Investigating the Gait of Lower Limb Amputees Regarding the Present Classification of Mobility Grades

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Abstract: The mobility grade determined for German patients with a lower limb amputation based on the profile survey, which is a subjective classification in one of the five mobility grades (0 to 4). It is recommendable to establish objective examinations to determine the mobility grade of lower limb amputees. Gait parameters captured with mobile sensors could be suitable for the distinction between amputees of the different groups (grade G2, G3 or G4). Within a study, standard gait parameters were determined with the InvestiGAIT system based on inertial sensors. A descriptive analysis of the data of the twenty-one subjects (G2: 4, G3: 6, G4: 11) indicates that there are gait parameter (especially gait velocity, step and stride length) which can be used to make the classification of the three mobility grades. The temporal gait parameters (stride duration, swing and stance phase, one-leg-stance and double-leg-support) as well as angles during heel strike and toe off can be additionally used for the classification. Nevertheless, further investigations have to done to get a larger database in order to confirm the presented results regarding generalization and to check, whether the found classification can be implemented as a kind of decision support system.

1 INTRODUCTION

The Medicare's Functional Classification Level (MFCL) system is used to distinguish persons with lower limb loss in five functional levels (K-Level-0 to K-Level-4) (Balk et al., 2018). This classification is based on the level of the amputee to walk with his prosthesis (Agrawal et al. 2013a, 2013b, Gailey et al. 2002, 2006, Theeven et al. 2013). The established MFCL system is a kind of an activity level categorization (Dudek et al., 2008), which is questioned by different researchers and research groups due to its subjectivity. In Germany, a similar system is used for the classification of lower limb amputees in order to specify which prosthesis components should be financed by the health insurances or other funding agencies (e.g. trade association). The system is called mobility grades and has the same categories as the U.S. MFCL system. This classification is based on the profile survey sheet of the German Medical Service of Leading Associations of Healthcare Insurance Providers, which is also a very subjective assessment (MDS, 2008).

Addressing the lack of objectiveness, Gailey et al. (2002) developed the Amputee Mobility Predictor (AMP), which is a clinical tool existing in two versions: AMPPRO (assessment with prosthesis) and AMPnoPRO (assessment without prosthesis). The AMP system is a 21-item measuring instrument considering different functional abilities such as sitting, standing, walking, balancing, etc. As described in the AMP instrument instructions, the average time for an experienced examiner is less than ten minutes. The low examination time is a big advantage of the AMP tool. The result depends on the experience of the examiner. It is a "point system" with a maximum score of 47 points, where the examiner assigns a number of points (0 to 1, 0 to 2 or 0 to 5) per item (Gailey et al., 2002). However, objective measures based on a stopwatch are included in the AMP tool.

Nevertheless, the classification should be based on an objective assessment. Agrawal et al. (2013a, 2013b) showed that there are different parameters (such as external work and symmetry of work) which are changing wearing different feet classified for the functional level (tested K1-, K2- and K3-foot and gait training with the different feet). That is why objective

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methods should be used to find the best setting of prosthesis components for each affected person.

A current research project deals with the development of a diagnosis system based on different sensors measuring and quantifying the abilities of the lower limb amputees:

(1) the power of the hip muscles (maximum power, endurance),
(2) the balance (static and dynamic), and
(3) the flexibility of the hip joint.

The developed diagnosis system addresses the lack of objectiveness of the German profile survey actually used for the classification. The aim of the project is the examination of different parameters (power, balance, flexibility) regarding their potential to be used for the determination of the mobility grade (G0 to G4). Besides static and dynamic balance tests conducted on a force plate, the gait of amputees is an additional indicator of the dynamic balance, which is also examined in the current research project. It could be conducted without the diagnosis system and used as an additional objective indicator.

The amputee gait is captured using the InvestiGAIT system (Orlowski et al., 2015, 2016, 2017). The results of the gait analysis are presented regarding the classification of the transfemoral amputees into one of the three mobility grades (G2 to G4), which was performed during their individual clinical or rehabilitation process after the amputation.

This paper attempts to answer the following question: Are there gait parameters, which are different for amputees of different mobility grades?

2 MATERIALS & METHODS

The InvestiGAIT system consisting of four inertial sensors (6-DOF) is used to capture the gait of the subjects on a 9 m or 13 m long straight walkway, respectively[1]. Two sensors are attached to the distal part of the lower leg, slightly above the ankle, and two are fixed to the upper body (in the middle of the posterior superior iliac spine and at cervical vertebra II) using elastic straps (Orlowski et al., 2017). The subjects were asked to walk the walkway at least 12 times with their self-selected gait velocity.

In-/Exclusion Criteria:
Subjects with a unilateral transfemoral amputation of the lower limb were included in the study. The age criteria was determined to 18 to 65 years, but due to difficulties to find enough subjects fulfill this criteria also subjects older than 65 years were approved to the study, when they feel healthy enough to perform the given tests of the study (examination of power, balance, mobility and gait).

Participants:
Overall, twenty-one subjects with unilateral transfemoral amputation of the lower limb took part in the examination. Table 1 shows the distribution of subjects in the mobility grades. Additionally, table 1 presents the number of subjects, their mean age, body height, stump length and time since amputation for each grade.

Informed written consent was obtained from all subjects prior to study participation. The study was approved by the local ethics committee of the Otto-von-Guericke university Magdeburg (no. of vote: 31/18) and carried out in line with the Declaration of Helsinki.

Data Analysis:
The gait parameters were calculated from the captured acceleration and angular velocity based on the detection of gait events (initial contact (IC), midswing point and terminal contact (TC)). The first two trials were omitted from further statistical analysis due to their training effect. The calculations were performed using the in-house software InvestiGAIT developed in MAT-LAB™ (TheMathworks Inc., Natick, MA, USA).

Table 1: Anthropometric data (age body height, stump length and time since amputation) of the subjects with transfemoral amputation. The number of subject per group (mobility grade) is given.

Mobility Grade	Number of subjects (male, female)	Age (yrs) mean±sd	Height (cm) mean±sd	Stump length (cm) mean±sd	Time since Amputation (yrs) mean±sd
G2	4 (4 m, 0 f)	69.8 (±13.1)	177.5 (±14.1)	26.0 (±10.2)	33.0 (±30.1)
G3	6 (4 m, 2 f)	63.5 (±11.6)	174.8 (±7.8)	30.8 (±4.5)	20.5 (±13.8)
G4	11 (11 m, 0 f)	49.3 (±12.3)	182.9 (±7.0)	37.4 (±12.5)	13.1 (±13.0)

[1] The investigations were conducted in both institutions (Brandenburg and Magdeburg).

Table 2: Gait parameters as mean value and standard deviation.

Parameters	Affected Leg			Sound Leg		
	G2	G3	G4	G2	G3	G4
Stride (s)	1.35 (± 0.20)	1.12 (± 0.09)	1.13 (± 0.09)	1.34 (± 0.20)	1.12 (± 0.09)	1.13 (± 0.08)
Swing (%)	40.60 (± 5.38)	43.97 (± 9.56)	47.53 (± 5.23)	38.63 (± 1.82)	43.12 (± 2.51)	42.08 (± 3.27)
Stance (%)	59.40 (± 5.38)	56.03 (± 9.56)	52.47 (± 5.23)	61.37 (± 1.82)	56.88 (± 2.51)	57.92 (± 3.27)
One-Leg-Stance (%)	38.50 (± 1.90)	43.09 (± 2.56)	42.04 (± 3.42)	40.64 (± 5.39)	43.93 (± 9.51)	47.52 (± 5.37)
Double-Leg-Support (%)	18.86 (± 6.86)	12.69 (± 9.04)	10.49 (± 5.36)	16.92 (± 7.65)	12.87 (± 9.16)	10.49 (± 5.28)
Put-on-angle (°)	15.61 (± 2.61)	17.85 (± 5.84)	23.33 (± 3.57)	18.64 (± 4.75)	17.81 (± 2.02)	19.05 (± 4.09)
Take-off-angle (°)	-38.40 (± 2.69)	-38.97 (± 6.05)	-42.38 (± 7.24)	-40.23 (± 6.87)	-40.84 (± 5.18)	-44.40 (± 7.92)
Gait velocity (m/s)	0.77 (± 0.15)	1.16 (± 0.14)	1.31 (± 0.17)	Same Values as affected Leg, these parameters are not determined separately for each leg		
Stride length (m)	1.01 (± 0.08)	1.29 (± 0.10)	1.47 (± 0.14)			
Step length (m)	0.60 (± 0.06)	0.71 (± 0.09)	0.77 (± 0.11)	0.62 (± 0.06)	0.73 (± 0.07)	0.85 (± 0.06)

Due to the small sample size a descriptive data analysis was conducted. The mean values and standard deviation of standard gait parameters were considered to give an overview of the difference between the groups (e.g. G2, G3, G4).

3 RESULTS

Table 2 contains the mean value and the standard deviation of the gait parameter displaying an overview of the characteristics of the found differences of the three considered groups (G2, G3 and G4). Furthermore, a comparison of both legs of each group and compared to the other groups is possible.

The parameters gait velocity, stride and step length show a clear increase from G2 over G3 to G4. This increase can be registered for the affected and the sound leg. While the gait velocity and the stride length are the same for both legs, a difference for the step length of the affected and the sound leg is clearly visible. On average the step length of G2 (0.60 and 0.62 m) and G3 (0.71 and 0.73 m) is shorter than the step length of G4 (0.77 and 0.85 m). Moreover, the difference between the affected and the sound legs is smaller in amputees of G2 and G3 (0.02 m) compared to amputees of G4 (0.08 m).

Regarding the take-off-angle, it can be noted that the mean values of the amputees G2 and G3 (affected: -38.40 and -38.97°; sound: -40.23 and -40.84°) are similar having a larger difference to the mean of the G4 (affected: -42.38°; sound: -44.40°). The parameters stride duration (s), stance phase (%), and double-leg-support (%) show a decrease with the higher mobility grades (G2 to G4), while the parameter swing phase (%) and one-leg-stance (%) have an increase for higher mobility grades with one exception of the G3 for the affected leg.

4 DISCUSSION

The results suggest that a distinction between amputees of the mobility grades G2, G3 and G4 is possible using the presented gait parameters. The gait parameters gait velocity, stride length and step length seem to be characteristic and suitable for describing the three considered mobility grades. All the other parameter are as well characteristic and can be additionally used for the classification of transfemoral amputees based on gait analysis.

Batten et al. (2019) examined the gait speed of amputees (transtibial 78, transfemoral 30, and knee disarticulation 2 with mean age 63 (±13), range 24-85 years) based on the 10-m walk test, whereby the patients walked 12 m indoors on even floor. The determined gait speed found by Batten et al. (2019) was slower for all groups (K2: 0.38 (0.25-0.54); K3: 0.63 (0.50-0.71); K4: 1.06 (0.95-1.18)) as well as for the whole group (median (IQR): 0.52 (0.37-0.67), with a range from 0 to 1.43 m/s).

Lemaire et al. (1993) published the average gait speed for elderly transtibial amputees (8 subjects, mean age of 68.75 (66 to 72) years) which is comparable (mean: 1.20 (0.95 - 1.46) m/s) to the gait speed determined in our examination. Unfortunately, no information about the mobility grade of the subjects is given. Lemaire et al. (1993) compared the determined gait speed with those of other investigations of amputees of little lower age groups (55-67 years, 43-77 years, 21-73 years, 39-57 years, 36 -76 years) detecting an average speed ranging from 0.75 to 1.22 m/s (1.22 m/s, 1.07 m/s, 1.07 m/s, 1.17 m/s, 0.75 m/s).

Lemaire et al. (1993) also investigated the average stride length of elderly amputees. A comparison with data from other studies is presented. Lemaire et al. (1993) determined an average stride length of 1.41 m of the subjects (mean age of 68.75 years) which is little higher than the stride length found in the other studies (range 1.10 to 1.40 m). Based on the distinction in the mobility grades in our investigation the determined stride length is comparable and comprehensible (G2: 1.01 m, G3: 1.29 m and G4: 1.47 m).

The main advantage of the gait analysis using the InvestiGAIT system is the simplicity of usage. Gait captures and analysis can be done within a few minutes, are feasible almost anywhere and no large spaces are needed. These facts support the usage in the daily clinical routine. In contrast to the InvestiGAIT system or other mobile gait analysis systems (GAITRite walkway, MVN Biomech from Xsens), 3D motion capture systems (Vicon) or specialized systems (GRAIL - Gait Real-time Analysis Interactive Lab (Oude Lansink et al., 2017) or CAREN - computer-assisted research environment (Darter and Wilken, 2011)) are not very interesting for doctors and clinicians working with patients in the clinical routine due to time aspects. These systems have a large overall complexity (required space, knowledge, time) and do not appear to be appropriate for the clinical routine.

Compared to 3D-systems the accuracy of inertial gait systems is sometimes lower, especially to spatial gait parameters, e.g. step and stride length. These parameters are affected by systematic errors. Due to those facts, these parameters have small deviations.

Limitations of the Study:

Most of the subjects (38 % and 47 %) investigated in this study were categorized with mobility grade 3 and 4. The mean age of these both groups are 59.1 (±10.9) and 46.1 (±12.2) years. Considering the facts, it should be noted that the more active and slightly younger persons affected from lower limb loss took part in the examination. While the group of subjects with mobility grade 4 consists of 20 % persons older than 62 years, 40 % older than 55 years and 40 % younger than 40 years, the age distribution in G3 is different. Within the group G3, there were 33.3 % of subjects older than 63 years and 91.7 % older than 50 years. This does not seem to be representative of the total amputee population.

Furthermore, the number of subjects (G2: 4, G3: 6, G4: 11) within each group has to be critically viewed. Consequently, the results should be regarded as tendency and a generalization is currently not possible.

There is another limitation in this study. The analysis strongly relied on the assessment of the grade of mobility done by the subject's orthopedic technician/physician. Wurdeman et al. (2014) stated some reasons why this is problematic: "[…] the ambiguity under which patients are classified (Gailey et al., 2002) and the undeniable fact that the activity level for individuals ambulating with a prosthesis is not possibly four distinct categories but rather represented as a continuum across a spectrum. The only clinical tool available currently to help with patient classification in the Amputee Mobility Predictor (Gailey et al., 2002), but even this tool is known to have large standard deviations making it difficult on the individual level to objectively categorize patients.". Gailey (2006) indicated that professionals are able to determine the needs of the patients based on their long-lasting experience, but there were examinations from Stephen and Aitken (1987) showing that significant differences in classifications of amputees (assessment of mobility and self-care) were found in clinicians of the same rehabilitation team. For that reason, the validity of the subjective classification has to be questioned. It is, therefore, particularly important to develop objective methods to classify the patients. Additionally, it is necessary to implement objective methods to find out which prosthesis components are the best for each individual.

5 CONCLUSION

The results of the study indicate that selected gait parameters have the potential to be used to distinguish amputees of different mobility grades. Considering the three groups (G2, G3 and G4), the gait parameters gait velocity, stride and step length show clear differences for all three comparisons (G2 vs G3, G2 vs G4, G3 vs G4). These parameters are characteristic for the gait of amputees of different mobility grades investigated in the presented study. All the other presented gait parameters seem to be additionally useful for an objective classification of transfemoral amputees.

The potential of the gait parameters contributing to objective assessment has to be confirmed with further investigations. Based on a larger sample size a statistical analysis have to be performed in order to make generalized statements and to develop an algorithm to establish a decision support system for the classification of patients with a transfemoral amputation in one of the three considered mobility grades.

Furthermore, it could be recommendable for further studies to use the AMP tool additionally to the determined mobility grade based on the profile survey in order to have supplementary information.

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