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Benefits of an increased prosthetic ankle range of motion for individuals with a trans-tibial amputation walking with a new prosthetic foot

Daniel W.W. Heitzmann[a,*], Firooz Salami[a], Alan R. De Asha[b], Julia Block[a], Cornelia Putz[a], Sebastian I. Wolf[a], Merkur Alimusaj[a]

[a] *Movement Analysis Lab., Department of Orthopaedics and Trauma Surgery, Heidelberg University Hospital, Germany*
[b] *C-Motion, Inc., Germantown, MD, USA*

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ABSTRACT

Background: Individuals with trans-tibial amputation show a greater peak prosthetic ankle power (push- off) when using energy storing and returning (ESAR) prosthetic feet as compared to solid-ankle cushion-heel feet. ESAR feet further contribute to the users' body support and thus limit prosthetic ankle motion. To improve ankle motion, articulating prosthetic feet have been introduced. However, articulating feet may diminish push-off.

Research question: Does a novel prosthetic foot, with a serial layout of carbon fibre leaf springs, connected by a multi-centre joint construction, have advantages in kinematics and kinetics over a conventional ESAR prosthetic foot? >

Methods: Eleven individuals with unilateral trans-tibial amputation were fitted with the novel foot (NF) and a conventional ESAR Foot (CF) and underwent 3D gait analysis. As an additional power estimate of the prosthetic ankle, a unified, deformable, segment model approach was applied. Eleven matched individuals without impairments served as a reference.

Results: The NF shows an effective prosthetic ankle range of motion that is closer to a physiologic ankle range of motion, at 31.6° as compared to 15.2° with CF (CF vs. NF $p = 0.003$/NF vs. Reference $p = 0.171$) without reducing the maximum prosthetic ankle joint moment. Furthermore, the NF showed a great increase in prosthetic ankle power (NF 2.89 W/kg vs. CF 1.48 W/kg CF vs. NF $p = \; < 0.001$) and a reduction of 19% in the peak knee varus moment and 13% in vertical ground reaction forces on the sound side for NF in comparison to CF.

Significance: The NF shows that serial carbon fibre leaf springs, connected by a multi-centre joint construction gives a larger ankle joint range of motion and higher ankle power than a conventional carbon fibre structure alone. Consequently load is taken off the contralateral limb, as measured by the decrease in vertical ground reaction forces and peak knee varus moment.

1. Introduction

The calf muscles, namely, the soleus and gatrocnemius muscles, contribute substantially to forward propulsion during walking [1]. In a person who has had a trans-tibial amputation (PTTA) these muscles no longer cross a biological ankle and are inoperative, causing functional impairments, primarily a reduced push-off (peak prosthetic ankle power) during late stance. This is likely a cause for increased loading on the sound side and for compensations in non-involved joints [2,3]. In order to reduce such effects, many contemporary prosthetic feet are constructed with carbon fibre leaf springs. These so-called energy storing and returning feet (ESAR) offer an energy return during terminal stance and pre-swing 2–3 times greater than a SACH foot (solid-ankle cushion-heel) [4]. However, the positive power generation in late stance of ESAR feet is still lower than that in unimpaired individuals [5]. This finding is typical for all passive prosthetic feet [6].

In addition to generating power during late stance, the calf muscles also control forward progression of the tibia during the second foot rocker of the roll over and limit dorsiflexion in late stance [7,8]. This tibial progression also occurs in ESAR feet and is essential for loading

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Abbreviations: PTTA, person who has had a trans-tibial amputation; REF, matched unimpaired individuals for reference purposes; ESAR, energy storing and returning; SACH, solid ankle cushion heel; CoP, centre of pressure; CoM, centre of mass; H1-4, hypothesis 1–4; K-Level, Medicare established K levels in 1995, which are also referred to as Medicare Functional Classification Levels; CF, conventional prosthetic foot (i.e., Vari-Flex ®); NF, novel prosthetic foot (i.e., Pro-Flex®); AP, anterior posterior; H, height; GRF, ground reaction forces; UD, unified deformable segment; UD Power, unified deformable segment approach estimate prosthetic ankle power; OA, Osteoarthritis; MANCOVA, multivariate analysis of covariance

[*] Corresponding author at: Bereich Bewegungsanalytik, Klinik für Orthopädie und Unfallchirurgie, Universitätsklinikum Heidelberg, Schlierbacher Landstraße 200a, 69118 Heidelberg, Germany.

E-mail address: daniel.heitzmann@med.uni-heidelberg.de (D.W.W. Heitzmann).

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the carbon leaf spring. However, Silverman et al. reported that a normal soleus muscle makes a greater contribution to propulsion than a prosthetic foot, while the prosthesis absorbs more energy during stance, reducing the overall body propulsion [9]. De Asha et al. reported a similar effect and a reduction in that "braking effect" when analysing a hydraulic ankle prosthetic foot [10]. Although this hydraulic ankle dissipates more energy during stance and produces a lower power output than similarly stiff ESAR feet, the participants in this study walked at a faster self-selected walking speed and preferred it conventional ESAR foot [10].

These two functional aspects of calf muscles, power generation and control of shank forward progression, are concurring functional requirements for prosthetic feet. The progression of the prosthetic shank depends on the flexibility of the prosthetic foot during 2nd rocker, while the foot lever is enhanced by higher stiffness. Fey et al. and Adamczyk et al. highlight that there is a compromise between a better body support with the help of a stiffer prosthetic foot and extra forward propulsion as the stiffness of the prosthetic foot decreases [11,12]. In theory, this compromise cannot be avoided with passive prosthetic feet [6] and may deteriorate when using a foot with a single carbon leaf spring, which solely defines forefoot stiffness in conventional ESAR feet. A high stiffness might provide body support in late stance, but at the same time will be possibly hindering in earlier gait phases. This assumption match anecdotal, clinical evidence as PTTA have the perception to 'climb over' the prosthetic-limb [10]. Thus, an ideal prosthetic foot design should offer a gait-phase adapted stiffness.

In addition to consequences on the side of the prosthesis, Morgenroth et al. pointed out that a reduced power generation in late stance of the trailing prosthetic limb can result in greater impact force and an increased knee varus moment of the leading sound limb at initial contact. An experimental foot investigated in their study produced significantly reduced loads on the sound side, as compared to conventional ESAR feet [13].

In this context, the Pro-Flex®[1] a novel prosthetic seems promising. It provides a serial layout of flexible carbon fibre leaf springs, connected by a multi-centre joint construction, with its main pivot mimicking an anatomical ankle, potentially allowing for adaptive "ankle" joint motion.

In order to determine the potential benefits of the Pro-Flex®[1] foot, the aim of this study was to compare these effects to a common ESAR foot, i.e., the Vari-Flex®[2] using conventional 3D gait analysis (CGA) and the unified deformable segment model approach (UD Power) [14].

We hypothesised that the novel prosthetic foot (NF) would show:

1. a more effective (i.e., closer to normal) prosthetic ankle range of motion (H1),
2. no detrimental effect on effective prosthetic ankle joint moment (H2),
3. a better (i.e., closer to normal) maximal power generation at push-off (H3),
4. reduced (i.e., beneficial) sound side loads (H4),

as compared to the conventional ESAR foot (CF) during self-selected walking speed on a paved floor.

2. Methods

2.1. Participants

Eleven participants, of whom ten were individuals with a unilateral trans-tibial amputation (PTTA) and K Level 3–4 (described, e.g., by Gailey et al. [15]), were included (Table 1). One participant with a transverse congenital deformity was included as her involved limb resembles a residual limb after a trans-tibial amputation in form and function. Exclusion criteria were residual limb issues such as edema, pressure sores or wounds and the need for walking aids (e.g. crutches, canes, etc.). Subjects were recruited through our institutional in-house prosthetics and orthotics department, and the outpatient clinic of the hospital. All eleven subjects were fitted at the in-house prosthetics and orthotics department. Their current, well-fitting socket was used throughout the study. Furthermore, subjective feedback was collected during data collection by unstructured interviews as reported in the online supplement.

Data were also collected from eleven age- and sex- matched, unimpaired individuals for reference purposes (REF, two women 37.2 ± 11.4years; 178.9 ± 8.1 cm; 76.4 ± 12.2 kg). Written, informed consent was given by all participants prior to data collection. The study was approved by the local institutional ethics committee and conforms to the Helsinki Declaration.

2.2. Prosthetic feet

The conventional foot (CF, Vari-Flex ®[2]) is a typical design originating from the Flex Foot, which was introduced in 1985 [16]. It consists of a J shaped spring and a heel leaf spring which is bolted to the J shaped spring (Fig. 1A CF).

The novel foot (NF, Pro-Flex®[1]) is a pilot production of a product that became commercially available in 2016. The design comprises a series of several carbon fibre leaf springs. A foot board (bottom blade), a short J-shaped spring (Top Blade), and a flat spring (Middle Blade/ Fig. 1A NF). The top and middle blades are connected via a linkage by three pivot points. During walking this mechanism allows for rolling motion around the main pivot, simulating the 2nd foot rocker in normal gait [7,8]. In the CF, forward progression is achieved via flexing the j shaped spring.

2.3. Study design

PTTA were initially fitted with CF by the same certified prosthetist utilising a L.A.S.A.R Posture®[3] and following the alignment recommendations of Blumentritt et al. [17]. PTTA were allowed to become familiar with the CF for two weeks before data collection. On the day of data collection, prior to measurements, all PTTA were first fitted with NF and, to become accustomed to it, walked for approximately 30–45 mins or 1.5 km, both indoors and outdoors around the hospital, over mixed terrains, including level ground, uneven ground, slopes with different gradients and stairs. The PTTA were able to rest during this period; however none of the PTTA needed a longer rest during the accommodation period for NF. Afterwards, data for NF were collected. Subsequently, the prosthetic foot was changed back to CF and subjects had a minimum of 15 mins to become re-accustomed to the prosthetic configuration, they had used previously. Finally, the CF gait data were collected.

Prosthetic alignment between NF and CF was intra-individually recreated utilising the L.A.S.A.R Posture®[3] as follows; immediately prior to data collection the vertical laser line was tagged on the CF prosthesis. Additionally, while fitted with the CF, a lateral height marking was added on the socket. Then, the CF – including the pylon – was removed by opening two screws at the proximal, female, pyramid adapter, in order to preserve the settings. NF was then attached using a suitable pylon to reproduce the height, marked with the CF attached. Alignment for NF was adjusted, such that the vertical laser line (L.A.S.A.R Posture®[3]) matched the marking of the CF prosthetic alignment. After gait analysis, NF and pylon were detached from the socket and the CF

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[1] Supplier of Pro-Flex® prosthetic foot, Össur Corporate, Reykjavik, Iceland

[2] Supplier of Vari-Flex® prosthetic foot, Össur Corporate, Reykjavik, Iceland

[3] Supplier of alignment testing device L.A.S.A.R Posture®, Otto Bock HealthCare GmbH, Duderstadt, Germany