A Single Electrical Acupuncture Needle with Bipolar Electrodes for Biotissue Discrimination

Giseok Kang[1], Jae-Cheon Kim[1], Sohee Kim[1,2] and Jong-Hyun Lee[1,2]
[1]*Department of Medical System Engineering, Gwangju Institute of Science and Technology, Gwangju, Republic of Korea*
[2]*Department of Mechatronics, Gwangju Institute of Science and Technology, Gwangju, Republic of Korea*

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Abstract: In oriental medicine, acupuncture is an essential treatment for the muscle tissue relaxation. For treatment, electrical stimulations to the tissue conducted with multiple electrical acupuncture needles have generally been used. However, the sting depth of a needle can be handled only by the sense of the oriental medicine doctor. Moreover, it is difficult to use multiple needles to focus the electrical stimulation on a tissue of small volume, and, likewise difficult to distinguish various tissues. In order to overcome the aforementioned shortcomings, we developed a single acupuncture needle that has bipolar electrodes on the surface of the needle tip by using a novel flexible parylene C film photomask. The interdigitated electrodes, 31.25 μm in width and 32.00 μm in gap, were passivated by parylene C film to prevent metal debris from spreading into the tissue. The electrical acupuncture needle was developed based on the conventional acupuncture needle (400 μm in diameter), so that the needle will give a familiar sensation to patients. We demonstrate the metal patterning technique with a high resolution that has less than 2.95 % dimensional error compared to the designed metal pattern dimensions. The biotissues were well distinguished by phase angle at 1 MHz of 14.6°, -32.7°, and 43.6° for skin, muscle, and ligament of a chicken, respectively.

1 INTRODUCTION

Acupuncture is an Asian alternative medicine methodology that uses metal needles inserted into the skin for patient treatment. The treatment, based on traditional medicine theory, insists that human body imbalances, due to unstable flow of the qi, can be controlled by acupuncture (Langevin and Yandow, 2002). Though current scientific research has reported the physiological efficacy of the acupuncture, some studies have still concluded that the efficacy of acupuncture can be explained by the placebo effect (White et al., 2003). In order to clear up this controversy, acupuncture needs more research from the scientific point of view.

Most of acupuncture treatments are focused on muscle tissue relaxation, additionally supported by electrical stimulations (Sandberg et al., 2003). In this conventional stimulation, multiple needles are needed because a single needle acts as only one electrode. When the volume of tissue to be treated is small, it is difficult to use a conventional electrical acupuncture needle to locate the designated tissue in a one shot. Therefore, it is difficult to distinguish between various tissues by means of electrical signals. In addition, the single conventional needle is not efficient in stimulation of the target tissue because the electrical signal tends to disperse into the surrounding tissue. For effective acupuncture treatment, thus, accuracy of detection and localization of electrical stimulation are indispensable.

In this paper, we have developed bipolar electrodes on a single acupuncture needle surface using micro-electromechanical systems (MEMS) technology. In order to fabricate the acupuncture needle, a novel flexible photomask made of parylene C film is used. The flexible photomask is designed to make direct contact with a curved substrate, which makes it possible to pattern the electrodes on the surface of conventional acupuncture needles with high resolution. Parylene C is a material featuring high biocompatibility and good electrical insulation for the electrode passivation.

To validate the developed electrical acupuncture needle, various biotissues (skin, muscle, and

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ligament of a chicken) were characterized in terms of electrical impedance. For steady and precise results, every test was conducted using an automated real-time measurement system under identical conditions.

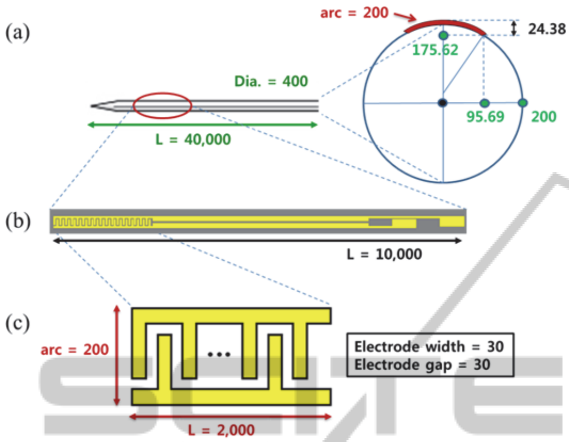


Figure 1: Schematics of the conventional acupuncture needle and bipolar electrodes pattern [dimensions in µm]; (a) overall view of the conventional acupuncture needle (400 µm in diameter, 30 mm in length) and cross-section view of the electrodes on the needle surface, (b) overall view of the bipolar electrode pattern made of Ti/Au (200 µm in width, 10 mm in length), and (c) detailed view of the interdigitated electrode (2 mm in length; both width and gap are 30 µm).

2 DEVICE CONFIGURATION

A flexible parylene C film photomask has been developed to fabricate high resolution patterns on the curved surface of the conventional acupuncture needle, whose diameter can be as small as 400 um. Compared to the previous flexible polydimethly-siloxane (PDMS) photomask (Kim et al., 2009), the patterning capability in this study was greatly improved, showing a smaller pattern size and no cracks in the metal layer. This improved patterning was achieved by locating the parylene masking layer on the neutral axis (geometric centroid of the beam or membrane) that contains no longitudinal stresses or strains (Bedford and Liechti, 2000). The Cr layer (around 150 nm thick) can be located in the centroid of the parylene C layers with a very low eccentricity. This is because the parylene C is deposited by chemical vapor deposition (CVD), which shows a few tens of nm error in thickness (Yang et al., 1998).

The dimensions of the designed electrical acupuncture needle are illustrated in Figure 1. Considering the dimensions of the biotissue under testing the interdigitated electrode (IDE), the electrical sensing part on the acupuncture needle, was designed to have 30 µm both in width and gap, and to have 2 mm in length. The acupuncture needle was electrically insulated by the biocompatible polymer, parylene C (Schmidt et al., 1988). This will also prevent metal debris from spreading into the living tissue during operation. Figure 2 shows the electrical acupuncture needle passivated with parylene C.

3 BIOTISSUE EXPERIMENTS

To evaluate the fabricated electrical acupuncture needle, an *ex-vivo* efficiency test of the biotissues was conducted. Arrows in Figure 3 indicate the biotissues (skin, muscle, and ligament) of the chicken.

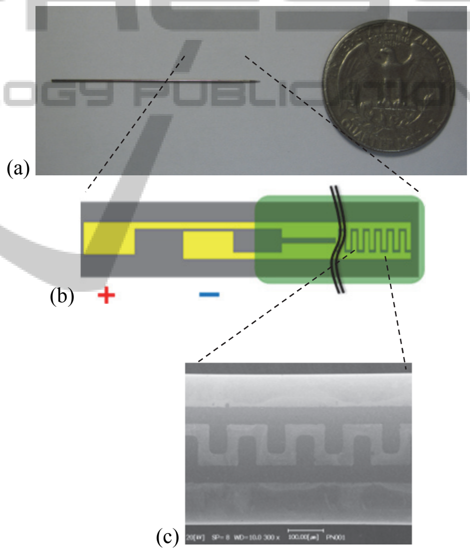


Figure 2: Configuration of the electrical acupuncture needle passivated by parylene C: (a) fabricated electrical acupuncture needle, (b) schematic of the Ti/Au bipolar electrodes (bright yellow), the conventional acupuncture needle (dark gray) and parylene C electrical insulation layer (translucent green), and (c) SEM image of a part of the IDE.

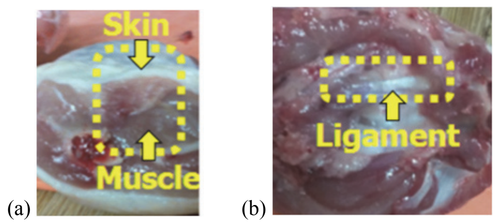


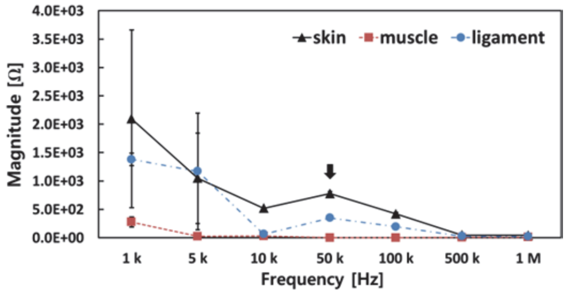
Figure 3: Chicken biotissues: (a) skin (white) and muscle (pink), and (b) ligament (white line).

The test maintained identical environment conditions (room temperature of 26 °C, room humidity of 50%) in a clean booth. The bipolar electrodes of the electrical acupuncture needle were connected to an impedance analyzer (HP4294A, USA) and a laptop in order to automatically measure the electrical signals of the biotissues. Constant voltage (0.5 V_{pp}) and current (0.1 mA) were applied to the biotissues from the impedance analyzer at 7 frequencies from 1 kHz to 1 MHz, as shown in Figure 4. The sinusoidal electrical signal was applied to the electrodes located on the needle through the impedance probe kit (HP42941A, USA). The probe kit performs a 4-wire (or Kelvin) measurement method which automatically compensates the lead and contact resistance to measure impedance characteristics accurately (Siegal and Galloway, 2008). Visual basic for application (VBA) in Excel (Microsoft, USA) was used to control the impedance analyzer and to collect raw data into text files.

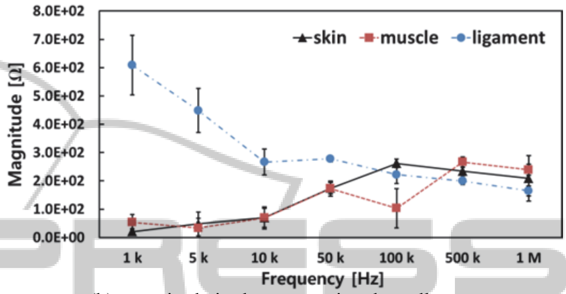
To verify the effectiveness of the developed needle for the biotissue discrimination, a conventional method using two electrical acupuncture needles (separation distance 5 mm) was evaluated as well. The tip of the conventional needle, whose diameter is identical to that of the developed needle, was not electrically passivated

The validation of the electrical acupuncture needles as a sensor was performed by measuring the electrical impedances of various biotissues (skin, muscle, and ligament of a chicken). The electrical impedances of the tissues, the magnitude, and the phase angle were measured, with results as shown in Figure 4. All the data points corresponding to each frequency indicate the average values calculated with 200 data points of electrical response data for each biotissue. Furthermore, the data points, including the error bar (a standard deviation value), are clearly differentiated between the biotissues at the particular frequencies of the components of the electrical impedance.

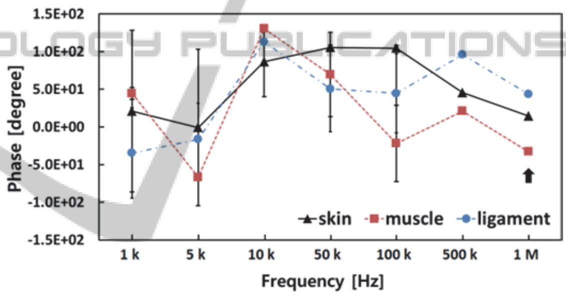
As shown in Figure 4, only the developed needle can distinguish the biotissues both in the magnitude and phase. We believe that the high performance of the developed needle as an electrical sensor is attributed to the electrodes in micro scale. In the test using the bipolar needle, impedance magnitude of the skin is larger than that of the muscle. That can be explained by the fact that electrical signals is easily conducted through each fiber (very large individual cells) of muscle, but the skin is highly inhomogeneous resulting in the most resistive tissue in the human body (Miklavcic et al., 2006).



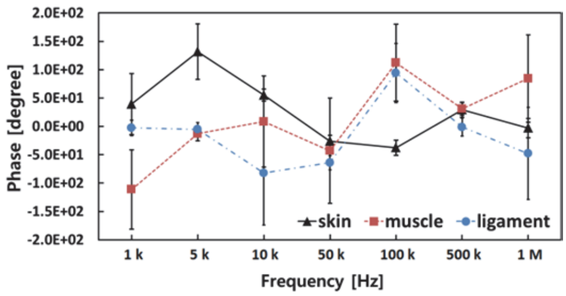
(a) magnitude in the developed needle test.



(b) magnitude in the conventional needle test.



(c) phase angle in the developed needle test.



(d) phase in the conventional needle test.

Figure 4: Electrical impedance responses as a function of the frequency for the skin, muscle, and ligament of the chicken: (a) magnitude in the developed needle test, (b) magnitude in the conventional needle test, (c) phase in the developed needle test, and (d) phase in the conventional needle test. The vertical bars represent the error, defined by the standard deviation. The arrows indicate the frequency at which the differentiation index reaches the maximum value.

In order to quantitatively evaluate the effectiveness of the differentiation, differentiation index (D), was used, as in our previous work:

$$D = G/D_A, \quad (1)$$

where G and D_A are the gap and the average difference, respectively (Kang, Yoo, Kim and Lee, 2012). A negative value of D means that the data points overlapped, while a positive value of D close to 1.0 (the maximum value of D) means that the data points are well distinguished with a low-variance.

To validate the difference of the electrical impedance between the biotissues, the D values were estimated following the sequence of tissues as the needle penetrated the tissues; D_{SM} corresponds to the differentiation index between the skin and muscle; D_{ML} corresponds to the differentiation index between muscle and ligament. The maximum D values of the magnitude and phase angle for the biotissues are summarized in Table 1. The best case for the biotissue discrimination took place for the phase angle at 1 MHz; 0.97 for both D_{SM} and D_{ML}.

The differentiation indices, based on the electrical impedances, were confirmed to have efficiently distinguished the biotissues. This electro-thermal acupuncture needle, integrated with a microheater to focus heat-effects on a localized area, can be a good medical appliance for a precision treatment.

Table 1: Maximum differentiation index values of magnitude and phase angle for biotissue discrimination.

Biotissue	**Differentiation index**	**Magnitude** *at 50 kHz*	**Phase angle** *at 1 MHz*
Skin & muscle	D_{SM}	0.95	0.97
Muscle & ligament	D_{ML}	0.93	0.97

4 CONCLUSIONS

We designed and fabricated a novel electrical acupuncture needle with bipolar electrodes for biotissue discrimination. With the developed acupuncture needle, various biotissues were electrically characterized, and were definitely distinguished at a particular frequency in real-time. It is expected that the developed electrical acupuncture needle with enhanced sensing accuracy will be greatly beneficial to patients.

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