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Can Foot Orthoses Prevent Falls? A Proposal for a New Evaluation Protocol

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Abstract: Foot pain represents one of the most common symptoms in lower limb issues, especially in elderly individuals. This condition, often associated with other pathologies, increases the risk of falling. To better understand the risk of falls, it is essential to assess patients' postural stability. In this pilot study, we aimed to set a protocol to prevent the falling risk. We propose the use of inertial sensors (IMUs) to detect even minimal body oscillations in a non-invasive, rapid, and cost-effective way. We have analyzed a sample of 35 patients (age = 58 ± 14 years, female = 20/male = 15) to investigate the total range of body sway in the anteroposterior (AP) and mediolateral (ML) directions during static balance in relation to their age and BMI. The analysis of the collected parameters (sway area, sway pathAP, and sway pathML) has showed a lower stability at t1, at the time of orthosis application, with respect to the previous condition, implied by the necessary period of adaptation to the new plantar device. In fact, the postural parameters have visibly improved at 30 days (t2). Comparing the results obtained in the different postural exercises, we have obtained significant differences between the natural standing position with eyes open and the others. According to these results, we can suppose that using inertial sensors associated to postural exercise is the best way to assess a patient's postural stability and that the progressive improvements may be more marked over a longer period, such as six months (t3).

Keywords: wearable sensor; foot orthoses; inertial sensor; risk of falling

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Academic Editor: Mark King

Received: 19 December 2024
Revised: 21 January 2025
Accepted: 24 January 2025
Published: 27 January 2025

Citation: Montesissa, M.; Raimondi, I.; Baldini, N.; Mazzotti, A.; Brognara, L. Can Foot Orthoses Prevent Falls? A Proposal for a New Evaluation Protocol. *Appl. Sci.* **2025**, *15*, 1297. https://doi.org/10.3390/app15031297

1. Introduction

The WHO defines falls as unintentional and unexpected downward movement from a standing, seated, or lying position [1,2]. Falls represent a significant issue due to possible related physical injuries, reduced quality of life, and the consequent increased healthcare costs [3–6]. Foot problems are prevalent among older adults, affecting between 20% and 45% of this population [7,8]. These issues often lead to discomfort and pain, which can significantly heighten the risk of falls. As individuals age, maintaining foot health becomes crucial not only for mobility but also for overall safety and well-being [5]. In fact, lower limb disorders can cause mobility difficulty with walking problems and limitation, impaired physical functioning with significant impact on the quality of life and healthcare costs, especially in the case of older patients [9–11]. In particular, the fall in older adults is often a consequence of experiencing foot pain, hallux valgus, lesser toe deformities, and plantar fasciitis. They also show decreased ankle mobility, weaker toe strength, and higher plantar pressures [12]. However, there are no significant differences in calluses, corns, or foot posture between fallers and non-fallers [13]. The diagnosis and prevention of falls is not so easy to assess by the healthcare professional, such as physiatrists and podiatrists, and generally, they are based on physical examination coupled with a clinical scoring system and staging scales [14–19]. The intervention and therapeutic approach to prevent the older patient falling commonly involves the use of the foot orthotic system to improve the plantar pressure distribution and stability. In particular, the use of custom-made foot orthoses improved the level of forefoot pain in rheumatoid arthritis, hallux abductus valgus, and secondary metatarsalgia as it increases sole pressures [20,21]. Orthoses can be an effective strategy to improve balance by reducing foot pain and preventing falls in the elderly, but little research has been conducted on the effectiveness of custom-made orthoses in improving balance in patients with foot pain who are at risk of falling. The purpose of this study is to introduce a novel method for assessing the outcomes of custom-made foot orthoses in patients experiencing foot pain and at risk of falling. In fact, the use of new technologies such as wearable sensors can be a possible solution and opportunity to obtain new clinical information and an outcome useful for the healthcare professional to determine the efficacy of the custom-made orthosis. The wearable technologies and sensors possess different advantages, principally connected to a low cost, easy application, and the possibility of measuring different biomechanical parameters not only in the traditional laboratory environment but also in real-life experience [22–34]. In particular, in the case of fall prevention, the balance of the patient is crucial and can be used as a clinical outcome for identifying the risk of falls [35–41]. Here, the use of inertial sensors is useful in assessing equilibrium and stability through some motion tasks of the patients after the insole application at different experimental time points (up to 30 days). In line with previous studies conducted [37,42–45], we used a wearable posturographic sensor system with validated Inertial Measurement Units (IMUs) (mSway, mHealth Technologies, Bologna, Italy) for postural assessments; this sensor is equipped with a tri-axial accelerometer, gyroscope, and magnetometer. In this paper, the use of an inertial sensor, applied to the lumbar region, to assess anteroposterior and mediolateral oscillations was investigated under different conditions to assess the stability of patients with foot pain. The analysis will help in the development of a protocol and study design for future large-scale studies and long-term follow-ups.

2. Materials and Methods

2.1. Participants Selection

The clinical pilot study was conducted under ethical approval obtained from the authors' institution's ethics committee (reference: CE AVEC: 659/2021/Sper/IOR, 18 August 2021). The enrolled patients were among those attending the podiatry clinic of the Rizzoli Orthopedic Institute, in need of foot orthoses for painful foot symptoms with no age restrictions and provided their consent from July 2024 up to October 2024. The Inclusion criteria were (1) individuals of either gender; (2) individuals aged 10 or older; and (3) individuals experiencing foot pain. Exclusion criteria were (1) individuals with severe cognitive impairment or uncontrolled psychiatric issues; (2) individuals with active foot ulcers; (3) cancer patients; (4) retinopathy patients; (5) individuals with Charcot foot; (6) individuals who had suffered lower limb injuries or fractures in the past six months; (7) individuals who had undergone orthopedic lower limb surgery in the past year.

In total, 44 patients were enrolled, but only 35 were included; nine patients were excluded from the final analysis because they did not conclude the test for every experimental time point. The included patients' characteristics in terms of age and the Body Mass Index (BMI) are reported in Table 1.

Table 1. Patients' characteristics in terms of age and the BMI.

Characteristics	Mean ± Dev Std (Min–Max)
Age	57.66 ± 14.57 (29–82)
BMI	26.99 ± 5.62 (18.94–40.43)

2.2. Study Design

Inertial measurement units (IMUs) are a wearable inertial sensor system composed of a tri-axial accelerometer, gyroscope, and magnetometer. In this study, the sensor used was developed by the mHeath Technologies (mSway, mHealth Technologies, Bologna, Italy, Figure 1A). According to the sensor specifications, the sampling frequency is 200 Hz, with an acceleration range of ± 8 g and a gyroscope range of ±1000 dps. The time point was chosen in line with previously published studies on the validation of insoles [43,46,47]. In particular, the wearable sensor has been placed on the patients' back with elastic strip on the lumbar zone, at the level of the L5 vertebra (Figure 1B), as indicated in the sensor's manual and according to the review by Ghislieri et al. [48]. The postural data of each patient were collected under two different conditions: first, while wearing their usual footwear (time point: t0) and second, with customized foot orthotics having been inserted into their shoes (time point: t1). Four different foot orthotics were used in this study: a biomechanical insole made of polypropylene (PP), biomechanical insole in PP and forefoot/rearfoot posting; and accommodative insole made of resin with or without retrocapital bar/olive. After assessing each subject's forefoot-to-hindfoot alignment in order to identify forefoot deformities, the subject's foot was positioned over a foam casting box. The neutral position of the subtalar joint was then palpated. The subject was instructed to fully relax while the entire foot was gently pressed into the foam material. Throughout this procedure, the neutral position of the subtalar joint was continuously palpated. The four types of foot orthotics chosen for this study represent the most commonly used insoles in clinical practice. Their hardness and elasticity are customized based on a comprehensive podiatric examination. Notably, polypropylene is a rigid material often utilized for corrective insoles, while resin is used to create accommodative or palliative insoles. The second assessment was repeated after a 30-day adaptation period (time point: t2), during which patients were recommended to wear the insoles daily during their regular walking and daily activities. The patients' equilibrium and balance were evaluated at these three distinct experimental time points (t0, t1, and t2) through the following postural exercises (Figure 1C,D).

(1) Natural standing position with eyes open (EO);

(2) Natural standing position with eyes closed (EC);

(3) Tandem standing position (TANDEM), allowing the patient to choose which foot to place forward in relation to the opposite foot.

All the postural exercises were carried out for 30 s. A representation of the study design is reported in Figure 1.

The following biomechanical parameters were collected and evaluated:

- Sway area [mm^2/s]: it represents the area covered by the movement of the center of pressure (COP) while maintaining an upright position;
- Sway pathAP [mm/s]: it represents the trajectory length of the center of pressure (COP) movements along the anteroposterior direction during the postural stability test;
- Sway pathML [mm/s]: it represents the trajectory length of the center of pressure (COP) movements along the mediolateral direction during the postural stability test.

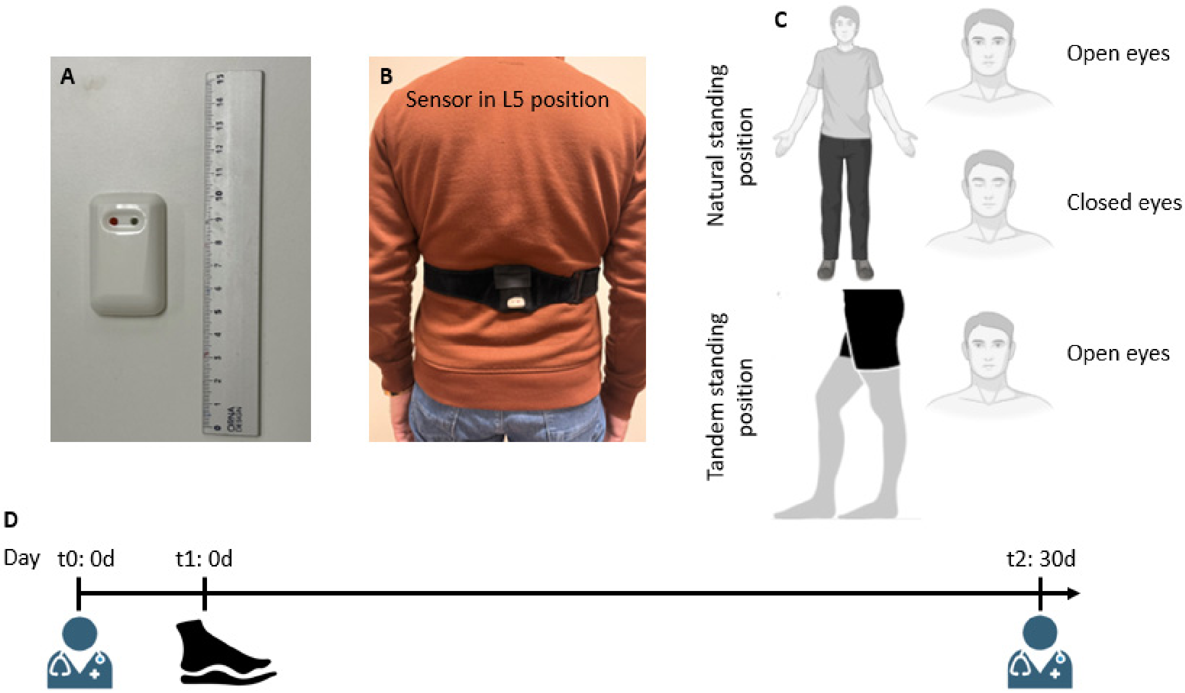

Figure 1. (**A**) inertial sensor used for the equilibrium and balance evaluation applied with elastic strip to the lumbar zone (**B**). In (**C**), the three different postural exercises are reported, and in (**D**), the three time points where the data are collected.

The data analysis was conducted using Jupyter Notebook on Anaconda Platform, a web-based interactive computing platform that utilizes the Python programming language. A script was written in order to analyze data considering several characteristics, including age, gender, BMI, and the type of insole used; the aim is to categorize data by those ones.

For this purpose, patients were divided into different groups based on their characteristics. They were divided into two groups based on age and sex (Table 2). While taking into account BMI distribution, patients were classified into five BMI categories, based on the classification of Weir C.B. et al. [49]. The number of patients obtained for every classification is reported in Table 3.

Table 2. Patients' classification in function of the age (A) and sex (B).

(A) Age	
<65 years old	21
>65 years old	14
(B) Sex	
Male	15
Female	20

Table 3. Patients' classification in function of the BMI.

BMI	
<18.5 (underweight)	0
18.5–24.9 (normal weight)	13
25.0–29.9 (overweight)	11
30.0–34.9 (obese class I)	9
35.0–39.9 (obese class II)	1
>40 (obese class III)	1

To ensure direct data management, subjects with erroneous or missing measurements were excluded from the analysis, as detailed in Section 2.1. Below, we provide a description of the code implemented in Jupyter Notebook for data analysis. The first step involved reading the Excel file where all data had been stored in a table format.

For the BMI analysis of the patients, the Body Mass Index (BMI) was calculated by dividing the weight column by the square of the height column (the BMI formula was used). Based on these values, participants were classified into BMI categories: normal weight ($18.5 \leq \text{BMI} \leq 29.9$) and obesity ($\text{BMI} \geq 30$). The data were reorganized using the pd.melt() function to facilitate analysis and visualization. Subsequently, box plots were created using the sns.boxplot() function, resulting in the graphical representations included in this paper. This process was repeated for all three conditions: 'eyes open', 'eyes closed', and 'tandem'.

The same methodology was applied to the three parameters: 'sway pathAP', 'sway pathML', and 'sway area'. Additionally, the analysis was extended to other groupings, such as age and sex.

Further steps were implemented in the code to enhance the clarity and representation of the plots, ensuring the results were effectively communicated.

In the end, the patients were divided in function of the foot orthotics of different types of insoles that have been worn individually, which had been chosen taking discrete foot problems into consideration (Table 4).

Table 4. Patients' classification in function of the four different foot orthotics applied.

Plantar Type	
Biomechanical insole with polypropylene	6
Accommodative insole with resin and retrocapital bar/olive	11
Biomechanical insole with polypropylene and forefoot/rearfoot posting	11
Accommodative insole without retro capital bar/olive	7

2.3. Data Analysis

Statistical significance was analyzed using one-way ANOVA in GraphPad Prism software (8.0.1 v, GraphPad Software Inc., California City, CA, USA). Differences were considered significant when p-value < 0.05.

3. Results

3.1. Overall Population Analysis

Before starting with the analysis between the different subgroups chosen, the analyses were conducted on overall patient characteristics. The parameters—sway area, sway pathAP, and sway pathML—were analyzed, distinguishing between exercises performed with eyes open, eyes closed, and in the tandem position.

The boxplot in Figure 2 below shows the comparison of sway areas (mm^2/s) across three time points (t0, t1, and t2) under the three different tasks. The sway area under the first condition remains relatively low across all three time points; median values are slightly increased in t1 with respect to t0 and t2. The InterQuartile Ranges (IQRs) are small, indicating consistent results across the group. Under the eyes-closed condition, a similar trend is seen, with slightly higher sway areas compared to the previous one. The tandem condition exhibits the largest sway areas and values with significant differences with respect to EO and EC natural standing conditions, highlighting its higher difficulty (t0: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$; t1: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$; and t2: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$).

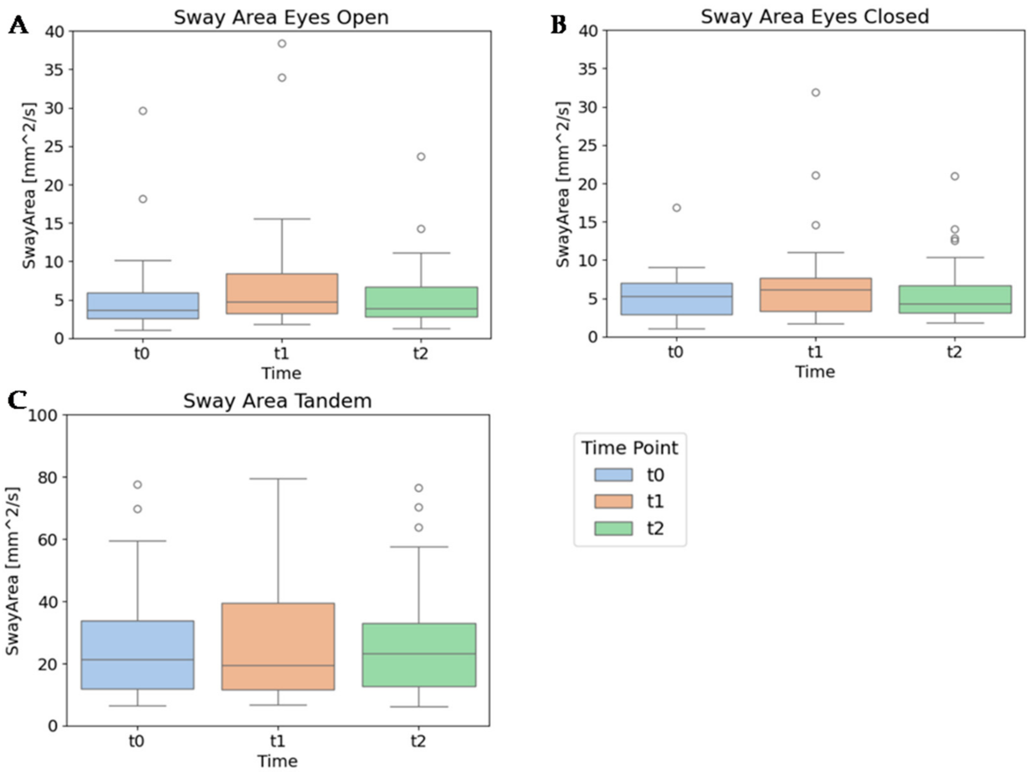

Figure 2. Sway areas calculated at the three different time points of all the patients ((**A**) under the eyes-open condition; (**B**) under the eyes-closed condition; and (**C**) under the tandem condition).

In Figure 3, the sway pathAP boxplot across three time points (t0, t1, and t2) under three task conditions is reported. Under the eyes-open condition, the median sway pathAP values are stable across t0, t1, and t2, with no significant differences. The IQR remains relatively narrow, showing small variability in performance for this task condition. Under the eyes-closed condition, there is a slight increase with respect to the eyes-open condition, with significant differences at t0 ($p < 0.05$) and t2 ($p < 0.05$). The IQR widens slightly at t1 and t2, indicating greater variability in performance as the task became more challenging without the visual input. Under the tandem condition, there are not any variations with respect to the previous condition. The task performed under tandem standing condition possesses a higher value in terms of sway pathAP with respect to the eyes open natural standing condition, with significant differences at t0 ($p < 0.01$) and t2 ($p < 0.01$).

Finally, in Figure 4 is presented the sway pathML in mm/s across the three time points under the three task conditions. Under the eyes-open condition, the median sway pathML remains consistent across t0, t1, and t2, suggesting stable performance over time. The same situation can be seen in the eyes-closed condition, with no significant differences with respect to the eyes-open condition. The tandem task consistently shows the highest median sway pathML values among all conditions, indicating the greatest challenge for the patients (t0: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$; t1: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$; and t2: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$).

3.2. BMI Analysis

Instead of maintaining the classic BMI category division as reported in Table 3, two groups were created by combining the first three categories (normal class) into one group and the last three categories (obese class) into another. To achieve a clearer representation, outliers with values extremely higher with respect to the mean (deviating by more than a hundred) were excluded from the visualization.

3.2.1. Sway Area

Figure 5 shows the sway area obtained for the two different classes. In particular, in Figure 5A,B, better balance stability and tighter variability characterize the normal class BMI group. On the contrary, the higher BMI group displays slightly higher median sway area values and more variability in terms of wider InterQuartile Ranges (IQRs). Considering different time points, there is a decrease in the median value sway area from t0 to t2, suggesting an improvement in stability over time. Compared to the EO condition, in the EC condition, the median values for the sway area are slightly higher for both BMI groups, reflecting the impact of removing the visual input on stability.

In Figure 5C, the tandem box-plot graph is showed. In this position, both BMI groups show significantly higher sway area values compared to EO and EC (normal class—t0: EO vs. T, $p < 0.0001$, EC vs. T, $p = 0.0001$; t1: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.001$; and t2: EO vs. T, $p < 0.001$, EC vs. T, $p < 0.001$; obese class—t0: EO vs. T, $p < 0.001$, EC vs. T, $p < 0.05$; t1: EO vs. T, $p < 0.01$, EC vs. T, $p < 0.01$; and t2: EO vs. T, $p < 0.01$). A smaller median sway area and tighter IQRs could be seen in the normal class. However, the higher BMI group shows wider IQRs, indicating greater variability and difficulty maintaining balance. Both groups show a slight reduction in median sway area values from t0 to t2.

As could be seen in Figure 5, across all three tests considered, i.e., EO, EC, and tandem, in the group with higher BMI values, we can observe a greater median; this suggests increased difficulty in maintaining balance for these subjects. Analyzing the graphs, it is evident that there are no significant differences between the eyes-open and eyes-closed conditions in terms of the mean, median, or data variation except a slight increment. Nevertheless, the eyes-closed condition shows a higher presence of outliers. In the tandem position, median values are higher compared to both eyes-open and eyes-closed conditions. Considering the differences between the measurements at the three selected time points, we can observe that in most cases, the values at the time point t1 are higher with respect to the other two. This suggests an adaptation to the use of the insole.

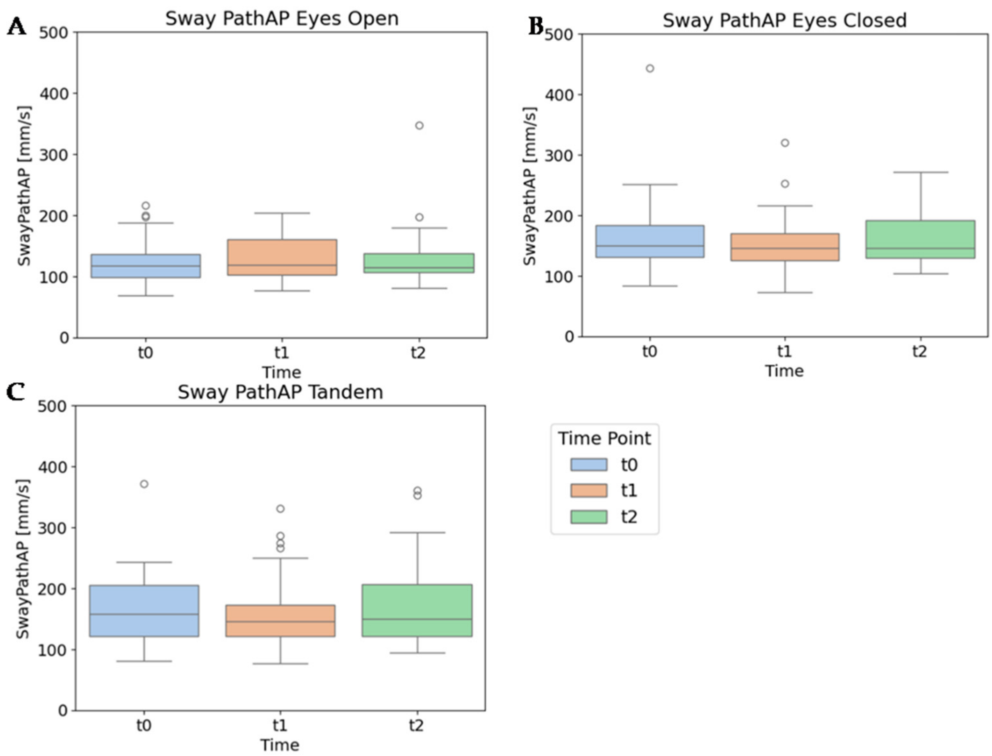

Figure 3. Sway pathAP calculated at the three different time points of all the patients ((**A**) under the eyes-open condition; (**B**) under the eyes-closed condition; and (**C**) under the tandem condition).

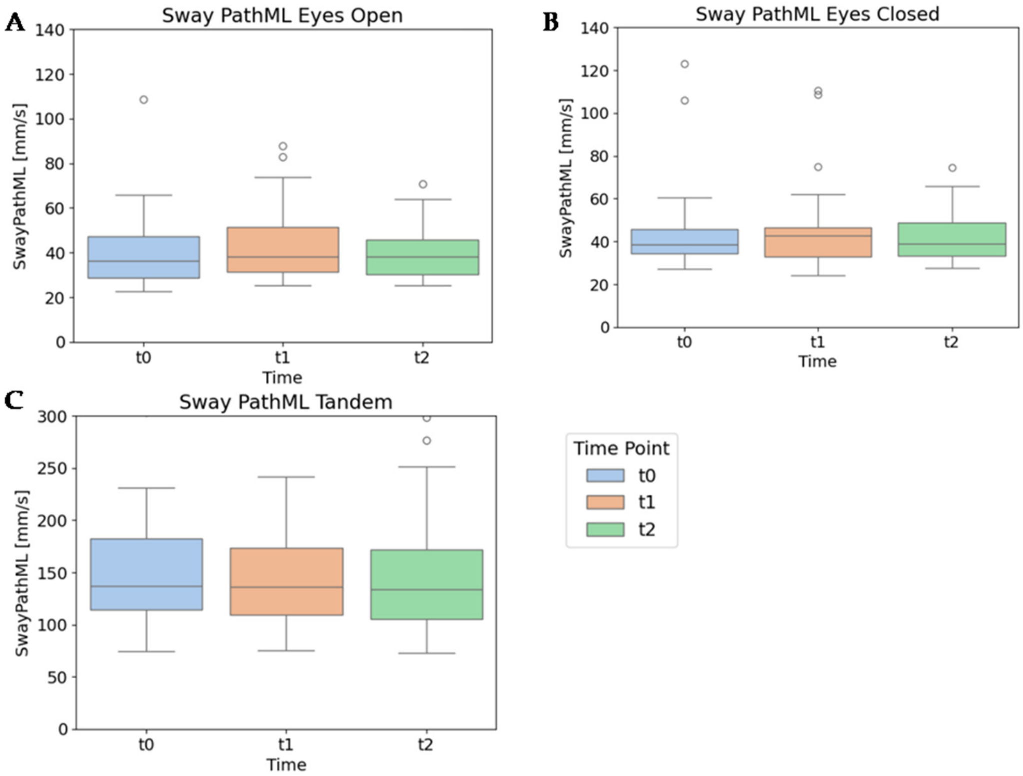

Figure 4. Sway pathML calculated at the three different time points of all the patients ((**A**) under the eyes-open condition; (**B**) under the eyes-closed condition; and (**C**) under the tandem condition).

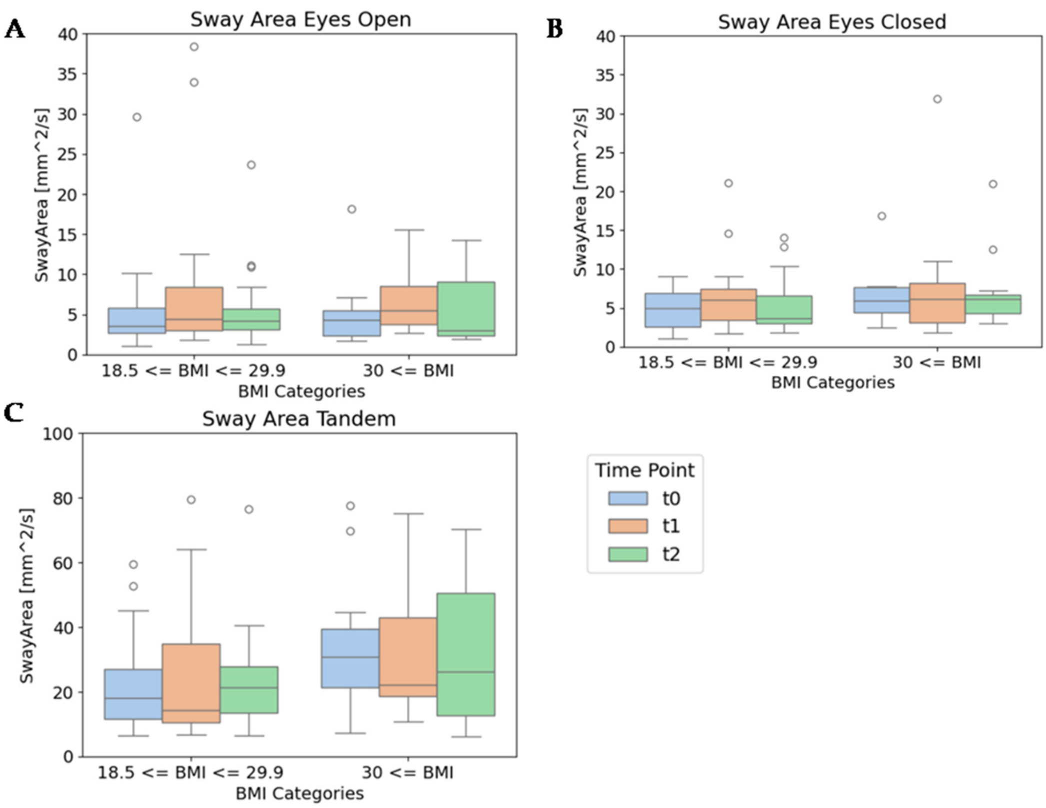

Figure 5. Sway areas calculated at the three different time points for the patients divided with respect to the BMI ((**A**) under the eyes-open condition; (**B**) under the eyes-closed condition, and (**C**) under the tandem condition).

In conclusion, the data indicate that the higher BMI and more challenging balance conditions, particularly in the tandem standing position, are associated with increased sway areas, pointing to potential challenges in postural stability for individuals with an elevated BMI. Across all conditions, there is a variation in sway areas between the time points (t0, t1, and t2). However, these differences appear relatively minimal, suggesting that sway areas might not dramatically change over time or with the intervention being measured.

3.2.2. Sway PathAP

Figure 6 displays the sway pathAP obtained for the two different classes. In the open and eyes-closed conditions (Figure 6A,B), the lower BMI group shows lower median sway path values and tighter IQRs than the higher BMI group, indicating better balance stability. The obese class BMI group displays slightly higher median values and wider variability in both cases, i.e., EO and EC. Another common characteristic is the slight reduction in the median sway path observed from t0 to t2, indicating the improvement over time in both BMI groups. In the tandem condition (Figure 6C), the sway pathAP values are significantly higher than in the EO and EC conditions (normal class—t2: EO vs. T, $p < 0.05$). However, also in this case, the considerations reported for the other two conditions remain valid. At the same time, we can observe that the median values for the eyes-open condition are lower than the other two conditions; this confirms that the subject has more difficulties in maintaining balance in eyes-closed or tandem conditions instead of the eyes-open condition. In this case, the observation made for the sway pathAP between t1 and t0, t2 is valid only for the eyes-open test. In the other two condition tests, this situation is no longer observed; on the contrary, at time t1, the data appear to have lower values compared to the other two time points.

3.2.3. Sway PathML

Considering the sway pathML parameter, the observations are similar to those of the previous parameters (Figure 7). Both BMI groups exhibit relatively low sway path values compared to the other conditions. The lower BMI group shows slightly lower medians compared to the higher BMI group. In both groups, the median sway path decreases from t0 to t2, reflecting an improvement in balance over time. In the second BMI group, a more presence of outliers could be seen. Overall, the EO condition appears to be the least challenging, as suggested by low median values as reported in Figure 7A. In the second condition (EC, Figure 7B), both BMI groups show similar behavior in sway pathML values compared to the EO condition. Both groups show a reduction in median sway paths from t0 to t2, but the improvement is more evident in the lower BMI group. This condition highlights the importance of the visual input for balance, particularly in individuals with higher BMIs. In the case of the tandem position (Figure 7C), both BMI groups show significantly higher sway path values compared to EO and EC conditions, reflecting the increased difficulty of maintaining a stable position (normal class—t0: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$; t1: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$; and t2: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$; obese class—t0: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.001$; t1: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.001$; and t2: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.01$). Considering different time points, the sway pathML assumes higher values at t1 either in eyes-open and eyes-closed conditions. In the tandem one, an opposite condition could be seen.

3.3. Age Analysis

The patients were divided into two different groups: the first group includes patients under 65 years old (named 'young'), while the second one includes patients over 65 years old (named 'old'). Below, the parameters of sway area, sway pathAP, and sway pathML across the three different conditions are presented: Eyes Open (A), Eyes Closed

(B), and Tandem (C) positions categorized by two age groups (≤65 years and >65 years) and evaluated at three time points (t0, t1, and t2).

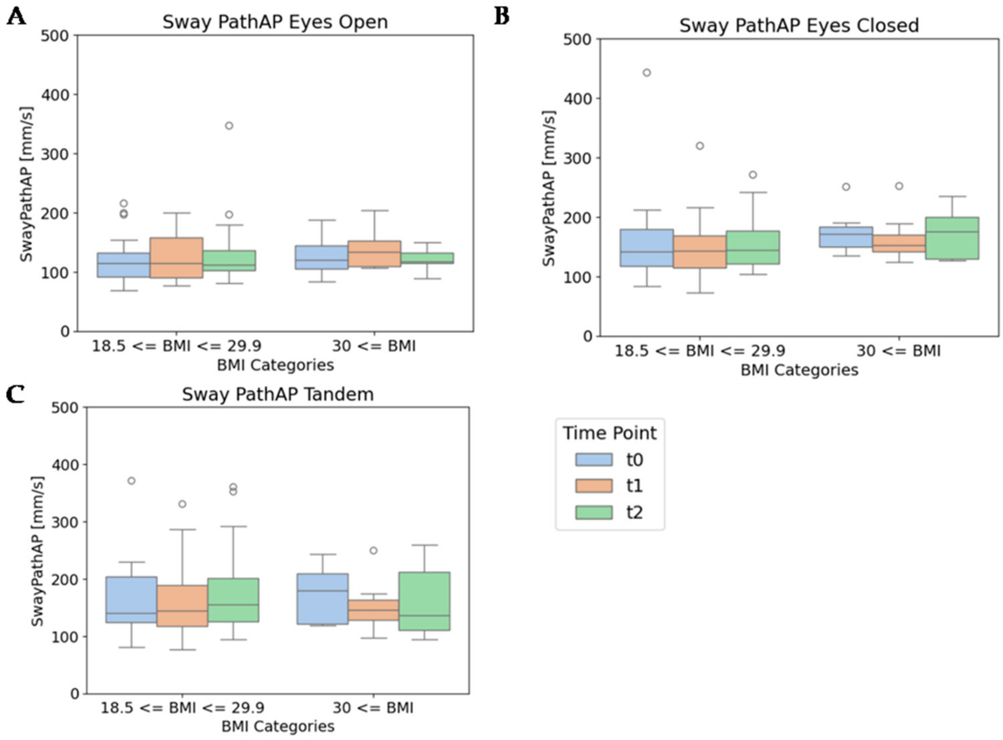

Figure 6. Sway pathAP calculated at the three different time points for the patients divided with respect to the BMI ((**A**) under the eyes-open condition; (**B**) under the eyes-closed condition, and (**C**) under the tandem condition).

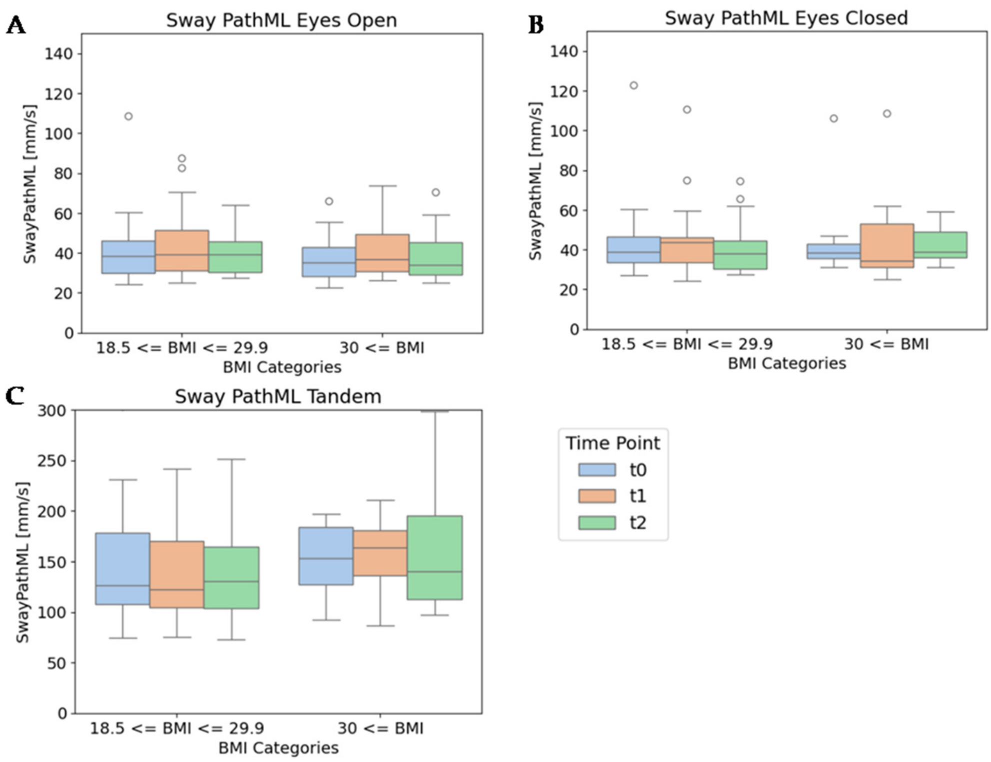

Figure 7. Sway pathML calculated at the three different time points for the patients divided with respect to the BMI ((**A**) under the eyes-open condition; (**B**) under the eyes-closed condition, and (**C**) under the tandem condition).

3.3.1. Sway Area

Figure 8 shows the sway area obtained for the two different ages. In Figure 8A (EO) and Figure 8B (EC), the sway area parameter remains low for all time points and, in particular, the young group exhibits lower median values and tighter IQRs compared to the old group, suggesting poorer balance control with increased age. The main difference is that in the EO condition, there are minimal variations observed between the time points (t1 values are higher than t0 and t2 values in both age categories). Instead, in the EC condition, there is not a clear trend. The postural exercise performed under tandem conditions shows a significant increase in the sway area with respect to the two previous conditions (Figure 8C) (young—t0: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$; t1: EO vs. T, $p < 0.001$, EC vs. T, $p < 0.01$; and t2: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$; old—t0: EO vs. T, $p < 0.0001$, EC vs. T, p-value < 0.01; t1: EO vs. T, $p < 0.01$, EC vs. T, $p < 0.001$; and t2: EO vs. T, $p < 0.01$, EC vs. T, $p < 0.01$). The tandem position demonstrates higher variability and sway area across both age groups. These findings suggest that the tandem position is more challenging, particularly for older individuals, and highlights the impact of age and time on balance performance. The values in Figure 8B are slightly higher than in the eyes-open condition, especially for the >65 years group, reflecting the increased difficulty of the task. In the tandem position (Figure 8C), there is a minimal increase in the >65 years group, suggesting greater difficulty in maintaining balance. In contrast, the ≤65 years group maintains relatively stable values across time points.

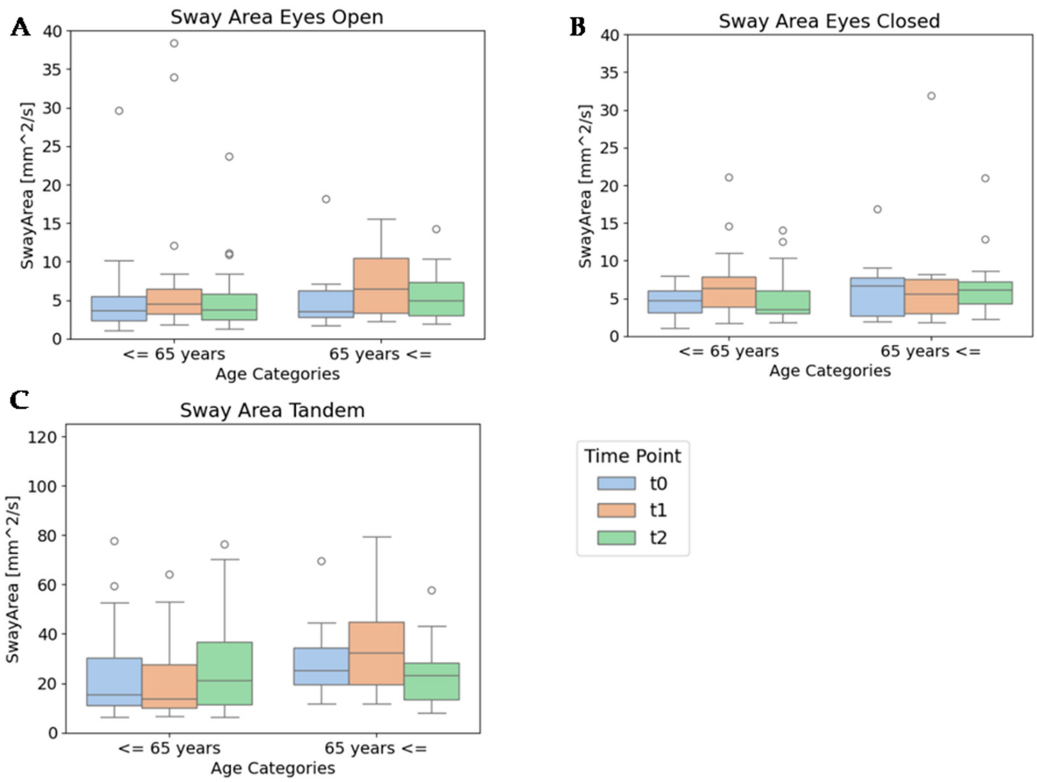

Figure 8. Sway area calculated at the three different time points for the patients divided with respect to age ((**A**) under the eyes-open condition; (**B**) under the eyes-closed condition, and (**C**) under the tandem condition).

3.3.2. Sway PathAP

The different sway pathAP obtained for young and old patients are reported in Figure 9. In Figure 9A, both age groups show relatively consistent values across time points in eyes-open condition; a slight increase can be noticed at t1 for both groups, though the differences are minor. In Figure 9B (the EC condition), the values are slightly higher than in the EO condition, especially for the >65 years group, reflecting the increased difficulty of the task.

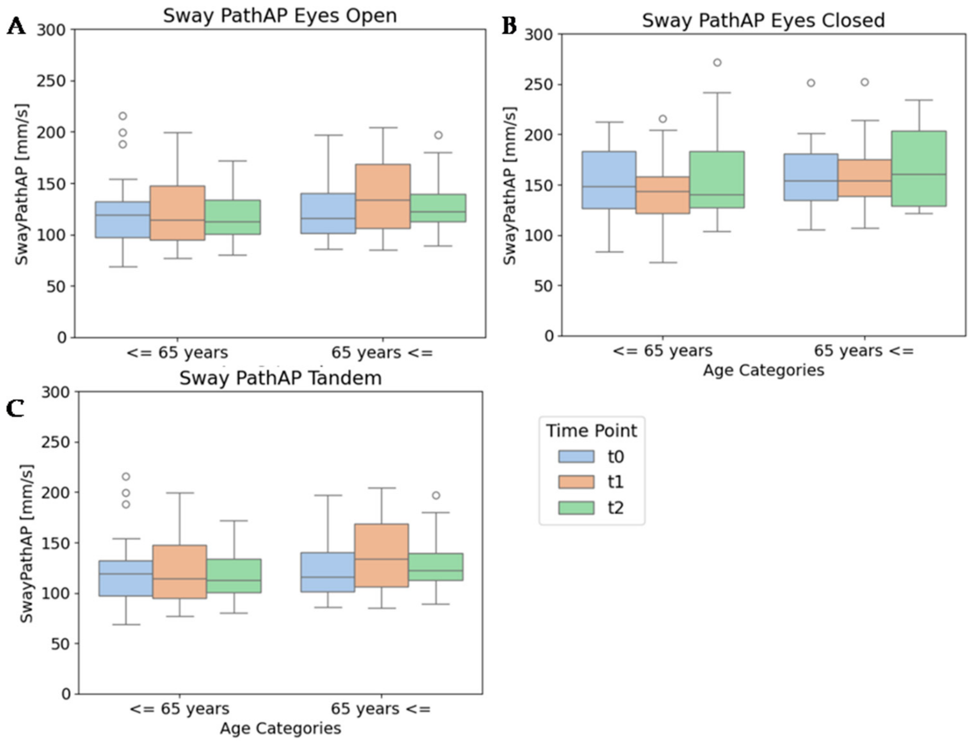

Figure 9. Sway pathAP calculated at the three different time points for the patients divided with respect to age ((**A**) under the eyes-open condition; (**B**) under the eyes-closed condition, and (**C**) under the tandem condition).

The tandem position shows the highest sway path values (Figure 9C); in fact, both age groups display greater variability compared to the other conditions. At t1, there is a slight increase in the second group (old patients), suggesting greater difficulty maintaining balance.

Across all the test conditions, the younger group shows slightly lower median sway values and tighter IQRs compared to the older group, indicating better balance stability. The eyes-closed condition and tandem position show higher values for the >65 years group, indicating that these tasks are more challenging for older individuals. In general, t1 displays minimal higher values, potentially reflecting an adjustment period or increased instability. The ≤65 years group shows more stability across time points and conditions, showing better balance control in younger patients.

3.3.3. Sway PathML

In the EO condition (Figure 10A), both age groups show low sway pathML values. There is a minimal of variability in the data, and no significant differences are observed between t0, t1, and t2. In the second setup (Figure 10B), the values remain relatively low but are slightly higher than in the first condition, particularly in the >65 group. A minor increase is observed at t1 for both age groups, followed by stabilization at t2.

As in the first two groups, also in the tandem position, the ≤65 years group shows lower values compared to the older group (>65 years), indicating an age-related decrease in stability.

In Figure 10C, the highest sway pathML values are also observed, especially in the >65 years group. For the >65 years group, t1 shows slightly higher sway pathML values compared to t0 and t2. The time point t1 shows slight increases in sway pathML values for all conditions and age groups, suggesting possible instability or an adjustment period.

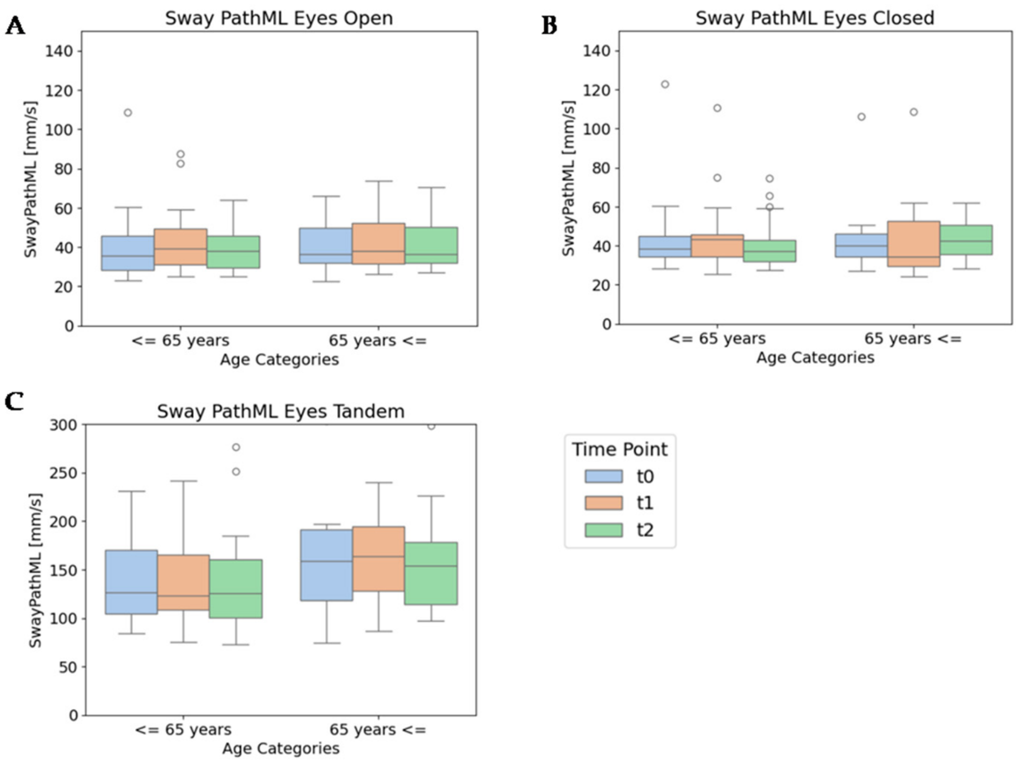

Figure 10. Sway pathML calculated at the three different time points for the patients divided with respect to age ((**A**) under the eyes-open condition, (**B**) under the eye-closed condition, and (**C**) under the tandem condition).

3.4. Male vs. Female Analysis

3.4.1. Sway Area

The sway area values obtained for the patients' evaluated under EO, EC, and TANDEM conditions are reported in Figure 11. In particular, in Figure 11A, some trends could be seen. While males' median sway area remains small across time points with limited variability and few outliers, female patients' median sway area is larger than males with increased variability. For either gender, no drastic changes could be seen, except for a slight decrease in the sway area at t2 compared to the earlier time points. This behavior can be understood as adjustment to the insole after 30 days.

In Figure 11B, i.e., the EC condition, the male's sway area increases compared to the eyes-open condition. Also, the variability is slightly higher, but it remains more controlled than in females. A minimal increase could be seen from t0 to t1, with a decrease at t2. Females exhibit larger differences between time points, suggesting greater sensitivity to time-related factors.

Regarding the postural exercises under the tandem condition (Figure 11C), the median sway area values and variability are higher than in previous conditions for both groups. The median sway area of the female population is much higher than that of the male, with extremely wide variability. Considering time point differences, both male and female show variations across t0, t1, and t2, with no specific trend.

In general, across all conditions, female patients tend to show a higher median sway area, indicating greater postural sway compared to males. Males tend to exhibit smaller sway areas, with more variability and fewer outliers, indicating more consistent performance. In general, the data registered at t0 show the smallest sway area; at t1, the data generally show an increase in the sway area for both sexes and conditions, suggesting a potential worsening in balance. At the latest time point t2, patients tend to be more stable, indicating potential adaptation over time. Based on the graphs, the balance difficulty increases through the tests. The tandem stance shows the largest sway area and variability.

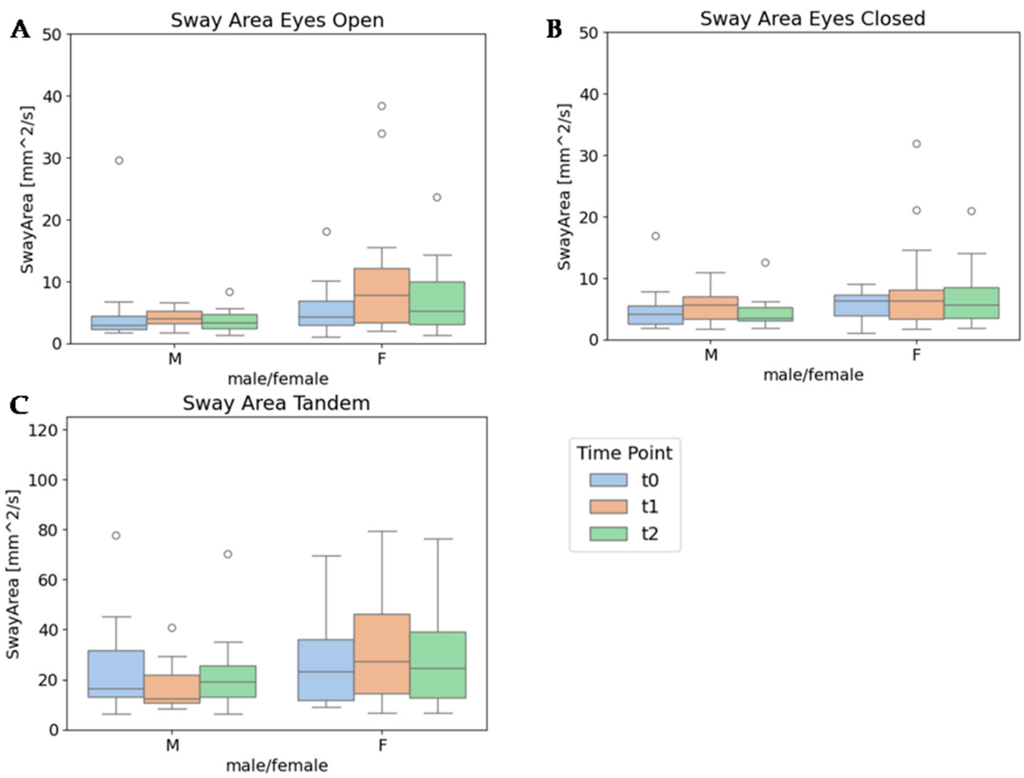

Figure 11. Sway area calculated at the three different time points for the patients divided with respect to sex ((**A**) under the eyes-open condition; (**B**) under the eyes-closed condition, and (**C**) under the tandem condition).

3.4.2. Sway PathAP

Figure 12A shows the data regarding the sway pathAP obtained under the eyes-open condition; males tend to show smaller variability and a lower median sway across all time points compared to females. On the other hand, females exhibit slightly higher median sway and greater variability. Outliers could be seen in both groups, indicating variability. For both genders the sway pathAP decreases over time (from t0 to t2), except for the female sway pathAP in eyes-closed condition as shown in Figure 12B. Both male and females display higher sway values overall compared to the EO condition, indicating the influence of vision on balance and the proprioception sensor system.

Regarding the analysis of the eyes-closed condition (Figure 12B), the median sway pathAP of females is higher than that of males and remains consistent across t0, t1, and t2. Outliers are prominent in both sexes, but they appear at greater frequencies and higher values in females. This condition highlights a notable difference between sexes, as females have consistently higher sway metrics.

As other conditions described, both males and females show significantly higher sway path values in the tandem test (Figure 12C) (male—t2: EO vs. T, $p < 0.05$; female—t0: EO vs. T, $p < 0.05$). As could be seen, both males and females show significantly higher sway pathAP values in this condition compared to the eyes-open and eyes-closed conditions. The male group exhibits relatively lower sway metrics and slightly smaller variability. Across time points (t0 to t2), the sway path appears to stabilize slightly for both genders, as median values decrease, particularly for males. In conclusion, females generally exhibit higher sway path values and greater variability compared to males under all conditions and at all time points. Across t0, t1, and t2, there is a general trend of reduced sway path values over time for both genders, particularly evident in the eyes-open and tandem conditions. The reduction may reflect learning effects, adaptation, or improved balance performance over time.

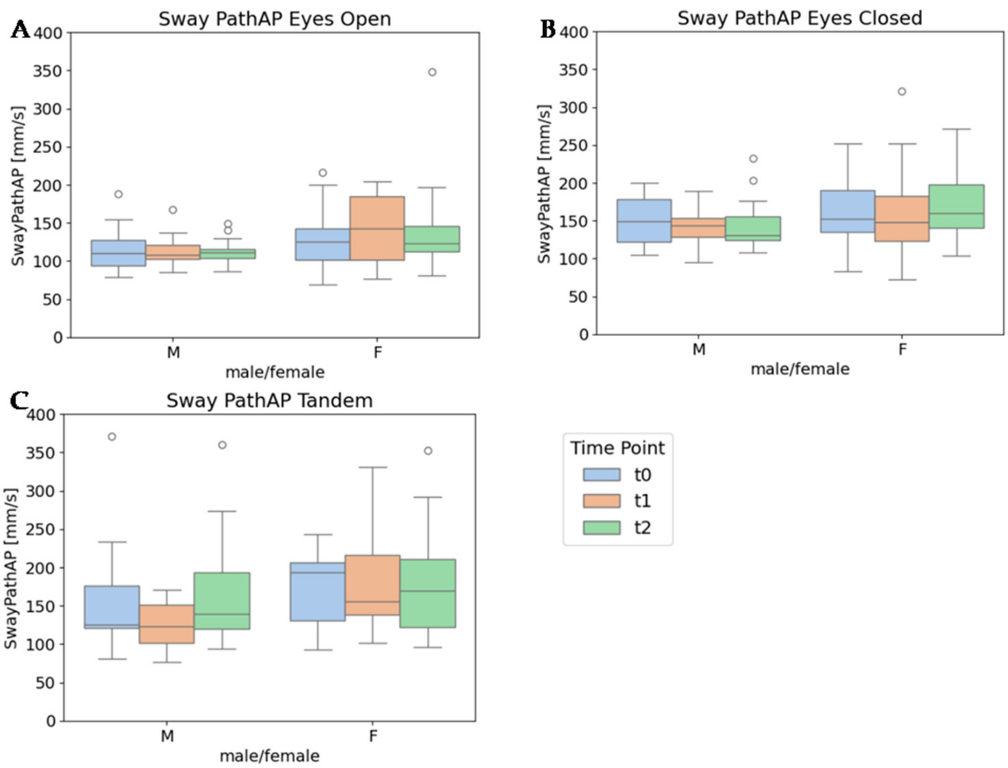

Figure 12. Sway pathAP calculated at the three different time points for the patients divided with respect to sex ((**A**) under the eyes-open condition; (**B**) under the eyes-closed condition, and (**C**) under the tandem condition).

3.4.3. Sway PathML

In Figure 13, the area calculated for sway pathML is reported and divided according to sex. For the eyes-open condition (Figure 13A), males generally exhibit lower sway values compared to females; instead, outliers are present in both sexes. Across time points (t0 to t2), males exhibit a consistent reduction in sway paths, while females show less pronounced changes.

In Figure 13B, the EC condition, both males and females exhibit higher sway values compared to the EO condition, indicating a correlation between vision and lateral stability. For males, the median sway values are consistent across time points with minimal variability. In females, the variability of median sway values is higher than males and increases slightly at t1 and t2. Outliers are observed in both groups, but they are more frequent and extreme in females, extending beyond 100 mm/s. The data suggest that females experience greater difficulty maintaining balance without the visual input.

Figure 13C shows the results about the tandem condition, where both males and females demonstrate significantly increased sway pathML values compared to the other two conditions in standing position (male—t0: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$; t1: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$; and t2: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$; female—t0: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.001$; t1: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$; and t2: EO vs. T, $p < 0.0001$, EC vs. T, $p < 0.0001$). In addition, males have consistently lower median medio-lateral sway path values and reduced variability across time points compared to females; this last group displays higher sway path values, particularly at t1 and t2, with considerable variability and numerous extreme outliers (some exceeding 400 mm/s, excluded from the image to have a better visualization). The tandem stance condition amplifies the observed gender differences in sway paths and variability.

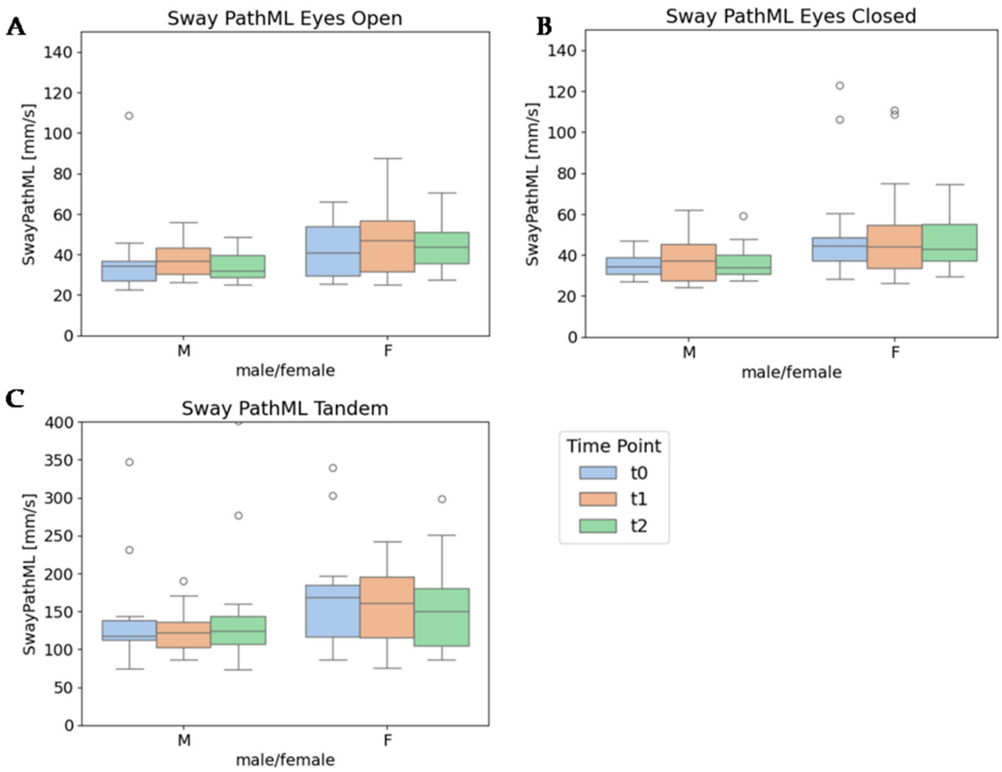

Figure 13. Sway pathML calculated at the three different time points for the patients divided with respect to sex ((**A**) under the eyes-open condition, (**B**) under the eyes-closed condition, and (**C**) under the tandem condition).

Males demonstrate consistent improvements in sway path metrics across t0, t1, and t2, while females exhibit smaller reductions in sway pathML over time, particularly under more challenging conditions.

The tandem stance condition introduces the greatest difficulty, as indicated by the highest median values, greatest variability, and most frequent extreme outliers.

4. Discussion

Foot problems, particularly foot pain, hallux valgus, and lesser toe deformities, are associated with an increased risk of falls in older adults [50–52]. Documenting these issues and referring patients to foot care specialists should be a regular part of fall risk assessments. Research indicates that fallers experience significantly more foot pain than non-fallers (57.9% vs. 42.1%) and exhibit higher pressure under their feet [13,53]. The link between foot pain and falls is stronger than other common risk factors such as cognitive impairment and depression [54]. This highlights the crucial role of podiatrists in multidisciplinary teams to prevent falls and treat foot impairment disorders [55–60]. Evidence shows that targeted interventions by podiatrists can reduce fall rates among older individuals with foot pain [61,62].

In particular, here, we have investigated the use of wearable devices such as inertial sensors to define and develop a new protocol to evaluate the balance in patients affected by foot pain. In fact, different foot orthotics are used in the patients, and through the application of a wearable inertial sensor system, composed of a tri-axial accelerometer, gyroscope, and magnetometer, their equilibrium was evaluated using three postural exercises to evaluate the postural sway at different time points. In fact, in the literature are reported the evident connection and relation between the postural sway and the risk of falling [63–65]. The effect of BMI, sex, and age of patients on stability and biomechanical parameters was evaluated.

First, an overall population analysis was performed to observe differences in the application of the different parameters natural standing with eyes open, natural standing with eyes closed, and tandem standing. No significant differences were observed between the results of tests performed at t0, t1, and t2 in the three different tasks. However, a significant difference in the measurement of sway areas was observed in pathAP and pathML by making a comparison of natural standing (eyes open and closed) with the tandem condition.

Beginning with the analysis across BMI categories (i.e., normal class and obese class). In fact, in the obese condition, the body geometry is altered with respect to the physiological condition, and these differences can affect the postural stability [66]. Several works have showed that the body weight could influence and increase the center of pressure velocity, which is a parameter connected to the stability maintenance [67] with a strict relationship between obesity and postural instability [68–70]. In fact, the adipose tissue accumulation and excessive body weight can alter the body geometry, with influences on the biomechanics of different daily activities and increasing difficulties in the center of pressure displacement control. In our study, a clear difference between the median value and IQRs emerged. Patients in the normal BMI category demonstrate better balance maintenance compared to those in the obese category, confirmed by the lower median value, narrower IQRs and the minor presence of outliers. This observation is consistent across all the three task, i.e., EO, EC, and TANDEM, always taking into consideration the results for all the biomechanical parameters. These behaviors are confirmed by the results obtained by Yümin E.T. et al. [71], which highlighted a significant decline in postural stability among women with higher BMI values. In addition, Wu et al. provide an insight into this theme, showing that individuals with higher BMIs exhibit reduced plantar sensitivity [72]. This reduced ability to perceive changes in pressure on the plantar surface has been directly linked to poorer postural control and balance performance. Therefore, we can suppose that this degradation in neurosensory feedback from the plantar surface may be a cause for our results, i.e., lower median and narrower IQRs, as human standing balance control relies on feedback from the proprioceptive system, and obese individuals are less stable than normal [73]. Regarding the age categories (i.e., young and older groups), it can be observed that the older group finds greater challenges in maintaining balance across all three biomechanical parameters. Generally, the young group exhibits lower median values and tighter IQRs compared to the older group, and this suggests poorer balance control with increased age. The more stable condition showed by the ≤ 65 years group across time points and conditions highlights the better balance control in younger patients rather than the older group. These findings could be linked to the results of Mileti I. [74], where less stability in older adults with respect to younger ones is reported. The effect of age on postural sway is consistently observed, with older adults showing greater movement compared to younger adults, as noted by Šarabon et al. [65]. The postural sway differences obtained between the young and old patients confirm that these inertial sensors and postural tasks can be a predictive tool for assessing the risk of falling because it occurs principally in older patients and people [75]. Ageing could change the musculoskeletal system in terms of muscular strength and flexibility; so, postural stability can be affected by these behaviors [76–79]. In addition, other age-related pathologies, such as decrease in vision, dizziness, sensory deficits, and vestibular dysfunctions can contribute to stability and balance maintenance reduction. The differences between males and females remain consistent across the parameters and the evaluation. In particular, the median values for all the three parameters across all time points in the male patients remains small, with limited variability and few outliers. On the other hand, female patients' parameters are higher than those of males. This suggests greater sensitivity to time-related factors. In general, across all conditions, female patients tend to show a larger median sway area, indicating greater postural sway compared to males. In the case of comparison between male and female, several physical and physiological aspects need to be taken into account that could have an effect on the results obtained. In particular, different physiological factors in terms of muscle and fat mass could have an effect on the results obtained. In addition, referring to the age of the subjects, hormonal aspects could come into play (e.g., menopause in older women) that could influence the results obtained in terms of stability. A more in-depth analysis of these parameters, e.g., hormone levels and muscle and fat mass, could be brought out in future studies to obtain more significant differences according to gender.

Focusing on differences across time points, a similar trend could be observed in most cases. Specifically, at the time point t1, there is an increment of all the biomechanical parameters, which may suggest an initial major instability due to adaptation to the use of the foot insole. Additionally, another similar characteristic between the parameters is that the values at t0 are similar to the t2 values, suggesting an improvement in stability over time. However, to evaluate the long-term effectiveness of the insole more accurately, it would be necessary to extend the interval between the first and last time points. A longer observation period, such as three or six months, could provide more differences in terms of postural sway, and it can predict the efficacy of foot orthotic application to reduce the risk of falling.

Finally, some differences were noticed between the different postural exercises used to test the patients. In general, for the parameters and patient's characteristics, the worst stability is noticed in the case of TANDEM exercise with respect to the natural standing position (EO and EC). These effects can be easily explained because the tandem standing position alters the normal and natural standing position so the ability of the patients to maintain the correct equilibrium and the neurosensory feedback (vestibular and proprioception systems) have great influence [80,81]. In particular, a significant difference is noticed between the young and old patients between the TANDEM and natural standing positions, which underlined how age can have an effect on the ability to maintain the equilibrium and avoid the risk of fall. In fact, several studies have reported that around 30% of the older people are involved in dizziness and imbalance episodes [82]. Some differences are also noticed between the natural standing with eyes open and closed. In fact, an increase in the sway area values is reported; in fact, the vision is involved in the antero-posterior and medio-later postural control, so it plays an important feedback role in the maintenance of equilibrium [83]. Several studies have demonstrated how restricted and low vision can cause instability, increasing the body sway and postural oscillation [84]. The evaluation effect of the vision system on the risk of falling is particularly important in the elderly people, where the vision problems can influence their ability to prevent the risk of falling [85,86]. In general, the postural sway tests are applied in the eyes-open and natural standing positions [65]; however, we have demonstrated how different postural conditions can alter the resulted equilibrium, and they can be used as the most predictable parameters to assess the risk of falling.

Limitations and Future Directions

This study has several limitations. First, it did not consider other ailments and conditions that may have contributed to the pain experienced by the subjects, which could have influenced the results. Furthermore, a high Body Mass Index (BMI) can occur in individuals with significant muscle mass; therefore, participants may have been more accurately categorized using body fat percentage.

In particular, the principal limitations are:

- The number of patients recruited is limited, and the number of patients for groups compared is unequal.
- The short-term follow-up: The length of the follow-up period can be increased to three or six months in future studies.
- The BMI comparison can be influenced by the body fat and muscle percentages. Therefore, the comparison based on the body fat and muscle percentages in future studies can improve the results obtained.
- The physical (bone density and muscle and fat masses) and hormonal level differences between males and females were not taken into account during this preliminary study.
- More detailed classification of different ages can be achieved after recruiting a larger number of patients.

In this pilot study, we focused on the set up of the study design before implementing large-scale studies and a long-term follow-up. In particular, the assessment of the biomechanical parameters, which can be used to design a relevant, economical, and of statistically adequate sample size, was studied, and the obtained preliminary data will be useful in future study design.

5. Conclusions

It is well established in the scientific literature that foot pain is associated with an increased risk of falling. Foot orthoses have been shown to effectively reduce foot pain. Understanding on how foot orthoses prevent falls in patients with foot pain and how to quantify these results over time is limited. In this study, we have explored the possibility to use a new protocol to evaluate and prevent the risk of falling in patients affected by foot pain with a wearable inertial sensors system for the assessment and monitoring of patients' balance and equilibrium over time. Specifically, no significant difference was observed in the natural standing condition between eyes open and eyes closed, but applying a tandem standing condition can represent a better experimental condition for developing a protocol for fall prevention. The obtained results represent a starting point in the development of a low-cost and time-consuming protocol to be applied in future large-scale studies and long-term follow up to improve the risk of falling evaluation and prevention.

Author Contributions: Conceptualization, M.M., A.M. and L.B.; methodology, M.M., I.R. and L.B.; formal analysis, M.M. and I.R.; data curation, I.R.; writing—original draft preparation, M.M. and I.R.; writing—review and editing, M.M., N.B., A.M. and L.B.; visualization, M.M. and I.R.; supervision, N.B., A.M. and L.B.; funding acquisition, N.B. All authors have read and agreed to the published version of the manuscript.

Funding: The authors acknowledge co-funding from Next Generation EU in the context of the National Recovery and Resilience Plan, Investment PE8—Project Age-It: "Ageing Well in an Ageing Society". This resource was co-financed by the Next Generation EU [DM 1557 11.10.2022]. The views and opinions expressed are only those of the authors and do not necessarily reflect those of the European Union or the European Commission. Neither the European Union nor the European Commission can be held responsible for them.

Institutional Review Board Statement: This study was conducted in accordance with the guidelines of the Declaration of Helsinki and was approved by the Institutional Review Board of Rizzoli Orthopedic Institute (reference: CE AVEC: 659/2021/Sper/IOR, 18 August 2021).

Informed Consent Statement: Informed consent was obtained from all subjects involved in this study. All the patients provided their written informed consent at admission upon data collection.

Data Availability Statement: The data presented in this study are available on request from the corresponding author; however, restrictions apply to the availability of these data, which were used under license for this study, and they are thus not publicly available.

Conflicts of Interest: The authors declare no potential conflicts of interest with respect to the research, authorship, and publication of this article. The funders had no role in the design of the study; in the collection, analyses, or interpretation of the data; in the writing of the manuscript; or in the decision to publish the results.

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