 2 en la lumbar) y una cámara de vídeo, fueron evaluadas 66 mujeres mayores a través de pruebas de equilibrio en diferentes condiciones, bipedestación y apoyo monopodal, ojos abiertos y cerrados, condiciones dinámicas y estáticas, y de la marcha. Cada prueba se repitió 3 veces.

**Resultados:** El acelerómetro situado en L5 explica el 88% y el 73% de los resultados obtenidos con los acelerómetros situados en la zona dorsal y L4, respectivamente. Los resultados también mostraron una alta correlación entre la edad y la aceleración media para el equilibrio dinámico monopodal. Por otra parte, se observó un aumento del vector aceleración en el curso de las 3 repeticiones (excepto en la marcha normal).

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**Conclusiones:** Aunque los datos obtenidos en L4 y L5 se han empleado en numerosos estudios de manera aleatoria, en realidad hay diferencias en los registros que proporcionan. Los datos obtenidos confirman que no existen diferencias significativas entre la elección de la cuarta o la quinta vértebra lumbar para la colocación de estos dispositivos. Por lo tanto, la elección de la L4 no solo no reduce la información cinemática proporcionada por los acelerómetros sino que también simplifica el proceso de evaluación y análisis.

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## Definição do ponto de colocação adequado para a avaliação do equilíbrio com acelerômetros em mulheres idosas

### R E S U M O

**Palavras-chave:**  
Acelerômetro  
Avaliação do equilíbrio  
Centro de gravidade  
Antropometria  
Idosos

**Objetivo:** comparar o comportamento dos diferentes níveis da coluna vertebral para a análise acelerométrica e assim definir o ponto de colocação adequado dos mesmos.

**Método:** Usando três acelerômetros triaxiais (um na zona dorsal e dois na lombar) e uma câmera de vídeo, foram avaliadas 66 mulheres idosas através de testes de equilíbrio em condições diferentes, apoio com um e dois pés, olhos abertos e fechados, condições dinâmicas e estáticas, e da marcha. Cada teste foi repetido três vezes.

**Resultados:** O acelerômetro situado na L5 explicaram 88% e 73% dos resultados obtidos com os acelerômetros localizados na região dorsal e L4, respectivamente. Os resultados também mostraram uma alta correlação entre a idade e a aceleração média para o equilíbrio dinâmico monopodal. Além disso, se observou um aumento do vetor de aceleração no decurso de três repetições (exceto marcha normal).

**Conclusões:** Apesar dos dados obtidos em L4 e L5 têm sido usados em numerosos estudos de maneira aleatória, na realidade existem diferenças nos registos que fornecem. Os dados obtidos confirmam que existem diferenças significativas entre a escolha da quarta ou da quinta vértebra lombar para colocação destes dispositivos. Portanto, a escolha de L4 não só reduz as informações cinemática fornecida pelos acelerômetros mas também simplifica o processo de avaliação e análise.

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### Introduction

The adults may suffer from physical deterioration which will result in a loss of balance and impairment of proper coordination of movements. Winter et al.<sup>1</sup> have already expressed the importance of understanding how this system works to quantify and qualify its status over time.

In parallel, in the last years, accelerometers have become a tool for monitoring and encouraging physical activity effectively in this population.<sup>2</sup> Moreover, balance is usually quantified by the measurement of the stability control. This parameter is strictly associated with the center of mass (CM) of the body,<sup>3</sup> which, according to Mapelli et al.,<sup>4</sup> results from a multisegmental conception, or in other words, a system of rigid bodies whose center of mass is the average of all the centers of mass of such segments, statement that follows the proposal line by Hodges et al.<sup>5</sup> The control of the CM is an inherent task the successful completion of most activities of daily living.

To measure the balance, the conventional method is to use the force platform.<sup>1</sup> The stabilization of the center of pressure on the body is a diagnostic parameter of the state of stabilization systems of the dynamic balance.<sup>6</sup> Although there has been observed that is independent of the patient's risk of falling and is not always an accurate representation of the overall behavior of the body in space.<sup>7</sup>

These platforms compare the displacement of the CM and the center of pressure beneath the feet. However, new precise instruments smaller in size and cost have been developed recently. These instruments such as the accelerometer, have gained relevance and acceptance by researchers.<sup>8</sup> Comparative studies between these two instruments showed equivalence between the center of pressure of the platform and humans body accelerometry.<sup>9,10</sup>

However, there are not enough studies to support the validity of accelerometer-based protocols. That is why it is necessary to continue this line of research, and to establish a protocol which allows to measure the displacements of the CM with accelerometers.<sup>11</sup>

It is important to know the accelerations and velocities, in the three axes: sagittal, frontal and vertical for the triaxial accelerometers, of the CM in both a static and a dynamic position. A recent study conducted by Van Schooten et al.<sup>12</sup> that indicated that the variability of the stride during walking and its dynamic stability are promising factors for the identification, with accelerometry, of fall risks. This study suggests that the gait analysis as well as the participant's health are key factors in the balance study, especially older adults with fall risks.<sup>13</sup>

The exact location of the CM in the body has been studied several times. These works are characterized by the use of expensive equipment and complex assemblies equipped with inertial sensors, many reflective markers and infrared cameras, in order to obtain an individualized and accurate determination of the CM.<sup>14,15</sup> As in clinical practice this process is not feasible and it would prevent the application of the kinematic study as a method of evaluation, this work aims to compare the behavior of the spinal levels for the accelerometric analysis and thus to define a proper placement point. In this way, we advance in the research initiated by Moen-Nilssen<sup>16</sup> and advanced by Maygoitia et al.,<sup>17</sup> Marchetti et al.<sup>18</sup> and Kim et al.,<sup>19</sup> in order to go on defining accelerometric assessment parameters and participate in the process of defining the use of accelerometry as a protocolarized and standardized tool. We seek to understand the biomechanics of the CM and facilitate the use and understanding of the accelerometers by health professionals. If the use of accelerometers in health services is generalized, the assessment of the physical condition of the elderly and the design of custom physical improvement plans will be optimized.

## Method

A descriptive and cross-sectional study in a convenience sample of older persons from the city of Ourense (Spain) was made. In this study, the participants who met the requirements of the exclusion criteria will not be able to participate in the test: people who were not able to walk independently or without external orthotics, who could not stand for 60 s or more or people with any specific contraindications to the valuation tests.

This study involved 66 healthy women with a mean age of 64.89 years old ( $SD = 7.63$ ), with a total analysis of 46 957 accelerations records (three series of repetitions for each accelerometer). For each participant, measures of waist and thorax circumference were taken.<sup>20</sup>

Finally, the three accelerometers were placed: one in the thorax postero-medial zone (at axillary height, approximately coincident with T4), and the other two in the lumbar postero-medial zone (coincident with L4 and L5 respectively). These specific locations were chosen because according to the biomechanical findings these two lumbar vertebrae reflect the behavior of the CM.<sup>21</sup> The dorsal point was chosen to test the connection between the upper and the lower parts of the trunk.

In order to carry out the measurements of the accelerations of the CM, each participant made three trials which were repeated three times (without further break than the preparation time for the next trial). Start and end time of each trial expressed in hours, minutes and seconds was written down on a record sheet to contrast and adjust them to the video camera clock. All trials were recorded.

The trials performed were:

- One leg balance with closed eyes (OLBCE).
- Dynamic one leg balance with open eyes, on a foam mat to cause an onset of dynamic equilibrium reactions (DOLB).
- Normal gait to a cone/buoy located at 10 m. Each participant went around it and came back to the starting point (NG).

OLBCE and DOLB trials had a fixed duration of 30 s. The duration of NG trial varied depending on the time that the participant needed to finish the circuit.

The first step of the procedure was to explain to the participants the purpose of the study and to give them a brief description about what they were supposed to do. Each participant was given an informed consent form. Once the informed consent form was signed, the participants' data (i.e. full name and age) were collected. Then, the anthropometric measurements were done in the following order: thorax circumference, waist circumference, trunk size and total size.

Afterwards, three accelerometers were placed on the participant's body. The devices were attached with adhesive tape to avoid displacements. Next, the trial was explained to the participants and they were accompanied to the corresponding measurements room for testing.

The sequence of the trials was determined taking into account the possible fatigue of the lower limb. Then, the trials structure order was as follows: OLBCE-NG-DOLB-NG-OLBCE-NG-OLBCE-DOLB-DOLB. That is, each trial (OLBCE, DOLB and NG) was performed three times.

The last phase consisted of the data analysis and interpretation. In order to do that, it was necessary to analyze each trial observing the videos with the accelerometer data: data of the acceleration module vector. We used the videos to confirm whether the acceleration threshold that indicates destabilization in reality is an imbalance movement really. In the analysis of the images, we detected the following alterations: tilts trunk (left and right), pushes trunk, abductions and adduction of the hip, jumping

rebalancing (jumps over the kickstand to regain the support base), irreversible loss of balance (like touching the ground with the foot or a total loss of the support base).

For that, we review each video recording the seconds of each test in which a large destabilization occurred. Later, we check each of these seconds with the accelerometer measurement. Thus, we check faithfully how the accelerometers recorded balance disturbances.

Six accelerometers GT3 Plus were used. They were chosen for being triaxial and also for being able to calculate the acceleration vector (three axes module) measured in milligrams (mg). Each accelerometer was initialized for data collection with the specific software. Following, the data were sent via software after each round of data collection.

From the gravity acceleration vector obtained by each accelerometer, the angles which mark the position of the participant are determined, where  $A_x, A_y, A_z$  are the accelerations for each axis and  $\sqrt{x^2 + y^2 + z^2}$  is their module of the acceleration vector (1)-(3).

$$\text{axis 1 : } \alpha(\alpha) = \arctan \left( \frac{A_x}{\sqrt{A_y^2 + A_z^2}} \right) \quad (1)$$

$$\text{axis 2 : } \beta(\beta) = \arctan \left( \frac{A_y}{\sqrt{A_x^2 + A_z^2}} \right) \quad (2)$$

$$\text{axis 3 : } \gamma(\gamma) = \arctan \left( \frac{\sqrt{A_x^2 + A_z^2}}{A_z} \right) \quad (3)$$

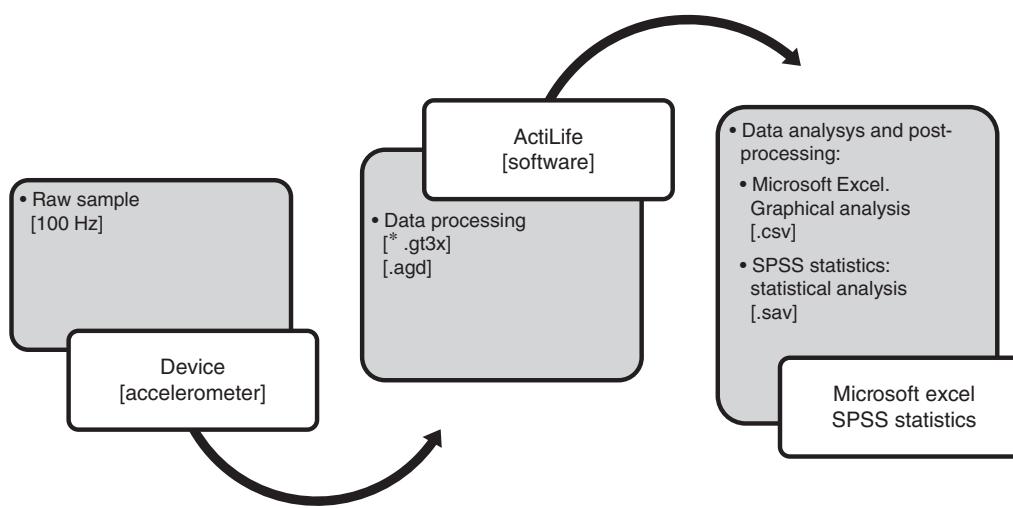
Accelerometers provide data on body movements in three axes: axis 1 corresponds to the acceleration in the vertical axis (transverse/horizontal plane); axis 2 to the sagittal axis (coronal/frontal plane); and axis 3 measured acceleration in the perpendicular axis (antero-posterior plane). The accelerometer measurements were configured for a time frame of 1 s.

In addition, we correlated the accelerometer data with the analysis of the video images that were taken simultaneously to check if the alterations numerically detected by the accelerometers were a reflection of the kinematic behavior of the body. For recording the trials a SONY HD video camera was chosen which was mounted and fixed on a tripod for measurements. A digital clock POLAR to record the time of each trial was used.

The acceleration data was sampled by a 12 bit analog to digital converter at rates of 100 Hz. Although low frequency allows eliminating any acceleration noise, which is important for the study of population groups who move slowly (i.e. the elderly), 100 Hz frequency was selected in order to achieve greater accuracy in the analysis of postural balance. Raw data was collected at the selected sample rate (100 Hz) and it was processed in the ActiLife software (Fig. 1). The accelerometers used in the tests were synchronized using a PC and ActiLife software.

### Statistical analysis

The internal consistency reliability of the accelerometric measurement was evaluated using an average inter-item correlation test. The first step was to check whether the signals detected by the inertial sensors showed consistency among trials, both within and between subjects. The signals recorded by each sensor for all the trials for the same subject were compared. The inter-item correlation coefficient was calculated for each sensor and for all signals for each subject. This correlation served as an indicator of the degree to which the subject repeated the same accelerations between trials. The repeatability of the data for each individual was also evaluated.

**Fig. 1.** Data collection and processing.

Descriptive statistics were used as a measure of central tendency and the standard deviation as a measure of dispersion. The Pearson's  $r$  value was calculated to assess the correlation between the duration calculated using different sensors. The significance level was  $P < 0.05$ . All calculations were performed using SPSS for Windows version 17.0.

## Results

The average inter-item correlation test was used to determine whether the accelerations measured by the inertial sensors had internal consistency, i.e., if the waveform was consistent between trials for the same subject. The results show that the devices located in L4 and L5 have more internal consistency than the device located in dorsal ( $r = 0.76$ ;  $0.64$ ;  $0.6$ ; for vertical, sagittal and perpendicular axis, respectively). The devices located in L4 have a high correlation between trials ( $r = 0.95$ ;  $0.74$ ;  $0.84$ ; for vertical, sagittal and perpendicular axis, respectively). The devices located in L5 have similar values of correlation than L4 ( $r = 0.89$ ;  $0.78$ ;  $0.8$ ; for vertical, sagittal and perpendicular axis, respectively).

Is also interesting, to calculate the similarity of signals among subjects. The test calculates the correlation between each pair of signals and then calculates the average of all these resultant correlations. The results indicate that the L4 accelerations in sagittal ( $r = 0.86$ ) and perpendicular ( $r = 0.8$ ) axis show the greatest difference among subjects. In the contrary, the accelerations in dorsal and L5 obtain values of correlation among subjects between 0.5 and 0.72.

**Table 1** shows the ranges and mean values for each axis and accelerometer placement. The accelerations obtained with the devices located in L5 correlated with those obtained with the accelerometers located in L4,  $r = 0.88$ ,  $p < 0.01$ ; and in dorsal,  $r = 0.73$ ,  $p < 0.01$ , which means that the accelerations obtained with the devices located in L5 represent the 88% and the 73% of the results obtained with the accelerometers situated in L4 and dorsal, respectively. That is, placing the accelerometer on the L4 or the L5 will display similar results. The results of average correlations coefficients were calculated over all subjects for the three trials of each task.

The average accelerations study showed that the acceleration vector increased following the order of the trials. That is, cumulative effect of fatigue was observed. In the graphical representation of behavior movement angles, calculated from the accelerations, in DOLB test shows how the accelerations in the sagittal and vertical axes little gradually increase with each repetition.

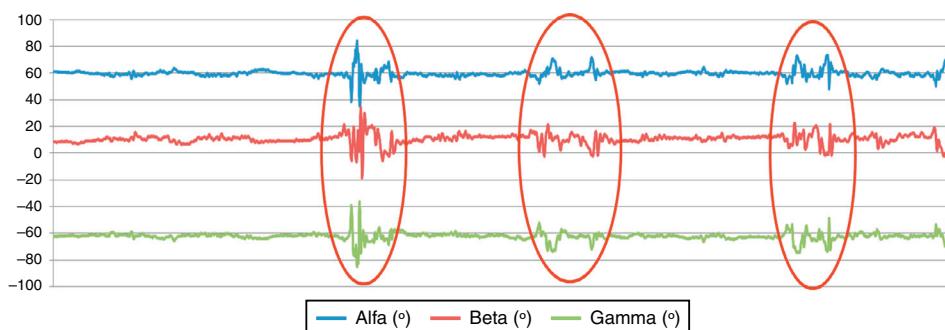
The maximum accelerations were produced during the central seconds of the trial, regardless the repetition or the trial in progress, both in OLBCE as DOLB. This phenomenon can be observed graphically in **Fig. 2** (circled in red) which represents the performance of a subject during the test OLBCE.

Meanwhile, the age did not correlate with the results of the gait analysis regarding the maximum accelerations and the average unbalance for the series two and three ( $p > 0.05$ ). However, it was observed a correlation between the age and the average unbalance during the first series of the gait trial ( $r = 0.4$ ,  $p = 0.01$ ). The main duration of the gait trial for the three series was similar (series 1:  $18.39 \pm 3.45$  s; series 2:  $18.3 \pm 3$  s; series 3:  $18.5 \pm 5.68$  s). Fatigue effects were not observed in the participants. There was a significant correlation between the age and the duration of the gait analysis for the three series (series 1:  $r = 0.53$ ,  $p < 0.01$ ; series 2:  $r = 0.21$ ,  $p < 0.01$ ; and series 3:  $r = 0.2$ ,  $p < 0.01$ ). Analyzing each axis separately, the waist circumference was only correlated with the average acceleration in all three axes in series 1 ( $r = 0.79$ ,  $p < 0.000$ ), while a positive correlation between the waist size and the acceleration on axis 1 for all the series of the gait trial always existed (**Table 2**).

With the study of the video images collected was observed that all events such as imbalances, foot supports, inclinations, falls, etc. corresponded to accelerations higher than  $6\text{ mG}$ . This allowed to determine for each test the threshold above which there is an irreversible loss of balance, i.e. a fall. With the identified changes, we proceeded to determine the threshold for which the imbalance occurred in the three measurement points, taken as cutting parameters the alterations that caused an irreversible loss of balance.

**Table 1**  
Ranges and mean values for each axis and accelerometer placement.

Variables	Dorsal	L4	L5
<i>Axis 1 (mG)</i>			
Max	$78 \pm 13$	$33.2 \pm 15$	$34.4 \pm 12.5$
Min	$7 \pm 2$	$8.2 \pm 3.5$	$2.9 \pm 3.1$
Mean	$44.6 \pm 14.8$	$36.9 \pm 9.2$	$36.5 \pm 10.3$
<i>Axis 2 (mG)</i>			
Max	$28.9 \pm 11$	$49.6 \pm 11.94$	$46.8 \pm 12$
Min	$5 \pm 4.1$	$5.2 \pm 6.5$	$5.2 \pm 2.6$
Mean	$25 \pm 8.8$	$20 \pm 9.3$	$19.6 \pm 6.1$
<i>Axis 3 (mG)</i>			
Max	$53 \pm 13.8$	$45.6 \pm 12.7$	$48.5 \pm 11.4$
Min	$10.8 \pm 6$	$9.1 \pm 4.2$	$8.8 \pm 4.8$
Mean	$29.8 \pm 9.2$	$20.2 \pm 7.3$	$21 \pm 6.6$



**Fig. 2.** Angles of measuring tilt during third trial of OLBCE [example of a participant].

**Table 2**

Results of the analysis of waist perimeter and average acceleration correlation in the three axes for the three gait series.

Accelerometric variable	Waist	
	Pearson's correlation	P value
<i>Series 1</i>		
Axis 1	-0.66	0.03*
Axis 2	0.56	0.02*
Axis 3	-0.83	0.001*
<i>Series 2</i>		
Axis 1	-0.4	0.02*
Axis 2	0.28	0.09
Axis 3	-0.54	0.08
<i>Series 3</i>		
Axis 1	-0.47	0.02*
Axis 2	0.4	0.07
Axis 3	-0.3	0.08

\* The correlation is significant at level 0.05 [bilateral].

## Discussion

Regarding the results obtained in relation to one leg balance with closed eyes (OLBCE), it was observed that the average acceleration in the acceleration vector for each accelerometer showed an increase between the first and last series. The same situation can be found in dynamic one leg balance tests (DOLB). These increases resulted in greater postural adjustments or corrections, which have caused, in the majority of cases (after analyzing the videos), an imbalance (loss of the support base due to the displacement of the CM projection) or have affected the foot support, which is in line with the inverted pendulum proposed by Winter et al.,<sup>1</sup> and is especially related to the multisegmental position.<sup>5</sup> There are several causes for this increase in the values and among them fatigue is included.<sup>22</sup> Fatigue seemed to occur mainly in the stabilizing muscles of the lower limb (abductors both in hip and ankle), altering the support base and forcing a readjustment of the column stabilizing musculature (oblique and column). However, after observing the acceleration data for the gait trial we can point out that this did not occur. Such data did not show that fatigue could alter normal gait, possibly because while walking it is more difficult to lose balance because the projection of the CM remains inside the supporting base that produce both lower limbs.

In addition, taking into account the average age of the sample (64–65 years old), regardless of the gait (there is no correlation between the age and the maximum accelerations and imbalances in this trial), it can be observed how this also affects the postural control, as previous studies that link the loss of postural control with age made by Martínez-Ramírez et al.<sup>23</sup> or Chen et al.<sup>24</sup> indicated.

Based on the results of the moment that presented the highest accelerations, it could be possible that all the participants (even despite their biological individuality) experience a common

critical phase during the trial that coincided with the central seconds of the same. Hereafter, a small acute adaptation of the neuromuscular system to the one leg balance stress could occur. Such acute adaptation would happen only during that interval and it would not transfer to the following trials. The fatigue generated may be related to greater accelerations during the last trials. However, a more analytical study may be needed, since there are no sources that can support this hypothesis.

Regarding the results, it is noteworthy the correlation between the waist perimeter or circumference and the execution time of all gait analysis and it was also particularly remarkable the fact that it always existed a relationship between the waist perimeter or circumference and the acceleration on the axis 1. Taking into account that axis 1 corresponds to the longitudinal axis of the body, and that this intersects with the horizontal plane, it is deduced that the waist circumference is associated with movements in this plane, that is, rotations. Such movements in the horizontal plane are part of the six normal gait determinants in which the studies of Hayot et al.<sup>25</sup> are based: specifically the pelvic rotation produced largely by the abdominal minor oblique activation (musculature that is part of the abdominal muscles). It is also worth mentioning that with age the responsiveness of the neuromuscular system is lower than in younger participants. This explains the high correlation between the age and the execution time of the gait analysis. However, this does not explain why the accelerations in the three axes are only related to the circumference in the first trial and not in all of them.

A plausible explanation for this phenomenon may be that a larger abdominal circumference (due to a more or less intense overweight) makes participants less agile.<sup>26</sup> Therefore, having too much body mass in the abdomen region where the CM of the individual is located, is a handicap for making rapid setting movements. But, on the contrary, it is not involved in the processes of fatigue or learning that appear with the repetitions and make the participants show higher or lower accelerations, respectively. That is why this phenomenon was only identified in the accelerations belonging to the first trial. Therefore, overweight makes older people less agile something that is highly relevant since the imbalances in real life (unlike in the lab environment) occur suddenly, without prior notice. The presence of a larger circumference warns that the ability to respond to an imbalance will be restricted. On the contrary, the times were improved perhaps by the effect of trust that produces learning the journey.

The analyses of the images are an added value to this study because it allowed to correlate the kinematic data with the videos of the tests. After analyzing all the videos of the trials, it was observed that of the total recorded incidents, approximately over 60% were imbalances and foot supports and nearly 90% were produced by small inclinations in the front plane (swinging) both of the trunk and the hip.

Due to the high correlation between the data of the three devices, the entire analysis could be reduced to a single

accelerometer. Furthermore, these data corresponded to those obtained by the accelerometers in those time intervals which marked accelerations above 6 g in the vector module. Therefore, it can be affirmed that the balance is multisegmental and involves a constant readjustment of the neuromuscular system. Moreover, factors such as age and fatigue can be determinants. It is also noteworthy that falls (total loss of the projection of the CM without the possibility to recover it) are rare for this sample of healthy population, in accordance with other studies.

However, it should be clarified that after observing the gait analysis, fatigue does not appear to influence this action in respect to balance, and only age alters the participants' execution time. In addition, in absence of obstacles, there were no falls, unlike what had happened with the one leg balance (OLBCE and DOLB) tests. Also, here it could be noted that the waist circumference influences the pelvic rotation, which is one of the normal gait determinants.

Regardless of the stated above, the combination of the records of different anatomical points as a biomechanical assessment method would describe how somatosensory-visual and vestibular information is integrated to maintain stability and can be an avenue of research in the future. Therefore, the accelerometer needs to be incorporated public health for the many possibilities that it offers to the health services such as improving the evaluation methods and the design of programs to improve physical health.

In what future lines are concerned, contributing to the accelerometric analysis can open many areas of study in the field of health and physical exercise. Precisely these studies can contribute to the approach between these two areas of knowledge (so far in the legislative sphere). The knowledge of the human balance (which implies the proprioceptive system) can help in the research of improvement programs for different purposes (more similar to the motor sciences) or rehabilitation (closer to the health branch), through methods that were initially part of a single area of knowledge and became multidisciplinary.

Although, the accelerometric data obtained in L4 and L5 have often been used arbitrarily for balance evaluation, actually there are differences in the records that made. These differences detected respond to the various mechanical demands that they are exposed and the different structural relationships they maintain with the pelvis: L5 is directly exposed to the shear forces over the sacral base and it tends to be affected by the movements of rotation of the sacrum. Thus, and in order to facilitate the biomechanical analysis of the body changes, in a defined space and to avoid introducing an extraneous variable that represents the intrinsic mobility of the pelvic girdle, we recommend to choose the fourth lumbar vertebra as a suitable place for the kinematic registration.

## Ethical approval

**Protection of human and animal subjects.** The authors declare that the procedures followed were in accordance with the regulations of the responsible Clinical Research Ethics Committee and in accordance with those of the World Medical Association and the Helsinki Declaration.

**Confidentiality of data.** The authors declare that they have followed the protocols of their work centre on the publication of patient data.

**Right to privacy and informed consent.** The authors must have obtained the informed consent of the patients and/or subjects mentioned in the article. The author for correspondence must be in possession of this document.

## Conflicts of interest

The authors have no conflicts of interest to declare.

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