ORGANIZATION & QIBA PROFILE

1. Organizational structure updates, e.g., brief description of new QIBA Committees, Task Forces (e.g., Profile writing groups) or new QIBA members being elected.

QIBA Steering Committee recently implemented the following organizational changes:

A. Coordinating Committees (CC) will be responsible for the oversight and planning of all activities within the modality to ensure alignment with the overall QIBA goals and provide a forum for discussions on best practices. Co-Chairs of these committees can be self-nominated. CC members can be self-nominated.

B. QIBA Steering Committee (SC) will meet bi-weekly, e.g., brief description of new SC members.

2. Profile Development - status update

A profile is the QIBA document that describes the methods to be used to make QIBA compliant measurement of a quantitative biomarker such as SWS. The final complete version of this profile was published in May 2015 by the profile writing task force as an open-source QIBA member committee for comment. The claims section of the profile contains placeholders for bias and variance claiming rules pending the completion of the phase II project.

3. Conformance procedure update

The first version of this document will be drafted as part of the new version of the profile currently being written.

4. Groundwork project status/results/follow-up

A. US SWS Technical Projects

B. US SWS Clinical Project

US SWS TECHNICAL PROJECTS

1. Phase Viscoelastic phantom study

Objective: Perform a comparison of shear wave speed (SWS) measurements between commercially-available systems using calibrated phantoms that have viscoelastic behavior similar to that observed in normal and fibrotic liver.

Methods: - CBCT (Norfolk, VA) fabricated 3 phantoms (E225-A1, B3, C1) using a proprietary oil-water emulsion in a Zerdine® hydrogel. - The phantoms were shaped to fit the footprint of each ultrasound scanner capable of measuring SWS. - The phantom test analysis was conducted to evaluate the inter- and intra-system variability for each phantom. - The phantoms were shipped to and measured at academic, clinical, and government venues using different systems with varying shear wave speeds at multiple focal depths (10, 13, 17.5). - The shear wave speed results were compared to the system claims.

Vendor System Model

Hitachi Aloka Prosound Alpha 8
Hitachi Aloka Prosound Gamma 5
Samsung Medison RS80A
Philips Epiq 7
General Electric (phantom mode) LOGIQ E9
Toshiba Aplio 500

Results

SWS measurements for each system (randomized order) in each phantom for each focal depth. Each box plot represents the 25th - 75th percentile range of all measurements made with that particular system. The whiskers represent the range of the measurements. The mean shear wave speed for each system is indicated by the triangle in each box plot.

Conclusions

1. All of the current-generation ultrasound SWS measurement systems were able to report SWS that differentiated each of the viscoelastic materials tested in this study.

2. The focal depth displacement greatly impacted the system shear wave speed for phantom (maximum of 11.7% as evaluated by IQR).

3. Inter-system variability was consistent across all 3 phantoms and was not a function of system. Median SWS estimates for the greatest outlier system in each phantom/focal depth range from 10.5 to 17.5.

PHASE IV VISCOELASTIC PHANTOM STUDY

2. Digital phantom study

Objective: Create a Finite Element Model (FEM) simulation data matching the viscoelastic Phase II phantom for a variety of focal configurations to test shear wave estimation algorithms.

Deliverable


RIVUS CLINICAL STUDY

Purpose of the study: To evaluate the accuracy of ultrasound elastography in the assessment of fibrosis using different systems, and to assess variation at different depths, forces and distance from central axis of the transducer.

Abstract submitted for 2015 annual AUA/IHCSB convention

A. US SWS CLINICAL STUDY

Methodology

This was an independent single-institution prospective study. 20 patients underwent ultrasound elastography as part of their routine ultrasound examination. All patients had undergone phase I clinical trials at their respective sites. After the median SWS was calculated and validated, and the area under the receiver operating characteristic curves (AUCs) were compared against a gold standard.

Results

A total of 20 subjects (17F/3M) with a mean age of 54 years and varying fibrosis stages (F0-F4) were evaluated. SWE measurements were obtained at three different locations under force of 0, 5, 10N. Spearman correlations of shear wave speed with fibrosis stage were calculated and the area under the receiver operating characteristic curves (AUCs) were compared against a gold standard.

Conclusions

1. In this small study, S2 and S4 systems performed best for differentiation between advanced fibrosis stages, as well as for a global assessment of fibrosis. S3, S5, and S6 systems performed similarly and best for differentiation between stage F0 and F1. As a result of the study, there was a statistically significant difference (p=0.003) between values obtained at three different depths, with the highest correlation (r=0.667, p=0.003) and AUC (0.94, 95% CI: 0.91-0.96) at a depth of 7cm. Similarly, for Scanner 4, the correlation (r=0.93, p<0.001) and AUC (0.85, 95% CI: 0.68-0.92) was highest at the tangent of the meniscus, but the difference in shear wave speeds was not statistically significant. Variation in predicted force at a 5cm measurement depth made no statistically significant difference (Table). Measurements along the central axis had the highest AUC for all systems.

Deliverable

1. Author's personal website

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