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Evolution of gait parameters in individuals with a lower-limb amputation during a six-minute walk test

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A R T I C L E I N F O

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A B S T R A C T

Background: A recent amputation leads to decreased functional capacities in the lower limb amputees (LLA), especially during walking. Assessments of LLA's gait in clinical settings are used to provide feedback on their evolution without quantifying gait parameters distinctly, unlike new technologies, such as inertial sensors (IMUs), which have demonstrated their effectiveness in different environments and populations.
Research question: How do the spatial-temporal gait parameters and kinematics of the LLA evolve quantitatively over a six-minute walk test (6MWT) and is the use of inertial sensors relevant in clinical practice to quantify those parameters?
Methods: Fifteen LLA from a study cohort performed a 6MWT post-rehabilitation, wearing inertial sensors on both feet to provide gait parameters (i.e., minimum toe clearance (minTC), speed, cadence, stance time and foot flat ratio (FFr)) over this test. A non-parametric ANOVA was conducted comparing the evolution of each parameter over the 6MWT (12 intervals of 30 s). Significance level was set at $P \leq 0.05$. Post-hoc Wilcoxon signed-rank tests were performed if a main effect was detected.
Results: MinTC and stance phase variability along the 6MWT were significantly different over time. Cadence variability and speed variation were significantly different between both feet (amputated and non-amputated leg).
Significance: The increased variability in gait parameters along the 6MWT suggests a greater risk of future mobility problems following a return in community. The data provided by the IMUs reflect the potential of the clinical rehabilitation programme and could, therefore, help clinicians to refine their interventions.

1. Introduction

A total of 44,430 lower limb (LL) amputations have been performed in Canada between 2006 and 2012 [1]. Individuals with a LL amputation are known to have decreased functional capacities, especially the capacity to walk. Physical rehabilitation after LL amputation usually targets at a successful reintegration of the patients into the community by improving their functional mobility [2]. However, clinical tests used to assess lower limb amputees' (LLA) mobility provide an overview of their functional capacities without quantifying precisely the gait strategies they adopt and their evolution over a long period of walk (representative of the functional demands of community living). For instance, a literature review conducted in 2005 [3] revealed that the decrease of functional capacities following LL amputation is evaluated in clinical settings with the use of tests such as the timed up and go (TUG), the six-minute walk test (6MWT) and adapted balance evaluations. The 6MWT has been validated in the lower limb amputees' (LLA) population [4] to differentiate adequately exercise capacity among participants. This test consists of a continuous overground walk of six minutes and allows the evaluation of the total distance travelled along this period. LLAs' reduced functional capacities are also assessed with physiological measurements such as the evolution of the heart rate over a period of cardiovascular exercise and/or within a gait trial.

To quantify gait strategies by the spatial-temporal and/or kinematic variables, optoelectronic motion capture (MOCAP) systems are used in laboratories. Previous studies using this technology have shown altered gait strategies in LLA, as a decreased walking speed, decreased minimum toe clearance and a decreased step length [5].

Although MOCAP systems are the gold-standard in human motion's quantification, they are not appropriate for routine clinical use. Indeed, they are time consuming, expensive, requiring specific motion capture volume and constrained by space [6].

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Inertial measurement units (IMUs), have been recently considered in clinical settings to allow "out of laboratories" measurement of gait parameters. IMUs are allowing kinematic evaluation of human motion using tri-axial accelerometer, gyroscope and magnetometer. Having fewer operational constraints [7] (e.g., no pre-defined specific path, not assuming data from only a few steps, reduced required time for setting up the instrumentation and to analyze the data), IMUs may allow a valid evaluation of the human movements in a clinical context [8]. Indeed, IMUs have already been used in several populations, as the elderly, multiple sclerosis, post-stroke and community-dwelling older people to evaluate foot clearance, speed and fall detection [9,10]. Those studies state that the gait speed is an important determinant of the physical performance and is a predictor of functional dependence and survival in older adults [10]. It also affirms that foot clearance parameters allow the characterization of risky gait patterns potentially influencing a safe return in community living.

Therefore, the aim of this study is to quantify the evolution of gait parameters (i.e., spatial-temporal parameters and foot kinematics) along a 6MWT in LLA population with the use of IMUs. We hypothesized that gait parameters would deteriorate over a six-minute period due to an increasing tiredness of the LLA individuals.

2. Material and methods

2.1. Participants

After completing their rehabilitation programme (Fig. 1) at the *Institut de réadaptation en déficience physique de Québec* (IRDPQ), fifteen participants (Table 1) have been recruited. The study protocol was approved by the IRDPQ's research ethical committee. All participants were informed about the study protocol and gave written consent to take part in the study.

The inclusion criteria were the following: more than 18 years old, completely healed stump, capacity to walk over six minutes without walking aids, at least six weeks of walking practice with the prosthesis, no other amputations and no central nervous system disorders. The rehabilitation centre where the study took place also had inclusion criteria: having some potential for rehabilitation and an adequate skin condition at the stump to allow the wearing of a prosthesis.

2.2. Apparatus

Two inertial sensors (*Physilog*®4, Lausanne, Switzerland) [11] (Fig. 2) placed on top of each foot with velcro strips were used to collect kinematic data and spatial-temporal parameters of both feet (200 Hz). Both sensors were synchronized wirelessly and each of them was composed of a three-dimensional (3D) accelerometer ($\pm$ 3 g) and a 3D gyroscope ($\pm$ 600°/s). These sensors have been validated in several populations, especially in the elderly [9]. They enable long-term movement recording in daily life activities [10] to a low power and light weight. The direct integration algorithms of this system allow the calculation of 25 gait parameters [11].

Electrodes of a heart rate (HR) monitor (Polar® RS800CX™, Kempele, Finland) [12] were also placed around the thorax of the LLA with an elastic waistband. This sensor allows the calculation of the time interval between each heart beat (1000 Hz).

2.3. Procedures

The cause of amputation, prosthesis type, number of days spent in physical rehabilitation programme, height (m), weight (kg) and the length of the shoes (cm) were registered (Table 1). The 6MWT was conducted on a 25 m corridor in the clinicians' laboratory. The instructions given to the participants were in accordance with the 6MWT guidelines [13].

The inertial sensors and the HR monitor were turned on and off manually. The pain level was assessed at the beginning and the end of the test using a visual analogue scale (VAS) ranging from 0 (no pain) to 10 (worst pain) and could refer to any kind of pain (e.g., stump pain, dyspnea, discomfort). Following the 6MWT, all participants had to perform a Timed Up and Go (TUG) test. This test is known to quantify the physical mobility, balance, walking ability, and fall risk of the elderly population [14], despite the fact that its change is not the sole factor for fall risk prediction. For this test, participants had to rise from an arm chair, walk 3 m and return to the chair at their own comfortable and safe walking speed. This test is reliable and valid across elderly patients with lower extremity amputation [15]. LLAs were also administered the Amputee Mobility Predictor with prosthesis (AMPPro) test [16] to quantify LLA's functions and to classify their functional levels (K-levels).

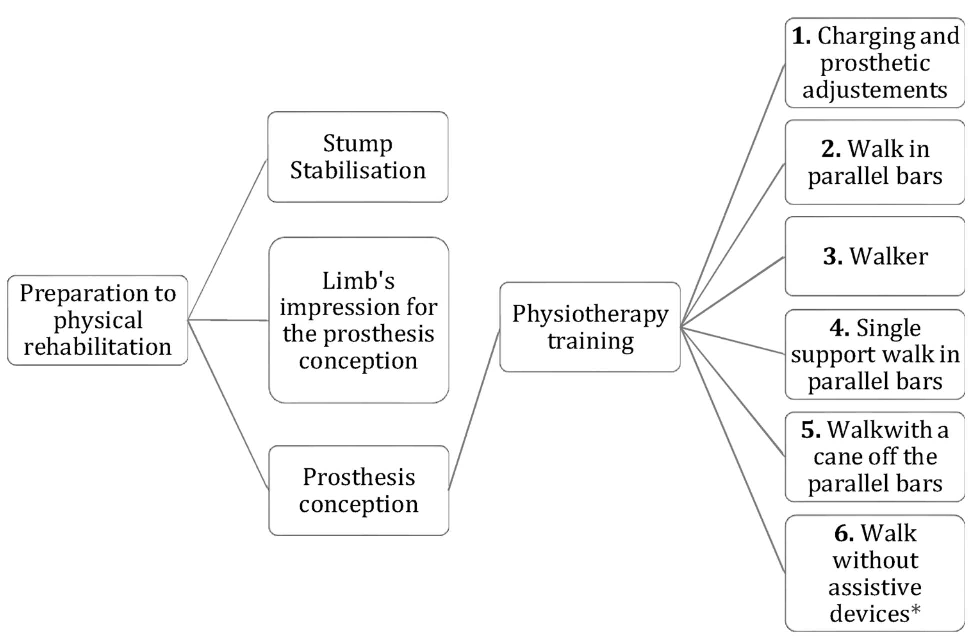

Fig. 1. Rehabilitation program design. * The step 6 is reached by 80% of the patients attending this rehabilitation programme. The other steps are reached by all the patients.

Table 1
Characteristics of the participants.

Patient code	Sex	Age	Body weight (kg)	Height (m)	BMI (kg/m^2)	Days since injury	Amp level	Amp side	Cause of amp	Prosthesis type	TUG (sec.)
AMP001	F	45	68.90	1.77	22	216	TT	Left	Trauma	Triton foot	6.65
AMP002	M	72	N/A	N/A	N/A	122	TT	Left	Vascular	1D10 Foot	11
AMP003	F	60	75.70	N/A	N/A	86	TT	Right	Vascular	1D10 Foot	12.66
AMP004	M	45	N/A	N/A	N/A	106	TT	Left	Vascular	1D10 Foot	13.16
AMP005	M	56	70.80	1.56	29	101	TT	Left	Vascular	1D10 Foot	7.77
AMP008	F	68	N/A	N/A	N/A	121	TT	Right	Vascular	Assur Foot	13.57
AMP009	M	N/A	58.97	1.68	21	196	TT	Left	Vascular	Allure Foot	10.8
AMP013	F	68	81.65	1.60	32	133	TT	Left	Vascular	Térion Foot	11.03
AMP014	M	57	77.11	1.91	21	145	TT	Left	Vascular	VS2-promenade ortho active	N/A
AMP015	M	73	86.18	1.83	26	N/A	TT	Right	Vascular	N/A	N/A
AMP016	M	62	77.11	1.70	27	122	TT	Right	Vascular	1D10 Foot	16.69
AMP017	F	33	58.97	1.75	19	184	TF	Left	Tumor	3R80 Knee/ Triton Foot	8.21
AMP018	M	71	68.95	1.78	22	122	TF	Left	Vascular	3R78 Knee	30.57
AMP019	M	68	76.20	1.80	24		TF	Left	Vascular	N/A	11.69
AMP020	M	48	90.72	1.68	32	218	TF	Right	Trauma	X3 Genium Knee/ Triton foot	8.04
MEAN	5F	59	74.27	1.73	25	138	11TT	10L	13 vasc.	N/A	12.45
	10M	±	±	±	±	±	4TF	5R	1 traum.	N/A	
SD	N/A	12	9.66	0.10	5	40	N/A	N/A	1 tumor.	N/A	6.11

Amputation level (Amp. level): trans-tibial (TT) or trans-femoral (TF).

Fig. 2. Two inertial sensors (*Physilog*®4, Lausanne) worn on both feet.

2.4. Data analysis

The software provided with the *Physilog*®4 (i.e., RTK V.1.1.1) was used to analyze the data from the two synchronized inertial sensors. This software runs algorithms allowing the detection of the gait parameters. The ones analyzed in this study were the following: minTC, maximal heel clearance (maxHC), loading ratio (LDr), flat foot ratio (FFr) and swing width during the oscillation phase, stride length (Fig. 3.), stance time ratio and cadence. Data collected from the 6MWT were divided in 12 intervals of 30 s (I1 to I12) and their mean and standard deviation (SD) were calculated. Values associated to turns have been discarded from the gait analysis in order to focus on the evolution of gait strategies and parameters on straight corridors. According to Salbach and colleagues, the first and last 4.3 m of walking represent the maximal walking distance needed to reach the steady state of the gait speed or the complete stop [17]. As the average stride length amongst all participants of the present study was 1.11 ± 0.22 m, we removed the first and last 10 strides of the 6MWT trial from the analysis to ensure that the steady state of gait had been reached for all participants.

The HR data were transmitted to the Polar® ProTrainer 5 software on the host computer to be further analyzed. As gait variables, the HR data were divided and analysed using 12 intervals of 30 s (I1 to I12) and their mean and standard deviation (SD) were calculated. Functional levels were determined with K-levels ranging from 0 to 4 (0 : incapacity to ambulate or transfer safely with or without assistance; 4 : exceeds basic ambulation skills [18]).

2.5. Statistical analysis

Non-parametric repeated measures ANOVA tests were performed using nparLD package 2.1 [19] from R software 3.3.3. This package performs several nonparametric tests for the relative treatment effect with global alternatives for repeated measure data in various factorial designs. The repeated measures independent variables were the intervals (I1-I12) and the feet (prosthetic leg: AL or biological leg: NAL). There were no intergroup variables. The nonparametric Wilcoxon signed rank test was also used for post-hoc analysis when global effect was detected. Those tests are known to be effective in small groups (n) and longitudinal data and are insensitive to outliers. Significance level was set at $p \leq 0.05$.

3. Results

The characteristics of the sample are displayed in Table 1. Results

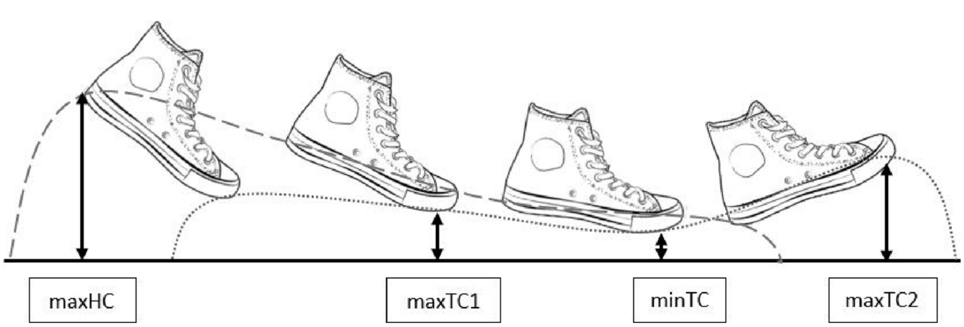

Fig. 3. Foot clearance parameters along the swing phase.

Table 2
Kinematics characteristics of the amputated limb (AL), the non-amputated limb (NAL) and their interactions within the 6MWT (mean ± SD) intervals.

	AL	NAL	Foot (p)	Interval (p)	Foot: Interval (p)
HR (mean) (bpm)	105.34 ± 24.15	N/A	N/A	0.03*	N/A
Stance (mean) (% gct)	64.24 ± 6.22	63.99 ± 4.83	0.70	0.08	0.50
Stance (SD) (% gct)	2.93 ± 1.71	3.39 ± 3.54	0.85	0.33	0.04*
FFr (mean) (% stance)	57.38 ± 11.55	60.79 ± 10.69	0.06	0.10	0.47
FFr (SD) (% stance)	6.72 ± 7.02	5.49 ± 4.40	0.52	0.80	0.28
minTC (mean) (mm)	34.1 ± 15.3	30.7 ± 12.5	0.56	0.03*	0.40
minTC (SD) (mm)	16.38 ± 10.81	21.29 ± 15.82	0.29	0.38	0.61
Cadence (mean) (steps/min)	90.02 ± 30.42	90.09 ± 30.53	0.96	0.08	0.46
Cadence (SD) (steps/min)	5.09 ± 4.52	5.12 ± 5.52	0.17	0.04*	0.24
Speed (mean) (m/s)	0.92 ± 0.31	0.92 ± 0.33	0.66	0.18	0.67
Speed (SD) (m/s)	8.13 ± 5.85	7.35 ± 5.80	0.02*	0.21	0.14

SD: Standard deviation; HR: Heart rate; Stance: Stance period of the gait cycle; FFr: Flat foot ratio; minTC: minimal toe clearance; %gct: Pourcentage of the gait cycle time. *: Significant difference; Bold: statistical trend.

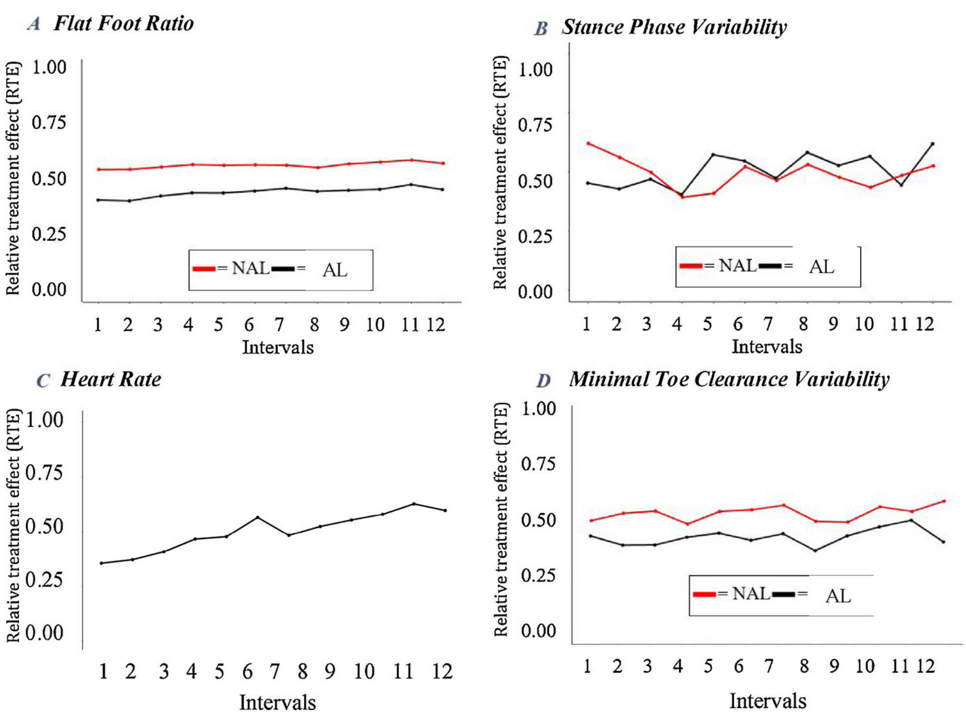

Fig. 4. Relative treatment effect along the 6MWT for each intervals of 30 s on flat foot ratio, stance phase variability, and minimal toe clearance for both limbs (AL and NAL) and heart rate.
NAL: Non- amputated limb; **AL:** Amputated limb **A**: Comparison of the relative interval (I1-I12) effect from the mean of the flat foot ratio for both limbs (AL and NAL); **B**: Comparison of the relative interval effect from stance phase variability on both limbs; **C**: Comparison of the relative interval effect from minimal toe clearance variability on both limbs. **D**: Comparison of the relative interval (I1-I12) effect from the mean of the heart rate

are presented in Table 2 and Fig. 4. The amputation levels of the LLA were trans-tibial (TT) (73,3%) or trans-femoral (TF) (26,6%). The causes of amputation among the 15 LLA of the sample resulted from vascular complications (n = 12), tumour (n = 1) or trauma (n = 2) and the types of prosthesis used by the participants were designed for different functional levels (K1 to K3).The minimal walking ability required for this research has been reached by all LLA participating in the study following their rehabilitation programme, as quantified by the AMPPro results, ranging between 35 and 46/47 (representing a mobility level of K2 to K4 [16]).

3.1. Evolution of gait parameters over the 6MWT

The mean distance travelled during the test was 305.91 ± 137.72 m. The mean speed on the first 10 m of the 6MWT was 0.99 ± 0.37 m/s. Kinematics characteristics of the amputated limb (AL), the non-amputated limb (NAL) and their interactions within the 6MWT intervals are detailed in Table 2. Significant interactions were observed between the intervals of the 6MWT. Foremost, the cadence variability ($p < 0.04$) and the mean minTC ($p < 0.03$) were significantly different between the 12 intervals of the 6MWT on both limbs. A significant interaction along the 6MWT has been found among the feet. Indeed, the speed variability was systematically higher on the AL along the 6MWT ($p < 0.02$). The FFr tended to be lower on the AL side although the difference was not significant (AL: 57.38 ± 11.55%, NAL: 60.80 ± 10.69%, $p < 0.06$) (Fig. 4A.). Finally, significant differences were found between the feet (AL and NAL) and the intervals (I1 to I12). Indeed, the stance phase variability increased following I4 for the AL (Table 2 and Fig. 4B.).

3.2. Evolution of HR during the 6MWT

The 6MWT was well tolerated by all participants. The mean HR ranged from 98 bpm to 113 bpm with a statistical difference between the intervals ($p = 0.03$). Fig. 4E illustrates the variations along the 6MWT.

3.3. Functional level and pain

The pain level calculated on the VAS was nil and did not evolve in five of the fifteen participants over the 6MWT. Five participants did not report any pain from the execution of the test. The major causes of pain were dyspnea and fatigue related to exertion. A patient reported pain from a bursitis at the stump.

The TUG test was performed on thirteen of the fifteen participants, according to the choice of the clinicians. The TUG test mean time was 12.45 ± 6.11 s (able-bodied mean time: 8 ± 2 s [20]). Four participants completed the task in ten seconds or less and were classified as "normal adults" and the other nine participants completed the task in more than ten seconds and were classified in the normal limits of disabled adults [21].

4. Discussion

The objective of this study was to quantify the evolution of gait parameters in the LLA population along a 6MWT with the use of IMUs. This objective responds to the lack of quantitative data in LLA's clinical gait rehabilitation. The etiology of our cohort is representative of the LLA's community as the vascular trans-tibial amputations accounted for the majority (80%) [1] of the sample.

4.1. Evolution of gait parameters over the 6MWT

The total distance reached along the 6MWT (305.91 ± 137.72 m) was lower than the results of 544.6 ± 64.5 m obtained by Lin (2008) in a LLA population [4]. However, our sample has a larger proportion of vascular LLA (80%), compared to Lin (31%). Indeed, as stated by Raya (2010), vascular LLA are the poorest ambulators, has she found in the 6MWT [22]. Also, our study group is innovative compared to this other experiment as the 6MWT took place at the end of their rehabilitation instead of in their community life. Those reasons could explain the difference in the total distance reached along the 6MWT.

Gait variability is defined as a fluctuation in gait characteristics from one step to the next and is an important indicator of impaired mobility in older adults [23]. Variability of several gait parameters can be correlated to future falls and greater stance time variability is a predictor of mobility problems in the following 54 months [23]. Therefore, augmented stance time variability following I4 (Fig. 4B.) suggests a higher risk of future mobility problems in LLA's gait in the last four minutes of the 6MWT. As described by Fang (2018), the average cadence and speed for healthy elderly from 50-59 years old are 116.5 steps/min and 1.21 m/s, respectively [24]. In the LLA population (62–66 years old), those values are 104.9 steps/min and 1.14 m/s, respectively [25]. Contrariwise, in our sample, the mean cadence and speed were 90.02 steps/min, 0.91 m/s highlighting mobility impairments caused by a recent amputation. Consequently, those results indicate the clinical relevance of the information provided by the use of IMUs for the evaluation of the spatial temporal and kinematics parameters.

Opposed to the expected results, the high and variable minTC on the AL (34.07 ± 15.32 mm) from our sample could reflect a hip hiking strategy explained by a large foot clearance from the ground to counteract the lack of ankle dorsiflexion of the affected limb [26]. This pattern suggests an incapacity of the prosthesis to replicate the healthy behaviour of the foot [27,28].

4.2. Evolution of HR during the 6MWT

The significant HR variability along the 6MWT, resulting from a continually increasing HR (from 98 to 113 bpm), mirrors the LLA's suitable functional level for the walking test. However, in future studies, the use of perceived exertion's rating, as with the Borg CR10 rating scale, could provide additional information on the perceived fatigue of the LLA over the 6MWT [29] that could help in the interpretation of the HR values.

4.3. Functional level and pain

As found with the VAS, the pain increased in ten individuals of the group sample over the 6MWT and the prosthetic friction at the stump and/or the physical exhaustion were the main reasons explaining this increase. Those reasons could be the cause of future perceived impaired dynamic stability [30] when returning in their community life. Hence, the use of clinical tools as the VAS added to the data obtained with IMUs provide unprecedented content allowing the interpretation of the standard clinical observations.

The mean functional level (K2-K4) of the sample at the end of the LLA rehabilitation programme differs from the prosthesis types used. Indeed, their functional levels allow ambulation at variable cadences and exercise that demand prosthetic use beyond simple locomotion (K3) and/or exceed basic ambulation skills with high impact, stress or energy levels (K4). Therefore, the prosthetic type and fitting of the prosthesis could influence the gait strategies adopted by the LLA. For those reasons, future studies should compare the spatial temporal and kinematics effects of each prosthesis types independently.

4.4. Limitations

The small number of participants and the heterogeneity of the sample relating to age, sex, level and cause of amputation and the number of days spent in a rehabilitation programme limit the possibility to generalize those outcomes. However, it provides an overview of clinical and functional aspects related to gait adaptations encountered on a long walking period of K2-K4 LLA population after completing a rehabilitation programme. Future researches should analyse the evolution of gait parameters in larger samples as well as in more homogeneous LLA populations.

5. Conclusion

Though some limitations must be considered, this study provides unique data on gait parameters (spatial-temporal and foot kinematics) in LLA over a long period of walk, which could influence their rehabilitation outcomes. This study also innovated by the integration of inertial sensors in clinical settings to provide objective results with a quantitative investigation of the evolution of LLA's gait parameters over a 6-minute walk. The high stance phase variability following the fourth interval on the AL and the variability of the cadence along the 6MWT on both limbs show the strategies adopted by the LLA over a long period of walk. Therefore, the use of inertial sensors in this study shows its potential to bring new insights for clinicians with the assessment of the evolution of LLA's gait parameters during physical rehabilitation. The data provided by the IMUs can also reflect the potential of the clinical rehabilitation program and could, therefore, help clinicians to refine their interventions.

Conflict of interest statement

None of the authors had conflicts of interests with the work presented in this study.

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