Technical Report

Development of Shear Wave Measurement with a Reliability Indicator

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Strain Imaging was the first ultrasound elastography technique used clinically to improve the diagnosis of breast disease. More recently, Shear Wave Elastography, a technique which measures the propagation speed of shear waves in tissue, has been introduced and is widely used for the assessment of chronic liver disease. We have developed Shear Wave Measurement (SWM) technology which adds a reliability indicator to each shear wave velocity measurement, giving a quantitative indication of the appropriateness of the measurement. This function could contribute to the improvement of the diagnostic performance. The aim of this report is to describe the principles of SWM and the usefulness of the reliability indicator, evaluated using an elastography phantom.

Key Words: Shear Wave Elastography, Reliability Indicator, Elastography Phantom, Measurement

1. Introduction

Ultrasound Elasticity imaging has been shown to be clinically useful as a new ultrasound diagnostic tool for examining tissue stiffness.

Current elasticity imaging techniques commercialized in the market are classified into two main categories. The first, Strain Imaging, displays the distribution of relative strains based on the measured displacement of tissues after manual compression. Hitachi Aloka Medical was the first company to commercialize this technology as Real-time Tissue Elastography [*1] (RTE) in 2003. The other method is Shear Wave Imaging which estimates and displays the shear modulus based on the propagation velocity of shear waves in tissues following excitation by an external vibration. Acoustic Radiation Force Impulse (ARFI) or mechanical vibrations of the probe are the common excitation methods used.

Hitachi Aloka Medical has developed Shear Wave Measurement (SWM) that uses the ARFI principle with a convex probe for examination of liver. [*2] Table 1 shows the position of our RTE and SWM techniques in the classification of elastography published in the guidelines of The Japan Society of Ultrasonics in Medicine (JSUM) and World Federation for Ultrasound in Medicine and Biology (WFUMB)[2)3)].

Development of the SWM function enables the use of Strain Imaging and Shear Wave Imaging techniques in one system.

These techniques have their respective advantages: the former generates strain images with high spatial resolution that accurately reflect tissue structures at a high frame rate. The latter enables quantitative evaluation of shear wave velocity without requiring compression to reduce examiner dependency. A description of the principles of SWM and its unique feature, the reliability indicator, follows. Evaluation of its usefulness with phantom studies is also introduced.

2. SWM Sequence and Safety

Shear Wave Imaging using the ARFI method generates shear waves using a push pulse to excite the tissues followed by tracking pulses to measure the speed of propagation of shear waves generated.[4)5)] Figure 1 shows the SWM transmit/receive sequence. Push pulses are transmitted in one direction to generate shear waves and tracking pulses are alternately transmitted and received in 2 different directions to detect the shear wave propagation. This push-track sequence is automatically repeated to measure the shear wave propagation speed several times in a short time period. This is followed by a probe cooling time when all wave transmission is stopped.

Regulations applicable to ultrasound diagnostic systems include Pharmaceutical and Medical Device Act (PMD Act) in Japan, FDA 510(k) in the United States, and CE Marking in Europe. The same upper power limits used in normal diagnostic systems apply to SWM. Table 2 shows the result of SWM power measurements. As the table shows, all indexes are below the limits given in the PMD Act and by the FDA.

International Standard IEC60601-2-37 requires that the temperature rise at the surface of the probe for superficial use must be no more than10 ºC. The cooling time of about 2 seconds provided in the SWM meets the requirements for the probe surface temperature rise to remain below this limit and the requirements in the afore-mentioned Ispta power regulations, protecting the safety of the patient.

3. SWM Signal Processing and Error Detection (Fluctuation Removal)

The block diagram in Figure 2 shows the SWM signal processing. The echo signals from the 2 tracking pulses are detected; the phase is determined; noise reduced; and the peak positions of the shear waves are detected for the 2 track directions. The shear wave velocity (Vs) is measured using peak positions at several points in the ROI depth direction. The Vs statistical calculation is performed as described in the following section to derive the final Vs value.

The motion of the microvasculature due to cardiac motion and vascular flow can make echo signals fluctuate over time in the parenchyma of the liver.

This fluctuation overlaps with shear waves generated by ARFI preventing the detection of shear wave peaks. Normally, the examiner visually confirms large arteries so that they are not included in the measurement ROI, but in many cases it is difficult to set the ROI to exclude microvasculature and vascular flow.

Our SWM technique is designed to detect phase fluctuations caused by blood flow and micro-vibrations to overcome this problem. By eliminating these fluctuation regions, the shear wave velocity, Vs, can be calculated with high accuracy.

Noise reduction method is explained referring to Figure 3, which shows blood vessel fluctuation as an example. In Figure 3(a), the longitudinal axis represents the ROI depth direction and the transverse axis the time. Gray scale colors indicate the amount of phase change. The red line in track 1 and blue line in track 2 represent shear wave peaks. In each track, a band with a significant phase change (gray scale) is seen in the time axis direction. (In this example, the band in track 1 exists at a different depth to track 2.) These bands represent phase fluctuation from blood vessels. We use the graph picking up the shear wave peaks as in Figure 3 (b) to calculate Vs from the shear wave peak positions. ΔT (time difference between red line of track 1 and blue line of track 2), and ΔX (distance between Track 1 and 2) are used in the equation $Vs = \Delta X/\Delta T$ to calculate Vs at each depth as shown in Figure 3(c) (ΔX is fixed geometrically by the position of the transmit beams of tracks 1 and 2. Refer to Figure 1.). If phase fluctuation is not removed, the shear wave peaks are mistakenly detected in these regions, and the accuracy of the Vs value will be reduced by calculating the average Vs in the depth direction.

We use frequency analysis of the phase shift in the time direction to detect phase fluctuations. Compared to the depth where shear waves exist, the phase periodically changes in the phase fluctuation region. For this reason, peaks of

Table 1: Classification of Elastography

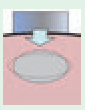
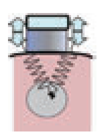
Methods / Excitation methods	Strain imaging	Shear wave imaging
Manual compression	Strain elastography  RTE	N/A
Acoustic radiation force impulse excitation	ARFI Imaging 	Point shear wave speed measurement  SWM Shear wave speed imaging
Controlled external vibration		Transient elastography 

Table 2: SWM Power Measurement Result

	MI	TIS	TIB	Ispta (mW/cm²)
Measured value (max.)	1.56	0.88	3.43	523
Upper limit of regulations	1.9	6.0	6.0	720

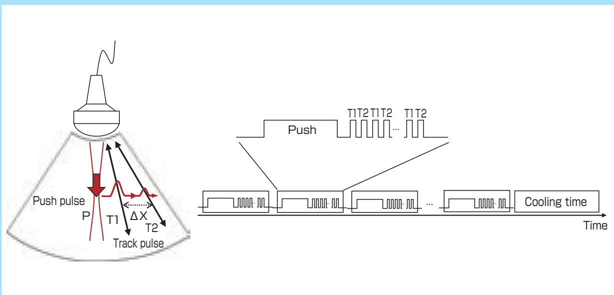


Figure 1: SWM Transmit/Receive Sequence

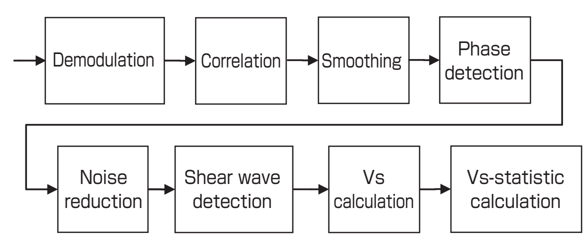


Figure 2: Block Diagram of SWM Signal Processing

high strength appear at particular frequencies, which enables their differentiation from shear waves using intensity difference of the power spectrum. The high accuracy of the Vs measurement is achieved because Vs can be calculated using only the shear wave peaks as shown in Figure 4.

4. Reliability Indicator VsN

It is common to display just one median value of Vs for the data measured inside the ROI in fixed point Shear Wave speed measurement methods.[6] However, it can be difficult to judge whether the measurement is appropriate or not from the Vs value alone because of disturbance such as body motion, respiratory movement of the patient, unsteady handling of the transducer by the examiner, etc. Additionally, even when the standard deviation is displayed, it could be difficult to distinguish if the variation is due to characterization of the tissues or caused by measurement error.

We have added an indicator for evaluating measurement reliability quantitatively to overcome such problems. This index statistically uses sets of Vs acquired from multiple Push-Track sequences and multiple Vs in the depth direction inside of the ROI for each sequence. Values are rejected from the Vs sets using the 3 criteria to be described later, and the ratio of remaining Vs sets (Vs after rejection /total number of Vs) is defined as Vs efficacy rate, and displayed as a percentage. Vs effective rate is named VsN, where N stands for NET (net volume or quantity). Median Vs and interquartile range (IQR) are calculated as statistical values from the histogram of Vs sets after rejection (Figure 5). Three rejection conditions are described below as shown in Figure 6 (1) through (3).

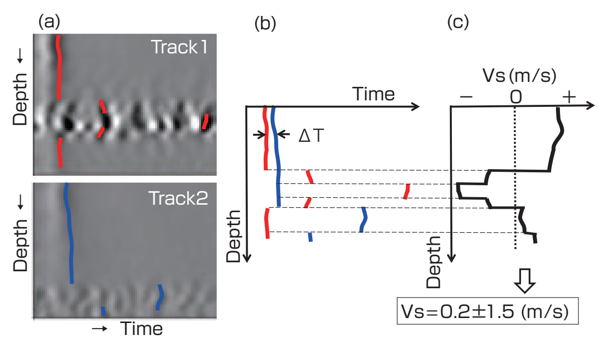


Figure 3: Schematic Diagram of Fluctuation Removal (before Removal)

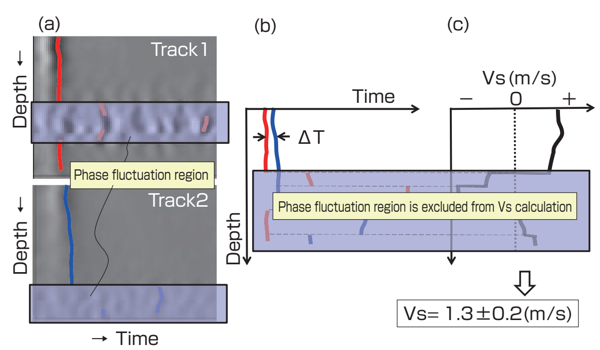
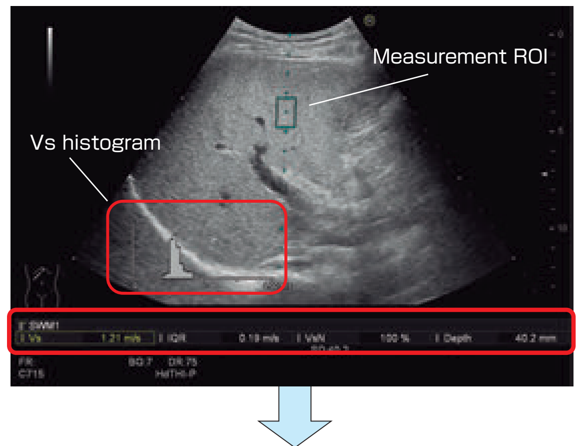


Figure 4: Schematic Diagram of Fluctuation Removal (after Removal)



Display item	Unit	Description
VS	m/s	Shear wave propagation velocity (median of Vs group)
IQR	m/s	Interquartile range of Vs group (width of median ± 25%)
VsN	%	Vs efficacy rate
Depth	mm	ROI center depth

Figure 5: SWM Measurement Screen

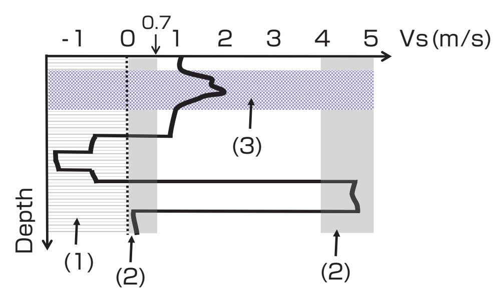


Figure 6: Schematic Diagram of Rejection Conditions in VsN Calculation

(1) Negative Vs

Vs takes a negative value when the peak of track 2 is detected at an earlier time than the peak of track 1 due to, for example, disturbed shear waves. Shear waves in this case are not correctly detected and thus the value is rejected.

(2) Vs is outside of a defined range

Likely Vs values are expected to be covered by a certain range that will be clinically dependent on the organs and tissues being examined. If Vs values are beyond that range, the value is regarded as a detection error of the shear wave speed and rejected.

The range differs according to the diagnostic target. The current SWM is targeted to the liver, so the range is set from 0.7 to 4.0m/s. It is considered important for liver examinations to optimize the accuracy in the range below 3.0m/s, therefore, Push-Track intervals are adjusted based on this value. According to Quantitative Imaging Biomarkers Alliance (QIBA) reports[7], the third quartile point in Vs value distribution for liver fibrosis corresponding to biopsy F4 is approximately 3.0m/s, so we considered it appropriate to set the upper limit to 4.0m/s.

(3) Phase fluctuation detected at a particular depth

As described in Section 3, phase fluctuations due to blood vessel and blood flow are different from shear waves and rejected as a detection error.

We analyse whether the shear wave propagation is detected correctly and if unnecessary components other than those generated by the shear wave propagation exist in the ROI by rejection conditions (1)-(3), and display the efficacy rate (VsN) on the monitor. The histogram display of Vs values after rejection is supported as well (horizontal axis is Vs, and vertical axis is frequency).

The Vs distribution uniformity in the ROI (the distribution width) and the size of VsN (area of distribution) can be checked using this histogram, and the measurement reliability can be assessed qualitatively by the shape of the histogram (refer to histogram in Figure 5).

5. Operation of SWM

Figure 7 shows the operation of SWM. The measurement ROI (15mm height x 10mm width) as shown in Figure 5 is displayed when the SWM mode is started.

SWM commences by moving the ROI to the desired location and pressing the measurement button. The measurement result is displayed on the monitor after auto freeze. The frozen image is recorded automatically at this time. The image can be unfrozen after a cooling time of approximately 2 seconds.

SWM enables measurements to be made easily and repeatedly because Vs measurement and automatic image recording are possible using a single button.

6. Accuracy of Phantom Evaluations

SWM accuracy evaluation using phantoms is described here.

Measured SWM Vs values were compared with stiffness values obtained with the mechanical tester INSTRON[*3] Model 2519 (after conversion to Vs values using Young's modulus and assuming a density value of 1) to verify measurement accuracy using 7 phantoms of different stiffness (1.19 to 3.79m/s; specially ordered from OST Co., Ltd., Japan). The probe was fixed on a jig and water placed between the probe and phantom to avoid direct compression. For each phantom, 10 different probe positions were selected for measurement. At each measuring position, average Vs, coefficient of variation (%CV; standard deviation/average) showing measurement reproducibility, and accuracy level (ΔVs%) showing the difference compared with the mechanical tester were acquired. Measurements were taken at depths of 20, 40 and 60mm.

Figure 8 (a) shows the Vs scatter diagrams of SWM compared to INSTRON. The measurement reproducibility (%CV) was between 3 to 16% and measurement accuracy level (ΔVs) within ±15%. No significant difference of Vs values were observed depending on the depth. Figure 8 (b) shows the average reliability index VsN for each phantom. VsN remained over 80% for up to 3m/s phantom stiffness, indicating that the measurement is stable. On the other hand, VsN of the stiffest phantom falls to between 25 to 60%, showing that the measurement reliability decreased. As described in the rejection conditions for reliability index in Section 4, the upper

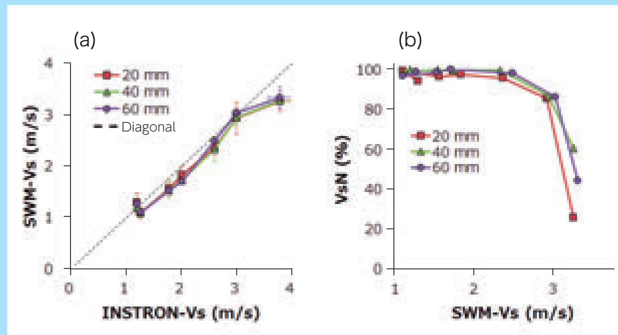


Figure 8: Phantom Accuracy Evaluation Result

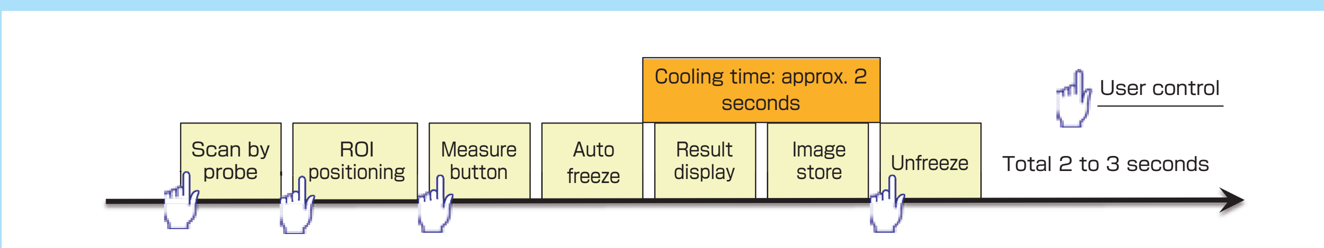


Figure 7: SWM Operation Procedure

limit of rejection is set at 4.0m/s for SWM. VsN of phantoms close to 4.0m/s tends to decrease with decreasing ΔVs. We therefore consider that the reliability can be accurately evaluated by using the VsN.

Based on the above analysis, it is expected that measurement reliability can be evaluated quantitatively using VsN in the clinical situation.

7. Summary

The principles of SWM, the first Shear Wave speed measurement method of Hitachi Aloka Medical, and the reliability indicator, its unique feature, are introduced. The combined use with Strain Imaging (RTE) [8] is expected to accelerate the development of elasticity imaging technology in the future as we gain experience in various clinical applications utilizing the respective advantages of RTE and SWM.

8. Acknowledgment

We would like to express our gratitude to Doctor Masatoshi Kudo and Doctor Norihisa Yada, Faculty of Medicine, Kinki University, with whom evaluation of clinical usefulness of this function has been jointly studied in all stages from prototype to the implementation on the system.

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