# State-of-the-Science Review of Transtibial Prosthesis Alignment Perturbation

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**Background:** Bench alignment is the initial alignment produced during prosthesis fabrication before it is placed on the patient, and often follows guidelines established and provided by the manufacturers of prosthetic feet and knees. Static alignment is undertaken with the prosthesis on the patient and some weight bearing, and occurs before walking. It often involves examination and correction of pylon height and general alignment of the prosthetic components.
**Objectives:** A systematic review of research on the effects of transtibial prosthesis alignment perturbation on gait was carried out following guidelines prepared by the American Academy of Orthotists and Prosthetists.
**Criteria for selecting studies for this review:**
**Types of studies:** All studies examined the effects of perturbations of transtibial prostheses as a primary or secondary research goal, describe the perturbations quantitatively, and report results quantitatively. Three tpe of studies were used: controlled before-after-trial, cross-sectional study, and case series.
**Types of participants:** Persons with transtibial amputation
**Types of interventions:** Total body (I, total body measures), both limbs (II, bilateral comparisons), and the prosthetic limb (III, prosthetic limb). Total body measures (I) studies examined the subjective acceptability of alignment, oxygen uptake, total body and joint work or energy, walking speed, and cadence. Bilateral comparisons (II) studies compared the prosthetic and contralateral limbs or examined measures of symmetry. Category III studies presented outcomes for the prosthetic limb.
**Types of outcome measures:** The broad categories of outcome variables were gait temporal-spatial characteristics (phase duration, step length or stride duration), electromyogram (EMG) activity, ground reaction force or pylon force (extremes-peak magnitudes, extremes-timing, impulse, center of pressure trajectory, or location), joint kinematics (range of motion _ROM_/peak angles, peak angle timing, and angular velocity), joint kinetics (moment, impulse, power, and work), and intrasocket forces (normal pressures, shear forces). The intrasocket force subcategories of normal pressure and shear forces, which were applicable only to the prosthetic limb, were further divided into the following categories: extremes-magnitude, extremes-timing, patterns/ durations, and impulse. (Evidence Statements Table 5)
**Search strategy for identification of studies:** Searches were undertaken using the RECAL, RECAL Legacy, MEDLINE,Web-O-Knowledge, Cochrane Reviews (Wiley InterScience), CINHAL, and ScienceDirect databases.
**Conclusion:** (Evidence Statements Table 5) Prosthetists have been able to produce acceptable alignments for years with minimal scientific knowledge, or “evidence,” and it is reasonable to ask what can be gained from further research on alignment. Several benefits can be identified. First, the sophisticated and complex ankle components coming on the market may require higher standards of alignment to achieve their biomechanical potential. Second, manufacturers of such components need to develop designs whose alignment requirements match the capabilities of clinicians. Third, clinicians need to be able to detect, diagnose, understand, and correct gait problems caused by alignment. Alignment is one of the major determinants of discomfort for the amputee. Given the importance of achieving cost effectiveness in rehabilitation programs, it is important to minimize discomfort and energy expenditure to the extent possible, so that the most effective use of expensive prosthetic components can be achieved.

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Table 5. Evidence statements—total body, symmetry, and temporal-spatial measures

| ES[a] | | References (ER, study type, sample size, μ=stat test) | Level of confidence |
|---|---|---|---|
| | **At acceptable alignment** | | |
| 1 | Vertical peak ground reaction forces are significantly higher on the contralateral limb than on the prosthetic limb. | 2, ES, 17, μ<br>6, ES, 6<br>9, OS, 6<br>14, ES, 2<br>16, ES, 14, μ<br>28, ES, 5, μ | Moderate |
| 2 | Ground reaction force impulse exhibits no significant difference between the prosthetic limb and the contralateral limb. | 6, ES, 6<br>14, ES, 2<br>16, ES, 14, μ<br>25, ES, 1, μ | Moderate |
| 3 | Knee peak flexion angles and peak angle timing exhibit significant differences between the prosthetic limb and the contralateral limb. | 1, ES, 1, μ<br>2, ES, 17, μ<br>6, ES, 6<br>10, ES, 5, μ | Moderate |
| 4 | Peak external knee extension moment, impulse, and work are significantly higher on the contralateral limb than on the prosthetic limb. | 2, ES, 17, μ | Moderate |
| | **Perturbation of an acceptable alignment** | | |
| 5 | Walking speed exhibits no significant change with perturbation of socket angular alignment, foot linear position, or foot transverse plane angular position. | 2, ES, 17, μ<br>5, ES, 1, μ<br>6, ES, 6<br>8, ES, 8, μ<br>22, ES, 2, μ<br>24, ES, 7, μ<br>28, ES, 5, μ | High |
| 6 | Cadence exhibits no significant change with perturbation of socket angular alignment, foot linear position, or foot transverse plane angular position. | 2, ES, 17, μ<br>5, ES, 1, μ<br>22, ES, 2, μ<br>28, ES, 5, μ | Moderate |
| 7 | Bilateral ground reaction force peak magnitude relationships (symmetries) exhibit no significant changes with perturbation of socket angular alignment, foot linear position, or foot transverse plane angular position. | 2, ES, 17, μ<br>6, ES, 7<br>9, OS, 6<br>16, ES, 14, μ<br>28, ES, 5, μ | Moderate |
| | **Gait initiation with an acceptable alignment** | | |
| 8 | Vertical ground reaction force peaks are significantly greater on the contralateral limb than the prosthetic limb for all maxima and minima events except first peak on the stance limb when it is the prosthetic limb. | 19, ES, 7, μ | Moderate |
| 9 | Vertical ground reaction force peak on the swing limb occurs earlier when it is the prosthetic limb. | 19, ES, 7, μ | Moderate |
| 10 | Anterior-posterior ground reaction force peaks on the swing limb are significantly greater when the swing limb is the contralateral limb rather than the prosthetic limb. | 19, ES, 7, μ | Moderate |
| 11 | Medial-lateral ground reaction force peaks on the stance limb are significantly greater when the stance limb is the prosthetic limb rather than the contralateral limb. | 19, ES, 7, μ | Moderate |
| 12 | Single support time on the stance limb (as measured by delayed onset of single limb support) is significantly shorter and has an earlier second peak vertical ground reaction force when it is the prosthetic limb. | 19, ES, 7, μ | Moderate |

[a]Among experienced unilateral transtibial amputees walking for short periods of time on a level surface in a controlled environment (e.g., gait lab or clinic) during experiments in which prosthesis alignment is being examined or varied.

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Table 6. Evidence statements - effects by type of perturbation

| References[a] | | References (ER, study type, sample size, μ=stat test) | Level of confidence |
|---|---|---|---|
| | Socket flexion-extension | | |
| ES 13 | A range of socket flexion-extension angular alignments and a range of foot anterior-posterior translations seem to be acceptable to the amputee, with interactions between the two alignment variables limiting acceptable combinations. | 2, ES, 17, μ<br>6, ES, 6<br>11, ES, 7, μ<br>18, ES, 5<br>27, ES, 6<br>33, OS, 10 | High |
| ES 14 | The roll-over shape of the prosthetic foot matches an "ideal" roll-over shape at acceptable alignment. | 11, ES, 7, μ | Moderate |
| ES 15 | The range of acceptable socket flexion-extension alignments varies from individual to individual. | 6, ES, 6<br>11, ES, 7, μ<br>18, ES, 5<br>27, ES, 6<br>33, OS, 10 | Moderate |
| ES 16 | The range of acceptable socket flexion-extension alignments decreases if the walking surface is inclined. | 27, ES, 6 | Moderate |
| ES 17 | Intrasocket peak pressure on the residual limb increases at the distal tibia and decreases at the patella tendon as socket alignment changes from acceptable to greater flexion, and intrasocket peak pressure on the residual limb decreases at the distal tibia and increases at the patella tendon as the socket alignment changes from acceptable to greater extension. | 5, ES, 1, μ<br>15, ES, 2<br>20, ES, 3, μ<br>22, ES, 2, μ<br>23, ES, 3<br>29, ES, 2, μ<br>34, ES, 1 | Moderate |
| | Socket abduction-adduction | | |
| ES 18 | A range of socket abduction-adduction angular alignments in combination with a range of foot medial-lateral translations seem to be acceptable to the amputee. | 13, OS, 16, μ<br>18, ES, 5<br>33, OS, 10 | Moderate |
| ES 19 | The range of acceptable socket abduction-adduction alignments varies from individual to individual. | 18, ES, 5<br>33, OS, 10 | Moderate |
| ES 20 | Peak vertical ground reaction forces on the prosthetic limb exhibit no significant changes when socket abduction-adduction alignment is perturbed relative to acceptable alignment. | 9, OS, 6<br>16, ES, 14, μ<br>28, ES, 5, μ | Moderate |
| | Prosthetic foot heel and forefoot wedging | | |
| ES 21 | Peak pressure at the distal end of the tibia is increased by heel wedging, and peak pressure in the subpatellar region is increased by forefoot wedging. | 26, ES, 17, μ | Moderate |
| ES 22 | The time to occurrence of peak pressure in the subpatellar region is increased by heel wedging. | 26, ES, 17, μ | Moderate |
| ES 23 | Signal power in the subpatellar region is decreased and signal power at the distal end of the tibia is increased by heel wedging. | 26, ES, 17, μ | Moderate |
| ES 24 | Signal power in the subpatellar region is increased and signal power in the distal end of the tibia is decreased by forefoot wedging. | 26, ES, 17, μ | Moderate |
| | Prosthetic foot anterior-posterior translation | | |
| ES 25 | The range of acceptable foot anterior-posterior alignments varies from individual to individual. | 6, ES, 6<br>11, ES, 7, μ<br>13, OS, 16, μ<br>18, ES, 5<br>27, ES, 6<br>33, OS, 10 | Moderate |
| ES 26 | Pressure on the distal tibia is increased as the foot is translated posterior relative to acceptable alignment and decreased as the foot is translated anterior relative to acceptable alignment. | 5, ES, 1, μ<br>15, ES, 8<br>22, ES, 2, μ | Moderate |
| | Prosthetic foot medial-lateral translation | | |
| ES 27 | The range of acceptable foot medial-lateral alignments varies from individual to individual. | 13, OS, 16, μ<br>18, ES, 5<br>33, OS, 10 | Moderate |
| ES 28 | Intrasocket pressures at the lateral distal tibia and anterior distal tibia increase as the foot is translated medial relative to acceptable alignment and decrease as the foot is translated lateral relative to acceptable alignment. | 5, ES, 1, μ<br>15, ES, 8<br>22, ES, 2, μ | Moderate |
| ES 29 | Intrasocket pressures at the lateral tibial condyle decrease as the foot is translated medial relative to acceptable alignment and increase as the foot is translated lateral relative to acceptable alignment. | 15, ES, 8 | Moderate |

*(Continued)*

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| References[a] | | References (ER, study type, sample size, μ=stat test) | Level of confidence |
|---|---|---|---|
| | Prosthetic foot internal-external rotation | | |
| ES 30 | The range of acceptable internal-external rotations varies from individual to individual | 2, E5, 17, μ | Moderate |
| ES 31 | Single limb support duration on the prosthetic limb is significantly shorter when the foot is rotated internally 6° relative to acceptable alignment, but not when the foot is rotated externally 6°; however an external rotation of 36° produces a significantly shorter stance phase duration. | 2, E5, 17, μ<br>8, E5, 8, μ | Moderate |
| ES 32 | Peak knee flexion angle is decreased significantly on the prosthetic limb at 6° of internal rotation. | 2, E5, 17, μ | Moderate |
| ES 33 | Peak ground reaction force magnitudes on the prosthetic limb exhibit no significant changes when the foot is rotated internally 6° or externally 36° relative to acceptable alignment. | 2, E5, 17, μ<br>28, E5, 5, μ | Moderate |
| ES 34 | Peak external knee moments in the sagittal plane on the prosthetic limb exhibit no significant changes when the foot is rotated internally 15° or externally 15° relative to acceptable alignment. | 2, E5, 17, μ<br>28, E5, 5, μ | Moderate |
| ES 35 | Knee joint impulse, and work in the sagittal plane on the prosthetic limb exhibit no significant changes with up to 6° of internal rotation and up to 6° of external rotation relative to acceptable alignment. | 2, E5, 17, μ | Moderate |
| ES 36 | Peak external knee extension moment, impulse, and work on the contralateral limb are significantly increased by 6° of internal rotation of the foot relative to acceptable alignment whereas 6° of external rotation does not increase significantly these measures. | 2, E5, 17, μ | Moderate |
| | Perturbation and gait initiation | | |
| ES 37 | Center of pressure trajectories of the prosthetic and contralateral limbs exhibit no significant changes with foot plantar and dorsiflexion by ±5°, foot inversion and eversion by ±5° and pylon length changes of ±2 cm relative to acceptable alignment. | 19, E5, 7, μ | Moderate |
| ES 38 | Ground reaction force peaks in all directions exhibit no significant changes with foot plantar and dorsiflexion by ±5°, foot inversion and eversion by ±5° and pylon length changes of ±2 cm relative to acceptable alignment. | 19, E5, 7, μ | Moderate |
| ES 39 | Ground reaction force peak magnitude timings and pressure patterns exhibit no significant changes with pylon height variation of ±2 cm from an acceptable alignment. | 19, E5, 7, μ | Moderate |
| | Alignment with SACH feet | | |
| ES 40 | Acceptable socket alignment occurs at a socket flexion of approximately 5° ±4° (STD DEV). | 11, E5, 7, μ<br>18, E5, 5<br>33, O5, 10 | Moderate |
| ES 41 | Acceptable socket alignment occurs at a socket adduction of approximately 3.5° ± 3.2° (STD DEV). | 33, O5, 10 | Moderate |
| ES 42 | Acceptable foot alignment occurs with a top foot bolt hole position 2.08 cm ± 1.55 cm (STD DEV) anterior with respect to the proximal center of the socket. | 33, O5, 10 | Moderate |
| ES 43 | Acceptable foot alignment occurs with a foot top bolt hole position approximately 0.19 ± 0.59 cm (STD DEV) lateral with respect to the proximal center of the socket. | 33, O5, 10 | Moderate |

[a]Among experienced unilateral transtibial amputees walking for short periods of time on a level surface in a controlled environment (e.g., gait lab or clinic) during experiments in which prosthesis alignment is being examined or varied.