



Original Article

Use of the pedometer in the evaluation of the effects of rehabilitation treatment on deambulatory autonomy in patients with lower limb arthroplasty during hospital rehabilitation: long-term postoperative outcomes

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Abstract. [Purpose] To provide data on the applicability of pedometers in the evaluation of the results of rehabilitative treatment on total daily walking activity after total knee arthroplasty (TKA) and total hip arthroplasty (THA). [Participants and Methods] One hundred fifty six hospitalized patients (age 63.9 ± 12.2 years) involved. On the day of hospitalization and at the end of the rehabilitation treatment the following were performed: clinical examination, X-ray examination and weight. On the same day the pedometer was applied and removed after 48 hours. Only on 30 participants, the same evaluation was carried out 5 days before the hospitalization to measure reliability and responsiveness. Compliance was measured by a face-to-face interview. Visual analogic scale (VAS), Barthel Index (BI) and Ambulation Index (AI) were used to better describe the analyzed sample. [Results] VAS, BI and AI improved by 29.8%, 19.4 and 60.6% respectively. The data obtained on testing-retesting showed a good reliability and a mean Total Error of 7.3% for steps and 15.8% for distance. A good response in the test-retest was detected. The deambulatory autonomy of patients passed from $2,070 \pm 740$ m to $3,100 \pm 810$ m. Average improvement in the number of daily steps is 25%. [Conclusion] The data showed a good applicability of pedometer. The results on responsiveness can be used to better interpret the results of rehabilitative treatment on total daily walking activity after THA and TKA.

Key words: Daily walking activity, Reliability, Responsiveness

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INTRODUCTION

Daily physical activity (PA) is important in maintaining a good state of health, especially in old age, and a worsening in deambulatory performance has been associated with a decrease in the quality of life, disability, increase in the number of hospitalization cases, incidence of chronic disease (diabetes, lung disease) and increased mortality¹⁻³⁾. Ambulation, especially in elderly patients, represents a significant part of daily PA²⁾ and is often penalized after orthopedic surgery on the lower limbs.

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Therefore, a valid and reliable method is fundamental in the study of daily deambulatory autonomy, one that can be easily used after the most common orthopedic surgeries on the lower limbs: total hip arthroplasty (THA) and total knee arthroplasty (TKA).

In a clinical setting, fitness tests or questionnaires and scales are more frequently used, but they only provide indirect indicators regarding total deambulatory activity (home-based walking activity and other walking activities). The pedometer is a valid option in assessing PA in both research and practice. Pedometers are most sensitive to deambulatory tests (walking and running) and can be useful for surveillance, screening and monitoring the effects of surgical interventions¹⁻⁴. Given the low cost of most pedometers, their ease of use and objective output, they are a feasible, fitting, and cost-effective measurement device^{1, 2, 4, 5}. Pedometers have been used to monitor PA in pregnant women, adults, children, adolescents as well as in patients affected by COPD, diabetes, cystic fibrosis and cardiovascular disease^{2, 4-6}. The device has been used in various cases to determine PA in patients with osteoarthritis⁷, after TKA and THA⁸⁻¹⁵, for the validation of scales¹⁶⁻¹⁸. Available evidence suggests that pedometers are valid for use in clinical and research environments in people with physical disabilities^{4-6, 19} and that they have been used in healthy adults²⁰, orthopedic and neurological patients. The pedometer, actually, has been frequently used for various types of studies over the last 20 years, but our research has not revealed any articles regarding its use in the evaluation of the outcomes of rehabilitation treatment in long-term postoperative conditions.

In cases of surgical interventions involving the lower limbs, the primary objective of the rehabilitation treatment is the recovery of deambulatory autonomy and the return to an adequate level of daily PA. Our idea was to use the pedometer to evaluate the effects of rehabilitative treatment on the total daily deambulatory autonomy after TKA and THA.

Considering the studies that have been carried out so far, there is no article in the scientific literature which reports data about the use of pedometers to study the effects of rehabilitation treatment and long-term postoperative outcomes. Therefore, the aim of our research was to provide data on the applicability of pedometers (compliance, reliability and responsiveness) in the evaluation and interpretation of the results of rehabilitative treatment on total daily walking activity after TKA and THA, considering a hospital environment and long-term post operation condition.

PARTICIPANTS AND METHODS

All patients involved in the study were informed of the methods and aims of the study and read and signed the consent form giving this information. The approval of the ethics committee of the hospital where the research was carried out was required and obtained. All procedures were carried out in accordance with the Declaration of the World Medical Association and with the Declaration of Helsinki guidelines. One hundred fifty six patients with an average age of 63.9 ± 12.2 years participated in the study. Seventy nine were males and 77 females. All patients were operated on by the same surgical team between 2014 and 2016. Among these, 80 were THA and 76 TKA. Exclusion criteria were: presence of other orthopedic prosthesis, surgery performed for over 45 or less than 20 days, radiographic signs of prosthetic mobilization, pain ≥ 7 (VAS), Barthel Index value ≤ 50 , AI ≤ 2 , postoperative infectious complications, difficulty performing the period of codified postoperative physiotherapy, cardiovascular and respiratory disease, obesity, age >75 years.

The following evaluations were performed by the physician and the radiologist, with the assistance of specialized nursing personnel: clinical examination, X-ray examination and weight. On the same day, at the end of the evaluation, the step length was measured by the physician and the physiotherapist, and then set in the pedometer worn later by the participants. The pedometer was applied by a nurse at 10:00 am and removed after 48 hours by the same operator. All examinations and procedures were carried out individually at the rehabilitation department of the hospital where the study was conducted.

The assessments were performed in the way described above in three different evaluation sessions: in a limited sample of 30 participants, 15 males (6 THA and 9 TKA) and 15 females (7 THA and 8 TKA) randomly selected among the study participants, 5 days before the hospitalization an evaluation was carried out (T0), the second one (T1) on the day of hospitalization for all participants (T1). On the discharge day, the same measures were repeated by the same operators at the end of the rehabilitation treatment for all patients (T2). The pedometer was applied always at the same time as the T1 and returned after 48 hours. In the 12 hours after the removal of the pedometer, a face-to-face interview was conducted by the physiotherapist and a nurse, to test the participant's compliance with the use of the pedometer (Fig. 1).

Among the commercially available pedometers, the Omron Walking StylePro Pedometer Hj 720 was chosen, which is already used for total daily walking activity and validated in other scientific works²¹. The effect of the pedometer position on step count accuracy was evaluated²¹.

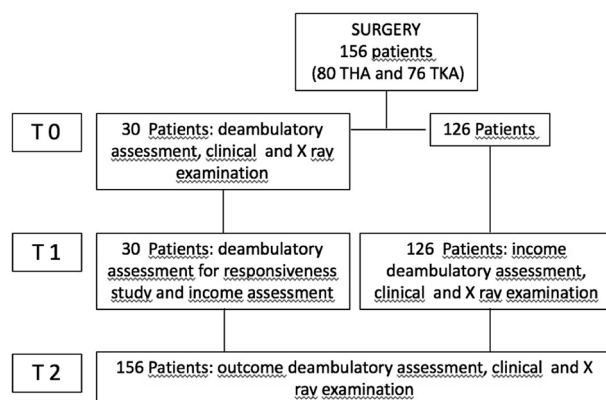


Fig. 1. Study protocol.

THA: Total hip arthroplasty; TKA: Total knee arthroplasty.

Differences between the left and right sides were demonstrated in relation to gait asymmetry. In our patients, the asymmetry was exacerbated by the constant presence of a lateral mono pathology.

For this reason, the pedometer was applied at the umbilical level. The positioning error was considered systematic because at T1 and T2 we used the same type of positioning and only considered the differences between the two measurements. The measurement was taken in the whole 48 hours and then the Daily steps was calculated as an average value of the 48-hour value.

The step length was measured on a coded path of 30 m (codified stop and go—shuttle walking test on 10 m). The step length test was video-analyzed using a high-speed digital camera (Casio Exilim FH020 Hi-speed, 210 fps) and the videos were analyzed off-line with a Dartfish 5.0 Pro (Dartfish, Fribourg, Switzerland). To assess the step length, the average of all the steps taken was considered.

For a better description of the sample some evaluation scales were used.

VAS is a tool for measurement of pain. VAS has also proved to be satisfactory in subjective measurement of orthopedics patients after hip and knee arthroplasty²²). VAS scale used is 10-cm lines anchored at the ends by words that define the bounds of various pain dimensions.

The BI is an ordinal scale used to measure performance in routine daily activities. It is one of the most commonly used clinical instruments for general assessment of physical function, especially in rehabilitation²³). Although more specific for neurological diseases, in our and other studies²⁴) it was used for global functional status evaluation²⁵). The maximum score is 100 and indicates autonomy in all routine daily activities²⁶).

The item “Ambulation” of the Adapted form of the Patient Evaluation Conference System” was used to assess autonomy during ambulation²⁷). The scoring system foresees a minimum value of 0 (not assessed) up to the maximum value of 7 (within normal limits—functionally independent).

All the participants in the study had performed for about 20 days a codified physiotherapy program at the hospital where they had undergone prosthesis surgery. The program lasted about 60 minutes a day and included: deambulation training, segmental passive joint mobilization, segmental active joint mobilization. Then they stayed a few days at home before being hospitalized and starting rehabilitation treatment.

The rehabilitation treatment started 28 ± 6 days after surgery and lasted 8 weeks (48 days of treatment) for all patients. Each day, the patients performed a total of 150 minutes of rehabilitation between 8:00 am and 3:00 pm at the rehabilitation day hospital ward. All patients performed the same coded rehabilitative treatment that included: 1) lower limb joint kinesitherapy to recover the range of motion and lower limb strength training; 2) indoor and outdoor walking training, balance training, bike training; 3) hydrokinesitherapy.

The lower limb joint kinesitherapy to recover the range of motion and the lower limb strength training was performed every day. On alternate days, indoor and outdoor walking training, balance training, bike training and hydrokinesitherapy were performed.

The test-retest method was used to evaluate reliability and responsiveness: a part of the sample (30 participants) performed all the assessments 5 days before admission (T0) and then again at the time of hospitalization (T1).

Reliability refers to the reproducibility of a measurement and is quantified simply by taking several measurements on the same patients. Poor reliability degrades the precision of a single measurement and reduces the ability to track changes in measurements in the clinic or in experimental studies.

Responsiveness is the sensitivity of a test in measuring a phenomenon, i.e. the capacity of a test to detect clinically important changes or changes over time, and is evaluated by various responsiveness statistics. The responsiveness is determined by comparing before and after scores. MDC and MCID are measures of responsiveness. The MDC expresses the minimal magnitude of change above or below which the observed change is likely to be real and not just a measurement error²⁸). The MCID is the smallest difference between the scores that the patient perceives to be beneficial²⁹). According to other authors³⁰) the values of the SEM, as well as those of the effect size and the SRM (which is a particular type of effect size), are reported as indicative of the MCID of a test. Cohen’s effect size and SRM provide a dimensionless assessment of the real effectiveness of a test. The SRM gives us the opportunity to assess the range of outcome values that can be expected on retesting³⁰). Considering the 95% CI, we can estimate that 95% of the times the measurement errors associated with the use of this test will fall within this range.

An interview with six yes-no questions was used to test the patients’ compliance with the measurement within 48 hours. The questions concerned: 1. General annoyances; 2. Daily activity limitation; 3. Hygiene; 4. Usefulness of the measurement; 5. Need to stop the measurement; 6. Need to call the healthcare staff for the management of the pedometer. All the questions involved a yes/no answer. More than two answers among questions 1, 3, 4 and 6 should be answered as “no” to be considered noncompliant. Questions 2 and 5 were barrier question and answering “no” to one of these automatically meant being noncompliant .

The data was collected using the Excel 2013 software (Microsoft, Redmond, WA, USA) and processed with the SPSS 19 software (IBM Inc., Armonk, NY, USA). In the text, data are given as mean and SD. We studied the normality of data with normality plots, Kolmogorov Smirnov and Shapiro-Wilk tests. The homogeneity of variance was analyzed using Levene’s test. To verify the difference between means pre-post we used the t-test. Pearson’s test was used to verify the correlation between variables.

The Cohen’s d effect size was used to study the effect size, according to the formula $M1 - M2 / SD$ pooled. Where M1 is

the mean value of the first measurement, M2 the average value of the second test, SD is the standard deviation.

Reliability was examined using a paired t-test and a correlation coefficient, TE (total error) between test and retest and Bland-Altman plot with 95% limits of agreement. We used the CV to describe stability across repeated trials. The effect size was also used to assess the difference between the two measurements.

Responsiveness: The Standard Error of the Mean (SEM) was calculated with the following formula: $SD \times [\sqrt{(1-\text{reliability})}]$. MDC 95% was calculated using the following formula: $1.96 \times \sqrt{2} \times [SD \times \sqrt{(1-\text{reliability})}]$ where 1.96 represents the 95% CI and SD is standard deviation. We calculated SRM according to the formula $(M1-M2)/SD$ change. Another useful variable for determining responsiveness is the MDC proportion where the percentage of participants evaluated in the test-retest has a higher value than that identified as MDC.

The value of significance was set at 0.05. Post hoc evaluation of research sample size and power of statistic were calculated as described by Cohen and set to α : 0.5, power value: 0.80.

RESULTS

As regards the interviews on compliance, 100% of the patients answered “no” to all the questions. All the results relating to the daily deambulatory autonomy are shown in the tables as steps or meters per day and were obtained by the measurement performed within 48 hours divided by two.

Table 1 describes the characteristics of the sample. As can be noted, mean age and SD are very similar between males and females. BMI confirmed that the participants involved in the study were not obese, both males and females.

Table 2 shows the effects of rehabilitation treatment on deambulation performance. The average improvement of stride length is 2.3%, that of steps per day 43.4%.

The average improvement in Distance (meters per day) reaches 49.8%. Distance is the result of the product between stride length and number of daily steps, so an increase in distance may be due to the increase in stride length, number of steps or both. No statistically significant correlations were demonstrated between increase in stride length and in distance traveled, while there was a high correlation between increase in number of steps and in distance ($r=0.98$; $p=0.001$).

Regarding Distance, a minimum improvement value of -830 meters and a maximum value of 5,630 m with a range of 6,460 m was measured.

Table 3 summarizes the data of the reliability of the pedometer test. Reported values are related to the total 48-hour measurement. The 48 h pedometer measurement showed good reliability. In test-retest, the r values and effect size values (Table 3) show a very good association between repeated measures with high correlation levels and low effect size values. The data obtained on testing-retesting showed a mean TE of 7.3% for steps (95% CI: 5 to 15%, mean value 317 steps) and 15.8% for distance (95% CI: 10 to 18%, mean value 236 m).

Figure 2 reports the Bland and Altman Plot. The value of Z at 95% is 1.96. There is a 95% chance that the group's true mean values lie between 3,468 and 2,388 steps and between 2,492 and 1,708 m.

Table 4 summarizes the data of the responsiveness of the pedometer test. The MDC can be expressed in absolute terms (in our case 637 for steps and 462 m for distance) or in proportions of, respectively, 6 and 8%. In assessing the responsiveness of the test a good response in the test-retest was detected.

Another useful variable for determining responsiveness is the MDC proportion, where the percentage of participants evaluated in the test-retest has a higher value than that identified as MDC. In this group, MDC proportion indicates that only 1% for steps and 8% for distance of the test participants in the test-retest have a value that exceeds MDC value. This confirms the good responsiveness of the test.

The average amount of steps of the group is 2,928.9 and the SEM is 276 steps while, as regards distance, the values are 2,100 m and 200 m (SEM) respectively. SRM shows a good large effect both for distance (0.9) and steps (0.7). In TKA participants the SEM value for Daily steps is 259 and for Distance of 150 meters, while in THA patients the SEM value for Daily steps is 189 and for Distance of 146 meters.

Table 5 shows the values of the evaluation scales normally used to estimate pain, everyday life autonomy and deambulatory performance. These data describe the characteristics of the sample for the variables analyzed at the beginning of the rehabilitation treatment. As can be observed, all the variables are positively influenced by the rehabilitation period: the VAS improves on average by 29.8%, BI by 19.4 and AI by 60.6%.

DISCUSSION

Rehabilitation treatment produced, on average, an increase on total daily walking activity: the use of a pedometer permitted the measurement of this improvement. The rehabilitative treatment was fairly effective in improving the deambulatory autonomy of patients who passed from $2,070 \pm 950$ m on the day of admission to $3,100 \pm 801$ m on the day of discharge. The effect size value for distance shows a large effect size (effect size: 1.3; Table 2). The average improvement obtained ($1,030 \pm 540$ m, 27%) for distance seems to be associated more with the increase in number of strides than their lengths. Other authors³¹⁾ showed that, in the six weeks following surgery, the stride lengths did not increase: measurements conducted in the present study confirm this data.

Table 1. Characteristics of the sample

	Age (years)	Weight (kg)	Height (cm)	BMI (kg/m ²)
Males N: 79	64.1 ± 12.3	74.1 ± 9.1	178.0 ± 5.6	24.1 ± 3.5
Females N: 77	63.8 ± 13.6	63.4 ± 7.8	163.2 ± 6.6	23.5 ± 2.1

BMI: Body Mass Index.

Table 2. Deambulation performance of 156 patients

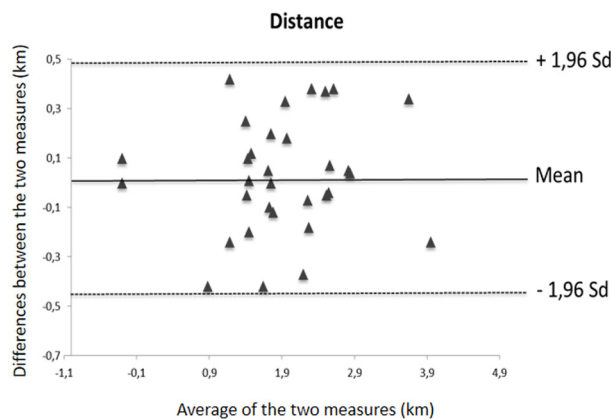
N=156	T1	Min-max	T2	Min-max	Effect size
Stride length (cm)	69.3 ± 4.6	55–76	70.9 ± 3.7	62–76	0.3
Steps (steps per day)	3,007 ± 1,348	1,040–8,318	4,312 ± 1,134.5	1,576–10,193	0.9
Distance (m per day)	2,070 ± 950	730–5,150	3,100 ± 801	970–7,740	1.3

Data are reported as meters and steps per day. Steps per day is the average value of that measured in the 48 hours of detection. T1: day of admission; T2: day of discharge. Cohen's d effect size, between 0 and 1, was used to highlight the differences between T1 and T2.

Table 3. Reliability of 48 h pedometer measurement related to 30 patients

N=30	Effect size (standardized units)	Correlation (standardized units)	CV (% value)	TE
Steps (steps)	0.14	0.90	10.4%	317
Distance (m)	0.03	0.91	12.3%	236

CV: Coefficient of variation; TE: Total error.

**Fig. 2.** Results of reliability study of the measure for distance using Bland and Altman plot (30 patients).

Distance is the result of the product between stride length and number of daily steps.

Table 4. Responsiveness of 48 h pedometer measurement related to 30 patients

N=30	SEM	SRM (standardized units)	MDC
Steps (steps)	276	0.9	637
Distance (m)	200	0.7	462

SEM: Standard error of measurements; SRM: Standardized response mean; MDC: Minimal detectable change.

Table 5. Results of evaluation scales of 156 patients

N=156	T1 mean ± SD	Min-max	T2 mean ± SD	Min-max
VAS	4.7 ± 2.7	0–9	3.3 ± 2.4	1–9
BI	73.2 ± 6.5	53–95	87.4 ± 8.3	68–98
AI	3.3 ± 1.1	0–6	5.3 ± 1.1	3–7

Evaluation of pain (VA: Visual analogic scale), everyday life autonomy (BI: Barthel index) and deambulatory performance (AI: Ambulation index). The table shows the values recorded before (T1) and after (T2) the rehabilitation treatment.

Descriptive data analysis of the differences between T2 vs. T1 (delta value) provide useful information. Regarding distance, the minimum value improvement was -830 m and the maximum $5,630$ m, the range was $6,460$ m. Considering these data, we can identify a negative characteristic value of non-responders equal to -830 m, a mean characteristic value of normal-responders equal to 990 m and a typical value of high-responder patients to the rehabilitation treatment equal to $5,630$ m. These data can be very useful for the clinician.

Average improvement in the number of daily steps of the analyzed participants after rehabilitation treatment is 25%, which is statistically significant ($p=0.002$). Relationships between PA and health indices have already been described by other authors³²). Our data must be considered in the context of the increase in PA recommended to obtain health improvements³³).

Increases of 2,000 steps per day have been recommended to enhance health-related quality of life (HRQoL)³⁴). The improvement achieved by our participants does not therefore seem sufficiently high to produce improvements in HRQoL. The total number of daily steps performed on average by our participants is less than 4,000 steps per day, which other authors recommend in order to maintain continuing good health for special populations of the same age³⁴).

In our participants, increase in daily walking distance is associated with an increase in a number of steps rather than with a rise in stride length. It is possible to hypothesize that stride length is in relation to biomechanical aspects of ambulation, while number of steps is in relation to endurance. Therefore, it appears that in long-term postoperative patients it would be better to improve endurance rather than other aspects of ambulatory performance but new research would be useful to confirm this hypothesis.

The effect size for stride shows a small improvement (average increase of $1.6 \text{ cm} \pm 0.9 \text{ cm}$, effect size=0.3), while the increase in number of steps is higher (increase in steps of $1,305 \pm 756$, effect size=0.9).

Given the diverse improvement in distance, steps and stride, a separate analysis of the variables is recommended. At the commencement of treatment for patients with hip and knee arthroplasty, data from this study can be used as reference data for the evaluation and planning of rehabilitation treatment, although studies conducted on a greater number of patients are however advisable. During rehabilitative treatment and at its termination, instead, an evaluation of the three variables is useful to understand how and to what extent the patient responds to the treatment itself.

There is a clear relationship between the increase in daily ambulation and the age of the patient. A statistically significant association was found between the age of the patients and the increase in daily distance traveled, showing that younger participants have a greater improvement ($r = -0.43$; $p=0.002$). Lower age is also associated with a greater increase in number of steps ($r = -0.42$; $p=0.002$), while no association was found between age and stride length. No statistically significant correlation was found between the gender of participants and the improvement achieved.

These data can be used by the clinician to optimize the treatment planning phase, paying more attention to older subjects.

In our study we have considered patients after treatment of THA and TKA. Even if not the aim of our article, it seems interesting enough to consider that no statistically significant correlations were found between the type of surgery and improvement in deambulatory autonomy. There is no doubt that pre-surgical data on the patients' conditions would have been useful for studying the rehabilitation treatment response. In this context, new longitudinal studies on the matter are desirable.

A limitation of the present study is the impossibility of having data prior to surgery. The goal, however, was not to evaluate the effectiveness of surgical treatment but to verify the use of a pedometer in order to control the rehabilitation treatment effects. In this context, the absence of pre-surgical data does not seem significant: the aim was evaluation of pedometer applicability in terms of measurement reliability and patient compliance.

None of the patients complained about problems relating to the use of the pedometer for 48 hours, thus showing good compliance with the measurement.

The pedometer evaluation of deambulatory autonomy is often used to evaluate patient recovery at different times of the rehabilitation treatment. However, the interpretation of the results could be conditioned by the certainty of measurement quality³⁵). For this reason, a study was conducted using the test-retest method.

Thanks to the study on responsiveness, the clinician can obtain two types of information: 1. On the measurement error and 2. On the clinical relevance of measured data. Good reliability of the test (Table 3) is highlighted by the low effect size value (0.14 for steps and 0.03 for distance) between repetitions of the two measurements, good association related to the high correlation between them ($r=0.90$ for step and $r=0.91$ for distance) and TE values. However, the clinician must consider that the minimal detectable change of the pedometric deambulatory test was equal to 462 m for distance and 637 steps. Therefore, variations in distance and step values lower than those just mentioned should be considered not clinically relevant, but potentially related to an error inherent in the test^{35, 36}).

The stability of the test (response stability) is a function of random measurement error and can be considered as another type of reliability. Response stability can be described using various statistical indices including CV and SEM. Our results of CV and SEM can be used in future studies as reference values.

Further studies based on different methods are possible using the described indices and are desirable in order to select the best test.

MDC may be considered as a starting point to define change but it is usually too small to represent a meaningful difference in the patient's response³⁵). Clinicians have to identify how much change is clinically relevant. MDC gives information on the test effectiveness, while MCID provides a useful parameter for rehabilitation team interpretation of the pedometer evaluation of deambulatory autonomy. SEM value, indicative of MCID, is 200 m for total distance and 276 steps. Therefore, with regard

to our data, treatment effectiveness is set for increments of more than 300 m per day. The percentage of patients who exceed the value of MCID, known as MCID proportion, can be useful in helping clinicians examine the effectiveness of intervention on the group. In our group, 67.6% exceed the meaningful change (300 m). In cases of orthopedic patients two years after surgery, Quintana et al. describe responsiveness data for other more widespread autonomy evaluation systems (Womac scale) with MDIC proportions between 70 and 80%³⁷).

Analyzing the reported data, these values can then be considered as indicative of the MCID for steps and distance. The values of MDC and MCID should be considered in studies with measurements being repeated before and after surgery treatment and further studies in this area are desirable.

By using the SEM values we can calculate a benchmark for evaluating an individual patient's performance over time where SEM is indicative of the range of scores than can be expected on retesting.

Our data show a good applicability of pedometer in terms of compliance, reliability and responsibility. The results on responsiveness can be used by other authors and clinicians to better interpret the results of rehabilitative treatment on total daily walking activity after THA and TKA in long-term postoperative conditions.

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Conflict of interest

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