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Motorized Leg Length Discrepancy Measure: A New Device for Clinical Use – A Cross-sectional Study



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Original Article

Yaghoub Salekzamani¹[®], Nargess Abolghassemi Fakhree^{2*}[®], Afshin Ebrahimi³, Hamed Heravi⁴, Neda Dolatkhah¹

Abstract

Objectives: This study aimed to construct a device that could measure leg length discrepancy (LLD) automatically. **Materials and Methods:** The LLD measure device measures LLD with pelvic-tilt method (Program 1) and weight-based method (Programs 2 & 3). Tests were done in 3 phases. 1: Two examiners using the LLD Measure device made -50 to 75 mm artificial LLD in two healthy subjects measuring the degree of pelvic tilt and the load bearing of lower limbs. 2: Sixteen healthy volunteers were asked to stand on the device to measure LLD with program 2 and then with both knees extended to measure LLD with program one. 3: 32 patients who had underwent lower limbs CT scanogram enrolled, and the LLD measurement with program 1 compared with those obtained by CT scanogram.

Results: Data's obtained in the first phase showed excellent repeatability (intra-class correlation coefficient [ICC] > 0.9) and very good reproducibility (ICC > 80%) except for measuring the limb load while both knees were extended (ICC \approx 60%). In the second phase, we found no statistically significant difference between measuring LLD using programs 1 and 2 (P = 0.49). In the third phase, there was no statistically significant difference between measuring LLD using program 1 and CT scanogram (P = 0.80). **Conclusions:** We have developed a device to measure LLD semiautomatic with less need for examiner expertise. The results of our new device would be reliable and accurate compared to CT measurements.

Keywords: Pelvis, Leg length inequality, Weight-bearing, Spiral cone-beam computed tomography

Introduction

Leg length discrepancy (LLD) is where the legs are different lengths (structural LLD) or appear to be different lengths because of misalignment (functional LLD).

The prevalence of LLD is about 70% (1); In most cases, LLD is compensated by mechanisms such as pelvis lateral tilt or hip and knee flexion (2-4). However, if the length discrepancy is >20 mm or, depending on the age, occupation, and level of the body activity, even <20 mm (5-7), it can result in musculoskeletal disorders such as stress fracture, low back pain, osteoarthritis etc which has to be diagnosed and treated appropriately (6,8-15).

The methods for measuring LLD could be categorized as clinical and imaging studies. Clinical methods are simple, cheap, and available everywhere, so they are the first step to assess LLD. Two clinical measurements are direct (tape measurement) and indirect (making pelvis landmarks level by raising the shorter leg, e.g., with calibrated blocks). Some factors like obesity and difficulty in localization of the landmarks might cause these clinical methods to be less accurate if the examiner was not an expert. Therefore, when there is a need to measure LLD more precisely, it is accepted to use imaging techniques like orthoroentgenogram, scanogram, etc (6). However, these techniques are expensive and may expose the subject to radiation.

In this respect, it would be highly desirable to develop a method that can measure LLD without the need for x-ray exposure and be accurate, reproducible, and cost-effective. Such a method would be useful for screening, diagnostics, and clinical studies but it can also be used numerous times for follow-up purposes in clinical interventions such as measuring the effectiveness of using shoe raise or prostheses.

Materials and Methods

This was a cross-sectional study, and tests were done in 3 phases. The participants in each phase were as follow:

- Phase 1: Two women (both 33 years old) with no lower limb deformity and LLD in a physical exam.
- Phase 2: We include 16 healthy volunteers (6 men and 10 women) with 9-60 years old from the clients of the Physical Medicine and Rehabilitation Department and exclude all those who had lower limbs problems (pain, apparent LLD, and sagittal or coronal deformity).
- Phase 3: 32 participants (20 men and 12 women) with 10-83 years old who had been referred to the radiologic center for evaluating LLD with a CT scanogram. The exclusion criteria were disability to stand upright

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¹Physical Medicine and Rehabilitation Research Center, Aging Research Institute, Tabriz University of Medical Sciences, Tabriz, Iran. ²Physical Medicine and Rehabilitation Specialist, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran. ³ICT Research Center, Faculty of Electrical Engineering, Sahand University of Technology, Tabriz, Iran. ⁴College of Engineering, Design and Physical Sciences, Brunel University London, Uxbridge UB8 3PH, UK.

*Corresponding Author: Nargess Abolghassemi Fakhree, Tel: +989141097363, Email: NargessAFakhree@yahoo.com

Key Messages

- The LLD Measure device is a new motorized device for clinical measuring of LLD.
- Measurements with this device are reliable.
- The degree of pelvic tilt is correlated with LLD value if there was no coronal or sagittal asymmetry.
- The limb load is correlated with LLD value in the case of flexing longer lower limb with no truncal tilt.

without aid, coronal/ sagittal asymmetry, and those with functional LLD.

All tests had done in the research center of Physical Medicine and Rehabilitation Department of Imam Reza hospital, Tabriz, Iran from February 2018 to September 2018.

Materials

LLD Measure Device

The device has been developed in Tabriz, Iran (Tabriz Medical Equipment Technology Incubator Center, https:// metic.tbzmed.ac.ir/) by Tocea Tadbir Tavan Teb Company (Rehabsoon. Co) (Figure 1).

The mechanical part of the device is a moving pedal and a fixed pedal. The moving pedal moves in the positive and negative range according to the fixed pedal with a precision of 1 mm, and its moving range is about 20 cm. After each test, the moving pedal automatically returns to the zero position. The electronic part of the device consists of several sections, as described below.

Mainboard: An ARM (Advanced RISC Machines) microcontroller has been used as a processor in the mainboard and processing the received sensor signals and applying the appropriate control signal to the motor (Figure 2).

Motor driver: A PWM-based (pulse width modulation) electronic driver is used to fine-tune the pedal movement. This driver with 20 A current bridges drives the DC Motor. *Sensors:* 3 different sensors are used in this device.

- 1. The tilt sensor ZCT245AN-TTL is a micro electromechanical systems (MEMS) based sensor that measures pelvic tilt with 0.1 degree accuracy. It connects to the mainboard and processor with tiny wires.
- 2. The load cell sensors are located below each pedal. They connect to the mainboard and provide weight data. These sensors have analog output, and the accuracy of measuring weight depends on the analog-to-digital (ADC) converter. This device uses a 24-bit converter equivalent to \pm 10 mg accuracy.
- 3. Infrared proximity sensor: This sensor GP2Y0A21YK has an analog output and was designed by SHARP Company (Japan). It measures distance based on emitting/receiving infrared beams. The sensor is located on the bottom of the device and directly under the moving pedal. When the pedal moves, its



movement can be measured by the sensor. The device measures the level of LLD by 3 programs:

Program 1: Pelvic-Tilt Based Method

The subject stands on the device, placing each foot on each pedal. The examiner fastens the belt around the subject's pelvis symmetrically, considering bony landmarks. The tilt sensor, which has been fixed on the belt, has to be placed at the posterior midline of the subject. With starting program 1, the movable pedal would go up or down till the tilt sensor shows a number <1°. Then the moving pedal would be stopped, and the difference between the heights of the 2 pedals would be shown as the LLD measurement result (Figure 3).

Program 2: Weight Based Method

The subject stands upright, placing each foot on each pedal. The load cell sensors below each pedal would detect each foot's weight-bearing, and the examiner can make the movable pedal goes up or down till both sides show the same weight. Then the examiner would stop the program and read the height difference between the 2 pedals as the result of the LLD measurement.

Program 3: Weight Based Method

This program is just like program 2, except it works all automatically. We presumed that the shorter leg might



Figure 3. Components of the LLD measure device: The infrared proximity sensor has been placed on the bottom of the device exactly under the moving pedal and measures the height of the moving pedal; Motor drivers make the moving pedal goes up or down; Each load cells under the moving and fixed pedals measure the limbs load; Tilt sensor measures the degree of pelvic tilt. (a) For measuring LLD with pelvic tilt method the subject stands on device placing each foot on each pedal with both knees extended (b) the movable pedal would go up or down according to data's obtained from tilt sensor till it shows degree less than 1 then it would stop and the device would show the difference between the height of each pedal as the result of LLD measurement.

tolerate more load, in this respect. When starting this program, if the movable pedal shows less weight than the fixed pedal, it would go down and vice versa till the difference between the 2 sides become less than 0.5 kg for several continuous seconds. Then the moving pedal would stop, and the difference between the heights of the 2 pedals would be shown as the LLD measurement result.

Methods

The present study was conducted in three phases.

Phase 1

The examiner A used different heights of movable pedal regarding the fixed pedal to simulate different values of LLD in each test (ranged from -50 to 75 mm with 5 mm increments); in this respect, the limb on the lower pedal represented as the short leg, and the limb on higher pedal represents as the longer leg.

The subject stood upright, placing each foot on each pedals symmetrically and soles in contact with the pedals. The examiner B fastened the belt around the subject's pelvis as defined before using bilateral anterior superior iliac spines as the bony landmarks. To eliminate the effect of lateral trunk shift, examiner B asked the subject to align the mid face and the naval with a plumb line in front. Then, examiner A recorded each foot's weight-bearing and the degree of pelvic tilt (the results were just visible for the first examiner).

All tests had done by each examiner twice with 2 weeks intervals respecting both flexion and extension position of the simulated longer leg.

Phase 2

In this phase, we asked subjects to stand upright, placing

each foot on each pedal at an ease position (allowing knee flexion) for measuring LLD with weight-based method and then with both knees extended to measure LLD with program 1. The results of using both approaches were compared with each other. We just used program 2 to measure LLD with the weight-based method, because it is necessary for an individual on the device to keep his/her balance for a few seconds with equal weight distribution on both legs while using program 3, and most of the volunteers, were not able to achieve this.

Phase 3

In phase 3, the accuracy of the proposed method was compared with available standard methods. In previous studies, radiologic and CT methods were defined as the standard approaches to measure LLD. The CT scanogram is the method of choice due to less radiation exposure than conventional radiographs (6). In this phase, the LLD was measured once with a CT scanogram and again with the LLD Measure device (program 1 and both knees extended), by two independent clinicians, without knowing each other's results. We did not use the weightbased method because some patients in this phase had lower limb pain, and could not bear weight equally on both feet.

We used positive or negative signs for a left or right short leg in all phases, respectively.

Statistical Analysis

This was a pilot study, so we did not calculate the sample size or power of the test. The normality of the data was tested by the Kolmogorov-Simonov test. Interobserver reproducibility and intraobserver repeatability were evaluated using the intra-class correlation coefficient (ICC). The relation between different values in each phase was evaluated by Pearson correlation analysis. R square was calculated for variables with a correlation coefficient higher than 0.7. The paired *t* test was used to compare the two methods in phases 2 and 3. Statistical significance was assumed at P < 0.05. All analysis was done with SPSS software (SPSS 16.0, SPSS Inc., Chicago, IL).

Results

Intra-rater Reliability

The analysis of data obtained by each examiner in phase 1 showed excellent repeatability of measurement for belt positioning (the degree of simulated pelvic tilt) and measuring the weight distribution on the fixed pedal in both extended and flexed knee positions (ICC > 0.9) (Table 1).

Inter-rater Reliability

The ICC values showed all measurements reproducibility in phase 1 was excellent except for measuring the percent of limb load whilst both knees extended (ICC \approx 0.6) (Table 2).

Table 1. Intra-rater Reliability for Measuring the Weight Dist	ribution on Fixed Pedal and Belt-Positionin	ning in Subjects with Simulated LLD (n = 80)
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	Examiner A			Examiner B			
	ICC	95% CI	P Value	ICC	95% CI	<i>P</i> Value ^a	
FD	0.92	0.87-0.95	0.0000	0.91	0.86-0.94	0.0000	
ED	0.99	0.99-0.99	0.0000	0.99	0.98-0.99	0.0000	
FW	0.98	0.96-0.98	0.0000	0.98	0.97-0.98	0.0000	
EW	0.95	0.93-0.97	0.0000	0.94	0.91-0.96	0.0000	
FW%	0.98	0.97-0.98	0.0000	0.98	0.97-0.98	0.0000	
EW%	0.96	0.94-0.97	0.0000	0.95	0.92-0.97	0.0000	

CI: Confidence interval, ED: Degree of pelvic tilt (both knees extended), EW: Weight distribution on the fixed pedal (both knees extended), EW%: Percent of weight distribution on the fixed pedal (both knees extended), FD: Degree of pelvic tilt (longer limbs knee flexed), FW: Weight distribution on the fixed pedal (longer limbs knee flexed), FW%: Percent of weight distribution on the fixed pedal (longer limbs knee flexed), FW%: Percent of weight distribution on the fixed pedal (longer limbs knee flexed), FW%: Percent of weight distribution on the fixed pedal (longer limbs knee flexed), FW%: Percent of weight distribution on the fixed pedal (longer limbs knee flexed), a ICC test (Intra-class correlation coefficient).

Table 2. Inter-Rater Reliability for Measuring the Weight Distribution on Fixed Pedal and Belt-Positioning in Subjects with Simulated LLD (n = 80)

		ICC	95% CI	<i>P</i> Value ^a
FD	Excellent	0.92	0.88-0.95	0.0000
ED	Excellent	0.99	0.99–0.99	0.0000
FW	Very good	0.86	0.79–0.91	0.0000
EW	Poor	0.53	0.28-0.70	0.0003
FW%	Very good	0.87	0.80-0.91	0.0000
EW%	Poor	0.60	0.38–0.74	0.0000

CI: Confidence interval, ED: Degree of pelvic tilt (both knees extended), EW: Weight distribution on the fixed pedal (both knees extended), EW%: Percent of weight distribution on the fixed pedal (both knees extended), FD: Degree of pelvic tilt (longer limbs knee flexed), FW: Weight distribution on the fixed pedal (longer limbs knee flexed), FW%: Percent of weight distribution on the fixed pedal (longer limbs knee flexed), FW%: Percent of weight distribution on the fixed pedal (longer limbs knee flexed), FW%: Percent of weight distribution on the fixed pedal (longer limbs knee flexed), FW%: Percent of weight distribution on the fixed pedal (longer limbs knee flexed), a ICC test (Intra-class correlation coefficient).

The Comparison Between Right and Left Foot Placement on Fixed Pedal

To determine if the right or left foot placement on a fixed pedal might change the results; the data related to placing the right foot on a fixed pedal compared with those obtained from placing the left foot on a fixed pedal using the mean values of each examiners measurement in the first and second time. According to Table 3, there was no difference between the right and left limb to be placed on a fixed pedal when measuring the degree of pelvic tilt or limb load while both knees were extended or allowed longer limb's knee to be flexed, respectively.

Association Between Pelvic Tilt and Limb's Load with the Level of Simulated LLD

As shown in Table 4 the degree of pelvic tilt and the percent of limb load were correlated with the level of simulated LLD while both knees extended and flexed longer limbs, respectively. We found an important relationship between simulated LLD with the degree of pelvic tilt while the knee was extended ($R^2 = 0.96$, P < 0.01) and the limb load whilst flexing the knee of a longer limb ($R^2 = 0.51$ -0.71, P < 0.01).

Comparison Between Program 1 and 2 for Measuring LLD

According to data obtained in phase 2, the average absolute value for LLD using the pelvic-tilt method was 5.25 ± 4.64 mm. The average absolute value for LLD using the weight-based method was 3.75 ± 4.67 mm. The 95% confidence interval of the mean difference between these two methods was -2.32-5.32 mm; and there was no statistically significant difference between programs 1 and 2 for measuring LLD (*P* = 0.41). But there was no meaningful correlation between these two methods (r = -0.18, *P* = 0.49).

	Examiner A		Examiner B	
	Differences ^a	<i>P</i> Value ^b	Differences ^a	<i>P</i> Value ^b
FD	-2.25 ± 2.09	0.00	-2.09 ± 2.05	0.00
ED	-0.20 ± 1.89	0.50	-0.43 ± 1.58	0.09
FW	-0.99 ± 3.71	0.09	-0.40 ± 1.93	0.19
EW	-2.66 ± 3.88	0.00	-0.90 ± 2.16	0.01
FW%	-0.01 ± 0.06	0.09	-0.00 ± 0.03	0.18
EW%	-0.05 ± 0.07	0.00	-0.01 ± 0.03	0.01

Table 3. Analysis of the Difference between the Right and Left Foot Placement on Fixed Pedal (n = 40)

^a Data are presented as mean \pm SD. ^b Paired t test.

ED: Degree of pelvic tilt (both knees extended), EW: Weight distribution on the fixed pedal (both knees extended), EW%: Percent of weight distribution on the fixed pedal (both knees extended), FD: Degree of pelvic tilt (longer limbs knee flexed), FW: Weight distribution on the fixed pedal (longer limbs knee flexed), FW%: Percent of weight distribution on the fixed pedal (longer limbs knee flexed), FW%: Percent of weight distribution on the fixed pedal (longer limbs knee flexed), FW%: Percent of weight distribution on the fixed pedal (longer limbs knee flexed).

	Examiner A		Examiner B		
	R	<i>P</i> Value ^a	R	<i>P</i> Value ^a	
FD	0.50	0.00	0.46	0.00	
ED	0.98	0.00	0.97	0.00	
FW	0.74	0.00	0.84	0.00	
EW	0.30	0.00	0.36	0.00	
FW%	0.71	0.00	0.83	0.00	
EW%	0.28	0.01	0.33	0.00	

^a Pearson correlation.

ED: Degree of pelvic tilt (both knees extended), EW: Weight distribution on the fixed pedal (both knees extended), EW%: Percent of weight distribution on the fixed pedal (both knees extended), FD: Degree of pelvic tilt (longer limbs knee flexed), FW: Weight distribution on the fixed pedal (longer limbs knee flexed), FW%: Percent of weight distribution on the fixed pedal (longer limbs knee flexed), FW%: Percent of weight distribution on the fixed pedal (longer limbs knee flexed).

Comparison Between Program 1 and CT Scanogram for Measuring LLD

In phase 3 of the study, the average absolute value for LLD using pelvic -tilt method was 11.44 ± 16.66 mm. The average absolute value for LLD using a CT scanogram was 11.22 ± 18.07 mm. The 95% CI of the mean difference between these two methods was -2.02-1.58 mm; and there was no statistically significant difference between the pelvic-tilt method and CT for measuring LLD (*P* = 0.80). There was a high and positive correlation between these two methods (r = 0.96, *P* < 0.01).

Discussion

The previous studies have defined the indirect clinical methods of LLD measurement to be more accurate and useful than direct clinical methods (6,16). Consequently, an indirect approach was used to measure the LLD. We tried to make our method independent of the clinician's skill and experience. The clinician's only part affected is fastening the waist belt on the bony landmarks when using program 1 (pelvic-tilt method). According to the results obtained in phase 1, we showed that the belt positioning inter/ intra rater reliability is excellent (ICC > 0.9). There might be a relation between simulated LLD and the degree of pelvic tilt (17). We also found an important relationship between the value of simulated LLD and the degree of lateral pelvic tilt when the subject extends both knees ($R^2 = 0.96$, P < 0.01). But the relation would be less when allowing the longer leg to be flexed. Also the comparison between results of our method and a standard method such as CT scanogram in determining LLD shows that there is no significant difference in the accuracy (P = 0.80), which makes our proposed method acceptable. However indirect clinical methods may not be comparable with CT measurement, because of different position of the subject while measuring and different landmarks used for measurement. In previous studies, the accuracy of radiologic methods has been reported and compared. For example, CT scanogram is the best method to measure LLD when knee flexion is greater than 30 degree (18). Otherwise, the results of radiologic studies were similar (18-21). Furthermore, there is no difference between

standing and supine radiologic measurements in lower limbs in the case of mechanical axis deviation less than 20mm (20). Most of these radiologic methods are used for structural LLD measurements. None of the patients had flexion contracture or varum/valgum deformity of the knee, and we excluded those with functional LLD. So we assumed that the upright or supine position of the patients wouldn't change the results.

Our study showed a good correlation between the pelvic-tilt method and CT scanogram measurements (r = 0.96, P < 0.01), and the 95% CI of the mean difference between these two methods was -2.02 to 1.58 mm. These results are better than some other studies (22-24) which had compared different clinical methods with imaging studies (Table 5). Hence, it is possible to conclude that our proposed new method is more accurate than calibrated blocks and tape measurements.

A very important factor when discussing the relation between the results of two methods is the value of the LLD. The mean difference between different methods of measurements might be 5-10 mm, but the correlations between results might be high or low, including severe or mild LLD values (23-29). The results of our study in phases 2 and 3 could be explained in the same way. We found a good correlation between program 1 measurements and CT scanogram in patients but no correlation in healthy subjects of phase 2. So the difference between the two methods could be considered more relevant for judging about precision and validity of the measurement. In most of these studies, the mean difference of about 5-10 mm between the two methods has been considered acceptable. The 95% CI of the difference between program 1 and CT scanogram LLD measurement was -2.02 to 1.58 mm (P =0.8), so it could be claimed that this is a valid method for measuring LLD.

Another novelty of our method is to use of Weight to measure LLD. According to our findings in phase 1, measuring weight-bearing of each foot is repeatable and reproducible when allowing the longer leg to be flexed. Also, we found that the shorter leg bears more weight if the subject bends the longer leg. In a study (30) authors have found no correlation between the value of LLD and

Table 5. Comparison of the Results of Different Studies					
Author, Year (Ref.)	Methods	Subjects	Correlation	Difference	
Lampe et al, 1996 (22)	Calibrated Blocks / Orthoradiogram	Patients		Mean difference = -14 to 16 mm	
Jamalluddin et al, 2011 (23)	TMM (nearest 5 mm)/ CT	LLD 28 ± 20 mm	ICC = 0.85	Mean difference = -4.7 to 6.5 mm	
Harris et al, 2005 (24)	Clinical methods/CT	LLD ≤ 20 mm	No correlation	Average absolute difference = 7.24 ± 7.98 mm	
Beattie et al, 1990 (25)	TMM/Radiographic	Healthy	ICC = 0.35		
		Patients	ICC = 0.77		
Gogia and Braatz, 1986 (26)	TMM/ X-ray	Leg length 88 \pm 6 cm	ICC = 0.99, r = 0.98		
Neelly et al, 2013 (27)	TMM/ CT	Leg length 87 \pm 6 cm	ICC > 0.95		
	PGM/ X-ray	Femoral/Tibial length			
Khamis et al, 2017 (28)		LLD <20 mm	r > 0.80	No difference between the two methods ($P = 0.2$)	
Leporace et al, 2018 (29)	PGM/ scanogram	LLD <20 mm	No correlation, P >0.05		
Our study (Phase 2)	Weight based method/ Pelvic- tilt method	Healthy volunteers	No correlation, $P = 0.49$	Average absolute difference = -1.50 ± 7.16 mm	
Our study (Phase 3)	Pelvic-tilt method/ CT	Patients	r = 0.96, <i>P</i> < 0.01	Average absolute difference = -0.22 ± 5.00 mm	

CT: Computerized tomography, PGM: Plug-in-gait-model, TMM: Tape measurement method.

differences in a load distribution between shorter and longer limbs, although the difference in weight bearing between two legs and also the center of pressure (COP) sway velocity was higher in subjects with LLD than the healthy control group. As show, there is a moderate correlation between the value of LLD and mean COP sway velocity. So mediolateral postural sway or lateral trunk shift could be a confounding factor when measuring the weight distribution of lower limbs. We used a plumb line just in the middle and front of our device and asked the subjects to align mid-face and naval with this line so we eliminate the probable effect of lateral shift of trunk. The other important factor is the sagittal plane symmetry between two lower limbs (2). We found no difference between shorter and longer legs weight-bearing when extending both knees. Still, there was an increasing value of short legs weight-bearing with simulating increasing values of LLD while the longer leg was flexed. The relation between these parameters (r > 0.7) was less than the relation between the degree of pelvic tilt (while both knees extended) and the value of LLD (r > 0.9). In addition to coronal and sagittal asymmetries, some other factors like the amount of muscle activity might affect the results when measuring LLD with weight-bearing method.

It could be claimed that using the difference of weightbearing of lower limbs for measuring LLD won't be as accurate as of the pelvic tilt method because we could not control all the confounding factors; However, we could consider a role for program 3 in the field of treatment as it might be used as a balance training in those have asymmetric muscle contraction.

This was a pilot study, and our study's low sample size might have affected the results. Because of sampling problems, the study results cannot be generalized to the whole community. The other issue is using a CT scanogram as the standard method because of the different positions and landmarks used for measurement. Though, it is recommended to include other LLD measurement methods such as telemetry for comparison. Further, the reliability and validity of the proposed method should be studied in follow-up studies with a bigger sample size and more representative population. Also, the use of the weight is a new field for measuring and maybe treating patients with LLD, which needs to be studied more.

Conclusions

In summary, we were able to design a setup that can measure lower limb discrepancy in a clinical and functional context that has accuracy compared with a CT scanogram. The advantages of our developed setup over available methods are ease of use and semi-automated measurements with high accuracy, which makes the measurements reproducible. Further, Weight based approach is a novel method to measure LLD, which requires further studies. Not only the Weight-based approach can provide information about the amount of LLD, but also it might be possible to develop treatment interventions for LLDs caused by muscular imbalance. This can be achieved by standing on the setup and trying to balance the body according to the feedback from the setup, which will result in muscle strengthening and, finally, rehabilitation from LLD.

Authors' Contribution

YSZ was the intellectual owner of the plan and supervised all the stages. AE and HH designed and constructed the new device. HH wrote the relevant part of the manuscript. NAF designed the study, gathered the data and wrote the manuscript. ND analysed the data, reviewed and edited the manuscript.

Conflict of Interests

Authors declare no conflict of interest or financial interest with the Tocea Tadbir Teb Company.

Ethical Issues

The examiner explained the process for all participants and they all filled the informed consent form. This study has been discussed and approved by

the regional Medical Ethics Committee of the Tabriz University of Medical Sciences with the code of IR.TBZMED.REC.1395.1174.

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