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Clinical Question: What are the functional and clinical differences between carbon fiber prosthetic feet and fiberglass prosthetic feet in patients with lower limb amputations?

Background: The primary goal for patients that have undergone a lower limb amputation is to restore mobility. Patients that are highly active, K-3 functional level or higher, benefit from the prescription of a dynamic elastic response (DER) foot. DER feet aid in increasing activity levels by storing energy during midstance and releasing it during push-off.² Prior research provides ample evidence of DER feet producing improved gait biomechanics, such a normalized, symmetrical gait and production of normal hip and knee power in both transtibial¹ and transfemoral subjects.² Recently, the production of DER feet composed of fiberglass composite became marketed to clinicians. Since its introduction into the field, information regarding the validity of the claimed benefits or the functional outcomes of fiberglass feet compared to carbon fiber feet has not been widely investigated. This gap in knowledgeable literature suggests the benefit of a CAT comparing these differences between fiberglass and carbon fiber feet.

Search Strategy:

Databases Searched: PubMed, OVID, www.oandp.org, ScienceDirect, Google Scholar, Researchgate
Search Terms: Combinations (AND/OR) of the following terms were used: "Dynamic elastic response feet," "Carbon fiber", "Fiberglass", "Prosthetic feet", "lower limb", "glass composite"
Inclusion Criteria: Written in English, published from 2000-present, primary peer reviewed
Exclusion Criteria: Articles from a secondary sources/reviews, product specific advertisements

Synthesis of Results: Five studies were identified (see Evidence Table). Three studies involve human subjects with sample sizes ranging from 1-10^{4-6,7}. Two studies involve mechanical testing of composite prosthetic feet.^{3,8} Fiberglass feet were found to have a greater stiffness at the heel and forefoot and demonstrated the least amount of hysteresis compared to certain carbon fiber feet. All feet investigated increased instantaneous stiffness as loading level increased.⁸ The trade-off between stiffness and patient reported stability was not clinically addressed and should be a case specific consideration during the prescription process. In fiberglass athletic feet, the benefits of both stiff and compliant feet are seen through increased peak load and shock absorption respectively.⁶ A quasi-passive Variable-Stiffness Prosthetic Ankle (VSPA) Foot fabricated out of a fiberglass leaf spring, demonstrated an increase in ankle range of motion more closely matching abled-body dorsiflexion (DF) than energy-storing-and-return (ESR) feet.⁷ Mechanical testing was limited by in vitro "ideal circumstances" that cannot be validated in vivo due to environmental barriers such as learned gait deviations, uneven terrain, fatigue or angular forces. Direct comparisons of commercially available carbon fiber feet to a novel fiberglass foot under four ambulation conditions in human subjects found that the fiberglass foot significantly increased ankle DF and plantarflexion power generation by 31% compared to the carbon fiber feet under equivalent conditions.⁵ Additionally, patient preference in appearance and utility of the fiberglass foot significantly increased.⁵ During stance phase, carbon fiber and fiberglass continuous-lever feet in transtibial amputees were found to produce a gait within statistically acceptable deviations from the ideal foot conditions free of dead spot phenomoemas.⁶ Limitations that were effective on all five studies included limited samples size/clinical trials and high variability.

Clinical Message: Overall, the results of these five publications suggest differences exist between fiberglass prosthetic feet over carbon fiber feet and proposes a new alternative prosthetic foot prescription for DER feet candidates. However, additional research and validation of the results already published are required. Future studies should incorporate large subject samples, further investigation of specific functional properties, such as flexibility and energy return of fiberglass feet, as well as direct comparisons of objective and subjective patient outcome measures before the validity of the differences between the two composite materials can be supported.

References

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	Webber and Kaufman, 2017 ⁸	Kaufman and Bernhardt, 2016 ^{4,5}	Hamzah et al, 2018 ³	Klenow et al, 2016 ⁶	Shepard and Rouse, 2017 ⁷
Population	No human subjects <u>Hypothetical Model</u> <i>Gender</i> : Male <i>Weight</i> : 90.7kg <i>Amputation Level</i> : Transtibial <i>Side Affected</i> : Right <i>Functional levels</i> : ≥K-3	Number of subjects: 10 Ages: 40-58 (mean = 49 years) Genders: Male (10) Years of prosthetic use: 10.4 \pm 9.8 years Causes of amputation: Unspecified Amputation Level: Transtibial (10) Side Affected: Unilateral (10) Functional levels: \geq K-3 (10) Additional Characteristics: BMI 29+7 kg/m^2	No human subjets	Number of subjects: 4 Ages: 32-69 (mean = 45 years) Genders: Male (4) Years of prosthetic use: 8-42 (mean 23.3years) Causes of amputation: trauma (2), congenital (1), and infection (1) Amputation Level: Transfemoral (2) Transtibial (2) Side Affected: BL (1, Rt used for study), Rt (2), Lf (1) Functional levels: \geq K-3 (4) Additional Characteristics: Healthy and stable residual limb, Current prosthetic user	Number of subjects: 1 Age: 40 Gender: Unspecified Years of prosthetic use: Unspecified Causes of amputation: Unspecified Amputation Level: Transtibial Side Affected: Unspecified Functional levels: Unspecified Additional Characteristics: Uses a Freedom Innovations Senator Foot (ESR), 3 years post-amputation
Study Design	Mechanical testing	Repeated Measures Cross-over Trial	Mechanical Testing, Theoretical study	Randomized, double-blinded repeated measures	Non-randomized pilot study
Intervention	Loading/unloading compression trials of seven dynamic elastic response feet including: (A) RUSH 87, (B) Freedom Renegade AT, (C) Ossur Talux, (D) Otto bock Triton IC61, (E) Ohio Willow Wood Fusion and	Fiberglass foot (Ability Dynamics Rush)	Load deflection and impact test of two different designs of glass fiber reinforced athletic feet. Design A is constructed with a 68% fiber volume fraction and design B is constructed with a 70% fiber volume fraction.	Walking over five, foot conditions (A) Carbon fiber (CF), continuous lever, low profile, (B) Single spring, Carbon fiber, high profile, (C) Integrated spring, glass composite (GC), high profile,	One subject performed various mobility tasks while wearing the VSPA Foot in an athletic shoe.

Evidence Table

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	(F) Pathfinder II, and (G) TaiLor Made Prosthetics foot.			(D) Continuous lever, glass composite, high profile, (E) Hydraulic ankle, carbon fiber, high profile	
Comparison	Each foot independently compared to one another	Each participant's data was compared to their current Carbon Fiber Foot (Otto Bock Triton, Ossur Variflex, Ossur Variflex EVO, Ossur Reflex Shock, Freedom Renegade, Freedom Pacifica, Freedom Thrive with Vertical Shock, Freedom Highlander, and Freedom Agilix)	Each foot independently compared to one another	Foot 0 - Hypothetical ideal condition without a dead spot occurrence	The VSPA Foot's torque-angle curve and ankle angle at various slider positions (stiffnesses) is compared against the theoretical "ideal" torque-angle curve for a passive (or quasi-passive) ankle
Methodology	The Static Proof Testing was conducted in accordance with ISO 10328 on both the heel and forefoot Three consecutive loading and unloading trials were conducted controlled by Multipurpose TestWare Software at two different loading levels, corresponding to walking and moderate running.	The participants were given four weeks to acclimate to the fiberglass intervention foot. Half of the subjects began the study with the fiberglass foot and the other half started with their carbon fiber foot. Gait analysis was generated using 10 cameras and six force plates to capture full-body motion. Researchers collected data at a self-selected walking speed and normalized walking speed on level ground and while both ascending/descending a 10- degree ramp. The researchers administered a Prosthesis Evaluation Questionnaire (PEQ) to each participant	Load deflection tests were performed to measure the deflection (dorsiflexion angle) of the foot for 0° and 25°-foot positions by applying a vertical load that is equal to three times body weight on both feet. Impact response tests were taken using an impact foot tester device while raised and dropped at angles ranging from 25-60°. Impact force was measured as the foot hit the impact plate.	Subjects performed a static calibration pose and dynamic walking at a preferred self- selected gait velocity for 10 prosthetic foot strikes on the force plate for each condition. 15 minutes of accumulation and 15-minute rest between feet	The subject walked on a treadmill at a self-selected speed at five stiffness levels: x =-20 mm, -10 mm, 0 mm, 10 mm and 20 mm. After, the patient indicated which stiffness felt most comfortable at the selected speed. Following level-ground walking, the subject ascended/descended a 4-step staircase and a 4.4m long ramp with an 11° incline. Five stiffness levels were tested: x =-30 mm, -20 mm, -10 mm, 0 mm and 10 mm for 3 trials (1 practice, 2 recorded). Subject stiffness preference was recorded

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Outcomes	Instantaneous stiffness at the heel and forefoot via load displacement curves Hysteresis (energy loss) was calculated as the difference between loading input energy and unloading input energy	Peak plantar flexion moment during stance Peak ankle power generation Peak and time of peak knee flexion during swing Self-Reported PEQ	Peak impact time and peak impact load for each angle Efficiency of the loading and unloading test	Trajectory, kinetic and kinematic data recorded Center of pressure (mean of GRF acting on the foot at any given time) Dead Spot Presence - qualifying time (% stance), area (mm-s), magnitude (mm/s), magnitude location (% stance), and CoP sagittal velocity	Ankle angle (ROM) and ankle torque across different slider positions (stiffnesses) during various mobility tasks Patient reported stiffness preference during each mobility task
Key Findings	The glass composite (Rush 81) foot had the greatest stiffness at both loading levels The glass composite foot has the least hysteresis at the heel. Heel stiffness was always greater than forefoot stiffness As loading level increased instantaneous stiffness increased Ohio Willow Wood Fusion had the greatest absolute and percent hysteresis The most compliant feet were D and E under running and walking load.	Fiberglass feet showed an increase in ankle dorsiflexion (p<0.01) and ankle power generation (p=0.01) Walking in the fiberglass foot increases plantarflexor power production by 31%. The PEQ found greater satisfaction with the fiberglass foot (p=0.02), with significant increases in appearance and utility.	Under the same load value, design B has a higher stiffness design A. The dorsiflexion angle of design B is more than design A. Design A has a higher ability to absorb shock as seen by its longer first peak compared to design B Design B has a higher first peak load (As stiffness increases impact peak load increases)	In both transtibial subjects, the CF and GC continuous-lever feet were not found to be significantly different from the ideal condition A lack of significant similarity between the feet and ideal conditions were found in transfemoral subjects The continuous-lever GC foot had no detectable dead spot in the transtibial subjects	ROM increased at lower stiffness levels during walking on level ground, stairs, and ramps. Peak DF during ground-level walking decreased at stiffer torque- angle curves, but the peak torque increased. Peak PF immediately following heel strike did not decrease At $x = 10$ mm and 20 mm, the peak PF increased, and the relative timing between foot- flat and push off was altered For level-ground walking, the subject preferred a greater stiffness level than predicted During stair descent, the ROM increased at lower stiffness levels, however, $x=-30$ it also delayed energy return

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					During stair descent, the preferred stiffness caused an increase in ROM, more closely matching abled body DF than ESR feet.
Study Limitations	Only simulates ideal gait cycles Does not account for environmental changes In vitro perspective verse in vivo Angular measures of torsional stiffness (insight on muscular activity) cannot be measured	The study is funded by Ability Dynamics. Raw data is not accessible and numerical data is limited. Small sample size	5% error in fiber volume fractions between design A and B Limited number of trials In vitro model verse in vivo perceptive on running Lack of statistical analysis comparing the numerical data of Design A and B	Small sample size and one subject did not walk at the minimum gait velocity considered K-3 functional level Not enough acclimation time to the feet causing compensatory gait patterns Small observational periods	Optimization of the ideal primary torque-angle curve is required to validate results Stiffness preference may be subject specific Only performed pilot study on one patient model The subject could alter their walking speed if experiencing discomfort which can lead to varied perceptions of certain stiffnesses 5mm increments of change in stiffness is difficult to decipher