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Biomechanical Evaluation of Elliptical Leaf Spring Prosthetics for Unilateral Transtibial Amputees During Dynamic Activities

Qiu-Qiong Shi [1], Kit-Lun Yick [1,*], Chu-Hao Li [1], Chi-Yung Tse [2] and Chi-Hang Hui [1]

[1] School of Fashion and Textiles, The Hong Kong Polytechnic University, Hong Kong, China; gaby-qiuqiong.shi@polyu.edu.hk (Q.-Q.S.); rudy-chuhao.li@polyu.edu.hk (C.-H.L.); andy1004.hui@polyu.edu.hk (C.-H.H.)
[2] Centre for Orthopaedic Surgery, Hong Kong, China; oandp@cos.hk
* Correspondence: kit-lun.yick@polyu.edu.hk

Abstract: This study explores the biomechanical impact of an elliptical leaf spring (ELS) foot on individuals with unilateral below-knee amputation. The ELS-foot, constructed with carbon fiber leaf springs and an ethylene-vinyl acetate rocker bottom sole, aims to balance energy storge and dissipation for effective cushioning and energy management. Six participants were recruited and visited the laboratory twice within a 3-to-5-day interval. The ELS-foot is compared with their own prosthesis through various mobility and balance tests, including the Timed Up and Go test, Four Square Step Test, 10 m walk test, Berg Balance Test, eyes-closed standing test, Tandem Test, jumping and walking test, and a subjective evaluation. Passive-reflective markers are placed on the participants according to the plug-in full body model. An eight-camera motion capture system synced with two force plates mounted under a walkway is used for the gait analysis. The results show that participants move faster during the Four Square Step Test and demonstrate better balance during the eyes-closed standing test and Tandem Test and jump higher with the ELS-foot. The unique ELS-foot design mechanism and rocker bottom sole facilitates better energy transfer and stability, thus enhancing the postural stability. These findings offer valuable insights for future prosthetic technology advancements.

Keywords: elliptical leaf spring; prosthetic foot; biomechanical impact; balance; mobility

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1. Introduction

In 2017, approximately 57.7 million people globally had a limb amputated with Asia reporting the highest numbers. In China, 1.58 million individuals lost their lower limb in 2006, and it is projected that by 2030, 2.33 million people in China will be living with an amputation [1]. Prostheses play a crucial role for amputees, significantly impacting their mobility and independence. Due to substantial advancements in prosthetic technology, individuals with lower-limb amputations can restore basic mobility and participate in various social community and sports events, such as marathons and hikes, thereby greatly enhancing their quality of life [2–5].

While current energy storing and returning prostheses have made significant strides in enhancing walking and running, they may not fully meet the complex demands of more intensive activities like jumping or provide the necessary stabilization on varying terrain [6]. Adding actuators to an ankle–foot prosthesis can improve mobility by supplying the necessary propulsion forces but often involves bulky and costly components [7,8]. These issues highlight the need for a low-cost, high-functioning prosthesis that supports a wider range of physical capabilities.

There are prostheses that incorporate leaf springs due to their superior mechanical strength and ability to reduce the ground impact of the initial contact, particularly on uneven surfaces. This is achieved by varying the spring deflection, which allows potential energy to be stored as strain energy and then gradually released [9]. These springs have been explored and used in various prosthetic foot designs, such as C-shaped or J-shaped feet [10]. These designs often aim to mimic the energy storage and release characteristics of natural feet.

There are different types of leaf springs, including elliptical, transverse, and platform leaf springs. The elliptical leaf spring (ELS) is formed by using two semi-elliptical leaf springs that face away from each other to create an oval shape. The elastic strain energy stored in this spring is released to absorb shock when the spring returns back to its original shape [11]. Springs have been made by incorporating composite fibers like carbon and glass fiber filaments that are 3D-printed to offer enhanced stabilization because they significantly reduce the contacted ground impact. Thus, they can effectively absorb bumps, potholes, and other irregularities on the uneven surface of roads to provide a smoother and more comfortable experience for drivers and their passengers [9,12]. The mechanical properties of ELSs allow for better ground contact and stability, which can better navigate uneven surfaces and facilitate engagement in lateral or multi-directional movement. However, research on the application of ELSs for designing prosthetic feet is limited, and the potential benefits of this spring design in terms of energy storage and release, stress distribution, and overall movement performance for individuals with transtibial lower limb amputation thus remain unknown. Prosthetic feet are integrated into the lower extremities to facilitate the interaction of muscle–tendon units with the skeletal system by generating, storing, dissipating, and transferring energy between segments [13] while stabilizing the joints and controlling balance [1,14]. This integration saves energy, thus allowing for walking with less effort [1,15].

This study aims to comprehensively evaluate the biomechanical effects of a novel ELS-foot design for individuals with unilateral below-knee amputation. The ELS-foot, constructed with carbon fiber springs and a rocker bottom sole, is designed to enhance energy efficiency, stability, and mobility during dynamic activities. By comparing the ELS-foot to participants' existing prostheses through a series of functional tests, the research demonstrates significant improvements in balance, movement, and jump performance. These findings provide valuable scientific evidence and design insights to guide the development of advanced prosthetic technologies, ultimately aiming to improve the quality of life for amputees.

2. Materials and Methods

2.1. Design of a Novel ELS-Foot Prosthesis

The ELS-foot design includes upper and lower layers of leaf springs, which were constructed by using carbon fibers, spring sleeves, a sleeve housing, side locks, and a rocker bottom sole, which was made by using ethylene-vinyl acetate (EVA) (Figure 1). The ELS-foot was designed to innovatively provide optimal balance between cushioning and efficient energy management through the leaf springs, which effectively store and return elastic energy. The rocker bottom sole improves propulsion by redistributing load and smoothing the ground reaction forces. It reduces peak GRF and creates a more controlled movement, helping maintain stability by ensuring a smoother shift in the center of pressure during walking. This minimizes abrupt changes that could cause imbalance. The curved design, along with a platen platform, also provides cushioning and support, reducing the risk of falls by preventing sudden forward momentum or instability.

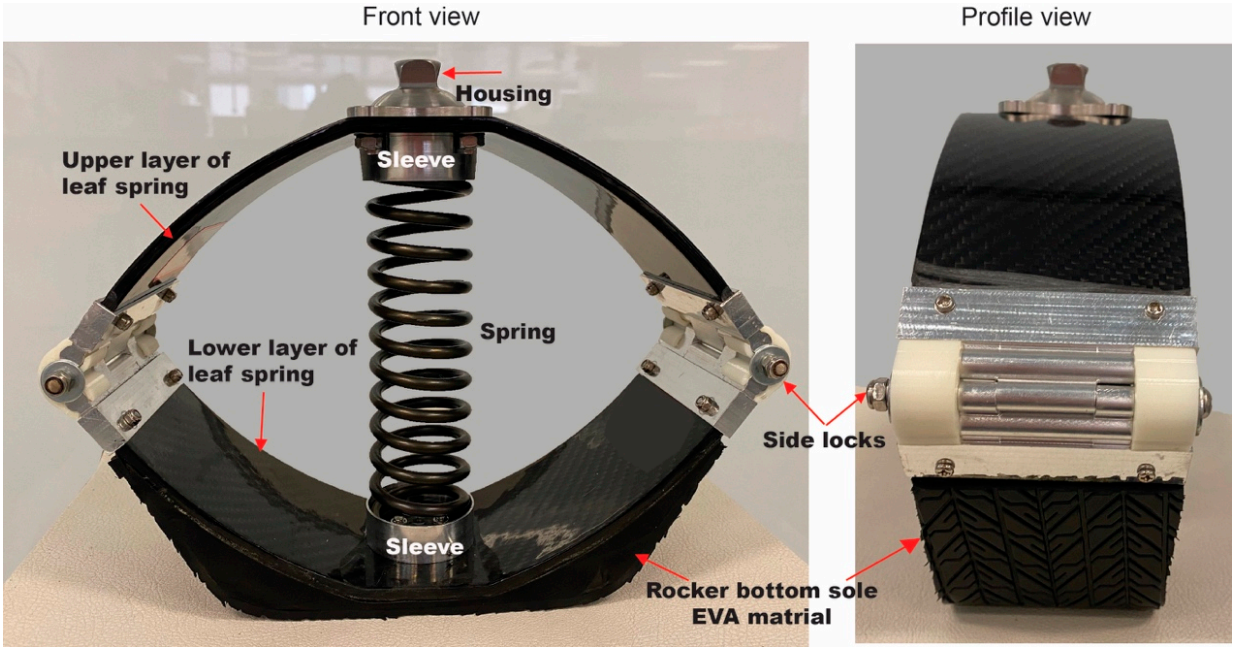
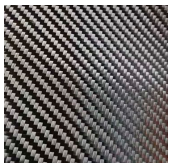
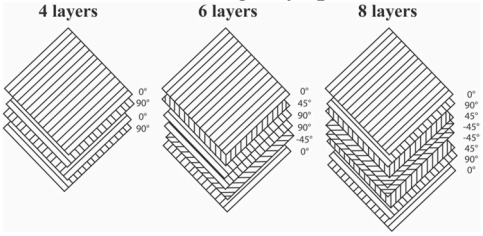


Figure 1. ELS-foot design features.

To identify the most suitable composite material for the ELS-foot design, pre-impregnated materials including 3K twill weave carbon fibers and 150 gsm unidirectional carbon fibers provided by TORAY INDUSTRIES (Tokyo, Japan) were used to prepare the specimens. To account for the influence of material thickness and orientation on the mechanical properties, a total of 6 samples were prepared in configurations of a four-layer laminate [0°/90°/0°/90°], six-layer laminate [0°/+45°/90°/90°/−45°/0°], and eight-layer laminate [0°/90°/+45°/−45°/−45°/+45°/90°/0°] (see details in Table 1). This structured approach allows for a detailed comparison of the material performance under tensile stress, thus providing invaluable insights into their suitability for ELS-foot designs [16]. The thickness and weight of the specimens prepared with different number of layers and material orientations are listed in Table 1.

Table 1. Details of carbon fiber fabric specimens.

	Unidirectional Carbon Fiber			**Woven Carbon Fiber**		
Carbon Fiber						
Structure Fabrication	Uni-directional			Woven Twill		
Layers and Stacking Sequence	Pre-Preg Layup 					
Composite Code	UD4	UD6	UD8	W4	W6	W8
Thickness (mm)	0.4	0.97	1.24	1.06	1.48	1.92
Weight (g)	108	136.8	190.18	148.3	190.1	256.3

Note: UD indicates unidirectional carbon fiber, and W indicates woven carbon fiber.

Tensile tests were conducted to evaluate the mechanical properties of the materials with different layers and orientations. The tests were carried out by using an Instron 6000 mechanical testing machine. Each specimen was subjected to 10 cycles to ensure reliability of the results. The specimens were designed to have a rectangular bar shape with dimensions of 250 mm × 25 mm × 5 mm (see Figure 2). Six replicates of each specimen were prepared, and their average tensile strength was calculated.

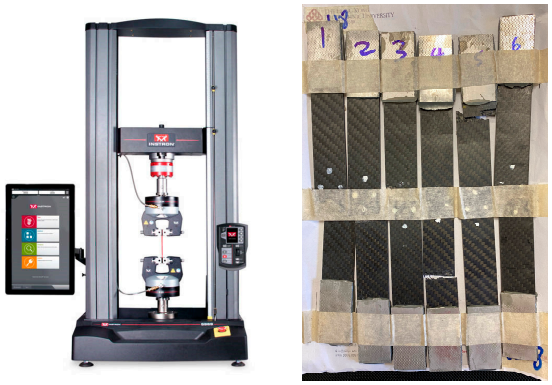


Figure 2. Instron 6000 and specimens used for tensile test.

Figure 3 plots the tensile strength of the composite materials. The samples are denoted as UD for unidirectional carbon fiber and W for woven carbon fiber. The W8 sample shows exceptional tenacity amongst the 6 samples studied and has a peak tensile strength of 20,936 N/tex. The gradient of the stress–strain curve of W8 shows that this sample has good elastic properties, thus confirming that W8 can recover its original shape after the applied load is removed, which is suitable for use in the ELS-foot. Table 2 lists the weight for each component of the ELS-foot.

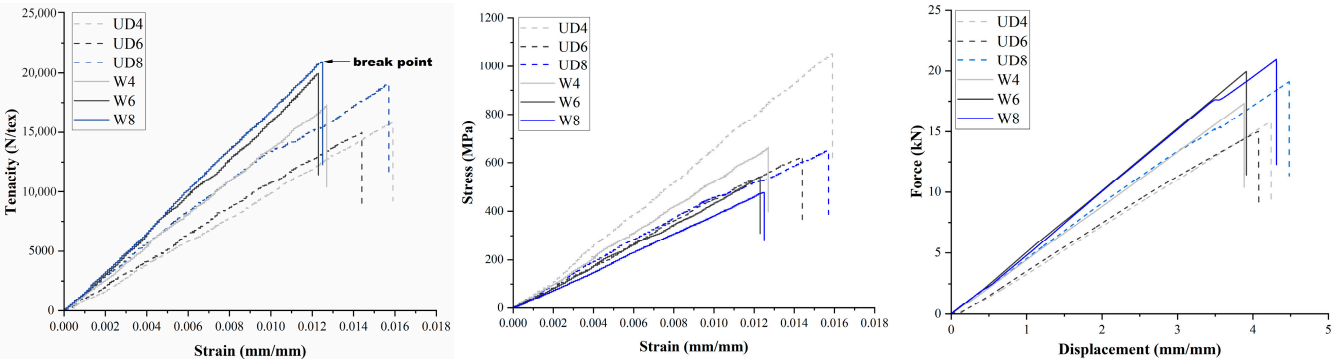


Figure 3. Tensile strength of different layers and orientations of fibers.

Table 2. Details of ELS-foot components.

Type of Material	Component	Unit	Total Weight (g)
Carbon fiber	Semi-elliptical leaf spring	2	284.0
	Side joint	4	116.0
	Holder	4	15.2
Metal	Rotational pyramid	1	50.0
	Spring sleeve	2	57.6
	Spring	1	32.3
	Screws for side joints	6	32.0
Steel	Screws for pyramid	4	14.4
	Screws for spring sleeves	2	32.0
Total	633		

2.2. Participants

To evaluate the performance of the ELS-foot during dynamic activities in real-life scenarios, six individuals including two females and four males were recruited from an orthotic and prosthetic association in Hong Kong. Table 3 presents the information of participants recruited between 1 October 2023 and 31 December 2023. Human subject ethics approval was obtained from the university ethics committee (HSEARS20220411007) for this study. The inclusion criteria are that the participants have to (1) have a unilateral transtibial amputation, (2) be using a prosthesis classified as Medicare Functional Classification Level (MFCL or K Level) [17] 2 (K2) or higher, and (3) be able to walk freely without the use of any additional walking aid like a stick, crutches, or a walker. Prior to the commencement of the study, the recruited participants were informed about the study's content and signed consent forms agreeing to the use of their testing data for analysis. Then a certified prosthetist–orthotist conducted the fitting and alignment procedures for each participant. The participants underwent a two to three-week acclimatization period to adjust to their individual socket alignment and ELS-foot [18,19]. The prosthetist–orthotist conducted a subjective evaluation to ensure proper fit and alignment of the prosthetic feet, sockets, and components (e.g., wire diameter of the spring) for each participant prior to the wear trial. Each participant visited the laboratory two times during a 3-to-5-day interval for the wear trial. Furthermore, they were required to wear the same tight-fitting garments, shoes, liner, and sockets for the two visits to reduce any variability.

Table 3. Participant profiles.

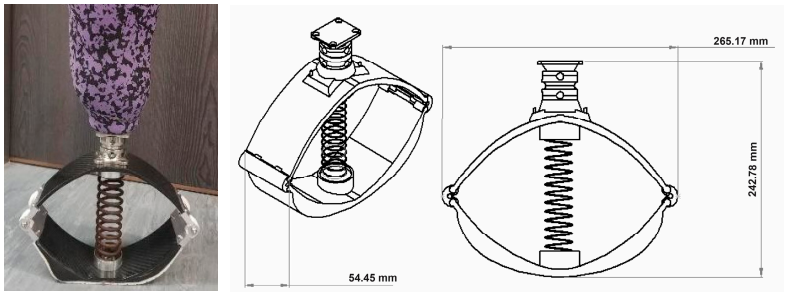
Participant Number	1	2	3	4	5	6	Mean (SD)
Gender	F	M	M	M	F	M	
Age (years old)	52	70	46	51	64	36	53.2 (12.3)
Body mass (kg)	67.1	63.5	76.0	72.3	69.0	82.0	71.7 (6.6)
Height (cm)	157	165	182	171	158	181	169.1 (10.8)
Residual limb side	R	L	R	L	R	L	
Years of using prosthetic foot	21	42	17	30	48	6	27.3 (15.8)
Type of prosthetic foot used	Pro-Flex® XC	AllPro fillauer	Pro-Flex® XC	Pro-Flex® XC	Triton	Rush Lo-Pro	
MFCL	K3	K4	K3	K3	K2	K2	
Average daily walking speed (km/h)	4.2	4.0	6.1	4.0	4.1	4.1	4.4 (0.8)

Notes: F indicates female; M indicates male; L indicates left; and R indicates right. The MFCL guides the type of prosthetic component that can be used for activity level, where K2 indicates that the individual has the ability or potential for limited community ambulation; K3 indicates the ability or potential for ambulation with variable cadence and capability to transverse most environmental barriers and partake in vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion; and K4 indicates the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, which involve high impact, stress, or energy levels [20].

2.3. Experimental Protocols

The participants either used the ELS-foot (experimental, 633 g) or their own prosthesis (control, i.e., ProFlex XC foot, 500 g) (Figure 4) in a randomized order during the experiment in the following conditions: (1) to conduct basic mobility functions, including (a) the Timed Up and Go (TUG) test, which requires standing up from a chair, walking 3 m, turning around and walking back to the chair, and then sitting on the chair. More than 13.5 s for completion of the TUG test indicates high risk of falling [21], (b) Four Square Step Test (FSST), during which the participants stepped forward, backward, and sideway, while time to complete the test was measured [22], and (c) 10-Meter Walk Test [23]; (2) balance function tests, including (a) the Berg Balance Scale (BBS) test, which has 14 tasks [24]. The total score for all tasks is a maximum of 56. A score of 0–20 indicates a high risk, 21–40 indicates a medium risk, and 41–56 indicates a low risk of falling [24,25], (b) eyes-closed standing test [25], (c) Tandem Test [26], participants stood with one foot in front of the other, heel touching toes, and (d) Functional Reach test, during which the participants move from

a vertical standing position to their maximum leaning forward position, with feet firmly placed on the floor with either the ELS-foot or control and performed three times. The average distance (cm) with the two prostheses are compared [27]; (3) jumping feasibility test; (4) gait pattern with different prostheses through lower limb joints' kinematic and kinetic analyses; and (5) subjective evaluation by using the Locomotor Capabilities Index (LCI) questionnaire, which has 14 items to assess locomotor skills and level of independence with the use of a lower-limb prosthesis. Each item is rated on a 5-level scale (0, unable; 1, high difficulty; 2, moderate difficulty; 3, little difficulty; and 4, no problems) [28].



ELS-foot (experimental) Example of prosthetic foot of participant (control)

Figure 4. Prostheses used in this study.

The force plate (Bertect, Columbus, OH, USA; 400 × 600 mm; 1000 Hz) was used to determine performance during the eyes-closed standing and jumping tasks. For the former task, each participant stood still in the center of the force plate with either the ELS-foot or control for 30 s, and the testing was repeated three times. Then, each participant was asked to perform three countermovement jumps on the force plate on either the ELS-foot or control. During the countermovement jump, the participant was required to use a self-selected depth and place their hands on their hips to eliminate the influence of arm swing [29]. They conducted the countermovement maximum jump at least three times with either the ELS-foot or control to ensure the acquired data were suitable for analysis.

Thirty-nine passive-reflective markers of 14 mm in diameter were placed on the participants (Figure 5) according to the landmarks set of the plug-in full body model [30]. An 8-camera motion capture system (VICON, Nexus 2.0 Inc., Oxford, UK) and 2 force plates (Advanced Mechanical Technology, Inc., Watertown, NY, USA) mounted under the walkway were utilized for the gait analysis and recorded 100 frames per second simultaneously. All of the systems were calibrated before the experiment started. The participants walked over the force plate at a self-selected walking speed by using his/her normal gait [31,32], and the foot would land on the force plate naturally [6,31]. Their average self-selected walking speed was 3.7 ± 0.4 km/h. Each participant repeated the walking trials until a minimum of 5 "clean" foot force plate contact was acquired with both the left and right limbs [33,34].

2.4. Data Analysis

To compare the outcome variables with the ELS-foot and control, the average center of pressure value was calculated by using Noraxon software (Version 3.14.78) for the anterior–posterior stability index (APSI) and medial–lateral stability index (MLSI) obtained through the eyes-closed standing test to evaluate the postural stability with the use of each prosthesis. The average jump height from three trials, along with vertical ground reaction force values during the different jump phases (i.e., weighing, unweighting, braking, propulsion, flight, and landing), was compared between the two prostheses. Kinetic and kinematic data from five gait cycles of both the intact and residual limbs were analyzed to evaluate the gait pattern with different prostheses. One-way repeated measures analysis of

variance was conducted using SPSS Statistics 22 (IBM Corporation, Armonk, NY, USA) to evaluate the performance between the ELS-foot and control for within-subject comparison. Statistical significance was set at $p < 0.05$.



Front view Profile view Back view

Figure 5. Landmarks attached onto participant.

3. Results

3.1. Mobility, Balance, Jumping, and Subjective Evaluation

The results are shown in Table 4, in which it can be observed that the only significant difference between the two prostheses is for TUG. In terms of mobility function, the participants walk faster during the FSST with the ELS-foot compared to the control (8.67 ± 2.53 vs. 9.75 ± 1.87, respectively). Except for the Functional Reach test, the participants on average are able to better balance during eyes-closed standing and the Tandem Test with the ELS-foot. Additionally, they have a slightly higher maximum jump height with the ELS-foot compared to the control (10.50 ± 4.53 cm vs. 9.88 ± 5.12 cm, respectively). Figure 6 shows that the average flight time with the ELS-foot is 0.23 s, which is longer than the control of 0.17 s. On the other hand, the average LCI score of the ELS-foot is slightly lower compared to the control (56 ± 0.00 vs. 54.33 ± 1.53).

Table 4. Test results: ELS-foot vs. control.

Test Items			Control	ELS-Foot	F	*p*	h^2
Mobility Function	TUG (s)		9.62 ± 0.60	9.75 ± 1.97	0.91	0.02 *	0.01
	FSST (s)		9.75 ± 1.87	8.67 ± 2.53	5.15	0.15	0.72
	10 m walk test (s)		4.48 ± 0.06	5.08 ± 1.32	0.57	0.53	0.22
Balance Function	BBS (score)		56	56			
	Eyes-closed standing (mm)	APSI	39.77 ± 4.52	32.30 ± 15.92	0.52	0.23	0.23
		MLSI	27.98 ± 11.47	23.38 ± 6.50	0.53	0.22	0.22
	Tandem Test (mm)	APSI	45.58 ± 9.91	39.60 ± 8.25	0.13	0.75	0.75
		MLSI	36.54 ± 2.57	33.42 ± 3.84	0.34	0.43	0.43
	Functional Reach test (cm)		35.03 ± 8.56	32.73 ± 4.69	0.52	0.55	0.21
Jumping Performance	Jump height (cm)		9.88 ± 5.12	10.50 ± 4.53	1.3	0.37	0.4
Subjective Evaluation	LCI (score)		56	54.33 ± 1.53			

Note: * indicates significance, and s indicates second.

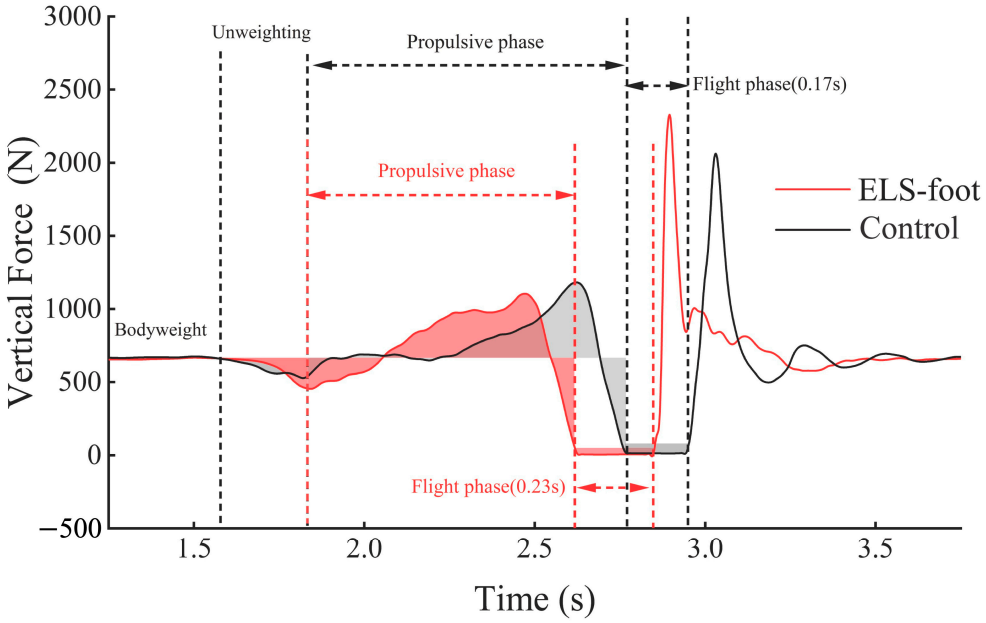


Figure 6. Vertical force during jumping: ELS-foot vs. control.

3.2. Gait Analysis with Different Prostheses

3.2.1. Kinematic Outcomes

Table 5 presents the kinematic outcomes for the intact and residual limbs during walking. For the hip joint, no significant differences can be found for both limbs when using the two prostheses ($p > 0.05$). Figure 7 plots the measured hip angle, which shows that the two prostheses have similar patterns. However, for the knee joint, a notable difference is observed in the maximum knee flexion of both limbs, which is significantly lower when using the ELS-foot compared to the control (ELS-foot vs. control, intact limb: $48.33 \pm 13.00^\circ$ vs. $55.53 \pm 13.59^\circ$, $p = 0.003$, respectively, and residual limb: $39.96 \pm 19.01^\circ$ vs. $57.17 \pm 8.38^\circ$, $p = 0.03$, respectively). Additionally, the range of motion (ROM) of the residual limb of the knee joint is significantly lower when using the ELS-foot ($48.36 \pm 19.53^\circ$ vs. $63.93 \pm 11.03^\circ$, $p = 0.02$). For the ankle joint, significant differences for the residual limb can also be observed between the two prostheses, especially for maximum ankle plantarflexion and dorsiflexion moments when wearing the ELS-foot (Table 4 and Figure 7).

3.2.2. Kinetic Outcomes

Table 6 presents the kinetic changes of the intact and residual limbs across gait cycles. For the former, no significant difference is found between the two prostheses during walking. However, in terms of the power (W/kg) of the residual limb, the maximum hip power generation is significantly reduced during the pre-swing phase (ELS-foot vs. control: 1.54 ± 0.69 vs. 2.41 ± 0.72, $p = 0.005$) with the use of the ELS-foot, while maximum knee power absorption also shows a significant decrease (-2.14 ± 1.16 vs. -3.55 ± 0.85, $p = 0.04$) during the stance phase, and the ankle joint has significantly lower maximum power generation (0.22 ± 0.08 vs. 2.52 ± 0.58, $p < 0.001$) and absorption (0.18 ± 0.10 vs. -1.44 ± 0.45, $p = 0.002$). Additionally, the hip power curves show that the two prostheses have similar trends for both limbs, while notable differences can be observed in the ankle and knee of the residual limb in Figure 7. Regarding the moment (N·m/kg) of the residual limb, using the ELS-foot, a significant decrease is found at maximum hip flexion (-0.77 ± 0.39 vs. -1.45 ± 0.43, $p = 0.02$) and ankle plantarflexion (0.37 ± 0.16 vs. 1.12 ± 0.54, $p = 0.01$) (see Table 5 and Figure 7).

Table 5. Kinematic outcomes of lower limb during walking: ELS-foot vs. control.

	ELS-Foot (Experiment)		Control		*p* Value	
	Intact	Residual	Intact	Residual	I	R
Hip angle						
Max flexion (°)	32.53 ± 10.97	42.00 ± 5.71	34.56 ± 13.06	38.39 ± 10.22	0.70	0.27
tmax flexion (%CT)	89.33 ± 4.14	78.39 ± 14.15	82.07 ± 24.68	78.50 ± 14.41	0.56	0.99
Max extension (°)	−7.28 ± 6.67	0.82 ± 10.10	−6.51 ± 11.18	−5.13 ± 12.16	0.88	0.08
tmax extension (%CT)	53.17 ± 2.67	50.72 ± 1.91	53.94 ± 1.32	50.89 ± 2.17	0.40	0.91
ROM (°)	40.40 ± 7.16	50.73 ± 6.58	45.97 ± 9.43	49.22 ± 7.33	0.13	0.67
Knee angle						
Max flexion (°)	48.33 ± 13.00	39.96 ± 19.01	55.53 ± 13.59	57.17 ± 8.38	0.003	0.03
tmax flexion (%CT)	73.11 ± 2.83	71.06 ± 3.70	73.44 ± 1.56	69.83 ± 4.83	0.74	0.70
Max extension (°)	−9.48 ± 11.71	−2.03 ± 10.49	−3.32 ± 8.39	0.31 ± 8.43	0.20	0.53
tmax extension (%CT)	60.67 ± 29.15	52.17 ± 16.92	50.94 ± 35.93	70.94 ± 26.79	0.19	0.14
ROM (°)	59.35 ± 6.94	48.36 ± 19.53	62.05 ± 14.39	63.93 ± 11.03	0.47	0.02
Ankle angle						
Max dorsiflexion (°)	15.79 ± 7.57	3.74 ± 2.89	17.40 ± 4.62	21.34 ± 5.43	0.40	0.001
tmax dorsiflexion (%CT)	59.53 ± 13.51	39.00 ± 11.84	52.87 ± 4.60	50.73 ± 3.42	0.24	0.06
Max plantarflexion (°)	−12.17 ± 9.39	−2.31 ± 5.00	−13.41 ± 5.55	−0.71 ± 2.14	0.60	0.55
tmax plantarflexion (%CT)	66.80 ± 2.78	64.53 ± 13.92	54.20 ± 27.53	14.27 ± 13.86	0.36	0.01
ROM (°)	28.25 ± 3.65	8.04 ± 3.09	30.82 ± 1.49	23.30 ± 5.16	0.21	0.01

Note: I indicates intact; R indicates residual.

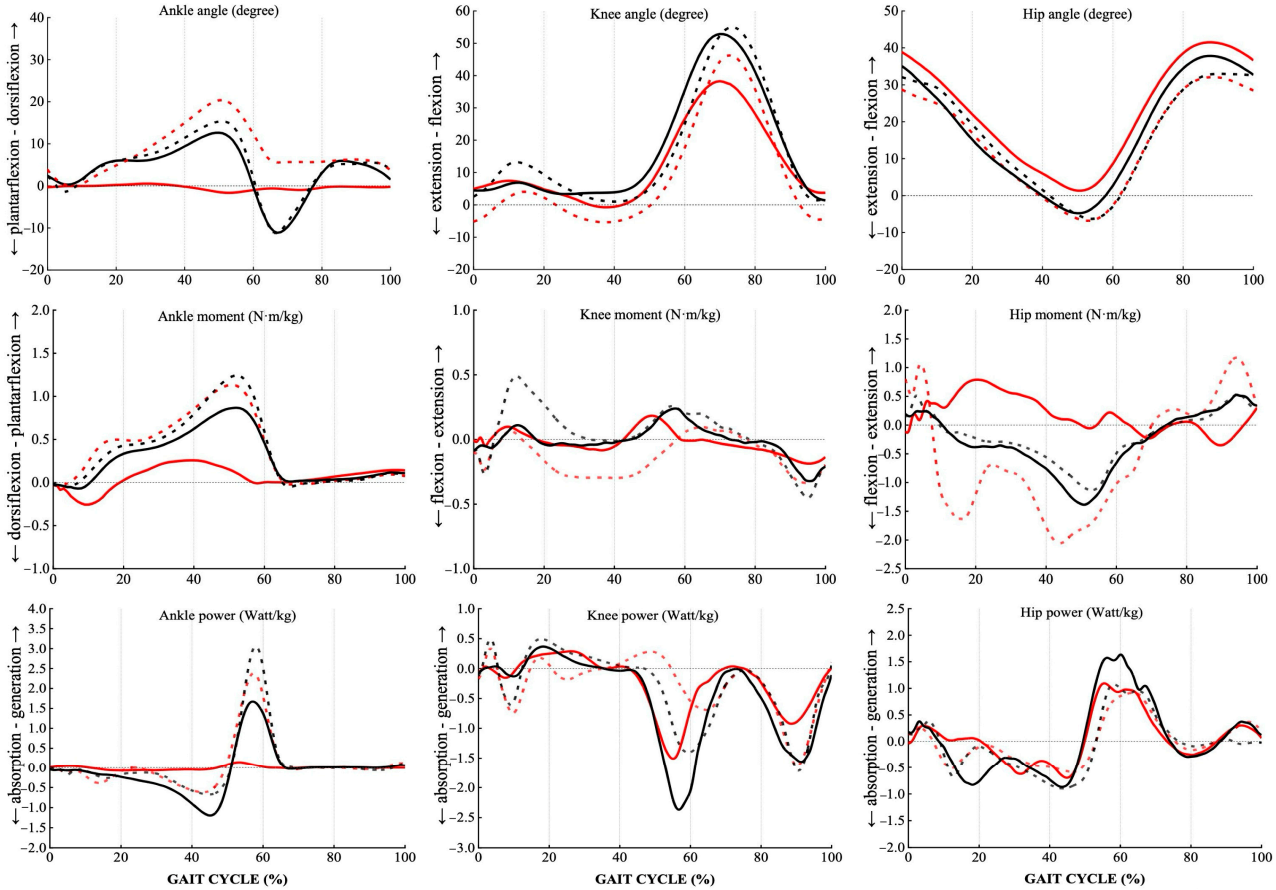


Figure 7. Mean of kinematics and kinetics of lower limb across gait cycle with ELS-foot and control prostheses. 0% indicates heel strike; 100% indicates subsequent heel strike; red solid lines indicate residual limb side with ELS-foot, and red dotted lines indicate intact limb side with ELS-foot; black solid lines indicate residual limb side of control, and black dotted lines indicate intact limb of control side.

Table 6. Kinetic outcomes of lower limb with during walking ELS-foot vs. control.

	ELS-Foot (Experiment)		Control		*p* Value	
	Intact	Residual	Intact	Residual	Intact	Residual
Power (W/kg)						
Hip						
Max generation during pre-swing	1.33 ± 0.30	1.54 ± 0.69	1.53 ± 0.31	2.41 ± 0.72	0.29	0.005
Max absorption during stance	−0.97 ± 0.57	−1.29 ± 0.41	−1.21 ± 0.47	−1.53 ± 0.78	0.55	0.30
Knee						
Max generation in single support	0.85 ± 0.40	0.61 ± 0.26	1.22 ± 0.43	0.62 ± 0.12	0.21	0.96
Max absorption during stance	−2.27 ± 0.69	−2.14 ± 1.16	−2.53 ± 1.11	−3.55 ± 0.85	0.46	0.04
Ankle						
Max generation	2.94 ± 1.49	0.22 ± 0.08	3.31 ± 1.32	2.52 ± 0.58	0.39	<0.001
Max absorption	−0.84 ± 0.38	−0.18 ± 0.10	−0.89 ± 0.26	−1.44 ± 0.45	0.80	0.002
Moment (N·m/kg)						
Hip						
Max extension	0.86 ± 0.24	0.64 ± 0.14	0.95 ± 0.16	0.69 ± 0.22	0.52	0.61
Max flexion	−0.86 ± 0.56	−0.77 ± 0.39	−1.19 ± 0.54	−1.45 ± 0.43	0.46	0.02
Knee						
Max extension	0.27 ± 0.11	0.40 ± 0.24	0.54 ± 0.24	0.53 ± 0.20	0.10	0.26
Max flexion	−0.54 ± 0.17	−0.44 ± 0.22	−0.58 ± 0.20	−0.49 ± 0.22	0.76	0.69
Ankle						
Max plantarflexion	1.17 ± 0.58	0.37 ± 0.16	1.27 ± 0.23	1.12 ± 0.54	0.58	0.01
Max dorsiflexion in loading response	−0.12 ± 0.06	−0.39 ± 0.19	−0.16 ± 0.10	−0.36 ± 0.46	0.36	0.78

4. Discussion

To the best of our knowledge, this is the first study that comprehensively explores the mechanism that underlies the ELS-foot design and focuses on its impact on mobility, stability, and biomechanical efficiency across various tests for unilateral transtibial amputees. The findings showed that participants walk faster during FSST, while they have notably better balance and jump higher with the ELS-foot. These findings provide valuable design strategies and scientific evidence that can inform future advancements in prosthetic technology.

4.1. Mobility

The TUG test is a sensitive and specific measure for identifying fallers and non-fallers [21]. Dite and Temple [17] indicated that 13.5 s is the cutoff time for the TUG test and identified multiple fallers and a healthy group. On the other hand, healthy elderly require 8.4 to 15 s to conduct the TUG test. Although the walking speed of the participants is significantly slower with the ELS-foot during the TUG test, the time ranges from 7.78 to 11.72 s, which means that the participants would not be at risk of a fall in this study. Additionally, the FSST is designed to include a higher level of complexity in stepping tasks compared to existing clinical balance tests. A crucial aspect of this test is to evaluate the ability to quickly shift one's weight throughout the stepping sequence. Although there is no significant difference between the two prostheses for the FSST, the study participants move faster during the FSST with the ELS-foot compared to the use of the control (8.67 ± 2.53 vs. 9.75 ± 1.87, respectively). Dillon [35] found that higher K-levels result in faster walking speed. The findings in this study show that the ELS-foot can provide better flexibility with its unique elliptical shape and rocker bottom sole that is constructed with EVA so the participants are able to move faster and quickly shift their weight during complex movements but not at the risk of a fall.

4.2. Balance

Falls are associated with functional decline and are closely related to imbalance and loss of mobility. To maintain balance, amputees must be capable of holding specific postures, make the appropriate adjustments for voluntary movements, and respond to various external factors. In our study, lower APSI and MLSI values are found for both eyes-closed standing and Tandem tests when the ELS-foot is used, thus indicating that the participants have less body sway when performing postures in these two tests to calculate the two indexes with the ELS-foot. Arifin et al. [25] concluded that the postural steadiness of below-knee amputees is significantly influenced by their prosthesis when visual cues are absent, and the absence of visual input increases postural sway and poor balance. Notably, Major et al. [36] found that the most passive prostheses have restricted ROM in the frontal plane, which may impact the ability to maintain tandem standing as this position requires some foot eversion and possibly internal rotation, while a poor ability to execute controlled internal rotation may also limit performance during a 360-degree turn on the spot. This indicates that the ELS-foot may directly contribute to the aforementioned more rapid transitions in complex environments and higher mobility range scores due to its better stabilization function. Although the BBS test may not be sensitive enough to compare the two types of protheses with the same results in this study, it still revealed a low risk of falling. The lack of confidence in maintaining balance and a fear of falling can significantly restrict the ability to move freely, engage in social activities, and participate in community events. These limitations can lead to a diminished quality of life because they reduce opportunities for exercise, social connections, and active involvement in community life. The mechanical characteristics of the ELS-foot design improve ground contact and stability, thus amputees feel more confident in participating more freely in various activities.

4.3. Jumping Performance

The participants are able to obtain a higher maximum countermovement jump height with the ELS-foot, and the average flight time is longer (0.23 s) than that of the control (0.17 s) during propulsion (Figure 6). Willwacher et al. [37] found that a below-knee amputee can achieve a similar jump distance as that of world-class athletes who do not have an amputation by using a more effective take-off technique in the long jump. The take-off phase involves the transition from downward movement (countermovement) to upward propulsion. A longer take-off time can allow for greater force development and more effective use of the stretch-shortening cycle, which can enhance the jump height. Hobara et al. [38] found that sprinters who are below-knee transtibial amputees have a longer flight time than other transfemoral amputee and non-amputee sprinters during jumping, which indicates that they can jump higher at a given frequency. Our findings show that the ELS-foot design improves the power generation at push off, and this energy can be effectively transferred to propulsion and result in a higher jump height.

4.4. Gait Pattern with Different Prostheses

Quantitative evaluations of prostheses depend on the kinematic and kinetic characteristics. Su et al. [39] found that individuals with lower limb amputation exhibit reduced ankle dorsiflexion and knee flexion during the stance phase, along with a lower peak ankle plantar flexor moment and reduced positive ankle power (energy return) in the late stance. Additionally, there is an increase in both positive and negative hip power. Participants in this study seem to show less-efficient gait at the ankle and knee joints evidenced by reduced ankle and knee joints movement. But both hip power absorption and generation are reduced with the ELS-foot compared to the control. They exhibited pelvic lifting on the swing side during gait, a compensatory action referred to as hip hiking. This move-

ment is commonly observed in individuals with a unilateral transtibial or transfemoral amputation [40]. It is believed to be a compensatory mechanism to increase prosthetic foot clearance due to the inability to dorsiflex the prosthetic ankle [41]. In this study, the unilateral below-knee amputees show reduced hip hiking during walking with the ELS-foot. As such, the ELS-foot may reduce their energy expenditure and increase their gait efficiency at the hip joint. However, further modifications to the ELS-foot that can enhance gait efficiency across the lower limb joints including ankle and knee joints during walking are needed. They may also contribute to enhancing the subjective perception of amputees towards the practical use of the ELS-foot.

4.5. Limitations

This study has several limitations that should be addressed in future research. First, the sample is limited to unilateral below-knee amputees with a K2 or higher mobility level who use a prosthesis. Future studies can include a larger and more diverse sample to enhance the generalizability of the findings. Second, most of the participants in this study have been using their own prosthesis on average for over twenty years. This long-term use may cause bias when they compare the ELS-foot to their own prosthesis. Lastly, for practical applications, further modifications and improvements to the ELS-foot are necessary. Future studies should focus on refining the design to better meet the needs of users and provide more direct evidence (e.g., ergonomic-wise analysis) on the effectiveness of the prosthetic foot.

5. Conclusions

This study has provided a comprehensive analysis of the ELS-foot prosthetic design and its impact on the mobility, stability, and biomechanical efficiency of unilateral transtibial amputees. Our findings indicate that the ELS-foot may enhance certain aspects of physical performance, including walking speeds, balance, and jump heights, potentially due to its elliptical shape and rocker bottom sole. These features appear to facilitate energy transfer and stability. While the study highlights the potential benefits of the ELS-foot in improving mobility and participation in activities, further research is needed to fully understand its impact across diverse user populations and settings. The insights gained from this study contribute to the ongoing development of prosthetic technologies aimed at enhancing the functional capabilities and life experiences of individuals with lower limb amputations.

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Abbreviations

The following abbreviations are used in this manuscript:

APSI	Anterior–posterior stability index
BBS	Berg Balance Scale
ELS	Elliptical leaf spring
EVA	Ethylene-vinyl acetate
FSST	Four Square Step Test
LCI	Locomotor Capabilities Index
MLSI	Medial–lateral stability index
TUG	Timed Up and Go

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