The effects of crossover feet on function in individuals with unilateral transtibial amputation

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Clinical Question: In persons with unilateral transtibial amputation, do posterior-mounted crossover feet improve function compared to conventional distal-mounted feet?

Background: Lower limb (LL) amputation adversely affects an individual's function and ability to perform activities of daily living.[1] To help best restore this loss of function, prosthetic feet that have been tuned to perform a specific type of activity are used (e.g., low-level activities such as walking, high-level activities such as running). This activity-based performance discrepancy between prosthetic feet is reflected in the distinct designs of energy-storing feet (ESF) and running-specific feet (RSF). The former are intended to facilitate smooth walking at variable speeds, with a heel lever constructed to simulate heel contact during gait and a split keel to accommodate to uneven terrain. Running-specific feet, however, are designed to be stiffer and more robust, with the expectation they will experience higher loads during running as compared to walking. They typically have a longer keel section to store and return more energy,[2] and lack a heel lever thus decreasing stability and smooth progression during gait. As a result, individuals with LL amputation require multiple prostheses with different prosthetic feet in order to optimally engage in a variety of low- and high-level activities.[3] However, for many individuals it may not be feasible to obtain a secondary prosthesis for specific activities due to lack of coverage by insurance and the subsequent financial burden.[4]

Crossover feet (XF) are designed to incorporate aspects of both ESF (heel lever, split keel) and RSF (extended keel, posterior mount) in order to expand the range of activities that can be performed with a single prosthesis. Anecdotal evidence for the XF is promising, suggesting it increases users' function and ability to participate in meaningful activities. Therefore, this CAT examines the benefits of XF on users' function.

Search Strategy:
Databases Searched: PubMed, CINAHL, Web of Science
Search Terms: (transtibial OR "below knee") AND ("crossover foot" OR "posterior lamination" OR (posterior AND mount*) OR "low profile" OR "high profile") AND (prosthes* OR prosthetic)
Inclusion/Exclusion Criteria: Original research, English, 2010 – present, peer-reviewed

Synthesis of Results: Four studies were identified[5–8] that discussed the effect of XF on function in individuals with unilateral transtibial amputations as compared to ESF. The number of participants ranged from 5 to 27,[5–8] and were generally young active males with amputation due to trauma.[5–8] Two studies[5,7] were cross-sectional in nature, whereas the other two studies were a randomized crossover study[6] and focus-group.[8] Performance-based measures were used in three[5–7] studies and self-report measures or participant discussion following open-ended leading questions in two.[6,8] When using the XF, trends of improved function were reported in both performance-based[5–7] and self-report[6] measures assessing a variety of functional outcomes. Statistically significant results were only found in one study;[6] however, this is in part due to the lack of inferential statistics[5,8] and small sample size.[5,7,8] When participants compared the XF and ESF, the majority of users preferred the XF,[6,8] particularly for higher-level activities[6] and for the perceived increase in ability to complete vocational and avocational activities.[8] While the methods of each study varied, each demonstrated a trend toward improved function when using the XF.[5–8] However, due to the small[5,7,8] and relatively homogenous samples[5–8] coupled with studies that assessed only in-laboratory performance,[5,7] clinically-meaningful conclusions to be drawn regarding the benefits of the XF on function are limited. In addition, all four studies were conducted by the same research team, further limiting generalization of results.

Clinical Message: These studies suggest that the XF has potential to improve function, but its benefits cannot be fully assessed with performance-based measures, and more evidence is required to definitively support XF use. Future research should focus on identifying outcome measures sensitive to changes in prosthetic feet and include user-perception to obtain more conclusive results regarding the functional benefits of the XF.

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Evidence Table

	Hafner (2018)[5]	Morgan (2018)[6]	Halsne (2018)[7]	McDonald (2019)[8]
Purpose	Compare functional outcomes in persons with transtibial amputation when using XF vs ESF	Compare functional outcomes in persons with transtibial amputation when using XF vs ESF	Compare functional outcomes in persons with transtibial amputation when using XF vs ESF in low- and high-level activities	Investigate what outcomes mattered to individuals who had experience using both ESF and XF prosthetic feet
Study design	Cross-sectional study, repeated measures	Randomized crossover study	Cross-sectional study, repeated measures	Focus group study
Population	Number of subjects: 7 Sex: male (5), female (2) Age: mean 42.6±8.9 years Amputation etiology: trauma (4), infection (1), congenital (1), other (1) Time since amputation: 11.1±12.1 years K-level: unspecified History of XF use: yes (7)	Number of subjects: 31 recruited, 27 analyzed Sex: male (22), female (5) Age: mean 42.3±11 years Amputation etiology: trauma (20), infection (2), cancer (1), other (4) Time since amputation: mean 11.7±10.6 years K-level: K2 (1), K3 (16), K4 (10) History of XF use: unspecified	Number of subjects: 7 Sex: male (7) Age: mean 37.0±9.8 years Amputation etiology: trauma (6), infection (1) Time since amputation: mean 12.9±11.6 years K-level: K3 (3), K4 (4) History of XF use: yes (7)	Number of subjects: 7 recruited, 5 participated Sex: male (4), female (1) Age: mean 45.6±7.7 years Amputation etiology: trauma (2), infection (2), other (1) Time since amputation: mean 7.1±4.7 years K-level: unspecified History of XF use: yes (7)
Recruitment source	Convenience sample from Davidson Prosthetics (Puyallup, WA)	Convenience sample from local prosthetic clinics (Seattle, WA)	Convenience sample from local prosthetic clinics (Seattle, WA); recruited from previous participants in Morgan (2018)	Purposive sample from local prosthetic clinic (Seattle, WA)
Inclusion and exclusion criteria	Inclusion: 1) adults, 2) unilateral transtibial amputation with at least one year experience with a prosthesis, 3) non-dysvascular etiology, 4) owned prostheses with both ESF and XF, 5) able to complete study protocol, 6) able to read/write English Exclusion: health comorbidities that would prevent completion of study	Inclusion: 1) adults, 2) unilateral transtibial amputation at least one year prior, 3) non-dysvascular etiology, 4) currently using a prosthesis with either ESF or XF, 5) able to complete study protocol Exclusion: 1) any other amputation, and 2) health comorbidities that would prevent completion of study	Inclusion: 1) adults, 2) unilateral transtibial amputation at least one year prior, 3) non-dysvascular etiology, 4) use of a prosthesis for at least 6 months, 5) K3 or higher Exclusion: health comorbidities that would prevent completion of study	Inclusion: 1) adults, 2) lower-limb amputation(s) with at least one year experience with a prosthesis(es), 3) experience with both ESF and XF Exclusion: unspecified

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Intervention	XF prosthesis (model not specified; participant provided)	XF prosthesis (Össur Cheetah Xplore; study provided)	XF prosthesis (Össur Cheetah Xplore; participant provided)	N/A
Comparison	ESF prosthesis (2 Össur Elation, 1 Freedom Freestyle, 4 Freedom Renegade; participant provided)	ESF prosthesis (Össur Vari-Flex; study provided)	ESF prosthesis (Össur Vari-Flex; participant provided)	N/A
Relevant outcomes	Endurance, perceived exertion, walking performance, and mobility	Endurance, perceived exertion, walking performance, step activity, mobility, fatigue, balance confidence, activity restrictions, and functional satisfaction	Lower extremity strength and balance, mobility, dynamic stability, core strength, and agility	Balance, stability, endurance, gait quality, naturalness, confidence, and mobility
Outcome measures	Performance: 6MWT, TUG, GAITRite mat for walking performance Self-report: Borg RPE CR100	Performance: 6MWT, GAITRite mat for walking performance, step activity monitor for step activity Self-report: Borg RPE CR100, PLUS-M, PROMIS-F, ABC, TAPES-AR, TAPES-FUN	Performance: 5xSTS, TUG, FSST, and CHAMP Self-report: none	Focus group with discussion
Other outcomes	None	Aesthetic satisfaction (TAPES-AES) and prosthetic foot preference (interview)	None	None
Frequency of measurement	Data was collected in a single day; outcome measures administered once for each prosthetic condition	Data was collected following one month of accommodation for each prosthetic condition, for a total of two data collections	Data was collected in a single day; outcome measures administered twice for each prosthetic condition	Focus group was held on a single day
Key findings	<u>Overall</u> Improved mobility, endurance, and walking performance (walking speed, cadence, sound-side step lengths), and reduced exertion when using the XF in majority of participants <u>Effect sizes</u> Medium (d>0.5) to large (d>0.8) effect sizes with XF in all outcomes, except two aspects of walking performance (e.g., step width & prosthetic step length)	<u>Overall</u> Significantly improved sound-side step length, mobility, fatigue, balance confidence, activity restrictions, and functional satisfaction when using the XF <u>Effect sizes</u> Medium effect sizes (d>0.5) with all significant outcomes, except for sound-side step length (d=0.3, small) and functional satisfaction (d=1.11, large) when using XF	<u>Overall</u> Improved function demonstrated with majority of participants when using the XF. Use of the XF on average improved scores on the 5xSTS by 10%, the TUG-comf by 3%, the TUG-fast by 6%, and the FSST by 7% <u>Effect sizes</u> Medium effect size on 5xSTS (d=0.63) and FSST (d=0.52)	<u>Overall</u> Users responded that the XF improved stability and was more responsive. Because of the balance and stability, users felt safer and more confident to participate in activities they had previously avoided. Users also reported that when using the XF, they felt they could walk longer and had a more natural and smoother gait. Individuals in the focus group stated that their mobility was improved, which allowed them to complete vocational and avocational activities more effectively

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Key findings, cont.	Minimum detectable change Criteria not met	Minimum detectable change Not assessed	Minimum detectable change Criteria not met	
Additional findings and considerations	Individuals react differently to the XF (e.g., only four participants demonstrated improved endurance and reduced exertion concurrently when using the XF; the rest exhibited conflicting data) MDCs for selected outcome measures may not be accurate, as referenced literature's participant sample was mostly older patients with majority having knee disarticulation or transfemoral amputations	Majority of participants (17/19) preferred the XF compared to the ESF. Majority of users preferred XF when performing the following activities: walking on inclines (14/19), ascending stairs (14/19), walking quickly (18/19), walking over uneven terrain (11/19), walking while carrying a heavy load (13/9), playing sports (12/19), and running (15/19)	Improved scores on outcome measures were observed on average when using the second prosthetic condition. Differences were not statistically significant; however, an order effect is implied Largest effect observed with XF was during 5xSTS (*d*=0.63). Possible that the XF inherently improves kinetic symmetry based on its design during the sit-to-stand maneuver as compared to the ESF	Outcomes of importance differ between prosthesis users; thus, it is important to consider the individual when selecting outcome measures Use of both qualitative and quantitative outcome measures should be considered to allow a more complete assessment of user experiences and changes in function Included individuals with bilateral lower limb amputations
Key limitations	Small sample: yes Homogenous sample: yes Out-of-clinic data: no Blinding: no Accommodation period: no Standardized prostheses: no Other: did not include test trial with the TUG to eliminate unfamiliarity with measure. Did not specify crossover foot used	Small sample: no Homogenous sample: yes Out-of-clinic data: yes Blinding: no Accommodation period: yes Standardized prostheses: yes Other: potential threat to statistical conclusion validity on ordinal measures (ABC and TAPES-AR). Utilized t-tests to compare means of outcome measures, however, means cannot be taken on ordinal data	Small sample: yes Homogenous sample: yes Out-of-clinic data: no Blinding: no Accommodation period: no Standardized prostheses: yes Other: order effects present	Small sample: yes Homogenous sample: no Out-of-clinic data: N/A Blinding: N/A Accommodation period: N/A Standardized prostheses: N/A Other: single focus group. Did not assess for saturation of data. Did not triangulate results. Unclear if member-checking was performed to validate data

Abbreviations: 5xSTS = Five Times Sit to Stand, 6MWT = Six Minute Walk Test, ABC = Activities-Specific Balance Confidence, CHAMP = Comprehensive High-Level Activity Mobility Predictor, ESF = Energy-Storing Foot, FSST = Four Square Step Test, MDC = Minimum Detectable Change, PLUS-M = Prosthetic Limb Users Survey of Mobility, PROMIS-F = Patient-Reported Outcomes Measurement Information System Fatigue, RPE = Rating of Perceived Exertion, TAPES = Trinity Amputation and Prosthesis Experience Scales, AES = Aesthetic Satisfaction, AR = Activity Restrictions, FUN = Functional Satisfaction, TUG = Timed Up and Go, XF = Crossover Foot

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