HHS Public Access
Author manuscript
Prosthet Orthot Int. Author manuscript; available in PMC 2016 February 01.

Published in final edited form as:
Prosthet Orthot Int. 2016 February ; 40(1): 75–82. doi:10.1177/0309364614545419.

Effects of physical exertion on trans-tibial prosthesis users' ability to accommodate alignment perturbations

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Abstract

Background—It has long been reported that a range of prosthesis alignments is acceptable in trans-tibial prosthetics. This range was shown to be smaller when walking on uneven surfaces. It has also been argued that findings on gait with prostheses that were obtained under laboratory conditions are limited in their applicability to real-life environments.

Objectives—This study investigated the hypothesis that efforts to compensate for suboptimal alignments by active users of trans-tibial prostheses become less effective when levels of physical exertion increase.

Study design—A 2 × 2 repeated-measures analysis of variance was conducted to compare the effects of physical exertion and subtle alignment perturbations on gait with trans-tibial prostheses.

Methods—The gait of eight subjects with trans-tibial amputation was analyzed when walking with two different prosthesis alignments and two different physical exertion levels. The main and interaction effects were statistically evaluated.

Results—Bilateral step length symmetry and measures of step variability within the same leg were found to be affected by the intervention. There was no significant effect on index variables that combined kinematic or kinetic measures.

Conclusion—Findings showed that persons with trans-tibial prostheses responded heterogeneously to the interventions. For most variables, the research hypothesis could not be confirmed.

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Author contributions: GF - study design, IRB application, data collection, post-processing, evaluation, article write-up, graphs, and tables. B.A.S.—subject recruitment, data interpretation, and article proof reading. KMO'C - study concept and article early draft revision. ROS - discussion and conclusions, and article proof reading. BJH - article revision, editing for content, and background and reference updating.

Declaration of conflicting interests: None declared.

Clinical relevance: Findings support the practice of allotting several sessions to the alignment of trans-tibial prostheses, as users' gait responds differently to perturbations when external factors (e.g. exertion) change. Furthermore, the found inhomogeneity in the population of persons with trans-tibial amputation supports the use of technical gait assessment methods in clinical practice.

Keywords

Gait; prosthetics; rehabilitation of prostheses users; rehabilitation; gait analysis

Background

Alignment of leg prostheses, for example, the spatial orientation of the functional components of the prosthesis with respect to each other, is generally a compromise between dynamic efficiency and static stability. Clinical alignment processes, which are intended to facilitate safe and effective use of a prosthesis, are informed by a multitude of factors specific to an individual patient, including residual limb dimensions, joint range of motion, and overall activity level.

It has been reported that a range of alignments may be deemed acceptable to trans-tibial prosthetic users.[1–4] This notion implies that once a level of acceptability has been reached, continued alignment efforts may be unnecessary. However, it has also been reported that the range of acceptable alignments may be reduced when users walk on uneven ground.[2] This indicates that the increased biomechanical and/or bioenergetic demands required for users to successfully negotiate challenging terrains may affect clinical acceptability of prosthetic alignment. Alignments obtained in the clinic or in a gait laboratory may also be limited by the idealized conditions in which alignment processes are performed (i.e. steady-state walking over flat, level terrain) and may not entirely translate to real-life situations.[5] Fatigue or exertion as an independent variable has not been widely included in previous alignment studies. Research on the effects of alignment perturbations under real-life conditions is therefore needed to investigate whether the range of acceptable alignments differs in situations in which users are challenged.

Prosthetic users may also have the ability to accommodate suboptimal prosthetic alignments. It could be reasoned that prosthesis users are capable of compensating for unfavorable subtle alignment perturbations,[6–10] so that their gait does not visibly change as the consequence of the alignment change. Such a compensation mechanism may be biomechanically or bioenergetically disadvantageous, as it would require detrimental or counterproductive efforts from the prosthesis user. This can be illustrated with a simple example: a small increase in prosthesis length may be compensated by circumduction or hip hiking of the prosthetic leg during swing phase. A less obvious compensation pattern may include vaulting on the contralateral side to provide clearance during the prosthesis swing phase. However, such a strategy is also fairly tiresome which is why users' potential to accommodate suboptimal alignments may change as they fatigue. Fatigue has been shown to detrimentally affect gait and induce gait compensations in persons with limb loss.[11,12] With increasing physical exertion, compensatory efforts should become less effective, and the effect of subtle misalignments may become increasingly measurable. In the previous example, the ankle plantar-flexors would provide less of an exaggerated push-off impulse and the necessary ground clearance would instead have to be obtained by more readily observed prosthetic leg circumduction.

The purpose of this research was to investigate whether trans-tibial prostheses are differentially susceptible to alignment perturbations at different levels of physical exertion. It was hypothesized that subtle perturbations to foot plantar-flexion would have a greater effect on users' quality of gait, for example, gait symmetry and variability, when they are physically exerted than prior to being exerted. Gait symmetry has been widely used as an indicator of optimal alignment,[3,11–15] presumably because it represents one of the major objectives in prosthetic intervention, namely, restoration of unimpaired healthy locomotion. A related measure to assess alignment is step-to-step variability, which has been interpreted as an indicator of gait stability.[16,17] It was also investigated whether kinematic and kinetic outcomes, for example, joint angles and moments, are similarly affected by foot plantar-flexion when users are exerted. Joint angles are assessed to describe leg motion and joint moments indicate leg utilization.

Methods

Subjects were recruited by advertising participation in local amputee support groups, prosthetics workshops, and online media. Inclusion criteria were age of 18 years or greater, unilateral trans-tibial amputation, use of a prosthesis, moderate or higher activity level (K-Level 2 to 4[18]), and ability to walk pain-free and without aids for at least 30 min. Exclusion criteria were skin breakdown in the residual limb or use of a prosthesis that prohibited temporary perturbation of ankle plantar-flexion. Recruiting procedures and study protocol were approved by the University of Wisconsin–Milwaukee Institutional Review Board. Informed written consent was obtained.

Retroreflective markers were applied to subjects' anatomical landmarks. A modified Cleveland Clinic marker set was used, including three-marker clusters on the lateral aspects of thigh and shank. Foot markers were placed on the malleoli, metatarsal heads, anterior aspect of the halluces, and posterior aspect of the calcanei. Knee markers were placed lateral and medial of the compromise knee center of rotation described by Nietert.[19] Marker placement on the prostheses was mirrored from the sound leg. Pelvis markers were placed over the *anterior* superior iliac spines and sacrum. Three head markers were distributed equidistantly around the horizontal circumference of the skull.

Subjects, wearing their original prostheses, walked at self-selected speed through the capture volume of a motion analysis laboratory. Kinematics were captured at 100 Hz using a 10-camera system (Cortex®; Motion Analysis Corporation, Santa Rosa, CA, USA) and kinematics were measured at 1000 Hz with three force plates (AMTI, Watertown, MA, USA). Sampling rates were comparable to studies of persons with lower limb amputation reported in the literature.[20–22] Gait analysis data were post-processed using OrthoTrak 6.5 (Motion Analysis Corporation), consistent with previously described methods.[23]

All prosthetic modifications were performed by a trained prosthetist. Subjects' initial alignment and gait were reviewed by the study prosthetist and determined to be clinically acceptable. Prior to data collection, plumb lines were transferred to socket and foot of the doffed prosthesis to document subjects' original alignments. Subsequently, prosthetic foot plantar-flexion was increased by 2°, as measured by a goniometer (Protractor; Prestige

Medical, Northridge, CA, USA). The investigators selected 2° as a compromise between producing the desired effect (i.e. subtle gait deviations under fatigued conditions) and ensuring subjects' safety (i.e. limiting alignment perturbations to avoid undue risk of injury). The magnitude of this deliberately subtle alignment perturbation was also within the "range of acceptable" alignment in other studies[2,3,24–28] and was therefore believed to not affect subjects in the baseline condition, but when they were exerted. Set screw rotations that produced a 2° plantar-flexion change to each subject's foot were documented and used to rapidly perturb alignment during subsequent experiments.

Subjects were asked to walk over the force platforms. To maximize the number of usable trials, force platform locations were noted to subjects. They were instructed to target the force plates in stride, as possible, while maintaining a natural walking pattern. This modification of standard protocol where subjects are blinded to force plate location has been shown to have minimal effects on the data[29,30] and was deemed acceptable in this study so as to avoid inconsistently fatiguing subjects across multiple trials. As degree of exertion was an independent variable in this study, it was purposefully controlled. At low exertion, the physical demands of multiple walking trials would lead to an undesirable increase in exertion. Conversely, at high exertion, multiple walking trials may allow for an undesirable recovery from the increased exertion level. Accordingly, only one trial per subject was collected at each condition and exertion level.

Data were collected under two conditions, baseline and increased exertion. For each condition, two trials were conducted. For the first trial, the subject walked over the force platforms in their normal, optimally aligned prosthesis. Immediately after the subject passed through the capture volume, their prosthetic foot was rapidly adjusted, that is, plantar-flexed 2°, without removing the prosthesis. For the second trial, the subject was asked to again walk through the capture volume with the plantar-flexed prosthesis. After the second trial, the subject's normal alignment was restored and they were asked to walk continuously through a looped path through the building, which included multiple turns, doorways, and staircases. Subjects were instructed to continue walking until their rating of perceived exertion (RPE) reached a "strong" level, as described by a level 5 of Borg's "Category Ratio" 11-point CR10 scale.[31] The CR10 scale lists paired response options that include both numerical ratings and descriptive categories (e.g. "3" and "moderate") to enhance subjects' ability to indicate their RPE. Once the RPE level of 5 was reported—usually after about 10–30 min of walking—two additional trials (3 and 4) were conducted, using the protocol described in trials 1 and 2. In total, four different conditions were assessed as follows:

1. Normal alignment and low exertion (PRE/NORM),
2. Perturbed plantar-flexion and low exertion (PRE/PF),
3. Normal alignment and strong exertion (POST/NORM),
4. Perturbed plantar-flexion and strong exertion (POST/PF).

Subjects' heart rates during the trials were also measured using a heart rate monitor (PHRM36; Pyle Audio, Brooklyn, NY, USA) in order to quantify acute exertion. However,

the decision to begin trials 3 and 4, that is, exerted trials, was based upon subjects' RPE. The rationale for this protocol was to recreate a natural quality of exertion, as it would occur from ambulating with a prosthesis. In cases where walking did not significantly raise the subject's exertion level, they were asked to ascend and descend stairs several times to induce additional exertion.

Following data collection, gaps in kinematic marker position data were filled and temporal–spatial, kinematic, and kinetic variables of interest were extracted using Cortex software (Motion Analysis Corporation). Outcome variables included for both legs were as follows: step length, stance phase duration, knee flexion angle, ankle flexion angle (Figure 1), knee flexion moment, ankle flexion moment, ankle abduction moment, ankle rotation moment, pelvis tilt, and pelvis obliquity. Maxima and the time of maxima were extracted for the following variables: knee flexion angle, ankle flexion angle, knee flexion moment, ankle flexion moment, ankle abduction moment, ankle rotation moment, pelvis tilt, and pelvis obliquity.

Standardized indices[32–34] of asymmetry for each outcome variable were calculated by dividing the absolute difference between limbs by their mean. Indices are non-dimensional and a value of 0 signifies perfect bilateral symmetry.[3] Asymmetry indices across variables were averaged to compute an overall asymmetry index, as well as asymmetry sub-indices for only kinetics and kinematics outcomes.[35] Leg-wise effects were investigated by comparing interventions across conditions within legs, including the two additional variables of maximal pelvis obliquity and maximal pelvis tilt.

Prior to conducting statistical analyses, collected data were tested for the assumption of normality. Repeated-measures analysis of variance (RMANOVA) or Friedman tests and respective post hoc tests were conducted, as appropriate, based on the results of the normality testing. Given the small sample and exploratory nature of these experiments, no adjustments were made to account for multiple comparisons. Statistical evaluations were completed using IBM SPSS, version 19. A critical alpha of 0.05 was defined.

Results

Eight subjects (mean age = 51 years, standard deviation (SD) = 12 years; mean weight = 90 kg, SD = 19 kg; mean height = 181 cm, SD = 9 cm) participated in the study (Table 1). Subjects were generally active and experienced prosthetic users. Averages of self-selected gait velocities were 0.73 m/s in the rested conditions (PRE/NORM and PRE/PF) and between 0.69 m/s (POST/NORM) and 0.76 m/s (POST/PF) in the exerted conditions. Average gait speed differences between rested and exerted conditions were not significant ($p = 0.94$).

The normality assumption was found to be violated for the majority of the individual asymmetry indices. Therefore, statistical tests were conducted using the Friedman test for repeated-measures analysis and the Wilcoxon signed-rank test for post hoc comparisons of conditions. The combined gait asymmetry indices met the normality assumption and were analyzed by RMANOVA.

Comparison of symmetry variables and indices

Univariate comparisons showed that step length asymmetry differed across conditions (χ^2 = 7.8, *p* = 0.050). Post hoc tests showed that PRE/NORM step length asymmetry was significantly greater than PRE/PF (*z* = 1.960, *p* = 0.050) asymmetry. PRE/PF step length asymmetry was, however, significantly greater than POST/PF asymmetry (*z* = 2.380, *p* = 0.017) (Figure 2). This indicates that after increasing the foot plantar-flexion, asymmetry in step length was improved at low levels of exertion, but not at higher level of exertion. Differences in symmetry indices for all other individual temporal-spatial, kinematic, or kinetic variables were not significant.

The computed overall symmetry index shows no indication that exertion or subtle alignment perturbation had effects on gait symmetry, or that a significant interaction effect existed. Likewise, no differences in gait symmetry were found via the kinematic or kinetic asymmetry indices. Asymmetry indices for the sample and individual subjects are shown in Figures 3 and 4.

Comparison of gait variables within the same leg

Within-leg differences in peak knee flexion (χ^2 = 8.2, *p* = 0.042), peak knee moment (χ^2 = 9.0, *p* = 0.029), and peak dorsiflexion moment (χ^2 = 8.5, *p* = 0.037) were found for the prosthesis side. Post hoc tests showed POST/PF peak knee flexion was significantly higher than PRE/PF (*z* = 2.275, *p* = 0.023) knee flexion. POST/NORM peak knee moment was significantly greater than PRE/NORM (*z* = 2.511, *p* = 0.012) and PRE/PF (*z* = 2.275, *p* = 0.023) knee moments. Finally, PRE/NORM peak dorsiflexion moment was significantly greater than POST/NORM (*z* = 2.353, *p* = 0.019) dorsiflexion moment. No significant within-leg differences were found for the contralateral side. Similarly, no significant differences in pelvis tilt or obliquity were found between any of the studied conditions.

Discussion

It was shown that few aspects of prosthesis users' gait symmetry appear to change with perturbed alignment and an increased level of exertion. A noted exception was that subtle alignment perturbations (2° plantar-flexion) that had an immediate positive effect on step length symmetry were mitigated when subjects were fatigued.

Previous studies reported that subtle alignment changes do not significantly affect gait symmetry.[2,3] While the indices described in those studies were slightly different than those used here, our findings confirm that neither the kinematics nor the kinetics symmetry indices were significantly affected by plantar-flexion or exertion. However, the difference in the step length asymmetry measured in our study contradicts previous findings. It has often been reported that no significant effect of alignment perturbation could be identified on variables contributing to step length, such as walking speed,[3,9,24,25,36-38] cadence,[9,24,37,38] and bilateral ground reaction forces.[3,9,24,39,40] Findings of previous studies, such as by Chow et al.,[3] who concluded that within the range of acceptable alignments, various gait parameters have differing optima over the continuum of alignment alterations, may draw into question the clinical utility of symmetry indices for the evaluation of gait. This conclusion was

supported by our data, as no significant differences in gait kinematics or gait kinetics indices were found.

Although the combined indices of bilateral gait symmetry did not indicate significant effects from the subtle alignment perturbation performed or the increased exertion experienced by the subjects, the individual effects appeared to be considerable (Figure 4). Large individual differences between subjects' results demonstrate how heterogeneous amputee gait responds to interventions of alignment perturbation and exertion. Considering that individual trends across subject varied markedly in magnitude and orientation, it could be debated whether generalizable outcomes should be expected.

Individual symmetry comparisons (Figure 4) showed no consistent trends, but rather revealed that in some cases the asymmetry increased with plantar-flexion and/or exertion and decreased in others. An explanation for this may be that individuals varied in their fitness level and motivation. To reach an RPE level of 5, Subject 2, for instance, raised his heart rate from 65 to 139 beats per minute (BPM), whereas Subject 3 recorded a maximal heart rate increase from 71 to 102 BPM. Gait asymmetry data of these two individuals as they responded to the interventions follow opposing trends (Figure 4).

An interesting finding was that for some subjects (specifically 4, 5, 7, and 8), changes in the kinematics index were inversely related to changes in the kinetics index. This suggests that measurement of kinematic asymmetry (as might be done with observational gait analysis) is not indicative of kinetic changes that may affect the prosthesis user. Thus, there may be a need for clinical methods to assess kinetic parameters.

The majority of subjects had no sizeable decrease in symmetry as a result of the combined alignment perturbation and exertion. According to our hypothesis, there would be generally a negative effect on gait symmetry when an alignment change is made and when the prosthesis user gets too exhausted to accommodate the perturbation. Our preliminary data lead to the conclusion that this hypothesis should be rejected, at least for the modest alignment changes made here.

However, alternative explanations for our findings may be tested in future studies. For example, some participants of this study may have experienced positive, short-term effects from the applied alignment perturbation that might become more apparent over a longer period of acclimation. A study that required users to wear the adjusted prosthesis for a longer period of time may show more pronounced effects. Furthermore, there is a possibility that subjects' prostheses were not optimally aligned, and that the modest alignment perturbation we applied may have improved the subject's alignment. A study with larger or multiple, incremental alignment perturbations (including an increase in dorsiflexion) may address that limitation potentially present in this study. It appears recommendable to include perceived alignment quality as a dependent variable as well.

It is also possible that the exertion induced in this study was not sufficiently large for subjects to feel the effects of the perturbed alignment. As noted, the magnitude of the alignment was fairly subtle and the degree of physical and mental exhaustion that may be needed to challenge control and energetics of the prosthesis user's gait pattern may be great.

Amending the protocol to induce higher levels of exertion, however, may raise ethical concerns about putting subjects at-risk for fatigue-related injury. Furthermore, identifying subjects capable of such exertion may limit the target population, as it is unadvisable to subject some prosthesis users to strenuous exertion protocols. Furthermore, a measure of sincerity in subjects' self-reporting of exertion levels may have to be included in future studies.

Absolute accuracy and reliability of alignment changes and exertion measurements in this study were also limited by our protocol. Because subjects were expected to rapidly recover from their exerted state, we wanted to apply alignment changes quickly before the subject's exertion level returned to normal. Changing the alignment took at least 20 s, which for most subjects was enough time to substantially lower their heart rates (by up to 10 BPM). This suggests that level of exertion during testing may have been lower than desired or varied across subjects. The attempt to reduce the number of alignment changes also disallowed an otherwise desirable randomization of trials.

A final limitation is that no homogenization of prosthetic components or designs was attempted. Here, it was deemed impractical to standardize these variables. Instead, we assumed that subjects' prescribed prostheses were optimally designed, built, and functioning. Future efforts may consider standardization of components to control for these factors. Doing so would add to the expense and time of the study but may limit the number of potentially confounding variables.

Conclusion

The results of this study suggest that the interactions of exertion and alignment are complex and do differentially affect prosthetic users. While our findings contradict the initial hypothesis that the amputee gait pattern at elevated levels of exertion (e.g. under real-life conditions) would be worse than the one displayed at low levels of exertion (e.g. during optimization sessions in the prosthetics laboratory), it remains a considerable finding that on an individual basis the gait pattern does change with exertion after all. For clinical purposes, this could suggest it may be desirable to let patients walk on a new prosthesis until strongly exerted, before the final alignment rectification is attempted. Our results support the notion that there is good reason for multiple alignment sessions, and that a prosthesis alignment cannot be optimized within one session. It is also suggested to allow amputee's exertion levels to increase during alignment sessions. Furthermore, kinetics parameters should be considered in the assessment of gait symmetry in amputees, as they are not always proportionally related to kinematics parameters.

Amputee gait biomechanics need to be considered on an individual basis, and future work should address the assessment of individual effects of prosthesis alignment changes. Mobile data collection methods may be used for that purpose. Mobile data collection would also allow measurement of within-trial variability, a potentially important outcome that was found to be affected by exertion in this study. By evaluating a number of consecutive steps, investigators might be able to more accurately estimate variance between trials or interventions.

Acknowledgments

Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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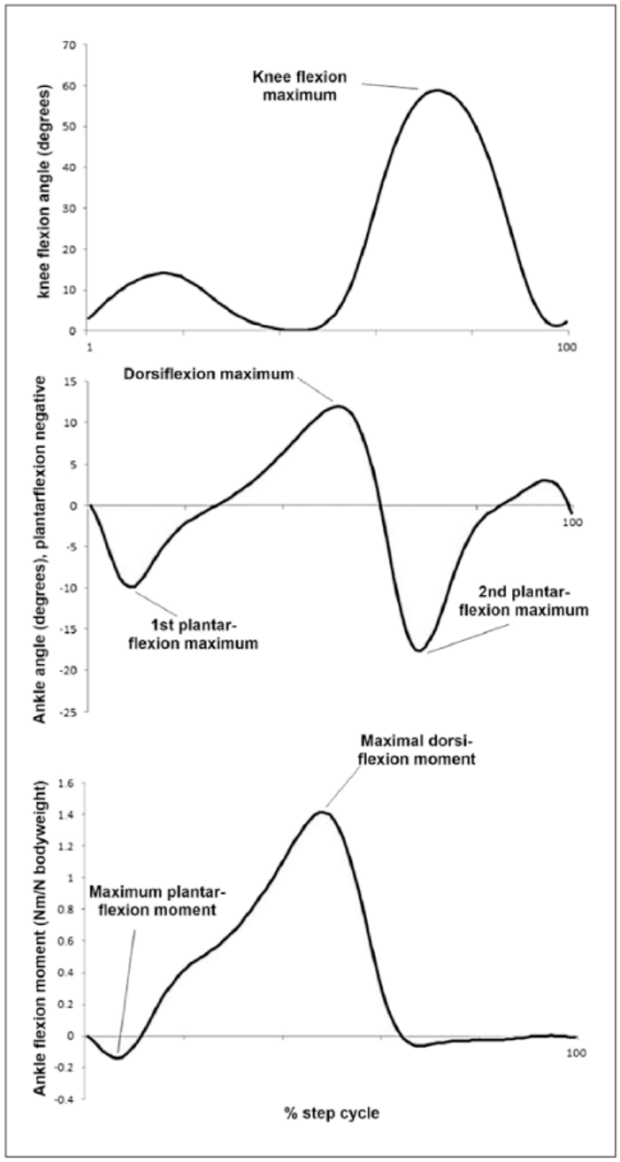

Figure 1.

Illustration of the definition of a subset of landmark data points used for analysis of gait curves. Magnitude and timing of the marked peaks were evaluated.

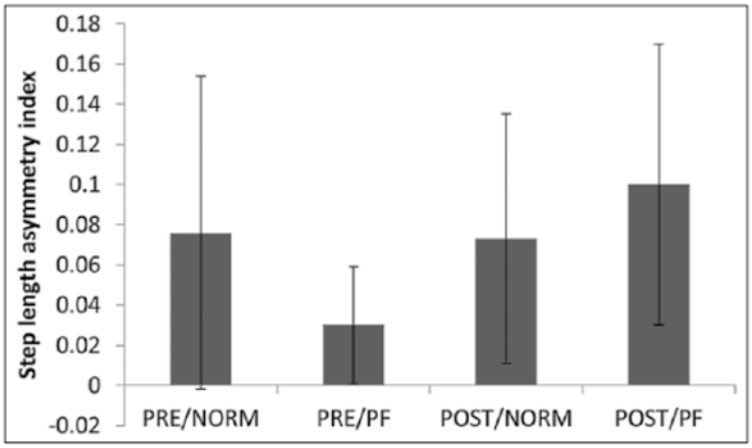

Figure 2.

Step length asymmetry means and standard deviations over the four tested walking conditions. Differences between PRE/NORM and PRE/PF as well as between PRE/PF and POST/PF are significant at the 0.05 level.

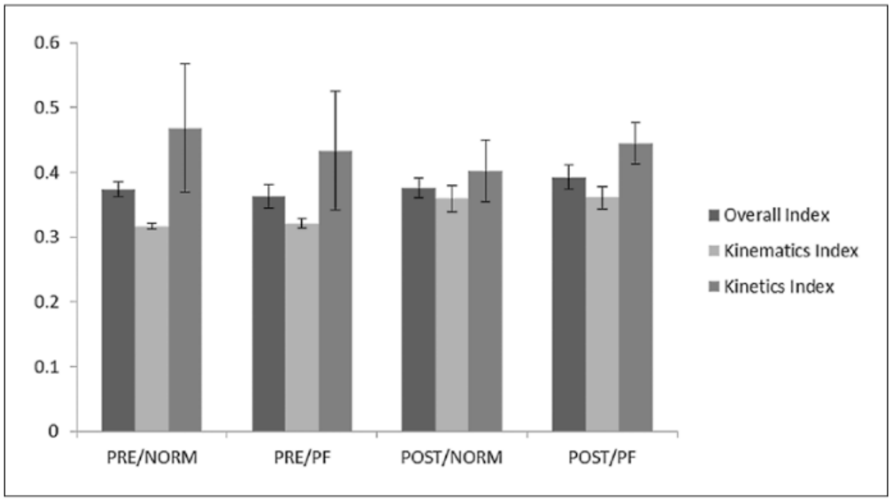

Figure 3.
Comparison of asymmetry indices, averaged over all eight subjects. Perfect bilateral symmetry would be represented by an index value of 0. Error bars illustrate the variance over the sample. Differences were not statistically significant.

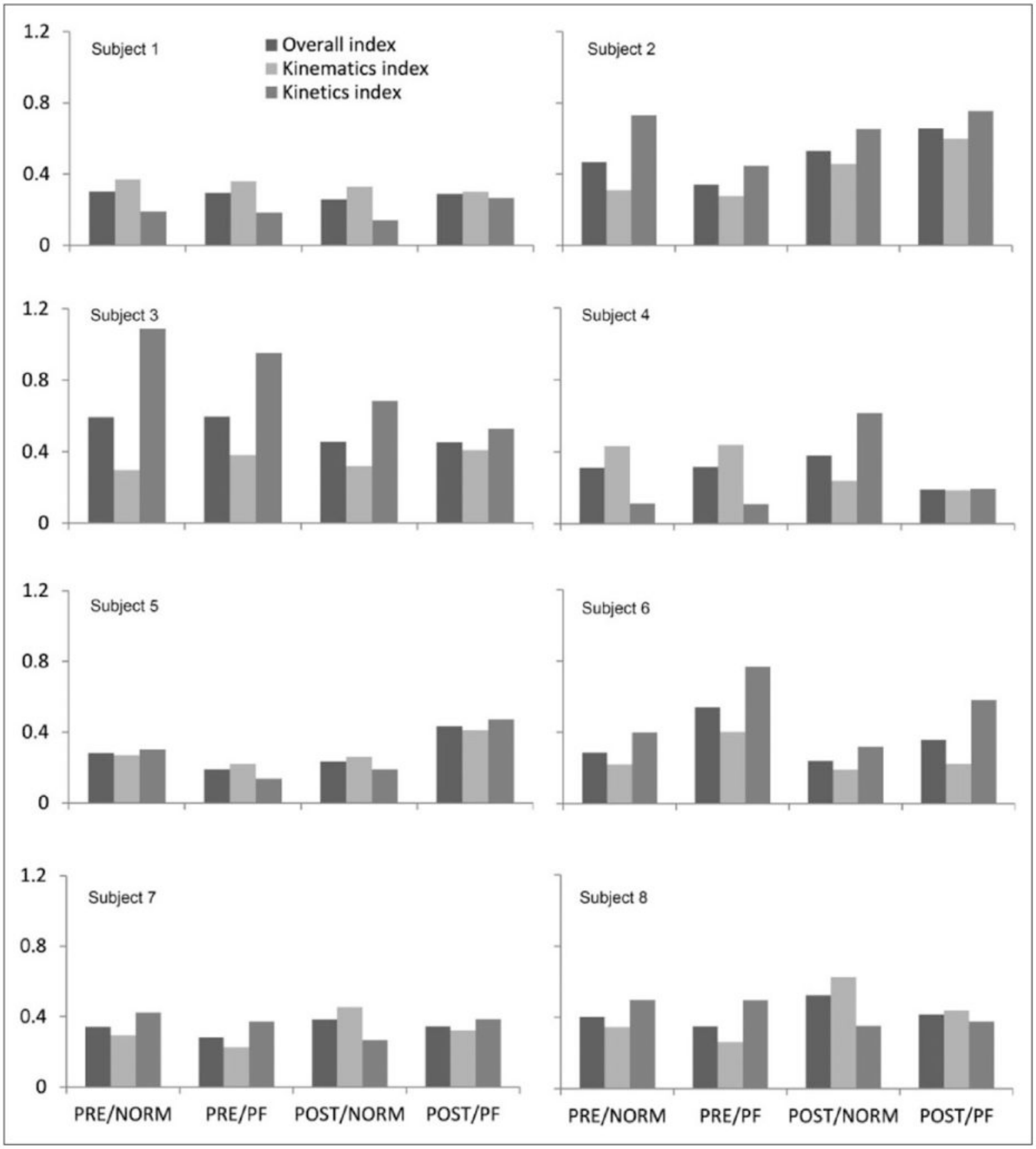

Figure 4.
Individual asymmetry indices for all eight subjects. Perfect bilateral symmetry would be represented by an index value of 0. One step per subject and condition was analyzed.

Table 1

Demographic and anthropometric information on study subjects.

Subject number	Sex	Age (years)	Weight (kg)	Height (cm)	Residual limb length (cm)	Time since fitting (years)	Preferred walking speed (m/s)	Heart rate rested/exerted	K-level
1	F	46	64	168	14	0.5	1.45	75/140	4
2	M	29	81	179	17	5	1.28	65/139	4
3	M	59	118	188	22.5	2	1.13	71/102	2
4	M	50	82	187	20	10	1.20	60/130	4
5	M	59	82	190	18	5	1.42	75/134	3
6	M	60	91	173	15	8	1.27	85/138	3
7	M	38	84	173	23	2	1.35	84/162	3
8	M	65	118	189	23	3	1.52	88/141	4