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Original Article

Assessment of the relationship between rectus femoris cross-sectional area and knee extension strength in the prosthesis users with transtibial amputation: A case-control study

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ABSTRACT

Objectives: This study aims to investigate cross-sectional area of the amputated-limb rectus femoris compared to the intact-limb and controls and to determine its correlation with functional strength and walking tests in prosthesis users with transtibial amputation.

Patients and methods: Between October 2018 and April 2019, a total of 14 prosthesis users (12 males, 2 females; mean age: 47.1±16.2 years; range, 26 to 73 years) who met the inclusion criteria, and 14 age-, sex-, and dominancy-matched able-bodied controls (12 males, 2 females; mean age: 47.1±16.2 years; range, 26 to 73 years) were included in this case-control study. Cross-sectional area of rectus femoris (CSA-RF) was evaluated bilaterally by two independent examiners. Knee extension strength was measured bilaterally by using a handheld dynamometer. Functional strength and walking were assessed by Step-Up-Over and Walk-Across tests of the NeuroCom Balance Master® device.

Results: The CSA-RF was found to be reduced in amputated-limb compared to the intact-limb and able-bodied controls ($p<0.01$). In the prosthesis users, the cross-sectional area difference between both limbs rectus femoris muscles was shown to be correlated with actual and functional knee extension strength, step length, and walking speed ($p<0.05$). Intra- and inter-observer reliability of CSA-RF on both sides were found to be good to excellent (intraclass correlation coefficient: 0.856-0.936).

Conclusion: Ultrasonographic measurement of CSA-RF is a valid and reliable tool to assess the functional strength and walking in the prosthesis users with unilateral transtibial amputation.

Keywords: Amputees, muscle strength, rectus femoris, rehabilitation.

Knee extension strengthening is one of the key elements of rehabilitation in prosthesis users with transtibial amputation.[1,2] It is crucial in improving functional mobility, preventing the risk of fall, and the development of knee osteoarthritis.[3,4] Therefore, objective measurements to evaluate changes in functional strength and walking are needed to evaluate the success of rehabilitation. However, most of the objective measurement methods require expensive and sophisticated equipment such as force plates, motion tracking systems, and devices.[5]

Ultrasound is a non-invasive, fast, cost-effective, and increasingly easily accessible imaging tool. Ultrasound measurement of cross-sectional area was found to be valid and highly correlated with magnetic resonance imaging and dual-energy X-ray absorptiometry measurements[6] and shown to reflect the strength and functional outcomes in various

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diseases.[6,7] Moreover, several studies examining the value of ultrasound in the assessment of training programs have reported that cross-sectional area of rectus femoris (CSA-RF) is an indicator of knee extension strength.[8,9] Although CSA-RF was also evaluated in both limbs of prosthesis users with transtibial amputation,[10,11] its relation with functional strength and walking have not been previously investigated.

In the present study, we hypothesized that the CSA-RF of amputated-limb was correlated with functional strength and walking. The first objective of this study is to reveal the CSA-RF alteration measured with ultrasonography in prosthesis users with transtibial amputation compared to able-bodied controls and establish its correlation with functional strength and walking tests. The second objective is to determine intra- and inter-observer reliability and validity of CSA-RF measured by ultrasound in prosthesis users with transtibial amputation.

PATIENTS AND METHODS

This single-center, case-control study was conducted at Marmara University Faculty of Medicine, Physical Medicine and Rehabilitation Department between October 2018 and April 2019. Prosthesis users with transtibial amputation and their age, sex- and dominancy-matched (1:1) able-bodied controls to provide an amputation-independent reference were included. Dominancy was evaluated by asking which foot would use to kick a ball.[12] Inclusion criteria were as follows: unilateral transtibial traumatic amputation on the right side, using the prosthesis for more than one year, being able to use the prosthesis without pain and discomfort, and being able to walk without a walking aid. Exclusion criteria were as follows: the presence of concomitant health issues (diabetes mellitus, peripheral artery disease, and other vascular diseases, etc.), ongoing pathology with the contralateral or residual limb (pressure sore or ulcer etc.), taking medication that is known to affect balance, and the presence of diseases that might alter balance such as polyneuropathy, multiple sclerosis, inner ear issues. The rigid inclusion criteria were used to achieve a homogeneous transtibial amputated group and to remove confounding factors such as dominancy or amputation side as much as possible. Vascular etiology was excluded, as it was found to be related to sensory deficits, other comorbidities, and inactivity.[13,14] A total of 20 prosthesis users with

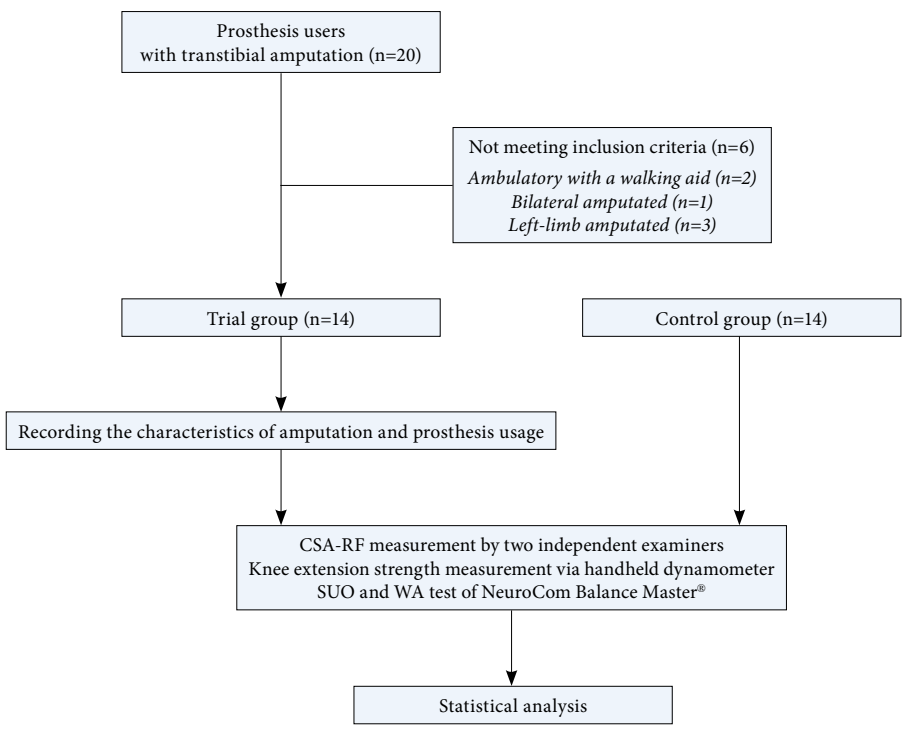

Figure 1. Study flow chart.
CSA-RF: Cross-sectional area of rectus femoris; SUO: Step-Up-Over; WA: Walk-Across.

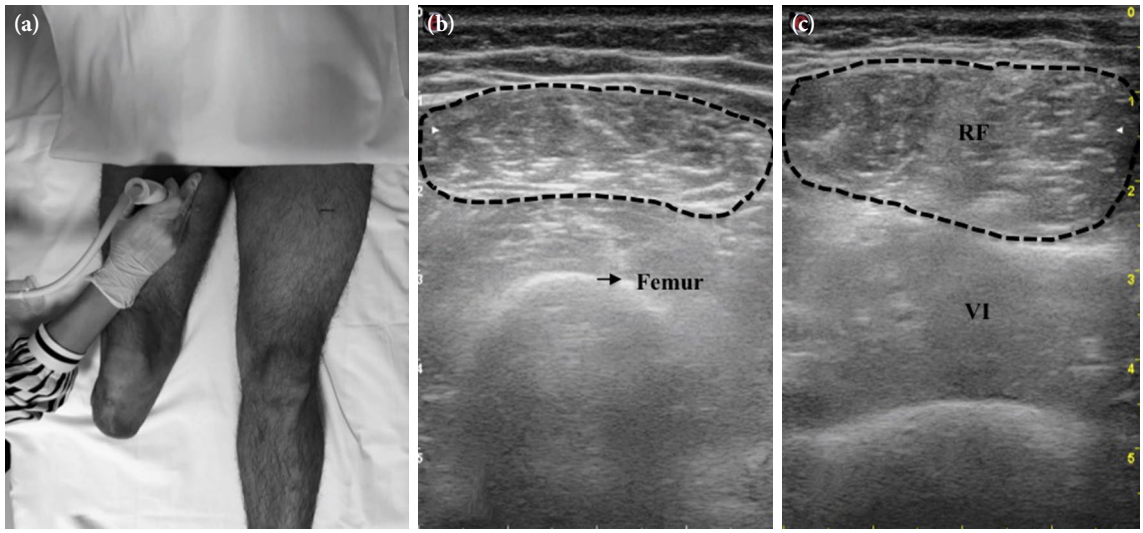

Figure 2. **(a)** The position of the patient on the examination table while performing ultrasound measurements; **(b)** Cross-sectional area of rectus femoris on the amputated-side; **(c)** Cross-sectional area of rectus femoris on the intact-side.
RF: Rectus femoris; VI: Vastus intermedius.

transtibial amputation were assessed for eligibility. Of these, 14 prosthesis users (12 males, 2 females; mean age: 47.1±16.2 years; range, 26 to 73 years) who met the inclusion criteria, and 14 age-, sex-, and dominancy-matched able-bodied controls (12 males, 2 females; mean age: 47.1±16.2 years; range, 26 to 73 years) were included in the study (Figure 1).

Bilateral CSA-RF was measured by two independent examiners using a 6- to 18 MHz linear array probe (Logiq P5, General Electric Ultrasound System, IL, USA). For standardization of the image setting, frequency (12 MHz), time gain compensation (32 dB) and depth (5.5 cm) were kept constant. The participant lied in supine position with lower limbs extending and relaxed. Images were obtained midway between the anterior superior iliac spine and the upper pole of the patella, at the bulkiest area of muscle at mid-thigh. The probe was held axially with a light touch in order not to cause any difference in the muscle volume (Figure 2a).[10] The CSA-RF (mm^2) was calculated automatically by the ultrasound device (Figure 2b, c). Both examiners with at least five years of experience in musculoskeletal ultrasonography obtained the images independently on the same day for the inter-observer reliability. The first examiner, then, re-assessed them 24 h later for the intra-observer reliability.

Bilateral knee extension strength was measured with a handheld dynamometer (Jamar®, Bolingbrook, IL, USA) located 5 cm above the intermalleolar line. All participants were tested while sitting position with the knees flexed 90° (Figure 3). For the amputated-limb, the prosthesis was used in place.[4] First, all participants were allowed to practice the procedure, until they felt comfortable. Then, three trials with at least 10 sec

Figure 3. The position of the patient on the examination table while performing knee extension strength measurement via a handheld dynamometer (Jamar®, Bolingbrook, IL, USA).

of a resting period were performed in the maximal strength for 5 sec. The average strength measurement (kg) of the three trials was taken.

Functional strength and walking were assessed using the Step-Up-Over (SUO) and Walk-Across (WA) tests of the NeuroCom Balance Master® device (NeuroCom International, Clackamas, OR, USA). An 18×60-inch pressure platform connected to the computer system and a 20-cm high box were used for these tests to detect the center of gravity direction and movement speed. For the SUO test, all participants stood still behind the box placed on the pressure platform and to prompted to move immediately after seeing the sign on the computer screen. The movement was defined as three phases: first stepping onto the box with one limb, second carrying the body over the box, and third landing with the other limb on the opposite side of the box (Figure 4a-c). After participants were allowed to practice, until they comprehend the task, three tests for both limbs were performed with at least 10 sec of a resting period, and the average results were taken.[15] The lift-up index (percentage of the body weight), the maximal vertical force recorded as the body raised onto the box, and the impact index (percentage of the body weight), the maximal vertical force recorded at the touch-down, were measured during the first and third phases respectively. Movement time (sec), the time from initiation of the movement until the touch-down was achieved from all three phases.[4] The lift-up index as characterizing the leading leg's knee extensor concentric control, the impact index as marking the leading leg's knee extensor eccentric control, and the movement time including both were found to be objective measurement options reflecting knee function in patients with anterior cruciate ligament reconstruction.[4,16] In addition, the intra- and inter-session reliability was determined very good to good in healthy subjects.[17] For the WA test, all participants were asked to start walking as briskly as possible along with the pressure platform after seeing the sign on the computer screen. The average step width (cm), step length (cm), and speed (cm/s) were calculated after three repetitions.[12] The knee extension strength measurement, functional strength, and walking tests were assessed, when the prosthesis was on and after the prosthetic fit was ensured by a prosthetist, orthotist, and physiatrist specialized in amputee rehabilitation.

Statistical analysis

Preliminarily, the sample size calculated including five patients and five controls. The mean and standard deviation (SD) of right CSA-RF was found to be 631.8±105.3 mm^2 and 806.7±169.8 mm^2 for prosthesis users and controls, respectively. Power analysis using a power of 90% and a margin of error of 5% determined 14 prosthesis users and 14 controls to detect a significant difference between groups.

Statistical analysis was performed using the SPSS for Windows version 18.0 software (SPSS Inc., Chicago, IL, USA). The normal distribution of quantitative values was assessed using a histogram, a Q-Q plot, and the Shapiro-Wilk test. Descriptive data were expressed in mean ± SD, median (min-max) or number and frequency, where applicable. The Wilcoxon test was used to compare quantitative variables in-between the prosthesis users, whereas the Mann-Whitney U test to compare quantitative variables between the prosthesis users and controls. The Spearman's rho correlation

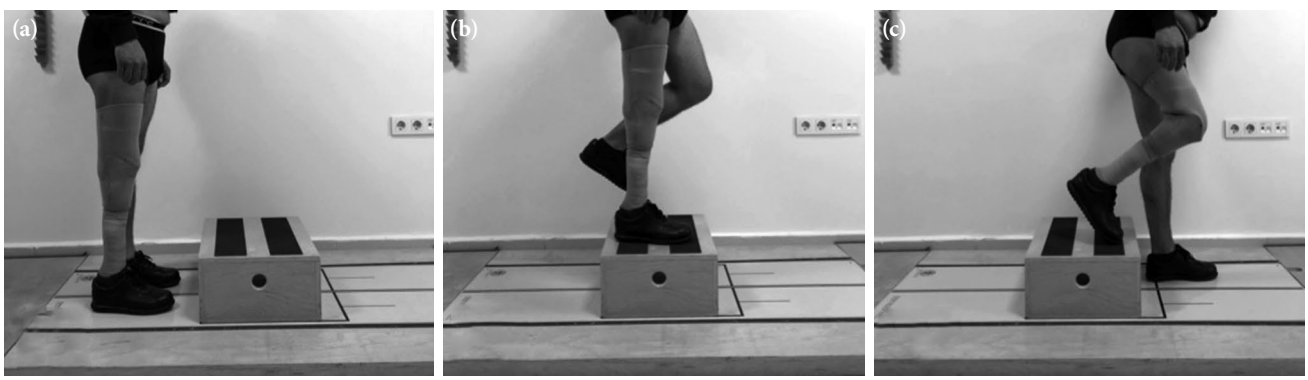

Figure 4. Step-up-over (SUO) of NeuroCom Balance Master® device (NeuroCom International, Clackamas, OR, USA); **(a)** Stepping onto the box with one limb; **(b)** Carrying the body over the box; **(c)** Landing with the other limb on the opposite side of the box.

analysis was performed to examine the relationship between muscular parameters and functional tests in the prosthesis users' group. The intraclass correlation coefficient (ICC) estimates and their 95% confidence intervals (Cis) for inter-, intra-observer, and inter-trial reliability analysis were calculated based on single measurement, consistency, two-way random-effects model for CSA-RF, and three times repeated measurements. A *p* value of <0.05 was considered statistically significant.

RESULTS

A total of 20 prosthesis users with transtibial amputation were assessed for eligibility. Of these, 14 prosthesis users met the inclusion criteria, and 14 age-, sex-, and dominancy-matched able-bodied controls were included in the study. Demographic characteristics and clinical features of the participants are shown in Table 1.

The mean CSA-RF and knee extension strength were lower, whereas the mean lift-up index and impact index were higher in the amputated-limb compared to the intact-limb of prosthesis users (p=0.001). Comparing the prosthesis users to able-bodied controls, the mean CSA-RF on the amputated-side and knee extension strength on both sides were reduced (p<0.001). The mean lift-up index on the intact-side, step length, and walking speed were decreased, whereas the mean impact index on the amputated-side and movement time on both sides were increased (p<0.05) (Table 2).

The duration since amputation and the stump length was not related to muscular parameters or functional tests (p>0.05). The CSA-RF and knee extension strength on the amputated-side was moderately positively correlated (rho=0.528, p=0.005). The CSA-RF and knee extension strength on the amputated-side and CSA-RF difference between both sides showed varying degrees of correlations with functional strength and walking tests. The CSA-RF on the amputated-side was positively correlated with the lift-up index and the impact index on the intact-side and step length (rho=0.385-0.482, p<0.05). It was negatively correlated with the impact index on amputated-side and movement time on the intact-side (rho=-0.383--0.490, p<0.05). The CSA-RF difference between amputated-side and intact-side was positively correlated with the movement time on both sides and the impact index on the amputated-side (rho=0.465-0.551, p<0.05). In addition, it negatively correlated with the lift-up index and the impact index on the intact-side, step length, and

TABLE 1
Participant characteristics

	Sex	Age (year)	Height (m)	Mass (kg)	Amputated limb	Stump length (cm)	Time since amputation (year)	Cause of amputation	Prosthesis system
1	M	34	1.78	75	R	7.5	15	Trauma	Active vacuum
2	M	57	1.70	85	R	9	6	Trauma	Active vacuum
3	M	69	1.70	80	R	18	3	Trauma	Active vacuum
4	M	38	1.67	70	R	14	16	Trauma	Liner pin
5	M	34	1.68	58	R	9	16	Trauma	Active vacuum
6	M	42	1.70	80	R	6	18	Trauma	Active vacuum
7	M	37	1.65	78	R	10	27	Trauma	Active vacuum
8	M	40	1.78	75	R	9	23	Trauma	Active vacuum
9	M	66	1.83	95	R	10	2	Trauma	Active vacuum
10	F	73	1.70	75	R	11	2	Trauma	Liner pin
11	M	35	1.75	80	R	8.5	20	Trauma	Active vacuum
12	F	39	1.55	85	R	12	11	Trauma	Active vacuum
13	M	26	1.61	65	R	6	5	Trauma	Active vacuum
14	M	70	1.72	89	R	12	13	Trauma	Active vacuum
Prosthesis users	(F=2, M=12)	47.1±16.2	1.7±0.1	77.9±9.5	(R=14)	10.1±3.2	12.6±8.1		
Controls	(F=2, M=12)	47.1±16.2	1.7±0.1	77.9±7.5					

F: Female; M: Male; R: Right; L: Left.

TABLE 2
Comparison in-between the prosthesis users, and between prosthesis users and controls

	Prosthesis users (n=14)			Controls (n=14)		
	Median	%95 CI	*p*†	Median	%95 CI	*p*‡
CSA-RF (mm²)						
Right	509.38	439.53-596.54		720.67	664.35-809.96	**<0.001**
Left	629.76	546.64-694.53	0.001**	651	604.16-787.84	0.308
Difference	112.39	69.92-145.16		-28.33	-91.23-8.92	**<0.001**
Knee extension strength (kg)						
Right	8.33	7.69-10.45	0.001**	13.33	11.95-14.67	**<0.001**
Left	10.33	9.69-12.83		12.5	11.82-14.27	0.032*
Step-up-over						
Lift-up Index (%)						
Right	50.67	42.79-55.92	0.001**	37.67	31.38-54.43	0.089
Left	23.5	19.6-30.12		34.67	29.38-48.19	0.007**
Movement time (s)						
Right	2.48	1.92-4.9	0.730	1.41	1.24-2.02	0.013*
Left	2.33	1.99-3.88		1.64	1.37-2	0.001**
Impact Index (%)						
Right	109.33	101.51-164.2	0.001**	64.5	49.01-75.99	**<0.001**
Left	36.83	29.42-71.36		70.33	55.17-78.64	0.129
Walk across						
Step width (cm)	19.12	17.6-21.97		18.02	15.24-19.98	0.346
Step length (cm)	56.88	48.31-67.27		65.32	62.39-76.01	0.027*
Speed (cm/s)	62.6	52-73.36		78.15	71.7-95.2	0.01*

CI: Confidence interval; CSA-RF: Cross-sectional area of rectus femoris; † Wilcoxon signed-rank test; ‡ Mann-Whitney U test; * p<0.05. ** p<0.01.

walking speed (rho=-0.398-0.748, p<0.05). The knee extension strength on the amputated-side showed positive correlations with step length and walking speed (rho=0.392-0.432, p<0.05) and negatively correlated with the impact index on amputated-side and movement time on the intact-side (rho=-0.376-0.606, p<0.05) (Table 3).

The intra- and inter-observer reliability of CSA-RF on both sides were found to be good to excellent (ICC=0.856-0.936). Inter-trial reliability of knee extension strength on both sides and the WA test parameters were shown to be good (ICC=0.707-0.856), whereas all SUO test parameters to be good to excellent (ICC=0.801-0.964) (Table 4).

TABLE 3
Relationship between muscular parameters and functional tests in the prosthesis users

	CSA-RF (Right) (mm²)		CSA-RF (Left) (mm²)		CSA-RF (Difference) (mm²)		Knee extension strength (Right) (kg)		Knee extension strength (Left) (kg)	
Step-up-over	*p*		*p*		*p*		*p*		*p*	
Lift-up Index (%)										
Right	-0.294	0.136	-0.289	0.144	0.081	0.689	-0.098	0.618	-0.108	0.585
Left	0.482	0.011*	-0.088	0.663	-0.748	<0.001	0.356	0.063	0.133	0.498
Movement time (s)										
Right	-0.162	0.418	0.212	0.288	0.466	0.014*	-0.316	0.101	-0.065	0.742
Left	-0.383	0.048*	-0.015	0.940	0.551	0.003**	-0.376	0.049*	-0.086	0.665
Impact Index (%)					0.465	0.015*	-0.606	0.001**	-0.411	
Right	-0.49	0.01*	-0.165	0.412	-0.571	0.002**	0.07	0.722	-0.223	0.03*
Left	0.412	0.033*	0.040	0.844						0.254
Walk across										
Step width (cm)	-0.06	0.767	-0.075	0.710	0.023	0.909	-0.271	0.163	-0.22	0.261
Step length (cm)	0.385	0.048*	0.274	0.166	-0.398	0.04*	0.392	0.039*	0.259	0.183
Speed (cm/s)	0.291	0.141	0.143	0.477	-0.402	0.037*	0.432	0.022*	0.178	0.366

CSA-RF: Cross-sectional area of rectus femoris; * p<0.05; ** p<0.01; Correlation coefficient (*p* value).

TABLE 4
Intraclass correlation coefficient and 95% confidence interval values of parameters

	Intra-observer		Inter-observer	
	ICC	%95 CI	ICC	%95 CI
CSA-RF (mm^2)				
Right	0.936	0.864-0.970	0.856	0.709-0.932
Left	0.928	0.918-0.983	0.904	0.802-0.955
	Inter-trial			
Knee extension strength (kg)				
Right	0.886	0.799-0.941		
Left	0.852	0.745-0.923		
Step-up-over				
Lift-up Index (%)				
Right	0.801	0.666-0.894		
Left	0.922	0.949-0.986		
Movement time (s)				
Right	0.964	0.934-0.982		
Left	0.929	0.954-0.988		
Impact Index (%)				
Right	0.965	0.936-0.983		
Left	0.875	0.781-0.935		
Walk across				
Step width (cm)	0.707	0.531-0.839		
Step length (cm)	0.801	0.666-0.894		
Speed (cm/s)	0.751	0.593-0.865		

ICC: Intraclass correlation coefficient; CI: Confidence interval; CSA-RF: Cross-sectional area of rectus femoris.

DISCUSSION

The present study demonstrated that CSA-RF could be reliably measured with ultrasonography and showed significant correlations with actual and functional knee extension strength and walking. These results confirmed the hypothesis of the study. Nevertheless, the relationship with functional tests was more remarkable with the CSA-RF difference between the amputated and intact limbs. This finding, in accordance with previous studies, emphasizes that sufficient attention must also be paid to the intact-limb, particularly for functionality.[18,19] Sahin Onat et al.[10] evaluated the influence of the prosthesis type on the cross-sectional area of four heads of the quadriceps femoris. Vastus medialis, vastus intermedius, and rectus femoris cross-sectional area values were shown to be decreased on the amputated-side compared to the intact-side and not to be affected by the prosthesis type. Schmalz et al.[11] also investigated the cross-sectional area of quadriceps femoris on the amputated-side and found it to be lower than the intact-side. Although researches assessed the CSA-RF in both limbs, its comparison to able-bodied controls and relation with functional strength and walking have never been studied. To the best of our knowledge, this study is the first on this subject.

In the prosthesis users with transtibial amputation, knee extension strength on both sides was found to be reduced, compared to the controls. The step length and walking speed were shown to be correlated with the knee extension strength on the amputated-side and the CSA-RF difference between both sides. Powers et al.[3] demonstrated that decreased step length and walking speed was related to both knee extension strengths. Lloyd et al.[4] showed that muscular weakness and asymmetry impacted gait function and symmetry in patients with transtibial amputation. Langlois et al.[2] investigated gait adjustments of prosthesis users on sloped surfaces and revealed that slope down walking speed was associated with knee extension strength of the intact-limb. Vrieling et al.[18] indicated increased load while walking on the intact-limb in highly active unilateral lower limb amputees. Eshraghi et al.[19] found greater load during balance tasks on the intact-limb in children with transtibial amputation. This study, along with the previous ones, highlights the role of knee extension strength of both limbs on walking in the transtibial amputated prosthesis

users and points out the importance of strength improvement during rehabilitation.

Static and dynamic instability was shown to be one of the major problems limiting activities of daily living in individuals with lower extremity loss.[18,20] Limits of stability, one of the tests of the NeuroCom Balance Master® device, was found to be valid for assessing postural stability in transtibial amputation.[21] The SUO, another test of the same device, was used to evaluate functional knee extension strength in this study. The lift-up and impact indexes were determined to be increased in the amputated-side compared to the intact-side, and the impact index was correlated with the muscle strength and CSA-RF on the amputated-side. The movement time was also increased on both sides in the prosthesis users, compared to the controls and found to be related to knee extension strength on the amputated-side and the CSA-RF difference of both sides. The lift-up and impact indexes, both reflecting the maximal vertical force on the pressure platform, could be influenced by the prosthesis material weight. On the other hand, movement time, the time from initiation until the end of the movement, was expressed independently from the weight. Therefore, the movement time was able to provide more objective data, although all three parameters of SUO were shown to demonstrate the knee extension strength of prosthesis users.

One of the limitations of this study is the relatively small sample size, although it was adequate to define the difference between CSA-RF of amputated-limb, compared to the other limb and controls. Moreover, only right limb amputated prosthesis users were included to provide scientific data without any confounds for the amputation side. The results can be safely generalized for left limb transtibial amputees. Another limitation is that only the contribution of the rectus femoris muscle was measured. However, other lower extremity muscles such as gluteus and the hamstrings contribute significantly to the functional assessments which can be the topics of further studies. Finally, the details of the biomechanical properties were excluded in this study, and the evaluation of the prosthetic was included. Differences between different types of prostheses can be evaluated in the future. The strength of this study, to the best of our knowledge, is the first study that reveals the CSA-RF alteration in prosthesis users with transtibial amputation compared to able-bodied controls and determines its correlation with functional strength and walking tests.

In conclusion, the CSA-RF is a valid and reliable assessment tool in prosthesis users with a unilateral transtibial amputation. The difference between the CSA-RF of both sides is shown to reflect functional strength and walking. These data can be implemented in the follow-up during the rehabilitation process.

Ethics Committee Approval: The study protocol was approved by the Marmara University Faculty of Medicine Ethics Committee (date/no: 05.01.2018/09.20118.025). The study was conducted in accordance with the principles of the Declaration of Helsinki. The study was registered at ClinicalTrials.gov (NCT04262297).

Patient Consent for Publication: A written informed consent was obtained from each participant.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Concept, design, resources, data collection, analysis, writing, critical review; K.G.A.; Concept, data collection, analysis, writing, critical review; Ö.K.C.; Concept, materials, data collection, literature search, writing, critical review; E.G.; Concept, supervision, resources, literature search, writing, critical review; O.H.G.; Concept, design, supervision, resources, materials, analysis, literature search, writing, critical review; İ.Y.

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