QIBA Ultrasound Shear Wave Speed Biomarker Committee: Overview and Status Update

Quantitative Imaging Biomarkers Alliance RSNA

Arinc Ozturk, MD; Mark Palmeri, MD, PhD; Manish Dhyani, MD; S. Kaisar Alam, PhD; Richard G. Barr, MD, PhD; Ioan Sporea, MD, PhD; Shigao Chen, PhD; Kathryn Nightingale,PhD; Ned Rouze, PhD; Stephen McAleavey, PhD; Matthew W. Urban, PhD; Jun Chen, PhD; Luzeng Chen, MD; Vijay Shamdasani, PhD; Michael MacDonald, PhD; Nancy Obuchowski, PhD; Hua Xie, PhD; Ted Lynch, PhD; Andy Milkowski, MS; Keith A. Wear, PhD; Timothy J. Hall*, PhD; Paul L. Carson*, PhD; Brian Garra*, MD; Anthony E. Samir*, MD, MPH

Need for Standardization

- Nearly all high-end clinical ultrasound systems offer shear wave elastography imaging (SWEI)
- There are many "free parameters" in commercial implementations of SWEI
- Each system should provide equivalent shear wave speed estimates in the same material
- Manufacturers can validate their implementation with known phantoms
- Users can validate their techniques and perform system quality assurances

Profile Development and Conformance Plans

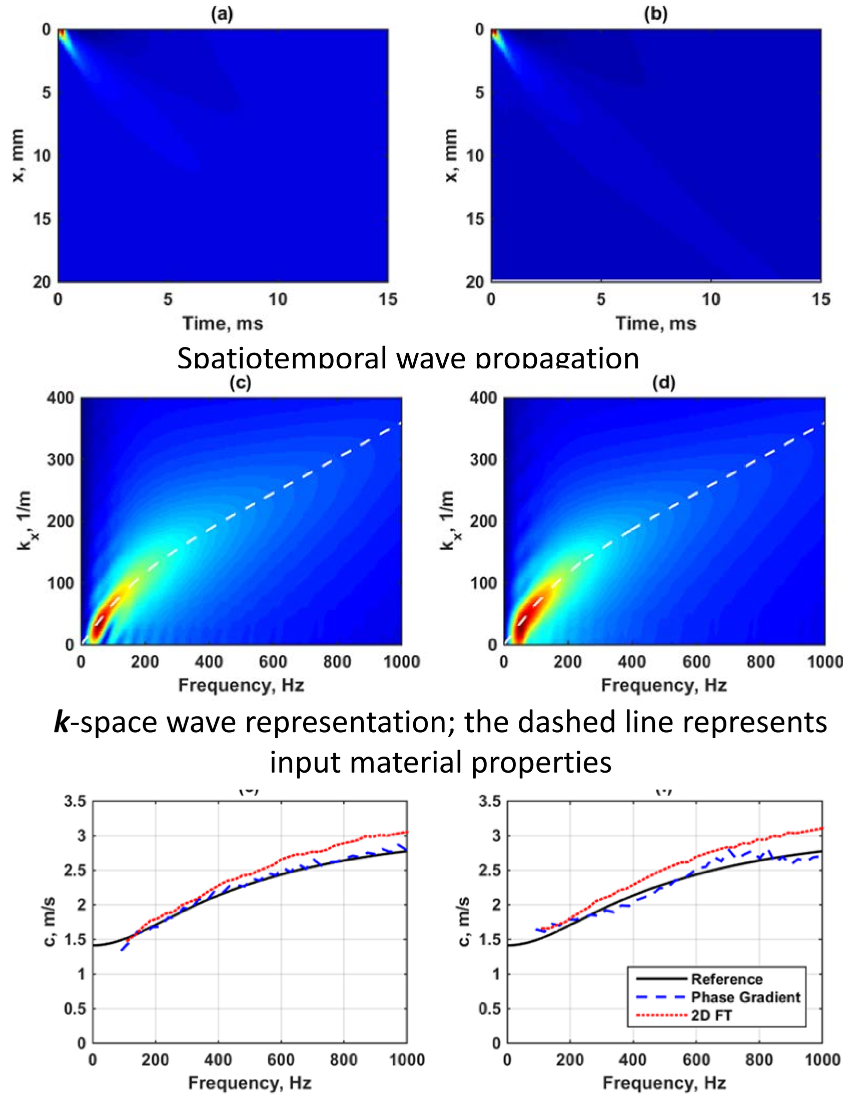
- Draft Profile document, with detailed protocols and checklists, is complete
- A request for public comment will be sent to subject matter experts around Jan.2018
- **Checklist** summarizes the profile. It is ready for public use. Please scan the code below to reach the checklist.
- Manufactures are testing their conformance informally with similar phantoms. New stable, elastic phantoms will be specified for manufacturer self testing for claims

Groundwork Projects

Digital Reference Object
Simulation study comparing input and output of two commercial finite element modeling software

Palmeri et al. Guidelines for Finite-Element Modeling of Acoustic Radiation Force-Induced Shear Wave Propagation in Tissue-Mimicking Media, 2017

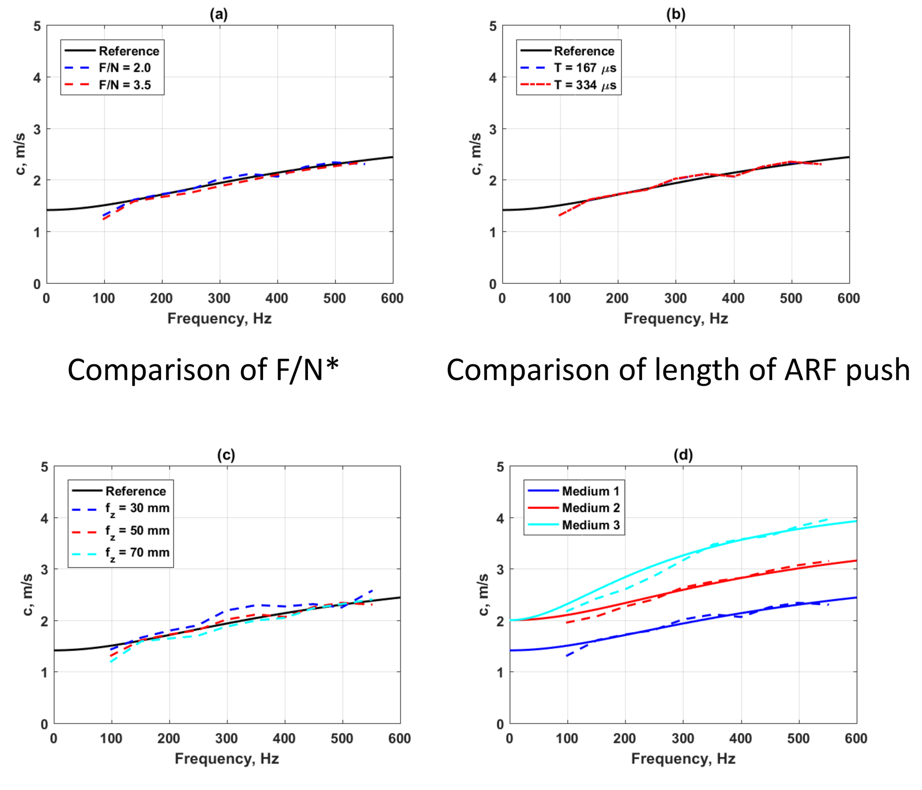
- Simulating acoustic radiation force beam data and analysis
- Computing wave motion with 2 different finite-element modeling packages
  - LS-DYNA
  - Abaqus
- Extraction of motion and processing the data
- This simulation can be useful for developing and testing algorithms for academic and industrial researchers involved in making quantitative shear wave-based measurements of tissue material properties.



Spatiotemporal wave propagation

k-space wave representation; the dashed line represents input material properties

Phase velocities



Comparison of F/N*

Comparison of length of ARF push

Comparison of focal depth

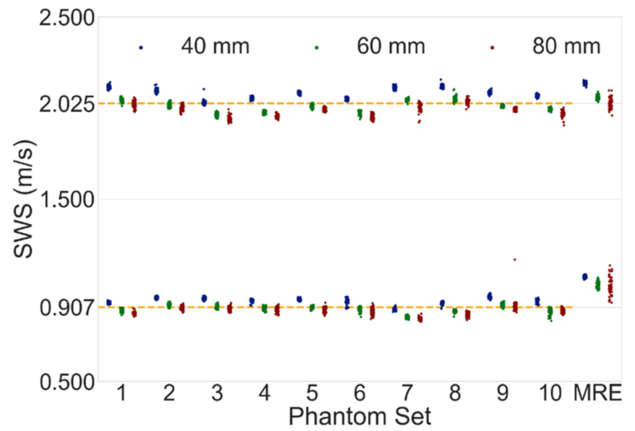
Comparison of viscoelastic materials

*The focal number, *F/N* = *z f* /*D*, where *z f* is the focal depth and *D* is the aperture width.

Groundwork Projects (continued)

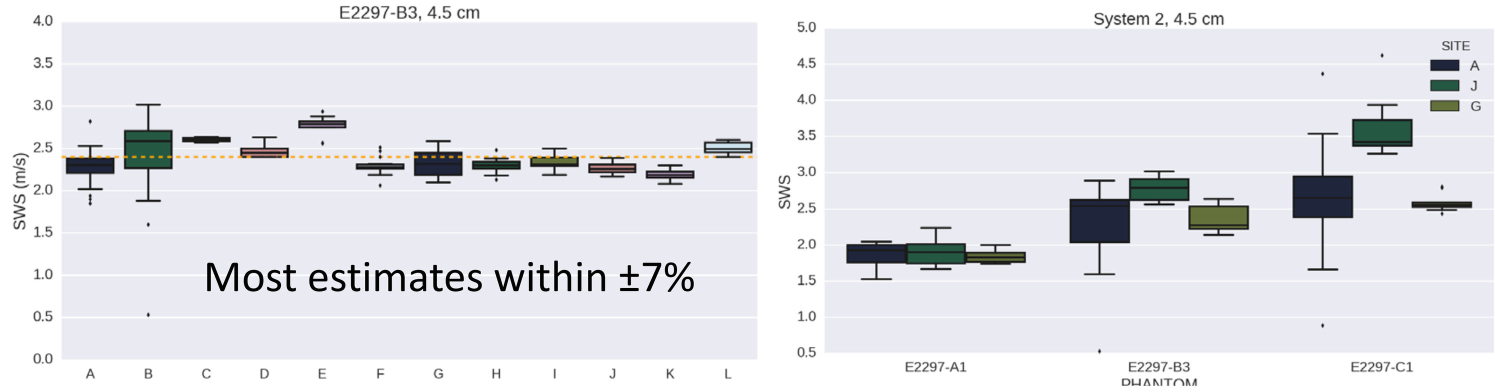
Elastic Phantom Study
Understanding bias and variance in lossless phantoms

Two phantom stiffnesses (SWS)
Measurements at 3 depths

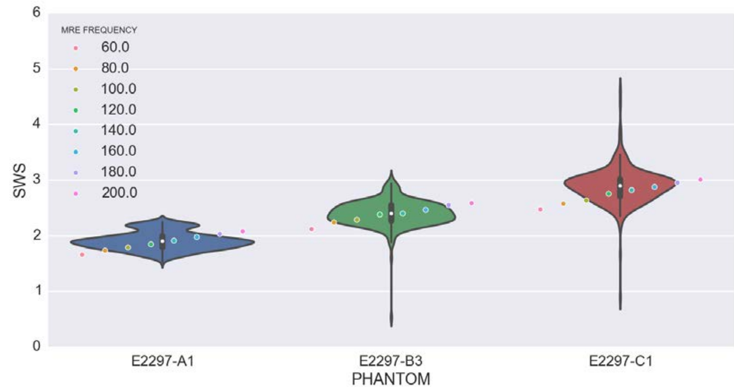


- Good agreement among systems (10 ultrasound systems and MRE)
- Some depth dependence in SWS for some systems (now corrected)

Viscoelastic Phantom Study
Understanding bias and variance in lossy phantoms



- Good agreement among systems (A—L)
- Majority of systems within ±7% of the consensus median SWS
- Some systems considerably challenged in stiffer media and deeper depths
- Violin plot of combined ultrasound data demonstrates excellent agreement with MRE when operating at equivalent frequency



Claims

Claim1(technical performance)
A SWS measurement has a within-subject coefficient of variation(wCV) of X%

Claim 2(longitudinal claim)
- Same imaging systems
- Two time points
- Change If the measured % change is ≥ Z%

Claim 3(longitudinal claim)
- Different imaging systems
- Same site
- Two time points
- Change If the measured change is ≥ W%

Claim 4(longitudinal claim)
- Different imaging systems
- Different sites
- Two time points
- If the measured change is ≥ G%

Claim 5(cross-sectional)
For a given SWS measurement of Y, a 95%CI for the true SWS(in m/s) is Y±(1.96 x Y x X/100)

	SWS in Claims	4.5cm depth	7cm depth
SWS<1.2	X	5%	8%
	Z	14%	22%
	W	19%	25%
	G	17%	19%
1.2<SWS<2.2	X	4%	5%
	Z	11%	14%
	W	14%	17%
	G	17%	19%
SWS>2.2	X	10%	12%
	Z	28%	33%
	W	33%	39%
	G	33%	39%

Table1- SWS values for claims

Profile Impact in Clinical Trials

SWS profile is designed to overcome the limitations of sonographic liver elastography exam which includes operator and patient dependent factors. A clinical study is designed to test the feasibility of the profile.

Technical Conformation Study
- 30 patients with biopsy proven liver fibrosis
- Profile compliant 10 SWS acquisitions with each machine
- 2 sonographers measure liver stiffness in two visits to assess inter-rater and intra-rater reliability

Massachusetts General Hospital
- Toshiba
- Siemens
- GE
- Fibroscan

Veterans Affairs Hospital Washington DC
- Siemens
- GE
- Philips

Deviations from the profile

What if we use only 3 acquisitions?

Fibrosis Stage	Acquisition number	Median SWS in m/s	Range	Std Dev	p value
0	Profile compliant	1.32	[1.22-1.41]	0.06	1
	Non-compliant	1.31	[1.3-1.32]	0.01	
1	Profile compliant	1.27	[1.23-1.37]	0.05	0.23
	Non-compliant	1.33	[1.27-1.39]	0.06	
2	Profile compliant	1.59	[1.42-1.72]	0.1	0.06
	Non-compliant	1.43	[1.34-1.44]	0.05	
3	Profile compliant	1.69	[1.61-1.73]	0.04	0.86
	Non-compliant	1.67	[1.67-1.72]	0.02	
4	Profile compliant	2.27	[1.97-2.45]	0.16	0.23
	Non-compliant	2.15	[2.1-2.18]	0.04	

What if patient is not able to hold breath?

Fibrosis Stage	Breath	Median SWS in m/s	Range	Std Dev	p value
0	Profile compliant	1.32	[1.22-1.41]	0.06	0.005
	Non-compliant	1.39	[1.29-1.49]	0.05	
1	Profile compliant	1.27	[1.23-1.37]	0.05	0.96
	Non-compliant	1.29	[1.11-1.38]	0.08	
2	Profile compliant	1.59	[1.42-1.72]	0.1	0.05
	Non-compliant	1.38	[1.31-1.71]	0.14	
3	Profile compliant	1.69	[1.61-1.73]	0.04	0.62
	Non-compliant	1.665	[1.62-1.73]	0.03	
4	Profile compliant	2.27	[1.97-2.45]	0.16	0.15
	Non-compliant	2.15	[1.7-2.34]	0.18	

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