Development of Automatic Manipulation Device for Acupuncture (AMDA)

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***Abstract*—Needle lifting and thrusting manipulation is one of common skills in acupuncture. However, there exists artificial error in frequency and amplitude due to individual difference when performing lifting and thrusting during acupuncture. For providing stable and quantified effects and higher frequency when doing lifting and thrusting manipulation, a well controlled device is needed. The aim of this article is to report the preliminary results of the development of Auto Manipulation Device for Acupuncture (AMDA) and characterization of its functional parameters. A tissue-simulating Agar gel phantom with 4.8%, 5.2%, and 5.4% concentrations was prepared and used for characterization of the AMDA. Tests of the linearity, reliability and safety of the AMDA were implemented with conditions of different drive voltages, frequencies, and simulated tissues. Our preliminary results have demonstrated the developed AMDA its plausibility in the clinical application of acupuncture.**

I. Introduction

It is well known that changes in tissue mechanical properties such as the elastic modulus can be sensitive indicators of pathology. Palpation, the routine physical examination process used by physicians to distinguish between normal and abnormal tissues is a method for qualitative estimation of tissue elasticity. Imaging technique (such as Magnetic Resonance Elastography, MRE) that exploits the shear modulus, or stiffness, of an object have great potential in medical application [1-6]. Changes in mechanical properties may also indicate the physiologic state of the tissue, e.g., relaxed and contracted states of muscle [7-9]. Acupuncture has been used in traditional Chinese medicine for more than 3000 years as a treatment for many diseases, based on the theory of meridian [10-11]. Many previous studies reported manual or electro-acupuncture (EA) have effect for post-stroke recovery [12-14]. In clinical practice and studies, EA is more popular because of its repeatability and feasibility of standardization. Additionally, EA provides successive stimulation in the whole treatment period that manual acupuncture cannot do. However, manipulation of acupuncture is the key point of acupuncture treatment, as described in the book of *Huangdi Nei Jing* (Huangdi Internal Classic) [15]. Some studies compared the effect of manual acupuncture with and without manipulation and revealed manipulation of acupuncture enhanced the effect [16-17]. In addition, lifting and thrusting manipulation is one of common skills in acupuncture. However, there exists artificial error in frequency and amplitude due to individual difference when performing lifting and thrusting during acupuncture. For providing stable and quantified effects and higher frequency when doing lifting and thrusting manipulation, a well controlled device is needed. Therefore, the purpose of this study is to combine MRE and the development of Auto Manipulation Device for Acupuncture (AMDA) to exploit and validate new approach of auto manipulation of acupuncture [18-22] to the treatment efficacy of stroke and lower back myofascial pain syndrome patients. This article presents the preliminary results of the development of AMDA and characterization of its functional parameters.

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II. Material and Methods

A. AMDA setup

The developed AMDA includes a main frame to hold the piezo-electric actuator (SB6020008, APC International, Ltd., Mackeyville, PA, USA), a signal generator (ELVIS II, National Instrument, Austin, TX, USA) and amplifier (EPA-104-115, PIEZO SYSTEMS INC., Woburn, MA, USA) to drive the actuator to generate vibration for the acupuncture needle. The amplitude and frequency of needle's vibration can be adjusted with the signal generator and measured with the laser displacement sensor (CD3S-50, Glory Design, Inc., Buffalo, NY, USA). The corresponding displacement of the acupuncture needle (standard 1.5 inch) was converted into millimeter (mm) and displayed with a user interface written in LabVIEW (National Instrument, Austin, TX, USA). The block diagram of the AMDA and the experimental setup is shown in Fig. 1.

B. Gel Phantom Preparation

A tissue-simulating Agar gel phantom (ST BIO, Inc., Taipei, Taiwan) with 2%, 4%, 4.8%, 5.2%, and 5.4% concentrations was prepared and used in this study for characterization of the AMDA. The gels were prepared by dissolving different amounts of gelatin powder in distilled water. The phantoms used for the characterization testing were made from the same batch of gel. Special care was taken to ensure the homogeneity of the gel phantoms.

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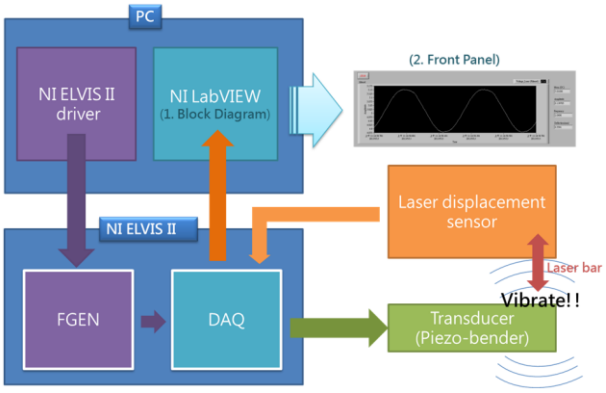


Figure 1. Block diagram of the AMDA and the experimental setup.

A glass beaker (5 cm diameter, 7 cm high) was used to make the gel phantoms for the tests using an acupuncture needle. The tissue-simulating Agar gel phantom with 2% and 4% concentrations, which in general are softer than human being, was used for testing the linearity (applied voltage vs. displacement of the needle) of the piezo-element actuator with or without the Agar gels. The rest of the Agar gels were considered similar to human tissue and used for the reliability tests of the AMDA.

C. *Procedures to Characterize the Functional Parameters of the AMDA*

Tests of the linearity for the AMDA were proceeded under drive voltage of 0-25 V (5, 9, 12, 15, 20 and 25V) and frequency of 0.5-10 Hz (0.5, 1, 2, 4, 6, 8 and 10 Hz) without using gel and with gel concentrations of 2% and 4%. During the test of linearity, displacements of the AMDA for each frequency with six different drive voltages were recorded and repeated five times under the conditions without the gel and with gel concentrations of 2 % and 4%. Mean displacement values and their standard deviations (y-axis) under different frequencies (x-axis) with different drive voltages were measured to see if they were linear. Effect of the media (without and with the gel) on the linearity of the AMDA was also analyzed.

In addition to test the linear functionality of the AMDA, tests of the reliability were verified with reproducibility and endurance tests on the gel concentrations of 4.8% (simulating softer tissue), 5.2% (normal), and 5.4% (harder) as suggested by our clinical collaborators. For the test of reproducibility, displacements of the AMDA for each frequency with six different drive voltages were recorded and repeated three times under the conditions of three simulated tissues. Mean displacement values and their standard deviations (y-axis) under different frequencies (x-axis) with different drive voltages were recorded to see if they were reproducible under two initial insertion depths (3 and 8 mm).

As to the test of endurance, only displacements of the AMDA for two frequencies (2 and 10 Hz) with a fixed drive voltage (20 V) and initial insertion depth (8 mm) were recorded every ten minutes for a total length of 180 minutes under the conditions of three simulated tissues. To simulate the damage on the tissue that is caused by the AMDA, three different combinations of the vibrating frequency and drive voltage (6 V, 10Hz; 15 V, 5 Hz; 24 V, 1 Hz), representing small, medium, and large displacements, with the fixed initial insertion depth (8 mm) were applied to the AMDA to measure the maximum damage areas under three simulated tissues for the durations of 5 and 30minutes. Finally, the safety tests (damage areas on the Agar gel) of the AMDA were measured with the fixed frequency (10 Hz) and two drive voltages (20 and 25 V) for the same three simulated tissues for a length of 180 minutes.

III. Results and Discussion

The aim of this article is to report the preliminary results of the development of AMDA and characterization of its functional parameters. A tissue-simulating Agar gel phantom with 2%, 4%, 4.8%, 5.2%, and 5.4% concentrations was prepared and used in this study for characterization of the AMDA. Tests of the linearity, reliability and safety of the AMDA were implemented with conditions of different drive voltages, frequencies, and simulated tissues. The functional parameters of the AMDA are summarized in Table I.

A. *Linearity tests*

In the test of linearity for the AMDA, mean displacements values and their standard deviations (y-axis) under different frequencies (x-axis) with different drive voltages were measured and shown in Fig. 2. As can be seen, displacement of the AMDA at each individual frequency is in the range of 0.1 and 1 mm, and increased as the applied drive voltage is increased. This linearity can be seen in the results of all three conditions. In addition, there was no effect of the media (without and with the gel) on the linearity, but the effect of the media was seen in the displacements of the AMDA as the concentration of Agar gel is increased. Furthermore, the displacement of the AMDA is decreased when the vibrating frequency is increased.

TABLE I. FUNCTIONAL PARAMETERS OF THE AMDA.

Operating voltage	5 ~ 25	V
Operating frequency	0.5 ~ 10	Hz
Insertion depth	3, 8	mm
Concentrations of Agar gel phantoms	4.8, 5.2, 5.4	%
Average range of displacements	0.045~0.69	mm
Average wound areas of simulated tissue phantoms	< 1	mm^2
Average vertical wound areas of simulated tissue phantoms	< 1	mm^2

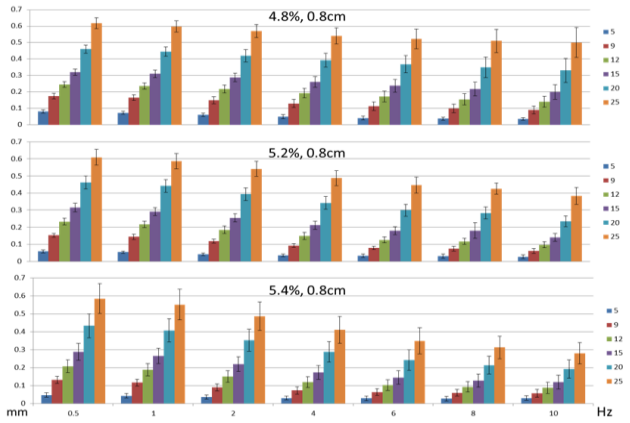
Figure 2. Mean displacements values and their standard deviations (y-axis) under different frequencies (x-axis) with different drive voltages.

B. *Reliability test*

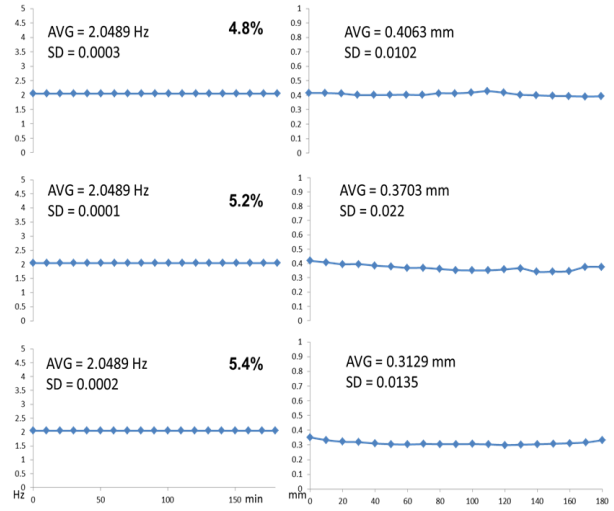
In addition to test the linear functionality of the AMDA, tests of the reliability were verified with reproducibility and endurance tests on the gel concentrations of 4.8% (simulating softer tissue), 5.2% (normal), and 5.4% (harder) as suggested by our clinical collaborators. During the test of the reproducibility, mean displacement values and their standard deviations (y-axis) under different frequencies (x-axis) with different drive voltages were recorded to see if they were reproducible under two initial insertion depths (3 and 8 mm). Displacements of the AMDA under different conditions were recorded and presented in Fig. 3(a). The results in Fig. 3(a) confirm the linearity of the AMDA and show similar effects of the Agar gel concentrations and the driving frequency on the AMDA. As to the test of endurance for the ADMA, displacements of the AMDA for two frequencies (2 and 10 Hz) with a fixed drive voltage (20 V) and initial insertion depth (8 mm) were recorded every ten minutes for a total length of 180 minutes under the conditions of three simulated tissues. The results of Fig. 3(b) verifies the endurance test of the AMDA and indicates that the driving frequency (2 Hz) and displacement of the AMDA over three different simulated tissues and a period of 180 minutes are still consistent. Similar results could be seen also for the driving frequency of 10 Hz.

C. *Damage test on the simulated tissue (phantom)*

To simulate the damage on the tissue that is caused by the AMDA, three different combinations of the vibrating frequency and drive voltage as described previously were applied to the AMDA under three simulated tissues for two durations (5 and 30 minutes) to test the endurance and measure the maximum damage areas. In Fig. 4, only endurance tests of the AMDA with three different combinations of the vibrating frequency and drive voltage under harder simulated tissue for durations of 5 and 30 minutes were shown in Fig. 4(a); and the safety tests (damage areas on the Agar gel) of the AMDA with the fixed



(a)



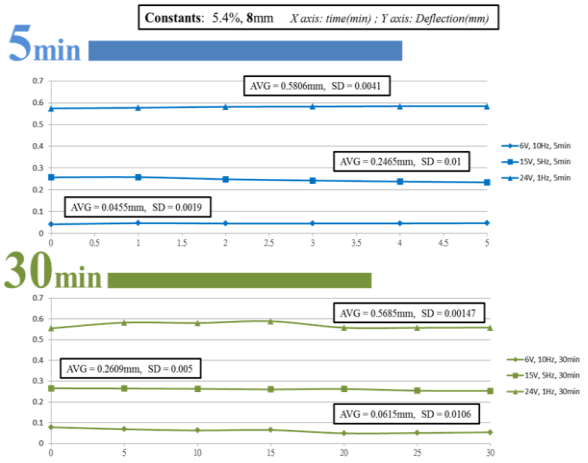
(b)

Figure 3(a) Displacements of the AMDA under different conditions; (b) Displacement of the AMDA over three different simulated tissues and a period of 180 minutes under the condition of the driving frequency of 2 Hz.

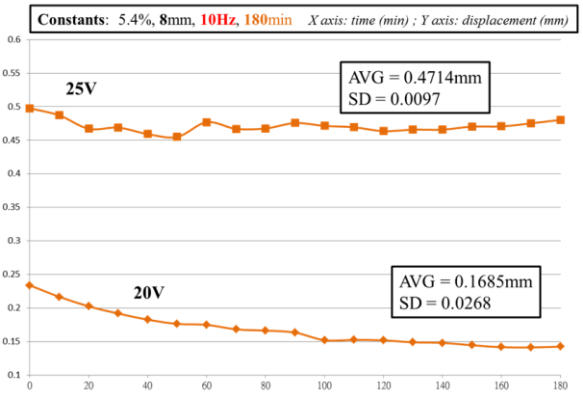
frequency (10 Hz) and two drive voltages (20 and 25 V) for the same harder simulated tissue to last for 180 minutes were measured and reported in Fig. 4(b); finally pictures of the damage areas for conditions of Fig 4 (a) and (b) were shown in Fig. 4(c). As can be seen, the average damage areas due to the worst conditions are in general within 1 mm^2.

IV. SUMMARY

The aim of this article is to report the preliminary results of the development of AMDA and characterization of its functional parameters. A tissue-simulating Agar gel phantom with 2%, 4%, 4.8%, 5.2%, and 5.4% concentrations was prepared and used in this study for characterization of the AMDA. Tests of the linearity, reliability and safety of the AMDA were implemented with conditions of different drive voltages, frequencies, and simulated tissues. The functional parameters of the AMDA are summarized in Table I. Observation of physiological reaction and safety when using AMDA on animal will be the next step.



(a)



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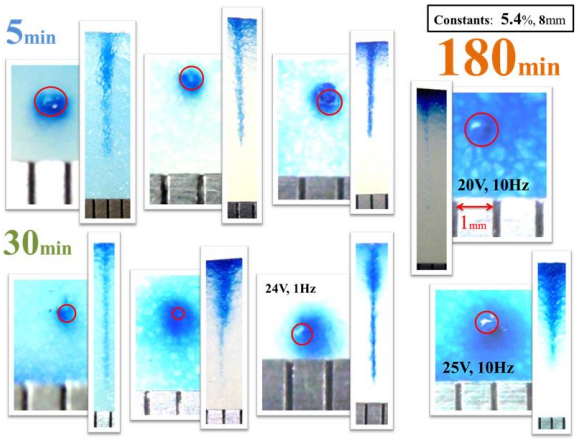

(c)

Figure 4(a) Displacements of the AMDA under three different combinations and two durations; (b) Displacement of the AMDA over three different simulated tissues and a period of 180 minutes under the condition of the driving frequency of 10 Hz; (c) Pictures of the damage areas for conditions of Fig 4 (a) and (b). Red circles identifies the damage areas on the simulated tissue.

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