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Inter-observer agreement of ultrasound shear wave elastography measurements of renal cortical stiffness and morphometry in diabetic patients

Fahad F. Almutairi[1,2,3,4]✉

Shear wave elastography (SWE) is increasingly used in renal imaging to assess cortical stiffness, potentially reflecting tissue alterations in conditions such as diabetic kidney disease. However, the reproducibility of SWE and traditional morphometric measurements remains a challenge. This is primarily due to factors such as operator dependency, variations in patient positioning, differences in breathing patterns during scanning, and the inherent technical limitations of ultrasound imaging. This pilot study aimed to assess the inter-observer agreement in ultrasound-based measurements of renal cortical stiffness, cortical thickness, length, and width in diabetic patients. In this prospective study, 30 adult diabetic patients underwent renal ultrasound performed by two independent observers. Parameters measured included cortical stiffness (kPa), cortical thickness (cm), kidney length (cm), and width (cm). Intraclass correlation coefficients (ICC), Bland–Altman plots, and Pearson's correlation were used to evaluate inter-observer variability and bias. Cortical stiffness measurements demonstrated good inter-observer agreement (ICC = 0.824 for left kidney, 0.762 for right kidney). Morphometric measurements such as renal length and width showed excellent agreement (ICC > 0.9), although systematic and proportional biases were present. Cortical thickness exhibited poor agreement (ICC < 0.5), despite the absence of systematic bias. SWE has potential role in detecting early changes in renal tissue stiffness. Cortical stiffness shows reproducible between observers and can be considered reliable in diabetic patient. Morphometric parameters show high variability in certain aspects, particularly cortical thickness.

Keywords Shear wave elastography, Renal stiffness, Ultrasound variability, Diabetic nephropathy, Inter-observer agreement, Cortical thickness, Renal morphometry

Diabetes mellitus is a leading cause of chronic kidney disease (CKD), and early detection of structural and functional renal alterations is key to preventing disease progression. In clinical practice, renal ultrasound is routinely used to evaluate morphometry, including cortical thickness, length, and parenchymal echogenicity. However, these conventional parameters often lack sensitivity for early pathological changes, particularly in diabetic kidney disease (DKD) where histological alterations may precede measurable functional decline[1–3].

Shear wave elastography (SWE) has emerged as a promising imaging tool to assess renal cortical stiffness, which may reflect fibrosis, glomerulosclerosis, and interstitial inflammation—hallmarks of DKD[4–6]. SWE has been validated in liver, breast, and thyroid imaging, demonstrating good reproducibility in many applications[7–13]. In renal applications, however, the depth, vascular pulsation, heterogeneous parenchymal composition, and respiratory motion present unique technical challenges that can affect measurement consistency[14–16].

While prior studies have explored SWE values in diabetic and non-diabetic populations, fewer have focused on the reproducibility of these measurements, particularly in diabetic patients where subclinical

[1]Department of Diagnostic Radiology, Faculty of Applied Medical Sciences, King Abdulaziz University, Jeddah 21589, Saudi Arabia. [2]Animal House Unit, King Fahd Medical Research Center, King Abdulaziz University, Jeddah 21589, Saudi Arabia. [3]Smart Medical Imaging Research Group, King Abdulaziz University, Jeddah 22252, Saudi Arabia. [4]Medical Imaging and Artificial Intelligence Unit, The Center of Modern Mathematical Sciences and their Application (CMMSA), King Abdulaziz University, Jeddah 22252, Saudi Arabia. ✉email: ffalmutairi@kau.edu.sa

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1

renal involvement may influence stiffness heterogeneity[12]. Similarly, conventional ultrasound morphometric measurements are operator-dependent and may vary based on observer skill, image acquisition plane, and anatomical interpretation[15–17].

Thus, this pilot study aimed to assess the inter-observer agreement of SWE and morphometric ultrasound measurements in diabetic patients. By quantifying variability in cortical stiffness, thickness, length, and width, this research contributes to the validation of SWE as a tool in diabetic renal assessment.

Materials and methods
Study design and participants
The study was approved by the Institutional Review Board at King Abdulaziz university hospital (ref. HA-02-J-008-Nov22-06). All participants provided written informed consent. The study was conducted in accordance with the Declaration of Helsinki.

This prospective cross-sectional study was conducted on 30 adult diabetic patients referred for routine renal ultrasound. Patients were recruited from a King Abdulaziz university hospital. Inclusion criteria were: (1) diagnosis of type 2 diabetes mellitus, (2) age ≥ 18 years, and (3) adequate acoustic window. Exclusion criteria included pregnancy, known kidney anomalies such as unilateral renal agenesis, polycystic kidney disease, or hydronephrosis of grade 2 or higher, cystic lesions > 1 cm, or prior renal surgery.

Ultrasound protocol
Ultrasound imaging was performed using a standardized protocol by two independent observers with 5 years of clinical experience in shear wave elastography technique. Both observers were blinded to each other's findings. Patients included in the study met the criterion of having an adequate acoustic window, defined as the ability to obtain clear B-mode images of the renal cortex with visible corticomedullary differentiation and successful SWE acquisition in at least 80% of measurement attempts. Examinations were conducted using Epic 9 Philips Ultrasound system with integrated SWE technology. For each kidney, the following measurements were recorded: 9 cortical stiffness (kPa) measurements in the upper, mid and lower poles of the cortex. Cortical thickness (cm) measurements taken from the renal capsule to the corticomedullary junction. Length and width (cm) were acquired in the longitudinal plane with hold inspiration technique. The mean cortical stiffness values from three poles were used for statistical analysis.

Statistical analysis
Statistical analyses were performed used SPSS v23. Intraclass correlation coefficient (ICC) was used to assess inter-observer reliability. The ICC < 0.5 considered poor agreement, between 0.5 and 0.75 moderate agreement, between 0.75 and 0.9 good agreement, and > 0.9 considered excellent agreement Also, Bland–Altman plots statistical tests was used to detect systematic and random differences. The mean differences between observers was assessed using student t-test and the correlation was evaluated using Pearson's correlation (r). A p-value < 0.05 was considered statistically significant.

Results
Patients characteristics
The mean age of patients was 59.7 ± 10.6 years, mean BMI was 25.2 ± 5.2 kg/m², and average eGFR of 80.6 ± 25.7 mL/min/1.73 m², indicating generally preserved renal function among diabetic individuals Table 1.

Cortical stiffness
The cortical stiffness between the left and right kidney showed good agreement with ICC of 0.824 (left), 0.762 (right), with an average ICC of 0.793(Table 2). The Bland–Altman analysis showed minimal mean bias with acceptable limits of agreement (Fig. 1). No significant proportional bias was found.

Cortical thickness
The cortical thickness of the left and right kidneys showed low agreement with ICCs of 0.436 (left), 0.417 (right), and 0.302 for the average value (Table 2). The Bland–Altman plots revealed wide variability and one outlier per side (Figs. 2, 3, 4 and 5) .No systematic bias, but variability increased with larger measurements.

Renal length and width
The correlation between the length of the right and left kidneys showed excellent agreement with ICC of 0.843 (left), 0.928 (right) with an average ICC of 0.886 (Table 2). Regarding the width, the ICC was 0.858 for the left and 0.908 for the right kidney, yielding an average ICC of 0.883 (Table 2; Figs. 6, 7, 8, 9, 10, 11 and 12). A

	M ± SD
Age	59.67 ± 10.6
BMI	25.17 ± 5.18
Height (cm)	165.03 ± 9.98
weight (kg)	83.11 ± 17.9
eGFR	80.63 ± 25.67

Table 1. Patients characteristics:

	ICC (Obs 1 vs. Obs 2)			One-Sample T-Test (Obs 1 vs. Obs 2)				
	Estimate	*P*-value	95%-CI	Observer 1 (M ± SD)	Observer 2 (M ± SD)	Difference (M ± SD)	*P*-value	Corr. (Case Mean vs. Case Diff.)
CS (L)	0.824	0.000	(0.635–0.916)	3.41 ± 1.96	3.75 ± 1.74	-0.336 ± 1.422	0.206	0.164
CS (R)	0.762	0.000	(0.505–0.886)	2.92 ± 1.11	3.13 ± 1.19	-0.215 ± 1.004	0.250	-0.086
CS average (of R/L)	0.843	0.000	(0.67–0.925)	3.16 ± 1.2	3.44 ± 1.12	-0.276 ± 0.834	0.081	0.100
CT (L)	0.436	0.055	(-0.129–0.725)	1.1 ± 0.14	1.16 ± 0.14	-0.055 ± 0.168	0.083	0.041
CT (R)	0.417	0.080	(-0.241–0.724)	1.23 ± 0.15	1.25 ± 0.26	-0.026 ± 0.257	0.589	− 0.523**
CT average (of R/L)	0.302	0.165	(-0.437–0.665)	1.16 ± 0.12	1.2 ± 0.16	-0.04 ± 0.176	0.221	-0.301
Length (L)	0.843	0.000	(0.407–0.942)	10.59 ± 1.13	11.12 ± 0.98	-0.53 ± 0.642	0.000	0.234
Length (R)	0.928	0.000	(0.794–0.97)	10.39 ± 1.21	10.91 ± 0.85	-0.296 ± 0.503	0.003	0.507**
Length average (of R/L)	0.898	0.000	(0.426–0.967)	10.49 ± 0.99	10.69 ± 0.96	-0.413 ± 0.424	0.000	0.361~
Width (L)	0.858	0.000	(0.703–0.933)	5.13 ± 0.78	5.09 ± 0.54	0.047 ± 0.478	0.594	0.543**
Width (R)	0.908	0.000	(0.796–0.957)	4.55 ± 0.85	4.72 ± 0.62	-0.166 ± 0.408	0.034	0.583**
Width average (of R/L)	0.909	0.000	(0.811–0.957)	4.84 ± 0.72	4.9 ± 0.5	-0.06 ± 0.359	0.371	0.631**

Table 2. Several indicators of agreement. * Significant under 0.05 level of significance (just significant). ** Significant under 0.01 level of significance (highly significant). ~ Nearly significant (P-value is slightly greater than or equal 0.05).
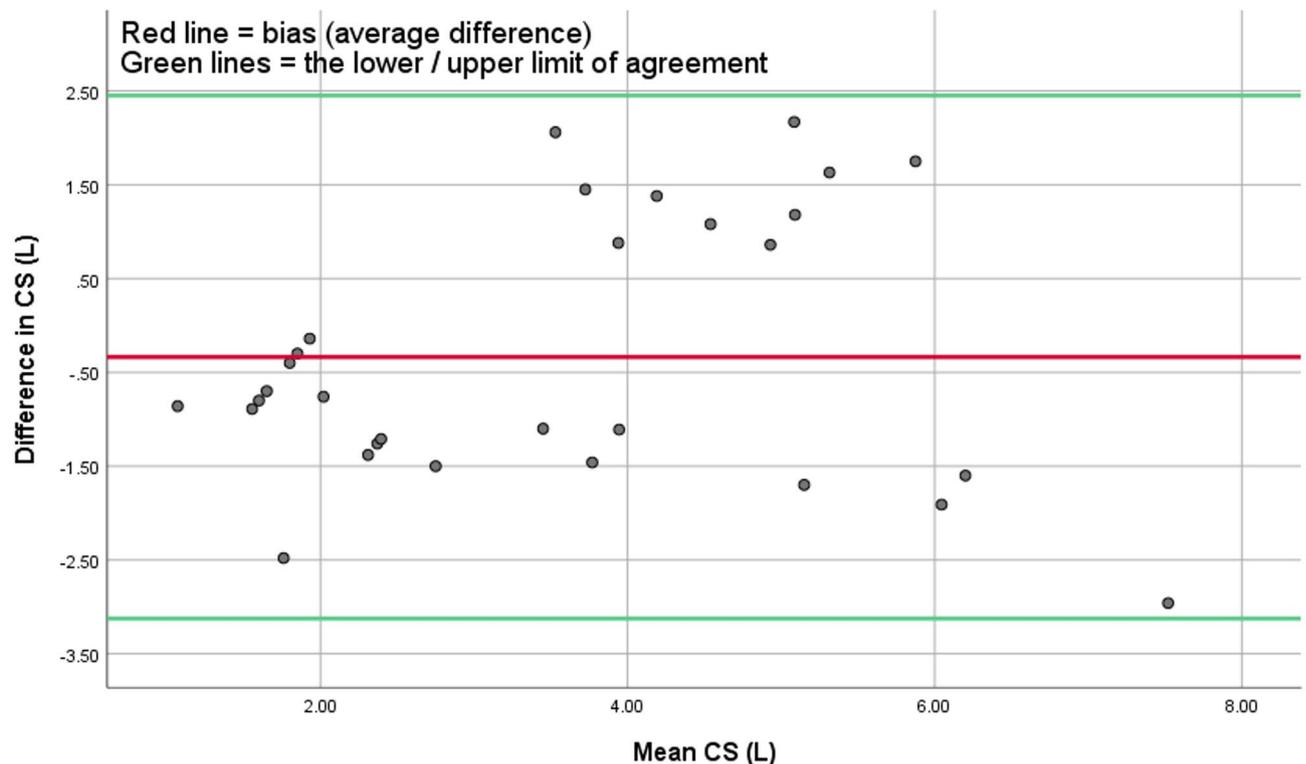

Fig. 1. Bland Altman plot for CS (L).

systematic bias was observed for renal length and right kidney width. A proportional bias was noted across all morphometric parameters ($r > 0.5$, $p < 0.01$).

Thickness–stiffness relationship
No significant correlation was observed between cortical thickness and stiffness ($r = 0.134$, $p > 0.05$) Fig. 13.

Discussion
This study evaluated inter-observer agreement for renal shear wave elastography (SWE) and conventional morphometric ultrasound parameters in a cohort of diabetic patients. Our findings indicate that cortical stiffness, as measured by SWE, demonstrates good reproducibility between observers. Conversely, conventional
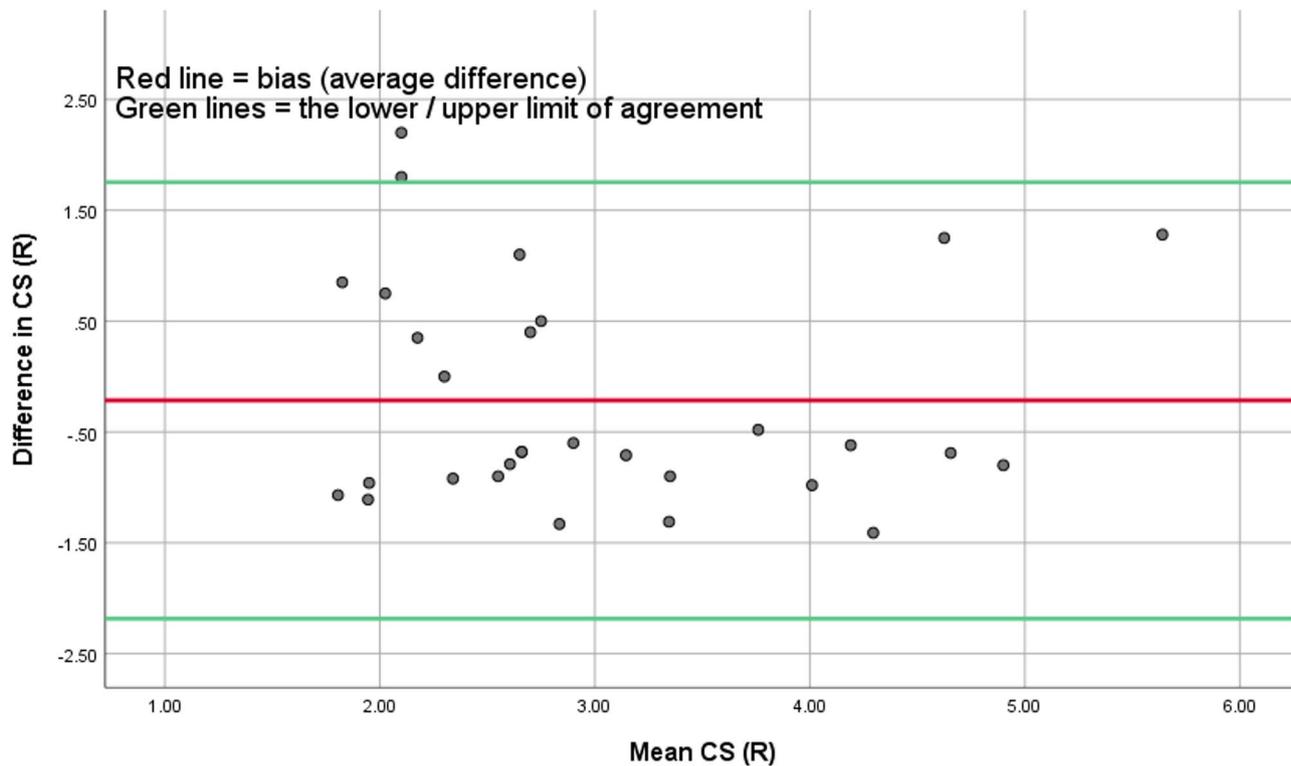
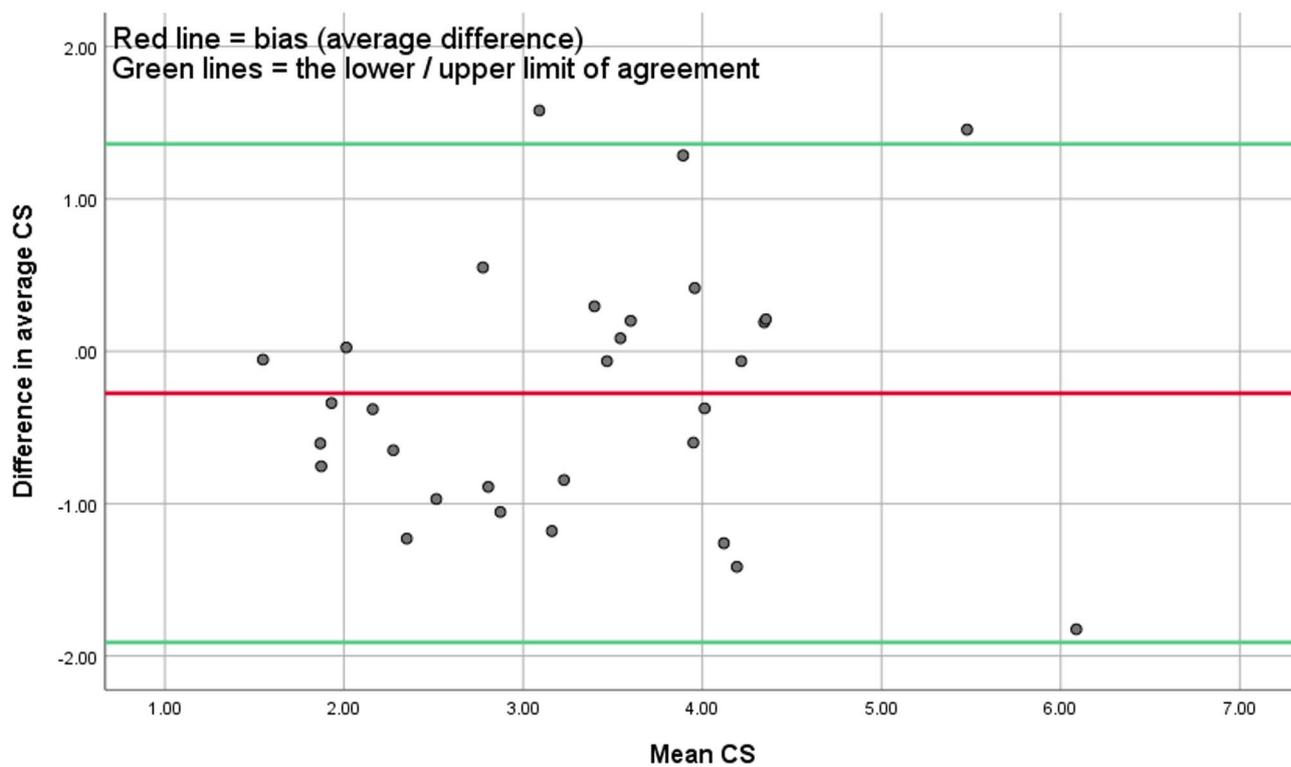**Fig. 2**. Bland Altman plot for CS (R).
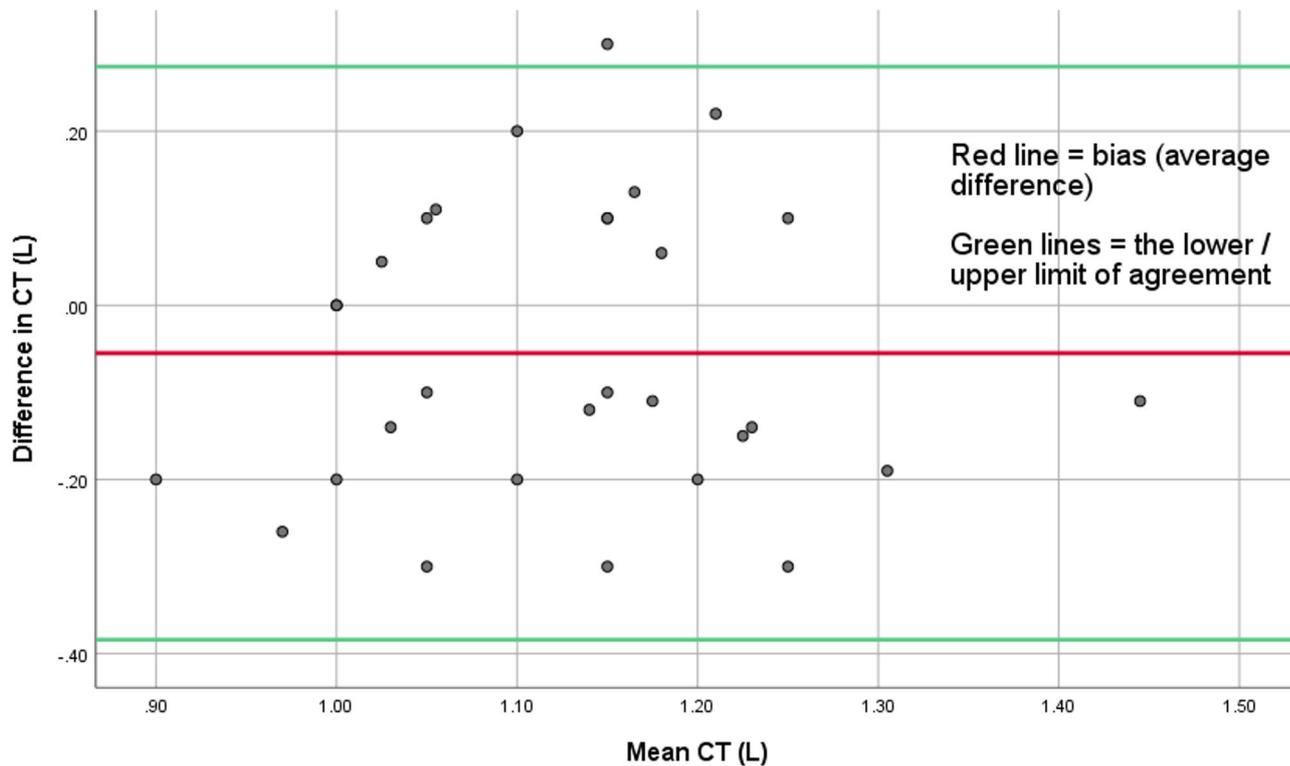

Fig. 3. Bland Altman plot for CS average (of L/R).

Fig. 4. Bland Altman plot for CT (L).
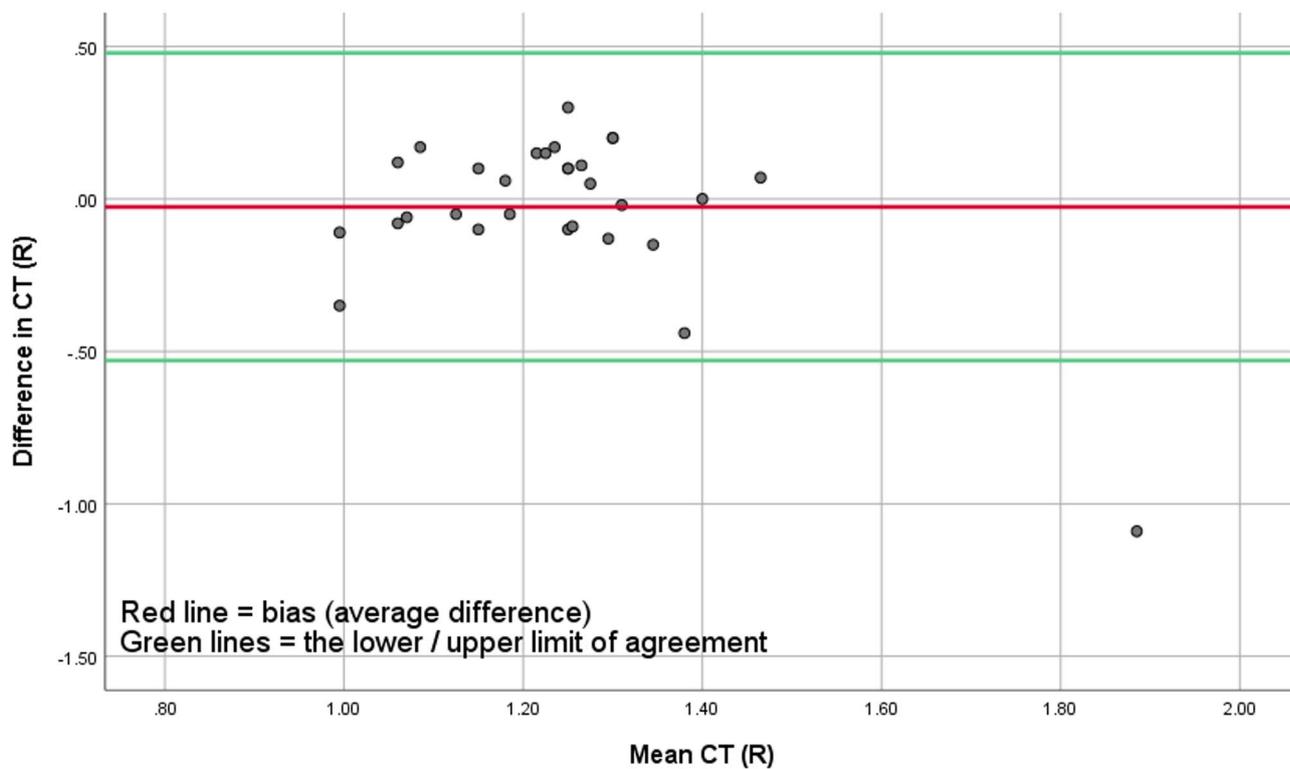

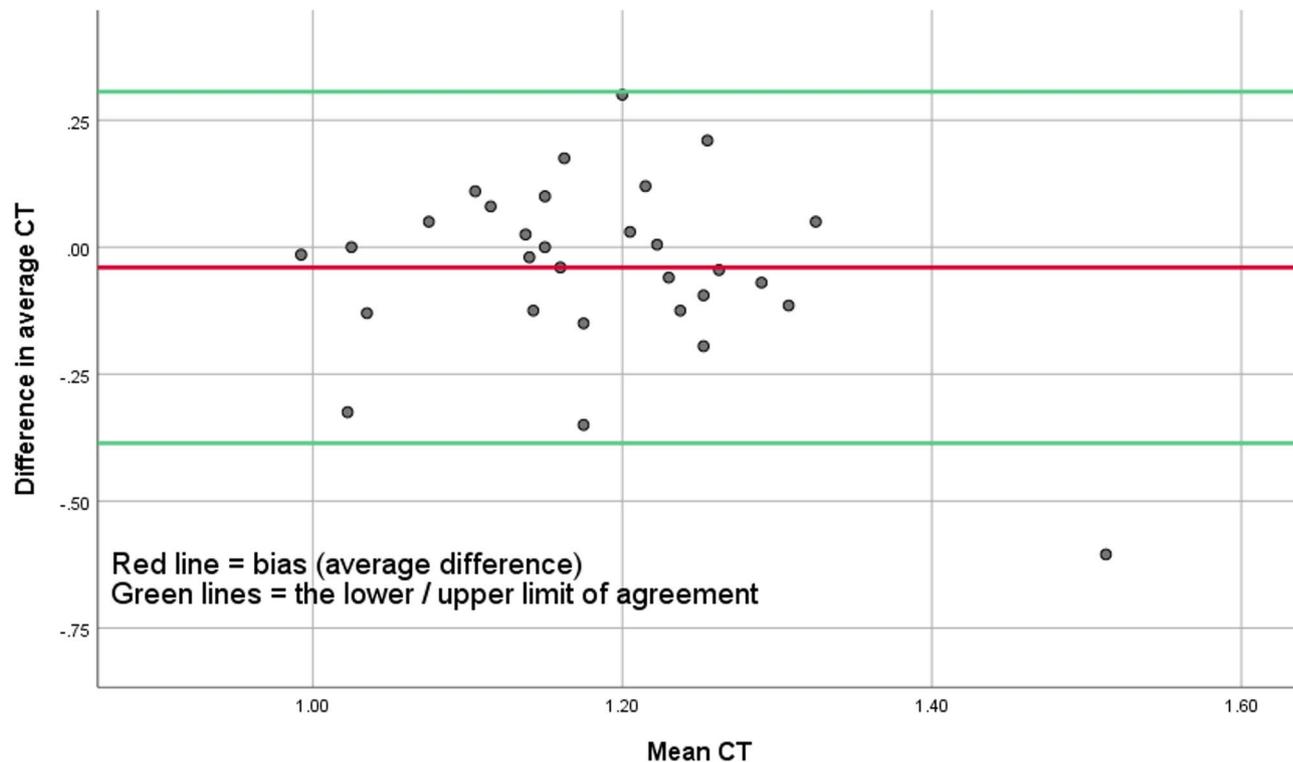**Fig. 5**. Bland Altman plot for CT (R).

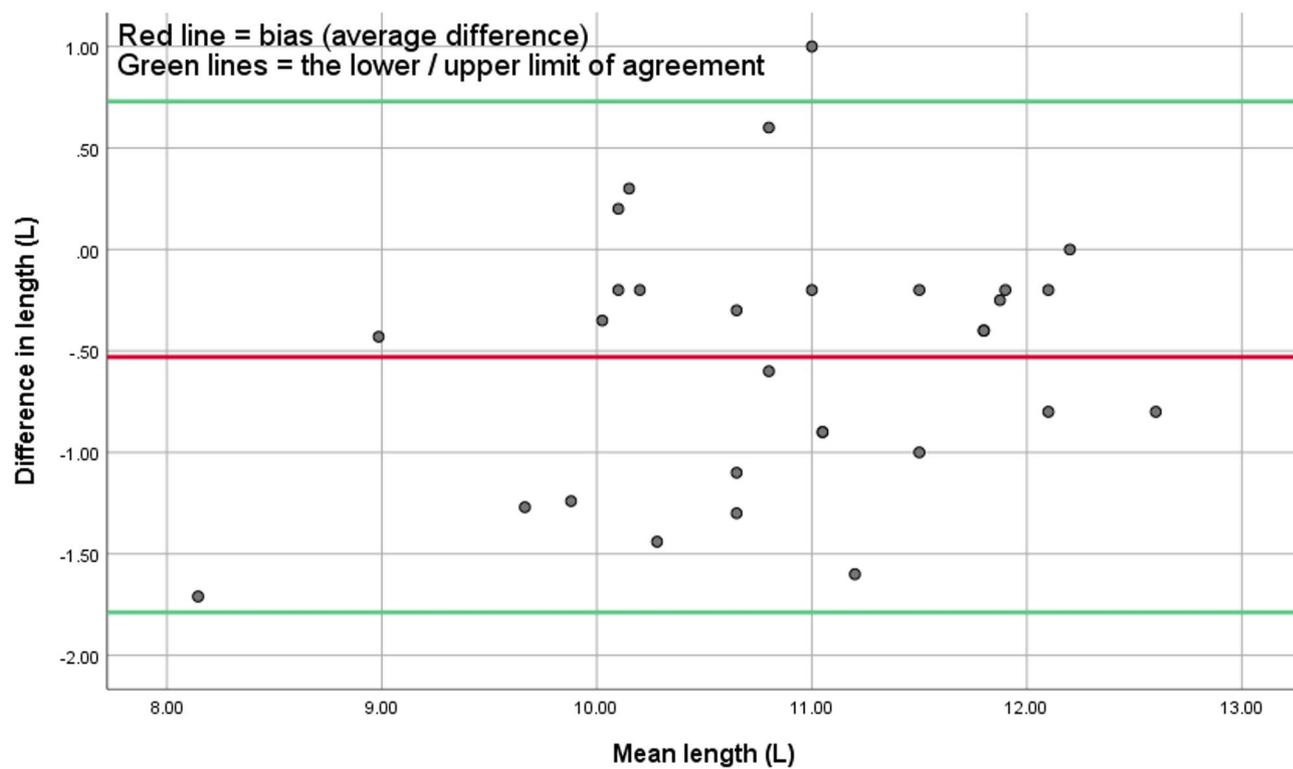**Fig. 6**. Bland Altman plot for CT average (of L/R).

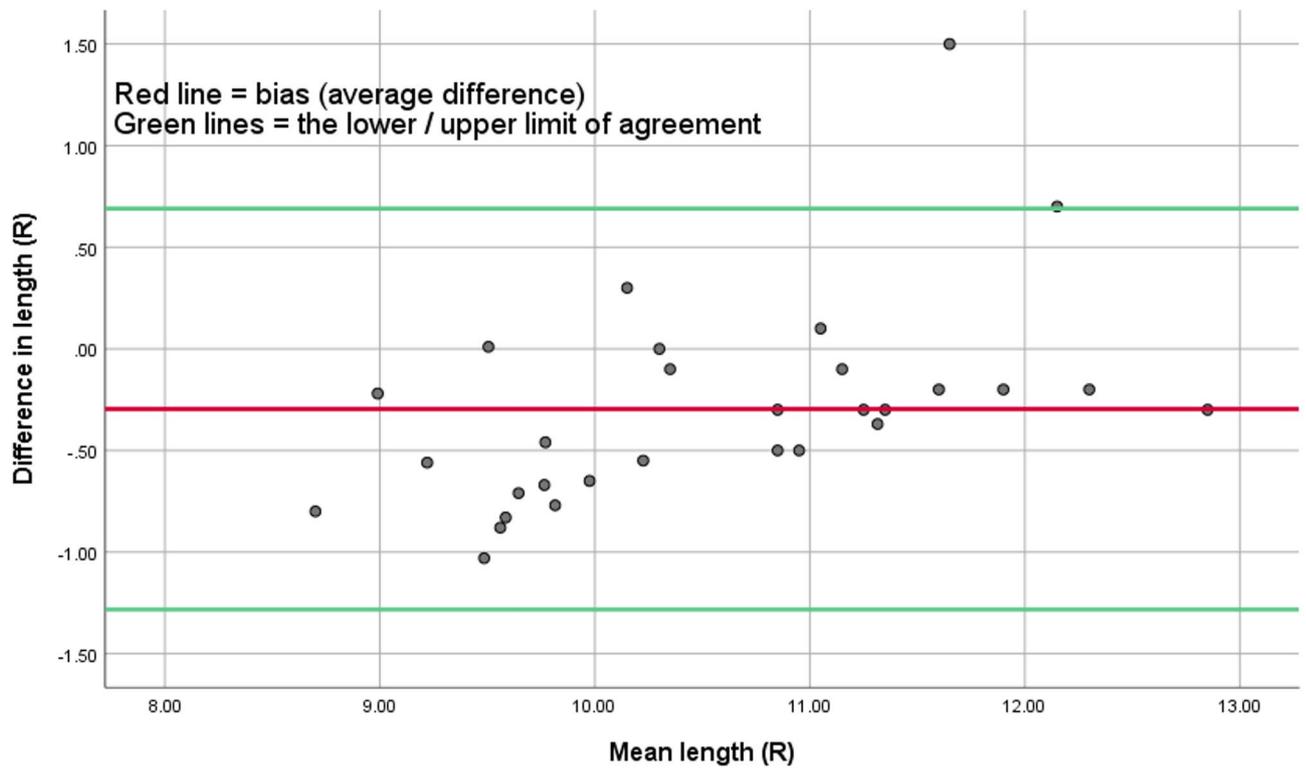**Fig. 7**. Bland Altman plot for length (L).
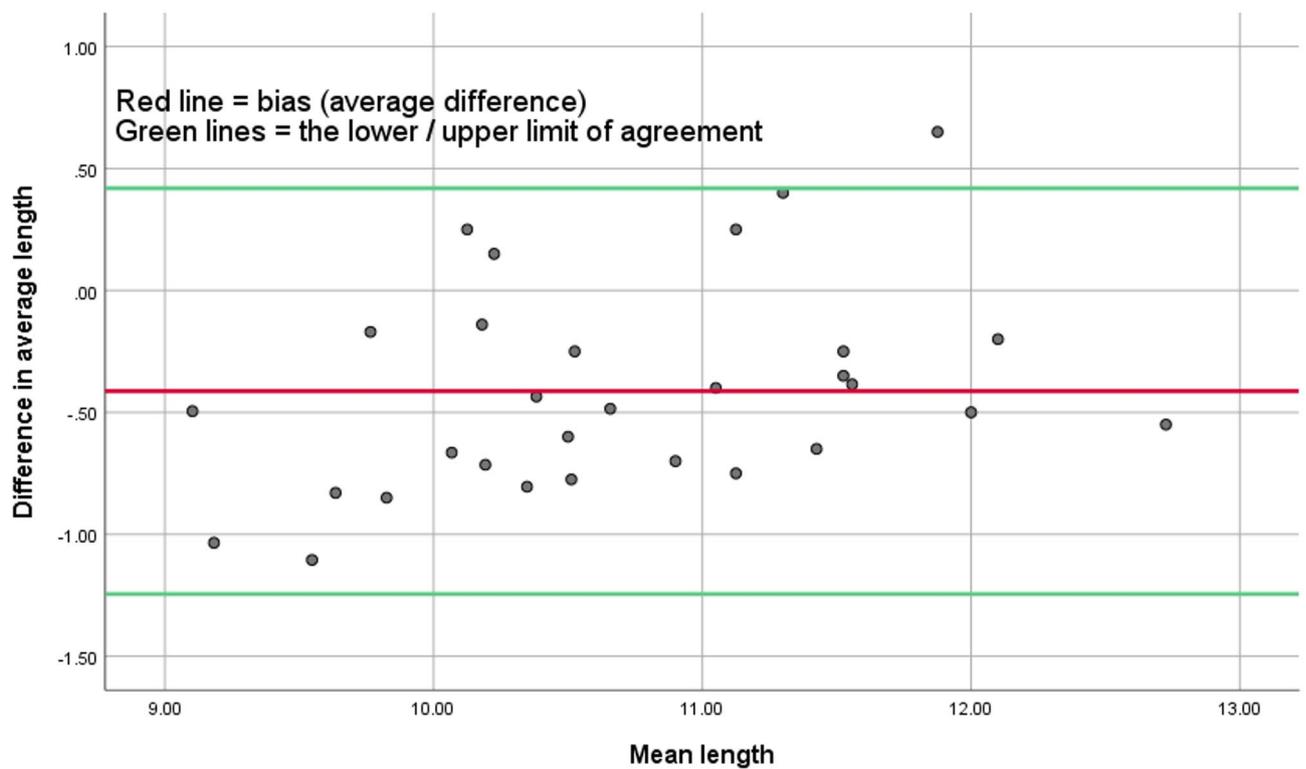
Fig. 8. Bland Altman plot for length (R).

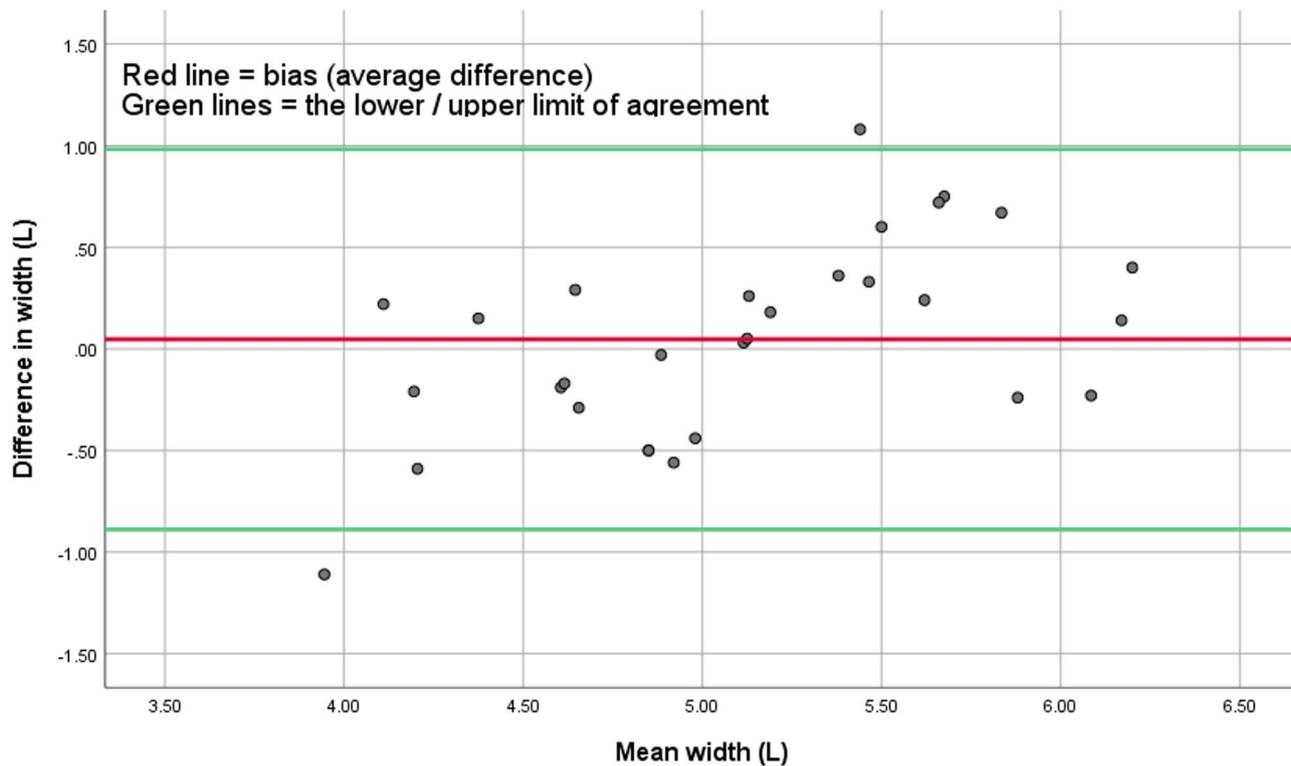
Fig. 9. Bland Altman plot for length average (of L/R).

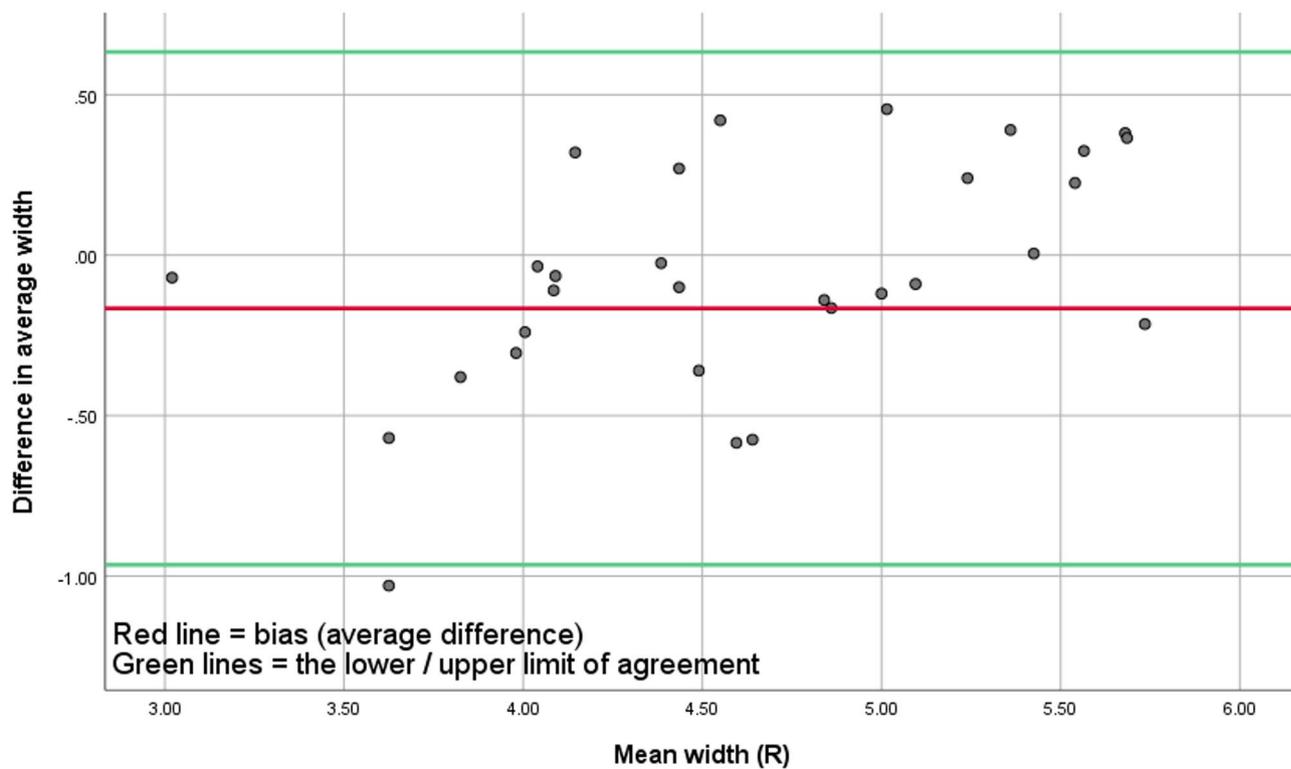**Fig. 10**. Bland Altman plot for width (L).

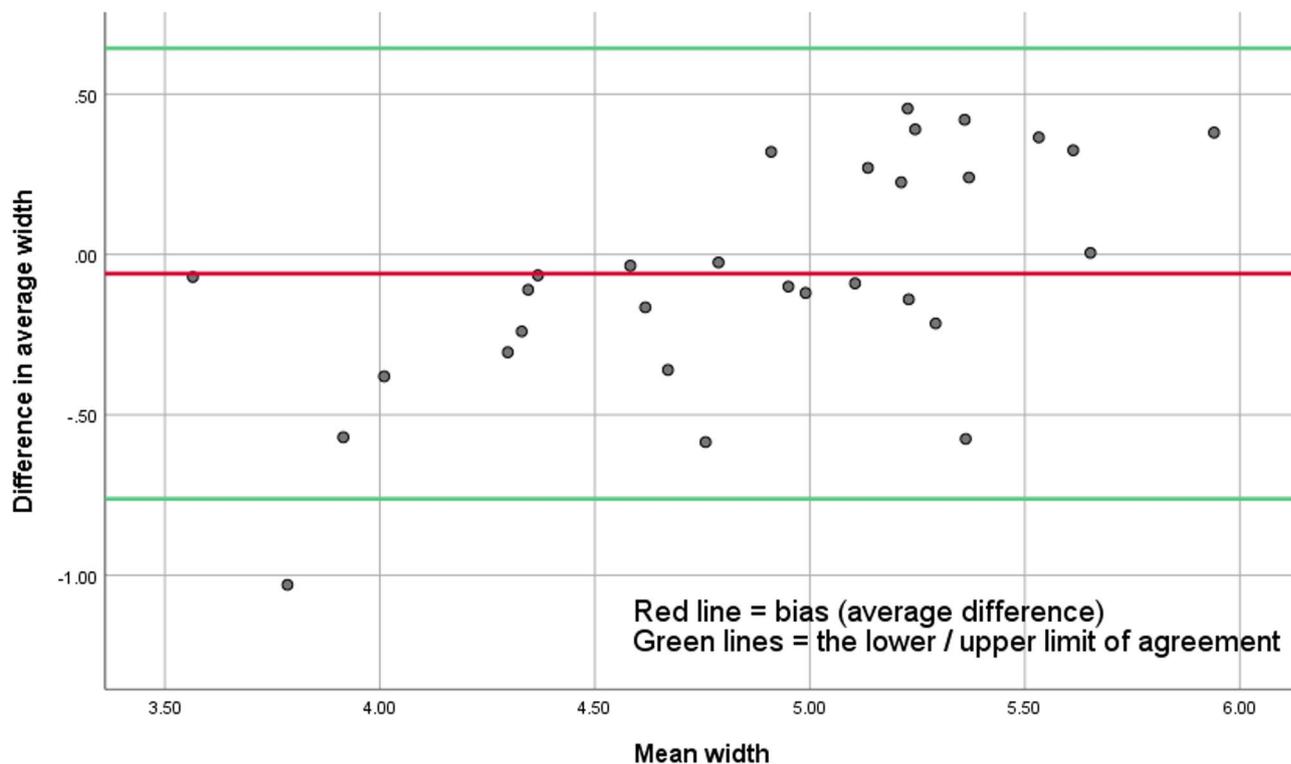**Fig. 11**. Bland Altman plot for width (R).

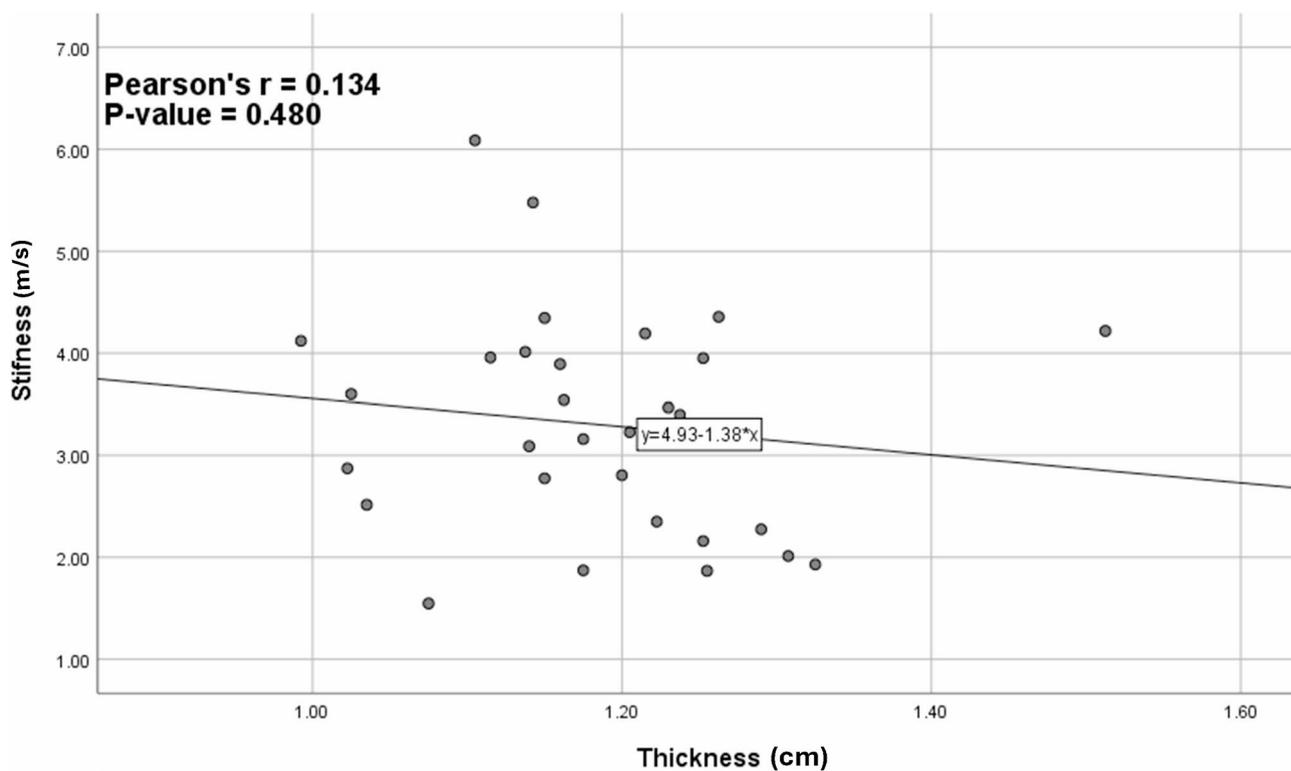**Fig. 12**. Bland Altman plot for width average (of L/R).

Fig. 13. The Correlation between kidney thickness and kidney stiffness.

sonographic parameters, particularly cortical thickness, showed limited agreement, highlighting the operator-dependent nature of morphometric assessments in renal ultrasound.

The good inter-observer agreement for renal cortical stiffness aligns with prior studies that have evaluated SWE reliability in renal applications. Leong et al. reported moderate-to-good reproducibility of SWE in kidney allografts (ICC > 0.75), emphasizing SWE's feasibility for routine follow-up in transplant settings[5]. Similarly, Lee et al. demonstrated that SWE had better intra- and inter-observer agreement when standardized protocols, including breath-holding and optimal ROI positioning, were used[18]. Our study supports these findings, particularly in the diabetic population, where cortical stiffness may have potential clinical value into early fibrotic changes not evident on conventional ultrasound.

Comparing these results to clinical applications, SWE has shown excellent reproducibility in many applications such as liver, thyroid and breast tissues[19–21]. However, the kidney poses unique challenges due to its retroperitoneal location, variable depth, heterogeneous perfusion, and respiratory motion. These factors contribute to greater measurement variability, particularly when standardized ROI depth or angle of insonation is not maintained.

The poor inter-observer agreement observed for cortical thickness reflects limitations to B-mode ultrasound and operator dependency. Cortical thickness is difficult to measure precisely due to blurred corticomedullary boundaries, particularly in diabetic nephropathy where diffuse parenchymal changes may mask anatomic landmarks. Similar findings were reported by Wilson et al., who noted poor reliability of cortical thickness in CKD patients when compared to SWE, which was less affected by observer technique[22]. In our study, although cortical thickness values were not systematically biased between observers, wide variability in their agreement suggests that thickness alone may not be a reliable parameter, especially in early-stage diabetic kidney disease.

Renal length and width measurements showed excellent ICC values but were affected by proportional bias. This finding aligns with studies in paediatric and adult populations showing that variability increases with organ size[23&24]. Small but statistically significant systematic biases may arise from differences in probe angulation or interpretation of renal margins. Although such differences may not have major clinical consequences in most cases, they highlight the need for standardization in ultrasound measurement techniques.

Importantly, we observed no significant correlation between cortical stiffness and cortical thickness. This could be attributed to the small sample size in this study which could not be enough to assess the corelation between the stiffness and thickness. Moreover, the function of kidney for the study group could explain this finding as the relative good eGFR level.

The use of SWE in this study could help detect biomechanical changes related to early fibrosis or altered vascular compliance, potentially leading earlier intervention or more monitoring strategies[25]. Moreover, SWE may serve as a non-invasive surrogate for histological fibrosis assessment, which is particularly valuable in diabetic patients where renal biopsy carries higher procedural risk[26].

Despite these promising results, several limitations must be acknowledged. This is a pilot study with a relatively small sample size, designed to assess feasibility and variability. This limits the generalizability of our findings, and the study did not assess intra-observer variability, which may further impact clinical reproducibility. Additionally, all imaging was performed using the same ultrasound system, limiting our ability to comment on inter-machine variability. We also did not correlate SWE measurements with histopathological findings, which would provide stronger validation of stiffness as a surrogate for fibrosis. Future research involving larger cohorts is needed to validate these findings and establish clinical utility.

Conclusion
This pilot study demonstrates that renal cortical stiffness measured using SWE exhibits good inter-observer reliability in diabetic patients and may provide a valuable biomarker for early renal assessment plan. These results underscore the importance of protocol standardization, observer training, and integrating SWE into clinical for renal assessment in diabetes.

Data availability
The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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Author contributions

The author confirms that he was solely responsible for the conception, study design, data collection, analysis, manuscript writing, and final approval of the submitted version.

Declarations

Competing interests

The authors declare no competing interests.

Additional information

Correspondence and requests for materials should be addressed to F.F.A.

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