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ORIGINAL ARTICLE

Comparison of the International Committee of the Red Cross Foot With the Solid Ankle Cushion Heel Foot During Gait: A Randomized Double-Blind Study

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Abstract

Objective: To compare the well-recognized solid ankle cushion heel (SACH) foot with the prosthetic foot developed by the International Committee of the Red Cross (CR Equipements SACH) during gait.

Design: Double-blind study was conducted to compare the influence on the biomechanics of gait of the CR Equipements SACH foot and the SACH foot.

Setting: University hospital research center.

Participants: Participants with unilateral transtibial amputation (N = 15) were included.

Interventions: Three-dimensional motion analysis system and 2 forceplates were used to capture body motion and ground reaction forces during gait at a self-selected speed and at 1.2m/s.

Main Outcome Measures: Nonparametric Wilcoxon matched-pairs tests were used to compare the 2 prosthetic feet with respect to their spatiotemporal (gait velocity, stride length, and percentage of stance phase), kinematic (range and peak angles of the pelvis, hip, knee, and ankle), and kinetic (peak moment and power of the hip, knee, and ankle) parameters.

Results: Compared with the SACH foot, the CR Equipements SACH foot demonstrated a significantly greater stance phase symmetry ratio (SACH: 94% vs CR Equipements SACH: 97%), a more extensive ankle range of motion in the sagittal plane (SACH: 7° vs CR Equipements SACH: 12°), a greater maximal dorsiflexion angle during the terminal stance phase (SACH: 10° vs CR Equipements SACH: 13°), and a higher ankle power (SACH: .31W/kg vs CR Equipements SACH: .40W/kg). No significant difference was found for the examined knee, hip, and pelvis parameters.

Conclusions: The CR Equipements SACH foot provides more symmetry and improves ankle kinematics and kinetics in the sagittal plane compared with the SACH foot. This study suggests that individuals using the CR Equipements SACH foot improve their gait biomechanics compared when using the SACH foot.

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War has played a fundamental role in increasing the occurrence of amputations around the world.[1-3] In the conflict countries, where the International Committee of the Red Cross (ICRC) carries out its mandate, a significant number of individuals with lower-limb amputations do not have access to an appropriately fitted prosthesis. Since 1979, the physical rehabilitation program of the ICRC[a] has provided more than 350,000 individuals with lower-limb prostheses around the world.[4]

In 1998, the ICRC developed and proposed a nonprofit prosthetic foot that was named the CR Equipements-solid ankle cushion heel (SACH) foot.[b] The CR Equipements SACH foot is manufactured by the company CR Equipements. Field studies have been conducted to improve the durability of the CR Equipements SACH foot.[4,5] Progress has been made in solving the primary problems of the CR Equipements SACH foot, which

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were linked to the breakdown of the sole of the forefoot and to the foot cover deterioration that occurs as a result of high-humidity exposure in tropical climates. To overcome these problems, the new foot manufacturing process aims at completing the polymerizing process and makes cells inert. At the present time, only 27% of the CR Equipements SACH feet that are distributed must be replaced after 16-19 months; by contrast, approximately 78% of the older version of the CR Equipements SACH foot required replacement after the same time period.[4,5] However, although the CR Equipements SACH foot is widely used throughout the world, and progress has been achieved in terms of providing this foot with greater durability, no study has evaluated the influence of this foot on the gait of its recipients.

One of the most important daily tasks for amputees is ambulation; successful ambulation is essential for societal reintegration[6] and could be influenced by the type of prosthetic equipment that these amputees possess.[7] Thus, the influence of numerous types of prosthetic feet on gait has been evaluated by a biomechanical approach that assesses these prostheses in terms of spatiotemporal, kinematic, and kinetic parameters (see Sagawa et al[8] for a review).

An important objective of analyses of the ambulation of individuals with lower-limb amputations is determining which prosthetic foot is able to provide the best gait velocity, spatiotemporal symmetry, mobility, and capacity to store and return energy.[8] In addition, an appropriately designed prosthetic foot could diminish the compensatory responses that occur in adjacent body segments.[9]

Most of the comparative studies that address the influence of prosthetic feet on gait use the conventional SACH foot manufactured by Otto Bock[c] as a reference, because the SACH foot is the most frequently used and studied. Therefore, its mechanical properties and its influence on the biomechanics of gait are well-known.[10-14]

Given the context previously described, the objective of this study was to determine the gait-related properties of the CR Equipements SACH foot with respect to spatiotemporal, kinematic, and kinetic parameters by comparing the CR Equipements SACH foot with the SACH foot in a group of individuals with traumatic unilateral transtibial amputation.

Methods

Participants

In total, 15 participants (3 women and 12 men) with unilateral transtibial amputation (table 1) were recruited to participate in this randomized double-blind study. The inclusion criteria for the study were the presence of a unilateral transtibial amputation that had been caused by either trauma or tumor, a level of functional ambulation of K3 or K4 according to the Amputee Mobility Predictor classification,[15] and had a minimum of 2 years of experience in walking with any prosthesis. The exclusion criteria for the study were an amputation related to vascular disease, an age that was <18 years old, and the presence of neurologic or orthopedic disorders that could affect the participants' gait or balance. None of the study participants had worn the examined prosthetic feet (ie, SACH and CR Equipements SACH feet) as a daily prosthesis prior to inclusion in the study protocol. All of the study participants completed an informed consent procedure before participating in this investigation.

List of abbreviations:

ESAR	energy storage and return
ICRC	International Committee of the Red Cross
SACH	solid ankle cushion heel
3D	three-dimensional

Evaluation protocol

The study protocol was approved by the local ethics committee. The CR Equipements SACH and SACH feet were compared and allocated to each participant in a randomized way.

All of the study participants had 3 gait evaluation sessions, including 1 session involving the use of their own foot (familiarization session), 1 session involving the use of the SACH foot, and 1 session involving the use of the CR Equipements SACH foot. The time period between each evaluation was 1 week.[16] Only the 2 last sessions were used to compare both feet (ie, SACH and CR Equipements SACH feet). Two qualified prosthetists performed all of the static and dynamic alignments of the prostheses, although each study participant consistently interacted with the same prosthetist. The study participants were blinded throughout the execution of the study protocol, whereas the evaluators were blinded until the end of the study's data analyses. To ensure that neither the participants nor the evaluators could recognize the types of foot prostheses that were used at a particular time, the study's prosthetists created a cosmetic covering that was used to cover both of the experimental foot types. Moreover, to avoid the confounding influence of shoe absorption effects during the gait evaluations, all of the study participants wore the same standardized flat shoes throughout the study protocol.

Description of the examined feet

The SACH foot (fig 1) has a contoured core and is composed of functional foam with a wooden keel. It can support a maximal weight of 125kg. Given its rigidity, it is typically prescribed for low-activity individuals. The SACH foot is also frequently prescribed because it is inexpensive, light, durable, and available in various heel heights, allowing its recipients to wear different types of shoes.

The CR Equipements SACH foot (fig 2) is similar to a SACH foot; however, in contrast to the original SACH foot, the CR Equipements SACH foot has a keel that is made of polypropylene. The CR Equipements SACH foot can support a maximal weight of 135kg.

Gait evaluation

A three-dimensional (3D) 12-camera Vicon motion analysis system[d] was used to capture the motion of the entire body during gait. Reflective markers were placed in accordance with the Davis et al protocol.[17] For the prosthetic side, 2 marker locations were estimated using the sound side as a guide (ie, knee joint center, lateral malleolus). Two force plates (AMTI[e]) embedded in the floor were used to capture the ground reaction forces. The motion and the force plate data were synchronized and sampled at 100Hz and 1000Hz, respectively. The marker trajectories and analog data were filtered using the predicted mean squared error[10] adaptive filter in version 1.7 of the Nexus software package. The joint kinematic and kinetic parameters were generated using the dynamic model Vicon Plug-in-Gait.[d] In addition, the joint moments were normalized for body weight (Nm/kg). For each participant, 3 good gait trials (ie, prosthetic foot on the force plate)