

A Hand-Held Device to Apply Instrument-Assisted Soft Tissue Mobilization at Targeted Compression Forces and Stroke Frequencies

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Instrument-assisted soft tissue mobilization (IASTM) is a manual therapy technique that is commonly used to treat dysfunctions in ligaments and other musculoskeletal tissues. The objective of this study was to develop a simple hand-held device that helps users accurately apply targeted compressive forces and stroke frequencies during IASTM treatments. This portable device uses a force sensor, tablet computer, and custom software to guide the application of user-specified loading parameters. To measure performance, the device was used to apply a combination of targeted forces and stroke frequencies to foam blocks and silicone pads. Three operators using the device applied targeted forces between 0.3 and 125 N with less than 10% error and applied targeted stroke frequencies between 0.25 and 1.0 Hz with less than 3% error. The mean error in applying targeted forces increased significantly at compressive forces less than 0.2 N and greater than 125 N. For experimental validation, the device was used to apply a series of IASTM treatments over three-weeks to rodents with a ligament injury, and the targeted compressive force and stroke frequency were repeatedly applied with an average error less than 5%. This validated device can be used to investigate the effect of IASTM loading parameters on tissue healing in animal and human studies, and therefore can support the optimization and adoption of IASTM protocols that improve patient outcomes. [DOI: 10.1115/1.4041696]

Keywords: massage, IASTM, manual therapy, medial collateral ligament, mechanotransduction, tendinopathy

1 Introduction

Ligaments are bands of dense fibrous tissue that provide joint stability by binding bone to bone. Ligament tears account for 50% of sporting injuries [1], are painful, restrict physical activity and can lead to chronic impairment [2]. Instrument assisted soft tissue

mobilization (IASTM) is a manual therapy technique frequently used by clinicians for treating dysfunctions in ligaments and other soft tissues [3]. Clinical studies have shown IASTM improves outcomes for individuals with shoulder and patellar tendinopathy [4,5] and chronic ankle pain [6]. In animal studies, IASTM has been shown to increase fibroblast proliferation [7–8] and accelerate the rate of functional restoration during healing [9–10]. Several IASTM techniques are currently practiced [11], and while each technique has minor differences in tools and treatment protocols, they all involve the manual application of dynamic compressive loads by cyclic stroking of the damaged tissue through the skin with an instrument. Notably, none of the prevalent IASTM techniques specify the loading parameters that are recommended during treatment. In order to identify loading parameters that result in optimal patient outcomes, it is important to develop research devices that can accurately apply compressive loads to animal and human subjects at targeted force magnitudes and stroke frequencies during IASTM.

Current techniques to apply IASTM in a research setting include instrumented hand-held devices and robotic manipulators. Hand-held devices are practical but have not yet been validated to apply targeted forces and frequencies [8–10,12–16]. Robotic manipulators have been used to control the compressive force and stroke frequency during soft tissue mobilization of muscle along a single axis [17,18]. However, these devices can be stationary, expensive, and time intensive to operate, making them less practical for animal experiments and human clinical studies. The objective of this study was to develop and validate a portable hand-held device that enables users to accurately apply targeted forces and stroke frequencies during IASTM treatments in animal and human studies.

2 Materials and Methods

2.1 Design Criteria. Two primary design criteria were considered for the IASTM device. First, the device should reproduce the beveled tip and hand-held form of clinical instruments used for IASTM (Fig. 1(a)). Second, the device should provide the operator feedback to accurately apply compression at targeted force magnitudes between 0.5 and 100 N and stroke frequencies between 0.25 and 1 Hz. These force magnitudes replicate a range of parameters used for small animal studies and clinical research [8–10,13,14,16,19].

2.2 Device Construction. The portable device (Figs. 1(b) and 1(c)) is made up of a custom machined aluminum tip, a uniaxial force sensor, a stainless steel shaft, a data acquisition module (DAQ) (National Instruments, Austin TX; cDAQ-9171 USB chassis & NI 9237 Module), and a tablet computer. The aluminum tip has a beveled edge similar to IASTM tools used in physical therapy clinics (Fig. 1(a)). A custom LABVIEW program was developed to view and record force data with a sampling rate of 20 Hz (Fig. 1(c)). The program allows the user to input a targeted treatment duration, peak compressive force, and stroke frequency. The program provides the user feedback by displaying a live waveform of the applied force overlaid with a square waveform that shows the targeted loading profile. In addition, the program creates an auditory signal that indicates when to start and end a stroke, acting as a metronome to guide stroke frequency. The peak compressive force is determined by taking an average of the data points measured during tissue contact. These data points are selected using a graded threshold algorithm that identifies clustered regions of the sample data (Fig. 2(a)). The stroke frequency is determined in post-processing by using a Fourier series summation to fit the raw force measurement data using a non-linear least squares fitting method (Fig. 2(b)). The software developed for data acquisition and analysis is free to download in the website link.²

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²<http://coen.boisestate.edu/ntm/software>

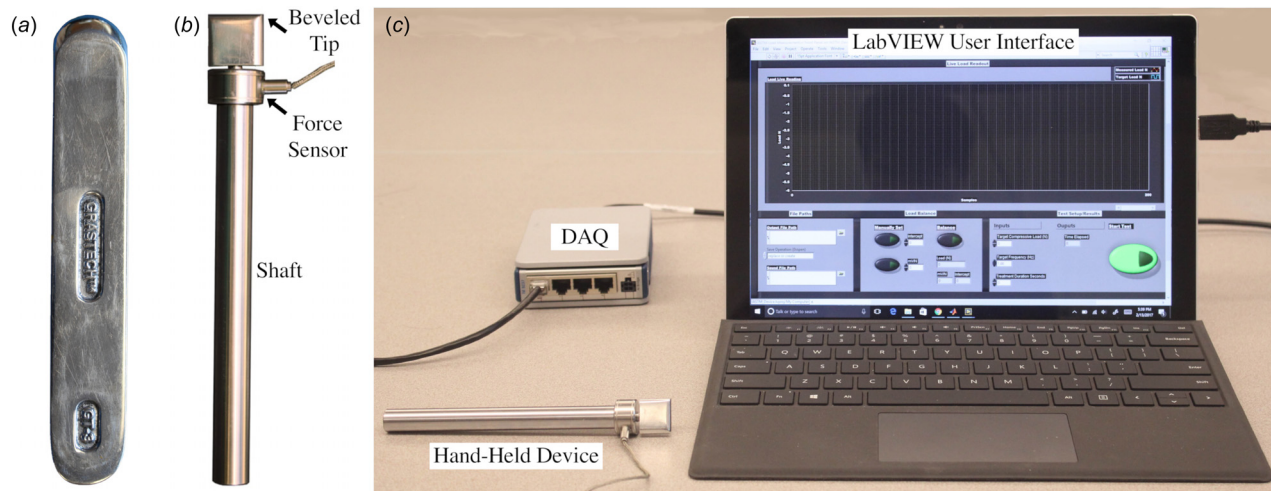


Fig. 1 Design and components of device: (a) Graston IASTM tool, (b) hand-held device, and (c) data acquisition and graphical user interface used with the hand-held device

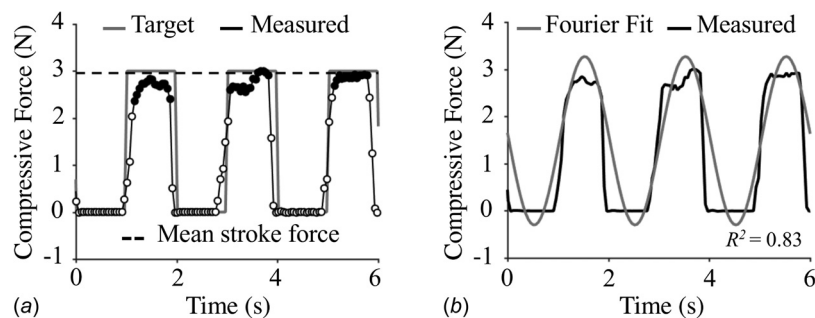


Fig. 2 Automated calculation of loading parameters: (a) force data measured by the device during performance testing overlaid with the target loading profile. Black circles represent data included in the overall calculation of mean stroke force, while open circles were excluded from this calculation. (b) Fourier series fit for measured force data with a target frequency of 0.5 Hz. This fit was used to measure frequency during testing. Note: the compressive force is applied every half cycle.

2.3 Device Performance Tests. Two tests were executed to evaluate device performance. The first test analyzed the device's error in measuring compressive force when varying the angle between the device's shaft and the surface being treated (i.e., shaft angle). This test was performed using three-dimensional printed blocks to anchor the device at five fixed angles between 50 deg and 90 deg (Fig. 3(a)). The device was equipped with a 10 N capacity force sensor (Omegadyne, Sunbury, OH; error = 0.2%). At each fixed angle, the device was manually loaded three times to 5 N based on the axial force measured by the device, P_{device} , while the compressive force normal to the surface, P_{surface} , was simultaneously measured with an auxiliary force sensor (Instron, Norwood, MA; Dynacell 2527; Fig. 3(a)). Data was collected for three minutes. The 0–5 N range selected for this test ensured that the device tip did not slip on the metal surface of the auxiliary force sensor, and therefore, the desired shaft angle was maintained throughout the test duration. The error in measuring the compressive force applied to the surface was defined as the absolute mean percentage error ($|P_{\text{device}} - P_{\text{surface}}|/P_{\text{surface}}$). These results were compared to the theoretically predicted error, which was estimated by calculating the compressive force applied to the surface using the sine of the shaft angle multiplied by the magnitude of the applied force (Fig. 3(a)).

The second test determined the device's accuracy and error in applying forces and stroke frequencies over a range of targeted

values. This test was performed by having three individuals, with no clinical experience, use the device to dynamically stroke a rigid foam block at eight different targeted forces relevant to small animal research (0.1, 0.2, 0.3, 0.4, 0.5, 1, 3, 5 N) [8–10], and load a silicone pad at eight different targeted forces relevant to human clinical treatments (10, 25, 50, 75, 100, 125, 150, 175 N) [13,14,16,19]. Targeted loads were applied above and below the normal range used during IASTM treatments (0.5–100 N) to determine the loading limits of the device. All targeted forces, P_{target} , were applied at three different targeted frequencies (0.25, 0.5, 1.0 Hz). A 445 N capacity load sensor was used to measure forces P_{device} above 10 N (Omegadyne, Sunbury, OH; error = 0.2%). The operators were instructed to perform a unidirectional 35 mm stroke. The velocity and acceleration of the stroke was not directly measured but an average velocity was estimated to be 17.5, 35, and 70 mm/s, corresponding to stroke frequencies of 0.25, 0.5, and 1 Hz, respectively. Each test was performed for one minute, and every test condition was performed three times by each operator. Prior to testing, each operator was allowed 30 min to practice using the device. In addition, a 1 min practice run was performed prior to each test condition. Accuracy in applying a targeted force (or stroke frequency) was defined as the absolute mean difference ($|P_{\text{device}} - P_{\text{target}}|$). The error in applying a targeted force (or stroke frequency) was defined as the absolute mean percentage error ($|P_{\text{device}} - P_{\text{target}}|/P_{\text{target}}$).

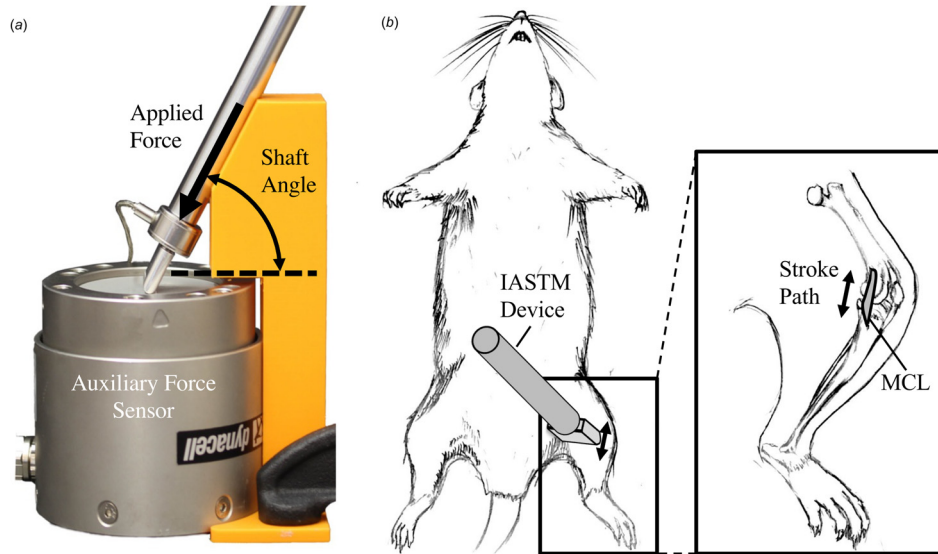


Fig. 3 Experimental setup: (a) device at a 60 deg shaft angle to determine error between the applied axial force measured by the device (P_{device}) and the compressive force applied to the surface (P_{surface}), which is measured by an auxiliary force sensor and (b) illustration of the device being used to apply IASTM to a rodent's MCL (gray structure in figure inset)

2.4 Experimental Validation. In order to test the repeatability of the device in a research setting on a living subject, a pilot study was conducted utilizing three Sprague–Dawley rats (age=6 months). The device was used to perform IASTM to medial collateral ligaments (MCL) that were injured through surgical transection. This pilot experiment followed an established protocol [10], and IASTM treatments were based on guidelines for the Graston Technique [20], where a compressive force is repeatedly applied along one direction for no longer than 1 min. For this study, a 2 N force was applied along the length of the MCL (Fig. 3(b)), between the tibial and femoral insertion (stroke distance = ~10 mm), at a rate of 1 Hz for 1 min. These IASTM treatments were repeated 6× times during a 3-week period but results from the first treatments were discarded due to a faulty force sensor, leaving five treatments for analysis. All procedures were approved by the Institutional Animal Care and Use Committee of Boise State University.

2.5 Statistical Tests. The effect of shaft angle on the device's error in measuring compressive force was analyzed using linear regression. The effect of force magnitude, stroke frequency, and operator on the device's error in applying the targeted loading parameters was assessed using a MANOVA, with Games-Howell post hoc analysis. This MANOVA analysis was independently performed for low forces relevant to small animal experiments (0.1–5 N) and high forces relevant to clinical applications (10–175 N). The effect of treatment time on the measured loading parameters during the animal experiment was assessed using repeated measures ANOVA. For all statistical tests, significance was set at $p < 0.05$.

3 Results

3.1 Device Performance Tests. For device shaft angles between 70 deg and 90 deg, the device measurement error was less than 5%. Below 70 deg shaft angles, the device measurement error was greater than 15% (Fig. 4(a)). The slope between the

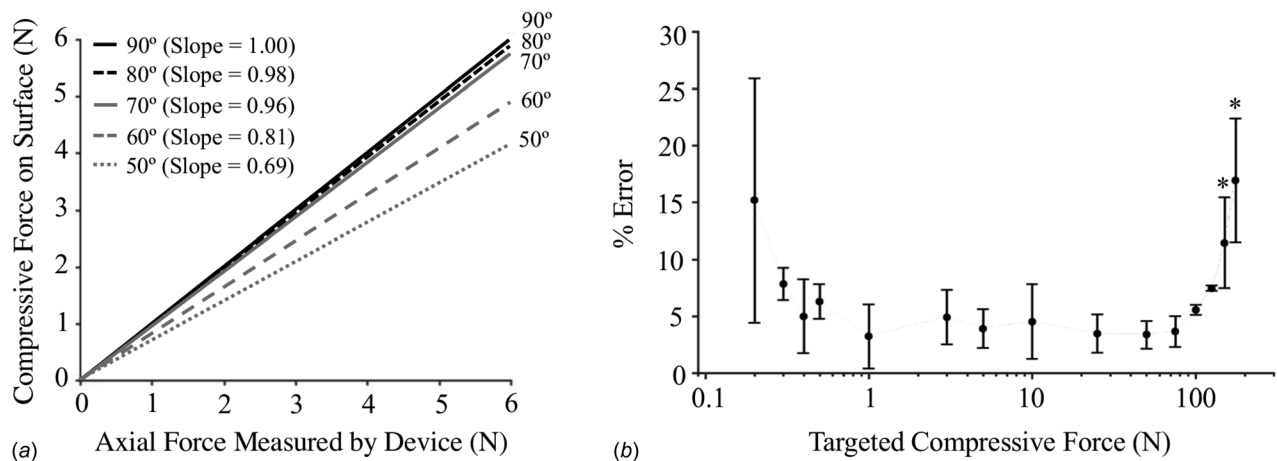


Fig. 4 Results from device performance tests: (a) comparison between the axial force measured by the device and the compressive surface force measured by the auxiliary force sensor. A slope of 1 indicates the force measured by the device equals the compressive force applied to the surface. (b) Percent error in applying each targeted compressive force (0.2, 0.3, 0.4, 0.5, 1, 3, 5, 10, 25, 50, 75, 100, 125, 150, 175 N; log scale), averaged over three different operators. The error bars indicate the standard deviation between operators. Note: the mean error at a 0.1 N target force was $78 \pm 35\%$ (not shown on plot). * = significantly greater error than other targeted forces (25, 50, and 75 N).

Table 1 Average error in applying each targeted stroke frequency over the range of compressive forces. The R^2 values are for the Fourier fit of the measured force data used to compute the measured frequency.

Loading range (N)	Target frequency (Hz)	Measured frequency (Hz)	Error (%)	R^2
0.1–5.0	0.25	0.25 ± 0.01	0.13 ± 0.10	0.69 ± 0.14
0.1–5.0	0.50	0.50 ± 0.01	0.09 ± 0.08	0.69 ± 0.15
0.1–5.0	1.00	1.00 ± 0.01	^a 0.04 ± 0.03	0.67 ± 0.14
10–175	0.25	0.25 ± 0.01	0.07 ± 0.08	0.86 ± 0.04
10–175	0.50	0.50 ± 0.01	0.07 ± 0.06	0.80 ± 0.06
10–175	1.00	1.02 ± 0.06	^a 2.35 ± 5.63	0.38 ± 0.17

^aSignificant difference in error within the same target force group.

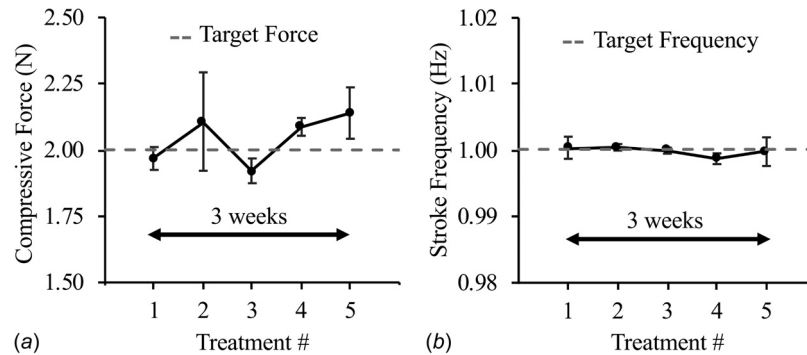


Fig. 5 Results from experimental validation: (a) average applied force and (b) average applied stroke frequency across five IASTM treatments for three rats

force measured by the device and the compressive force on the surface (Fig. 4(a)) had a high-positive correlation, with the slope estimated theoretically using the sine of the shaft angle ($R^2 = 0.98$). For low force magnitudes (0.1–5 N), compressive force was applied with an average percent error of $15.5 \pm 25.4\%$ and an average accuracy of 0.07 ± 0.07 N. For high force magnitudes (10–175 N) compressive force was applied with an average percent error of $7.1 \pm 4.8\%$ and an average accuracy of 14.4 ± 7.7 N.

The average error when applying compressive force was less than 10% for magnitudes between 0.3 and 125 N (Fig. 4(b)). Within this range (0.3–125 N), the mean error from the three operators had an average standard deviation of $2.3 \pm 2.0\%$ (Fig. 4(b)). The error in applying all targeted forces was not affected by stroke frequency ($p = 0.40$). The stroke frequency was accurately applied with less than 0.2% error for all targeted frequencies, with the exception of 1 Hz in the high loading range (Table 1). When applying lower forces (0.1–5 N), error decreased at higher frequencies; and when applying higher forces (10–175 N), error increased with increasing frequencies (Table 1). Changing operators had no effect on the error measured at each targeted force or stroke frequency ($p > 0.2$).

3.2 Experimental Validation. The average percent error in force magnitude and stroke frequency across IASTM treatments for the rodent experiment was $4.5 \pm 2.0\%$ and $0.1 \pm 0.1\%$, respectively (Fig. 5). Additionally, there was no effect of time of treatment on device accuracy ($p = 0.32$) (Fig. 5). At a 95% confidence interval, values for mean force across all treatments ranged between 2.4 and 2.0 N. Therefore, there is 95% confidence that time of treatment had less than a 10% effect on the mean force.

4 Discussion

This study developed a hand-held device that enables users to accurately apply targeted forces and stroke frequencies during IASTM treatments used on animal and human subjects. Important guidelines for use include: (1) using shaft angles greater than

70 deg, where the device measurement error is less than 4% (Fig. 4(a)); and (2) applying compressive forces between 0.3 and 125 N, where the error in applying a targeted force is less than 10% (Fig. 4(b)). Additionally, stroke frequencies of 1 Hz or less can be targeted with less than a 3% error. By designing a simple and intuitive device, this level of accuracy was achieved for new operators with only 30 min of practice. When using the device, the operators instinctively adjusted their stroke frequency based on the software's auditory queues. To reproduce the targeted force, the operators glanced at the tablet screen to get visual feedback of the applied compressive force and make adjustments. The portable tablet was positioned for easy viewing, and once operators got a feel for the targeted compressive force, they tended to look less at the screen. All operators had difficulty maintaining the muscular control needed to accurately apply targeted forces above 125 N.

To our knowledge, this is the first hand-held IASTM device that has been validated to assist users in applying forces at targeted magnitudes and stroke frequencies. Furthermore, this is the first study to demonstrate that these loading parameters can be repeatedly applied at multiple time points during in vivo animal experiments (Fig. 5). Several researchers have prescribed forces during soft tissue mobilization through various techniques including: using an IASTM tool on a force plate to acquire a kinesthetic feel for the amount of force applied prior to treatment [9,10], attaching force sensors to a soft tissue mobilization instrument [8,13] or to the fingers [12,14], and using a palm held device equipped with a three-dimensional piezoelectric strain gauge [15]. However, none of these methods were validated to apply a targeted force or stroke frequency. This study has provided validation that a simple device, using a uniaxial force sensor, allows users to achieve excellent accuracy within the range of forces and stroke frequencies used for small animal research and in clinical practice [8–10,13,14,16,19]. To assist the adoption of this technique by other research groups, the LABVIEW data acquisition software that provides visual and audio feedback to operators, and the MATLAB software that automates data analysis, is freely available to download in the website link.²

A robotic IASTM device could potentially provide the highest degree of force and frequency control. A drawback of the current hand-held device is that although a mean force can be applied with less than 10% error, the variation in percent error during each 1-min test ranged between 12 and 30%. A robotic manipulator may reduce this variation. For example, the use of force feedback in a previous robotic device [17] produced a 5% better coefficient of variation when applying 5 N of compressive force than our handheld device. Compared to hand-held devices, robotic manipulators may also be better suited to apply a consistent waveform, as human operators had poor waveform fits when applying loads above 10 N at 1 Hz (Table 1). Robotic manipulators have notable disadvantages as well when compared to hand-held devices. These disadvantages include less flexibility in the applied stroke path to account for anatomical variations, and a greater setup time, which may preclude the testing of large sample sizes.

This study has limitations. The hand-held device only measures the axial force component and therefore requires the shaft to be held at angles greater than 70 deg to the surface being loaded (Fig. 3(a)). To accurately measure force at any shaft angle, the device would require a tri-axial force sensor to capture both axial and transverse force components [13,16]. However, this would increase device complexity and cost. Additionally, while the sample size for the rodent pilot study can estimate the device's error in applying targeted loading parameters across multiple weeks of treatment (Fig. 5), future studies would require larger sample sizes to measure the effect of targeted IASTM treatments on ligament mechanobiology.

In conclusion, a portable hand-held device was developed and validated to enable users to apply targeted loading parameters during IASTM treatments. This device can support the optimization of IASTM protocols by investigating the effect of loading parameters on the functional restoration of damaged tissue in animal and clinical research studies.

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