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● *Original Contribution*

INTER- AND INTRA-OPERATOR RELIABILITY AND REPEATABILITY OF SHEAR WAVE ELASTOGRAPHY IN THE LIVER: A STUDY IN HEALTHY VOLUNTEERS

JOHN M. HUDSON,*‡ LAURENT MILOT,† CRAIG PARRY,† ROSS WILLIAMS,‡ and PETER N. BURNS*‡

* Department of Medical Biophysics, University of Toronto, Toronto, Canada; † Medical Imaging, Sunnybrook Health Sciences Centre, Toronto, Canada; and ‡ Sunnybrook Research Institute, Toronto, Ontario, Canada

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Abstract—This study assessed the reproducibility of shear wave elastography (SWE) in the liver of healthy volunteers. Intra- and inter-operator reliability and repeatability were quantified in three different liver segments in a sample of 15 subjects, scanned during four independent sessions (two scans on day 1, two scans 1 wk later) by two operators. A total of 1440 measurements were made. Reproducibility was assessed using the intra-class correlation coefficient (ICC) and a repeated measures analysis of variance. The shear wave speed was measured and used to estimate Young's modulus using the Supersonics Imagine Aixplorer. The median Young's modulus measured through the inter-costal space was 5.55 ± 0.74 kPa. The intra-operator reliability was better for same-day evaluations (ICC = 0.91) than the inter-operator reliability (ICC = 0.78). Intra-observer agreement decreased when scans were repeated on a different day. Inter-session repeatability was between 3.3% and 9.9% for intra-day repeated scans, compared with to 6.5%–12% for inter-day repeated scans. No significant difference was observed in subjects with a body mass index greater or less than 25 kg/m^2. (E-mail: hudsonjm@gmail.com) © 2013 World Federation for Ultrasound in Medicine & Biology.

Key Words: **Shear wave elastography, Reproducibility, Reliability, Repeatability, Ultrasound, Liver imaging, Intra-class correlation coefficient.**

INTRODUCTION

Liver fibrosis is a primary indicator of organ health and is an important consideration in the management of patients with chronic liver disease. Currently, tissue biopsy is the gold standard for staging and evaluation, but it is invasive (Castera et al. 1999), carries risk (Bravo et al. 2001) and is prone to sampling errors in cases of diffuse disease (Bataller and Brenner 2005). Tissue elastography has been proposed as a potential surrogate for biopsy in circumstances when the mechanical properties of an organ change with disease progression and treatment (Castera et al. 2005, 2008; Palmeri et al. 2011; Stauber and Lackner 2007). Numerous methods based on ultrasound imaging have been developed and are currently undergoing clinical evaluation. These methods include transient elastography (Degos et al. 2010; Muller et al. 2009), acoustic radiation force imaging (Nightingale et al. 2001, 2002), spatially modulated ultrasound radiation force (McAleavey et al. 2009) and supersonic shear wave elastography (SWE; Bercoff et al. 2004; Berg et al. 2012). Although the techniques can be distinguished by the technical details of their implementation, they all operate by the mechanical disturbance of tissue whose deformation (or rate of deformation) can be related to the local tissue's elastic properties.

Supersonic SWE is a technique that extracts viscoelastic properties from a medium by estimating the propagation speed of an acoustically generated shear wave using plane wave imaging (Bercoff et al. 2004). In the breast, SWE is reported as highly reproducible (Cosgrove et al. 2012) and improves specificity when added to current protocols of breast mass assessment (Berg et al. 2012). However, in the context of liver evaluation, clinical reproducibility studies of SWE have yet to be reported (Patijn 2006; Kottner et al. 2011). Compared with the breast and other superficial organs, abdominal ultrasound-based imaging methods present unique challenges that include depth, a limited acoustic window through the rib cage (Kim et al. 2009), variable thoracic belt thickness (Castera et al. 2008), cardiac and diaphragm motion and physiologic activity. The main aim

Address correspondence to: John M. Hudson, Imaging Research, S639, Sunnybrook Health Sciences Centre, S-639, 2075 Bayview Avenue, Toronto, Ontario, Canada. E-mail: hudsonjm@gmail.com

of this prospective study was to evaluate the reproducibility of SWE measurement in the liver and measure the effects of ultrasound operator, scanning location, time (same day vs. different day) and body habitus in a population of healthy volunteers.

MATERIALS AND METHODS

Patient demographics

This study was approved by the Institutional Research Ethics Board at Sunnybrook Health Sciences Centre, and informed consent was obtained from all participants. Subjects were drawn from a pool of young, healthy students and hospital staff members. The mean (min-max) age of the 15 volunteers was 27 y (range, 21–35 y) with a male-to-female ratio of 2:1, and a mean (min-max) body mass index (BMI) of 23.7 kg/m^2 (range, 19.6–31.7 kg/m^2). The volunteers were asked to fast for at least 8 h before each scan.

Ultrasound imaging protocol

Liver evaluation was performed using the Aixplorer system (Supersonic Imagine, Aix-en-Provence, France) with a C6-1 curvilinear probe in the default abdominal liver preset, running in SWE mode. The ultrasound imaging focus and SWE interrogation region was placed at least 1–2 cm below the liver capsule. The volunteers were positioned supine on a hospital bed and were asked to arrest their breathing for 5–10 s during each measurement. Each subject was scanned by two operators (with 8 and 4 years of ultrasound experience) in random order. The imaging protocol (*e.g.*, probe approach and orientation, imaging location, system settings) was established before scanning the first volunteer, and operators were blinded to all previous scan sessions. A measurement comprised the average of five sequential shear wave acquisitions obtained during arrested breathing without moving the probe. Each acquisition generated a color-coded parametric map of Young's modulus that was analyzed using the system's online quantification package (Q-box; Supersonic Imagine, Aix-en-Provence, France). The imaging system converts the measurements of shear wave velocity into an estimate of Young's modulus (E) following: $E = 3\rho V_s^2$ (ρ is tissue density and V_s is the shear wave speed; Tanter et al. 2008). Placement of a 1-cm^2 region of interest was guided by the anatomic scout image and was chosen to avoid blood vessels, obvious beam aberrations and image artefacts (Fig. 1). Acquisitions were identified as not quantifiable when the region of interest contained non-assigned numbers, often caused by excessive target motion or poor beam coupling. Each patient was scanned in four sessions spread over 2 d. Sessions 1 and 2 were performed during the first day and were separated by a minimum of 3 h. Similarly, sessions 3 and 4 were performed the following week (7 d later) allowing for both within-day and between-day comparisons. The measurements were cycled through three different imaging locations (*e.g.*, Couinaud Segment 6 → Segment 8 → Segment 2/3 → Segment 6) in succession, repeating the cycle three times. Segments 6 and 8 were acquired inter-costally in a sagittal-oblique orientation. Segment 2/3 was acquired using a sagittal approach.

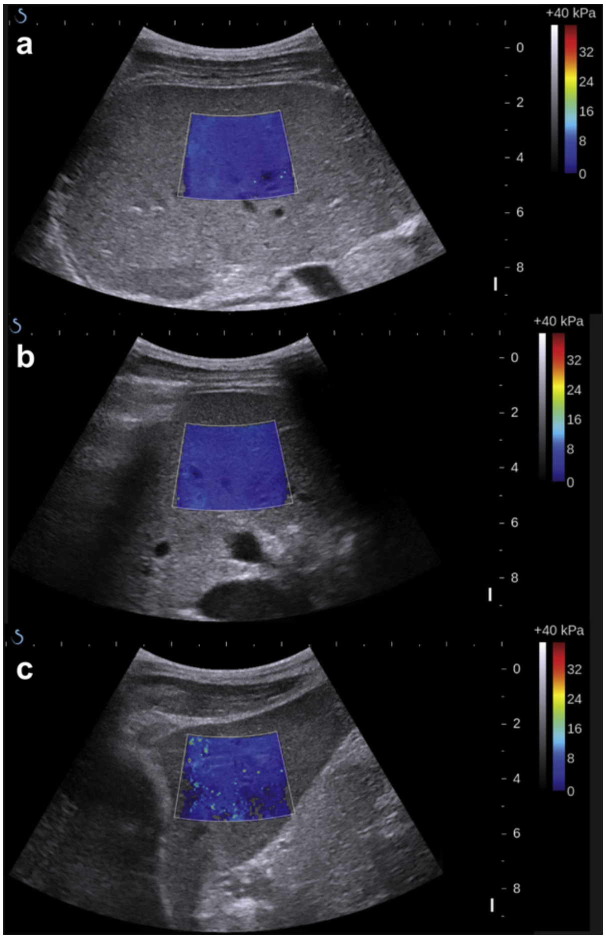

Fig. 1. Sample elasticity maps of a single patient. The color map represents Young's modulus in kPa. Locations: (a) segment 6, (b) segment 8 (c) segment 2/3.

Statistical analysis

The average Young's modulus in the healthy patient population was calculated in each imaging location for each observer. Differences were compared with multiple non-parametric tests with a significance level defined at $p = 0.05$ (Wilcoxon matched pairs signed rank test, Mann–Whitney test, using Graphpad; Prism; GraphPad Software, La Jolla, CA, USA).

Repeatability is defined as the variation in repeated measurements made on the same subject under identical

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