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Gait analysis in patients with transfemoral amputation

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Abstract

Background: Increased variability in gait is often associated with reduced coordination and increased instability during walking. Moreover, variability may also give an indication of the risk of falling. However, variability during walking in amputees has not been adequately analyzed in the literature.

Research question: The aim of this examination was to analyze the extent of kinematic variability in the gait pattern of transfemoral amputees. Additionally investigated were the effect of different types of walking surface on kinematic variability and its association to patient`s daily activity level.

Methods: This project is a prospective clinical examination. In the first part of the analyses, twenty patients with transfemoral amputation (17 male patients, age 43 ± 11 years, 3 female patients, age 48 ± 5 years) were compared to a group of twenty age-, height- and weight-matched healthy controls. Gait pattern during walking on level and uneven ground as well as on a slope were captured by eight infrared cameras (Vicon Nexus™, Oxford, UK). The variability of trunk and pelvic movement in the frontal plane was analyzed for both groups. Univariate ANCOVA and ANOVA with repeated measures and post hoc tests were used for statistical comparison. Additionally the association between fall history and variability in trunk and pelvic movement was assessed.

Afterwards, the association between kinematic variability and the level of daily activity was analyzed in a group of fifteen amputees. Daily activity was assessed using a three-dimensional acceleration sensor (VitaMove, Valkenswaard, Netherlands).

Results: In transfemoral amputated patients, trunk and pelvic movement variability was between 36% and 105% greater during walking on uneven and sloped ground compared to healthy controls ($p \leq 0.05$). Trunk and pelvic movement variability was greater during walking on uneven ground and on a slope compared to even ground for the group of transfemoral amputees up to 151% and the group of healthy controls up to 77% ($p \leq 0.05$).

Additionally, the results show a significant correlation between activity level and variability in trunk ($r=-0.58$; $p \leq 0.05$) and pelvic movement ($r=-0.63$; $p \leq 0.01$).

Conclusion: Amputation patients wearing a C-leg system showed increased kinematic variability in trunk and pelvic movement during walking on uneven and sloped ground, indicating that their gait pattern is more affected than healthy individuals. In addition, kinematic variability in trunk and pelvic movement is associated with the level of daily activity and therefore could be a potential marker for quality of gait with diagnostic implications.

Zusammenfassung

Hintergrund: Eine erhöhte Gangvariabilität kann mit eingeschränkter Koordination und einer erhöhten Instabilität beim Gehen in Verbindung gebracht werden. Gangvariabilität ist in der Literatur jedoch für Patienten mit einer Amputation der unteren Extremität bisher nicht ausreichend untersucht worden.

Fragestellung: Das Ziel dieser Untersuchungen war es das Ausmaß der kinematischen Variabilität im Gangbild bei Patienten mit transfemoraler Amputation zu untersuchen. Zusätzlich soll der Effekt verschiedener Untergründe beim Gehen auf die Variabilität sowie der Zusammenhang zur Alltagsaktivität der Patienten gezeigt werden.

Methoden: Diese Arbeit ist eine prospektive klinische Untersuchung. Im ersten Teil des Forschungsprojektes werden 20 Patienten mit transfemoraler Amputation (17 männliche Patienten 43 ± 11 Jahre, 3 weibliche Patienten 48 ± 5 Jahre) mit einer Gruppe von 20 gesunden Probanden verglichen. Die gesunden Teilnehmer waren bezüglich der Parametern Alter, Gewicht und Größer zu der Gruppe der Patienten gematcht. Das Gangbild wurde mittels acht infrarot Kameras (Vicon Nexus™, Oxford, UK) beim Gehen auf ebenem und unebenem Grund sowie einer Rampe auf- und abwärts aufgenommen. Die Variabilität der Oberkörper- und Beckenbewegung in der Frontalebene wurde während des Gehens in beiden Gruppen untersucht. Für einen statistischen Vergleich zwischen den Gruppen wurden eine univariate ANCOVA sowie eine ANOVA mit Messwiederholung gewählt. Zudem wurde der Zusammenhang zwischen Sturz und Variabilität der Oberkörper- und Beckenbewegung untersucht.
Anschließend wurde der Zusammenhang von kinematischer Variabilität und dem Ausmaß der täglichen Aktivität in einer Gruppe von 15 Patienten untersucht. Hierzu wurde die tägliche Aktivität mit Hilfe eines 3D-Beschleunigungssensor erfasst (VitaMove, Niederlande).

Ergebnisse: Die Variabilität der Oberkörper- und Beckenbewegung war während des Gehens auf unebenem Grund sowie einer Rampe auf- und abwärts in der Gruppe der Patienten zwischen 36% und 105% höher im Vergleich zu gesunden Probanden ($p \leq 0.05$). Die Variabilität der Oberkörper- und Beckenbewegung war

während des Gehens auf unebenem Grund und einer Rampe in der Gruppe der Patienten bis zu 151% und in der Gruppe der gesunden Probanden bis zu 77% erhöht im Vergleich zum Gehen auf ebenem Grund ($p \leq 0.05$).
Zudem zeigte sich eine signifikante Korrelation zwischen der täglichen Aktivität und der Variabilität der Oberkörper- ($r=-0{,}58$; $p \leq 0{,}05$) und Beckenbewegung ($r=-0{,}63$; $p \leq 0{,}01$) bei Patienten mit transfemoraler Amputation.

Zusammenfassung: Patienten mit einer transfemoralen Amputation zeigen eine erhöhte kinematische Variabilität in Oberkörper- und Beckenbewegung während dem Gehen auf unebenem Grund sowie auf einer Rampe. Dies zeigt eine Einschränkung des Gangbildes im Vergleich zu gesunden Probanden. Zudem zeigt sich, dass kinematische Variabilität der Oberkörper- und Beckenbewegung während des Gehens in Zusammenhang mit dem Ausmaß an Aktivität steht. Der Parameter Variabilität kann somit als Marker für Gangqualität und zur Verbesserung der Diagnostik bei Patienten mit transfemoraler Amputation beitragen.

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1 Background

1.1 Epidemiology lower limb amputation

Amputation is defined as the complete or partial removal of a part of the human body, in which the lower limbs are often affected. The German health insurance company, AOK, recorded 44,252 amputations involving the lower limbs and 3,891 amputation residuum revisions in Germany in 2001. Of these 44,252 amputations, 10,332 (23%) were transfemoral amputations, and 1,283 patients had a knee disarticulation (Wissenschaftliches Institut der AOK). The German Federal Statistical Office reported that 42,266 amputations involved the lower limb in 2015 (Statistisches Bundesamt, 2017, Table 1). At the BG Klinikum Murnau, 189 lower limb amputations were registered in the year 2018, with 13 of these being transfemoral amputations.
The main reason for lower limb amputation is related to arterial occlusive disease, especially in association with diabetes mellitus (Table 2).

Table 1.: Lower limb amputation rates in Germany according to etiology (Statistisches Bundesamt, 2017)

	Cause of amputation				
	Congenital disorder	Accident	Loss or damage during military or civilian service	Common disease	Others
Number of amputations of the lower limb	745	8,290	2,407	25,397	5,427

Table 2.: Percentage of lower limb amputations in industrialized and developing countries according to etiology (Greitemann et al., 2016)

Underlying disease	Industrialized nations	Developing countries
Arterial occlusive diseases → of which are diabetes mellitus	75-80% → 70%	15-20% → 60-70%
Trauma	< 5%	20-30%
Infection	3-5%	20%
Others (including tumors)	5%	5%
Congenital disorders	< 3%	< 3%

1.2 Gait in lower limb amputees

The residual limb length of amputees influences the control of leverages, proprioceptive input, the interaction of different muscles, as well as the energy input during walking (Mensch, 1998). A study from Bell et al. (2013) demonstrates that shorter residual limb length may lead to increased deviations and abnormalities in gait. Patients showed decreased gait velocity and increased trunk, as well as pelvic motion caused by muscular imbalance, for example. Additionally, these parameters and reduced leverage caused by shorter residual limb length may lead to a greater extent of muscle atrophy. Analyses from Jaegers et al. (1995) show that asymmetries in gait are related to the length of the residual limb in transfemoral amputees. Therefore, patients with a transfemoral amputation demonstrate very unstable gait with reduced velocity and increased stride width than healthy able-bodied adults. Their walking process is also very asymmetric, which results in an unnatural gait pattern compared to healthy persons (Jaegers et al., 1995; Mensch et al., 1998). The complicated walking process for transfemoral amputees leads to impaired movement control and instability in locomotion (Ku et al., 2014). Therefore, every second individual with a unilateral lower limb amputation reports at least one fall per year. Additionally, 49% of these patients express a fear of falling and 76% avoid certain activities because of this fear (Miller et al., 2001). Therapeutic treatments as well as prosthetic adaptions must be optimized individually to achieve an adequate walking stability for these patients. Thus, there is a need for an objective assessment of the gait pattern and walking stability of transfemoral amputation patients.

1.3 Gait variability in lower limb amputees

The parameter variability during walking is suggested as a measure of gait disturbance and stability in previous literature (Hausdorff et al., 2005; Dubost et al., 2006; Toebes et al., 2012). An increased variability of spatio-temporal parameters and trunk acceleration could be measured in frail older adults compared to active older adults (Moe-Nilssen et al., 2005). Furthermore, literature demonstrates increased gait variability in amputees compared to healthy adults (Svoboda et al., 2012; Sinitski et al., 2019). Additionally, the risk of falling, as well as fear of falling are associated with increased gait variability (Sawa et al., 2014; Ayoubi et al, 2014). Some studies also present a large variation in gait velocity and step length in patients with lower limb amputation and a history of falling (Vanicek et al., 2009). However, there are studies which present contrary results and show no differences in gait variability of amputee fallers and non-fallers (Parker et al., 2013) or even no increased variability in spatio-temporal parameters in amputees (Lamoth et al., 2010).

These previous studies analyzing amputees only considered the variability of basic spatio-temporal gait parameters (Vanicek et al., 2009; Svoboda et al., 2012; Parker et al., 2013; Lin et al., 2014), such as walking velocity or step length, trunk acceleration (Lamoth et al., 2010; Sinitski et al., 2019) or kinetic data (Svoboda et al., 2012) but not kinematic parameters including joint angles or body posture. Kinematic data is more challenging to collect and assess but may provide more detailed information about body movement and posture, the repeatability of gait pattern and gait stability beyond those obtained from spatio-temporal gait parameters. Kinematic data is able to describe human gait patterns and its quality in a very detailed way (Whittle, 1996).

In particular, variability in trunk movement during walking is associated with decreased stability in gait and an increased fear of falling in the elderly (Toebes et al., 2012; Sawa et al., 2014). However, there is a lack of published literature that analyzes trunk movement variability or variability of other kinematic data in lower limb amputees. Additionally, most studies focused only on level walking (Vanicek et al., 2009; Svoboda et al., 2012; Parker, 2013; Lin et al., 2014). There is a need, for detailed gait analysis conducted on uneven ground to assess lower limb amputees' ability to handle more challenging terrains which simulate outdoor walking. Walking on different types of surfaces pose a greater challenge to gait and might thus be more sensitive for the detection of gait variability; but to our knowledge has not yet been analyzed.

In addition there is no literature analyzing the association between gait variability measured in laboratory setting and parameters measured during patients` everyday life. To date, the potential relationship between kinematic variability during gait and daily activity levels has not been examined in patients with transfemoral amputation. However, patients with lower limb amputations have clearly limited opportunity to participate in certain activities, such as outdoor walking, stair climbing or sport activities, and have lower daily activity levels than their able-bodied counterparts (Collin et al., 1995; Burger et al., 1997; Miller et al., 2001; Bussmann et al., 2004). It could be hypothesized that an unstable gait pattern leads to an avoidance of activities and therefore is associated with a lower activity level.

Precise information about gait quality and level of daily activity is indispensable for prosthesis and prosthesis socket adaptation, as well as for rehabilitation planning.

2 Aims

The aim of this research project was to analyze variability in trunk and pelvic movement of transfemoral amputees and its relevance to patients' activity during everyday life. We hypothesized that kinematic variability in trunk and pelvic movement is greater in amputees compared to healthy controls and that increased variability is associated with parameters of daily living in amputees. Therefore this project contains two separate studies. The first study examined variability in trunk and pelvic movement during walking on different terrains in transfemoral amputees using a C-leg system compared to healthy controls. The results of this examination

were published in the study “Variability in trunk and pelvic movement in transfemoral amputees using a C-leg system compared to healthy controls” in the Journal “Human Movement Science” (Müßig et al., 2019; Appendix 6.1). In a second study, the association of trunk and pelvic variability and the level of daily activity in transfemoral amputees were analyzed. The research results were published in the study “Relation between the amount of daily activity and gait quality in transfemoral amputees” in the “International Journal of Rehabilitation Research” (Müßig et al., 2019; Appendix 6.2).
All measurements took place in the gait laboratory at the Institute of Biomechanics, BG Klinikum Murnau.
The following summary provides an overview of these publications.

2.1 Variability in trunk and pelvic movement in transfemoral amputees using a C-leg system compared to healthy controls

2.1.1 Aims and hypothesis

The aim of the first part of this research project was to determine the variability in lateral trunk bending and variability in pelvic obliquity in transfemoral amputees during walking compared to healthy able-bodied adults. In addition, the extent to which these parameters were affected by different walking surfaces was investigated. Finally, the potential relationship between fall history and the extent of trunk and pelvic movement variability in the patient group was explored. It was hypothesized that: (1) kinematic variability in trunk and pelvic movement during walking is greater in patients using a prosthetic knee joint system than healthy controls; (2) variability in trunk and pelvic movement is further increased in patients during walking on uneven or sloped surfaces compared to walking on level ground; and (3) kinematic variability in trunk and pelvic movement is associated with history of falls.

2.1.2 Study design

A prospective clinical observation study was used to examine patients’ variability in trunk and pelvic movement and to compare it to a population of healthy controls. The study was carried out in the rehabilitation unit of a Level 1 trauma center. The study protocol was approved by the responsible ethical committee (No. 13131).
A group of twenty patients (17 male patients, age 43 ± 11 years, 3 female patients, age 48 ± 5 years) with an above knee amputation (time since amputation 16.5 years

± 12) using the C-leg knee-joint system (Ottobock, Duderstadt, Germany) was recruited for this study and compared to twenty healthy controls matched for age (± 5 y), height (± 5cm), and weight (± 5 kg). All participants gave written consent for participation in the study.

Three-dimensional kinematic data for the trunk and lower limbs were collected with an eight camera infrared motion capture system (Vicon™, Oxford, UK) with a recording frequency of 200 Hz (Figure 1, Figure 2). Retro-reflective markers were fixed to the lower limbs and trunk according to the anatomical landmarks defined by the conventional gait model reported by Kadaba et al. (1990) (Figure 3). For visual analysis, two video cameras enable both a frontal (25 Hz) and sagittal (100 Hz) recording of gait.

Figure 1: Gait laboratory in the BG Klinikum Murnau

Figure 2: Technical structure of the gait laboratory in the BG Klinikum Murnau (produced by Vicon software)

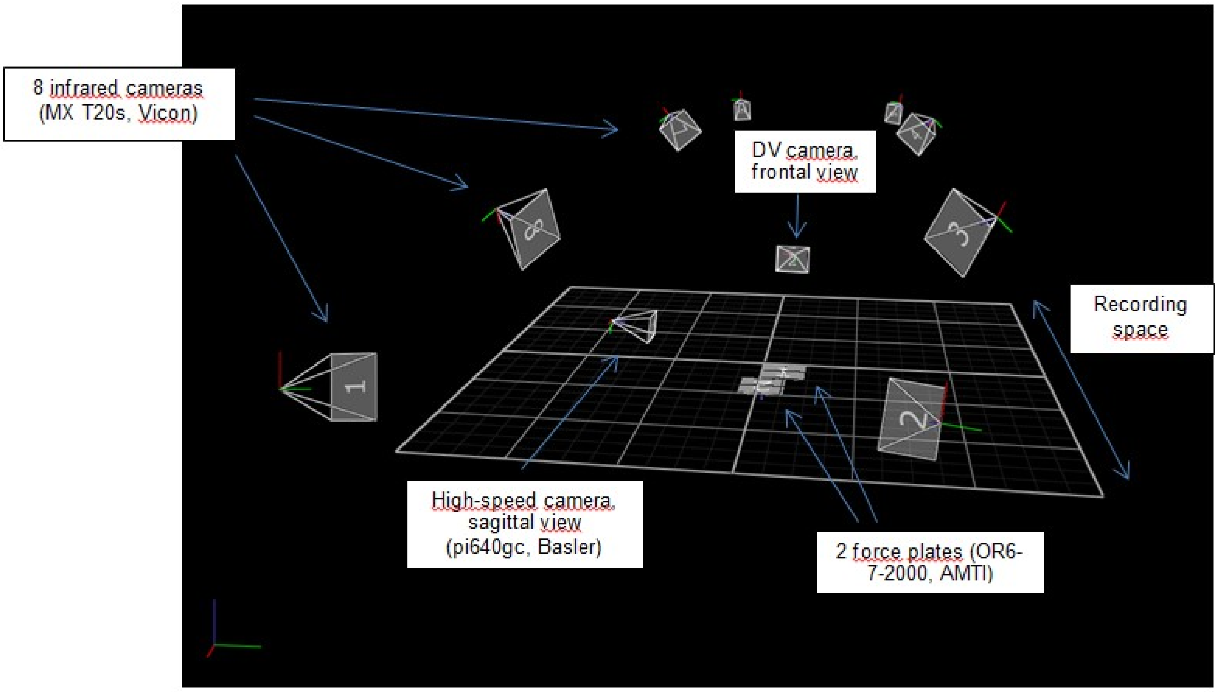
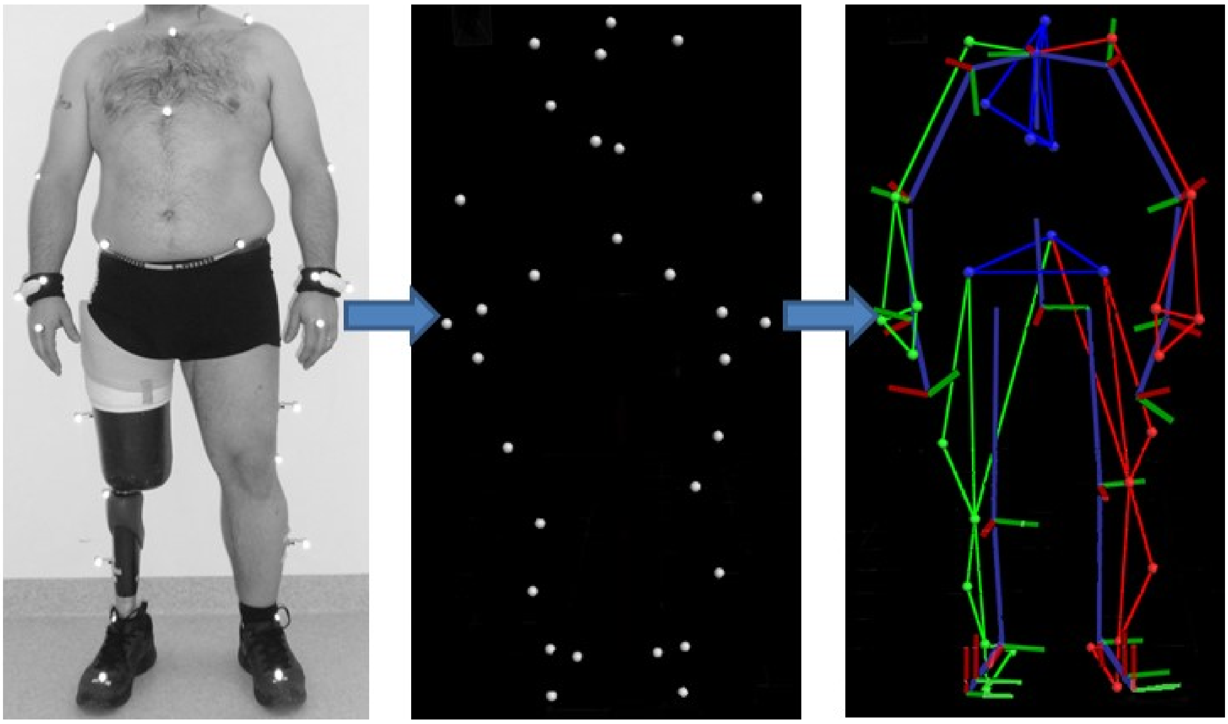
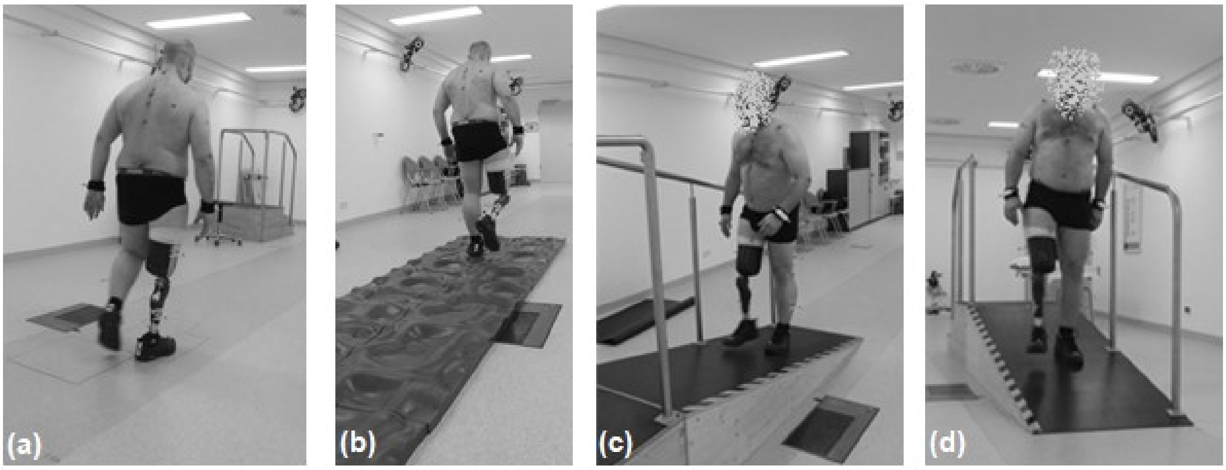


Figure 3: Patient with marker set (left), marker capture by software (middle), model construction by software (right)



The kinematic data of all participants from both groups were measured in four walking conditions: even and uneven ground as well as inclined and declined slope (Figure 4). Structural panels (terrasensa®, Hübner, Kassel, Germany) over a length of six meters simulated the uneven ground. Walking on an inclined and declined slope was facilitated by a three meter long mobile ramp.

Figure 4: Four different walking conditions: patients walked on even ground (a), uneven ground (b), an inclined slope (c), and a declined slope (d)



Each of the four walking conditions began with two warm-up trials to allow the participants to become familiar with the different surface types. Afterwards, every participant was instructed to complete five trials for each walking condition.
For determining the variability of gait as a measure of gait stability, kinematic data of trunk and pelvic movement were analyzed in the frontal plane. Previous studies show that variability in upper body motion is associated with a fear of falling and decreased gait stability in the elderly (Toebes et al., 2012; Sawa et al., 2014). Therefore, our examinations focus on the kinematics of trunk and pelvic movement and not of the lower limbs.
Occurrence of falls was retrospectively assessed in amputees by interview.

2.1.3 Statistical analysis

For statistical analysis, univariate ANCOVA was used to compare amputees and healthy controls regarding trunk and pelvic movement variability in different walking conditions. Gait velocity and step length were included as co-factors to minimize the likelihood of any influencing factors. Additionally, a Student´s t-test was used to compare the group of amputees and healthy controls regarding gait velocity and step length. For further analyses, univariate ANOVA with repeated measures and Bonferroni-adjusted post-hoc tests were used to compare the effect of different surface conditions on pelvis obliquity and lateral trunk bending variability. The significance level was set at $\alpha = 0.05$. All statistical analyses were performed using SPSS software (IBM SPSS 19, IBM Corp., Armonk, NY, USA).

2.2 Relationship between the amount of daily activity and gait variability in transfemoral amputees

2.2.1 Aims and hypothesis

The aim of this study was to examine the potential relationship between variability in trunk and pelvic movement during walking of patients with a transfemoral amputation and their level of daily activity. It was hypothesized that amputees with higher kinematic variability in trunk and pelvic movement during walking have lower levels of daily activity.

2.2.2 Study design

A prospective observational study was used to examine the association between variability in trunk and pelvic movement and daily activity levels in transfemoral amputees. The study protocol was approved by the responsible ethical committee (No. 13131).

Fifteen patients (14 male patients, age 44 ± 9 years, 1 female patient, age 45 years) with transfemoral amputation and fitted with a prosthetic limb containing a C-leg knee-joint system (Ottobock, Duderstadt, Germany) participated in this study. All patients gave their written consent before inclusion in the study. In the first part of this examination, kinematic variability in trunk and pelvic movement during walking on even ground was analyzed using instrumented gait analysis (Vicon^{TM}, Oxford, UK) (Figure 1-3). In the second component of this study, daily activity data was collected over three weeks via a 3D acceleration sensor (Activ 8, VitaMove, Valkenswaard, Netherlands) fitted to the patient’s prosthetic limb (Figure 5). Patients` daily mean value of activity was calculated out of seven consecutive days of measurement (Figure 6).

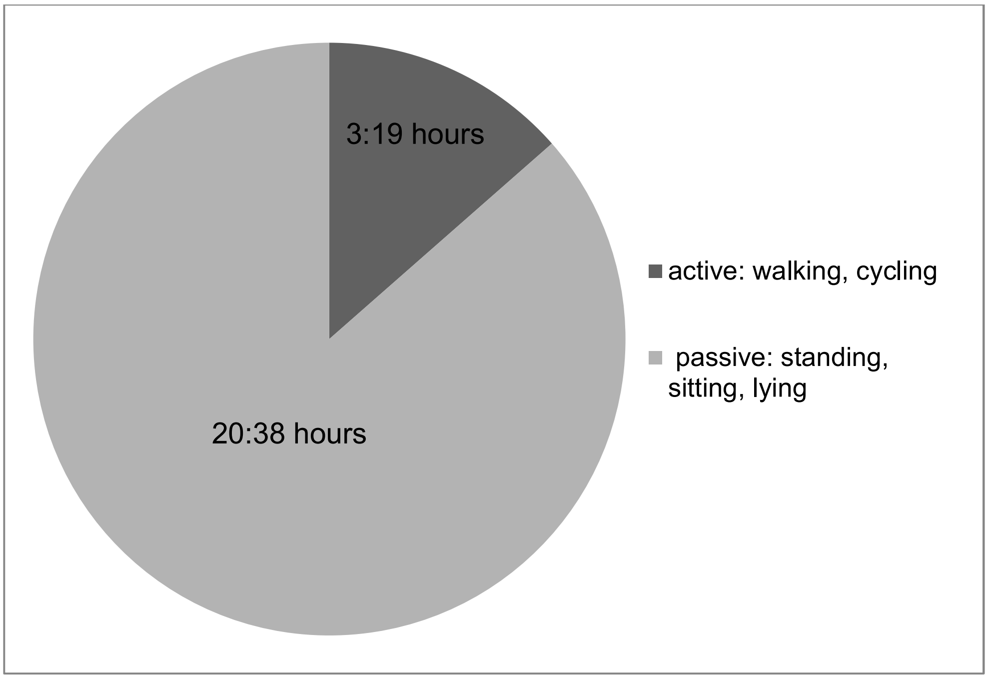
Figure 5: 3D-acceleration sensor fixed centrally on the front side of the prosthetic socket

Following parameters were measured by the 3D acceleration sensor:

- walking/cycling — active
- standing
- sitting/lying — passive

For further examinations just the duration of activity was used.

Figure 6: Daily activity value for one patient calculated out of seven days of measurement:



Additionally patients filled in an activity diary, if there were any abnormalities in their daily activity, for example less activity due to illness or injuries or higher activities caused by a special training (Appendix 6.3).

2.2.3 Statistical analysis

The association between mean activity of daily living and gait parameters, as well as variability of trunk and pelvic movement was evaluated by correlation and linear regression (Pearson´s) analyses using SPSS software (ver. 19, IBM Corp., Armonk, NY, USA).

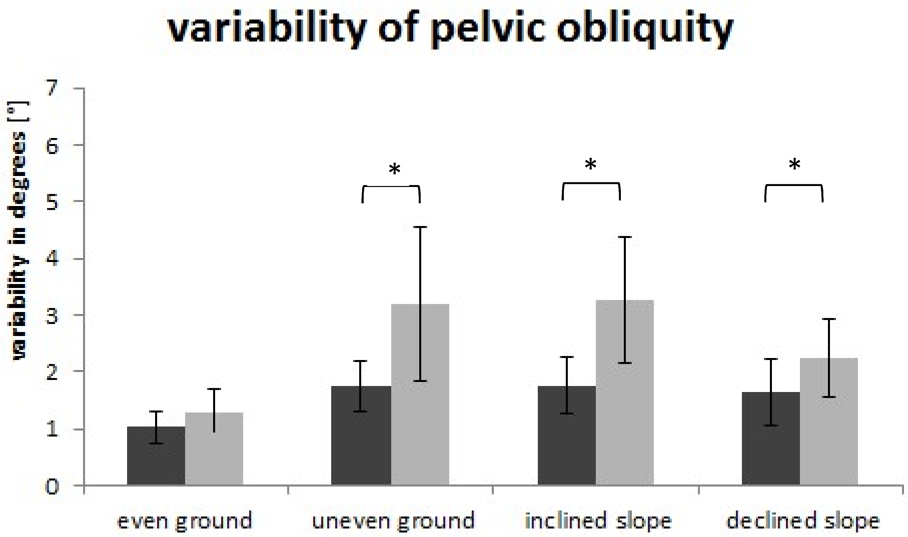
3 Summary of Findings

3.1 Variability in trunk and pelvic movement in transfemoral amputees using a C-leg system compared to healthy controls

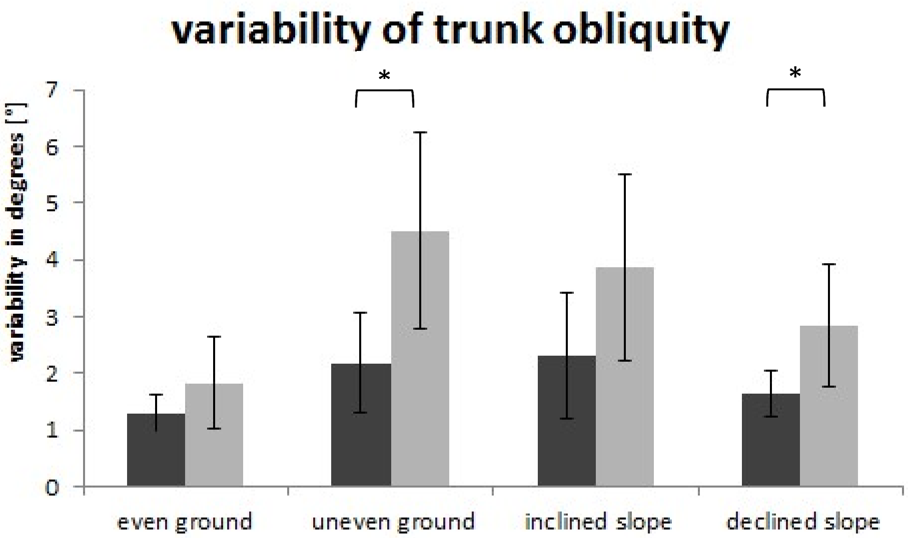
The data collected demonstrates that patients with transfemoral amputation and fitted with a C-leg knee-joint system (Ottobock, Duderstadt, Germany) have greater variability in trunk and pelvic motion compared to healthy, matched controls.

Although patients with transfemoral amputation showed a significant increase in variability of trunk and pelvis kinematics during walking on uneven and sloped surfaces, no increased variability was found in comparison to healthy controls when walking on even ground (Figure 7).

Figure 7: Means and standard deviations of variability of pelvic obliquity (a.) and lateral trunk bending (b.) in healthy controls and amputees during walking on different types of surfaces, * : $p < 0.05$



a.



b.

Altered spatio-temporal parameters in gait, such as gait velocity and step length, are known to influence kinematic data (Schwartz et al., 2008) and therefore inherently, the variability of this data as well. To assess possible influencing factors, spatio-temporal parameters considered to be potentially relevant were analyzed. The results show that transfemoral amputation patients walked significantly slower than healthy able-bodied adults did; irrespective of the walking condition tested (even ground, uneven ground, and slope). However, differences in gait velocity between the patient group and healthy controls were more pronounced during walking on uneven ground and slope than on even, flat ground (14% even ground: $p=0.001$; 26% uneven ground: $p \leq 0.001$; 24% inclined slope: $p \leq 0.001$; 21% declined slope; $p \leq 0.001$).

Additionally, amputation patients demonstrated a consistently shorter step length than healthy controls while walking on all four surfaces (11% even ground: $p=0.004$; 14% uneven ground: $p=0.001$; 14% inclined slope: $p=0.001$; 24% declined slope: $p=0.004$).

Previous literature shows that a shorter step length and slower gait velocity are associated with a greater risk of falling in unilateral transtibial amputees as well as older adults (Dite et al., 2007; Verghese et al., 2009; Gervásio et al., 2016). Thus the differences of gait velocity and step length between the group of amputated patients and healthy controls may have an influence on gait variability. Therefore, the statistical analysis of kinematic variability during walking was undertaken with gait velocity and step length used as covariates. However, even when controlling for gait velocity and step length, differences in trunk and pelvic movement variability during walking between the patient group and healthy able-bodied group were evident. Therefore, our data demonstrates that increased variability in trunk and pelvis motion of transfemoral amputees is independent of gait velocity and step length.

Variability in trunk and pelvic movement was increased during walking on challenging terrain compared to even ground in the group of amputees as well as healthy controls. Variability of pelvic obliquity was greater during walking on uneven ground (amputees: $p \leq 0.001$; healthy controls: $p \leq 0.001$), on inclined (amputees: $p \leq 0.001$; healthy controls: $p \leq 0.001$) and on a declined slope (amputees: $p \leq 0.001$; healthy controls: $p=0.002$) when compared to even ground for both groups. Among the three challenging walking conditions, amputees demonstrated no differences between walking on uneven ground and inclined slope ($p=1.0$), but exhibited a higher variability while walking on uneven ground ($p=0.049$) and on an inclined slope ($p=0.016$) compared to walking on declined slope. However, healthy controls showed no differences in variability between any of the walking conditions uneven ground, inclined slope and declined slope ($p=1.0$).

Lateral trunk bending variability was increased during walking on uneven ground (amputees: $p \leq 0.001$; healthy controls: $p=0.001$), inclined (amputees: $p \leq 0.001$; healthy controls: $p=0.005$) and declined slope (amputees: $p=0.003$; healthy controls:

p=0.012) when compared to walking on even ground for both groups. Among the three challenging walking conditions both groups demonstrated a significantly higher variability on uneven ground compared to declined slope (amputees: p=0.001; healthy controls: p=0.04). Neither group showed differences in variability during walking on an inclined slope compared to walking on uneven ground or (amputees: p=0.1; healthy controls: p=0.1) on a declined slope (amputees: p=0.178; healthy controls: p=0.096).

The results could not demonstrate any association between the history of falling and variability in trunk and pelvic movement during walking on even ground in the group of amputees.

There are some limitations of this investigation. For instance, falls history data were collected in a medical examination, without a standardized reporting procedure. Consequently, this data was unable to be statistically analyzed. Nevertheless, an initial impression of the association between kinematic gait variability and fall history was able to be demonstrated. Another limitation was that gait measurements were undertaken in a laboratory setting; an artificial environment differing from reality, with standardized walking surfaces and without any environmental influences, like for example weather or other road users. To minimize this potential limitation, each test person participated in a familiar session within the laboratory setting and afforded practice on the different walking tasks. This study also examined a relatively large but homogeneous group of patients with transfemoral amputation. All patients wore the same knee joint prosthetic system with a prosthetic foot manufactured by Otto Bock. Five patients used the 1C60 Triton foot system, six patients the 1C40 C-Walk, and two patients the 1E56 Axtion, whereby the functional principle of these foot types is very similar.

3.2 Relationship between the amount of daily activity and gait variability in transfemoral amputees

The data of this study clearly demonstrates that variability in trunk and pelvic movement in transfemoral amputation patients using a C-leg system (Ottobock, Duderstadt, Germany) was associated with the individual level of daily activity. Patients with lower activity levels showed increased variability in trunk and pelvic movement during level walking as well as reduced gait velocity (Table 3).

Table 3: Gait velocity and variability in trunk and pelvic movement and their association to daily activity (*p ≤0.05)

parameter	mean	standard deviation	r with activity	p-value
gait velocity	1.2 m/s	0.19 m/s	0.60	0.02 (*)
variability pelvis obliquity	1.4 °	0.4 °	-0.63	0.01 (*)
variability trunk obliquity	1.9 °	0.9 °	-0.58	0.02 (*)

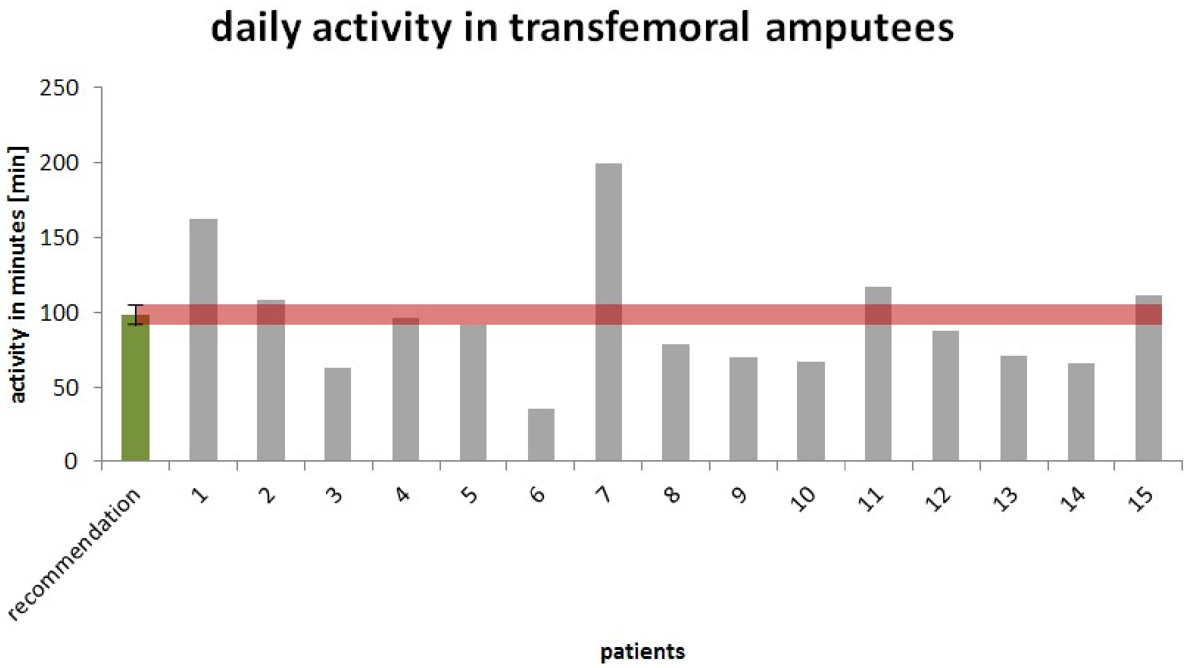
The overall duration of activity of patients ranged between 35 and 199 minutes per day, with an average daily activity duration of 95 ± 41 minutes. Patients showed an activity of 0 minutes running, 6 ± 12 minutes cycling and 89 ± 44 minutes walking per day. Based on this data and that of the self-reported activity diary, it may be concluded that patients demonstrated a moderate-intensity activity.

It is currently recommended that 10,000 steps per day is needed to achieve a healthy lifestyle and improve physical and mental well-being in healthy able-bodied adults (Tudor-Locke et al., 2004; Yuenyongchaiwat et al., 2016; Castres et al., 2017). Thirty minutes of moderate-intensity walking corresponds to approximately 3,000-4,000 steps (Tudor-Locke et al., 2004). Accordingly, 100 minutes of moderate-intensity activity per day is needed for a healthy lifestyle. The data collected in this study clearly demonstrates that transfemoral amputees undertake, on average, 5 minutes less physical activity than that required to achieve the recommended level of daily activity as stated in the literature.

The results of our gait analysis show that patients with transfemoral amputation took on average 102 ± 7 steps per minute. Hence, patients would have to walk approximately 98 minutes per day to achieve the recommended 10,000 step guideline. Therefore, in the current study patients undertook 3 minutes less activity per day on average than that required to meet the recommended number of steps. Of course some patients achieved or exceeded the daily recommended activity level. However most of the patients measured in our analyses, demonstrated markedly lower activity levels than recommended. These patients showed an average of 72 ±

17 minutes activity per day and therefore about 26 minutes less activity than recommended for a healthy life style (Figure 8). Of course it must be mentioned that the recommended 10,000 steps refer to healthy able-bodied adults. However, at this time, there is no recommendation for daily activity in lower limb amputees.

Figure 8: Patients' daily activity compared to the recommended daily activity needed to achieve a healthy lifestyle, in minutes



The data of this study clearly demonstrates that variability of pelvic obliquity and variability of lateral trunk bending during gait correlate with the duration of daily activity in transfemoral amputation patients (r=-0.6, $p \leq 0.02$).

Naturally, there are limitations to the performed investigation. Although the assessment of daily activity using 3D-acceleration sensors is considered to be a very objective, precise, and reliable method (van Poppel et al., 2010; Bassett et al., 2000; Prince et al., 2008; Pitta et al., 2006; Sequeir et al., 1995), it is dependent on patient compliance (Sliepen et al., 2017; Götte et al., 2017). Therefore, using body-worn sensors may lead to inexact activity data due to irregular or incorrect use of the sensor (Sliepen et al., 2017; Götte et al., 2017; Bassett et al., 2000). Several measures were taken in order to ensure accurate daily activity data collection in this study. By fixing the sensor to the prosthetic socket as opposed to a physiological location, the sensor did not affect patient comfort and lessened the likelihood of altered natural activity patterns. Moreover activity measures in this study were optimized by recording data over a relatively long measurement period (three weeks) compared to previous studies, which measured activity only over a period of 2-7 days (Bussmann et al., 2004; Stepien et al., 2007; Weiss et al., 2013; Lin et al., 2014). In addition, a self-reported activity diary which was completed by all patients facilitated cross-validation and elimination of aberrant sensor data (Appendix 6.3). A strength of this study is the homogeneous nature of the patient group in terms of their clinical picture.

While other studies involving amputees have focused on the variability of spatio-temporal parameters (Sagawa et al., 2011; Svoboda et al., 2012; Parker et al., 2013; Lin et al., 2014), this is the first study, to the best of the authors knowledge, that has evaluated the association between kinematic variability in trunk and pelvic movement and the duration of daily activity in patients with transfemoral amputation.

4 Discussion & Outlook

4.1 Variability in trunk and pelvic movement in transfemoral amputees using a C-leg system compared to healthy controls

This is the first study of its kind to show that patients with transfemoral amputation using a C-leg system have greater kinematic variability in the frontal plane movement of pelvis and trunk during walking when compared to healthy adults. However, contrary to our hypothesis, increased kinematic variability of the trunk and pelvis was not associated with fall history in our cohort.

Previous studies show that a stable gait pattern is based on regularity and reproducibility during walking; therefore the walking process occurs automated and every step can be anticipated (Kadaba et al., 1989; Growney et al., 1997; Sawa et al., 2012; Ayoubi et al., 2014). Whenever walking starts to become irregular and more variable, it may lead to an unstable gait pattern (Toebes et al., 2012; Sawa et al., 2014; Ayoubi et al., 2014).

Most previous literature only focus on walking on even ground (Vanicek et al., 2009; Parker et al., 2013; Svoboda et al., 2012; Lin et al., 2014), although there is a need for detailed gait analysis on uneven ground to assess patients' ability to handle more challenging terrains which simulate outdoor walking. Some studies have already examined gait pattern variability during walking on uneven ground, focusing on spatio-temporal parameters and demonstrate trends similar to the current study. Patients with a lower limb amputation show increased variability during walking on uneven ground as compared to even ground (Gates et al., 2012; Gates et al., 2012; Sinitski et al., 2019).

Walking on uneven ground is a necessary component of human motion. Deficits in walking on uneven ground may cause difficulties while walking outdoors and avoidance of daily activities (Miller et al., 2001; Bussmann et al., 2008; Kempen et al., 2009). Walking on cobblestones, inclined or declined streets, or excursions in nature could become a challenge for such patients. Patients may avoid these activities if they are unable to cope with such situations, potentially leading to decreased social as well as physical activities in life, which in turn could cause a decreased quality of life, further health problems and even mental disorders (Deans et al., 2008; Gailey et al., 2008). Our results clearly show that patients with transfemoral amputation demonstrate higher variability in trunk and pelvic movement during walking on challenging terrain compared to healthy persons. Therefore it could be hypothesized that a decreased quality of life, which has often been shown in amputated patients (Sinha et al., 2011), is partially based on the affected gait pattern. Further studies should clarify the association between quality of life, physical and mental health, and variability during walking on challenging terrain in transfemoral amputees.

This study also investigated the potential association between kinematic variability in trunk and pelvic movement and fall history in transfemoral amputees. The association between gait variability in spatio-temporal parameters and events that occur in daily living, such as fall history or the fear of falling are rarely analyzed in previous literature. In comparison to some studies that demonstrate higher variability in spatio-temporal parameters in neurological patients or elderly with fall history compared to non-fallers (Hausdorff et al., 2001; Verghese et al., 2009; Rochat et al., 2010; Schniepp et al., 2013; Pieruccini-Faria et al., 2018), our results show no association between the history of falls and kinematic variability in trunk and pelvic movement in patients with transfemoral amputation. Some studies analyzing lower limb amputees could also demonstrate an association between variability of spatio-temporal parameter during walking and fall history (Vanicek et al., 2009; Hordacre et al., 2015). However, Parker et al. report no association between falls and variability in spatio-temporal parameters in amputees (Parker et al., 2013).

Nevertheless, it appears that gait variability in patients with amputation is a conspicuous parameter in gait pattern of patients with lower limb amputation. Although this study was unable to demonstrate any association between fall history and variability in trunk and pelvic movement, the results clearly show abnormal kinematic variations in transfemoral amputees compared to healthy controls. Further examinations should analyze the association between the fear of falling and gait variability. An association between an unstable gait pattern and the fear of falling could be possible without any fall history. Often patients avoid activities and situations which could lead to falls caused by their fear of falling (Miller et al., 2001). It could be hypothesized that patients with an unstable gait pattern demonstrate an increased fear of falling and therefore avoid activities and challenging walking situations, which in turn could lead to a lower quality of life.

The measurement and detection of variability in gait pattern may be advantageous to many clinical sectors, enabling the individual optimization or even adjustment of prosthetic systems. Professional orthopedics could, for example, adapt the prosthetic shaft, change the statics of the prosthetic system or recommend optimal prosthetic feet or knee joint systems. Additional therapeutic approaches like gait training or muscle strengthening could also be prescribed. Analyses of variability in trunk and pelvic movement could also be used to measure significant gains of patients` gait quality after rehabilitation training or a new prosthetic fitting.

However, further research is needed to demonstrate to what extent variability of trunk and pelvic movement could be changed and optimized by modifying prosthetic systems or therapeutic training. Additionally, further investigation is needed to develop a solid evaluation basis for transfemoral amputees based on gait variability data. This work is an applied research study that makes a first step towards using kinematic variability of trunk and pelvic movement to assess patients' gait pattern and compare it to healthy controls. These results are the first to demonstrate greater kinematic variability in trunk and pelvic movement in transfemoral amputation patients during walking than healthy controls.

4.2 Relationship between the amount of daily activity and gait variability in transfemoral amputees

The results demonstrate that variability in trunk and pelvic movement in patient with transfemoral amputation during walking under laboratory conditions was related to their duration of daily activity outside of the laboratory when measured with triaxial accelerometers.

To the best of the authors' knowledge, no published studies to date have analyzed the association between variability in trunk and pelvic movement and the duration of daily activity in lower limb amputees. This study is the first to show that heightened variability in trunk and pelvic movement during gait is associated with less daily activity.

Previous literature already shows physical activity deficits in lower limb amputees. Halsne et al. demonstrate a reduced step count for patients with lower limb amputation, while Bussmann et al. report a decreased duration of physical activity compared to healthy controls. The study of Gallagher and colleagues show that lower limb amputees report restrictions in sports, leisure or cultural activities as well as employment and job seeking (Bussmann et al., 2004; Bussmann et al., 2008; Gallagher et al., 2011; Halsne et al., 2013).

Additionally abnormalities in the gait pattern of patients with a lower limb amputation, especially in terms of an increased variability of spatio-temporal and kinetic parameters are reported in previous literature (Lamoth et al., 2010; Tura et al., 2010; Gates et al., 2012; Svoboda et al., 2012). Variability in gait pattern could indicate gait instability and fall risk (Hausdorff et al., 2005). Ultimately, increased gait instability may lead to uncertainties in gait and therefore to avoidance of certain activities in daily living. O`Conner and colleagues demonstrate higher metabolic cost during walking with increased variability in spatio-temporal parameters (O`Conner et al., 2012). Therefore higher energy expenditure could also lead to less physical activity in daily living. Previous literature shows that daily activity is associated with health related quality of life in physical as well as mental domains (Acree et al., 2006; Bize et al., 2007; Asano et al., 2008). Therefore an avoidance or reduction of physical activity could in turn lead to a decreased quality of life as well as further mental and physical health problems (Miller et al., 2001; Kempen et al., 2009; Mausbach et al., 2011).

Our results demonstrate that data of gait variability could give information about patients` activity level at home. Therefore transfemoral amputees with increased variability in trunk and pelvic movement are affected in their daily living. Heightened variability in trunk and pelvic movement could indicate an affected gait pattern in amputees and the need of an individual gait training or special prosthetic fitting to improve patients` gait stability. This information may help to improve prosthetic, as well as therapeutic approaches and constitutes a basis for further research. Future studies should clarify the reason for heightened gait variability in transfemoral amputees and examine whether the duration of daily activity is influenced by variability in gait pattern or vice versa. It should also be examined if factors like residual leg length, age or reported pain also have an influence on the extent of gait variability. It could be hypothesized that patients with short residual leg length, higher age and increased pain show higher values of variability during walking and decreased daily activity. Further research studies should also clarify whether different prosthetic systems or special gait training are able to influence and therefore optimize and control variability of trunk and pelvic movements or daily activity in transfemoral amputation patients. It could be hypothesized that an optimization of the prosthetic system or special gait training could reduce the extent of gait variability in patients with transfemoral amputation. This knowledge could potentially enable more directed, individual, effective and optimized therapy planning and orthopedic care of patients with transfemoral amputation.

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6 Appendix

6.1 Original article “Variability in trunk and pelvic movement in transfemoral amputees using a C-leg system compared to healthy controls” published in the Journal “Human Movement Science”

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Full Length Article

Variability in trunk and pelvic movement of transfemoral amputees using a C-leg system compared to healthy controls

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ABSTRACT

Objective: Gait variability is a measure of gait disturbance, and therefore constitutes a useful parameter for gait assessment as well as planning of therapeutic and medical interventions. To date, variability during walking has not been adequately analyzed in amputees. The aim of this examination was to evaluate trunk and pelvic movement variability in transfemoral amputees. The effect of different types of walking surfaces on variability in trunk and pelvic movement was also studied.

Method: This prospective clinical examination compares 20 transfemoral amputees (17 ♂, 42 ± 16 years; 3 ♀, 48 ± 3 years) with a group of 20 age and mass matched healthy controls regarding the extent of variability in trunk and pelvic movement. Kinematic data of trunk and pelvic movement during walking on level, uneven ground and slope was captured by eight infrared cameras (Vicon Nexus ™, Oxford, UK). Variability in trunk and pelvic movement was analyzed. Univariate ANCOVA and ANOVA with repeated measures and post hoc tests were used for statistical comparison. Fall history was retrospectively collected from medical history to assess the association between falls and variability in trunk and pelvic movement.

Results: Trunk and pelvic movement variability in amputees was significantly higher during walking on uneven ground and slope compared to healthy controls ($p \leq 0.05$). Variability in trunk and pelvic movement was increased during walking on uneven ground and slope compared to even ground for both groups ($p \leq 0.05$).

Conclusion: Amputees showed increased trunk and pelvic movement variability during walking on uneven ground and slope, indicating an affected gait pattern in comparison to healthy controls. Therefore, trunk and pelvic movement variability could be a potential marker for gait quality with diagnostic implications.

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1. Introduction

Individuals who have lost a limb after trauma, arterial disease or sarcoma must cope with significant functional impairment as well as mental disorder (Narang, Mathur, Singh, & Jape, 1984; Greive & Lankhorst, 1996; MacKenzie et al., 2004; Sinha, van den Heuvel, & Arokiasamy, 2011). Every second individual with unilateral lower limb amputation reports at least one fall per year (Miller, Speechley, & Deathe, 2001). 49% of these patients expressed a fear of falling, and 76% avoid activities because of their fear of falling (Miller et al., 2001). Additional loss of the knee joint due to amputation further reduces movement control and stability during standing (Ku, Osman, & Abas, 2014). To achieve sufficient walking stability for transfemoral amputees, therapeutic treatments and prosthetic adaptations need to be optimized and customized on an individual basis. Thus, there is a need for an objective assessment of gait pattern and walking stability.

One factor which has been suggested as a measure of gait disturbance in several studies is gait variability. Risk of falling as well as fear of falling have shown to be associated with increased gait variability (Ayoubi, Launay, Annweiler, & Beauchet, 2014; Sawa et al., 2014). Furthermore, in patients with lower limb amputation and a history of falling, a large variation of swing duration was found (Vanicek, Strike, McNaughton, & Polman, 2009). However, there are also studies which present contrary results and show no differences in gait variability of amputee fallers and non-fallers (Parker, Hanada, & Adderson, 2013). All of these previous studies, which focused on gait variability in amputees and highlight the importance of this parameter, only considered the variability of spatio-temporal parameters such as gait velocity, step width or step length, but not any kinematic parameters such as joint angles or body postures. Kinematic data are inherently more challenging to collect and assess compared to spatio-temporal parameters; however, they may provide more detailed information about body movement, posture, gait pattern repeatability and stability beyond those obtained from spatio-temporal gait parameters alone. Kinematic data is able to describe humans` gait pattern and its quality in a very detailed way (Whittle, 1996). In particular, trunk movement variability during walking has been shown to be associated with a decreased gait stability and an increased fear of falling in the elderly (Sawa et al., 2014; Toebes, Hoozemans, Furrer, Dekker, & van Dieën, 2012). However, there is a lack of published literature that analyzes trunk movement variability or other kinematic data in lower limb amputees. The inconsistency of previous literature findings regarding gait variability in lower limb amputees (Lin, Winston, Mitchell, Girlinghouse, & Crochet, 2014; Parker et al., 2013; Vanicek et al., 2009) may possibly result from the exclusive use of spatio-temporal parameters neglecting analysis of kinematic data. It may be possible that spatio-temporal parameter variability is not statistically significant enough to present clear results. Furthermore, most previous literature is only focused on walking on even ground (Lin et al., 2014; Parker et al., 2013; Svoboda, Janura, Cabell, & Elfmark, 2012; Vanicek et al., 2009). There is a need, however, for detailed gait analysis to be conducted on uneven ground to assess lower limb amputees' ability to handle more challenging terrains which simulate outdoor walking. Walking on different types of surfaces poses exacerbated challenges and might thus be more sensitive for the detection of gait variability, but to our knowledge has not yet been analyzed.

The aim of this study was to compare the variability of lateral trunk bending and pelvic obliquity during walking in amputees to healthy controls. We further analyzed to which extent variability is affected by different walking surfaces. We hypothesized that kinematic variability during walking is increased in amputees using a prosthetic knee joint system compared to healthy controls, and that variability is further increased during walking on uneven ground or on slope in comparison to walking on even ground.

2. Methods

2.1. Participants

This prospective clinical examination study received approval by the responsible ethical committee (Ethikkommision der Bayerischen Landesärztekammer, Germany, No. 13131) and complies with the principles outlined in the Declaration of Helsinki. All test persons were informed about the procedure as well as their rights and gave written consent prior to participation in our study. A group of 20 transfemoral amputees using the C-leg knee-joint system (Ottobock, Duderstadt, Germany) were recruited for this study during their hospital stay and were compared to 20 healthy controls matched for age (± 5 y), height (± 5 cm), and mass (± 5 kg). Amputees were hospitalized for assessment of their prosthetic treatment. Time since amputation in patients was 16 years ± 12 years. We calculated that a sample size of 14 participants per group provided 80% power ($\beta = 0.20$) to detect a difference of ± 1 standard deviation for the parameters variability in pelvic obliquity and lateral trunk bending between both groups, assuming a significance level of 5% ($\alpha = 0.05$) (Faul, Erdfelder, Lang, & Buchner, 2007).

Inclusion criteria were: age between 18 and 65 years, unilateral transfemoral amputation or knee-disarticulation, use of the microprocessor-controlled prosthetic knee C-leg 2 or 3 (Ottobock, Duderstadt, Germany), suction socket type with valve or seal-in technique or a liner with pin and an ischial containment socket shape for transfemoral amputees and a suction socket type with seal-in technique for knee disarticulation. Additionally, all amputees had to show the ability to walk without walking aids other than the prosthesis in everyday life and had to be appropriately accustomed to wearing and walking with the C-leg system. The inclusion criteria also demanded a correct prosthetic alignment as well as an acceptable socket fit. These basic settings were checked in a medical entry examination (Table 1).

2.2. Procedure

All test persons participated in gait analysis walking trials using an eight infrared-camera motion analysis system (Vicon™, Oxford, UK). Thirty retro-reflective markers (14 mm diameter) were fixed on the lower limbs and the upper body following anatomical

Table 1
Description of study sample (group of transfemoral amputees $n = 20$ and healthy controls n = 20).

	Patients		Healthy test persons	
Gender	17♂	3 ♀	17♂	3 ♀
Age	42 y ± 16 y	48 y ± 3 y	43 y ± 11 y	48 y ± 5 y
Weight	93 kg ± 11 kg	65 kg ± 11 kg	92 kg ± 14 kg	62 kg ± 7 kg
Height	183 cm ± 6 cm	166 cm ± 3 cm	186 cm ± 7 cm	170 cm ± 5 cm
Transfemoral	12	3		
Knee-disarticulation	5	0		

landmarks according to the conventional gait model of Kadaba, Ramakrishnan, and Wootten (1990) and the guidelines of Vicon™ (Plug-in Gait Reference Guide, 2016) (Fig. 1).

Lower limb and upper body data were recorded at 200 Hz. Marker data were filtered using a Woltring filter with a predicted mean square error value of 10 mm^2 (Woltring, 1986). Kinematic data of trunk and pelvic movement of all participants from both groups were measured in four walking conditions: even and uneven ground, inclined and declined slope. The uneven ground was simulated by structural panels (Terrasensa®-plates, Hübner, Kassel, Germany) over a distance of 6 m. Walking on inclined and declined slope

Fig. 1. Marker placement (Plug-in Gait Fullbody model). Markers on the prosthetic system were placed at the same positions as on the intact limb. Upper body: C7 (Spinous process of C7); TH 10 (Spinous process of TH 10); RBAK (Centrical on the right scapula); CLAV (Jugular Notch); STRN (Xiphoid process of the sternum); LSHO and RSHO (Acromio-clavicular joint left/right); LELB and RELB (Lateral epicondyle left/right); LWRA and RWRA (Process styloideus radii left/right); LASI and RASI (Anterior superior iliac spine left/right); SACR (Sacrum).
Lower limbs: LTHI and RTHI (surface of the left/right thigh); LKNE and RKNE (flexion-extension axis left/right knee); LTIB and RTIB (surface of the left/right shank); LANK and RANK (lateral malleolus left/right); LHEE and RHEE (calcaneous left/right at the same height above the plantar surface of the foot as the toe marker); LTOE and RTOE (second metatarsal head).

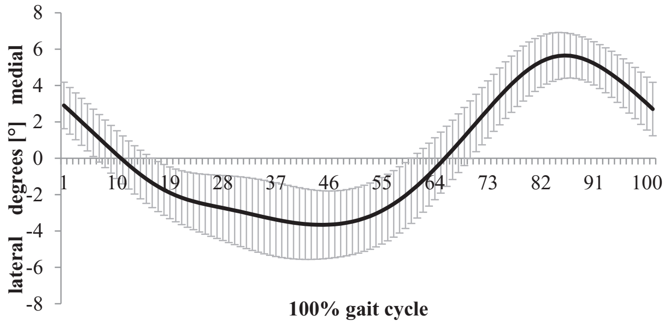

Fig. 2. Kinematic data of lateral trunk bending to the healthy side of one amputee while walking on even ground with variability indicated by the standard deviation. The averaged width standard deviation band constitutes the variability.

was facilitated by a mobile ramp, which had a length of 3 m.

Each of the four walking conditions started with two warm up trials to allow the subject to become familiar with the different surface types. Afterwards, each test person was instructed to complete five trials of each walking conditions. For healthy participants, kinematic data of trunk and pelvic movement as well as spatio-temporal parameters were measured and analyzed on the same side of the body as their matched amputee.

To determine the variability of gait as a measure of gait stability, kinematic data of trunk and pelvic movement were analyzed in the frontal plane. Previous literature clearly shows that evasive movements in trunk and upper body may be associated with an increased instability of gait in the elderly (Sawa et al., 2014; Toebes et al., 2012). Therefore, this study focuses on kinematic data of trunk and pelvic movement and not of the lower limbs.

Trunk and pelvic movement kinematic data were time normalized to 100% gait cycle and interpolated to 100 data points (Matlab R2013a, The Mathwork Inc., Natick, MA. USA). For each data point, the standard deviation was computed over five trials within each condition. To estimate gait variability in trunk and pelvic movement, standard deviations (σ_i) over all data points were multiplied by two and averaged (Eq. (1)) (Fig. 2):

$$variability = \left(\sum_{i=1}^{100} 2\sigma_i\right)/100 \tag{1}$$

Schwartz et al. showed that kinematic data variability could be influenced by spatio-temporal parameters such as gait velocity (Schwartz, Rozumalski, & Trost, 2008). To ensure that measured trunk and pelvic movement variability was not influenced by spatio-temporal parameters, gait velocity and step length were also examined in this study.

Occurrence of falls in amputees was retrospectively assessed by interview.

2.3. Data analysis

For statistical analysis, univariate ANCOVA was used to compare amputees and healthy controls regarding trunk and pelvic movement variability in different walking conditions. Gait velocity and step length were included as co-factors to minimize the likelihood of any influencing factors. Additionally, a Student's *t*-test was used to compare the group of amputees and healthy controls regarding gait velocity and step length. For further analyses, univariate ANOVA with repeated measures and Bonferroni-adjusted post-hoc tests were used to compare the effect of different surface conditions on pelvis obliquity and lateral trunk bending variability. The significance level was set at $\alpha = 0.05$. All statistical analyses were performed using SPSS software (IBM SPSS 19, IBM Corp., Armonk, NY, USA). Additionally, standard error of mean (SEM) and minimal detectable change ($MDC = SEM \times 1.96 \times \sqrt{2}$) for variability in trunk and pelvic movement were analyzed.

3. Results

3.1. Spatio-temporal parameters: comparison between the group of amputees and healthy controls

Step length (11% even ground: $p = 0.004$; 14% uneven ground: $p = 0.001$; 14% inclined slope: $p = 0.001$; 11% declined slope; $p = 0.004$) and gait velocity values during walking (14% even ground: $p = 0.001$; 26% uneven ground: $p \le 0.001$; 24% inclined slope: $p \le 0.001$; 21% declined slope; $p \le 0.001$) were significantly smaller in amputees compared to healthy controls. Thus, the statistical analysis comparing variability between the group of amputees and healthy controls was adjusted for these parameters.

3.2. Variability of pelvic obliquity and lateral trunk bending: comparison between the group of amputees and healthy controls

Variability in pelvic obliquity was consistently larger in amputees compared to controls (Fig. 3 a.). The differences were most pronounced during walking on uneven ground (81%, $p = 0.006$; MDC = 0.8°), inclined slope (85%, $p < 0.001$; MDC = 0.8°) and

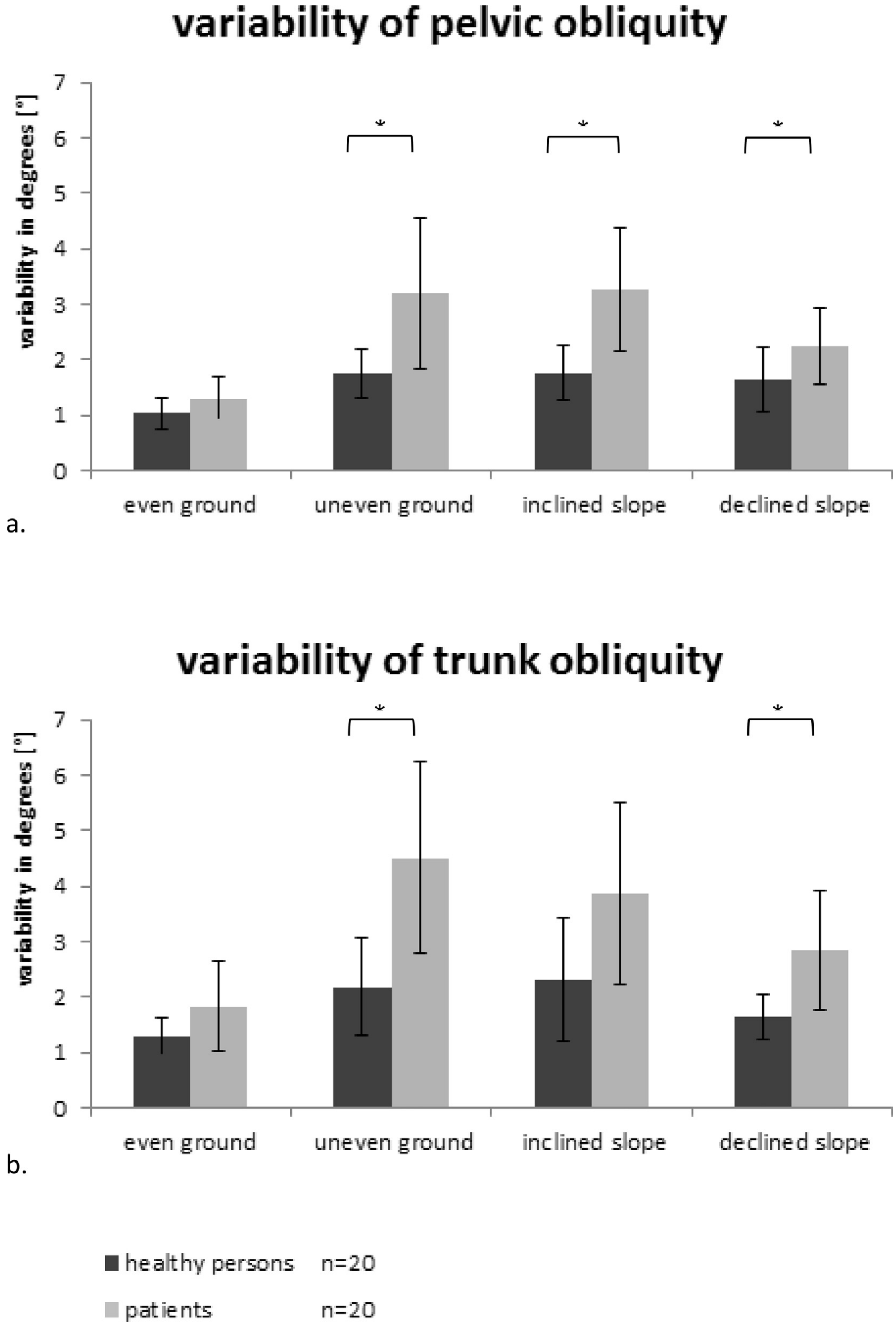

Fig. 3. Means and standard deviations of variability of pelvic obliquity (a.) and lateral trunk bending (b.) in healthy controls and amputees during walking on different types of surfaces, *: $p < 0.05$.

declined slope (36%, p = 0.03; MDC = 2.2°) (Fig. 3 a.). No significant differences between both groups were found during walking on even ground (25%; p = 0.089; MDC = 0.25°). Also, trunk variability was consistently larger in amputees compared to controls (Fig. 3 b). Again, the differences were most pronounced during walking on uneven ground (105%, p = 0.006; MDC = 1.1°), and on a declined slope (73%, p = 0.001; MDC = 0.6°) (Fig. 3 b.). No significant differences between amputees and healthy controls were found during walking on even ground (53%; p = 0.113; MDC = 0.5°) or on inclined slope (66%; p = 0.077; MDC = 1.1°).

3.3. Variability of pelvic obliquity and lateral trunk bending: comparison between different walking conditions

Pelvic obliquity variability was increased during walking on uneven ground (amputees: p ≤ 0.001; healthy controls: p ≤ 0.001), on inclined (amputees: p ≤ 0.001; healthy controls: p ≤ 0.001) and on a declined slope (amputees: p ≤ 0.001; healthy controls: p = 0.002) when compared to even ground for both groups. Among the three challenging walking conditions, amputees demonstrated no differences between walking on uneven ground and inclined slope (p = 1.0), but exhibited a higher variability while walking on uneven ground (p = .049) and on an inclined slope (p = 0.016) compared to walking on declined slope. However, healthy controls showed no differences in variability between any of the walking conditions uneven ground, inclined slope and declined slope (p = 1.0).

Lateral trunk bending variability was increased during walking on uneven ground (amputees: p ≤ 0.001; healthy controls: p = 0.001), inclined (amputees: p ≤ 0.001; healthy controls: p = 0.005) and declined slope (amputees: p = 0.003; healthy controls: p = 0.012) when compared to walking on even ground for both groups. Among the three challenging walking conditions both groups demonstrated a significantly higher variability on uneven ground compared to declined slope (amputees: p = 0.001; healthy controls: p = 0.04). Neither group showed differences in variability during walking on an inclined slope compared to walking on uneven ground or (amputees: p = 0.1; healthy controls: p = 0.1) on a declined slope (amputees: p = 0.178; healthy controls: p = 0.096).

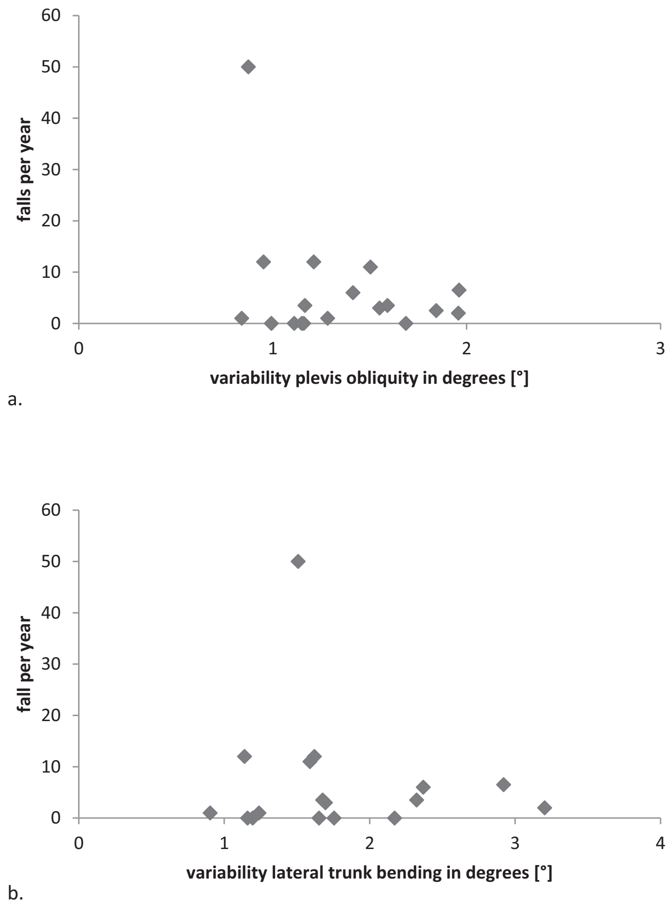

Fig. 4. Association between amputees` falls per year and the variability during walking on even ground in pelvic obliquity (a.) and lateral trunk bending (b.)

3.4. Association to history of falling in amputees

Amputees reported between 0 and 12 falls per year, with one patient reporting 50 falls over the last year. The number of reported annual falls showed no association with variability, in either the pelvis or the trunk (Fig. 4).

4. Discussion

The findings from our study suggest that variability of kinematic gait parameters is larger in amputees using a prosthetic knee joint system compared to healthy controls during walking on uneven ground or on slope. However, larger trunk and pelvic movement variability in amputees was not associated with an increase in fall tendency.

Previous literature shows that regularity and reproducibility of gait is the basis for a stable and confident gait pattern; every step can be anticipated and the motion sequence occurs completely automated (Kadaba et al., 1989; Growney, Meglan, Johnson, Cahalan, & An, 1997; Sawa et al., 2014; Ayoubi et al., 2014). Whenever walking starts to become irregular, it may lead to an unstable gait pattern with an increased risk of falling (Ayoubi et al., 2014; Sawa et al., 2014; Toebes et al., 2012). However, our data is unable to show any association between falls and variability during walking such as demonstrated in previous literature analyzing amputees or older people (Vanicek et al., 2009; Toebes et al., 2012).

Further studies reported no increased number of falls but rather an increased risk of falls and an increased fear of falling in patients with higher variability (Ayoubi et al., 2014; Sawa et al., 2014; Toebes, Hoozemans, Furrer, Dekker, & van Dieën, 2015). An increased fear of falling may lead to inactivity, which in turn could result in a lower quality of life and further health problems (Miller et al., 2001). Previous literature also demonstrates that transfemoral amputees with increased kinematic variability show lower levels of daily activity (Müßig et al., 2019). Therefore, it may be possible that patients with a high extent of variability did not necessarily demonstrate a high number of falls. Nevertheless, increased variability could indicate a deficit in stability and balance during walking and standing (Beauchet et al., 2009; Lamoth, Ainsworth, Polomski, & Houdijk, 2010). An unstable gait pattern can intensify the fear of falling and consequently decrease both daily activity and the quality of life (Lamoth et al., 2010; Terrier & Reynard, 2015; Toebes et al., 2015). Thus, the assessment of variability in gait pattern of transfemoral amputees could potentially be of clinical relevance. Our results clearly demonstrate that amputees show significant abnormalities in kinematic variability and therefore limitations in their walking quality and stability in comparison to healthy controls. Further research studies should clarify to which extent therapeutic approaches and orthopaedic treatments can be optimized and individually improved based on trunk and pelvic movement variability data.

Potential co-factors such as step length or gait velocity had no influence on trunk and pelvic movement variability during gait. Thus, our findings suggest that increased trunk and pelvic movement variability in amputees results from an irregular motion sequence during walking and is not associated with spatio-temporal parameters.

A limitation of this study is the retrospective retrieval of fall history. Retrospective reports of fall occurrence tend to be biased by expectation and by the subjective fear of falling. Nevertheless, our data suggest that, within our group of amputees, trunk and pelvic movement variability does not explain the occurrence of falls. Other factors not assessed in this study like activity level and type of activity might be more important factors associated with falls. Another general limitation of gait laboratory based analyses of gait pattern is the unfamiliar laboratory environment and spatial limitation of gait distances, in particular for walking on a slope. We tried to minimize these factors by providing ample time for participants to become accustomed to the laboratory environment.

Despite these limitations, our study demonstrates a novel approach in the research of lower limb amputees and is one of the very few examinations in the literature analyzing variability in amputees in this way. In previous literature, the regularity and reproducibility of gait pattern is only rarely analyzed in amputees. Furthermore, only the variability of spatio-temporal parameters, kinetic data or acceleration data were analyzed (Lamoth et al., 2010; Parker et al., 2013; Svoboda et al., 2012; Vanicek et al., 2009). Therefore, our study clearly demonstrates kinematic variability in transfemoral amputees walking on different types of surface compared to healthy controls. A further strength of our study is the very homogeneous group of amputees compared to previous literature, which examined more heterogeneous amputee groups (IJmker et al., 2014; Lamoth et al., 2010; Lin et al., 2014; Parker et al., 2013; Sagawa Jr. et al., 2011; Tanimoto, Anan, Sawada, Takahashi, & Shinkoda, 2016; Vanicek et al., 2009).

Tanimoto et al. (2016) acknowledged in their study that kinematic data variability could be a useful marker to assess gait pattern in healthy persons. Our study analyzed variability in trunk and pelvic movement in the frontal plane during walking. We intentionally decided to examine these parameters and not the kinematic data of lower limbs, on neither the intact limb nor the prosthetic side. Trunk and pelvis generate one entire unit of the body and represent the movement of the upper body in space. Additionally, trunk movement variability during walking has been shown to be associated with a decreased gait stability and an increased fear of falling in the elderly (Sawa et al., 2014; Toebes et al., 2012). Therefore, we determined kinematic data of trunk and pelvis motion to be most appropriate for our analyses.

In addition, we analyzed the influence of spatio-temporal parameters as well as the effect of different types of surfaces on variability in trunk and pelvic movement. These issues have not yet been adequately investigated in previous literature (Gates, Dingwell, Scott, Sinitski, & Wilken, 2012; Parker et al., 2013; Sawa et al., 2014).

Lastly, amputees wearing a C-leg system demonstrated an increased variability in trunk and pelvic movement during walking on uneven ground and slope.

5. Conclusion

This study analyzed kinematic variability in amputees in different walking conditions. Transfemoral amputees clearly demonstrated increased kinematic variability in trunk and pelvic movement, indicating that their gait pattern is affected in comparison to healthy controls. Therefore, variability in trunk and pelvic movement during walking could be a potential marker for gait quality with diagnostic implications.

Declaration of Competing Interest

All authors declare that they do not have any conflicts of interest.

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6.2 Original article ” Relation between the amount of daily activity and gait quality in transfemoral amputees” published in the „International Journal of Rehabilitation Research“

Relation between the amount of daily activity and gait quality in transfemoral amputees

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Gait variability is often associated with reduced coordination and increased instability during walking. Especially for patients with musculoskeletal conditions, variability in gait might be associated with the level of daily activity. Therefore, this study examines kinematic variability during walking and the association with daily activity in patients with transfemoral amputation. Therefore, 15 transfemoral amputees, using the C-leg prosthesis of Otto Bock, between 18 and 65 years were recruited during their hospital stay. All patients were able to walk without crutches in everyday life and were familiar with walking using the C-leg system. Gait parameters and data of variability were captured during walking in a gait laboratory by eight infrared cameras (Vicon). Daily activity was assessed using a three-dimensional acceleration sensor of VitaMove. Patients showed variability from 0.84° up to 1.96° in frontal pelvis motion and from 0.9° up to 4.02° in trunk obliquity. The results show a significant correlation between activity and variability in trunk ($r=-0.58$; $P \leq 0.05$) and pelvis ($r=-0.63$; $P \leq 0.01$) as well as gait velocity ($r=0.6$; $P \leq 0.05$). However, kinematic variability and gait velocity are not related to each other. In conclusion, the results show that kinematic gait variability is associated with the extent of activity and therefore presents an important parameter for assessing amputees' gait quality and daily activity. *International Journal of Rehabilitation Research* 42:139–144 Copyright © 2019 Wolters Kluwer Health, Inc. All rights reserved.

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Introduction

Daily activity has been suggested as a surrogate measure for quality of life (Gill *et al.*, 2013; Datta *et al.*, 2014). It is also frequently collected as a functional outcome measure in clinical studies examining lower limb amputees (Collin and Collin, 1995; Burger *et al.*, 1997; Bussmann *et al.*, 2004). Typically, information on daily activity is retrieved by standardized questionnaires or by body-worn three-dimensional acceleration sensors, which provide a more objective measurement method (Sequeir *et al.*, 1995; Pitta *et al.*, 2006; Prince *et al.*, 2008; Yang and Hsu, 2010).

Variability in gait is often associated with reduced coordination during walking and results in instability and a higher prevalence of falls (Vanicek *et al.*, 2009; Verghese *et al.*, 2009; Heredia-Jimenez *et al.*, 2015). There exists a high level of evidence that the level of daily activity decreases with aging and is particularly low in frail older adults (Fried *et al.*, 2001; Rockwood *et al.*, 2004; Zijlstra *et al.*, 2007). Furthermore, frail older adults show higher variability during walking compared with fit older adults (Moe-Nilssen and Helbostad, 2005). Thus, it can be assumed that individual daily activity levels might be associated with gait consistency. Previous studies suggest a significant association between the fear of falling and increased gait variability (Sawa *et al.*, 2014; Ayoubi *et al.*, 2015). Therefore, variability in gait pattern could potentially be associated with reduced activity in daily living.

It has been shown previously that variability in spatio-temporal parameters during walking is partly associated with physical activity and fall history in lower limb amputees (Parker *et al.*, 2013; Lin *et al.*, 2014). In addition, patients with lower limb amputations have limited opportunities for certain activities and have thus been shown to have a reduction in daily activity (Collin and Collin, 1995; Burger *et al.*, 1997; Bussmann *et al.*, 2004). So far, the association of kinematic variability in gait pattern with activity of daily living has not been examined in patients after amputations. However, especially for clinicians and orthopedic technicians working with amputees, precise information on gait quality and daily activity is indispensable for adaptation of prosthesis and prosthesis socket as well as planning of rehabilitation.

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Therefore, the aim of this study was to record activities in daily living and gait variability in trunk and pelvis movements in patients with transfemoral amputation and to examine the relation between both parameters. We hypothesized that amputees with an increased gait variability show less activity in daily living.

Patients and methods

The prospective clinical observation study was carried out in the rehabilitation unit of a level 1 trauma center. The study protocol was approved by the responsible ethical committee (No. 13131) and all patients obtained and signed informed consent.

A total of 15 patients with a unilateral transfemoral amputation (Table 1) were recruited during their hospital stay and provided informed consent for study participation. Patients were hospitalized for evaluation of their functional gain during walking with a new type of prosthetic system. Patients were dominantly male and experienced in wearing a prosthesis.

The inclusion criteria were as follows: age between 18 and 65 years, unilateral transfemoral amputation or knee disarticulation, use of the microprocessor-controlled prosthetic knee C-leg 2 or 3 (Otto Bock, Duderstadt, Germany), an ischial containment socket shape for transfemoral amputees, and a suction socket type with the seal-in technique for knee disarticulation. In addition, all patients had to show the ability to walk without walking aids in everyday life and had to be accustomed to wearing and walking the C-leg system. All patients received an individual gait training after their prosthetic treatment. Duration and content of prosthetic training depend on the patient's ability to deal with their prosthetic system and to achieve their individual aims in everyday life. Gait training was conducted by orthopedics or physiotherapists, who are especially qualified for gait training with lower limb amputees. The inclusion criteria also included a correct prosthetic alignment as well as a good socket fit; these basic settings were checked in a medical entry examination by a team of three orthopedic technicians who were especially educated in the prosthetic treatment of patients with transfemoral amputation.

All patients used a prosthetic foot of Otto Bock. Five patients used the 1C60 Triton foot system (Otto Bock, Duderstadt, Germany) and six patients used the 1C40 C-Walk, whereas two patients walked with the 1E56 Axtion. However, the operating principle of all three prosthetic foot types is very similar (C-leg product line, 2011; Otto Bock). Thus, no differences in gait pattern were expected. All individuals completed one measurement session of instrumented gait analysis. The gait analysis took place in a gait laboratory equipped with eight infrared-sensitive cameras (Vicon; Oxford Metrics Ltd, Oxford, UK). All cameras were calibrated before every session. Thirty retro-reflective markers (14-mm diameter) were fixed on the lower limbs and the upper body following anatomical landmarks according to the biomechanical model of Kadaba *et al.* (1990). The patients had to complete five walking trials on even ground while kinematic data of the lower limbs and upper body were recorded at 200 Hz. Marker data were filtered using a Woltring filter with a predicted mean square error value of 10 mm^2 (Woltring, 1986). Furthermore, kinematic data were normalized to 100% gait cycle (Matlab R2013a; The Mathwork Inc., Natick, Massachusetts, USA). To determine the variability in gait, kinematic data were analyzed in the frontal plane.

Table 1 **Description of the study population (*N*=15)**

Patient characteristics	*n*/mean±SD	Minimum	Maximum	Median
Sex				
Male	14	–	–	–
Female	1	–	–	–
Age (years)	44±9	26	55	47
Weight (kg)	92±17	69	121	94
Height (cm)	183±7	170	195	182
Time since amputation (years)	17±12	2	39	15
Transfemoral amputation	11	–	–	–
Knee disarticulation	4	–	–	–
Time wearing C-leg (years)	8±6	2	22	5
Employment				
Unemployed	4	–	–	–
Part-time job	2	–	–	–
Full-time job	9	–	–	–

It was consciously decided not to analyze any kinematic data of the lower limbs, neither the intact limb nor the prosthetic side. For this examination, kinematic parameters, which are almost similar in the basic setting for each patient, were selected. The trunk and pelvis are completely healthy and not directly influenced by an opposite side or the technical structure of the prosthetic system. The trunk and pelvis generate one entire unit of the body and are almost similar in all patients.

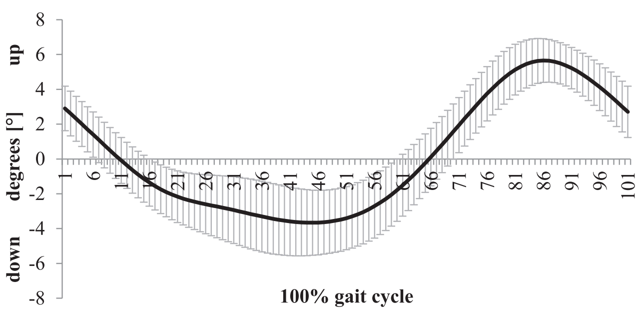
The whole gait cycle (heel strike to heel strike of the ipsilateral leg) was considered for trunk obliquity (deg.), describing upper body movement in the frontal plane as well as for pelvic obliquity (deg.), describing the body pelvis movements in the frontal plane.

Variability was determined by calculating the SDs of five walking trials for each time point of the full gait cycle (Fig. 1). Afterwards, twice the SD from all five trials was generated for each value. To achieve a measure of gait variability, twice the SD ($2\sigma_i$) of all 100 values were averaged as in Eq. (1):

$$\text{Variability} = \frac{\left(\sum_{i=1}^{100} 2\sigma_i\right)}{100}.$$

In addition, spatio-temporal parameters (gait velocity, step length, and step width), kinematic data (range of motion of trunk and pelvis movements), and variability in gait velocity and step length were calculated to show the association with daily activity and enable a comparison with the previous literature.

Fig. 1



Kinematic data of trunk obliquity of one patient while walking with variability indicated by the SD. The averaged width SD band constitutes the variability in gait pattern.

Fig. 2

Three-dimensional acceleration sensor was fixed centrally on the front side of the prosthetic stem.

Furthermore, the association between duration since amputation as well as wearing the C-leg system and the extent of daily activity were analyzed. Therefore, a possible influence of these parameters could be excluded.

After discharge from the hospital, patients were asked to wear an acceleration sensor (Activ 8; VitaMove, Valkenswaard, the Netherlands) continuously for 3 weeks to collect data of daily activity at home. The device had a size of 30×32×10 mm and an internal sample frequency of 12.5 Hz, with an operating time of over 30 days. The sensor was fixed centrally on the front side of the prosthesis stem (Fig. 2) to measure time of activity (walking and cycling) and time of inactivity (standing, sitting, and lying). Patients had to wear the sensor for the whole day. Before going to bed, the prosthesis with the sensor was removed. In the removed position, the sensor recorded 'lying'. A diary for noting everyday activity facilitated a more detailed and personal analysis of the measured data. Therefore, patients listed unusual events during the testing phase such as illness or if they did not wear the sensor for a few hours or days. In the data postprocessing, only the duration of wearing the sensor without unusual events was used for further examination. Out of this data set, seven consecutive days were selected randomly and averaged to form the mean period of activity for one day. Therefore, one complete week with five working days and two weekend days were analyzed for every patient.

The association between the mean activity of daily living and gait variability parameters was evaluated by correlation and linear regression (Pearson's) analyses using SPSS (version 19; IBM Corp., Armonk, New York, USA). In addition, the SEM and minimal detectable change ($\mathrm{MDC} = \mathrm{SEM} \times 1.96 \times \sqrt{2}$) for activity and gait variability were analyzed.

Results

The overall activity of the patients ranged from 35 to 199 min/day, with an average activity of 95 ± 41 min (SEM = 10.7; MDC = 29). Individual patients showed variability from 0.8° to 2.0° in their frontal pelvis motion and from 0.9° to 4.0° in trunk obliquity. The variability in frontal pelvis motion (1.4° ± 0.4°; SEM = 0.09; MDC = 0.25) was smaller than the variability in trunk obliquity (1.9° ± 0.9°; SEM = 0.2; MDC = 0.55).

The correlation analyses showed that patients with more daily activity walked faster (r = 0.6, P = 0.02) and had less variability in pelvic obliquity (r = –0.63, P = 0.01) as well as less variability in trunk obliquity (r = –0.58, P = 0.02). However, there was no association between gait velocity and variability in pelvic obliquity (r = 0.38, P = 0.18) or variability in trunk obliquity (r = 0.39, P = 0.15). There were also no associations between the range of motion in pelvis obliquity and the variability in pelvis motion (r = 0.26, P = 0.35) as well as no associations between the range of motion in trunk obliquity and the variability in

Table 2 Gait parameters and their association with daily activity

Parameters	Mean	SD	r with activity	P value
Gait velocity (m/s)	1.2	0.19	0.60	0.02*
Step length (m)	0.7	0.1	0.21	0.46
Step width (m)	0.2	0.06	0.43	0.11
ROM pelvis obliquity (deg.)	6.6	2.2	0.06	0.82
ROM trunk obliquity (deg.)	7.9	3	–0.39	0.15
Variability gait velocity (deg.)	0.06	0.03	–0.32	0.24
Variability step length (deg.)	0.03	0.01	0.12	0.67
Variability pelvis obliquity (deg.)	1.4	0.4	–0.63	0.01*
Variability trunk obliquity (deg.)	1.9	0.9	–0.58	0.02*

ROM, range of motion.
$P>0.5$, not significant.
*$P\leq 0.05$

trunk ($r=0.31$, $P=0.26$). In addition, no association was found between daily activity and any other measured gait parameters (Table 2) including the ranges of motion of pelvis motion and trunk obliquity.

There is neither an association between the duration since amputation and the extent of daily activity ($r=-0.08$; $P=0.77$) nor between duration since wearing a C-leg system and the extent of daily activity ($r=-0.28$; $P=0.31$) in patients with transfemoral amputation. In addition, no association between time since amputation and gait variability ($r=0.26$; $P=0.35$ variability in pelvis obliquity; $r=0.41$; $P=0.13$ variability in trunk obliquity) as well as between time since fitting the C-leg system and gait variability could be found ($r=-0.05$; $P=0.87$ variability in pelvis obliquity; $r=-0.15$; $P=0.60$ variability in trunk obliquity).

Discussion

The findings of this study show that variability in gait correlates strongly with activities of daily living in patients with transfemoral amputation. Statistically relevant changes at 95% confidence (minimal detectable change) were calculated to be 30 min in activity, 0.25° in pelvis variability, and 0.55° in trunk variability. The literature recommends about 30 min of moderate-intensity physical activity per day for a healthy life style and therefore supports our results that 30 min could be an important change in the extent of activity (Pate *et al.*, 1995; US Department of Health and Human Services, 1996; Tudor-Locke and Bassett, 2004).

These results are in agreement with the literature analyzing gait variability and physical activity in the elderly (Montero-Odasso *et al.*, 2005; Ciprandi *et al.*, 2017). However, it remains questionable whether patients are less active because of their gait variability and resulting instability or whether gait variability resulted from insufficient activity. Reduced activity in daily living could lead to muscle imbalances and even atrophy, which in turn could lead to an impaired quality in gait pattern. However, a reduced gait quality could cause less activity in daily living. Especially, the amputation of lower limbs leads to a loss of proprioception and therefore to an increased instability during walking and standing (Dornan *et al.*, 1978; Latanioti *et al.*, 2013). We assume that the loss of proprioception prevents a reproducible and steady gait pattern for amputees. Therefore, unexpected movements and variability in gait pattern increase. Patients with a high activity level have trainings as well as familiarization effects of walking with a prosthesis and are able to improve their gait pattern and gait quality. Therefore, further studies examining gait variability before and after training are necessary.

In addition, our results showed that there is a higher variability in trunk motion compared with pelvis obliquity. Mostly upper body movements are used to compensate instability during walking (Goujon-Pillet *et al.*, 2008; Rueda *et al.*, 2013). Previous literature already showed that gait variability is often associated with instability and the risk of falling (Buchner *et al.*, 1997; Stevens *et al.*, 1997; Verghese *et al.*, 2009; Toebes *et al.*, 2012; Weiss *et al.*, 2013; Sawa *et al.*, 2014).

Most studies only focused on the variability in spatio-temporal or kinetic parameters and not on kinematic data (Sagawa *et al.*, 2011; Svoboda *et al.*, 2012; Parker *et al.*, 2013; Lin *et al.*, 2014). However, examinations studying the variability in spatio-temporal parameters show different results. Some studies clearly show associations between the variability in spatio-temporal parameters and activity, whereas other studies do not (Brach *et al.*, 2007; Lin *et al.*, 2014; Ciprandi *et al.*, 2017). Our data could not show any association between range of motion in pelvis and trunk movements as well as between spatio-temporal parameters or their variability and daily activity in transfemoral amputees. Therefore, measurement of variability in kinematic data seems to provide better results for the group of patients with transfemoral amputation.

Our results also show an association between daily activity and gait velocity as has been reported previously (Montero-Odasso *et al.*, 2005; DePew *et al.*, 2013; Ciprandi *et al.*, 2017). However, variability in gait kinematic itself was not associated with gait velocity; therefore, variability in kinematic data seems to be an important parameter for assessing gait quality and daily activity in patients with transfemoral amputation.

The results clearly show that the range of motion, neither in pelvis nor in trunk movements, is associated with variability in these parameters. Therefore, kinematic variability is not influenced by affected gait or posture of the patients. Variability during walking indicates an unsteady gait pattern, whereby the normally expected reproducibility of the individual gait sequences is impaired. This gait disorder could not be identified by measuring range of motion of kinematic data.

Of course, there are also limitations in our examination. Although the assessment of daily activity with three-dimensional acceleration sensors is considered to be a very objective, precise, and reliable method (Sequeir *et al.*, 1995; Bassett *et al.*, 2000; Pitta *et al.*, 2006; Prince *et al.*, 2008; van Poppel *et al.*, 2010), it relies on the patient's compliance and frequency of wearing the sensor (Götte *et al.*, 2017; Sliepen *et al.*, 2017). Therefore, use of body-worn sensors could often lead to uncertain data of activity (Bassett *et al.*, 2000; Götte *et al.*, 2017; Sliepen *et al.*, 2017). A very detailed and time-consuming measuring procedure as well as additional tests in our study should eliminate all disruptive factors and ensure accurate data. The sensor was fixed on the prosthetic stem, therefore it did not affect patients comfort and could be easily forgotten. In contrast to previous studies, we optimized the results by recording data over a long measuring period of three weeks (Bussmann *et al.*, 2004; Stepien *et al.*, 2007; Weiss *et al.*, 2013; Lin *et al.*, 2014). In addition, an individual activity diary of all patients facilitates elimination of incorrect data of the sensor.

Despite this limitation, we believe that this study provides novel and relevant insights that form the basis for further research, especially as our study is the first to analyze the association between kinematic variability during gait and daily activity in patients with transfemoral amputation, whereas other studies in amputees focused on the variability in spatio-temporal or kinetic parameters only (Sagawa *et al.*, 2011; Svoboda *et al.*, 2012; Parker *et al.*, 2013; Lin *et al.*, 2014). In addition, our study is one of the very few examinations presenting a very homogeneous group in terms of patients' clinical picture.

Conclusion

Our study presents informative data that showed a positive relation between gait quality and daily activity. These results could lead to an improved understanding of individual activity levels in transfemoral amputees. This information could improve therapeutic as well as prosthetic approaches and constitute a basis for further research. Further studies should clarify the reason for gait variability in transfemoral amputees.

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Conflicts of interest

There are no conflicts of interest.

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6.3 Questionnaire daily activity / activity diary

Bewegungstagebuch

Hatten Sie innerhalb der letzten Wochen Schmerzen? ____________

Falls Ja, wie lange hatten Sie diese Schmerzen? ____________

Wo hatten Sie Schmerzen? ____________

Wie stark waren die Schmerzen?
Markieren Sie bitte auf der Linie, wo Sie ihre Schmerzen einordnen würden, in Ruhe und unter Belastung:

in Ruhe

kein Schmerz — maximal vorstellbarer Schmerz

unter Belastung

kein Schmerz — maximal vorstellbarer Schmerz

Gab es in den letzten Wochen ein Ereignis, bei dem Sie sich außergewöhnlich wenig bewegt haben (z.B. waren Sie im Urlaub)?

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____

Gab es in den letzten Wochen ein Ereignis bei dem Sie sich außergewöhnlich viel bewegt haben (z.B. habe Sie für etwas trainiert oder waren Sie auf Reha)?

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Hatten Sie Probleme mit dem Sensor und haben Ihn an manchen Tagen nicht tragen können (z.B. vergessen Ihn anzulegen oder aufgrund einer Tätigkeit nicht tragen können)? Bitte notieren Sie hierzu jeweils den Tag, die Dauer, wie lange der Sensor nicht getragen wurde, und warum:

Tag	Dauer	Tätigkeit

Falls Sie längere Strecken mit dem Auto, Zug oder Flugzeug zurücklegen, bitte notieren Sie Tag, Dauer und mit welchem Verkehrsmittel Sie sich fortbewegt haben:

Tag	Dauer	Verkehrsmittel

Hier können Sie weitere Besonderheiten aus ihrem Alltag notieren, welche einen Einfluss auf Ihre Aktivität in den letzten Wochen hatten:

Tag	Dauer	Besonderheit/Tätigkeit