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Effect of prosthetic alignment on gait and biomechanical loading in individuals with transfemoral amputation: A preliminary study

Tengyu Zhang[a,b,c], Xuefei Bai[b,d], Fei Liu[b], Yubo Fan[a,b,c,e,*]

[a] School of Biological Science and Medical Engineering, Beihang University, No.37, Xueyuan Road, haidian district, Beijing, China
[b] National Research Center for Rehabilitation Technical Aids, No.1, Ronghuazhonglu, BDA, Beijing, China
[c] Beijing Key Laboratory of Rehabilitation Technical Aids for Old-Age Disability, No. 1, Ronghuazhonglu, BDA, Beijing, China
[d] Key Laboratory of Human Motion Analysis and Rehabilitation Technology of the Ministry of Civil Affairs, No. 1, Ronghuazhonglu, BDA, Beijing, China
[e] Beijing Advanced Innovation Centre for Biomedical Engineering, Beihang University, No. 37, Xueyuan Road, haidian district, Beijing, China

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ABSTRACT

Background: Inappropriate biomechanical loading usually leads to a high incidence of hip and knee osteoarthritis (OA) in individuals with lower-limb amputation, and prosthetic alignment may be an important influencing factor. The effect of alignment on the lower limb loading remains quantitatively unclear, and the relationship between malalignment and joint diseases is undefined.
Research question: How does alignment affect spatiotemporal gait parameters and ground reaction force (GRF) in individuals with transfemoral amputation?
Methods: Gait tests of 10 individuals with transfemoral amputation were performed with recommended alignment and eight malalignments, including 10 mm socket translation (anterior, posterior, medial, and lateral) and 6° socket angular changes (flexion, extension, abduction, and adduction). Fifteen individuals without amputation were recruited as a control group. The differences in spatiotemporal and GRF parameters under different alignments were analyzed and compared with those of the control group. Statistical analyses were performed by one-way ANOVA, repeated measure multivariate ANOVA, and paired t tests.
Results: The medial GRF peaks and impulse on both sides and load rate on the intact side are significantly higher than those of the control group ($P < 0.0056$). The propulsive and braking peaks, vertical impulse, and medial and vertical load rates of GRF on the intact side are higher than those on the residual side ($P < 0.05$). The alignment of socket adduction significantly increases medial GRF peak and impulse on both sides ($P < 0.0056$).
Significance: Alignments exert remarkable and complicated effects on the biomechanical performance. The considerably higher GRF on the intact side of the individuals with transfemoral amputation may lead to internal stress changes of the intact joint, which may be an inducement for high incidence of joint diseases. Probably due to the increased lateral deviation of the center of gravity, the socket adduction alignment significantly increases medial GRF, which may lead to an increased risk of knee OA.

1. Introduction

The incidence of hip and knee osteoarthritis (OA) in individuals with lower-limb amputation is much higher than that in individuals without amputation [1–4]. This higher incidence may be related to biomechanical changes after amputation. Mechanical overload of a joint is an important risk factor for OA [5]. However, prosthetic alignment directly affects the biomechanical loading on lower limbs, such as ground reaction force (GRF), joint contact force, etc. Inappropriate alignment may cause instability, abnormal gait, increased loading [6], finally resulting in joint injury [7]. Clinical prosthetic alignment is usually optimized in accordance with visual gait observation from prosthetists and patient's feedback [8,9]. However, when the alignment changes slightly, individuals with amputation can adapt to the change using different compensatory strategies, such as to make the change in gait unobvious [10,11]. Although changes in kinematics parameters caused by different alignments may not be obvious [12], changes in mechanical loading on the lower limbs are sometimes considerable [6,13,14], but cannot be visually observed by prosthetists. Therefore, quantitative analyses of the mechanical loading changes caused by different alignments are necessary.

GRF is an important biomechanical parameter in studying the

* Corresponding author at: School of Biological Science and Medical Engineering, Beihang University, No.37, Xueyuan Road, haidian district, Beijing, China.
E-mail address: yubofan@buaa.edu.cn (Y. Fan).

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changes in loading on the lower limbs caused by amputation [15–18]. Several scholars have studied the effect of different prosthesis alignments on the GRF of individuals with lower-limb amputation. Pinzur et al. [6] analyzed the difference in the vertical GRF peak and impulse of individuals with transtibial amputation under different alignments. They found that the peak of vertical GRF has significant differences between the intact and residual sides but shows no significant differences between initial alignment and malalignment. Beyaert et al. [19] obtained similar conclusions on the effect of alignment on GRF peak. Tominaga et al. [20] performed a comparative analysis of the GRF peak and impulse of the residual limb for individuals with transtibial amputation running under different alignments, and found several significant differences. Velzen et al. [21] found that the alignment change considerably affects the anteroposterior GRF peak but marginally affects vertical and lateral GRF. Fiedler et al. [9] found that GRF parameters are correlated with the alignment quality of the prosthesis.

Although the effect of alignment on biomechanical loading has been studied, all of the above-mentioned studies have been performed on individuals with transtibial amputation, and some of them have only studied the biomechanical parameters on the residual side. Previous investigations have shown that the incidence of hip and knee pain or OA is much higher in individuals with transfemoral amputation than in transtibial ones [3], and the incidence of hip OA on the intact side is higher than that on the residual side [4,22,23]. Therefore, the effect of alignment on individuals with transfemoral amputation also deserves attention, and the effect on the intact and residual sides should be considered simultaneously. In this research, the spatiotemporal gait and GRF parameters of individuals with unilateral transfemoral amputation under various alignment conditions were analyzed, and the differences between the intact and residual sides were compared. The aim was to study the effect of different prosthetic alignments on the spatiotemporal gait and GRF parameters in individuals with transfemoral amputation, and analyze the possible adverse effects of malalignments.

2. Methods

2.1. Subjects

Ten individuals with a transfemoral amputation (Table 1) participated in the study, and fifteen individuals without amputation were recruited as the control group. The inclusion criteria of individuals with amputation were (1) unilateral transfemoral amputation, (2) using prosthesis for at least 6 months, (3) the length of residual limb is suitable for installing an alignment adjustment device on the prosthesis, (4) the intact joints have no sickness affecting the movement, and (5) ability to walk under malalignment conditions. All individuals with amputation used the Ottobock 3R78 prosthetic knee and SACH-type foot in this study. The study was approved by the Ethics Committee of the Rehabilitation Hospital of National Research Center for Rehabilitation Technical Aids. All subjects voluntarily signed an informed consent form prior to data collection.

2.2. Instruments

A motion capture system of eight cameras (Vicon, Oxford Metrics Limited, UK) with 100 Hz sampling frequency was used for kinematic data collection. Sixteen markers were placed in accordance with the Vicon Plug-in-Gait lower body marker set [24]. GRF was recorded with two force platforms (OR-65, AMTI, USA) at the center of a 10 m walkway with a sampling frequency of 1.5 kHz. A translation regulator (10A40/A, Ossur, Iceland) was installed between the socket and prosthesis for translational alignment adjustment. The angular alignment adjustment was performed by adjusting the connector between the socket and translation regulator, and the adjustment angle was determined using a laser alignment instrument and angulometer.

2.3. Protocol

The alignment of each prosthesis was performed by the same certified prosthetist. The bench and static alignment were performed following the recommendations of the manufacturer. Then, the alignment was adjusted during the dynamic trial fitting. When the alignment state satisfied both the prosthetist and subject, it was defined as the initial alignment. On this basis, eight malalignments were adjusted (Fig. 1), including 10 mm socket translational alignment changes (anterior, posterior, medial, and lateral) and 6° socket angular alignment changes (flexion, extension, abduction, and adduction).

In the test, the subjects walked at their self-selected speed. Each subject with amputation was tested first under initial alignment. Then, the malalignments were performed in a random order. After the adjustment of each alignment, the subject walked for 2 min to adapt to that alignment. Under each alignment, data of eight trials was used for subsequent analysis.

A 6 Hz Butterworth low-pass filtering was applied on the camera and force platform data, and the GRF was normalized by body weight. The gait events were extracted on the basis of the trajectory of markers on the heel and GRF data, then the spatiotemporal gait parameters (speed, stride length, stride width, gait cycle time, double support time, step length, step time and stance time) were calculated. Where, step time represents the period from the initial contact at the contralateral side to the initial contact at the ipsilateral side, while step length represents the distance from the heel of contralateral side contact the ground to the heel of ipsilateral side contact the ground. Thereafter, the load rate, peak and impulse of GRF were calculated. The load rate was calculated as the slope of the GRF curve between foot strike and the first peak. The impulse, which reflected the continuous cumulative effect of force during the gait cycle, was determined by integrating the GRF curves. The intact-to-residual ratio of GRF impulse was computed to evaluate loading symmetry.

Table 1
Characteristics of individuals with amputation.

ID	Gender	Age	Height (cm)	Body mass (kg)	Cause of amputation	Duration of amputation (years)	K-Level	Amputation side	Habitual prosthesis	Type of socket	Suspension method
1	Male	27	169	66	Trauma	21	4	Left	3R80	ischial containment	suction
2	Male	25	173	64	Trauma	13	4	Left	3R80	ischial containment	suction
3	Male	33	172	80	Trauma	7	3	Right	JB950	ischial containment	suction
4	Female	29	161	68	Tumor	1	2	Left	3R106	ischial containment	suction
5	Male	52	172	70	Trauma	2	3	Right	3R78	ischial containment	suction
6	Male	33	169	64	Trauma	6	3	Right	JB850	ischial containment	suction
7	Male	24	170	61	Tumor	12	4	Left	JB850	ischial containment	suction
8	Male	32	172	70	Trauma	1	3	Left	3R80	ischial containment	suction
9	Female	28	175	60	Trauma	3	3	Left	3R106	ischial containment	suction
10	Male	32	172	73	Trauma	14	3	Left	JB501	ischial containment	suction

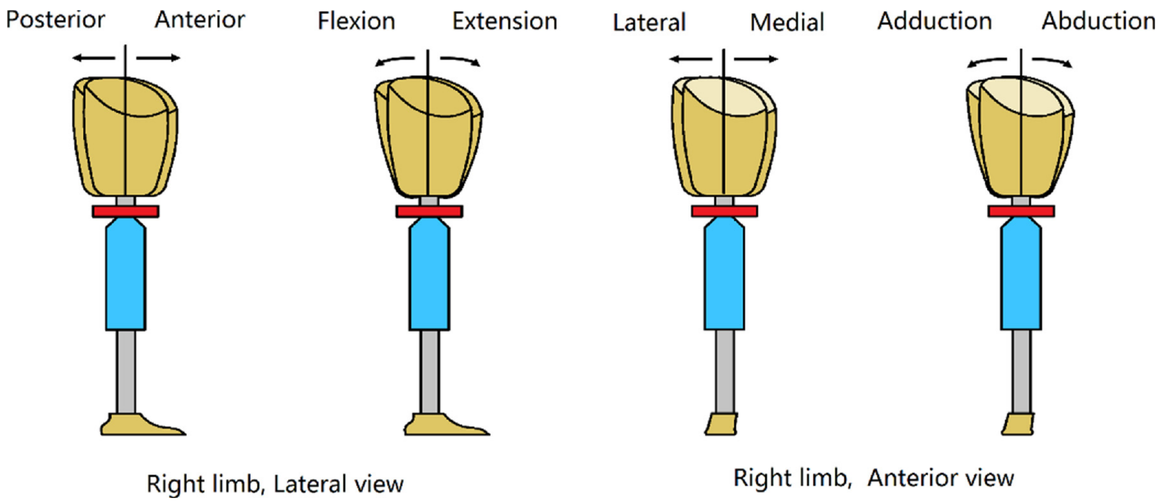

Fig. 1. Alignment conditions in this study.

Table 2
The spatiotemporal parameters of individuals with amputation and the control group.

Alignment	Speed (m/s)	Stride Length (m)	Stride width (m)	Step Length (m)	
				Intact	Residual
IA	0.88 ± 0.15[§]	1.10 ± 0.08[§]	0.19 ± 0.04[§]	0.54 ± 0.06	0.55 ± 0.07
ANT	0.89 ± 0.15[§]	1.10 ± 0.08[§]	0.18 ± 0.04[§]	0.56 ± 0.08	0.54 ± 0.09
POST	0.89 ± 0.15[§]	1.09 ± 0.09[§]	0.19 ± 0.03[§]	0.53 ± 0.05[§]	0.56 ± 0.07
MED	0.88 ± 0.13[§]	1.09 ± 0.07[§]	0.19 ± 0.04[§]	0.54 ± 0.08	0.56 ± 0.07
LAT	0.89 ± 0.13[§]	1.09 ± 0.08[§]	0.22 ± 0.03[§]	0.53 ± 0.04[§]	0.57 ± 0.07
FLEX	0.89 ± 0.15[§]	1.09 ± 0.09[§]	0.22 ± 0.05[§]	0.55 ± 0.05	0.54 ± 0.08
EXT	0.86 ± 0.14[§]	1.08 ± 0.07[§]	0.18 ± 0.03[§]	0.49 ± 0.08[§]	0.59 ± 0.05
ADD	0.87 ± 0.15[§]	1.08 ± 0.10[§]	0.20 ± 0.04[§]	0.52 ± 0.10[§]	0.56 ± 0.06
ABD	0.88 ± 0.15[§]	1.10 ± 0.08[§]	0.20 ± 0.06[§]	0.53 ± 0.07[§]	0.57 ± 0.05
CG	1.09 ± 0.11	1.22 ± 0.08	0.11 ± 0.02	0.62 ± 0.07	0.61 ± 0.05

Alignment	Cycle Time (s)	Double Support Time (s)	Step Time (s)		Stance Time (s)	
			Intact	Residual	Intact	Residual
IA	1.27 ± 0.15	0.33 ± 0.05	0.58 ± 0.04[†]	0.68 ± 0.11[§]	0.86 ± 0.12[†§]	0.74 ± 0.06
ANT	1.25 ± 0.13	0.33 ± 0.06	0.58 ± 0.04[†]	0.67 ± 0.12[§]	0.85 ± 0.12[†§]	0.75 ± 0.06
POST	1.24 ± 0.12	0.32 ± 0.06	0.57 ± 0.05[†]	0.68 ± 0.10[§]	0.85 ± 0.12[†§]	0.73 ± 0.06
MED	1.25 ± 0.12	0.33 ± 0.05	0.57 ± 0.04[†]	0.68 ± 0.11[§]	0.86 ± 0.11[†§]	0.75 ± 0.06
LAT	1.25 ± 0.10	0.32 ± 0.06	0.57 ± 0.05[†]	0.68 ± 0.07[§]	0.85 ± 0.10[†§]	0.71 ± 0.06
FLEX	1.24 ± 0.13	0.33 ± 0.06	0.57 ± 0.04[†]	0.67 ± 0.10[§]	0.85 ± 0.13[†§]	0.73 ± 0.07
EXT	1.28 ± 0.16	0.34 ± 0.05	0.55 ± 0.05[†]	0.73 ± 0.12[§]	0.89 ± 0.14[†§]	0.72 ± 0.07
ADD	1.26 ± 0.12	0.34 ± 0.07	0.57 ± 0.04[†]	0.69 ± 0.11[§]	0.88 ± 0.13[†§]	0.75 ± 0.06
ABD	1.27 ± 0.15	0.34 ± 0.07	0.57 ± 0.05[†]	0.70 ± 0.12[§]	0.87 ± 0.14[†§]	0.76 ± 0.09
CG	1.13 ± 0.09	0.27 ± 0.07	0.57 ± 0.06	0.55 ± 0.04	0.70 ± 0.06	0.72 ± 0.10

The intact and residual sides of the CG respectively correspond to the right and left sides.
Abbreviations: IA, initial alignment; ANT, socket anterior translation; POST socket posterior translation; MED, socket medial translation; LAT, socket lateral translation; FLEX, socket flexion; EXT, socket extension; ADD, socket adduction; ABD, socket abduction; CG, control group.
[§] A significant difference between the individuals with amputation and the control group.
[†] A significant difference between the intact and residual sides of individuals with amputation.

2.4. Statistical analysis

The spatiotemporal gait parameters, load rate, peak and impulse of GRF on both lower limbs of the subjects were compared. One-way ANOVA was used to compare the differences between the gait parameters of individuals with amputation under various alignments and those of the control group. Statistical significance was set to $\alpha = 0.05$. Bonferroni adjustment was used for the pairwise comparisons. Nine alignment conditions for the individuals with amputation were compared with those of the control group; thus, the value of α was adjusted to 0.0056 (0.05/9). Repeated measures multivariate ANOVA was used to determine if a significant alignment (initial alignment or malalignments), limb (intact or residual), or alignment-limb interaction effect was present on the GRF parameters of individuals with amputation. When significant effects were detected on the alignment factor, a univariate analysis with Bonferroni adjustment was used to determine which changes were statistically significant. Eight malalignments were compared with the initial alignment; thus, the value of α was adjusted to 0.00625 (0.05/8). Paired t tests were used to determine statistical differences between residual and intact sides ($\alpha = 0.05$).

3. Results

3.1. Spatiotemporal gait parameters

Table 2 shows that, in all alignment conditions, the speed and stride

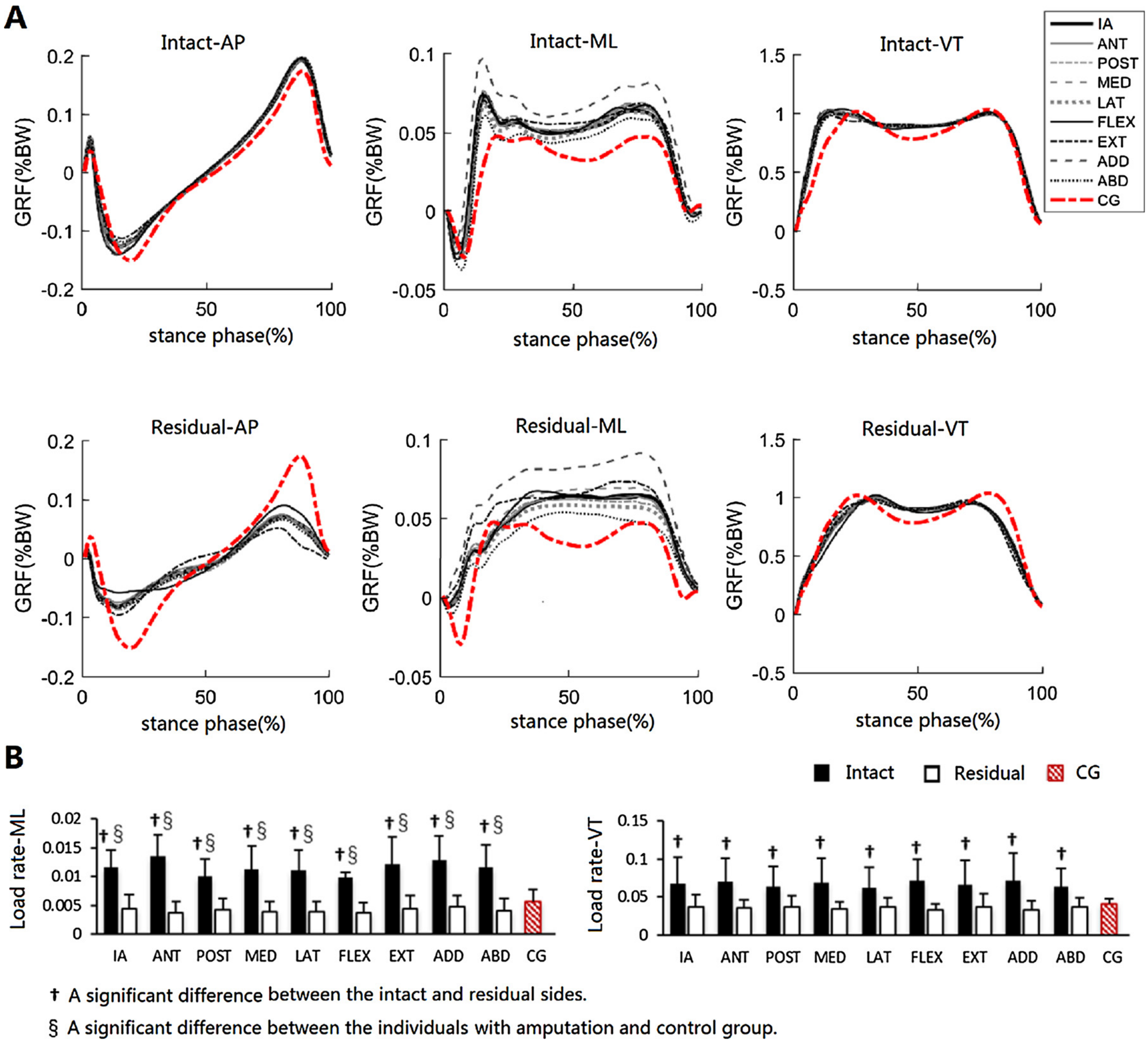

Fig. 2. GRF and load rate of individuals with amputation and the control group. (A) the mean GRF curve (B) the load rate.
Abbreviations: APanterior-posterior GRF; MLmedial-lateral GRF; VTvertical GRF; IAinitial alignment; ANTsocket anterior translation; POST socket posterior translation; MEDsocket medial translation; LATsocket lateral translation; FLEXsocket flexion; EXTsocket extension; ADDsocket adduction; ABDsocket abduction; CGcontrol group; BWbody weight.

length of individuals with amputation were significantly lower than those of control group ($P < 0.0056$). By contrast, the stride width was significantly larger than that of control group ($P < 0.0056$). In all alignment conditions, the step time of the intact side was significantly shorter than that of the residual side ($P < 0.05$), the stance time was significantly longer than that of the residual side ($P < 0.05$), and the step time of the residual side and stance time of the intact side in individuals with amputation were all significantly longer than that of the control group ($P < 0.0056$). No significant difference was found between the malalignments and the initial alignment.

3.2. GRF parameters

Fig. 2A shows the GRFs on both sides of individuals with amputation and those of the control group. The GRF curves revealed an evident difference between the individuals with amputation and the control group. The change in alignment also led to change in GRF.

3.2.1. GRF load rate

Fig. 2B shows that the medial-lateral and vertical GRF load rates of the intact side in individuals with amputation were significantly higher than those of the control group ($P < 0.0056$). The medial-lateral GRF load rates of the intact side were significantly higher than those of the residual side ($P < 0.05$). No significant difference was found between the initial alignment and malalignments.

3.2.2. GRF peak

Fig. 3 shows the GRF peaks of the control group and individuals with amputation under various alignments.

(1) Difference between intact and residual sides

The braking and propulsive GRF peaks of the intact side were significantly higher than those of the residual side ($P < 0.05$) except for the alignment of socket extension.

(2) Difference between initial alignment and malalignments

For the medial GRF of the intact side, the first and second peaks of socket adduction were significantly higher than those of the initial alignment ($P = 0.002$, $P < 0.001$), the first peak of socket abduction was significantly lower than that of the initial alignment ($P = 0.003$). For the medial GRF of the residual side, the first and second peaks of socket adduction were significantly higher than those of the initial alignment ($P = 0.003$, $P = 0.001$), and the first and second peaks of socket abduction were significantly lower than those of the initial alignment ($P = 0.001$, $P < 0.001$).

(3) Difference between the individuals with amputation and control group

The braking and propulsive GRF peaks of the residual side under all

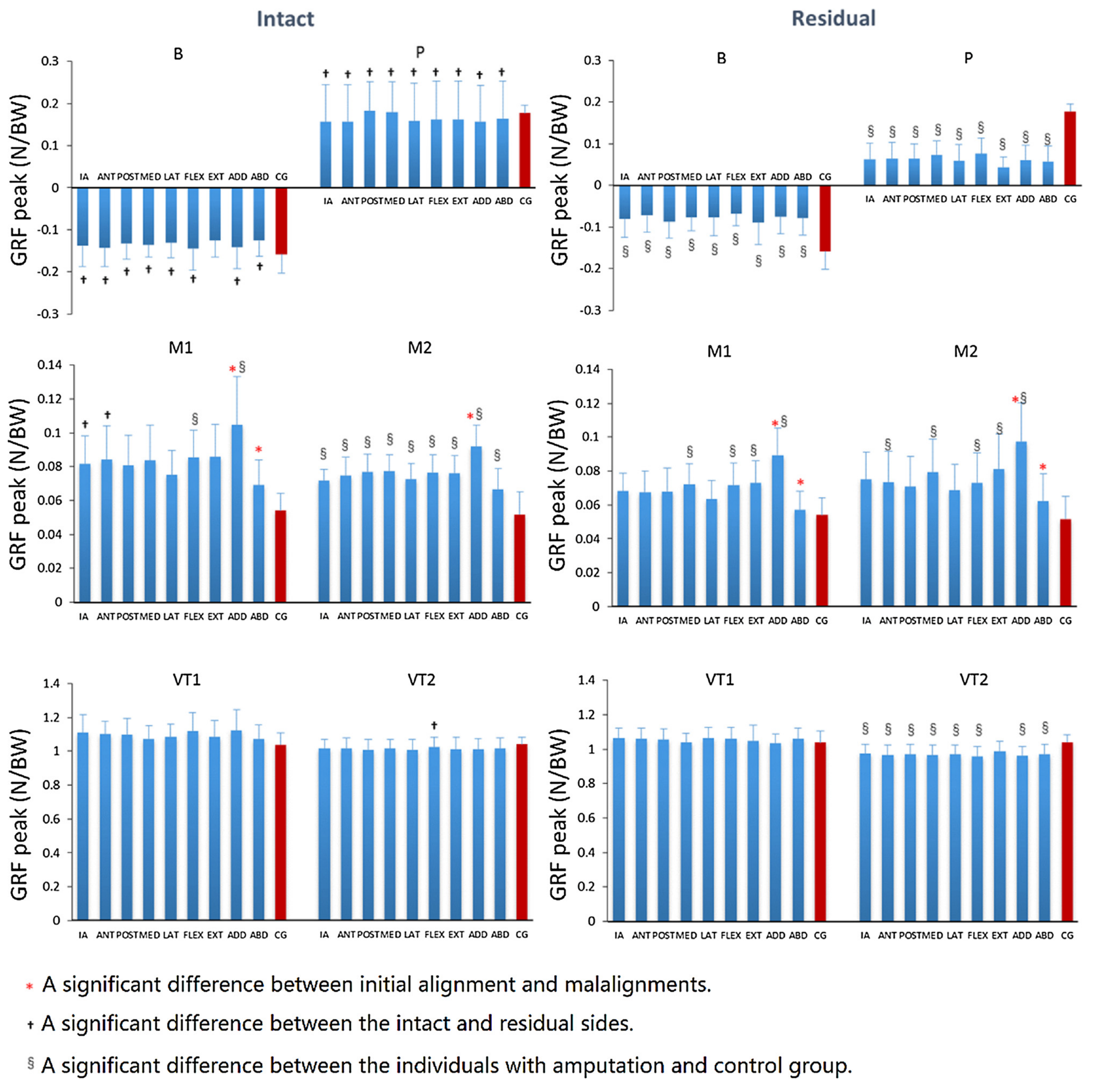

Fig. 3. The GRF peak of individuals with amputation and the control group.
Abbreviations: B, peak of braking AP-GRF; P, peak of propulsive AP-GRF; M1, first peak of medial GRF; M2, second peak of medial GRF; VT1, first peak of vertical GRF; VT2, second peak of vertical GRF; IA, initial alignment; ANT, socket anterior translation; POST socket posterior translation; MED, socket medial translation; LAT, socket lateral translation; FLEX, socket flexion; EXT, socket extension; ADD, socket adduction; ABD, socket abduction; CG, control group; BW, body weight.

of the alignment conditions were significantly lower than those of the control group ($P < 0.0056$). The medial GRF peaks of both sides under most of the alignment conditions were significantly higher than those of the control group ($P < 0.0056$). The second peak of the vertical GRF on the residual side was significantly lower than that of the control group except under the alignment of socket extension ($P < 0.0056$).

In addition, the valley between the first and second peaks of vertical GRF was analysed. The results showed that, the values of valleys in the residual side of individuals with amputation under all alignment conditions were significantly higher than that of the control group.

3.2.3. GRF impulse

Fig. 4 shows the GRF impulses of the control group and individuals with amputation under various alignments.

(1) Difference between intact and residual sides

Under almost all of the alignment conditions, the GRF impulses of the residual side were smaller than those of the intact side. The braking impulse of the intact side was significantly larger than that of the residual side except for the alignments of socket posterior translation, extension and abduction ($P < 0.05$). Under all of the alignment conditions, the propulsive and vertical impulses of the intact side were significantly larger than those of the residual side ($P < 0.05$).

(2) Difference between initial alignment and malalignments

Compared with the initial alignment, the braking impulse of the residual side significantly increased ($P = 0.002$) under the alignment of socket posterior translation, and the intact-to-residual ratio of the braking impulse significantly decreased ($P = 0.004$). The propulsive impulse of the residual side significantly increased ($P = 0.001$) under

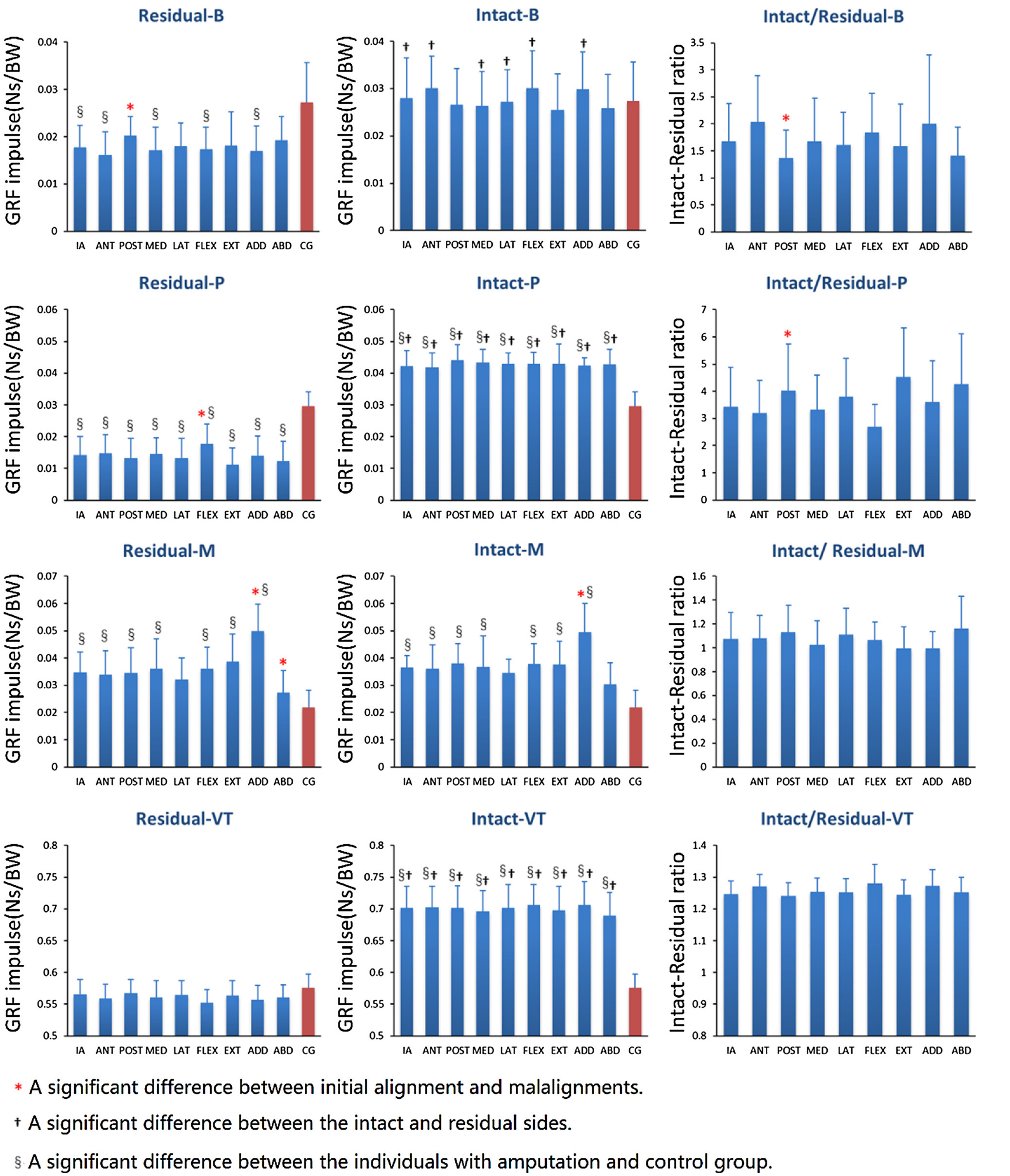

Fig. 4. The GRF impulse of individuals with amputation and the control group.
Abbreviations: B, braking impulse; P, propulsive impulse; M, medial impulse; VT, vertical impulse; IA, initial alignment; ANT, socket anterior translation; POST socket posterior translation; MED, socket medial translation; LAT, socket lateral translation; FLEX, socket flexion; EXT, socket extension; ADD, socket adduction; ABD, socket abduction; CG, control group; BW, body weight.

the alignment of socket flexion, and the intact-to-residual ratio of propulsive impulse significantly increased under the alignment of socket posterior translation ($P = 0.005$). Under the alignment of socket adduction, the medial impulse of both sides significantly increased ($P < 0.001$). On the contrary, the medial impulse of the residual side significantly decreased under the alignment of socket abduction ($P = 0.001$).

(3) Difference between the individuals with amputation and control group

The propulsive impulse of the residual side was significantly smaller than that of the control group under all of the alignment conditions, whereas that of the intact side was significantly larger than that of the control group ($P < 0.0056$). The medial impulse of both sides was significantly larger than that of the control group ($P < 0.0056$) except under the alignment of socket lateral translation and abduction. The vertical impulse of the intact side was significantly larger than that of the control group ($P < 0.0056$) under all of the alignment conditions.

4. Discussion

This research analyzed the differences of spatiotemporal and GRF gait parameters on both lower limbs in different alignments, and compared with those of the control group. It aimed to study the effect of alignment and contribute to explain why the joints of individuals with transfemoral amputation are exposed to degenerative joint disease.

The absence of muscles leads to reduced supporting ability at the residual side, and the individuals with unilateral amputation commonly shows less confidence on the use of the residual side. Therefore, a longer stance time is usually found at the intact side. Correspondingly, the step time of the residual side was longer. The load rates were much higher on the intact side at the beginning of the stance phase as the center of gravity shifted rapidly from the residual side to the intact side, while the unload rates at the end of stance phase were much lower on the residual side due to the weaker muscle force for pushing-off. The vertical GRF curve of the control group showed clear peaks and valley, while that of the individuals with amputation was flatter, which may be related to the significantly higher speed of the control group.

For individuals with transfemoral amputation, the medial GRF peak and impulse on both sides and the medial GRF load rate on the intact side were remarkably higher than those of the control group. Knee OA mostly occurs in the medial compartment, which is related to the continuous overload in the medial knee joint [25]. The considerably higher medial GRF may result in excessive loading on the medial side of the knee joint, which may be an inducement for the medial compartment knee OA. This may explain the high incidence of knee disease in individuals with lower-limb amputation.

In nearly all alignment conditions, the propulsive and braking GRF peak and impulse, the vertical GRF impulse and the medial and vertical GRF load rates of the intact side were all significantly higher than those of the residual side. These findings indicated that the instantaneous and sustained effect of GRF on the intact side during walking were all higher than those on the residual side. In addition, in most cases of alignment, the vertical impulse of the intact side was significantly larger than that of the control group, which perhaps further explained the higher injury rate on the intact side of individuals with lower-limb amputation than on the residual side. The results for the vertical GRF are consistent with those of previous studies on the individuals with transtibial amputation [19,21].

The results on effects of alignments showed that the alignment changes had no significant effect on spatiotemporal gait parameters but significantly affected GRF in individuals with transfemoral amputation. This finding is consistent with that of previous studies on individuals with transtibial amputation [12,21,26,27], which indicated that individuals with amputation have a certain gait adjustment ability to adapt to alignment changes, but the mechanical change cannot be ignored. In addition, the current study found that the anteroposterior alignment change significantly affected anteroposterior GRF, mediolateral alignment change significantly affected medial GRF, and alignment changes insignificantly affected vertical GRF (Figs. 3 and 4).

For socket posterior translation, the braking impulse of the residual side significantly increased, the intact-to-residual ratio of the braking impulse was evidently close to 1 (Fig. 4). These facts indicated that this alignment condition perhaps increased the loading on the residual side at the foot strike stage but improved the loading symmetry. However, the intact-to-residual ratio of the propulsive impulse significantly increased (away from 1) under the alignment of socket posterior translation, indicating that this alignment condition increased the loading asymmetry at the foot off stage. The propulsive impulse of the residual side increased significantly under the alignment of socket flexion, indicating that the residual side of individuals with amputation may need smaller active force to lift the foot off the ground under this alignment condition.

The alignment of socket adduction significantly increased the peak and impulse of medial GRF on both sides, and the mean value was much higher than the maximum value of the control group (Figs. 3 and 4). This finding indicated that the alignment of socket adduction perhaps greatly increased the medial loading on the lower limb of individuals with transfemoral amputation. Probably since under this alignment condition, the lateral deviation of the center of gravity increased in order to maintaining balance, a greater lateral force is needed to achieve the transfer of the center of gravity position, and the medial GRF increased correspondingly. However, during clinical prosthesis fitting for individuals with transfemoral amputation, socket adduction alignment is customarily used to resist the natural abduction of the residual limb [28,29]. Considering the correlation between excessive medial loading and knee OA, excessive adduction should be avoided when adopting this alignment method in the clinical practice.

There are several limitations in this study. The adaptation time for each alignment condition was relatively short, and the initial alignment was not quantified. When adjusting the angular alignment, the adjusting position is above the translation regulator, which differs to the common clinical practice. The subjects' feedback was not collected under each alignment condition. The trunk motion, which may be an influencing factor of medial-lateral GRF, deserves researching in future work.

In conclusion, this paper reports a preliminary research on the effect of prosthetic alignment on spatiotemporal gait and GRF parameters, which revealed the remarkable and complicated effects of different alignments on lower limb loading in individuals with transfemoral amputation. Asymmetric GRF may lead to changes in internal stress in the lower-limb joint, which is considered as an inducement of joint diseases. It remains unclear how does the joint reaction force and internal stress of the joint change under malalignments. Further research is needed to clarify these issues.

Conflict of interest

No conflicts of interest to declare.

Acknowledgments

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