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Comparison of Visual Transient Elastography, Vibration Controlled Transient Elastography, Shear Wave Elastography and Sound Touch Elastography in Chronic liver Disease assessment using liver biopsy as 'Gold Standard'

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ABSTRACT

Purpose: Chronic liver disease (CLD) is considered one of the main causes of death. Ultrasound Elastography (USE) is a CLD assessment imaging method. This study aims to evaluate a recently introduced commercial alternative of USE, Visual Transient Elastography (ViTE), and to compare it with three established USE methods, Vibration Controlled Transient Elastography (VCTE), Shear Wave Elastography (SWE) and Sound Touch Elastography (STE), using Liver Biopsy (LB) as 'Gold Standard'.

Method: 152 consecutive subjects underwent a liver ViTE, VCTE, SWE and STE examination. A Receiver Operator Characteristic (ROC) analysis was performed on the measured stiffness values of each method. An inter- intra-observer analysis was also performed.

Results: The ViTE, VCTE, SWE and STE ROC analysis resulted in an AUC of 0.9481, 0.9900, 0.9621 and 0.9683 for $F \geq F1$, 0.9698, 0.9767, 0.9931 and 0.9834 for $F \geq F2$, 0.9846, 0.9651, 0.9835 and 0.9763 for $F \geq F3$, and 0.9524, 0.9645, 0.9656, and 0.9509 for $F = F4$, respectively. ICC scores were 0.98 for Inter-observer and 0.97 for Intra-observer variability analysis.

Conclusion: ViTE performance in CLD stage differentiation is comparable to the performance of VCTE, SWE and STE.

1. Introduction

Chronic liver disease (CLD) is nowadays considered one of the main causes of death, leading to millions of deaths per year worldwide [1]. CLD causes continuous liver tissue inflammation leading to fibrosis development and cirrhosis. Cirrhosis can be fatal, leading to liver failure and often to Hepatocellular Carcinoma (HCC) development. The combined Cirrhosis and HCC deaths, account for 3.5 % of all deaths around the world [1]. Because the progress of many subtypes of CLD can be prevented or even reversed, its diagnostic accuracy is important and can

Abbreviations: Chronic Liver Disease, CLD; Visual Transient Elastography, ViTE; Vibration Controlled Transient Elastography, VCTE; Shear Wave Elastography, SWE; Sound Touch Elastography, STE.

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Table 1
Baseline characteristics of 152 subjects participated in the study.

Age (years)	56.43 ± 13.29
Sex	
Male	81 (53.29 %)
Female	71 (46.71 %)
Body Mass Index (kg/m^2)	27.93 ± 5.45
Chronic Liver Disease Etiology	
Chronic Hepatitis B	18 (11.84 %)
Chronic Hepatitis C	19 (12.5 %)
Alcoholic Liver Disease	11 (7.24 %)
Non-Alcoholic Liver Disease	22 (14.47 %)
Autoimmune Hepatitis	15 (9.87 %)
Primary Biliary Cholangitis	5 (3.29 %)
Other	16 (10.53 %)
Fibrosis Stage (Metavir)	
F0	46 (30.26 %)
F1	30 (19.74 %)
F2	14 (9.21 %)
F3	28 (18.42 %)
F4	34 (22.37 %)

lead to appropriate patient management and public health improvement.

Liver biopsy (LB) is currently viewed as the 'Gold Standard' for CLD diagnosis and CLD stage assessment. The Metavir 5-stage classification system is mostly preferred for CLD fibrosis staging, ranging from F0 to F4 [2]. LB is used as reference in CLD diagnosis and staging but is invasive, costly, is characterized by post-operative complications, death and technical failure [3,4], and suffers from inter-observer variability [5].

LB limitations have brought the development of non-invasive methods for CLD assessment, such as blood serum markers (BSMs) [5,6] and imaging methods, like magnetic resonance imaging (MRI) [5,7], computed tomography (CT) [5,6,8], and ultrasound (US) B-Mode [9]. These methods have limited accuracy in predicting liver fibrosis stage while MRI and MR-Elastography in particular, is accurate but costly and of limited availability.

US Elastography (USE) is an alternative, low-cost US-based method, that quantitatively estimates tissue stiffness and aids in CLD diagnosis through fibrosis-stiffness correlation. Multiple USE variants are commercially available, such as Vibration Controlled Transient Elastography (VCTE), known as Fibroscan, Real Time Elastography (RTE), Acoustic Radiation Force Impulse (ARFI) Elastography, Shear Wave Elastography (SWE) and Sound Touch Elastography (STE). All above methods, except RTE, provide quantitative stiffness measurements towards CLD stage assessment. Clinical studies evaluating USE performance are based on optimum stiffness cut-off value calculation (provided by LB) and correspondence to fibrosis stage groups [10–18]. These studies have shown that USE techniques are useful tools for CLD assessment, characterized by high performances (AUCs $\geq$ 0.80) when LB is used as reference. Medical equipment manufacturers have been developing advanced USE techniques, introducing US B-Mode guidance, 2D elastographic color-map visualization and measurement quality criteria.

Mindray recently developed **Vi**sual **T**ransient **E**lastography (ViTE), a similar to VCTE, USE technique that allows guidance, through B-Mode visualization. As ViTE is a USE newcomer, only two studies on ViTE performance on CLD assessment have been published. Yang et al. compared the performance of ViTE, SWE and STE on 106 LB validated patients, concluding that ViTE is an equivalent, to SWE and STE, USE method [15]. Ren et al enrolled 227 Chronic Hepatitis B patients that underwent ViTE and VCTE examinations and found correlation with patients' LB fibrosis stage of r = 0.852 and r = 0.813, respectively [16].

With the addition of US B-Mode guidance, ViTE proposes a novel technological approach in transient elastography, which could produce more accurate stiffness assessment than other elastographic techniques. Moreover, there are no studies evaluating ViTE's performance in CLD assessment in comparison to VCTE, SWE and STE in the same patient sample. This motivated us to compare ViTE's performance with VCTE, SWE, and STE on CLD patients using LB as 'Gold Standard'.

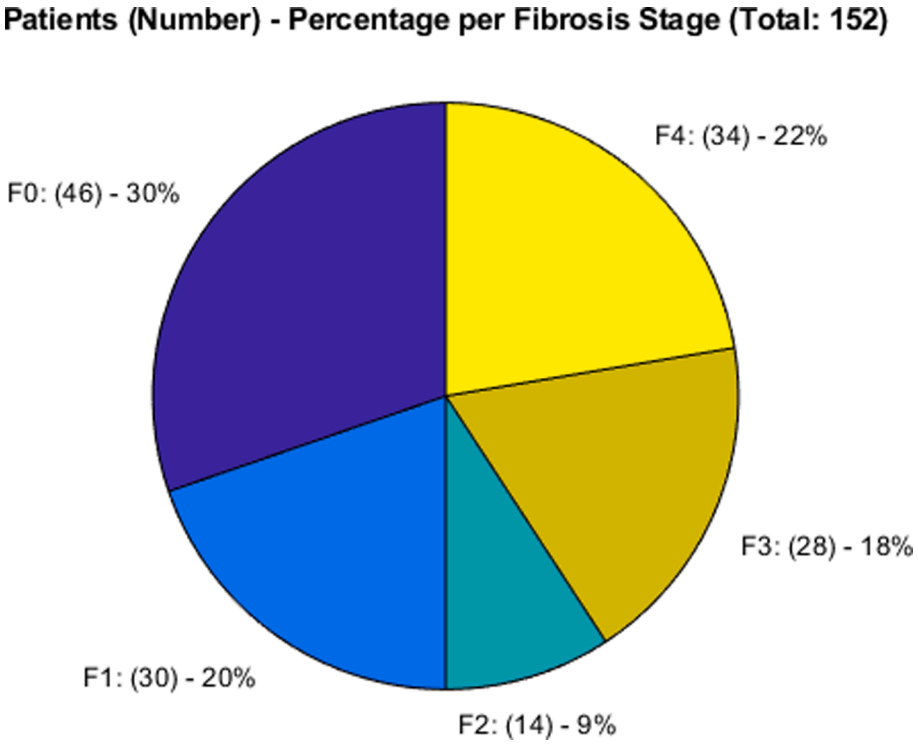

Fig. 1. Patients (Number) – Percentage per Fibrosis Stage (152 Total).

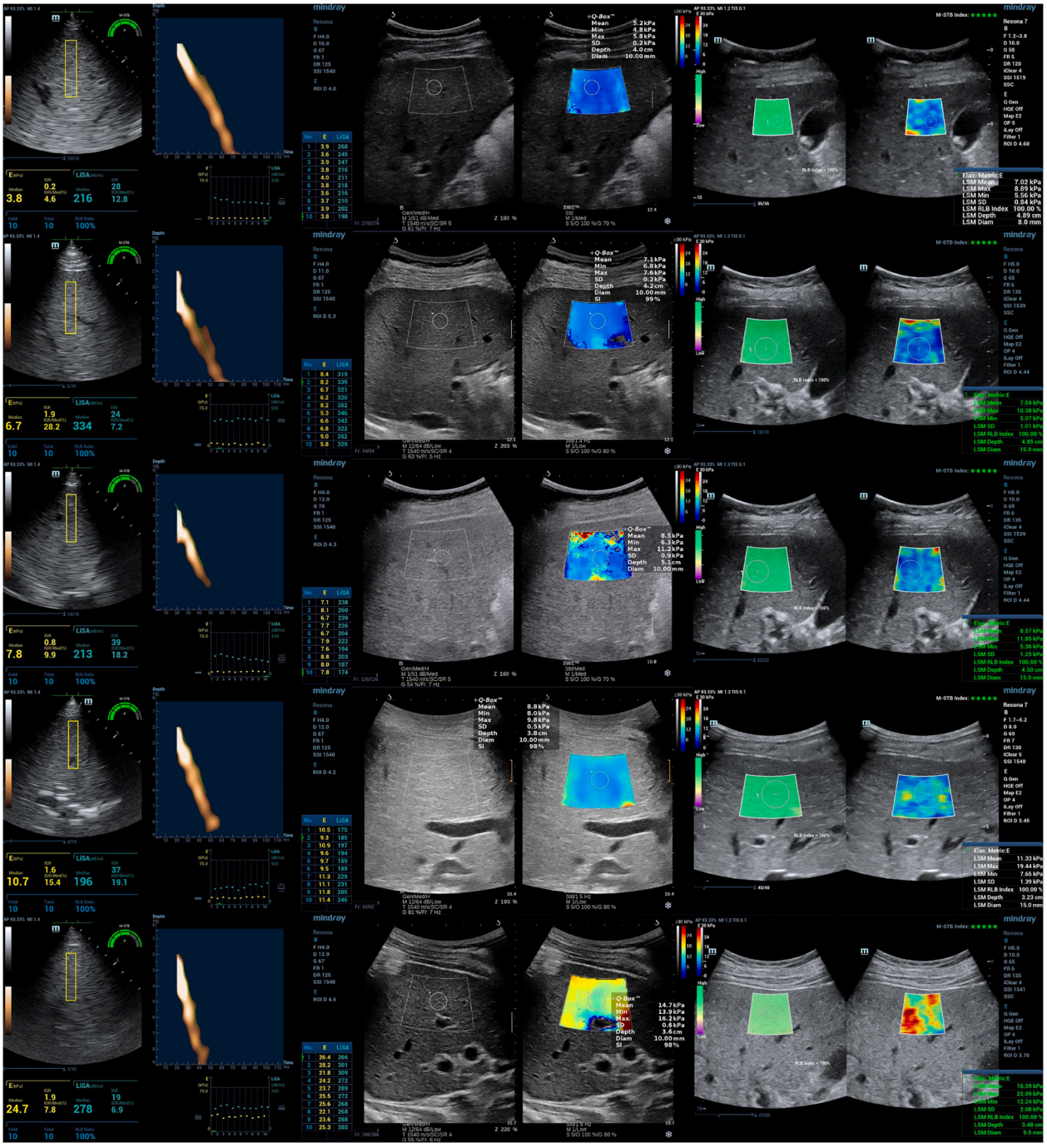

Fig. 2. ViTE (Left), STE (Middle) and SWE (Right) techniques. 1st row: normal case (F0), 2nd row: mild fibrosis case (F1), 3rd row: significant fibrosis case (F2), 4th row: severe fibrosis case (F3), 5th row: cirrhotic case (F4).

2. Materials and methods

a. *Clinical data*

For the purposes of this study, 193 subjects were processed from September 2020 to November 2021. 41 subjects were excluded from the study for not fitting at least one of the inclusion criteria presented below. 152 subjects (81 men, 71 women, mean age of 56.43 ± 13.29 years) were, therefore, included and analyzed. 46 were normal (F0) and 106 were CLD patients (30 F1, 14 F2, 28 F3 and 34 F4). Clinical and histological data collected during this study are shown in Table 1. Healthy subjects with no CLD clinical history, normal biochemical markers and no signs of liver pathology in the US examination were considered Normal (F0). F1-F4 fibrosis stage patients were validated through a LB and a histologic analysis by an expert histopathologist, blind to the ViTE, VCTE, SWE and STE measurements. The number of patients and their percentage per fibrosis stage as evaluated by LB are presented in Fig. 1.

This study was conducted in accordance with the ethical guidelines of the Helsinki Declaration and was approved by our institutional review board; a written informed consent was obtained from every subject participating in the study.

b. *Inclusion criteria*

Subjects were included in this study if all the following criteria were met:

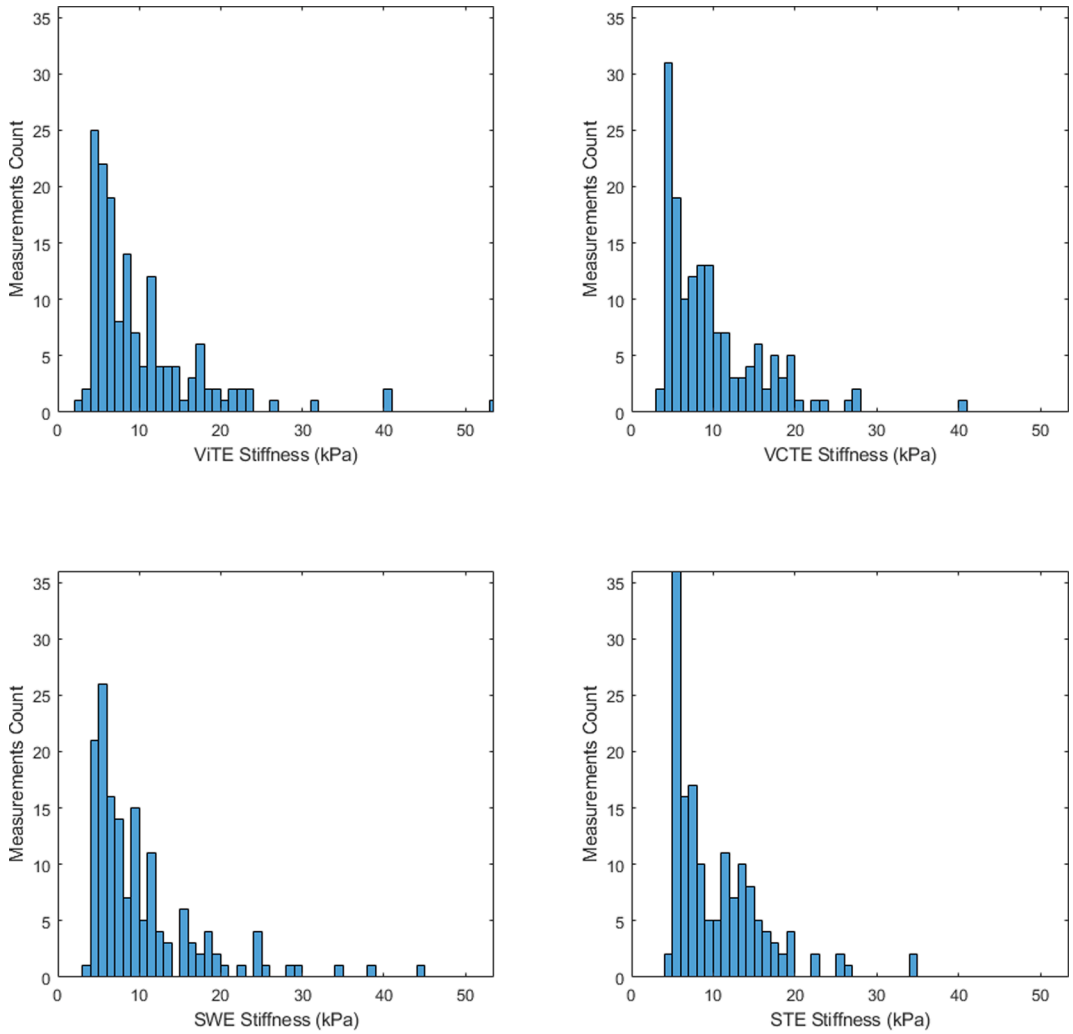

Fig. 3. ViTE, VCTE, SWE and STE measurements distribution (Histograms) on 152 LB validated Patients.

- Signing an informed consent form
- Having a time interval of less than 6 months between the LB and the ViTE/VCTE/SWE/STE measurement
- Having undergone ViTE/VCTE/SWE/STE examinations within 6 months
- No evidence for focal Liver lesions
- Securing a clear acoustic window
- Securing acceptable reliability criteria during the ViTE/SWE/STE examinations

c. Examiners and medical equipment

Both radiologists performing B-Mode, Color Doppler and ViTE/SWE/STE examinations are considered experts (EFSUMB experience level 3). Each radiologist has more than 10 years of experience in carrying out VCTE and SWE examinations, 3 years in STE examinations and 1 year in ViTE examinations. The ViTE and STE examinations were carried-out using the Resona 7 US system and the LFP5-1U and SC5-1U transducers. The SWE examination was carried-out using the Aixplorer US system (Supersonic Imagine, Aix-en-Provence, France) and the SC6-1 transducer. ViTE, SWE and STE examinations were performed during the same day for every subject. The VCTE examination results were carried-out in two collaborating medical centers with a Fibroscan US system using either M + or XL + probe, according to skin-to-liver capsule distance.

d. Examination protocol

ViTE, VCTE, SWE and STE measurements were performed on the right lobe of patients' liver, following both EFSUMB and WFUMB Guidelines [17,18]. In order to limit the risk of examiners' bias, the examination order between US systems, was random.

For VCTE, a standard examination was carried-out through probe placement over the center of the liver parenchyma and through mechanical inducement of a 50 Hertz shear wave. The median of ten measurements and the IQR score along with a detailed examination report were stored and sent to our clinic for analysis.

Regarding SWE and STE, a routine B-Mode and Color/Power Doppler US abdomen examination was carried-out for every subject. For the SWE/STE examinations the examiners established an appropriate acoustic window and activated the Elastography mode. To insure the validity of SWE/STE measurements, each US system's quality indices were utilized, according to the manufacturers' guidelines [14,19].

Regarding the ViTE examination process the probe was placed into an intercostal space, with the two sides of the probe's edge parallel to the ribs, ensuring that the US beam is not blocked. The examiner then, located a liver area avoiding vessels or cysts. The examiner kept the acquisition image as stable as possible and selected the ViTE/LiSA ROI mode to perform the measurements. The ViTE stiffness value is derived by default from the, automatically calculated, mean of 10 measurements, acquired from the same Liver area (Fig. 2). The ViTE measurement reliability criteria, the motion stability (M−STB) and Pressure (P)

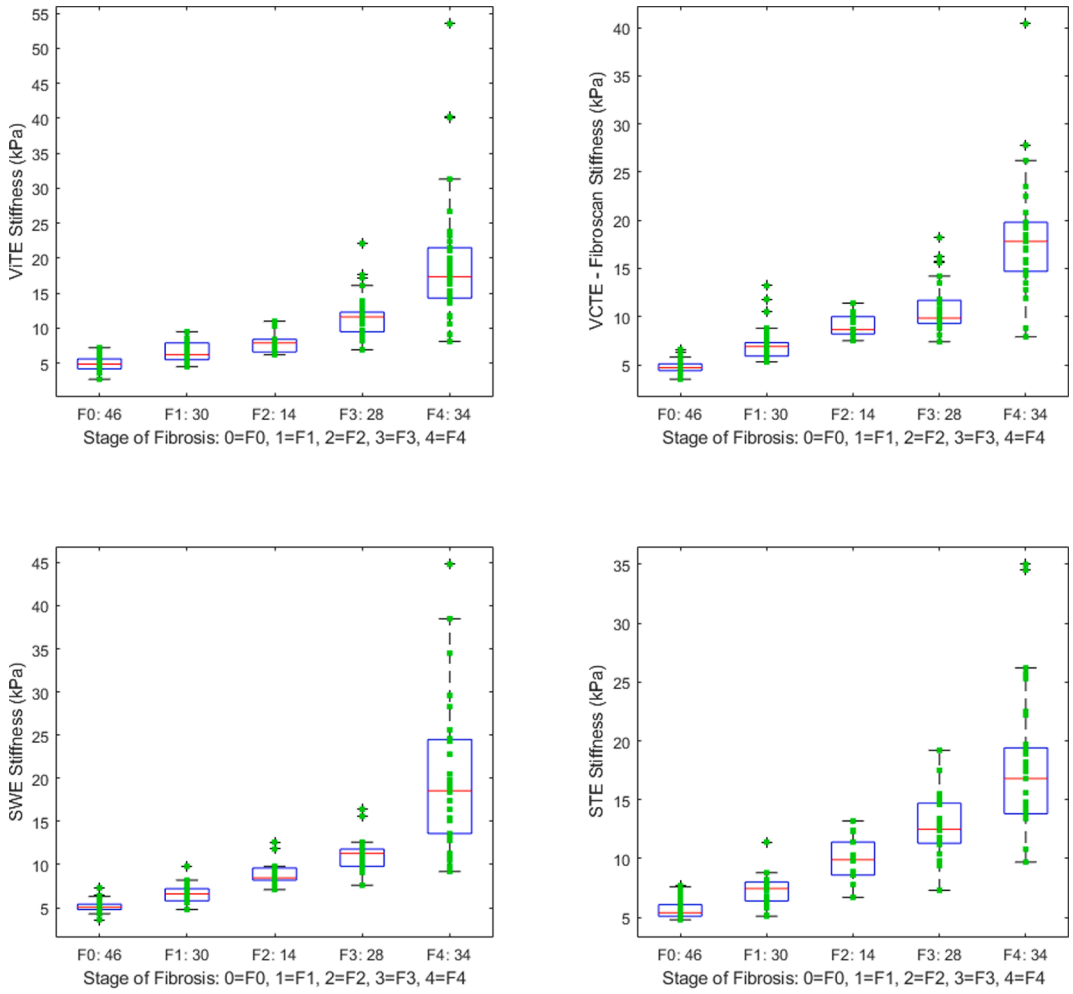

Fig. 4. ViTE, VCTE, SWE and STE measurements distribution (Box-Plots) along 152 Patients' Fibrosis Stages.

Table 2
Elastographic Methods' Correlation with LB (SCC/PCC).

	SCC	PCC
ViTE	0.9	0.72
VCTE	0.93	0.81
SWE	0.93	0.77
STE	0.92	0.82

Abbreviations: SCC = Spearman's Correlation Coefficient; PCC = Pearson's Correlation Coefficient;

indices were utilized to ensure measurement validity.

In order to further assure measurement reliability regarding elastography types used in this study, an IQR to Median ratio (IQR/M) less than 30 % was required. The Young's modulus was used to express elastographic measurements in kPa units. Indicative images acquired from the ViTE, SWE and STE examinations of a healthy (F0) and a cirrhotic (F4) subject, are presented in Fig. 2.

e. Statistical analysis

For CLD stage differentiation through optimum cut-off value calculation, a Receiver Operating Characteristics (ROC) analysis was performed on ViTE, VCTE, SWE and STE measurements, using LB fibrosis stages (Metavir) as 'Gold Standard'. Metrics including sensitivity, specificity, area under the curve (AUC) and balanced accuracy were calculated.

ViTE, VCTE, SWE and STE correlation with LB was also assessed through Pearson's Correlation Coefficient (PCC) and Spearman's Correlation Coefficient (SCC). Furthermore, the pairs of ViTE measurements by the two examiners were used through Intracorrelation Coefficient (ICC), PCC and SCC for inter- and intra-observer variability assessment. Finally, inter-Device variability with the aforementioned metrics (ICC, PCC and SCC) was assessed for each subject, as well as for each pair of US devices. The measurements used for inter-device variability were performed by the same examiner. The inter- and intra-observer variability analysis visualization was achieved through Bland-Altman plots. The inter-device variability analysis visualization was achieved through scatter plots.

3. Results

This section includes this study's results regarding measurement histograms per method (Fig. 3), distributions per method and fibrosis stage (Fig. 4), elastographic methods' correlation with LB fibrosis stages (Table 2), and ROC analysis (Figs. 5-6, Table 3). Inter- intra-observer variability (Fig. 7) and inter-device variability (Fig. 8, Table 4), are also presented below.

a. ROC analysis

In order to calculate optimum cut-off values for all techniques (ViTE, VCTE, SWE and STE) an ROC analysis was performed on $F \geq F1$, $F \geq F2$, $F \geq F3$ and $F = F4$ binary classifications of CLD staging. The AUC,

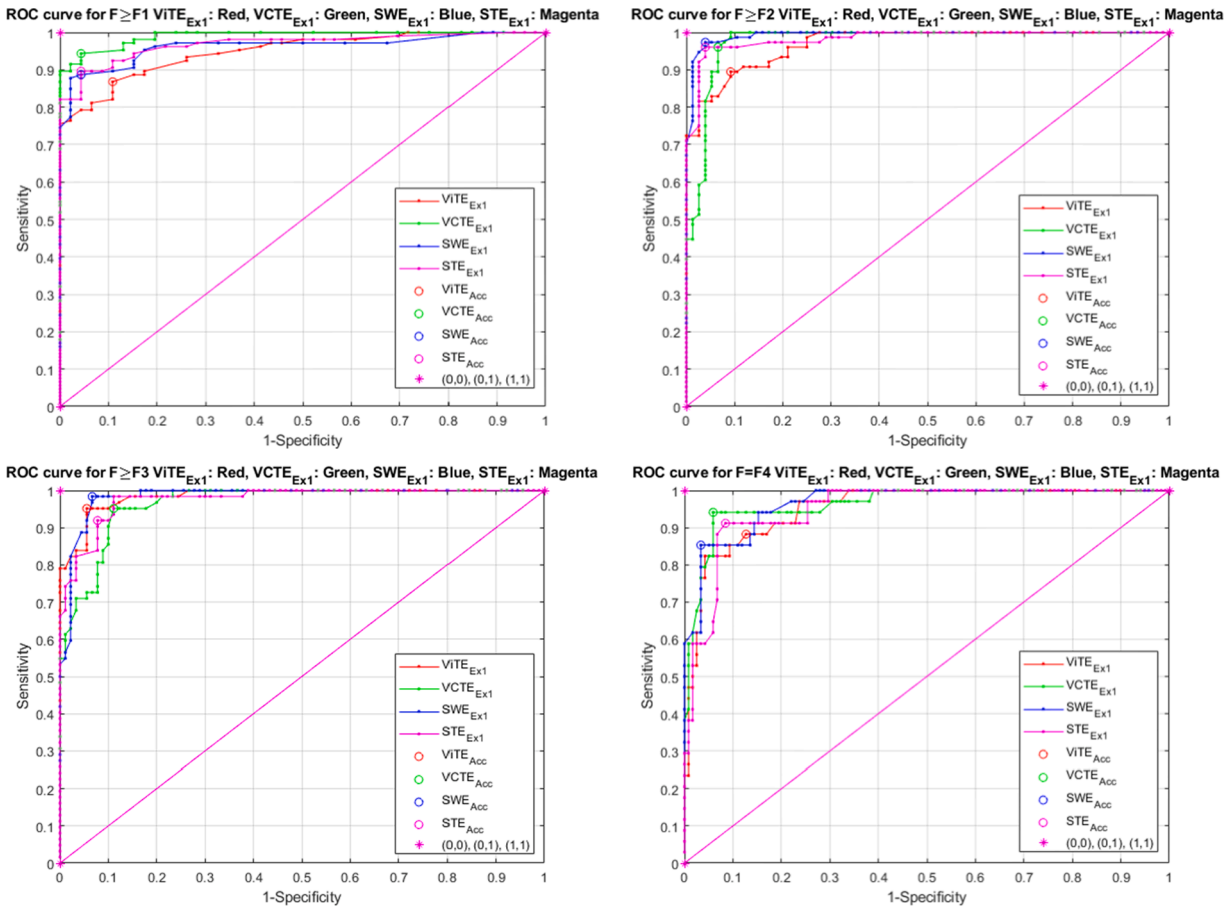

Fig. 5. ViTE (Red), VCTE (Green), SWE (Blue) and STE (Magenta) ROC Curves for F ≥ F1 (Top Left), F ≥ F2 (Top Right), F ≥ F3 (Bottom Left) and F = F4 (Bottom Right). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

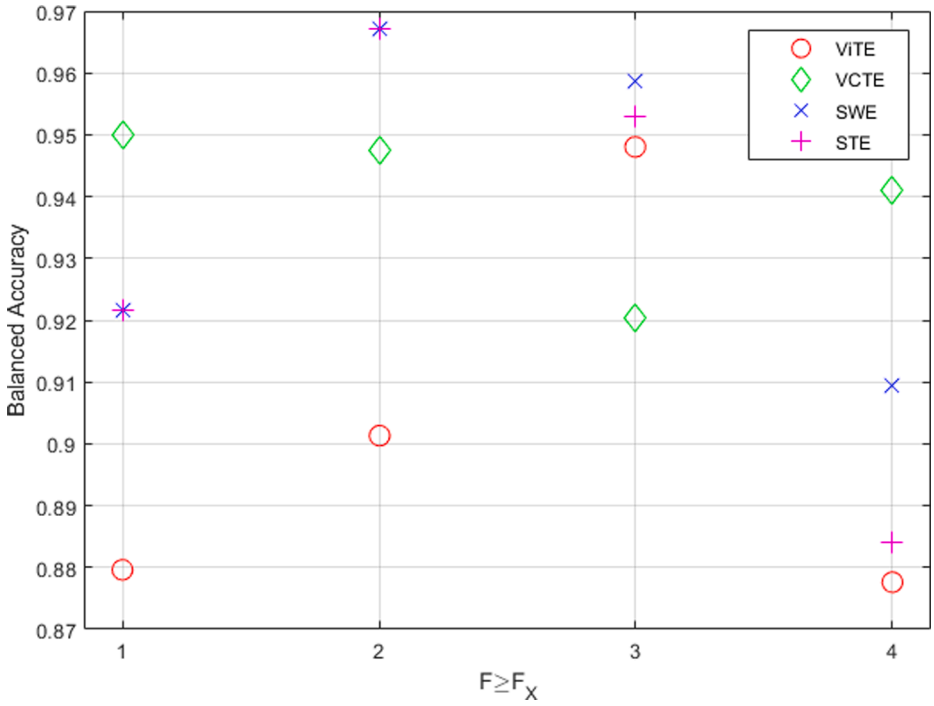

Fig. 6. Plot showing Balanced Accuracies of ViTE/VCTE/SWE/STE per F ≥ Fx stage group (x = 1, 2, 3, 4) of 152 LB validated patients. Colors and shapes are indicative of measurement method. ViTE: Red, VCTE: Green, SWE: Blue, STE: Magenta. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

Table 3
ROC Analysis results for F ≥ F1, F ≥ F2, F ≥ F3 and F = F4 for ViTE, VCTE, SWE and STE. Performances per fibrosis stage binary group classification are color-indicated. Minimum: Red, Maximum: Green.

	F ≥ F1	F ≥ F2	F ≥ F3	F = F4
AUC				
ViTE	0.9481	0.9698	0.9846	0.9524
VCTE	0.9900	0.9767	0.9651	0.9645
SWE	0.9621	0.9931	0.9835	0.9656
STE	0.9683	0.9834	0.9763	0.9509
Sensitivity				
ViTE	0.8679	0.8947	0.9516	0.8824
VCTE	0.9434	0.9605	0.9516	0.9412
SWE	0.8868	0.9737	0.9839	0.8529
STE	0.8962	0.9605	0.9194	0.9118
Specificity				
ViTE	0.8913	0.9079	0.9444	0.8729
VCTE	0.9565	0.9342	0.8889	0.9407
SWE	0.9565	0.9605	0.9333	0.9661
STE	0.9565	0.9605	0.9222	0.9153
Balanced Accuracy				
ViTE	0.8796	0.9013	0.9480	0.8776
VCTE	0.9500	0.9474	0.9203	0.9409
SWE	0.9217	0.9671	0.9586	0.9095
STE	0.9217	0.9671	0.9530	0.8841
Optimum Cut-Offs				
ViTE	6.2	8.0	8.8	11.6
VCTE	5.9	8.1	8.8	11.9
SWE	6.4	7.6	9.1	12.8
STE	6.4	7.6	9.4	11.5

Abbreviations: AUC = Area Under the ROC Curve.

sensitivity, specificity, balanced accuracy and best cut-offs are shown in full detail in Table 3. Corresponding ROC curves are presented in Fig. 5 below. Fig. 6 contains the balanced accuracies per device and fibrosis stage class binary group calculated by ROC analysis.

b. Inter- Intra-Observer variability – Inter-Device variability

The Inter- and Intra-observer variability analysis results for ViTE are presented in Fig. 7. The ICC, PCC and SCC were calculated as 0.98, 0.98, 0.98 for Inter-observer and 0.97, 0.97, 0.97 for Intra-observer variability analysis. Furthermore, the Inter-Device variability study was performed in all possible combinations of the ViTE/VCTE/SWE/STE US devices as shown in Table 4. Fig. 8 presents scatter plots of stiffness measurement pairs performed by the same examiner on both devices, along with the best cut-off values for each method drawn in colored straight lines to show True/False Positives/Negatives.

4. Discussion

The results indicate that all methods analyzed in this study perform similarly and can well differentiate fibrosis stage groups, as all balanced accuracies are higher than 0.875 and corresponding AUCs are also higher than 0.945. Even though all methods perform similarly, ViTE's performance is generally marginally inferior to the other elastographic techniques' performance in this study and superior only to VCTE in F > F3 patients. This may, firstly, be due to lack of examiners' experience using ViTE in comparison to the other techniques. Specifically, operators that performed VCTE examinations had more than 10 years of experience. Operators that performed SWE and STE examinations had more than 10 years of experience in carrying-out US Elastography examinations and more than 10 and 3 years using the SWE and STE features, respectively. SWE and STE are similar Shear Wave based technologies, both involving color elastograms, and sharing identical examination guidelines. The STE learning curve for an experienced SWE operator, therefore, should be short. ViTE, on the other hand, is a novel similar to VCTE technique that includes visualization, but has different examination guidelines to VCTE, SWE and STE. Furthermore, the VCTE, SWE, STE methods have been commercially available for years, during which they have been improved through software and hardware upgrades multiple times. ViTE used in this study, on the other hand, was the initial release version. Finally, it is worth noting that VCTE achieves high performance despite the fact that it is the only method without B-Mode/Elastogram visualization. It could be argued that B-Mode/Elastogram visualization limits the number of failed measurements, since the examiner has the opportunity to select an appropriate ROI. This assumption was not tested during this study, since rates of failure of each method were not calculated.

Despite ViTE's marginal inferiority in performance comparing with the other methods analyzed in this study, the method may have some advantages over them. It, firstly, adds the important element of visualization in the already established and validated technology of transient Elastography. This visualization could lead to decreased measurement failure rate. Furthermore, ViTE could provide more accurate measurements than competing solutions if some of the factors discussed in the previous paragraph are resolved. Finally, when the ViTE measurement is performed the system simultaneously performs an US-attenuation based measurement which is correlated with Liver Steatosis. Even though a similar procedure is also performed by Fibroscan's VCTE and CAP features, it constitutes an advantage over some US systems (i.e., the SuperSonic Aixplorer System that was used for this study) that are not able to quantify Liver Steatosis.

In existing studies that evaluate the performance of either, ViTE, SWE, STE or VCTE, similar results have been produced. Yang et al. compared the performance of ViTE, SWE and STE on 106 LB validated patients, concluding that ViTE performs equivalently to SWE and STE methods. Their analysis found AUCs of 0.88, 0.91, 0.92 for F ≥ F1; 0.84, 0.84, 0.84 for F ≥ F2; 0.80, 0.79, 0.77 for F ≥ F3; and 0.80, 0.76, 0.71 for F = F4 [15]. The corresponding AUC values of our study showed higher overall performance. Ren et al evaluated 227 Chronic Hepatitis B patients that underwent ViTE and VCTE examinations and found correlation with patients' LB fibrosis stage of r = 0.852 and r = 0.813, respectively [16]. The calculated AUCs for ViTE and VCTE were 0.819, 0.783 for F ≥ F2; 0.927, 0.902 for F ≥ F3; and 0.938, 0.925 for F = F4, respectively [16]. Corresponding correlation values (PCC) calculated in

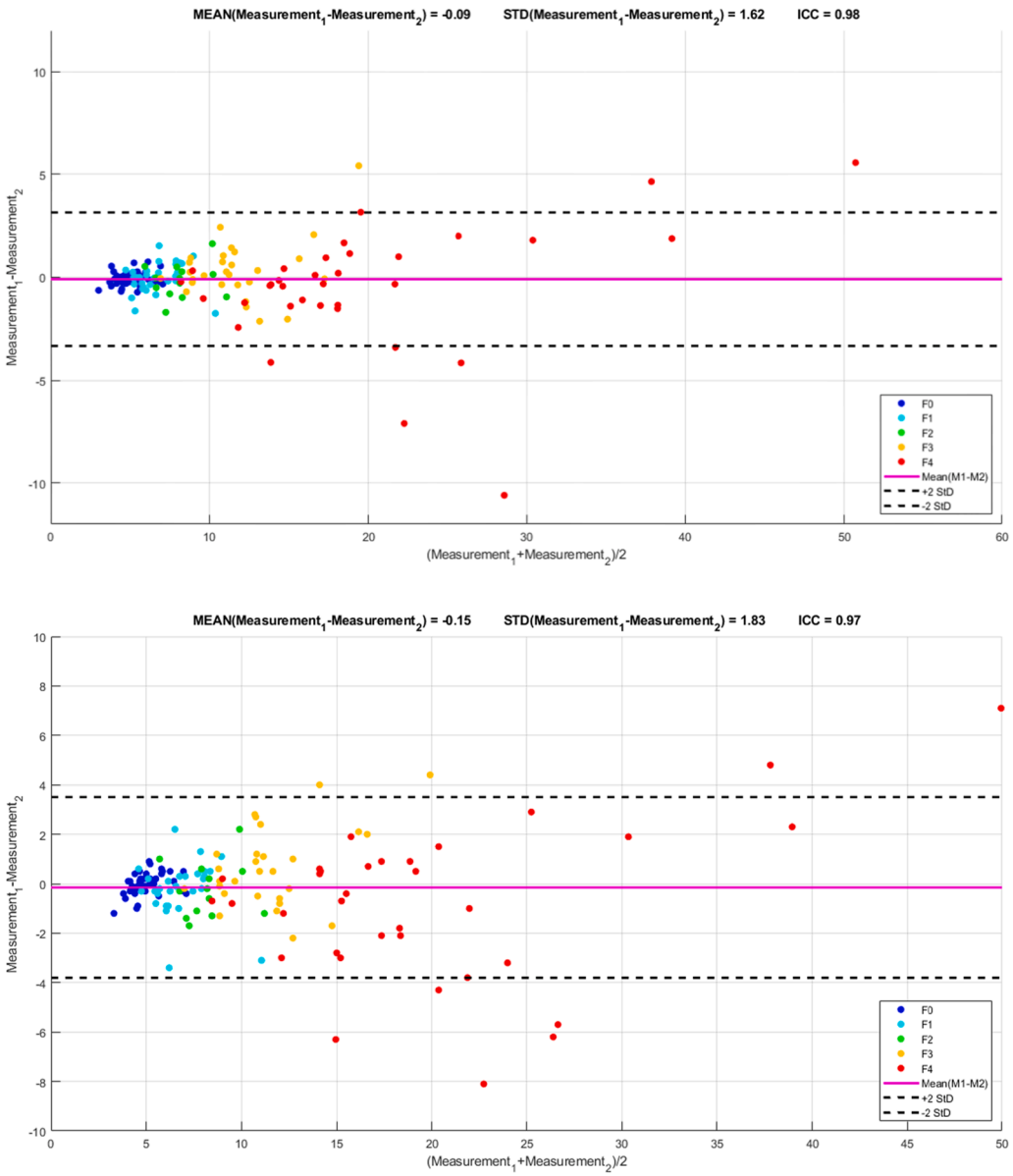

Fig. 7. Bland-Altman Plot showing the ViTE Inter- (Top) Intra- (Bottom) Observer variability on 152 LB validated patients. Colors are indicative of Fibrosis Stage: F0: Blue, F1: Aqua, F2: Green, F3: Orange, F4: Red. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

the current study are lower for ViTE and similar for VCTE (PCC_{ViTE}: 0.72, PCC_{VCTE}: 0.81). The corresponding AUCs achieved by ViTE and VCTE in this study are also similar to Ren et al study. Most other studies discussing the performance of USE techniques demonstrate similar results regarding SWE and VCTE performance for all fibrosis stage classes [10–18].

The inter- and intra-observer variability study, results show that ViTE has excellent reliability between both measurements of the same and different operators. These numbers are higher than the SWE, STE and VCTE methods have shown in previous studies [14,20–22]. As other studies involve different patient samples, comparisons should be made with caution.

Regarding inter-device variability, all pairs of different USE methods achieve ICC, SCC and PCC scores greater than 0.86, greater than 0.91 and greater than 0.87 respectively, showing very good agreement between each method's measurements and being in accordance with our previous study comparing VCTE, SWE, STE inter-device variability [14]. Highest agreement is observed between SWE and STE measurements while the lowest is observed between VCTE and the rest USE techniques. This may be due to the fact that VCTE was performed in different medical centers by different operators.

This is the first study comparing the ViTE performance (in terms of diagnostic accuracy, inter- intra-observer and inter-device agreement) with three already validated US elastographic methods, in CLD assessment. The advantage of studies like this is that they can directly compare different methods' performances on the same dataset.

Regarding limitations, it should be noted that ViTE, SWE and STE examinations were carried-out in the same clinic, which limits this study's generality. Moreover, even though improbable, a discrepancy between the patients' LB-validated fibrosis stage and the stage when ViTE/VCTE/SWE/STE examinations were performed, may occur. To reduce the effects of this limitation, we opted for a six-month interval between LB and ViTE/VCTE/SWE/STE examinations. According to multiple studies, CLD progression from stage to stage may take decades [23], rendering the 6-month interval adequate for this and our previous studies' validity [14,24–26]. Finally, this study's sample size was

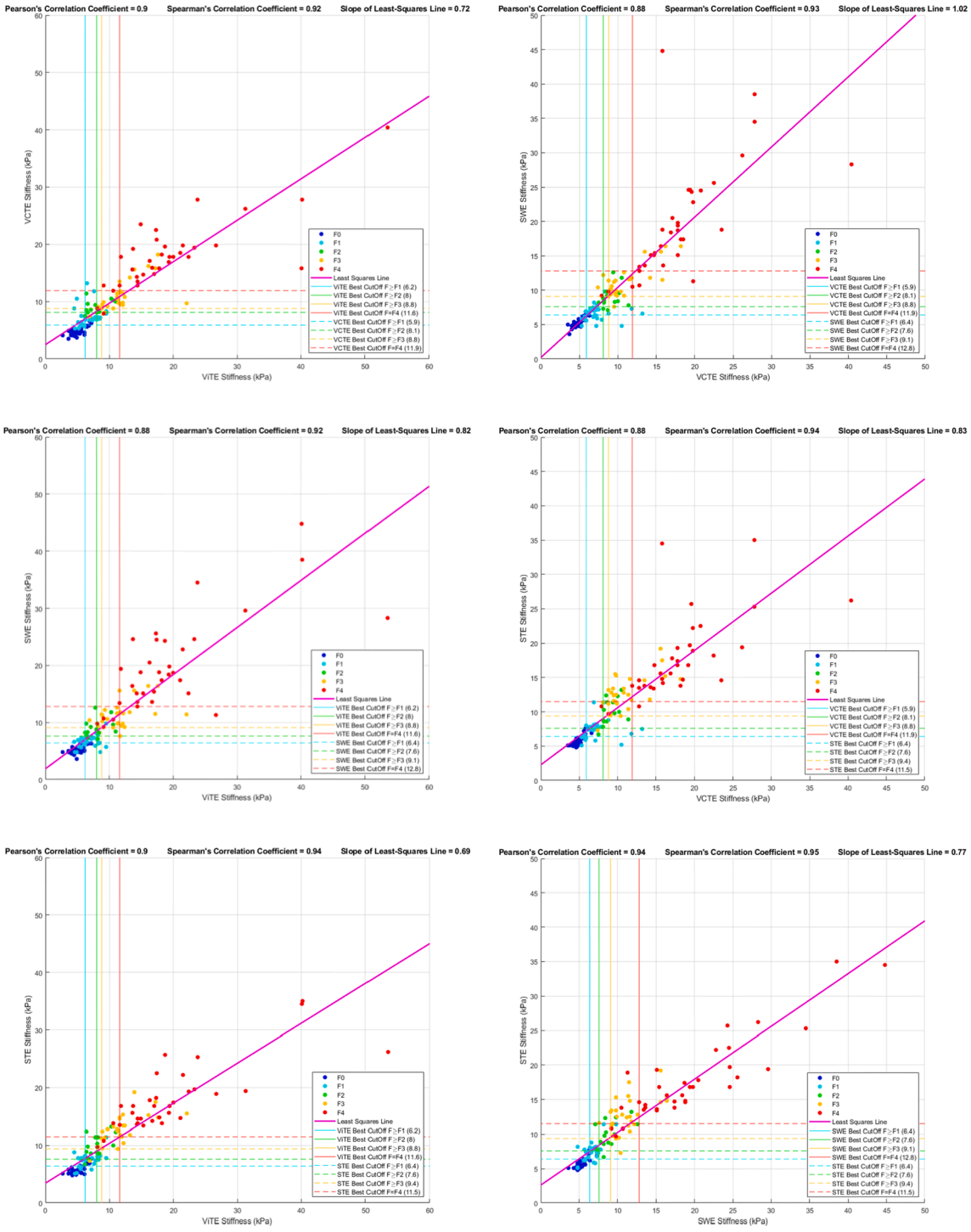

Fig. 8. Scatter Plots and Least Squares Lines extracted from pairs of measurements of all devices combinations of two on 152 LB validated patients. Top Left: ViTE (x-axis) and VCTE (y-axis), Top Right: VCTE (x-axis) and SWE (y-axis), Center Left: ViTE (x-axis) and SWE (y-axis), Center Right: VCTE (x-axis) and STE (y-axis), Bottom Left: ViTE (x-axis) and STE (y-axis), Bottom Right: SWE (x-axis) and STE (y-axis). Dot (measurement pairs) colors are indicative of Fibrosis Stage: F0: Blue, F1: Aqua, F2: Green, F3: Orange, F4: Red. Colored straight horizontal and vertical lines indicate best cut-offs for each device calculated by ROC Analysis: F $\geq$ F1: Aqua, F $\geq$ F2: Green, F $\geq$ F3: Orange, F = F4: Red. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

unevenly distributed between fibrosis stages, possibly affecting cut-off value calculation.

5. Conclusion

Concluding, this study compared the performance of ViTE, a new USE method, with the performance of three established USE methods, VCTE, SWE and STE. In accuracy terms, ViTE performs equivalently to VCTE, SWE and STE and may, therefore, be used as an alternative. All USE methods assessed in this study showed good inter-device variability. Future studies, processing larger sample sizes, may further validate ViTE as a reliable USE method.

Table 4
Inter-Device Variability (ICC, SCC, PCC) related results for ViTE, VCTE, SWE and STE measurements for each patient from the same examiner.

Method \Method	ViTE	VCTE	SWE	STE
ViTE	–	0.87/0.92/0.90	0.88/0.92/0.88	0.87/0.94/0.90
VCTE	0.87/0.92/0.90	–	0.87/0.93/0.88	0.87/0.94/0.88
SWE	0.88/0.92/0.88	0.87/0.93/0.88	–	0.92/0.95/0.94
STE	0.87/0.94/0.90	0.87/0.94/0.88	0.92/0.95/0.94	–

Abbreviations: ICC = Intraclass Correlation Coefficient; SCC = Spearman's Correlation Coefficient; PCC = Pearson's Correlation Coefficient;

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper: [Pavlos S. Zoumpoulis reports equipment, drugs, or supplies was provided by Shenzhen Mindray Bio-medical Electronics Co Ltd. Pavlos S. Zoumpoulis reports a relationship with Shenzhen Mindray Bio-medical Electronics Co Ltd that includes: speaking and lecture fees.].

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