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# Quantifiable Soft Tissue Manipulation (QSTM™) – A novel modality to improve clinical manual therapy with objective metrics.

Abhinaba Bhattacharjee, Stanley Y.P. Chien, *Senior Member, IEEE*, Sohel Anwar, *Member, ASME*, Mary. T. Loghmani, *Distinguished Fellow, National Academies of Practice (NAP).*

***Abstract*—Soft Tissue Manipulation (STM), a form of mechanotherapy, offers a clinical modality to examine and treat Neuromusculoskeletal (NMS) pain disorders and dysfunction. The, current STM practice is mostly subjective and reliant on anecdotal patient feedback and lacks quantification with objective metrics. This paper proposes Quantifiable Soft Tissue Manipulation (QSTM™), a sensor based computerized technological advancement in Soft tissue examination and treatment enabling new standard of practice in manual therapy. This novel medical device technology aims to produce optimum STM prescriptions using ergonomic, portable, handheld medical tools with specially contoured tips designed to palpate and assess tissue anomalies of specific musculoskeletal conditions. QSTM™ captures three–dimensional forces and motion of the mechatronic handheld tools to quantify STM treatment parameters, such as (resultant force, force application angle, rate, direction, and treatment time). Clinical practice using QSTM™ facilitates real-time visual feedback of treatment metrics and subsequent treatment documentation for comparison and analysis on a Windows based computer software (Q-Ware©). Pre-clinical testing using the QSTM™ medical device system clearly identifies inconsistencies among practitioners and distinguishes STM practice variabilities. Thus, QSTM™ is an apt tool for soft tissue treatment assessment, analysis, and individualized prescriptions for targeted STM dosing and commercialization.**

## I. Introduction

Manual therapy has gained popularity in recent years as a non-invasive/non-pharmacological treatment approach to remediate neuromusculoskeletal (NMS) impairments. The clinical practice of manually applied Soft Tissue Manipulation (STM) is a key method of physical therapy to attenuate NMS pain. It involves mechanical stimulation of soft tissue restrictions and scar by external force application, breaking down fascial adhesions either by hand massage or by specially designed rigid, wooden/steel tools. The efficacy of the later, known as Instrument Assisted Soft Tissue Mobilization (IASTM), offers a clinical advantage, as the tooltips enable deeper penetrability and precision to palpate and assess tissue restrictions during targeted force application.

Targeted IASTM cross fiber massage on rodent model demonstrated positive impacts with accelerated tissue level healing from elevated collagen fiber formation including enhanced regional tissue perfusion [1]. Similarly, controlled IASTM studies with human subjects, reported improvements in range of motion [2], modified gait performance [3] due to pain attenuation and increased mobility in quadricep activity. Clinical studies with instrument-assisted mechanotherapy indicates the consideration of several practice parameters [4] which exert myriad implications on biomechanical behavior and neurological activity of soft tissues. These practice parameters are directed at formulating objective metrics for standards of STM practice. Quantifying manual therapy (Therapeutic Massage Strokes) in terms of - the amount of mechanical load (force) delivered in stipulated time, treatment angle, directionality, and rate of stroke application; are the fundamental components in STM dose standardization.

Several mechatronic instrumentation[5]-[7] approaches have been adopted and studied to enumerate compressive and translational forces applied during therapeutic massage with varying rates for both human and rodent studies. But these robotic set-ups or mimetic devices are impractical for clinical applications as they may not be portable or handheld and lack the maneuverability or adaptations needed for different massage stroke patterns necessary for individualized care. Recent trends in wearable technology have also produced pressure-sensing gloves[8] with multiple piezoelectric or capacitive sensors for commercialized relaxation massage application. Certain gloves[9] can be used clinically, but mask the degree of palpation sensitivity, precision, and penetrability required to identify tissue irregularities associated with NMS pathology.

This paper introduces a novel technological advancement to traditional instrument assisted STM – Quantifiable Soft Tissue Manipulation (QSTM™). QSTM™ technology is a smart data requisition based medical device system involving handheld, portable, ergonomic mechatronic tools, with specialized tooltips, developed to measure force and motion parameters during STM treatment. This paper discusses the System architecture, Software overview, and Working principle of a Localized Force applicator device, for treating discreet body regions (eg: elbow, fingers; smaller areas; small animals). Some pre-clinical evaluations of QSTM™ practice along with the technology's market need are elaborated in the results and conclusion sections, respectively.

## II. System Architecture

The design criteria for QSTM™ development are dominated by form factor, ergonomics, cost, replicability, sensitivity, durability, portability, and marketability.

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Abhinaba Bhattacharjee, and Stanley Y.P. Chien are with the Department of Electrical and Computer Engineering, Purdue school of Engineering and Technology, IUPUI, IN 46202 USA {email: abhbhatt@iupui.edu, schien@iupui.edu}.

Sohel Anwar is with the Department of Mechanical and Energy Engineering, Purdue School of Engineering and Technology, IUPUI, IN 46202 USA {email: soanwar@iupui.edu}.

Mary. T. Loghmani, PT, PhD is with the Department of Physical Therapy, Indiana University School of Health and Human Sciences, IUPUI, IN 46202 USA, {e-mail: mloghman@iu.edu}.

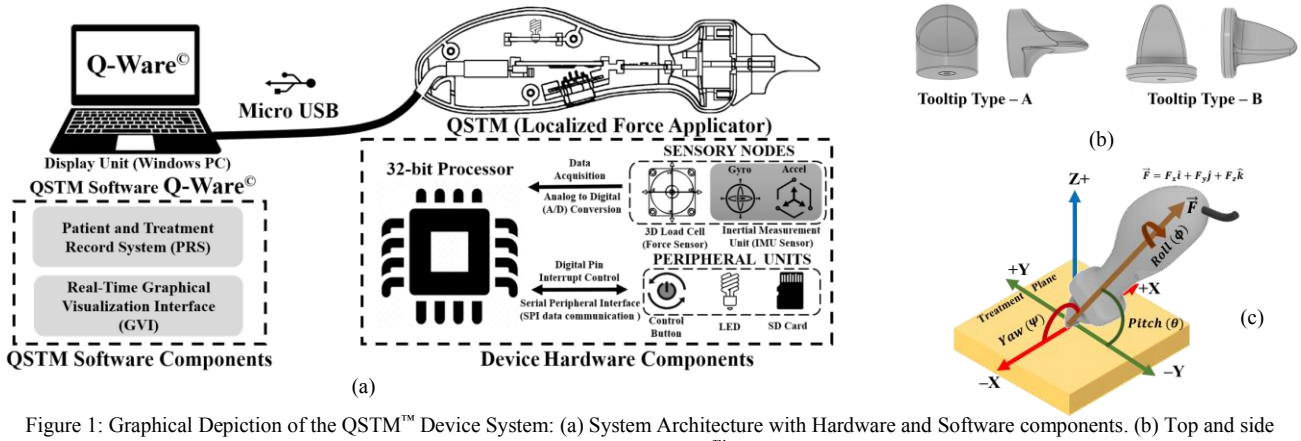



Figure 1: Graphical Depiction of the QSTM™ Device System: (a) System Architecture with Hardware and Software components. (b) Top and side view of tooltips type-A and type-B. (c) 3D representation of the QSTM™ Device showing treatment plane and device orientation

The preliminary designs were simulated in LabVIEW workbench, sufficing the proof-of-concept and feasibility for clinical use[10]. A finite element analysis[11] of similar design was performed on ANSYS workbench to study the stress/ strain distribution on a human tissue model. This analysis also revealed the necessity of 3D force and 3D motion quantification for characterization of STM treatment parameters in real-time. The system architecture for modified implementation is shown in Fig.1(a), which illustrates the Hardware and Software elements and the connection between the handheld device and Windows-based PC.

### A. *Hardware Design*

The Localized Force Applicator prototype includes an ergonomic handheld part which houses a compact 3D load cell for sensing Compressive (Vertical) up to 100 Newtons (N) and Translational (Shear and Tensile) at the point of contact of tool tip. Furthermore, the handheld housing comprises, a 9-DOF IMU sensor, with 3D accelerometer and 3D gyroscope, for tilt and angular motion sensing. The data from these sensors are acquired and processed by a 32bit ARMv4 processor for calculating treatment parameters. Additionally, a control button for changing the device operation states during treatment, along with a LED for visualization of these operation states are also facilitated in the hardware. Finally, an 8GB memory, is included to store system information and calibration data, which also serves the purpose of recording raw data history of a few past treatment sessions. Two tooltips have been designed as shown in Fig.1(b); of which the type-A with a circular edge serves cross fiber massage in human body parts (forearms, elbow, knees); while type-B with a pointed tapered edge serves deeper palpation on small animals and discreet regions of human body. The tooltips are made of steel which coupled with the contoured shape, magnifies palpation sensations by producing resonance-based reverberations as the tool glides over the tissue during treatment. The tooltip connected to the load cell by a load shaft transmits the vibrations to clinician's hands for detecting tissue irregularities. Moreover, a cradle is designed to secure the device and assist in uninterrupted calibration.

### B. *Software Design*

The software of the device system has two parts: Embedded Firmware running on the micro-controller and PC Software (Q-Ware©) for clinical use. The Embedded Firmware

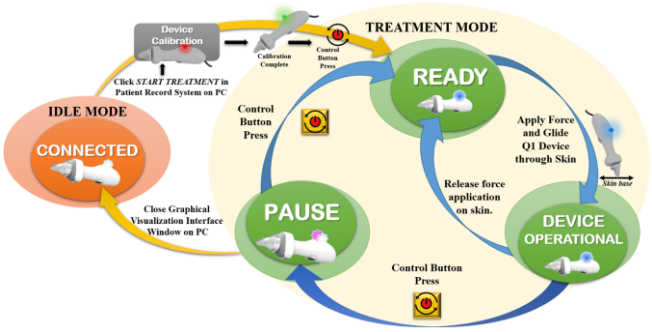



Figure 2: Diagrammatic illustration of QSTM™ operation with System Modes and States.

written in C++ performs data acquisition, device calibration, sensor fusion, signal processing and treatment parameter calculations. Whereas the PC software (Q-Ware©), written in Python is a user-friendly multiprocessing application. It features: a local Patient-Treatment Record System (PRS) analogous to an electronic health record; and a real-time Graphical Visualization Interface (GVI) to monitor live data stream of force and angle variations, at 100 samples per second. It also includes a post treatment graphical waveform analysis interface to compare and visually identify force waveforms of different treatment stroke-motion patterns performed by the clinician. The Patient-Treatment Record System (PRS) performs post-processing data analysis, calculates QSTM™ treatment parameters and generates Treatment report displayed on treatment report panel. The report panel offers assessing, commenting, and recording treatment vitals of all treatment sessions. In addition, Q-Ware© also enables retrieving treatment history for referencing practice inconsistencies and patient's STM-dose receptibility.

## III. METHODOLOGY

The computation of the QSTM™ device system is distributed between the handheld device Firmware and Q-Ware© on PC to ensure real-time system performance and efficiency. Fig.2 depicts the system operations indicating system modes, underlying working states and actions responsible for transition in between states and modes. The operations of the handheld device are characterized by two modes: Idle/Non-Treatment mode and Treatment mode.

### A. Idle or Non-Treatment Mode

The idle or non-treatment mode reflects boot-up and system initializations of the handheld device, where no therapeutic actions occur. This mode performs device to PC connectivity, and automatic device identification by Q-Ware© on PC, whenever the device is plugged-in. On the device, this mode is depicted by a 1Hz white LED Blink and the user can perform initial tasks of patient enrollment/selection on Q-Ware©, before treatment. This operation mode also supports data management, and the mode repeats itself after each treatment session, where the user records, comments and saves treatment report on PC.

### B. Treatment Mode

In treatment mode the device reads sensor values, processes, and converts them to forces in Newtons and angular orientation in degrees. This mode is activated by user actions on Q-Ware©. This mode starts when the PRS prompts for device calibration followed by the Graphical Visualization Interface (GVI) as shown in Fig.3 running on Q-Ware©. The device calibrates itself by indicating a solid red LED glow for 30-40 seconds and then turns solid green. The user is advised not to touch the device during calibration and the device is recommended to rest on its respective cradle at a predefined orientation. The green LED glow marks the completion of calibration process. Then the user can lift the device from cradle, press the control button and start treating patient.

During the treatment mode, the device performs force sensing and device orientation estimation by sensor fusion. It calculates Resultant Force from 3D force information. It also derives Yaw, Pitch & Roll angles of device as shown in Fig.1(c) with respect to gravity direction obtained from IMU's accelerometer and gyroscope data by using a complementary filter-based approach[12] to yield orientation Quaternions and their Euler transformations. These measured data are transmitted to Q-Ware© on the PC over serial communication at 100 Hz using a baud rate of 115.200 kbps. Q-Ware© performs real-time data visualization on its GVI and derives necessary treatment parameters: Compressive force, Average resultant force, Average treatment angle (Geomagnetic pitch-angle of device), Total treatment time, Absolute contact time, Average peak force (Target Force), Stroke frequency, etc. In a therapeutic session, the treatment mode is characterized into three executable states:

i. *Ready State* – This state occurs when no external force is applied on the tooltip and the device indicates a solid Blue LED glow. The device tooltip weighs around 50 grams, which exerts a negative tension force of about 0.5 Newtons (N) towards gravity on the load shaft. This noise is compensated based on the device angle relative to the horizontal plane. Ready state time accounts for the device inactivity time and adds up to the Treatment dead time.

ii. *Device Operational State* – This state appears when the user positions the device's tooltip on the patient's body, applies force on the skin and glides it along +Y direction on skin, as shown in Fig.1(c), to perform therapeutic massage. Measured real-time forces appear on PC at the GVI window of Q-Ware©, and the device indicates a solid Blue LED glow during this operation state which accounts for the actual contact time of treatment.

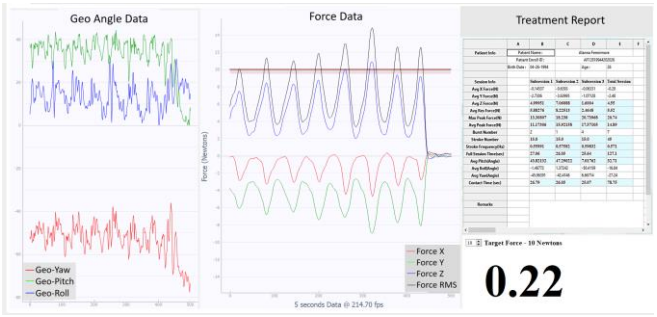



Figure 3: Screenshot of Graphical Visualization Interface (GVI) of Q-Ware©, showing force chart with target force, geo-angle chart, Real-time Force Monitor and Treatment Report

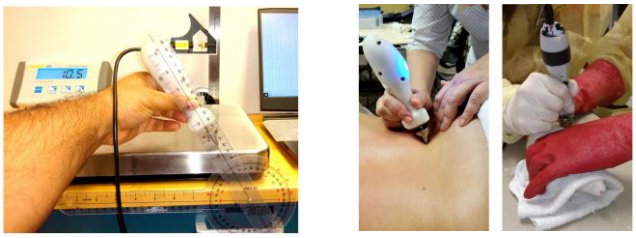
iii. *Pause State* – This state is activated when the user hits the device's control button right after a treatment session or sub-session. It enables the device to reset its memory and re-initialize itself to its calibration values without terminating the session. However, it allows the therapist to adapt treatment position or switch treatment sites in between treatment sub-sessions. The Pause state marks the absolute dead time of the session. It is indicated by an alternate white and pink LED blink per second.

The device terminates communication to PC, reboots itself and auto-reconnects to Q-Ware©, when the user closes the GVI after treatment. The PRS generates treatment report in form of 3D forces, geo-angles, rate & duration, at the end of each treatment session and saves to its database. The analysis is performed on the collected data, only once per treatment session. The PRS also facilitates treatment history retrieval for comparison, and treatment replication. Pre & Post treatment QSTM™ dose-effect measurements can be quantified by measuring – soft tissue elasticity with elastography, and pain thresholds with pressure algometry. Thus, QSTM™ opens a new door for clinicians and researchers to quantitatively analyze STM and generate suggested precise treatment.

## IV. Results

### A. Hardware and Software Testing

The handheld device operates at 5 Volts (V) DC drawn from the USB port. The sensitivity of Force measurement is determined by 10-bit A/D converter of the microcontroller, which quantizes the voltages in 1.2 to 1.5 mV range. This accounts to a force sensing resolution of ~0.1 Newton (N) in the Z-axis and ±0.05 Newton (N) in the X and Y axes of the load cell. An external force plate (PCE-PB 150 N), of 0.5N measuring resolution, has been used to validate the sensitivity of individual axes of the load cell at 10N, 20N, 30N, and 50N. The absolute percentage error was measured to be around 0 to 5.9%. The sensitivity of angular rates of the device, against the gravity reference, were measured on a set square & goniometer based experimental set-up shown in Fig.4(a). Experimental observations at 30º, 45º, 60º, 90º device angles were performed after device calibration which yielded accurate results with an error rate of ±2.12%. The stroke frequency of treatment with handheld device was tested on smooth textured surfaces applying varying rates. The stroke frequency of every burst (train of similar stroke sequence), determined through a decision-tree based algorithm, was



(a) (b) (c)

Figure 4: QSTM™ System Validation and Testing: (a) Angular force validation, (b) Device testing on human back, (c) Device test on rats.

observed to be 99% accurate by comparison with visual counting of strokes over stipulated time. Reliability was good with the tool at 60º to 90º angles using max compression against the force plate while visualizing output.

### B. *Pre-clinical Testing*

A rodent model was used for preliminary device testing on an animate subject Fig. 4(c). This model allowed for a rapid, cost-effective means of troubleshooting the prototype design, function, and display in a homogeneous, healthy population before use in humans. Animal behavioral experts trained the research team. Two examiners with similar levels of experience were blinded to QSTM™ analytics (without visual monitoring) to replicate clinical practice and instructed to use QSTM™ device to apply short, cross-fiber treatment strokes to the uninjured low backs of conscious rats. The latter is accommodated to handling, at a maximal pressure (i.e., just below the pain pressure threshold [PPT]), for 15 trials, an average of 3 attempts/trial, 15 sec/trial, during two sessions, that were spaced 4 hours apart, on the same day. The PPT is a commonly used means to determine the pressure threshold in rats. After testing, the rats were subsequently used in another study. Intra-rater reliability was less than good with (examiner A's interclass correlation coefficient [ICC] = 0.168; examiner B's [ICC] = 0.315); as was inter-rater reliability (ICC= 0.153). The high variability found within and between examiners points to a need for monitoring STM treatment pressures to improve consistency. Usability of the QSTM™ device system was also assessed; modifications were then made to improve usability before testing in humans.

## V. Discussion

Unlike mimetic massage devices or robotic applicators, which are typically programmed to apply constant forces at constant rate, the QSTM™ device system does not have a direct comparative. It offers adaptability maneuvered under the volitional control of the clinician. It also enables the user to set a "target force" as a visual guide for precise force application. The software (Q-Ware©) enables visualization of soft tissue irregularities as depressions in force waveforms of similar stroke patterns as the handheld device glides through tissue during treatment. Hence, it escalates manual therapy with scientific standards for studying neurobiological effect of varying STM dose prescriptions. Comparative studies between IASTM approaches need to be conducted to determine differences in treatment effectiveness. Based on pre-clinical findings, clinical trials are needed to determine optimal treatment dose response for a wide variety of NMS disorders. Participation in NSF Innovation Corps (I-Corps) program and Indiana philanthropic entrepreneurial Elevate Ventures Nexus program enabled our team to perform initial customer discovery research, conducted on local and national levels using open ended interviews and surveys. These findings revealed 97% of therapists (n=80) want a method to quantify STM with objective metrics and set-up protocols for practice standardization. We anticipate, research, sports (school and professional), and performing arts (music and dance) are the markets to be the early adopters of QSTM™ – wanting the edge in orthopedic manual therapy.

## VI. Conclusion

Progressive QSTM™ technology connects quantitative metrics with patient feedback and clinician perception to augment and improve clinical STM practice. Patients with NMS pain will benefit from QSTM™ state-of-the-art technology as it will facilitate faster and better tissue healing, repair and regeneration from standardized dosage of targeted STM. As large numbers of objective treatment records are accumulated for a variety of conditions in different stages of recovery, quantitative dose-effect analysis becomes feasible, advancing the field of manual therapy. Thus, we envision this innovative QSTM™ technology to become a manual therapy modality just like ultrasound units, dynamometers, or other modalities or exam tools found in most clinics.

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