EFFECTS OF A PROSTHETIC FOOT WITH INCREASED CORONAL ADAPTABLE ON CROSS-SLOPE WALKING

Altenburg B1*, Ernst M1, Maciejasz P2, Schmalz T1, Braatz F3, Gerke H1, Bellmann M1

1 Research Biomechanics, Ottobock SE & Co. KGaA, Göttingen, Germany.
2 Clinical Research and Services, Ottobock SE & Co. KGaA, Duderstadt, Germany.
3 Medical Orthobionics, Pivate University of Applied Sciences, Göttingen, Germany.
4 Institute of Biomechanics and Orthopaedics, German Sport University Cologne, Köln, Germany.

ABSTRACT

BACKGROUND: Walking on cross-slopes is a common but challenging task for persons with lower limb amputation. The uneven ground and the resulting functional leg length discrepancy in this situation requires adaptability of both user and prosthesis.

OBJECTIVE(S): This study investigated the effects of a novel prosthetic foot that offers adaptability on cross-slope surfaces, using instrumented gait analysis and patient-reported outcomes. Moreover, the results were compared with two common prosthetic feet.

METHODOLOGY: Twelve individuals with unilateral transtibial amputation and ten able-bodied control subjects participated in this randomized cross-over study. Participants walked on level ground and ±10° inclined cross-slopes at a self-selected walking speed. There were three prosthetic foot interventions: Triton Side Flex (TSF), Triton LP and Pro-Flex LP. The accommodation time for each foot was at least 4 weeks. The main outcome measures were as follows: frontal plane adaptation of shoe and prosthetic foot keel, mediolateral course of the center of pressure, ground reaction force in vertical and mediolateral direction, external knee adduction moment, gait speed, stance phase duration, step length and step width. Patient-reported outcomes assessed were the Activities specific Balanced Confidence (ABC) Scale, Prosthetic Limb Users Survey of Mobility (PLUS M) and Activities of Daily Living Questionnaire (ADL-Q).

FINDINGS: The TSF prosthetic foot adapted both faster and to a greater extent to the cross-slope conditions compared to the Triton LP and Pro-Flex LP. The graphs for the mediolateral center of pressure course and mediolateral ground reaction force showed a distinct grouping for level ground and ±10° cross-slopes, similar to control subjects. In the ADL-Q, participants reported a higher level of perceived safety and comfort when using the TSF on cross-slopes. Eight out of twelve participants preferred the TSF over the reference.

CONCLUSION: The frontal plane adaptation characteristics of the TSF prosthetic foot appear to be beneficial to the user and thus may enhance locomotion on uneven ground – specifically on cross-slopes.

INTRODUCTION

Real-life outdoor walking of persons with a lower limb amputation is continuously challenged by uneven ground, including bumps, obstacles, slopes and cross-slopes.

Cross-slopes are especially demanding, since many sidewalks are generally tilted for water drainage and often intersected with driveways. Such tilted ground induces a functional leg length discrepancy, which is an apparent problem, in particular when the prosthetic limb is positioned hillside and is effectively too long. This requires the user to perform compensatory strategies during gait. Conversely, an adaptive prosthesis may diminish compensatory user effort. In a lower limb prosthesis, the prosthetic foot is a
central component which offers an individual adaptability, depending on the design and materials used.3

Due to their carbon structure, common energy-storing-and-returning (ESR) feet have a certain degree of flexibility, which allows for limited adaptation under load.3 It has been shown in different studies4–8 that a mechanical ankle joint can increase the range of motion in plantar and dorsiflexion and that a sophisticated microprocessor control can improve the adaptation to uneven ground.7,9 Most studies have focused on adaptations in the sagittal plane. Only a few studies have investigated prototype feet that adapt in the frontal plane.10,11 Many ESR feet are equipped with a split-toe feature that is thought to add flexibility in the frontal plane.3 However, it has not yet been shown that such foot design benefits individuals with lower-limb amputations walking on inclined ground. Moreover, few studies have investigated amputees’ gait on cross-slopes.12–14 Most recently, Villa et al. revealed compensatory strategies of lower-limb amputees during prosthetic swing when the prosthesis was positioned hillside.

Individuals with transtibial amputation (ITTAs) showed increased hip and knee flexion in the residual limb for compensation and individuals with transfemoral amputation (ITFAs) increased hip hiking and vaulting.12 Such vaulting strategies of ITFAs were investigated in a previous article by Villa.13 Starholm et al.14 found that ITFAs use significantly more energy when walking on a surface moderately tilted in the frontal plane compared to walking with a tilt in the sagittal plane. They assume that when the prosthesis is on the slope side it becomes functionally too long and provokes a more energy consuming gait pattern. The existing literature shows that the most-investigated situation of cross-slope walking of amputees is walking with the prosthesis hillside, whereby the focus is placed on prosthetic swing, intact side stance and required compensatory strategies.

Building on these approaches, this study focused on the biomechanics of the prosthetic stance phase in both cross-slope conditions: foot positioned hillside (provokes eversion) and foot positioned valleyside (provokes inversion). The aim was to reveal the impact of the adaptability of the prosthetic foot on kinematics and kinetics of amputee gait on cross-slopes and to analyze the effects on balance and comfort by using self-reported outcome measures. The hypothesis was that a novel foot module with high frontal plane compliance enhances the locomotion of ITTAs on uneven ground.

METHODOLOGY

Participants

Twelve ITTAs participated in the study. This randomized cross-over study was approved by the ethics committee of the medical faculty of the University of Göttingen, Germany. Inclusion criteria were as follows: active individuals (K-level 3, 4)15,16 with unilateral transfibial amputation, at least 18 months post-amputation, stable residual limb volume, stable gait pattern, aged 18 years or older. Exclusion criteria were as follows: body weight exceeding 125 kg, any conditions that severely influence performance and gait like cardiovascular diseases or present socket issues. In addition, ten able-bodied individuals were included as controls. All participants provided written informed consent.

Prosthetic Feet

Three ESR feet were investigated (Figure 1). The novel foot was the Triton Side Flex (Ottobock, Germany). The TSF features a dedicated joint for frontal plane adaptations. This joint unit enables ±10° rotation (inversion/eversion) against a progressive resistance that is provided by a torsion bar.17 The rotational resistance increases towards the hard stop at 10° and is not user specific. The unit is screwed on a carbon base with split toes. The overall weight (size 27, including Spectra sock and cosmetic cover) is 860 g. The build height (heel to top of the pyramid) is 109 mm. In addition, two reference feet were tested. The Triton LP (Ottobock, Germany) contains the same carbon base as the TSF with matching properties in terms of dimensions and basic flexibility. The overall weight is 690 g and the build height 86 mm. The Pro-Flex LP (Ossur, Iceland) is a direct competitor of the Triton LP in the section of low profile ESR feet for active (K3 + K4) users. It features split toes as well, which are, however, asymmetrically designed. The overall weight (660 g) and build height (90 mm) are similar to the Triton LP.

Workflow

The study captured biomechanical data and patient-reported outcomes. Each participant tested the TSF and one reference foot. The selection of the reference foot and the order of tests (start with the TSF or reference) were randomized. All prosthetic assembling was done by the same certified prosthetist. The bench alignment followed the manufacturers’ specifications and was reproducibly done using a PROS.A. Assembly (Ottobock, Germany)18 followed by a static optimization19,20 on the L.A.S.A.R. Posture (Ottobock, Germany)21 and a final dynamic optimization to the prosthetist’s and participants’ satisfaction. The accommodation time for each foot was at least 4 weeks prior to performing the biomechanical assessments and patient questionnaires.

Setup

Gait analysis measurements were gathered using a motion capture system consisting of 12 Bonita cameras (Vicon, UK, sampling rate 200 Hz) and two force plates (Kistler, Switzerland, sampling rate 1000 Hz). A dedicated marker set with 39 passive markers was applied. This enables the
assessor to distinguish between the different contributions to the frontal plane adaptations of the foot including joint adaptation, carbon base deformation and shoe/foot shell deformation. For this purpose, the shoe and foot shell were modified and antenna markers were mounted directly on the carbon base (Figure 1). During measurements, all participants wore the same model of shoe with defined marker positions.

The studied situations were walking on level ground (using both force plates in the middle of the track) and walking on a 10° cross-slope, which was 8.5 m long and equipped with one force plate in the center. The participants were instructed to walk on the track at a self-selected, comfortable walking speed several times until eight valid recordings for each condition (level walking, four cross-slope conditions: 10° prosthesis hillside, 10° intact side hillside, 10° prosthesis valleyside, 10° intact side valleyside) were captured. The inclusion or exclusion of each recording was determined by an assessor next to the track (inclusion criteria: steady state of walking in the middle of the track, entire foot on the force plate without obviously aiming for it and without specific step length adaptation). As the physical cross-slope setup remained the same for all cross-slope measurements, the starting point was adjusted for each individual subject and both walking directions were captured. For the healthy controls both sides were measured in equal distribution in order to generate comparative data in 3 different conditions (level, hillside, valleyside).

In addition to the biomechanical measurements, participants completed a questionnaire evaluating amputees’ experience during 4 weeks or more of daily use. This questionnaire included the Activities-Specific Balance Confidence (ABC) Scale (16 questions), the Prosthetic Limb Users Survey of Mobility (PLUS-M) Scale (12-item short form) and a self-developed scale evaluating socket comfort and perceived safety in 40 situations of daily living (ADL-Scale). Among the situations evaluated with the ADL-Scale, there were 9 standing situations, 11 walking situations potentially affected by medial/lateral flexibility, 8 walking situations potentially unaffected by medial/lateral flexibility and 12 social activity situations. Both socket comfort and perceived safety were measured on a numerical rating scale from 0 (worst) to 10 (best). At the end of the study, participants were also asked which of the two tested feet they preferred for daily use.

**Data analysis**

Valid trials were further processed with VICON Nexus, customized VICON BodyBuilder (Vicon Motion System, UK) and MATLAB (R2018a, Mathwork Inc, US) scripts. The following spatiotemporal gait characteristics were considered: gait speed, step length, step width and stance phase duration. The lateral shoe markers, Figure 2 were used to automatically calculate these parameters with VICON Nexus. Furthermore, the following kinetic parameters were determined: ground reaction force in vertical (GRFv) and mediolateral (GRFml) direction; external knee adduction moment (EKAM), considered as EKAM peak (first maximum) and EKAM impulse (EKAM integral over duration of gait cycle (GC)).

**Figure 1**: Experimental setup and prosthetic feet used. (A) shows the 8.5m cross-slope with a force plate embedded in the center of the track (shown step) and a typical participant (prosthesis is valleyside limb, intact side is hillside limb). (B) display the marker set for estimating the CoP (markers on toe and heel of shoe) and the adaptation to the tilt (shoe markers and antenna markers through a cutout in the shoe and foot shell, attached to the carbon base). (C) shows the prosthetic feet tested: Triton Side Flex (left), Triton LP (middle) and Pro-Flex LP (right).
The adaptation of the shoe and carbon base in the frontal plane and the mediolateral course of the center of pressure (CoP) with respect to the foot were specific biomechanical parameters used in the study. The relative adaptation of the shoe in the frontal plane was determined in three steps. First, the angle between the projected connection line of medial and lateral shoe markers in the frontal plane and the horizontal surface was calculated ($\beta_{\text{shoe}}$ in Figure 2). Second, the adaptation of the shoe was calculated: $\alpha'_{\text{shoe}} = \beta_{\text{shoe}} + \alpha_{\text{shank}}$. Hereby $\alpha_{\text{shank}}$ represents the frontal shank angle ($\alpha_{\text{shank}}$ in Figure 2). Third, the relative adaptation of the shoe in the frontal plane was calculated by subtracting the adaptations found for level walking from the adaptations found for cross-slope situations: $\Delta \alpha_{\text{shoe}} = \alpha'_{\text{shoe,level}} - \alpha'_{\text{shoe,cross-slope}}$. The course of the CoP was estimated, first, by projecting the CoP of the force plate and the foot axis (defined by tip and heel marker) to the surface and, second, by calculating the orthogonal distance of the projected CoP to the projected marker line (CoP$_{\text{dis}}$ in Figure 2).

**Statistics**

For each situation, individual means (calculated from single trials) and group means (calculated from individual means) of the analyzed parameters were determined. To compare the effects of the different prosthetic foot types (reference feet vs. TSF) for certain setups (level, 10° hillside, 10° valleyside) a paired T-test was performed. If the assumed normal distribution (Shapiro-Wilks test) was not given, a non-parametric Wilcoxon test was performed. To account for multiple testing, the alpha level was set to 1%. The statistical analysis was performed with IBM SPSS Statistics (IBM Corp., US). We did not conduct a statistical analysis of the effects of the cross-slopes angle within the groups, i.e. level vs 10° hillside vs 10° valleyside, nor did we consider a statistical comparison between ITTAs and control subjects. We did, however, perform a statistical analysis of the ABC, PLUS-M and ADL-Scale scores. The ADL scores were
separately determined for each activity block (standing, walking – non-m/l, walking – m/l, and social activities) and each dimension (safety, comfort) – resulting in eight ADL scores per person and tested foot. The individual scores of participants obtained with different feet were compared using the paired T-test.

RESULTS

Twelve ITTAs with activity level K3 (Medicare Functional Classification Level) or higher, participated in this study. Further detailed demographic data are shown in Table 1. In addition 10 control subjects (age: 29±7 years; weight: 83±15 kg; height: 183±11 cm) were also recruited for the study.

The spatiotemporal parameters provided in Table 2 showed no statistically significant differences between the TSF and reference feet for any condition. Gait speed and step width tended to decrease from level to slope conditions for all feet. Control subjects walked on average with higher gait speed, and tended to decrease from level to slope conditions for all feet. The reference feet showed only minor adaptations after loading response, constantly increasing with progressing stance.

The amount of measured adaptation at mid stance (30% GC) was significantly (p<0.01) higher with the TSF compared to the reference feet in all slope conditions (Table 3). The measured shoe adaptation showed similar characteristics with a smaller difference between the studied feet. The TSF reached the same amount of adaptation as the controls.

The EKAM impulse was significantly reduced for the valleyside condition with the TSF. No differences were found for hillside and level walking (Table 3, Figure 4). EKAM peaks showed no differences in all conditions. Control subjects presented notably higher values of peak EKAM in all conditions.

The CoP paths of the control subjects showed a medial shift when the foot in question was positioned valleyside, but a close grouping for the hillside position and level walking. The TSF produced a similar grouping for level and hillside conditions, but a lateral shift for the valleyside condition. ESR feet revealed a different CoP path pattern with a distinct laterally shifted curve for the hillside and a medially shifted curve for the valleyside condition. A comparison of ESR and TSF feet demonstrated significantly different CoP paths for all conditions (Table 3).

GRFv showed no differences between the feet in all conditions. There was a trend towards an increased first maximum for the valleyside condition. GRFml differed significantly between the investigated feet in the valleyside condition (30% GC).

The results of the patient-reported outcomes are shown in Table 4. They found significantly (p<0.05) higher ratings for the TSF foot for perceived comfort while standing and perceived comfort and safety while walking in situations potentially affected by medial/lateral flexibility (ADL Scale). All other ADL sub-scales, as well as ABC and PLUS-M, tended towards higher ratings when using the TSF foot, but did not attain statistical significance. As far as foot preference was concerned, eight participants preferred the TSF, three participants preferred one of the reference feet (1x Triton LP, 2x Pro-Flex LP), and one participant had no preference.

Table 1: Demographic data of study participants with transtibial amputation and allocated prosthetic feet (randomized process).

| Participant | Age  | Weight (kg) | Height (m) | Gender | K-Level | Socket suspension | Foot #1       | Foot #2       |
|-------------|------|-------------|------------|--------|---------|-------------------|---------------|---------------|
| S01         | 51   | 69          | 1.83       | m      | 3       | Suction, One way valve | TSF Triton LP |
| S02         | 61   | 125         | 1.80       | m      | 3       | Soft socket, supracondylar | TSF Pro-Flex LP |
| S03         | 38   | 88          | 1.68       | m      | 4       | Suction, one way valve    | Pro-Flex LP   |
| S04         | 77   | 86          | 1.75       | m      | 3       | Pin lock                   | TSF Pro-Flex LP |
| S05         | 47   | 50          | 1.56       | m      | 3       | Suction, one way valve     | Pro-Flex LP   |
| S06         | 59   | 86          | 1.78       | m      | 3       | Suction, one way valve     | TSF Pro-Flex LP |
| S07         | 44   | 68          | 1.68       | w      | 3       | Suction, one way valve     | Triton LP     |
| S08         | 52   | 78          | 1.77       | m      | 3       | Suction, one way valve     | Triton LP     |
| S09         | 37   | 90          | 1.84       | m      | 3       | Suction, one way valve     | Triton LP     |
| S10         | 64   | 99          | 1.88       | m      | 3       | Suction, one way valve     | Triton LP     |
| S11         | 57   | 79          | 1.80       | m      | 4       | Suction, one way valve     | Pro-Flex LP   |
| S12         | 47   | 97          | 1.83       | m      | 4       | Pin lock                   | TSF Triton LP |
| Mean        | 52.8 | 83.9        | 1.77       |        |         |                   |               |
| SD          | 11.5 | 19.4        | 0.09       |        |         |                   |               |
| Range       | 37-77| 50-125      | 1.56-1.88  |        |         |                   |               |
Table 2: Spatiotemporal parameters of the TSF and reference feet for level walking and 10° cross-slope conditions. No statistically significant differences between foot types were found (p<0.01)

| Prosthetic foot | Condition | Gait velocity (m/s) | Step length (m) | Stance phase duration (% GC) | Step width (m) |
|-----------------|-----------|---------------------|----------------|-----------------------------|---------------|
| TSF             | Level     | 1.27 ± 0.12         | 0.74 ± 0.05    | 60.7 ± 1.3                  | 0.22 ± 0.03   |
|                 | 10° hillside | 1.25 ± 0.14       | 0.75 ± 0.05    | 61.1 ± 1.2                  | 0.21 ± 0.03   |
|                 | 10° valleyside | 1.23 ± 0.13    | 0.71 ± 0.05    | 60.3 ± 1.3                  | 0.20 ± 0.02   |
| Reference       | Level     | 1.27 ± 0.14         | 0.73 ± 0.06    | 61.3 ± 0.9                  | 0.22 ± 0.02   |
|                 | 10° hillside | 1.24 ± 0.14       | 0.75 ± 0.06    | 61.1 ± 1.4                  | 0.21 ± 0.02   |
|                 | 10° valleyside | 1.25 ± 0.15    | 0.72 ± 0.07    | 60.7 ± 1.2                  | 0.20 ± 0.03   |
| Controls        | Level     | 1.44 ± 0.15         | 0.79 ± 0.09    | 61.7 ± 1.1                  | 0.27 ± 0.03   |
|                 | 10° hillside | 1.42 ± 0.19       | 0.79 ± 0.08    | 61.8 ± 1.4                  | 0.25 ± 0.04   |
|                 | 10° valleyside | 1.43 ± 0.19   | 0.77 ± 0.08    | 60.8 ± 1.4                  | 0.26 ± 0.03   |

Table 3: Parameters of the prosthetic side for the different setups at the first maximum peak (GRFv, EKAM peak), whole GC (EKAM impulse) and at 30% GC (GRFml, $\alpha_{\text{base}}$, $\alpha_{\text{shoe}}$, CoP$_{\text{dist}}$). Statistically significant differences between foot types are marked bold (p<0.01) or bold and * (p<0.001).

| Parameter | GRFv (%bw) | GRFml (%bw) | $\alpha_{\text{base}}$ (deg) | $\alpha_{\text{shoe}}$ (deg) | CoP$_{\text{dist}}$ (mm) | EKAM peak (Nm/kg) | EKAM impulse (Nm/kg*s) |
|-----------|------------|-------------|-------------------------------|-------------------------------|--------------------------|-------------------|----------------------|
| Level TSF | 108 ± 11   | 4.4 ± 1.3   | -                             | -                             | 9 ± 5                    | 0.34 ± 0.12       | 0.09 ± 0.04          |
| Level reference feet | 108 ± 7   | 4.5 ± 1.2   | -                             | -                             | 14 ± 7                  | 0.32 ± 0.11       | 0.09 ± 0.04          |
| Level controls | 111 ± 5   | 2.0 ± 0.8   | -                             | -                             | 9 ± 6                   | 0.49 ± 0.10       | 0.19 ± 0.05          |
| Hillside TSF | 108 ± 13  | 4.2 ± 1.3   | -18.8 ± 1.6 *                 | -11.9 ± 0.8                  | 13 ± 5 *                | 0.27 ± 0.13       | 0.08 ± 0.04          |
| Hillside reference feet | 109 ± 12  | 4.5 ± 1.1   | -21.0 ± 0.6 *                 | -10.7 ± 0.8                  | 24 ± 5 *                | 0.26 ± 0.13       | 0.08 ± 0.04          |
| Hillside controls | 107 ± 6   | 2.2 ± 0.8   | -                             | -12.0 ± 0.9                  | 10 ± 7                  | 0.38 ± 0.10       | 0.16 ± 0.06          |
| Valleyside TSF | 112 ± 12  | 3.4 ± 1.5   | 7.9 ± 1.8 *                   | 11.9 ± 2.0                   | 13 ± 6 *                | 0.38 ± 0.14       | 0.11 ± 0.03          |
| Valleyside reference feet | 112 ± 11  | 2.4 ± 1.2   | 2.9 ± 1.0 *                   | 10.6 ± 1.2                   | 2 ± 5 *                 | 0.40 ± 0.12       | 0.14 ± 0.03          |
| Valleyside controls | 112 ± 7   | 1.2 ± 0.7   | -                             | 12.0 ± 1.0                   | 5 ± 6                   | 0.56 ± 0.16       | 0.22 ± 0.06          |

Table 4: Summary of the scores in the patient-reported outcomes for reference foot and the TSF. Significant differences in a parameter are marked bold for the p values (p<0.05).

| Analyzed parameter: | n | Reference feet (mean ± SD) | TSF (mean ± SD) | p |
|---------------------|---|---------------------------|----------------|---|
| ABC (Balance confidence) | 12 | 86.6 ± 8.6 | 89.2 ± 8.4 | 0.14 |
| PLUS-M (Mobility) | 12 | 56.6 ± 7.3 | 57.3 ± 7.8 | 0.67 |
| ADL: Standing situations (9 questions) |  |  |  |  |
| Perceived comfort | 12 | 8.4 ± 1.0 | 9.1 ± 0.8 | 0.02 |
| Perceived safety | 12 | 8.8 ± 0.8 | 9.2 ± 0.7 | 0.11 |
| ADL: Walking in situations potentially affected by the medial/lateral flexibility (11 questions) |  |  |  |  |
| Perceived comfort | 12 | 8.3 ± 1.1 | 8.9 ± 0.8 | 0.02 |
| Perceived safety | 12 | 8.4 ± 1.1 | 9.0 ± 0.9 | 0.04 |
| ADL: Walking in situations potentially not affected by the medial/lateral flexibility (8 questions) |  |  |  |  |
| Perceived comfort | 12 | 8.3 ± 0.9 | 8.8 ± 0.8 | 0.11 |
| Perceived safety | 12 | 8.4 ± 1.0 | 8.7 ± 1.0 | 0.34 |
| ADL: Social activities (12 questions) |  |  |  |  |
| Perceived comfort | 12 | 8.3 ± 1.0 | 8.9 ± 0.8 | 0.05 |
| Perceived safety | 12 | 8.6 ± 0.9 | 8.9 ± 0.9 | 0.12 |
The aim of this study was to investigate the effects of a novel prosthetic foot, with adaptability on cross-slope surfaces, using instrumented gait analysis and patient-reported outcomes.

Several results support the initial hypothesis that a foot module with easily accessible frontal plane adaptation can enhance locomotion on uneven ground. First, the early and extensive adaptation at the beginning of stance found in this study appears to be of importance and agrees with the findings of Yeates who suggested an improved balance on uneven ground derived from greater frontal adaptation in early stance. Here the TSF adapts both earlier (at loading response, 10% GC) and more extensively and keeps this adaptation until the end of stance (Figure 3). The users felt directly a different foot behavior when stepping on the cross-slope and reported a higher level of perceived safety. With the common ESR split toe concept of the measured reference feet, the maximum adaptation occurs at the end of stance with maximum toe load. The absolute value of adaptation is not exactly known since the measured position of the antenna markers fixed on the carbon base always reflects a combined adaptation of rotation of the carbon base, toe shift and toe twist. Nevertheless, the timing of adaptation is not affected. The frontal plane adaptation of the shoes reveals similar characteristics as the carbon bases with constant values for the TSF, but increasing adaptation as stance progresses for standard ESR feet.

However, the difference in adaptation is smaller compared to the carbon base data. This suggests movement, like tilt between carbon base, foot cover and shoe, that is usually not detected with conventional marker placement on the shoes. Consequently, every shoe as well as every prosthetic foot cover contributes to the overall adaptation. The data for shoe adaptation shows an overshoot in value for the TSF and control subjects (12° value on a 10° cross-slope). Load-dependent shoe-sole compression and a different shank orientation (by leaning to a side) when walking on cross-slopes are plausible reasons for this effect.

The EKAM is a clinically relevant parameter, since its first peak has been positively associated with medial compartment knee osteoarthritis (OA). The EKAM impulse is also commonly studied in conjunction with OA. According to Chang et al., it might even be the more comprehensive indicator of cumulative medial compartment loading during gait. This study showed a significantly reduced EKAM impulse for the valleyside condition using the TSF, but no differences in EKAM peak (Table 3, Figure 4A). However, compared to the clearly higher moments generated by the control subjects, the overall impact on OA risk appears negligible. Still, this effect of prosthetic side knee load reduction for valleyside conditions might increase in similar everyday life loading scenarios with higher gait speed or varying step width. In general, the clearly higher gait speed and wider step width of the control subjects has to be considered when comparing absolute knee loading.

![Relative frontal adaptation on the cross-slope for Triton Side Flex (left) and reference feet (right) for 10% to 50% GC (main loading interval). The solid red (hillside) and solid blue (valleyside) curves show the adaptation of the prosthesis via the antenna markers (α_{base}). The grey (control subjects) and dashed (prosthetic side) curves show the adaptation determined by the markers on the shoes (β_{shoe}).](image-url)
Figure 4: Parameters for the different studied situations. (A) EKAM, (B) mediolateral CoP course, (C) mediolateral ground reaction forces and (D) vertical ground reaction forces. The left column shows the prosthetic side values for the reference feet, the middle column the prosthetic side values for the TSF foot and the right column show the control subjects. The blue curves indicate the valley-side situations, the red curves indicate the hillside situations and the black curves indicate level walking. The associated standard deviations are given as shaded areas for the blue and red curves.
The CoP path shows clear foot-dependent differences (Figure 4B). It can be assumed that the additional joint of the TSF quickly adapts, similar to the subtalar joint of the control subjects, causing similarly grouped CoP paths for the TSF and control subjects. The limited adaptation capability of the low profile ESR feet forces a main load transfer towards the lateral rim of the foot base (hillside condition) or towards the medial rim (valleyside condition), respectively, causing clearly different CoP paths compared to the level walking condition. The authors assume that these deviations require more compensatory strategies by the user to safely walking on cross-slopes. The GRFml also showed a close grouping for the TSF and control subjects (Figure 4C). This effect might facilitate more predictable steps with less control effort on cross-sloped surfaces or similar terrain.

For the hillside conditions, there were no foot-dependent differences found for EKAM and GRFml, despite clear differences in frontal plane adaptation, COP paths and reported advantages while using the TSF. It can be assumed that the functional leg length discrepancy (35 mm longer prosthetic side on 10° cross-slope, 20 cm step width) is a major problem to overcome for the user that presumably requires higher control and energetic efforts. According to Walsh et al., leg length discrepancies greater than 5 mm require compensatory strategies during gait. The additional joint in the TSF allows for an effective shortening of about 5 mm in this condition which is a small proportion of the estimated 35 mm leg length discrepancy but seems to positively impact perceived comfort and safety. Still, it did not translate into the measured parameters EKAM and GRFml.

The patient-reported outcomes favored the TSF. However, it is noticeable that all ratings were found to be close to the maximum scores of the scales with relatively small differences between the feet tested. It has to be considered that all participants were active ambulators with highly functional components in their current prostheses and did not report major limitations in their everyday lives. They were all considered high-functioning, safe walkers. Nevertheless, statistically significant differences were found in 3 scales. It is believed that the increased perceived safety of the TSF is based on the fast adaptation at low loading and the resulting consistent GRFml (Figure 4C) on sloped surfaces. The reduced control effort may lead to diminished movement in the residual limb-socket interface and could be the reason for the increased perceived comfort. The preference question at the end of the study revealed, on the one hand, a clear preference by 8 of the 12 participants for the TSF. On the other hand, interesting arguments for its rejection were offered by the other participants. Two participants preferred the Pro-Flex LP because it was perceived to provide a more comfortable rollover. One participant preferred the Triton LP since he had an unstable knee and could not stabilize it in the frontal plane when using the TSF. This may hint at a possible contraindication for fitting such adaptive foot components that warrants further study.

Study limitations
Due to the long accommodation time (at least 4 weeks) for the test prosthesis, a blinding of the foot condition was not practicable, which introduced a potential bias in favor of the novel foot (expectation). The use of two different reference feet and grouping them into one reference is a limitation in methodology since it is to be assumed that both reference feet do not perform identically. The healthy control population was not an exact match to the experimental population in terms of age. This may impact gait characteristics.

CONCLUSION
This is the first study analyzing prosthetic side loading during cross-slope walking of individuals with transtibial amputation which has provided new quantitative results. Although the obvious problem of a functional leg length discrepancy during cross-slope walking cannot entirely be solved by the novel foot studied, the results suggest an improved frontal plane adaptability of the prosthetic foot. In particular a comprehensive adaptation starting at low loading in early stance may enhance locomotion on cross-slopes such as uneven ground.

ACKNOWLEDGEMENTS
We would like to thank the anonymous reviewers for their valuable and constructive feedback.

DECLARATION OF CONFLICTING INTERESTS
Mr. Björn Altenburg, Dr. Michael Ernst, Dr. Pawel Maciejasz, Dr. Thomas Schmalz and Dr. Malte Bellmann are full time employees of Ottobock SE & Co. KGaA.

AUTHOR CONTRIBUTION

- Björn Altenburg: study design, prosthetic fittings, gait lab measurements, data interpretation, draft manuscript.
- Michael Ernst: gait lab measurements, biomechanical data analysis, data interpretation, draft manuscript.
- Pawel Maciejasz: preparation, evaluation and analysis of the outcome measurements.
- Thomas Schmalz: supervision, revise manuscript.
- Frank Braatz: supervision, revise manuscript.
- Henrik Gerke: gait lab measurements, biomechanical data analysis.
• Malte Bellmann: study design, supervision, data interpretation, revise manuscript.

SOURCES OF SUPPORT

None.

ETHICAL APPROVAL

This randomized cross-over study was approved by the Ethics Committee of the Medical Faculty of the University of Göttingen, Germany. All participants provided written informed consent.

REFERENCES

1. Kockelmann K, Zhao Y, Blanchard-Zimmermann C. Meeting the intent of ADA in sidewalk cross-slope design. J Rehabil Res Dev. 2001;38(1):101-10.
2. Walsh M, Connolly P, Jenkinson A, O’Brien T. Leg length discrepancy – an experimental study of compensatory changes in three dimensions using gait analysis. Gait Posture 2020;12:156-61. DOI: 10.1016/s0966-6362(00)00067-9
3. Ernst M, Altenburg B, Schmalz T. Characterizing adaptations of prosthetic feet in the frontal plane. Prosthet Orthot Int. 2020; 44(4), 225-233. DOI: 10.1177/0309364620917838
4. Ferris AE, Aldridge JM, Rábago CA, Wilken JM. Evaluation of a powered ankle-foot prosthetic system during walking. Arch Phys Med Rehabil. 2012; 93 (11): 1911-8. DOI: 10.1016/j.apmr.2012.06.009
5. Schlayf M, Reed KB. Novel passive ankle-foot prosthesis mimics able-bodied ankle angles and ground reaction forces. Clin Biomech 2019;72:202-210. DOI: 10.1016/j.clinbiomech.2019.12.016
6. Heitzmann DWW, Salami F, De Asha AR, Block J, Putz C, Wolf SI, Alimusaq M. Benefits of an increased prosthetic ankle range of motion for individuals with a trans-tibial amputation walking with a new prosthetic foot. Gait Posture. 2018; 64:174-180. DOI: 10.1016/j.gaitpost.2018.06.022
7. Schmalz T, Altenburg B, Ernst M, Bellmann M, Rosenbaum D. Lower limb amputee gait characteristics on a specifically designed test ramp: Preliminary results of a biomechanical comparison of two prosthetic foot concepts. Gait Posture. 2019;68:161-167. DOI: 10.1016/j.gaitpost.2018.11.017
8. Ernst M, Altenburg B, Bellmann M, Schmalz T. Standing on slopes - how current microprocessor-controlled prosthetic feet support transtibial and transfemoral amputees in an everyday task. J Neuroeng Rehabil. 2017;14(1):117. DOI: 10.1186/s12984-017-0322-2.
9. Thomas-Pohl M, Villa C, Davot J, Bonnet X, Facione J, Lapeyre E, Bascou J, Pillet H. Microprocessor prosthetic ankles: comparative biomechanical evaluation of people with transtibial traumatic amputation during standing on level ground and slope. Disabil Rehabil Assist Technol. 2019;19:1-10. DOI: 10.1080/17431077.2019.1629112.
10. Yeates KH, Segal AD, Neptune RR, Klute GK. A coronally clutching ankle to improve amputee balance on coronally uneven and unpredictable terrain. J Med Devices. 2018; 12(3): 031001. DOI:10.1115/1.4040183
11. Collins SH, Kim M, Chen T, Chen T. An ankle-foot prosthesis emulator with control of plantarflexion and inversion-eversion torque. IEEE Int Conf Robot Autom. 2015; 1210-1216, DOI: 10.1109/ICRA.2015.7139345
12. Villa C, Loiret I, Langlois K, Bonnet X, Lavaste F, Fodé P, et al. Cross-Slope and level walking strategies during swing in individuals with lower limb amputation. Arch Phys Med Rehabil. 2017; 98: 1149. DOI: 10.1016/j.apmr.2016.10.007
13. Villa C, Drevelle X, Bonnet X, Lavaste F, Loiret I, Fodé P, et al. Evolution of vaulting strategy during locomotion of individuals with transfemoral amputation on slopes and cross-slopes compared to level walking. Clin Biomech. 2015;30:623-8. DOI: 10.1016/j.clinbiomech.2015.03.022
14. Starholm I-M, Gjovaag T, Mengshoel AM. Energy expenditure of transfemoral amputees walking on a horizontal and tilted treadmill simulating different outdoor walking conditions. Prosthet Orthot Int. 2010; 34: 184–194, DOI: 10.3109/030936490903585016
15. Gailey RS, Roach KE, Applegate EB, Cho B, Cunniffe B, Licht S, et al. The Amputee Mobility Predictor: an instrument to assess determinants of the lower-limb amputee’s ability to ambulate. Arch Phys Med Rehabil. 2002;83:613-27. DOI: 10.1053/apmr.2002.23209
16. Orenduff MS, Raschke SU, Winder L, Moe D, Boone DA, Kobayashi T. Functional level assessment of individuals with transtibial limb loss: Evaluation in the clinical setting versus objective community ambulatory activity. J Rehabil Assist Technol Eng. 2016; 2055668316636316. DOI:10.1177/2055668316636316
17. Ottobock Feet Mechanical [Internet]; Triton Side Flex 3D Animation video [cited 2021 May 14]. Available from: https://shop.ottobock.us/Prosthetics/Lower-Limb-Prosthetics/Feet--Mechanical/1C68-Triton-side-flex/p/1C68
18. Ottobock Planning & Equipping, Materials [Internet]; PROS.A Assembly [cited 2021 May 14]. Available from: https://pe.ottobock.com/en/ot/products/743a220-assembly.html
19. Blumentritt S, Schmalz T, Jarashc R, Schneider M. Effects of sagittal plane prosthetic alignment on standing trans-tibial amputee knee loads. Prosthet Orthot Int. 1999;23(3):231-8. DOI:10.3109/03093649909071639
20. Blumentritt S, Schmalz T, Jarashc R. Significance of static prosthetic alignment for standing and walking of patients with lower limb amputation. Orthopade. 2001;30(3):161-8. DOI:10.1007/s001320050590
21. Blumentritt S, A new biomechanical method for determination of static prosthetic alignment. Prosthet Orthot Int. 1997; 21, 107-13. DOI: 10.3109/03093649709164538
22. Powell LE, Myers AM. The activities-specific balance confidence (ABC) scale. J Gerontol A Biol Sci Med Sci. 1995;50(1):M28-34. DOI:10.1093/gerona/50A.1.M28
23. Hafner BJ, Morgan SJ, Abrahamson DC, Amtmann D. Characterizing mobility from the prosthetic limb user's perspective: Use of focus groups to guide development of the Prosthetic Limb Users Survey of Mobility. Prosthet Orthot Int. 2016;40(5):582-90. DOI: 10.1177/0309364615579315
24. Hafner BJ, Gaunaurd IA, Morgan SJ, Amtmann D, Salem R, Gailey RS. Construct validity of the Prosthetic Limb Users Survey of Mobility (PLUS-M) in adults with lower limb amputation. Arch Phys Med Rehabil. 2017; 98(2):277-85 DOI: 10.1016/j.apmr.2016.07.026.

25. Vicon Nexus Product Guide, manual [Internet]; [cited 2021 March 1]. Available from: https://documentation.vicon.com/nexus/v2.2/Nexus1_8Guide.pdf

26. Baliunas AJ, Hurwitz DE, Ryals AB, Karrar A, Case JP, Block JA, et al. Increased knee joint loads during walking are present in subjects with knee osteoarthritis. Osteoarthr. Cartil. 2002;10(7):573-579. DOI: 10.1053/joca.2002.0797

27. Mündermann A, Dyrby CO, Hurwitz DE, Sharma L, Andriacchi TP. Potential strategies to reduce medial compartment loading in patients with knee osteoarthritis of varying severity: reduced walking speed. Arthritis Rheum. 2004; 50:1172-1178. DOI: 10.1002/art.20132

28. Miyazaki T, Wada M, Kawahara H, Sato M, Baba H, Shimada S. Dynamic load at baseline can predict radiographic disease progression in medial compartment knee osteoarthritis. Ann Rheum Dis. 2002;61:617-622. DOI: 10.1136/ard.61.7.617

29. Thorp LE, Sumner DR, Wimmer MA, Block JA. Relationship between pain and medial knee joint loading in mild radiographic knee osteoarthritis. Arthritis Rheum. 2007; 57:1254-126031. DOI: 10.1002/art.22991

30. Creaby MW, Wang Y, Bennell KL, Hinman RS, Metcalf BR, Bowles KA, et al. Dynamic knee loading is related to cartilage defects and tibial plateau bone area in medial knee osteoarthritis. Osteoarthr. Cartil. 2010;18:1380–1388. DOI: 10.1016/j.joca.2010.08.013

31. Bennell KL, Bowles KA, Wang Y, Cicuttini F, Davies-Tuck M, et al. Higher dynamic medial knee load predicts greater cartilage loss over 12 months in medial knee osteoarthritis. Ann Rheum Dis.2011; 70;1770–1774. DOI: 10.1136/ard.2010.147082

32. Kito N, Shinkoda K, Yamasaki T, Kanemura N, Anan M, Okanishi N, et al. Contribution of knee adduction moment impulse to pain and disability in Japanese women with medial knee osteoarthritis. Clin Biomech. 2010; 25:914–919. DOI: 10.1016/j.clinbiomech.2010.06.008

33. Chang AH, Moisio KC, Chmiel JS, Eckstein F, Guermazi A, Prasad PV, et al. External knee adduction and flexion moments during gait and medial tibiofemoral disease progression in knee osteoarthritis. Osteoarthr. Cartil. 2015;23(7):1099-106. DOI: 10.1016/j.joca.2015.02.005

34. Favre J, Erhart-Hledik JC, Chehab EF, Andriacchi TP. General scheme to reduce the knee adduction moment by modifying a combination of gait variables. J Orthop Res. 2016;34(8):1547-56. DOI: 10.1002/jor.23151.