Title
Glenohumeral Joint Capsular Tissue Tension Loading Correlates Moderately with Shear Wave Elastography: A Cadaveric Investigation

Abbreviated Title
Shear Wave Elastography of Glenohumeral Capsule

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Conflict of Interest Statement

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ABSTRACT

Objectives: To investigate capsular tissue mechanical property changes using shear wave elastography (SWE) and a durometer under various tensile loads and SWE and durometer measurement reliability and correlation to evaluate if SWE technology could be used to assess tissue changes during capsule tensile loading techniques.

Methods: The inferior glenohumeral joint (GHJ) capsule from 10 fresh human cadaveric specimens were harvested. Tensile loading was applied to the capsular tissue using 1, 3, 5 and 8 kg weights. Blinded investigators measured tissue stiffness and hardness during loading using SWE and a durometer, respectively. Intra observer reliability was established for SWE and durometer measurements using intra class correlation coefficients (ICC). A Pearson product-moment correlation assessed association of SWE with durometer.

Results: The ICC_{3,5} for durometer measurements was 0.90 (95% CI 0.79-0.96, p<.001) and 0.95 (95% CI 0.88-0.98, p<.001) for SWE. Pearson correlation coefficient values for 1, 3 and 5 kg were 0.56 (p=.095), 0.36 (p=.313), and -0.56 (p=.089), respectively. When 1 and 3 kg were combined, ICC_{3,5} was 0.72 (p <.001) and 0.62 (p <.001) when 1, 3 and 5 kg were combined. The 8 kg measurements were severely limited due to SWE measurement saturation of tissue samples.

Conclusions: This study suggests SWE reliability to measure capsular tissue stiffness changes in vitro at lower loads (1 and 3 kg) and provides a baseline for non-invasive evaluation of effects of joint loading and mobilization on capsular tissues in vivo.
Key words

Joint capsule stiffness; joint capsule hardness; durometer; shear wave elastography; reliability
INTRODUCTION

The glenohumeral joint (GHJ) is a frequent site of pain and pathology with a reported prevalence from 7% to 23% in adults.\(^1,2\) Glenohumeral joint osteoarthritis (OA) can affect up to 33% of people over 60 years of age\(^3,4\) and adhesive capsulitis affects 2-5% of the general population and 10-15% of diabetics.\(^5,6\) In adhesive capsulitis, the capsule becomes contracted and thicker, particularly in the infra-glenoid recess and rotator cuff interval,\(^7,8,9\) and limits joint mobility.\(^10\) Inferior capsule thickening of more than 3.5 mm recorded using ultrasound is 66.7% sensitive and 92.5% specific for the diagnosis of shoulder adhesive capsulitis.\(^11\) Capsular tissue elasticity affects range of motion (ROM), or the allowed amount of joint plane specific motion (e.g. GH flexion), more than thickness, indicating a need for capsular tissue stiffness measurements.\(^12\) Capsular tightness restricts joint ROM and increases joint contact pressures leading to intra-articular pathology\(^13\) and can limit the ability to complete basic activities, such as dressing and hygiene.\(^3\) Clinicians commonly manage patients with ROM limitations, functional impairments and pain using stretching and joint mobilization techniques.\(^14,15,16\) Several authors\(^17,18,19\) reported that GHJ mobilization using loads of 20-80 Newtons increased capsule extensibility or elongation and improved patient symptoms.\(^20,21\) The proposed mechanical and neurophysiological changes responsible for increased joint ROM following joint mobilizations are not well understood and require further investigation.\(^22\) The SWE measurement is a reproducible method for evaluating muscle and tendon\(^23,24,25,26\) with demonstration of good repeatability with ICC coefficients of 0.81-0.91. This allows SWE to provide information on tissue diagnosis, injury, and/or healing states.\(^27,28\) However, no study has validated SWE readings in capsular tissue against a reference standard. Therefore, the purposes of this study were to investigate: (1) the reliability of SWE GHJ capsular tissue measurements under various
loads; and (2) the degree of correlation between GHJ capsular tissue tension properties measurements under various loads using a durometer versus SWE.

METHODS

This study was approved by the Ethics Sub-committee of the Department of Anatomy and exempted by . A convenience sample of ten GHJ frozen specimens (five right and five left) was acquired from five fresh cadavers through the Department of Anatomy. Specimens included four males and one female, ages 77.8 ± 5.4 years, height 1.65 ± 0.09 m, weight 59.6 ± 15.67 kg, and body mass index 21.6 ± 5.31.

The inferior capsular attachment to the humerus and scapula along with the GHJ capsule were excised to allow for testing. The samples were then trimmed to a 12 mm width for testing. The specimens were then placed in containers and frozen in storage until needed at -20°C. Tissue specimens were thawed for 1-2 hours and then tested at room temperature (18°C). Tissue specimens were connected to a standing frame using a custom clamp and a rope with the attached load (Figure 1) along with random testing selection of 1, 3, 5 and 8 kg loads using SWE and the durometer. Investigators recording durometer and SWE measurements were blinded to the loads applied to the tissue samples.

Shear Wave Elastography Measurement

The SWE procedures were performed at the Centre intégré universitaire de santé et de services sociaux de la Mauricie-et-du-Centre-du-Québec. The Aixplorer® (SuperSonic Imagine, Aix-en-Provence, France) diagnostic device using an XL-15-4 linear transducer which allows the
investigator to quantify tissue elasticity without probe compression. The investigator performing the SWE measurements was a medical physicist with over eight years of experience using SWE and 10 years of image processing.

Ultrasound gel was placed on the sample tissue followed by application of a conforming gelatin pad and secured with Opsite Flexifix® (Smith & Nephew, Andover, Mass.) (Figure 2). The ultrasound gel was applied to the Opsite® covering and then visualized with B-Mode ultrasound. Once an acceptable image of capsular tissue was achieved, the SWE was activated and image scanned for best resolution. Once the region of interest (ROI) was identified in the Q-box (provides field of view), the probe was removed. The ROI was then marked and saved using the Q-box tracer and used to acquire a measurement of elasticity (kPa) within the Q-box data area. Data were obtained for five measurements from each tissue specimen using loads of 1, 3, 5 and 8 kg for the shoulder in three trials to assess reliability (Figure 3). Reliability and correlation analyses were calculated using the mean measurements found for each load of each trial.

*Durometer*

The Shore A Durometer (Tongbao HT-6510A Shore A, Shenzhen, China), a digital, hand-held spring-loaded device (Figure 4), was calibrated, and the pressor was applied parallel to mid-portion of tissue specimens and held in contact for 1-2 seconds until a measurement was obtained. This was repeated for five measurements using randomly selected 1, 3, 5 and 8 kg loads in two trials separated by at least 5-minute intervals by a blinded investigator to assess reliability. Data were recorded for five measurements from the tissue specimens at each load in three trials to assess reliability. [Durometer: Figure 4 about here]
Descriptive statistics including mean, median, SD, ranges and minimum/maximum values were calculated for the durometer and SWE measurements. Durometer and SWE measurements reliability were established using intraclass correlation coefficient (ICC3,5). Data normality was assessed using the Shapiro-Wilk test, which indicated the SWE and durometer measurements were normally distributed for 1, 3 and 5 kg loads (SWE $p = .57-.96$ and Durometer $p = .44-.73$, respectively), and kurtosis and skewness coefficients were lower than ±1. Therefore, the associations between SWE and durometer measurements were assessed with Pearson Correlation Coefficients. Statistical significance was set at $p<.05$ for all analyses. All data and statistical analyses were performed using IBM SPSS statistics version 23 software (Armonk, NY: IBM Corp.).

RESULTS

The SWE and durometer measurement values are shown in Table 1. Intra-day reliability for the durometer measurements was 0.90 (95% CI 0.79-0.96, $p <.001$) and for SWE measurements was .95 (95% CI 0.88-0.98, $p <.001$). A moderate correlation was observed between the durometer and SWE tissue tensile loading measurements at 1 kg ($r = 0.56$, $p = .095$), combined 1 and 3 kg ($r = 0.72$, $p < .001$), and combined 1,3, 5 kg ($r = .62$, $p = <.001$), with a small correlation at 3 kg ($r = 0.36$, $p = .313$). The 5 kg load demonstrated a moderate negative correlation ($r = -0.56$, $p = .089$), which was likely reflected in part by the 800 kPa maximum SWE limit causing a ceiling affect. The 8 kg load could not be measured consistently due to tissue thinness with loading and SWE sample saturation with the 800 kPa measurement limit.
DISCUSSION

This is the first study to assess reliability of SWE and correlations between the durometer and SWE for GH joint capsular tissue properties under clinically applicable tensile loads using cadaveric tissue to eliminate neuromuscular influences. Tensile loads were selected based on durometer pilot testing of capsular tissue with good reliability (ICC\(_{3,5}\) = .87; CI .68-.95) and a high correlation between tensile load applied and durometer measurements for loads of 1, 2 and 5 kg and other prior studies of GHJ tissue properties.\(^{17,18,29}\) The SWE measurements for reliability and correlation in this study were performed by one observer in one day. The mean of five successive measurements was used to determine reliability. Such design allowed the best conditions to determine SWE reliability values. In this SWE study, the machine’s Q-box provided measurement selection through identification of the shear ROI. However, during 5 and 8 kg loads, saturation in some specimens due to the 800 kPa maximum SWE limit affected the mean tissue shear measurements, thereby creating a ceiling effect, which could have affected measurement validity at higher loads. Our findings showed that GHJ capsular tissue measurements under tensile loading using SWE had excellent reliability (ICC = 0.95). These findings suggest SWE is reliable for measuring GHJ cadaver capsular tissue during tensile loading. These results are in line with a previous in vivo study that evaluated GHJ capsular thickness and elasticity in two different positions with 0.93 intra-rater reliability value for posterior-inferior capsule elasticity.\(^{12}\)

Previous studies reported ROM changes after mobilization\(^5,18\) and tissue elongation after simulated oscillations\(^{29}\), but a better understanding of how these interventions affect tissue properties is needed. This study demonstrated that SWE technology may allow non-invasive
measurement of tissue changes during joint loading and capsule stretching procedures. Future studies evaluating the effects of tensile loading on capsular tissue in vivo are warranted to determine capsule behaviors during various mobilizations and whether changes in tissue properties are maintained post-loading.

The durometer measures a material’s hardness or resistance to deformation by applying an indentation load to the specimen, giving a measure of tissue hardness based on an arbitrary Shore unit (HA).\textsuperscript{30,31} The durometer has been used in various medical applications such as dermatology,\textsuperscript{32,33} organ\textsuperscript{34,35,36} breast\textsuperscript{37} and muscle\textsuperscript{38} tissue. The durometer measurements of intra-rater and inter-rater reliability measures were good to excellent using epidermal tissue.\textsuperscript{32,33} However, reliability has not been established in capsular tissue. Likewise, GHJ capsule hardness measurements with a durometer had high intra-rater reliability (ICC = 0.90) and could be used as a control method to validate diagnostic methods such as SWE.\textsuperscript{34} These findings establish the durometer as reliable and simple for measuring capsular tissue hardness in vitro. Selected durometer measurements at higher loads were difficult to obtain due to tissue sample thinness, which affected measurement location consistency in some specimens. This may explain why the reliability coefficients were not as high as those reported by Kissin et al.;\textsuperscript{33} however, our results were at the higher regions of Merkel et al\textsuperscript{32} for epithelial tissue measurements.

A modest connection was attained between SWE and durometer for GJH capsular tissue stiffness and hardness measurements during 1 kg, 1 and 3 kg combined, and a small correlation with 3 kg tensile loads. This indicates that as the load increased, GHJ capsule stiffness as measured by SWE and hardness as measured by durometer increased at lower loads. Similar correlation values between B-mode US and durometer were reported in muscle tissue.\textsuperscript{38}
indicating that both modalities measure different parameters that are closely related to the modulus of elasticity. Achilles tendon tensile loads and SWE have been moderately correlated under progressive loads. In the current study, the 5 kg tensile load resulted in moderate negative correlation between durometer and SWE; these results should be viewed with caution due to tissue thinness, durometer and SWE measurement location consistency, and SWE saturation levels at 5 kg tensile load.

There are some advantages to using SWE to evaluate joint capsule properties. First, it is a reliable measurement and can conveniently and quickly assess joint capsule elastic properties. In the present study, the time required for scanning and evaluating the capsule was only a few minutes. These advantages make SWE a promising modality to diagnose capsular pathology and evaluate treatment progression and efficacy of different interventions.

There were some limitations to our study. Soft tissues around the capsule were removed by hand and despite great care exercised to clear other tissue from around the capsule, any remaining non-capsular tissue could have contributed to some load resistance. Studies evaluating whether such properties are maintained over time and using other joint capsular tissue would be valuable. Further research is needed to determine the effects of tensile loading on capsular tissue and provide insight into the effects of stretching and joint mobilization loads on joint ROM changes in vivo.

In conclusion, SWE is a simple and reliable method of measuring GHJ capsule elastic properties in cadaveric tissue. Evaluation of capsular tissue tension properties during and following various loads, without the interference of the neuromuscular system, using SWE requires additional research.
REFERENCES


TABLES and FIGURES

Table 1: Mean measurements of 1, 3, and 5 kg loads of the durometer and SWE.

<table>
<thead>
<tr>
<th>Load (kg)</th>
<th>Durometer (± SD) (HA)</th>
<th>SWE (± SD) (kPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9.4 (± 1.8)</td>
<td>277.1 (± 30.0)</td>
</tr>
<tr>
<td>3</td>
<td>15.6 (± 2.5)</td>
<td>354.2 (± 33.0)</td>
</tr>
<tr>
<td>5</td>
<td>18.69 (± 2.5)</td>
<td>410.2 (± 37.2)</td>
</tr>
</tbody>
</table>

SWE = Shear Wave elastography; SD = Standard Deviation
Figure Legends

Figure 1: Testing Frame Setup. A standing frame with custom clamps secured superiorly and also inferiorly with a suspended 3 kg weight and stabilizing bar. The arrow indicates the location of GHJ capsular tissue prior to application of gelatin pad.

Figure 2: Measurement set up for tissue. The SWE measurement of capsular tissue using linear transducer over tissue surrounded by gelatin and secured Opsite Flexifix® material.

Figure 3: SWE Q-box measurement.

A. Display demonstrates statistical information and non-saturated display within Region of Interest. The Region of Interest is identified within the dotted line.

B. Display demonstrates statistical information and saturated display within Region of Interest. The Region of Interest is identified within the dotted line.

Figure 4: Shore A Durometer. The arrow indicates the device indenter.
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