Inter- and intraobserver reproducibility of Strain and 2D Shear Wave Elastography – a phantom study

Marina Dudea-Simon¹, Sorin Dudea², Călin Schiau², Răzvan Ciortea¹, Andrei Măluțan¹, Vasile Simon³, Alexandru Burde⁴, Anca Ciurea², Dan Mihu¹

¹²nd Department of Obstetrics and Gynecology, ²Radiology Department, ³Urology Department, ⁴Department of Dental Prosthodontics and Aesthetics, “Iuliu Hatieganu” University of Medicine and Pharmacy, Cluj-Napoca, Romania

Abstract

Aims: To analyse the intra- and interobserver variability of two elastographic methods of quantification available on the same machine, the technical factors that may influence variability as well as the intra- and interobserver variability for the same indices between two different ultrasound machines in an in vitro experimental setting. Material and methods: Three different types of silicone experimental devices (ED) were conceived for the purpose of this study. Two observers performed repeated measurements on two ultrasound machines. Strain elastography, with strain ratio determination between the ED was performed on both machines. Shear wave ratio was also assessed. The data obtained were used to calculate intra- and interobserver variability. Reproducibility was assessed in relation to the size of the elastographic region of interest (ROI) and to the difference in stiffness between the ED, through the value of the ICCs (Intraclass Correlation Coefficient). Results: Strain ratio had high inter- and intraobserver reproducibility, regardless of the machine used, on a large number of determinations. The choice of a small ROI diameter (5 mm) over a large ROI diameter (15 mm) increased reproducibility (ICC = 0.87 vs 0.78, p=0.000). It is observed that, by Shear Wave Elastography, only when analysing structures with a large difference in hardness, significance is obtained in terms of interobserver reproducibility (ICC = 0.75, p=0.000). Conclusions: On a large number of determinations, both techniques are inter- and intraobserver reproducible. It is preferable to opt for a smaller ROI diameter in order to increase interobserver reproducibility. SWE Ratio provides significant reproducibility only when analysing structures with large difference in hardness.

Keywords: strain elastography; shear wave elastography; interobserver reproducibility; intraobserver reproducibility; phantom study

Introduction

Focal or diffuse pathological processes can alter tissue stiffness; this is the principle underlying elastography, which has become an important addition to the ultrasound armamentarium [1-3]. In the last decade, elastography has found its utility in many clinical applications, including liver, breast, prostate, uterine cervix and musculoskeletal disease [4-8].

Several manufacturers have developed elastographic techniques using their own technical solutions. The implementation of certain methods on a large scale, either for diagnostic purpose, or for disease staging and follow-up, proves to be still problematic. The main types of elastography differ in the physical mechanism underlying the method. Strain Elastography (SE) involves the application of an external force, in the form of a mechanical compression; the force is applied vertically and is addressed to the Young modulus. Shear Wave Elastography (SWE) is characterized by shear force, which propagates transversely and addresses the Shear modulus. According to the type of results provided through elastography, different elastographic techniques express the rigidity of
the analysed structures either in absolute values (m/s or kPa, Young modulus or Shear modulus) or in stiffness ratios (strain ratio, shear wave ratio) [2].

In order to evaluate the reproducibility of various elastographic techniques, both phantom and clinical studies have been designed [9-11]. Of these, some assessed machine dependent variability for SWE [9,12-14]. Other studies evaluated intra- and interobserver variability of different elastographic techniques in a clinical setting [11,15-17].

The purpose of the current study is to analyse intra- and interobserver variability of two elastographic methods of quantification, available on the same machine. Also, the technical factors that may influence variability, as well as intra- and interobserver variability for the same indices between two different ultrasound machines were analysed in an in vitro experimental setting.

Materials and methods

Experimental devices

For the purpose of this study, a phantom containing three different types of experimental devices was conceived. The devices were labeled A, B and C, all composed of poly addition silicone rubber. All devices were prepared in the form of rounded tip silicone cylinders, with a diameter of 1.5 cm and a length of 2.5 cm, comprising a volume of 4.4 cm³. The devices were virtually designed using MeshMixer (Autodesk, USA) CAD software and produced out of a grey photopolymer resin through additive manufacturing via stereolithography by using a Form 2 (Formlabs, USA) 3D printer. After manufacturing, a negative mould of the device was obtained by using Elite Double 32 (Zhermack, Italy) duplication silicone. The inside of the mould was then sprayed with a release agent and silicon rubber was poured inside in order to obtain the actual device to be used for imaging examinations. After curing at room temperature for 24 hours, each device was removed from the mould.

The devices were made of different types of poly addition silicone rubber, as follows: A – translucent, high consistency, was created of ZA 13 (Zhermack, Italy) poly addition silicone rubber, with a mixing ratio of 1 part of base to 1 part of catalyst; B – translucent, low consistency, was also made of ZA 13 (Zhermack, Italy) poly addition silicone rubber, with a mixing ratio of 1 part of base to 1.6 parts of catalyst; C – pink, high consistency, was created by using Elite Double 8 (Zhermack, Italy) poly addition silicone rubber, with a mixing ratio of 1 part of base to 1 part of catalyst.

Devices A and C have physical properties clearly defined by the manufacturer, according to the technical specifications sheet. Their stiffness is expressed in durometer units, class Shore A, according to the manufacturer. The hardness (Shore-A) of ZA 13 (Zhermack, Italy) and Elite Double 8 (Zhermack, Italy) materials were converted to Young’s Modulus(E) in Microsoft Excel using the = EXP ((Shore-A Durometer)*0.0235-0.6403) [18]. Thus, we confirmed that the A and C devices have an approximate Shear modulus value (µ) of 238.5 kPA and 212 kPA, respectively. Therefore, devices A and C can be considered as standard materials, whereas device B was custom made from a material designated to be softer by the way it was created. By increasing the amount of catalyst relative to the base, we obtained a device of lower consistency.

The B device, both theoretically by way of construction and clinically, is softer, without characterization of hardness in kPA and without being able to formulate deductions regarding its numerical value. Devices A and C, both hard, were created to elastographically compare structures with very close tactile consistency. The purpose of creating the soft B device was to allow the comparison of structures with a very different tactile consistency.

Study groups

Five identical experimental boxes, containing each of the devices A, B and C were created. In each box of 11.5/7/4 cm the devices were embedded in 275 ml of gelatine.

The gelatine was prepared according to the manufacturer’s instructions, by adding 10 grams of gelatine powder for 100 ml of cold water and, after 10 minutes, heating the composition at a temperature of 60°C until completely homogenized. After cooling for 3 minutes, the gelatine was poured into the boxes, over the experimental devices and was allowed to harden at 4°C for 12 hours. For each box, the devices were labelled as follows: box 1 – devices A1, B1, C1 and so on (fig 1).

Ultrasound examination technique

Two ultrasound machines were used: first machine (M), Resona 7 (Mindray, Shenzhen, China) equipped with a L14-5WU linear transducer operating at 6.2-10.8 MHz for strain elastography and at Harmonic 12 MHz for shear wave elastography; second machine (H), Hitachi EUB 8500 (Hitachi, Ltd.; Kabushiki Kaisha Hitachi Seisakusho, Japan), with a L54M, 50 mm surface, linear probe, operating at 13 MHz. The first machine provides
both strain and 2D shear wave (SW) elastography. The machine computes both strain ratio (SR) and SW elasticity ratio derived from SW kPa measurements. The second machine only offers strain elastography (SRE) and it computes SR.

Both machines were operated under standard preset protocols. Parameters were set as follows: for machine M: strain elastography – preset, thyroid; frame rate, 20; mechanical index, 1.1; dynamic range, 140; IClear, 4; IBeam, 1; SSI, 1580; MAP, E; Opacity, 4; 2D SW – preset – thyroid; frame rate, 7; dynamic range, 140; distance, 4; Gain, 58; IClear, 4; SSI, 1580; Q Gen; HQE, Off; MAP, E2; Opacity, 4; IBeam Off; Filter, 0; Scale, 13; for machine H: strain elastography – preset, breast; frame rate, 17; Bidimensional Gain, 10; Elasto mode, dual; map L1 with density 2; pressure indicator, on; colour scale, on; dynamic range, 75; edge enhancement, 2; grey map, 5; Automated Gain Correction, 2; Resolution Filter A; Persistence, 6; Rejection, 0; Saturation, 255.

Elastographic acquisitions were performed according to the specifications of the manufacturer, with optimal quality indicators.

**Image acquisition**

**Strain elastography on machine M**

On the same image, two neighbouring devices, located in the same box, were assessed. To evaluate the devices located on the opposite ends of the boxes, the gelatine was removed, the devices were rearranged and the boxes were reassembled.

The transducer was applied to the gelatine surface, forming a 90° angle with the devices and the plane of the box floor. Conventional B-mode ultrasound was performed prior to SRE; a transverse view of 2 devices was obtained. The system was then switched to the SRE mode. A light displacement force was applied with the transducer, so as to comply with the quality standards indicated by the manufacturer. A simultaneous view of a grey scale image on the right side of the screen and the elastographic image, with the colour-coded stiffness map on the left side of the screen was obtained. Two circular regions of interest (ROI) were traced on the grey scale image, one on each device. The distance between the transducer surface and the centre of the ROI was identical for each device and between devices. SR was automatically computed by the device's software (fig 2).

The machine offers the possibility of presetting the diameter of the ROI; therefore, 3 types of ROIs were assessed: small ROI was set to 5 mm; medium ROI – 10 mm and large ROI – 15 mm.

**2D Shear Wave Elastography on Machine M**

The devices were arranged the same manner as for SR; after switching from conventional B-mode ultrasound to the 2D SW mode, a simultaneous view of a color-coded stiffness map on the right side of the screen and a color-coded image indicating the quality of the acquisition on the left side of the screen was obtained; SW elasticity ratio was computed by the machine based on the circular ROIs (small, medium and large) traced on each device, and presented results both in the form of a numerical ratio and in kPa (fig 3).

**Strain elastography on machine H**

The devices were arranged in the same manner as for machine M; image acquisition and the determination of SR were performed identically, as well, with the only noticeable difference that machine H does not offer the possibility of presetting the ROI size; therefore, only one type of ROI was assessed (fig 4).
For each pair of devices in the same box, 6 adequate images were obtained, on which SR on both machines and SW ratio on machine M were determined; therefore, for the 5 boxes, 30 ratios of each type were determined between each association of devices – A and B; A and C; B and C.

All the procedures were performed by two independent observers (MDS and CS), with 5 years, respectively 6 months, experience in elastography. One examiner (MDS) repeated all the procedures after 7 days, using the same protocols. The data obtained were used to calculate intra- and interobserver variability.

**Statistical analysis**

The descriptives of all variables were computed (mean, median, standard deviation). Additionally, the Shapiro-Wilk and Kolmogorov-Smirnov tests were used to assess normality. In the case of normally distributed variables, the Student test (t-test) for paired samples was employed in order to make comparisons between measurements. When data was not normally distributed, the nonparametric Wilkoxon test was applied, again, for pair comparisons. Reproducibility was assessed by determining the ICCs (Intraclass Correlation Coefficient), adequate for continuous variables: a low level of agreement is close to 0 and a high level of agreement tends to 1 [20]. ICC values ≥0.9 are perfect, 0.70-0.89 good, 0.50-0.69 moderate, 0.30-0.49 mediocre, ≤0.29 bad [21]. Analyses were run in SPSS v. 24.0 (IBM SPSS Statistics, Armonk, NY). Significance was considered at the standard 5% level.

**Results**

Interobserver reproducibility assessment of SE and SWE

All data obtained is summarized throughout Tables I-III; data is interpreted and commented on in the Discussion section. Table I shows an overview on a large number of determinations of SE and SWE interobserver reproducibility. Tables II and III analyse in detail interobserver reproducibility according to the ROI diameter selected and to the difference in hardness between the two examined devices.

| Elastographic technique, ultrasound machine | N  | ICC value | p value |
|--------------------------------------------|----|-----------|---------|
| Strain Ratio Machine M                      | 270| 0.855     | 0.000   |
| Machine H                                  | 90 | 0.884     | 0.000   |
| Shear Wave Ratio Machine M                  | 270| 0.568     | 0.000   |

*N = number of determinations performed by each observer, ICC = intraclass correlation coefficient; p<0.05 was considered significant.*
Intraobserver reproducibility assessment of SE and SWE

Tables IV–VI include the information on intraobserver reproducibility; Table IV presents an overview of SE and SWE intraobserver reproducibility. Tables V and VI analyse intraobserver reproducibility specifically according to the ROI diameter and to the difference in hardness between the structures analysed. Data is further examined in the Discussion section.

Discussion

Previous papers showed a high level of repeatability for all tested elastography techniques in an in vitro setting [19]. Our results do not entirely support previously published results.

**Table II. Interobserver reproducibility of Strain Ratio depending on the diameter of the ROI and on the difference in hardness of the analysed structures**

| Characteristic assessed | N  | Mean±SD Observer 1 | Mean±SD Observer 2 | ICC value | p value |
|-------------------------|----|---------------------|--------------------|-----------|---------|
| Small ROI, 5 mm         | 90 | 2.2347±0.8369       | 2.1098±0.7495      | 0.879     | 0.000   |
| Medium ROI, 10 mm       | 90 | 2.0816±0.7689       | 1.8890±0.6389      | 0.840     | 0.000   |
| Large ROI, 15 mm        | 90 | 1.8996±0.5180       | 1.7879±0.4518      | 0.784     | 0.000   |
| Analysed pair – Machine M |   |                     |                   |           |         |
| A/B                     | 90 | 2.1604±0.3264       | 2.0932±0.3851      | 0.206     | 0.140   |
| C/A                     | 90 | 1.3354±0.2830       | 1.2378±0.2388      | 0.428     | 0.005   |
| C/B                     | 90 | 2.7199±0.6703       | 2.4557±0.4824      | 0.627     | 0.000   |
| Analysed pair – Machine H |   |                     |                   |           |         |
| A/B                     | 30 | 3.8687±0.8104       | 3.9357±0.6461      | -0.409    | 0.820   |
| C/A                     | 30 | 0.8437±0.2746       | 1.1340±0.3596      | 0.337     | 0.137   |
| C/B                     | 30 | 3.6177±0.8215       | 4.0317±0.7437      | -0.358    | 0.792   |

* N = number of determinations performed by each observer, SD = standard deviation, ICC = intraclass correlation coefficient; p<0.05 was considered significant, ROI = region of interest, A, B, C – experimental devices categories; for the analysis of the reproducibility variation depending on the ROI diameter, the machine M was used.

**Table III. Interobserver reproducibility of Shear Wave Ratio depending on the diameter of the ROI and on the difference in hardness of the analysed structures**

| Characteristic assessed | N  | Mean±SD Observer 1 | Mean±SD Observer 2 | ICC value | p value |
|-------------------------|----|---------------------|--------------------|-----------|---------|
| Small ROI, 5 mm         | 90 | 1.8990±0.6754       | 1.8152±0.6528      | 0.552     | 0.000   |
| Medium ROI, 10 mm       | 90 | 1.5707±0.4873       | 1.6004±0.3868      | 0.367     | 0.016   |
| Large ROI, 15 mm        | 90 | 1.4200±0.3846       | 1.4523±0.2949      | 0.265     | 0.074   |
| Analysed pair           |    |                     |                   |           |         |
| A/B                     | 90 | 1.7012±0.6596       | 1.5041±0.4979      | 0.755     | 0.000   |
| C/A                     | 90 | 1.3306±0.3235       | 1.5896±0.3737      | 0.006     | 0.488   |
| C/B                     | 90 | 1.8479±0.5234       | 1.7743±0.5512      | 0.413     | 0.006   |

* N = number of determinations performed by each observer, SD = standard deviation, ICC = intraclass correlation coefficient; p<0.05 was considered significant, ROI = region of interest, A, B, C – experimental devices categories; all shear wave determinations were performed on machine M.
size of both ROIs and found that: it is preferable to use a small ROI (5 mm diameter for a circular ROI) to improve interobserver reproducibility, while intraobserver reproducibility remains very good regardless of the ROI size.

Interobserver reproducibility is not significantly influenced by ROI diameter. However, it is observed that as the ROI size increases, the interobserver reproducibility tends to decrease on the Mindray machine. Instead, the difference in hardness of the structures analysed by SR influences the interobserver reproducibility: the reproducibility is from weak to at most moderate (0.206, 0.428, 0.627), regardless of the machine.

Another elastographic technique, not assessed in this study, is strain elastography with colour scores. This method is considered more subjective, depending more on the experience of the examiner, as confirmed by Carlsen et al who showed a higher reproducibility of SR compared to colour scores in a phantom study [23]. However, other authors have reported good intra- and interobserver reproducibility for the visual analogue scale, evaluated by real-time elastography [24].

**Interobserver agreement – shear wave elastography**

Depending on the ROI diameter, SWE Ratio does not offer good interobserver reproducibility: it is observed,

### Table IV. General intraobserver reproducibility of Strain Ratio and Shear Wave Ratio

| Elastographic technique, ultrasound machine | N  | ICC value | p value |
|--------------------------------------------|----|-----------|---------|
| Strain Ratio, Machine M                    | 54 | 0.809     | 0.000   |
| Machine H                                  | 18 | 0.864     | 0.000   |
| Shear Wave Ratio, Machine M                | 54 | 0.507     | 0.006   |

N = number of determinations performed two times by the same examiner, ICC = intraclass correlation coefficient; p<0.05 was considered significant.

### Table V. Intraobserver reproducibility of Strain Ratio depending on the diameter of the ROI and on the difference in hardness of the analysed structures

| Characteristic assessed | N  | Mean±SD   | ICC value | p value |
|-------------------------|----|-----------|-----------|---------|
|                         |    | Observation 1 | Observation 2 |         |
| Small ROI, 5 mm         | 18 | 2.3900±1.1699 | 1.9578±0.6572 | 0.717   | 0.006   |
| Medium ROI, 10 mm       | 18 | 2.0011±0.8898 | 1.8472±0.6363 | 0.910   | 0.000   |
| Large ROI, 15 mm        | 18 | 1.8861±0.5470 | 1.8778±0.6219 | 0.883   | 0.000   |
| Analysed pair           |    |             |           |         |
| A/B                     | 18 | 1.9328±0.3861 | 1.9472±0.3214 | 0.790   | 0.001   |
| C/A                     | 18 | 1.3194±0.1798 | 1.1678±0.1501 | 0.643   | 0.02    |
| C/B                     | 18 | 3.0250±0.9196 | 2.5678±0.2503 | -0.212  | 0.652   |

N = number of determinations performed two times by the same examiner, SD = standard deviation, ICC = intraclass correlation coefficient; p<0.05 was considered significant, ROI = region of interest, A, B, C – experimental devices categories; all determinations were performed on machine M.

### Table VI. Intraobserver reproducibility of Shear Wave Ratio depending on the diameter of the ROI and on the difference in hardness of the analysed structures

| Characteristic assessed | N  | Mean±SD   | ICC value | p value |
|-------------------------|----|-----------|-----------|---------|
|                         |    | Observation 1 | Observation 2 |         |
| Small ROI, 5 mm         | 18 | 1.5311 ± 0.3862 | 2.0544 ± 0.7671 | 0.342   | 0.198   |
| Medium ROI, 10 mm       | 18 | 1.3239 ± 0.2010 | 1.4472 ± 0.3432 | 0.269   | 0.263   |
| Large ROI, 15 mm        | 18 | 1.1672 ± 0.2918 | 1.1411 ± 0.1428 | -0.336  | 0.721   |
| Analysed pair           |    |             |           |         |
| A/B                     | 18 | 1.3867±0.4012 | 1.3922±0.3448 | 0.866   | 0.000   |
| C/A                     | 18 | 1.2439±0.2676 | 1.2806±0.3416 | 0.399   | 0.152   |
| C/B                     | 18 | 1.3917±0.3124 | 1.9700±0.8115 | 0.372   | 0.173   |

N = number of determinations performed two times by the same examiner, SD = standard deviation, ICC = intraclass correlation coefficient; p<0.05 was considered significant, ROI = region of interest, A, B, C – experimental devices categories; all determinations were performed on machine M.
however, that the reproducibility decreases with the increase in the diameter of the ROI. It is observed that, by SWE, only when analysing structures with a large difference in hardness, significance is obtained in terms of interobserver reproducibility.

The comparison of the variability of the results obtained by SE and SWE represents the focus of several studies. However, the conclusions drawn by the authors are somewhat contradictory: intraobserver SWE reproducibility is superior to that of SE, assessed by SR [25]; SE and SWE provide equally good reproducibility at intermediate levels of elasticity, whereas SE is better than SWE (assessed by mean velocity values) at hard and soft levels [26].

It is to be noted that reproducibility was evaluated in this last study by plotting the ROC (Receiver Operating Characteristic) curve and analysing the AUC (Area Under the Curve) and not by the ICC assessment. Another observation is that the studies carried out so far have evaluated the reproducibility of SWE Ratio only for the Supersonic model (SSI) [19,25,27]. From this point of view, to the best of our knowledge, this is the first paper assessing the SWE Ratio reproducibility and comparison to SR reproducibility in an in vitro setting.

In our study, when comparing SR with SW Ratio it is noted that SR is more reproducible than SW Ratio. A possible explanation would be that SR, through the way of acquiring the elastographic information, addresses the Young modulus, while SW Ratio uses the Shear modulus. Since the Young’s modulus is 3 times larger than the Shear modulus, it conversely demonstrated that the same variability has 3 times greater effects on the Shear modulus than the Young modulus [19].

Intraobserver agreement – strain elastography

When considering intraobserver reproducibility, SR proves to be very reproducible, regardless of the machine used. However, considering the small number of determinations performed on Machine H, due to technical setting limitations, it was considered inappropriate to analyse the intraobserver variability in relation to difference in hardness. Regarding intraobserver reproducibility on Machine M, although all ROI diameters provide very good results, it is preferable to choose a medium or large ROI. It is not possible to describe intraobserver reproducibility depending on the difference in hardness between the analysed structures. However, the very small number of determinations could be a basis for this finding.

Intraobserver agreement – shear wave elastography

Similarly, no significance is obtained when assessing intraobserver reproducibility depending on the ROI diameter by SWE Ratio. A relatively small number of determinations could confirm the contradictory results regarding the analysis of intraobserver reproducibility depending on the difference in the rigidity of the structures assessed by the SWE technique. The existence of a very hard lesion in the analysis induces inconsistent results, as it produces both inter- and intraobserver variability [11]. For each of the pairs of targets analysed, we had at least one hard device. Given the contradictory results obtained in the analysis of intra- and interobserver reproducibility related to hardness, we support the observation of Ferraioli et al [11].

Some limitations of the study need to be addressed: first, this study was conducted on manufactured phantom devices, which implicitly have a homogeneous structure. The images obtained in clinical practice often target inhomogeneous structures, a factor that could technically affect reproducibility. However, we believe that the present study contributes to the theoretical knowledge database underlying these techniques. Secondly, the devices included in the custom-made phantom have no absolute values provided in kPa. An estimate of their hardness was made for devices A and C, but it was not feasible for device B. However, the purpose of the present study was to evaluate the intra- and interobserver reproducibility, and not to evaluate the accuracy of the techniques to render known absolute values, as also emphasized by Mun et al in their phantom study [27].

One of the most important observations highlighted by the current paper is that two different ultrasound machines provide different results using the same technique (SR), an aspect also noted by Mulabecirovic et al and [19]. Indeed, according to Franchi-Abella et al, the threshold values proposed in various studies should be used only for the method and transducer for which they were validated [25].

Additional studies are required in the future, involving more examiners, with different levels of experience; a larger number of acquisitions, especially in terms of intraobserver reproducibility, should be performed, to confirm the results of this study.

Conclusion

On a large number of determinations, strain elastography, assessed by SR and shear wave elastography, assessed by SWE Ratio, are both inter- and intraobserver reproducible. It is preferable to opt for a smaller ROI diameter in order to increase interobserver reproducibility. SWE Ratio provides significant reproducibility only when analysing structures with large difference in hardness. Future studies should involve more examiners with different levels of experience.

Conflict of interest: none
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