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Analysis of clinically important factors on the performance of advanced hydraulic, microprocessor-controlled exo-prosthetic knee joints based on 899 trial fittings

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Abstract

The objective of this work is to evaluate whether clinically important factors may predict an individual's capability to utilize the functional benefits provided by an advanced hydraulic, microprocessor-controlled exo-prosthetic knee component.

This retrospective cross-sectional cohort analysis investigated the data of above knee amputees captured during routine trial fittings. Prosthetists rated the performance indicators showing the functional benefits of the advanced maneuvering capabilities of the device. Subjects were asked to rate their perception. Simple and multiple linear and logistic regression was applied.

Data from 899 subjects with demographics typical for the population were evaluated. Ability to vary gait speed, perform toileting, and ascend stairs were identified as the most sensitive performance predictors. Prior C-Leg users showed benefits during advanced maneuvering. Variables showed plausible and meaningful effects, however, could not claim predictive power. Mobility grade showed the largest effect but also failed to be predictive.

Clinical parameters such as etiology, age, mobility grade, and others analyzed here do not suffice to predict individual potential. Daily walking distance may pose a threshold value and be part of a predictive instrument. Decisions based solely on single parameters such as mobility grade rating or walking distance seem to be questionable.

Abbreviations: alt = alternating, bilat. amput. = bilateral amputation, BMI = body mass index, cardio-vasc. dis. = cardiovascular disease, c-l = contralateral, dist. = distance, dist. circ. = distortion circulation, G = Genium, Otto Bock HealthcareProducts Austria, IC = Ischial Containment, KD = knee disarticulation, MAS = Marlo Anatomical Socket, MFCL = Medicare Functional Classification Level, MG = mobility grade, MOBIS = mobility grade classification, MPK = microprocessor controlled exo-prosthetic knee component, OPG = optimized physiological gait, prosth. = prosthesis, res. = residual, SACH = Solid Ankle Cushion Heel, TEP = total endoprosthetic replacement, TF = transfemoral, v.d. = vascular disease, var. = variable, vis. = visual, w. P. = with prosthesis, wear. = wearing.

Keywords: above knee amputees, microprocessor-controlled knees, mobility grade, prediction

1. Introduction

Microprocessor-controlled exo-prosthetic knee components (MPK) for the treatment of above knee amputees have evolved significantly since their first availability in the mid-1990s. Today, there is a range of such systems that show a large variance of technical capabilities and clinical performance.[1]

Advanced hydraulic MPKs such as Genium (G) and C-Leg (both Otto Bock Healthcare Products Austria) are among those being investigated most intensively.[2–4] Their use is associated with a variety of biomechanical and clinical benefits. To investigate the potential of an individual to utilize the functional benefits of advanced prosthetic components, trial fittings are routinely performed. In Germany, a significant number of trial fittings have occurred to investigate individual potential using an MPK.[5]

An international consensus on the appropriate indication for MPKs has still not been reached. In Germany, the individual assessment is a key element and the use of such systems has almost become a standard. Others countries have related their allocation decision to parameters like the Medicare functional classification levels (MFCL or K level) or functional scales that include walking capacity.[6,7] Access is often restricted to individuals with higher functional capability. This is in contrast to the findings of Kannenberg et al[8] and Wetz et al[9] who accentuated the overproportional benefits to individuals with more severe conditions and lower mobility grade ratings.

Although mobility scales have been helpful for classification, the extent of their predictive quality to guide decisions regarding access and denial of prosthetic components remains questionable. Recently Hahn and Lang[5] have shown that age, mobility grade

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rating, and etiology (specifically vascular disease) did not have predictive power with regard to an individual's potential to utilize the functional benefits of an MPK. About 40% of the trial population was graded Mobis Grade[10] MG 2. Between 80% and 93% showed a positive response to the trial device. The mobility grade changed from MG 2 to MG 3 in 50% of the subjects and this matched results shown earlier by Kahle et al[11] and Hafner and Smith.[12] Wong et al[13] developed a balance-based instrument to assess the mobility prognosis for community dwelling adults with lower limb amputation. They stated that individual characteristics such as age, amputation etiology (specifically vascular disease), or amputation level are not significant predictors.

Trial fitting data allow access to a population that is significantly larger than that which is available in controlled trials. The trial fitting assessment resembles clinical practice with a wide variety of subjects and prosthetic clinics represented. By the nature of trial fittings, a preselection is performed by the prosthetist to increase the likelihood of response.

It is the objective of this analysis to quantify and characterize the influence of a larger set of clinically important factors (variables) on the performance assessments used during trial fittings. The potential for using such variables as predictors will be assessed and a useful set of performance indicators will be identified.

2. Methods

Data from routine trial fittings were retrieved from the manufacturer's German customer support service in order to conduct a retrospective cross-sectional cohort analysis. Data were made available from 272 prosthetic workshops between 2011 and 2015. The original evaluations were accompanied by video documentation of the assessment sessions. The analysis of this video material is not part of the work presented here.

To employ data recorded during routine use of approved medical devices within its intended scope is regulated under German Medical Device Law and exempted from review by an external ethics committee. All subjects consented to the use of their data for scientific evaluation in writing. All applicable legislation and data protection regulations were followed.

Subjects qualifying for a trial fitting were first assessed on their existing prosthesis and then on the trial prosthesis. On average, this second assessment occurred after 1 week of use with the trial prosthesis. A careful introduction of the features and functions of the trial prosthesis was given after the initial fitting.

The indications for G and hence for this population are described in the Instructions for use[14] as: for patients with knee disarticulation, transfemoral amputation, and hip disarticulation (patients with hip disarticulation or hemipelvectomy must be fitted with the 7E10=* Helix3D hip joint); for unilateral or bilateral amputation; dysmelia patients with residual limb characteristics corresponding to knee disarticulation, transfemoral amputation, or hip disarticulation. The patient must fulfill the physical and mental requirements for perceiving visual/acoustic signals and/or mechanical vibrations.

Contraindications cite unusual activities such as extreme sports. Examples given are free climbing, parachuting, paragliding, and so on.

The manufacturer recommendations for trial fittings are described in the document "Requirements for trial fittings."[15] Data are collected in specifically designed questionnaires: user questionnaire for activities of daily living,[16] user questionnaire for trial fittings,[17] and prosthetist questionnaire for trial fittings.[18] All documents are available to the public.

The structure of the questionnaires resembles information that is required by the German social system. The aim of the trial fitting is to judge to which extent the user is capable of utilizing the functional benefits that are offered by the prosthetic system. It follows the indication suggestions given by the Clinical Assessment Center for Orthopedic Aids (University Münster) as set forth by Drerup et al.[19] The work of Kannenberg and Mileusnic et al[20] identified specific functional benefits for G and this provides further structure to the questionnaire.

Wetz et al[9] and Drerup et al[19] identified the following functional benefits that may be provided to users of advanced hydraulic MPKs: safety, harmonization of gait pattern, relief of the contralateral limb, possibility to divide attention, capability to vary gait speed, reduction of overall effort, reduction in number of aids, and change of mobility grade. These items are captured in the prosthetist questionnaire on a 5-point Likert scale. The validity of prosthetist's clinical assessment was discussed by Kuhr[21] and judged to be appropriate for clinical practice.

Subject's perception was assessed on a 5-point Likert scale. Items investigated here were the comparison of perceived safety while descending, ascending, or standing on stairs and slopes, the variation of gait speed and walking with small steps. More difficult situations such as walking backwards, stepping over obstacles, carrying heavy loads and carrying loads with visual obstruction of the ground were evaluated. Finally, situations such as walking in a busy crowd, walking through a heavy door, pushing a trolley and toileting were graded as well.

The Likert scales rated whether tasks were performed or perceived either clearly better (functional benefits) or more safe (subjects perception) with G, better/more safe with G, no difference with G, worse/less safe with G or clearly worse /less safe with G. A subject was classified a responder if tasks were performed or perceived clearly better/more safe with G or better/more safe with G.

The prosthetist assessment included grading of advanced maneuvers such as reciprocally ascending and descending stairs and ramps, walking backwards, and walking with small steps. Stepping over obstacles with the prosthetic and the contralateral side was evaluated. Complex movements graded include the so-called door-test, carrying weights with or without visual obstruction of the ground, and carrying heavy loads. The indicators for advanced maneuvers were rated according to whether or not the movements could be carried out at all. If they could be, then it was evaluated if the movement could be carried out alternatingly (stairs up/down, ramps up/down); harmonically; with relief of the contralateral side being observed or perceived; with less concentration being required; and with the task being performed more safely. We shall refer to the individual categories of functional benefits, perception and advanced maneuvers as performance indicators.

Stairs were defined to have at least 4, an incline between 25° and 45°, a step height of 17 cm and at least 1 handrail. For stair ambulation, specific attention was given to whether the subject was capable of initiating the stairs function; whether the foot was positioned properly; whether the subject was capable of carrying out an entire stair step; and whether movements were carried out alternatingly. Slopes were defined to have at least a 10° incline and a length of 5 m. Obstacles were defined to be foam bricks 38 cm wide, 10 cm deep, and either 13 cm or 18 cm tall. Subjects were asked to stand on both legs in front of the obstacle with weight equally distributed. Both the contralateral and in a second trial the prosthetic side were tested. It is recommended that the test be carried out with at least 1 handrail in the immediate vicinity of the subject. Standing tests were performed 5 minutes on level ground and 2 minutes on slopes. Change of gait speed was assessed by having the subject start with their self-selected walking speed and then change to preferred slower and faster walking speeds.

Small steps were tested in a figure of 8 marked by 2 obstacles set at a distance of 2 m apart. Specific attention was drawn to whether the subject was capable of initiating swing phase.

To assess walking backwards the subject started from a standing position walking backwards with the prosthetic side first until 10 steps were completed. A specific deviation was the so-called door-test. The subject started walking forward until a sign was given by the investigator in mid-swing. Then the subject immediately moved the prosthetic side backwards and performed 10 backwards steps.

Weights were simulated with a 5 kg bag. Visual obstruction of the floor was performed by carrying a standard tray. The test was performed on a level walkway that was at least 5 long and the subject was asked to change direction during the test.

Variables investigated as to whether they had an impact on performance were: age(years), years of wearing a prosthesis, body mass index (BMI), gender, daily walking distance (m), mobility grade, socket type (ischial containment, ischial support, Marlo Anatomical Socket (MAS), hybrid), etiology vascular disease, amputation level transfemoral–knee disarticulation, bilateral amputation, no comorbidities, diabetes mellitus, neuropathy in the leg, visual impairment, cardio-vascular disease, distorted blood circulation in the leg, artificial hip joint, discomfort with hip, back pain, paresis of lower extremity, paresis of upper extremity, amputation or malformation of the upper extremity, multiple impairment, complicated posttraumatic state, instability of contralateral joints (including pain and total endoprosthetic replacement TEP), further disease or impairment limiting fitting success, hip flexion contracture (–7 to +7°), scarred residual limb, vacuum socket, previous fitting with a C-Leg, prosthetic foot of standard prosthesis (high/moderate dynamic), prosthetic foot test prosthesis (high/moderate dynamic), carrying out a profession, managing a household independently, falls with prosthesis (yes/no), number of annual falls, status of residual limb (atrophied, normal, muscular), residual limb length (short, medium, long), residual limb loading, socket adhesion.

The variables stance function, sitting function, stairs and obstacle function and OPG (optimized physiological gait) characterize specific features of G and were highly correlated. The results are exemplarily presented by OPG.

Linear regression models were used to evaluate the Likert scale assessments of subject perception and the influence of functional benefits. The assessment of advanced maneuvers was rated by the prosthetists. Rating categories included: whether the task was performed at all; if it was performed, then was it was performed alternatingly where applicable; whether it was performed safely or clearly not in a safe manner; and whether further training may have been required. Those who could perform the task safely were classified as responders. As to the dichotomized nature of this performance indicator, logistic regression was performed. Here the most sensitive variables in this analysis are reported. For illustration purposes a compound measure called "functional benefit" (normalized mean) is displayed as a continuous scale. For statistical justification of this approach we refer to Carfio et al.[22]

Multivariate regression analysis with stepwise variable selection was performed. Descriptive analysis was performed using R (Version 3.2.3, R Foundation for Statistical Computing), Microsoft Winstat (Version 2012.1, R. Fitch Software) or Excel (Version 14.0, Microsoft). Missing entries were classified "n/a." Citation of percentages refers to the group of correctly assigned data. Regression models were performed in R. Each regression model was limited to datasets being complete in all selected variables.

3. Results

Data from 917 G trial fittings were made available. After removal of duplicates, 899 data sets qualified for analysis. Demographic data are shown in Table 1. Totally 78% of the subjects had at least 1 comorbidity including back pain (474), hip pain (239), heart condition (236), visual impairment (80), artificial hip joint (50), and neuropathy (47). A profession was pursued by 572 (37 missing) of the subjects. Daily walking distance was 3077 ± 2094 m. At least 1 fall per year was reported by 57.3% of the subjects. The median number of annual falls was reported to be 1 (range: 730).

Residual limb conditions were described as atrophied (2.7%), normal (61.6%) or muscular (35.7%). Residual limb length was described as short (20.1%), medium (41.2%), or long (38.7%). In total, 63 subjects were described as having a scarred residual limb. Loading capabilities of the residual limb were described as very good (315), good (449), or average (47). Prosthetic sockets were described as 103 MAS, 236 hybrid, 198 ischial containment, 85 ischium supported, and 227 with no specification. Liners were noted with 304 subjects, whereas 270 subjects were fitted with suction sockets. Adhesion was rated very good in 311 subjects, good in 448, and average in 58 subjects.

Prior prosthetic knee fitting was the C-Leg in 689 subjects. Other prosthetic knee joints included 4 axis polycentric (15), other polycentric (19), brake knees (9), mechanical hydraulic knees (38), locked knees (3), and pneumatic (22). The foot used with the G trial prosthesis had high dynamic response in 707 and moderate dynamic response in 129 cases. Basic feet (e.g. SACH foot) were used by 13 subjects and multiaxial feet by 18.

3.1. Responsiveness

The responsiveness for functional benefits as rated by the prosthetist is shown in Fig. 1. Total responsiveness ranges from 95 to 97%. The highest subcategory rating is 60.57% (variable

Table 1

Demographic characterization of investigated population.

Age	49.0 ± 12.9 y
Gender	83% male
BMI	26.6 ± 4.6
First prosthesis since	21.2 ± 15.6 y
Mobility grade	MG2: 12.5%, MG3: 64.1%, MG4: 22.8%
Etiology	68.9% trauma, 15.4% tumor, 6.0% vascular disease 9.7% other
Amputation level	TF 80.1% KD 18.9%

BMI = body mass index, KD = knee disarticulation, MG = mobility grade, TF = transfemoral.

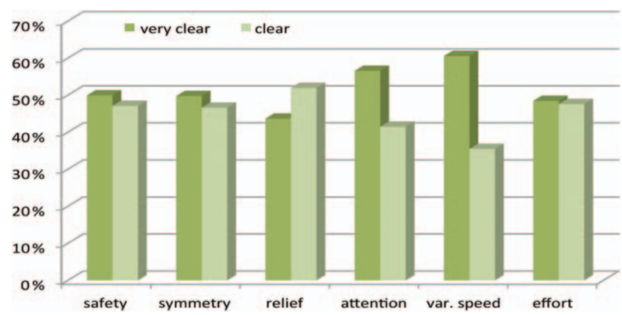

Figure 1. Responsiveness assessed by prosthetist. Difference in functional benefit compared to standard prosthesis. var. = variable.

gait speed). This is substantially below the threshold for ceiling effects. Responsiveness related to subject perception in the category "perceived more safely than standard prosthesis" is shown in Fig. 2. Total responsiveness ranges from 67% to 96% and the highest subcategory rating is 76% for standing on a slope.

The prosthetist rating for the performance of advanced maneuvers as technically safe: stairs down 70.52%, stairs up alternatingly 32.81%, obstacles 75.32%, ramp down 70.86%, ramp up 74.53%, small steps 74.94%, walking backwards 91.28%, door test 88.35%, carrying objects while visually obstructed 87.74%, carrying loads 72.73%. The rate of subjects being able to ascend stairs alternatingly is 64.29%.

Linear regression was performed to evaluate the impact of variables on the performance indicators. The effect estimate e (gradient) was derived, as well as the respective P value and r^2. Note that e (resembling the change on the respective Likert scale) must be related to the unit of the scale according to which the variable is categorized. For example, when looking at age, the unit is years, and when looking at residual limb condition, the categorized scale is atrophied, neutral, or muscular.

With a sensitivity level set to $P<0.05$ the most responsive performance indicators (in descending order by number of hits $P<0.05$) are: variable gait speed (22), divided attention (18), safety (14), and change of mobility grade (14). Most responsive subject perception performance indicators are: toileting (18), dual tasking (14), alternating stair ambulation (up, down) (13, 12), standing on ramps (11), variable gait speed (11), stepping on small obstacles (10), and carrying objects with visual obstruction (9). R squared values are in the range of a few per cent. Performance indicators with less impact on the investigated variables were omitted from further evaluation for the purpose of data.

Logistic modeling allows estimation of the impact of a variable on a dichotomized performance indicator. Logistic regression identified the following advanced maneuvers to be most responsive: descending and ascending stairs (25, 29), stance phase resistance adjustment (21), ramps (20), walking backwards (16), small steps (15), obstacles (15), heavy loads (14), and the door-test (13). Performance indicators with less sensitivity were omitted from further evaluation for the purpose of data reduction.

Variables with less than a total of 10 statistically significant effects on the performance indicators were omitted in the further evaluation for reasons of data reduction. Those variables were: BMI, socket MAS, socket ischial support, neuropathy, visual impairment, artificial hip, back pain, paresis lower extremity, paresis upper extremity, further amputation, malformation, contralateral joint instability/TEP/pain, osteoarthritis of the lower limb joints, hip contracture, scarred residual limb, prosthetic foot of standard prosthesis and annual falls (yes/no). The variable "managing a household independently" did yield 11 significances, but was also omitted. The effects were similar to "profession."

In Table 2 a summary of results of this analysis is shown. The most responsive performance indicators outlined above are displayed as performance categories (functional benefits, perception, advanced maneuvers). The e and P ranges in the respective performance indicators are shown. Exemplary results for the

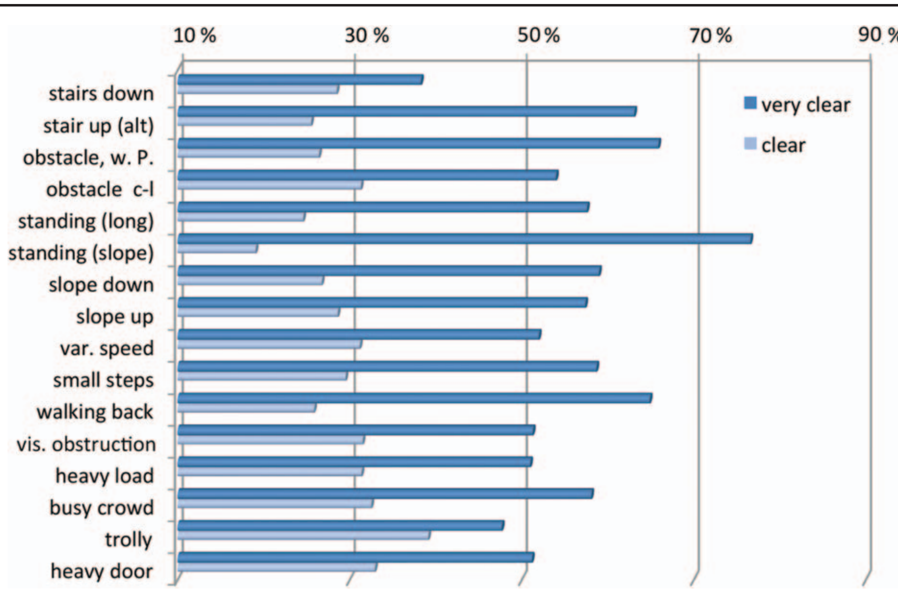

Figure 2. Responsiveness as rated by subjects. Compared perception for safety of task when compared to standard prosthesis. alt = alternating, c-l = contralateral, var. = variable, vis. = visual, w. P. = with prosthesis.

Table 2

Results of regression analysis for performance categories. Estimate and *P* range is displayed each investigated variable. No entries indicate that no significance was reached in the respective category.

	Functional benefits				Perception				Advanced maneuvers			
Variable	**e min**	**e max**	***P* min**	***P* max**	**e min**	**e max**	***P* min**	***P* max**	**e min**	**e max**	***P* min**	***P* max**
Age	−4.59E−03	−1.36E−02	2.09E−18	5.86E−03	−1.04E−02	−5.90E−03	1.18E−05	5.50E−04	−6.34E−02	−1.70E−02	1.53E−12	5.02E−03
Years wear. prosth.	−5.10E−03	−4.29E−03	1.11E−04	1.45E−03	−6.21E−03	−3.77E−03	5.63E−04	1.67E−02	−2.47E−02	−1.50E−02	1.40E−07	2.29E−02
Distance walked/d	2.38E−05	3.88E−05	2.38E−04	2.47E−02	3.08E−05	5.84E−05	1.35E−04	2.86E−02	9.71E−05	2.51E−04	1.86E−08	4.99E−02
IC socket	−2.48E−01	−1.65E−01	1.39E−07	3.68E−03	−1.67E−01	−1.67E−01	3.57E−02	3.57E−02	−4.80E−01	1.28E+00	2.92E−09	1.88E−02
Gender					−2.26E−01	−1.80E−01	1.75E−03	2.35E−02	4.38E−01	8.72E−01	8.95E−05	4.33E−02
Etiology v.d.		−3.30E−01		2.80E−04	2.81E−01	3.38E−01	1.55E−02	2.08E−02	−1.39E+00	−7.14E−01	5.41E−05	2.07E−02
Amputation level	1.10E−01	2.05E−01	1.23E−04	4.51E−02	1.83E−01	1.83E−01	2.86E−02	2.86E−02	−5.38E−01	9.55E−01	1.74E−04	4.99E−02
bilat. amput.	−4.01E−01	−2.66E−01	1.03E−03	3.16E−02					−1.27E+00	−1.04E+00	3.51E−03	3.13E−02
No comorbidity		1.25E−01		1.13E−02	−2.54E−01	−1.15E−01	1.66E−04	4.61E−02	3.78E−01	5.77E−01	1.27E−03	4.48E−02
Diabetes mellitus	−4.59E−01	−1.85E−01	1.41E−07	4.56E−02					−1.13E+00	−6.62E−01	3.12E−04	3.55E−02
cardio-vas. dis.	−1.37E−01	−9.08E−02	3.12E−03	4.16E−02	1.40E−01	1.92E−01	4.58E−03	3.58E−02	−7.25E−01	−3.09E−01	9.48E−05	4.49E−02
dist. circ. leg	−3.18E−01	−2.36E−01	1.89E−04	4.74E−03	2.20E−01	2.20E−01	4.64E−02	4.64E−02	−1.21E+00	−7.36E−01	1.38E−05	2.79E−02
hip problem					1.40E−01	2.41E−01	5.70E−04	2.49E−02	−5.30E−01	−3.33E−01	1.91E−03	3.36E−02
Further disability	−1.29E−01	1.36E−01	2.53E−02	2.54E−02	1.68E−01	2.81E−01	2.98E−04	2.35E−02	−5.32E−01	4.19E−01	3.01E−02	4.45E−02
Suction socket	−1.24E−01	9.43E−02	4.75E−03	3.07E−02	−1.82E−01	−1.64E−01	7.34E−03	9.93E−03	−4.00E−01	6.61E−01	1.25E−05	2.50E−02
Liner	1.09E−01	1.71E−01	5.83E−05	1.05E−02	1.69E−01	1.69E−01	3.55E−03	3.55E−03	−4.03E−01	5.13E−01	2.15E−02	3.09E−02
C-Leg	−1.11E−01	1.79E−01	2.42E−04	2.49E−02	−3.05E−01	1.64E−01	6.33E−05	2.09E−02	4.39E−01	1.71E+00	7.90E−20	7.02E−03
Foot G (dynamic)	1.52E−01	1.67E−01	8.63E−03	5.31E−03	1.30E−01	2.27E−01	3.06E−03	4.02E−02	4.46E−01	4.46E−01	2.41E−02	2.41E−02
G OPG functions		1.34E−01		7.56E−03					5.60E−01	2.00E+00	1.54E−20	3.05E−02
Profession	9.25E−02	2.51E−01	6.81E−09	3.37E−02	−1.84E−01	1.77E−01	1.92E−03	1.11E−02	3.45E−01	1.02E+00	2.54E−06	3.71E−02
res. limb condition	1.17E−01	2.60E−01	1.63E−06	2.78E−02	1.90E−01	2.52E−01	3.60E−03	1.71E−02	4.66E−01	1.35E+00	3.22E−05	4.98E−02
res. limb length	−7.59E−02	1.24E−01	1.23E−04	4.02E−02		1.53E−01		5.23E−03	3.49E−01	6.89E−01	2.76E−08	7.93E−03
res. limb loading	−9.85E−02	2.02E−01	1.31E−09	2.34E−02		1.45E−01		9.17E−03	3.58E−01	1.11E+00	1.52E−10	4.86E−02
Adhesion	−5.86E−02	1.43E−01	8.67E−05	3.16E−02					3.22E−01	7.90E−01	9.58E−11	2.66E−02
# falls per year	3.43E−02	5.63E−02	1.03E−03	4.26E−02	4.95E−02	1.08E−01	1.56E−05	3.54E−02		1.37E−01		1.77E−02
Mobility grade	−3.47E−01	3.67E−01	7.44E−38	1.44E−02	−1.50E−01	1.67E−01	2.31E−03	2.83E−02	3.27E−01	2.29E+00	6.42E−24	3.52E−02

bilat. amput. = bilateral amputation. cardio-vasc. dis. = cardiovascular disease, dist. circ. = distortion circulation, dist. = distance, G = Genium, IC = Ischial Containment, OPG = Optimized physiological gait, prosth. = prosthesis, res. = residual, v.d. = vascular disease, wear. = wearing.

Table 3

Results of regression analysis for most sensitive performance indicators. N indicates sample size analyzed with respect to the clinical variable.

	Variable gait speed			Toileting			Walking upstairs alternatingly		
Variable	**Estimate**	***P***	**N**	**Estimate**	***P***	**N**	**Estimate**	***P***	**N**
Age	−1.36E−02	2.09E−18	792	1.23E−03	5.70E−01	792	−4.24E−02	1.53E−12	880
Years wear. prosth.	−1.70E−03	2.06E−01	760	−6.21E−03	5.63E−04	768	−2.47E−02	1.40E−07	845
dist. walked / day	3.88E−05	2.38E−04	671	4.86E−06	7.37E−01	672	2.51E−04	1.86E−08	740
IC socket	1.02E−01	7.84E−02	587	−9.35E−02	2.36E−01	554	−1.33E−01	5.19E−01	622
Gender	1.98E−02	7.20E−01	806	−1.80E−01	1.56E−02	799	5.58E−01	2.08E−03	896
Etiology v.d.	−3.30E−01	2.80E−04	746	2.82E−01	1.84E−02	753	−3.78E−01	2.00E−01	830
Amputation level	2.05E−01	1.23E−04	740	9.95E−02	1.77E−01	704	7.32E−01	7.77E−04	789
bilat. amput.	−4.01E−01	1.03E−03	809	−1.37E−01	3.79E−01	801	−5.31E−01	1.75E−01	899
No comorbidity	1.25E−01	1.13E−02	809	−1.83E−01	6.89E−03	801	5.77E−01	1.27E−03	899
Diabetes mellitus	−4.59E−01	1.41E−07	809	1.22E−02	9.19E−01	801	−6.68E−01	2.10E−02	899
cardio-vas. dis.	−1.37E−01	3.12E−03	809	2.08E−02	7.39E−01	801	−3.37E−01	3.02E−02	899
dist. circ. leg	−3.18E−01	1.89E−04	809	6.98E−02	5.31E−01	801	−2.11E−01	4.50E−01	899
Hip problem	−8.05E−02	8.01E−02	809	1.94E−01	1.81E−03	801	−3.33E−01	3.17E−02	899
Further disability	−1.29E−01	2.53E−02	809	2.81E−01	2.98E−04	801	−1.35E−01	4.98E−01	899
Suction socket	9.43E−02	3.07E−02	809	−1.11E−01	6.55E−02	801	5.38E−01	7.15E−04	899
Liner	−8.24E−03	8.47E−01	809	1.69E−01	3.55E−03	801	2.09E−01	1.60E−01	899
C-Leg	1.69E−01	9.15E−04	809	−6.73E−02	3.06E−01	801	7.84E−01	1.06E−06	899
Foot G (dynamic)	−3.73E−02	5.19E−01	785	2.18E−01	7.93E−03	753	9.88E−02	6.24E−01	836
G OPG functions	−5.90E−02	3.23E−01	809	−1.12E−01	1.50E−01	801	1.31E+00	1.03E−11	899
Profession	2.51E−01	6.81E−09	778	−1.84E−01	1.92E−03	783	4.42E−01	3.00E−03	862
res. limb condition	2.60E−01	1.63E−06	425	1.11E−01	1.48E−01	393	7.82E−01	1.31E−04	445
res. limb length	1.24E−01	1.23E−04	535	3.88E−02	4.07E−01	507	6.89E−01	2.76E−08	568
res. limb loading	1.92E−01	3.34E−08	768	−9.00E−04	9.86E−01	726	5.18E−01	6.23E−05	813
Adhesion	1.43E−01	1.32E−05	777	−2.61E−02	5.75E−01	735	4.15E−01	5.31E−04	823
No. of falls per year	2.56E−02	1.38E−01	737	9.92E−02	1.56E−05	741	5.51E−02	3.64E−01	815
Mobility grade	3.67E−01	3.32E−26	770	−1.50E−01	3.03E−03	722	1.00E+00	6.14E−12	789

bilat. amput. = bilateral amputation, cardio-vasc. dis. = cardiovascular disease, dist. circ. = distortion circulation, dist. = distance, G = Genium, IC = Ischial Containment, OPG = Optimized physiological gait, prosth. = prosthesis, res. = residual, v.d. = vascular disease, wear. = wearing.

most sensitive performance indicators are shown in Table 3 (reduced set of variables.).

Multivariate regression with stepwise variable selection increased r^2 to a 10 to 20% level. The results underline the lack of explanatory power of the models.

3.2. Influence of variables

Age and years of wearing a prosthesis show neutral to low effects. Those are of high statistical significance in all performance indicators. Effect on functional benefit indicators is more prominent with an age >75 years. Daily walking distance prior to trial fitting did yield an e ranging between 2.38 to 3.88 (10–5): a change of ca. 0.02 on the Likert scale per km. Ten subjects stated daily walking distances prior to the trial fitting of up to 400 m. For those subjects, a high variability in the compound measurement of functional benefit as well as the individual performance indicators was found in this category. With daily walking distances higher than 400 m the variable leveled out.

Female subjects seem to perceive their situation better than male subjects. The prosthetist assessment of advanced maneuvers indicates better performance for males versus females. Age, etiology, and mobility grade were comparable in the male and female subgroup.

Subjects with vascular disease as an etiology perceive advantages when fitted with G. Advanced maneuvering with respect to technically safe performance as rated by the prosthetists was reduced. Subjects without comorbidities perceive fewer benefits: those having comorbidities perceive more benefits. Objectively, the advanced maneuver rating by the prosthetist is increased. Subjects having diabetes mellitus or compromised blood circulation in the lower extremity receive lower ratings in functional benefits and advanced maneuvers. Performance indicators associated with perception do not show statistical significance for diabetes. Generally, fewer subjects with comorbidities or further disabilities are rated as showing a clear benefit by prosthetists compared to other subjects. However, they perceived their profit higher than peer amputees without comorbidities or further disabilities.

An ischial containment socket (compared to hybrid) does yield a slight reduction when rated with respect to functional benefits. Five of 7 performance indicators for advanced maneuvers show positive effects. Having a suction socket shows a similar pattern, although effect estimates were somewhat smaller for advanced maneuvers. Liners show favorable ratings in functional benefits, perception and advanced maneuvers.

Better residual limb condition is associated with a higher rating in functional benefits, perception, and advanced maneuvering. Residual limb length, residual limb loading, and residual limb adhesion yield similar results with the range embracing neutral effects for functional benefits. Indicators in the perception category are less sensitive. For the small subgroup of subjects with atrophied residual limbs, the lowest rate of responsiveness is 83%. This occurs in spite of limitations during advanced maneuvering with both weights and obstructed vision as well as limitations with observed gait harmony.

Having been fit with a C-Leg prior to the trial fitting with G is associated with higher ratings related to most indicators in advanced maneuvers. Increased functional benefits are variation of gait speed, gain of attention, and 5 perception categories.

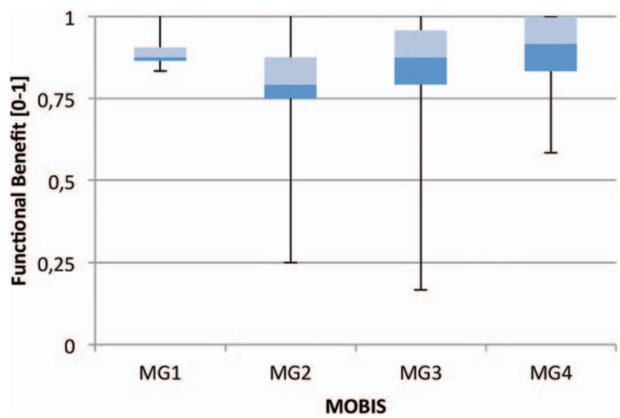

Figure 3. The variation of the compound measure "functional benefits" illustrates the invariance with mobility grade rating. MG = mobility grade, MOBIS = mobility grade classification.

Having a foot of higher dynamic response during the trial fitting leads to higher ratings in functional benefits, perception, and advanced maneuvering.

Subjects having a higher number of falls per year show a high number of neutral perception ratings.

Higher mobility grades yield higher ratings when assessed for advanced movements, but no clear effect is seen in functional benefits and perception. Mobility grade has the largest (e = 0.37) and most significant ($P < 1E-26$!) effect on the capability of a subject to vary gait speed. Since $r^2 = 0.13$ for this model, no explanatory power can be attributed to this variable. Multivariate regression yields $r^2 = 0.263$. The normalized compound measure for functional benefit with respect to mobility grade rating is displayed in Fig. 3.

Effect estimates from linear regression models range from –0.46 to 0.37. None of the variables and none of the regression models yield explanatory predictive power. Multivariate regression models do generally increase r^2, but not to a level required for prediction. Stepwise variable selection shows that variables significant in the models for different performance indicators do vary substantially. No coherent variable set can be selected.

4. Discussion

The group analyzed is one of preselected likely responders. Therefore, the absolute responsiveness in this sample does not surprise. All variables show plausible effects on performance indicators and many show very high statistical significance. Responders span the entire range indicated by the variables.

Most striking is the lack of explanatory power of the investigated variables on individual responsiveness in single and multivariate regression analysis. The fact that age, etiology, and mobility grade lack explanatory power as predictors for the utilization of functional and perceived benefits for individuals using advanced exo-prosthetic components coincides well with earlier results.[5,12] This work expands the number of clinical factors that lack explanatory power and questions the validity of using such factors to predict the effect of advanced hydraulic MPK use. Although mobility grade is among the factors with the highest impact on the investigated performance indicators, the model quality (r^2) does not sufficiently justify a prediction of performance. That is the case either alone or in combination with other parameters investigated here.

The results presented here coincide with findings from controlled clinical trials. Bell et al[23] investigated 21 unilateral transfemoral amputees (all MCFL 4) regarding the biomechanical aspects of ramp descent. Twelve subjects (57%) were capable of performing this activity in a way in which hand rail use would not interfere with the biomechanical measurements. We interpret this as a lower limit to responsiveness. In this investigation 71% of the subjects were rated as able to descend the ramp in a technically safe fashion. Furthermore, 86% were capable of performing the task in an alternating manner. Bell et al concluded that stair descent was faster (0.1 m/s compared to other knee joints with a microprocessor), the movement was more harmonized, and the loading of the prosthetic side more normative. Lura et al[24] reported similar results in an interventional randomized cross-over trial without reporting on responsiveness.

An unambiguous observable is the capability to ascend stairs. Aldridge et al[25] observed that 71% of subjects were capable of ascending stairs step over step in a population of 14 subjects with MCFL rating 3 and 4. Highsmith et al[26] reported that 14 out of 20 (70%) K3 and K4 transfemoral amputees who received training were able to ascend stairs reciprocally. Bellman et al[27] reported that 8 out of 10 subjects rated MG3 and MG4 were able to climb stairs in a step over step pattern.

In the cohort presented here, 64% of all subjects were observed ascending stairs alternatingly and 34% were assessed as being able to perform this task in a technically safe manner. If we extrapolate this to subjects rated as MG 3 and 4, then 73% of subjects were observed as being able to perform the task alternatingly and 38% were rated as being able to perform it in a technically safe fashion. Most of the controlled investigations mentioned above compared G to C-Leg. In this investigation, the variable C-Leg shows that effect estimate increases with most advanced maneuvers. A possible interpretation is that the former use of C-Leg has facilitated the acclimation to G and also the prosthetist assessment indicates functional improvements when G and C-Leg are directly compared. Effects on general functional benefits and perception have a higher variability. Subjects fitted with C-Leg prior to the trial fitting show improvement in "variable gait speed." Bellman et al[28] showed that the knee flexion angle during initial swing is significantly more constant and closer to the normative behavior when compared to C- Leg.

Using a higher dynamic response foot with G shows positive effects with all performance indicators. Liners also have positive effects on all performance indicators.

Effect estimates for age and the number of years that the subject has used a prosthesis were low. This indicates that those factors have no influence on an individual's capacity to utilize or perceive functional benefits. Responsiveness and compound functional benefit decline in those above 76 years. For individual responders, overall functional benefit may still suffice for device allocation.

Daily walking distance spans a large range with only a few subjects in this group indicating values below 400 m. A daily walking distance of 50m is defined in the SIGAM scale to distinguish the SIGAM mobility levels.[29] The French Health Authority HAS indicates a minimum walking capacity of 500m as an indication for C-Leg.[7] Although the subjects with lower walking capacity in this group were capable of utilizing the functional benefits of G, the use of a threshold value for walking capacity cannot be excluded as a possible predictor due to the low number of subjects. In conjunction with a balance indicator from the work of Wong et al,[13] a plausible hypothesis for future research could be posed. For the entire range of walking capacity the effect estimates were low, no effect is seen for daily walking distances larger than 400m.

Performance indicators vary in their sensitivity. This work identified the most sensitive. Variable gait speed was most sensitive in the category functional benefit and reflects the importance of this functional benefit in clinical practice. Toileting was the most sensitive indicator for subjects perception. This result was surprising. Retrospectively, it may be appreciated that the complexity of the toileting movements and the specific support requirements are apparent. We believe that this specific aspect may require more attention when assessing the support required by a prosthesis.

Performance indicators used for trial fittings in Germany may well be reduced to those of higher sensitivity.

5. Limitations

This work analyses the second largest population of users with advanced hydraulic, microprocessor-controlled exo-prosthetic knees, and the largest for Genium. Data were provided by 272 prosthetic clinics and as such resembles the practice conducted in Germany.

The data obtained in routine assessments span a large range of observations related to function and perception. They rely in their methodological approach on the criteria set forth by Wetz et al[9] and Drerup et al[19] and Kuhr[21] and error ranges were considered to be acceptable for clinical practice. The data do not rely on validated outcomes as recommended in controlled trials. This limits the accuracy of the findings specifically with respect to the magnitude of the effects.

The determination of the mobility grade was conducted according to the procedure specific to each prosthetic clinic individually. We are not aware of a generally accepted instrument accurately indicating mobility grades. We appreciate that different rating approaches may yield different individual's classification. However, the general finding that mobility grade rating does not impact utilization of functional benefits is still a valid finding in our opinion. The influence of acclimation time had been investigated by Schmalz et al.[30] They report that when transferring from C-Leg to G the biomechanical effects are seen within a few hours. They conclude that if movement patterns do not have to change, laboratory-based tests may deliver valuable information even after very short acclimation periods. If new motion patterns need to be learned, then longer adaptation and training phases may be required. Acclimation time may influence and hence limit the accuracy of responder classification.

Routine assessments are conducted in a commercial environment. We, therefore, do have to consider bias. A recent work shows that limits to bias in trial fittings were found to not exceed 10% and more likely are significantly smaller.[5] The data presented here seem to be in good agreement with the results obtained from controlled trials. The trends and influences derived from this analysis are well in line with clinical experience. This analysis focuses on the lack of predictability for the variables in a population of likely responders. There is no rationale to assume that bias is distributed in a way that would consistently mask such effect. The reported model parameters are insensitive to evenly distributed bias.

6. Conclusions

Responders to Genium trial fittings span a wide range throughout the entire investigated variables. None of those variables nor their combination seem to qualify as predictor for an individual response to a performance indicator. This is confirmed for mobility grade and further includes age, etiology, residual limb conditions, and comorbidities. BMI fails to exhibit statistical significance. Decision-making processes that rely on those variables without appropriately considering the subjects individual potential and capabilities do not seem to be supported by these findings. As no data is available supporting such approaches, the denial of access to advanced technology based on such variables may indeed be questionable.

A threshold value for walking capacity cannot be excluded and may pose a component of a possible predictor. Future research may consider a minimum walking capacity as a component of a predictive instrument.

Toileting was identified as the most responsive indicator in the subject's perception. Difficulties associated with this specifically demanding task may be insufficiently considered and may play a more important role when deciding upon the appropriate prosthetic components Future protocols for trial fittings may consider limiting the number of performance indicators to those with high differentiating power.

Subjects having previously been fitted with C-Leg show benefits when fitted with Genium. Most of these benefits can be found in perception and advanced maneuvers among which is stairs ascent. Liners and the use of a higher dynamic response foot further contribute to a better utilization of functional benefits.

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