Chapter 6

High-Tech Equipment for Moxibustion in Modern Medicine

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Additional information is available at the end of the chapter

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1. Introduction

1.1. Social background and medical needs

Japan is a super-aging society; year after year, the number of persons older than 65 years of age increases. Because they are frail, elderly persons require treatment methods that best suit their condition. Traditional medicine, which has been handed down and culled throughout history, is one such candidate treatment. Until recently in Japan, moxibustion therapy was provided in most households (Yamaoka, 2001). In recent years, hyperthermia treatment has spread widely in the field of orthopaedics, rehabilitation, and cancer treatment. Typically, medical sites require safe, sanitary treatment methods.

1.2. Characteristics and current practice of moxibustion

Moxibustion is widely used in East Asian countries and has long been a common feature of traditional East Asian medicine (Freire et al., 2005). Moxibustion, which entails the burning of moxa (mugwort), is a very important traditional treatment method that has been practiced from ancient times.

In the clinical practice of moxibustion, different treatment methods—for example, direct moxibustion wherein the moxa is applied directly to the skin, material-mediated (indirect) moxibustion wherein a material is placed between the skin and the moxa, and moxibustion with warming needles (Moxa needle) whereby moxa is applied via needle insertion of the skin —are selected and applied based on the condition of the patient (Beijing Digital Museum of TCM, 2012).

In Japan, there are laws regulating the practice of massage, finger pressure, acupuncture, and moxibustion. At present, there are 85 vocational colleges and 5 universities in Japan (Ido no nippon Editorial office, 2008) and more than 84,629 licensed moxibustion practitioners. The number of qualified moxibustion practitioners is almost equal to the number of physicians in Japan (Ministry of Health, Labour and Welfare-Japan, 2009). There are 71 schools in every prefecture that provide acupuncture and moxibustion training to persons who are visually impaired. For the visually impaired, moxibustion treatment is a challenging skill to learn because the risk of burn injury to patients exists, even in the case of general practitioners (Ministry of Education, Culture, Sports, Science and Technology-Japan, 2006). Simple moxibustion kits can be purchased by anyone in Japan at a drugstore or on the Internet (Sennenq, 2012).

1.3. Scientific research on moxibustion treatment

If, as seems to be the case, moxibustion treatment can be applied in modern medical settings, then it is possible to anticipate greater treatment efficacy. It has been reported that treating acupoint ST25, located on both sides of the umbilicus, with moxibustion helps the intestines become active and improves their function (Tabosa et al., 2004). We have successfully proved that heating the umbilicus increases the volume of blood flow in the superior mesenteric artery by using a heat conduction treatment device that we developed (Takayama et al., 2010, 2011; Seki et al., 2011). Heating the affected area with moxibustion can remedy the condition of acute lymphangitis. It has also been suggested that moxibustion enhances immune function and is an effective way to promote the blood flow of an animal's brain (Shen et al, 2006). However, there is little research that has quantitatively evaluated moxibustion treatment (Kim et al., 2011). Thus, it is critical to conduct a scientific evaluation of moxibustion treatment.

1.4. Issues related to moxibustion treatment

1.4.1. Difficulty of temperature control and invasiveness

It is vital to precisely control the temperature in a scientific evaluation of moxibustion treatment; however, this is quite difficult to do. Moxibustion is invasive because it poses the risk of a burn injury or leaving a scar on the skin, and women in particular would worry about the scar left on their skin. It is said that the skin tissue will degenerate and exhibit low-temperature burns when the temperature exceeds 44°C (Jiang et al., 2002).

It is difficult to ensure safe treatment unless the practitioner has been trained, because the temperature control depends on the experience of the doctor or practitioners of moxibustion in clinical practice. Moreover, patients whose skin has lost the ability to sense temperature are at risk for easily experiencing a burn injury. There is not only the risk posed by the lack of temperature control, but there is also the fact that, due to the impossibility of quantitative temperature control, the optimum temperature for moxibustion treatment and the relationship between temperature and treatment efficacy of moxibustion treatment have not been sufficiently debated.

1.4.2. Unsanitary

Moxibustion treatment is difficult to use in the hospital setting because of the copious amount of fumes emitted, and there was a case in which a patient with asthma experienced an asthma attack in a hospital because of moxibustion fumes. The use of moxibustion requires adequate management of the fumes emitted at hospitals where patients with diverse maladies are being treated.

1.4.3. Procuring equipment and user-friendliness

It is difficult to obtain adequate quality moxa in certain areas. Moreover, practicing moxibustion treatment on-site at clinics is time- and effort-intensive.

2. Purpose

The purpose of this research was to develop a treatment device that is safe; is capable of controlling temperature; does not emit fumes; can be substituted for indirect moxibustion, direct moxibustion, and moxa needle; and thereby evaluate such functions. The purpose of advanced temperature control is to prevent the risk of burning, provide appropriate treatment for each patient, contribute to scientific research on moxibustion treatment and achieve high treatment efficacy as a result.

In this research, we developed a thermo-control device that is capable of controlling temperature by using heat conduction and radiant heat. We have applied this device to many patients in clinical practice and have confirmed its treatment efficacy. Typical cases have been described further.

3. Methods and results

3.1. Device we developed

Our requirements for the device were (1) that it should not emit fumes and (2) be capable of precise temperature control, preventing the temperature from exceeding a certain level for safety. We developed three types of devices with heat conduction and one type with radiation heat (Figure 1).

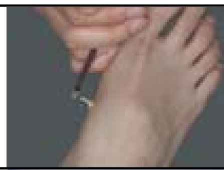
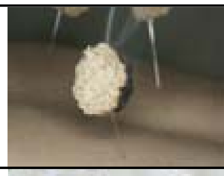
	Indirect Moxibustion	Indirect Moxibustion	Direct Moxibustion	Moxa Needle
Traditional Technic		None		
High-tech Equipment				
	Heat conduction treatment device (Disk shape)	Heat conduction treatment device (Portable Disk)	Heat conduction treatment device (Pencil shape)	Radiation heating treatment device

Figure 1. List of traditional technic and developed devices.

The following text includes information on device configuration and characteristic performance, as well as cases that are adaptable to basic clinical research and intractable cases.

3.2. Heat conduction treatment devices

3.2.1. Heat conduction treatment device: disc shape

We developed the hyperthermia control device using a heating disc with temperature control to replace the salt-mediated moxibustion (Maruyama et al., 2011).

3.2.1.1. Traditional treatment that can be replaced: indirect moxibustion

Problems

The problems of indirect moxibustion include its heating characteristic and the difficulty of controlling its temperature, as well as the great amount of fumes it emits. As shown in Figure 2A, it was difficult to control the temperature and the salt-mediated moxibustion emitted a great amount of fumes. Figure 2B shows the distribution of skin temperature after salt-mediated moxibustion is removed. This indicates a non-uniform distribution of temperature, in which the skin temperature at the centre of the area where salt-mediated moxibustion was applied is high and the skin temperature of the surrounding area is low.

3.2.1.2. Configuration

The heating disc is 100 mm in diameter and made of copper and coated gilding (Figure 3A). As shown in Figure 3B (disc-shaped configuration drawing), the present device is composed of a heating disc and a control device. A thermistor is used for measuring the temperature. The control device is capable of controlling the preset temperature and heating rate. Equipped with proportional control, this device is able to control the temperature without exceeding the

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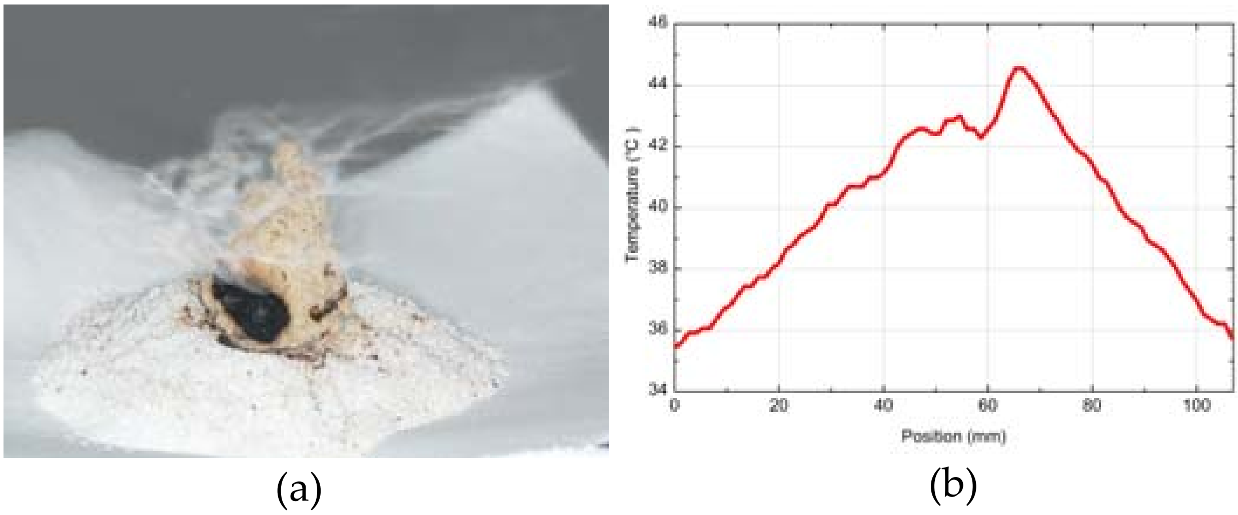


Figure 2. a) Indirect (Salt-mediated) moxibustion. (b) Temperature distribution after the moxibustion is removed.

preset temperature and thus decreases the risk of burn injury. In addition, use of copper, which has a high thermal conductivity rate, as the material for the heating disc can make the temperature on the heating surface uniform.

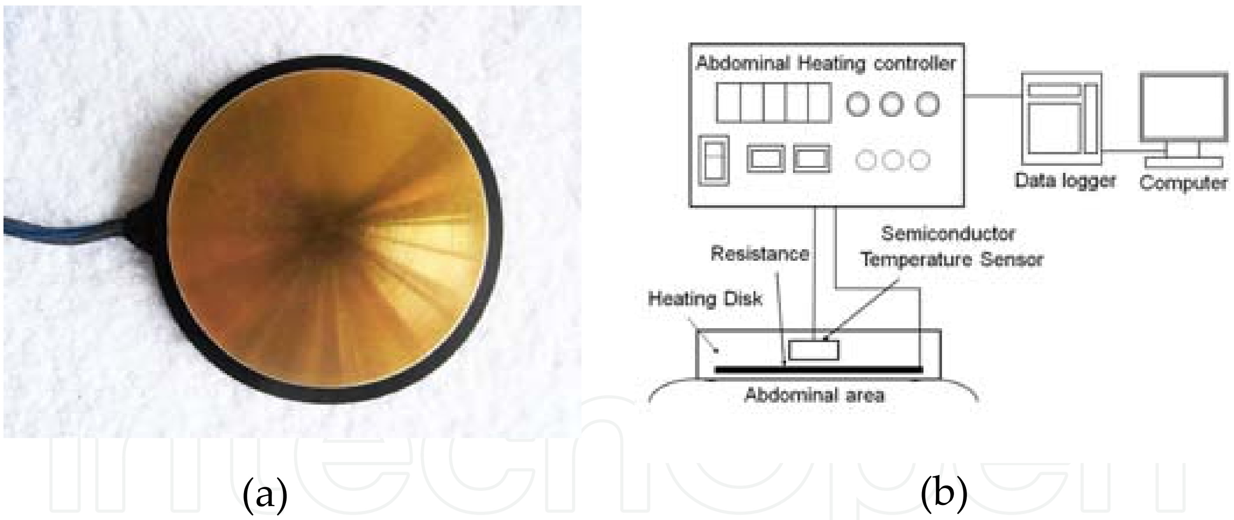


Figure 3. a) A picture of the heating disc. (b) The configuration drawing of the disc shape device.

3.2.1.3. Performance

Heating characteristic

Advanced temperature control within 0.1°C units.

Principle of temperature control

On/off control is used to control the preset temperature and heating rate. Heat is produced by applying a certain voltage to an electrical resistance, while the temperature is controlled by switching the heater power source on/off. Adjusting proportional gain (Kp) and using the on/off switch enables the controller to raise the temperature to the preset temperature within 0.1°C units. By changing the interval for on/off, it is possible to adjust the heating rate.

Figure 4 shows the formula of proportional control to determine the average of heat quantity. T_0 indicates the preset temperature.

$$\bar{\dot{Q}}(t) = K_P\left[T(t) - T_0\right]$$

Figure 4. The formula of proportional control.

Heating rate and achieving temperature

Figure 5A shows that when the four heating rates raised the temperature to the preset temperature of 42°C, all of the rates successfully raised the temperature without exceeding the preset temperature and stayed at the determinate temperature.

Distribution of the temperature on the heating disc

Figure 5B indicates the six temperature measurement points on the heating disc. Figure 5C shows the temperature change at each measuring point after application of heat in thermally insulating condition and indicates that the temperature at all six points changed in a nearly uniform manner.

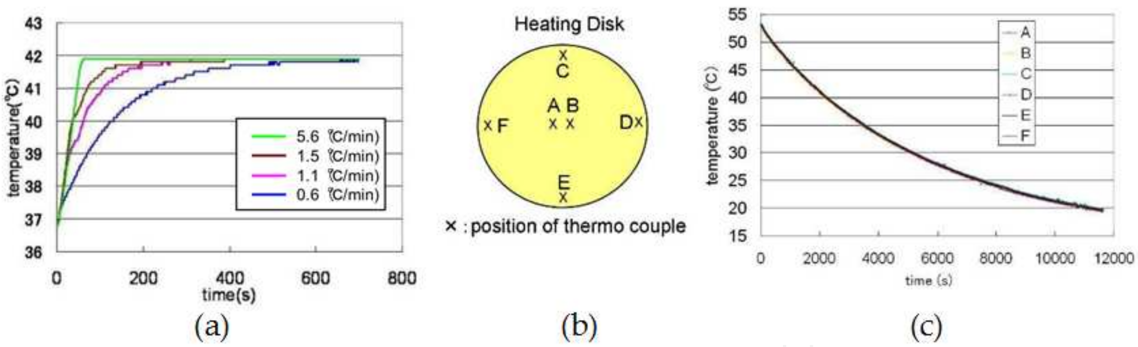


Figure 5. a) Change over time in the temperature of the heating disc. (b) Position of thermocouple. (c) Temperature distribution on the surface of the heating disk.

Temperature distribution on the skin

The distribution of skin temperature after being heated by the heat conduction treatment device on the abdomen is shown in Figure 6A. Temperature was measured using an infrared imaging device (manufactured by NEC Avio Infrared Technologies Co., Ltd., TVS-500). The temperatures within a 10-cm diameter heated by the disc were nearly consistent, which clearly shows the difference between the temperature distribution of the disc and the temperature distribution of the salt-mediated moxibustion, as seen in Figure 2B. Figure 6B is a thermography image of the same areas.

Also, the heating disc is made light enough so that patients feel comfortable when the disc is placed on their abdomens.

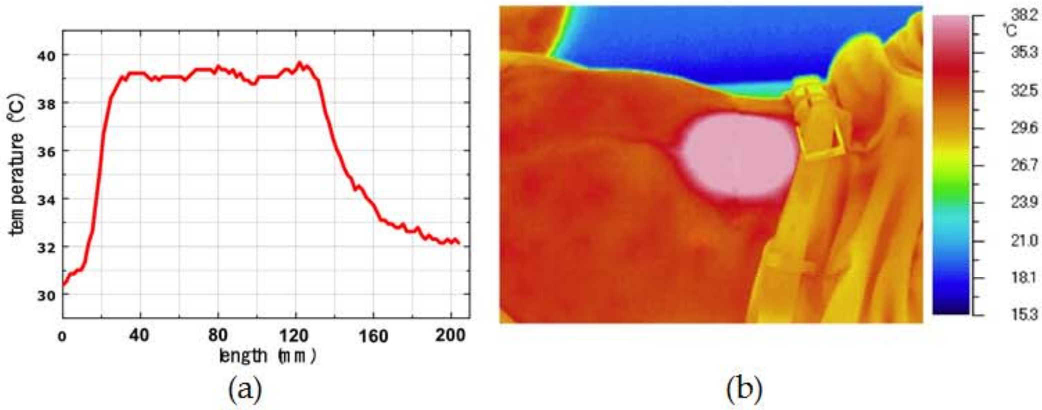


Figure 6. a) Temperature distribution on the skin surface after the heating controller was operated on the abdominal area and then removed. (b) Thermography image of the abdominal area.

3.2.2. Heat conduction treatment device: disc shape (portable type)

We developed the disc-shaped contact-type heating controller in a portable format so patients can easily apply it at home and to enlarge the range of applications of the device. Evaluations were then conducted.

3.2.2.1. Traditional treatment that can be replaced: indirect (material-mediated) moxibustion

Problem

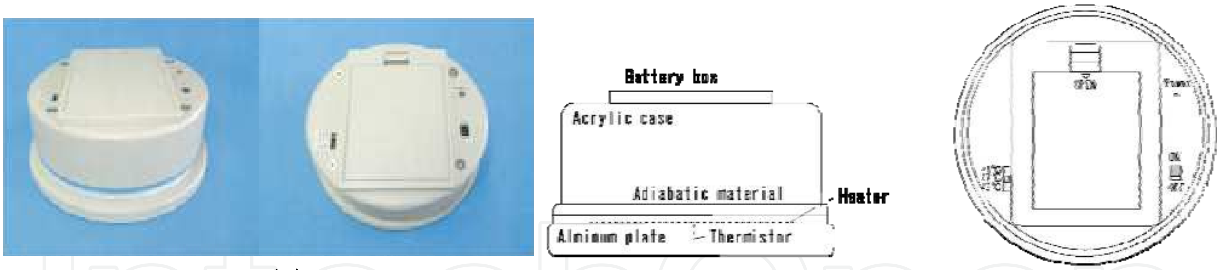
Indirect moxibustion cannot be applied while the patient is moving or unless placed on a level surface. Thus, such a treatment lacks portability.

3.2.2.2. Configuration

Unlike the first device, this device can be used while the patient is moving; thus, its usability has a wider range. This device is portable and enables easy, high-level, safe thermal treatment at home at a low cost. Figure 7A depicts the exterior of the device, and Figure 7B shows the configuration of the device.

3.2.2.3. Performance

The temperature control circuit uses lithium-ion batteries (NP-120 × 2) and is rechargeable. It takes three to four hours to charge the batteries, and the battery duration provides about 20 minutes of use per charge.



(a) (b)

Figure 7. a) A picture of the portable disc. (b) The configuration drawing of the portable disc.

The thermistor is used to detect the temperature, and after amplifying the temperature signal by error amplification and amplification, the heater attached to the aluminium plate is run through the constant current circuit of Power MOSFET. It heats up quickly at a low temperature through the rapid heating circuit and controls the temperature at approximately the pre-set temperature. The temperature can be set between 41°C and 45°C, within 1°C units. The thermostat is used to protect the aluminium plate from overheating.

Heating characteristics

It can achieve the targeted temperature and the temperature distribution on the skin. Figure 8A shows the change in temperature after putting the heater into contact with the skin after about 20 minutes when the heater heats up to near body temperature, under the following conditions: pre-set temperature of 42°C, surrounding temperature of 21.4°C, and humidity of 66.7%. This indicates that when the heater made contact with the skin, the temperature decreased slightly but quickly recovered and maintained a constant temperature. The highest temperature achieved was 42.4°C, with a temperature difference of only 0.2°C between the centre and the periphery.

Research has confirmed that the preset temperature can be maintained at other pre-set temperatures (data not shown). Figure 8B shows the time change after removing the device and the change of skin temperature distribution after the device heated the skin. This indicates that the heated surface maintained a nearly uniform temperature after heating. Figure 8C, 8D shows an image and picture of thermography of the abdominal area after it was heated by the same device. The thermography also confirmed that the treated part was uniformly heated. As a result, this device is deemed to be capable of having the same hyperthermic effect as the stationary type.

Safety

The duration time is limited to prevent overheating in the patient. Once the treatment is finished using the device, it can no longer be used unless it is charged again. By limiting the function in this way, human errors, such as patients excessively heating their skin, can thus be prevented.

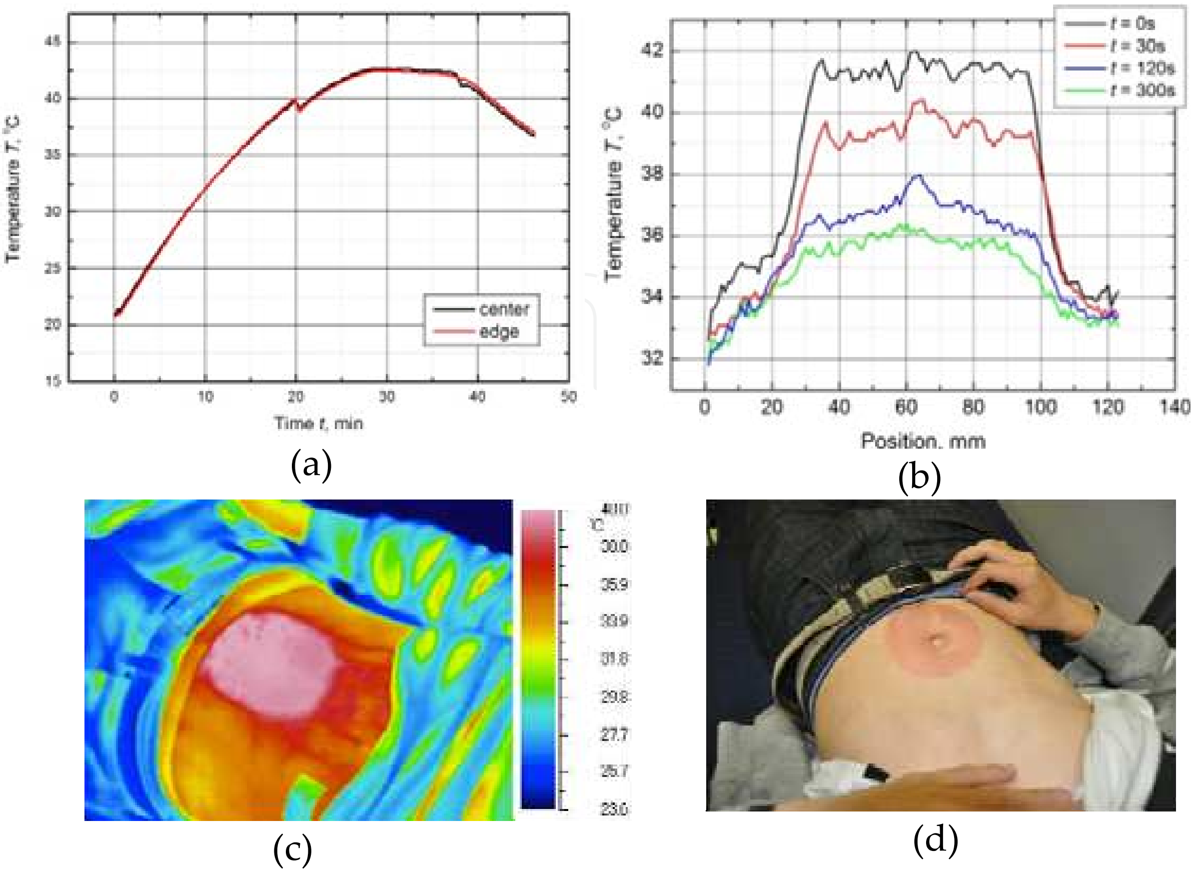


Figure 8. a) Change in temperature of the portable heating disc over time. (b) Time change of temperature distribution around the abdominal area after heating. (c)(d) Image and picture of heat around the abdominal area after it was heated.

3.2.3. Heat conductive treatment device: pencil shape

3.2.3.1. Traditional treatment that can be replaced: direct moxibustion

Problem

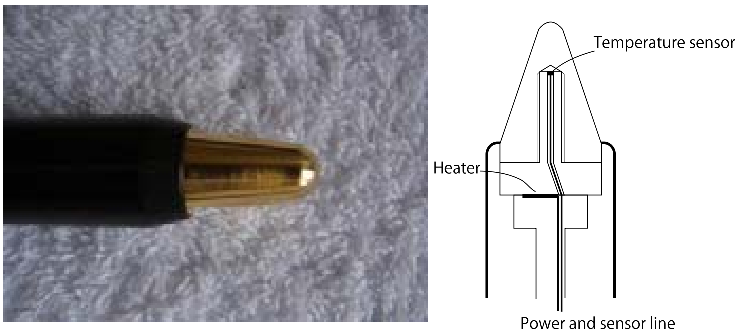
Direct moxibustion requires more experienced clinical practice than material-mediated moxibustion to be safe and effective. Also, the moxa used in direct moxibustion must be smaller and easier to harden than the moxa used in indirect moxibustion. Figure 9 is a picture of direct moxibustion.

3.2.3.2. Configuration

The configuration of the pencil shape is the same as the disc shape, and the heating part is made of copper and coated with gilding. The heating part, which makes contact with the skin, can be replaced with different sizes. Figure 10 shows the configuration and a picture of the pencil-shaped device.

(a) (b) (c)

Figure 9. The procedure of direct moxibustion.



(a) (b)

Figure 10. a) A picture of the pencil-shaped device. (b) The configuration drawing of the pencil-shaped device.

3.2.3.3. Performance

The pencil-shaped device has the same control as the disc-shape device.

3.3. The radiation heating treatment device

We developed this radiation heating treatment device to replace Moxa needle. This device is able to control the temperature to prevent the risk of burn injury and also distributes a consistent temperature over the applied area of the body (Maruyama et al., 2012).

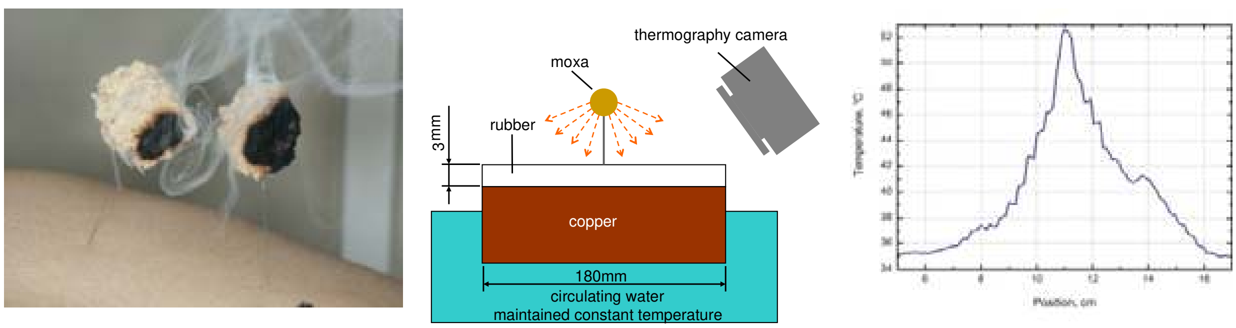
3.3.1. Traditional treatment that can be replaced: Moxa needle

Problem

Moxa needle is shown in Figure 11A. It is difficult to control the temperature. The only way to prevent the temperature from becoming too high is to remove the moxa burning at the top of the needle or to block the radiating heat by placing a piece of paper between the skin and the moxa. Moxa needles are inserted into the patient's body, followed by moxa on the needles, which is then ignited. Therefore, if the patient moves his or her body during treatment and the burning moxa falls on the skin, the patient may experience a burn injury. The risk of burning moxa falling onto the skin occurs when the temperature is being adjusted.

As shown in Figure 11B, a 3-mm-thick silicon rubber membrane with a thermal conductivity of 0.23 W/(m K) is adhered to an 8-mm-thick copper plate. The rubber has an emissivity of (ε) 0.95, which is close to the emissivity of the human body. We used ethanol to prevent air bubbles from forming within the bond between the rubber and the copper plate. We monitored the rubber membrane surface temperature T_{upper} using infrared thermography (TVS-500, manufactured by Nippon Avionics Corporation). At the time, the temperature of the copper plate was maintained at 37.0°C in the thermostat bath. We ensured that the lower surface of the rubber membrane made complete contact with the copper plate and that the temperature T_{lower} was 37.0°C, i.e., equivalent to the temperature of the copper plate. We stuck an acupuncture needle into the rubber membrane and burned the moxa laced on the needle.

Figure 11C shows the distribution of temperature caused by kyutoshin heating of the rubber membrane surface. The figure indicates the temperature distribution when the temperature is at its highest (20 seconds after igniting the moxa) during the burning of the moxa. This graph depicts a certain line on the horizontal axis, which delineates an image taken with an infrared thermograph. This indicates that the temperature at the centre had reached the level that causes burn injuries, while at the same the temperature of the surrounding area remained low.



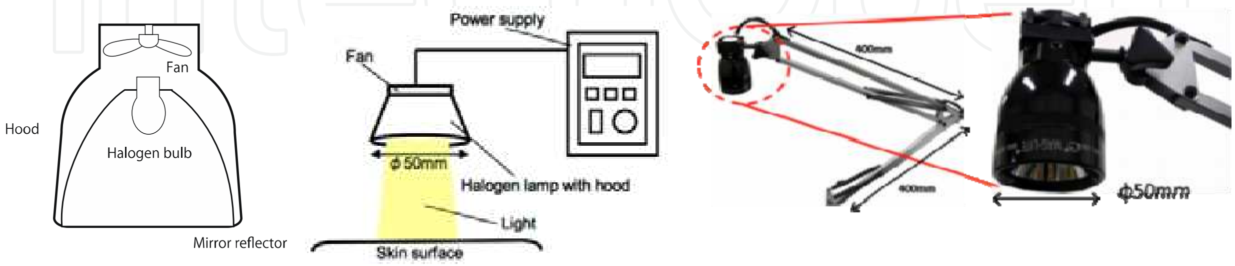
(a) (b) (c)

Figure 11. a) Moxa meedle. (b) Measuring the heating characteristics of moxa needle. (c) Temperature distribution of the rubber membrane heated by moxa needle.

3.3.2. Configuration

We used a halogen lamp with a rated power of 75 W (J12V75W-AXS, manufactured by Mitsubishi Electric Osram), available on the market, as the light source. However, we controlled the radiation intensity by using the power supply device adjustably with a power load lower than the rated power. We used a remodelled Maglite 4-Cell D Flashlight (manufactured by Mag Instrument, Inc.) as the reflection mirror. The reflection mirror is a parabolic mirror, which makes it possible to emit near-parallel light by adjusting the light source to the focal point position of the parabolic mirror. A fan (ICFAN E232190, RED(+), 0410N-12, DC12V, 0.09A manufactured by SHCOH Engineering) attached to the upper side prevents the reflecting mirror from overheating.

Because parallel light can be radiated through fine adjustment of the lighting source position with respect to the reflecting mirror, the temperature can be increased uniformly over the region radiated by the light. Figure 12 shows the exterior and the detailed interior of the radiation heating device developed in this research.



(a) (b) (c)

Figure 12. a) Detail of components in radiation heater. (b) The configuration drawing of the radiation heater. (c) Photograph of the radiation heater.

3.3.3. Performance

Radiation emission intensity

Figure 13A shows the results from measuring the intensity of the radiation emitted from the radiation heating device for multiple applied voltage values using the Fourier Transform Infrared Spectrophotometer: TTIR (FTIR-8600PC, manufactured by Shimadzu Corporation). The horizontal axis is displayed with the logarithmic axis in the figure. In addition, for comparison, the theoretical value of the ideal black body spectrum at 1,500 K is also stated. The radiation heating device showed a characteristic emission that peaks at about 2 μm, which is within the infrared range. This shows the wavelength range that influences the heating effect from the radiation heating device. Based on this, it is thought that radiation penetrates the skin to a certain degree.

Temperature distribution of the rubber membrane from radiation heating

We evaluated the radiation heating device we developed with the same device used to measure the radiating heat of moxa needle moxibustion and conducted multiple measurements by altering the voltage applied to the radiation heating device (Figure 13B).

Figure 13C shows the temperature distribution at the point where the temperature remains steady (about 10–15 minutes after heating). On the other hand, the temperature caused by the radiation heating device did not increase in an absolutely uniform manner. However, the range indicating the maximum temperature is nearly uniform. Figure 13D shows the temperature distribution of the rubber membrane using infrared thermography. This shows heat application at near uniformity of temperature.

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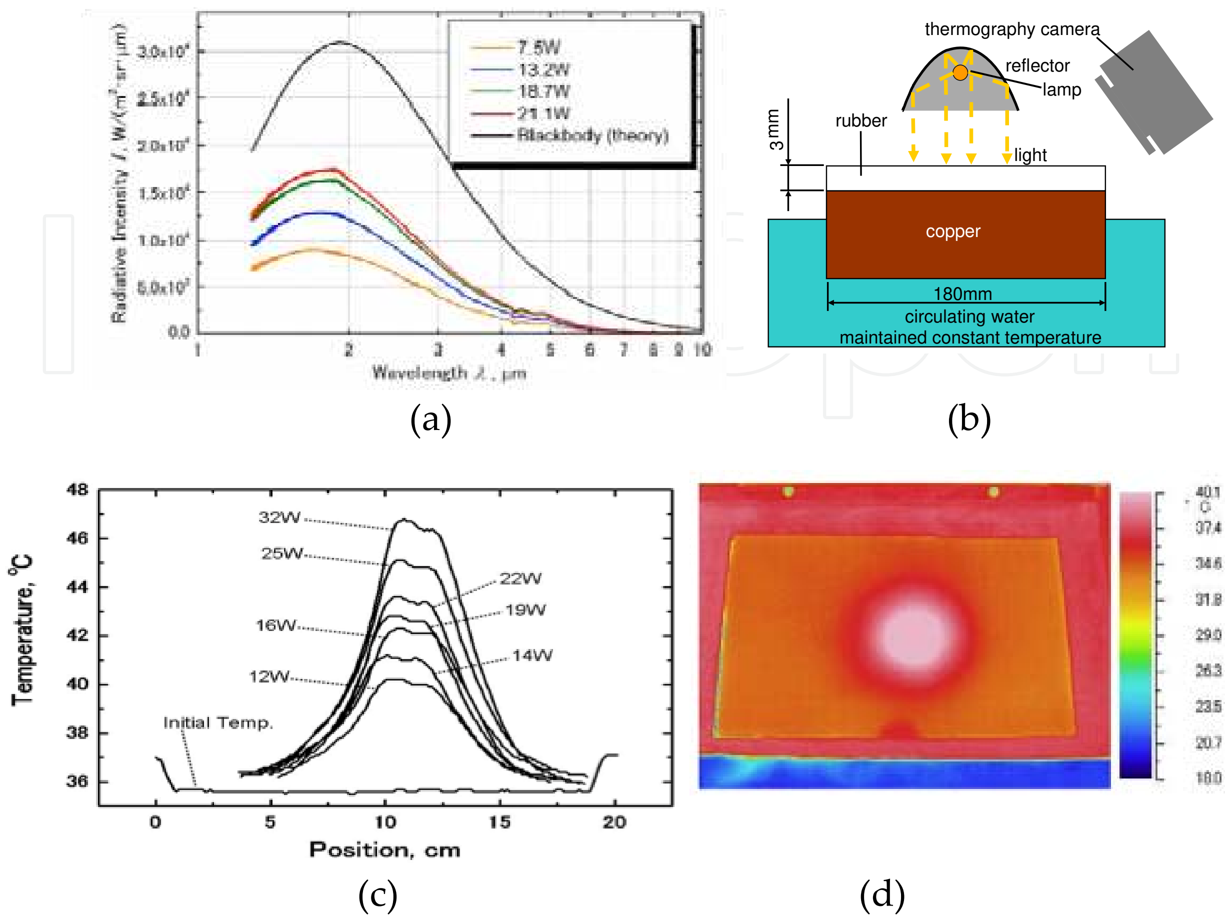

Figure 13. a) Spectral radiative intensity of the radiation heater considering absorption matters. (b) Schematic diagram of the experiment for temperature distribution measurement. (c) Temperature distribution on the surface of the rubber sheet heated by the radiation heater. (d) Thermograph of the rubber sheet heated by the radiation heater.

Advanced control of heat transfer amount

Figure 14A shows the results calculated for multiple applied voltages of the amount of heat transfer from the radiation heating device. The graph is generally linear except for some minor variability. The amount of heat transfer from the radiation heating device can be calculated by the following formula when the approximate curve is determined by plotting the least squares approximation:

$Q_{heater} = 0.155\ Q_{input}$, wherein

Q_{input} [W] is the applied voltage, and the determination coefficient R^2 value is 0.9812.

It is possible to estimate the relationship between the amount of heat transfer and the temperature of the skin at the time of hyperthermia treatment by using this formula.

This finding indicates that it is possible to control the amount of heat transfer by controlling the voltage applied to the radiation heating device. We thus anticipate a precise temperature control within the treated region, which will prevent the risk of burn injury.

Uniform temperature distribution on the skin

Figure 14B shows an image, taken by infrared thermography, of the abdomen of a subject heated by a radiation heater. It was also confirmed that the temperature distribution over the subject's body with the radiation heater was uniform.

The amount of heat transfer and the temperature of the skin

We radiated the subjects with light using the radiation heater and monitored skin temperature using infrared thermography. The abdomen of the subject, lying flat on his back on a bed, was heated by a radiation heater from a distance of 200 mm above. We repeated the experiment multiple times with varied voltages applied to the radiation heater. Further, we conducted the experiments in a temperature-controlled room equipped with air conditioning to maintain the same conditions as much as possible. When applying heat to the human body, it is reported to take approximately 20 minutes for the heat to reach to a stable level (Maruyama et al., 2011; Okajima et al., 2009; Incropera, et al., 2007). In this experiment, we used infrared thermography to monitor the temperature on the surface of the skin and continued the experiment until we observed a stable state with almost no changes in temperature. Hereafter, we deemed temperatures found in this stable state to be post-experiment skin temperature. The temperature indicates the peak value from the temperature distribution. The subjects included five healthy men in their 20s (mean (SD); age: 23 (2) years old; height: 171.4 (2.6) cm; weight: 64.2 (5.1) kg).

Figure 14C is a graph showing the correlation between the heat transfer rate and the subject's skin temperature. As indicated, even after heat has been applied through an identical quantity of heat transfer, the increase in skin temperature varies among different individuals. This suggests that the amount of bioheat varies among individuals. The increase in skin temperature varies between individuals if the body is heated with an equal amount of heat transfer. For example, the difference in the skin temperature among individuals with a heat transfer amount of 1.1 W from the radiation heater varies approximately between 40°C and 43°C.

3.4. Clinical studies

3.4.1. Basic research

3.4.1.1. Variability of temporal and spatial comfort temperature at the time of treatment with a disc-shape heater

Figure 15 shows the relationship between the optimal heating temperature and number of treatments for one subject. Focusing on the distribution of optimal heating temperature, we detected different values each time for each treatment. This finding appears to depend on the subject's surrounding environment, health condition, and mood at the time treatment is received. This particular patient showed a maximum difference of 5°C, which indicates a significant influence.

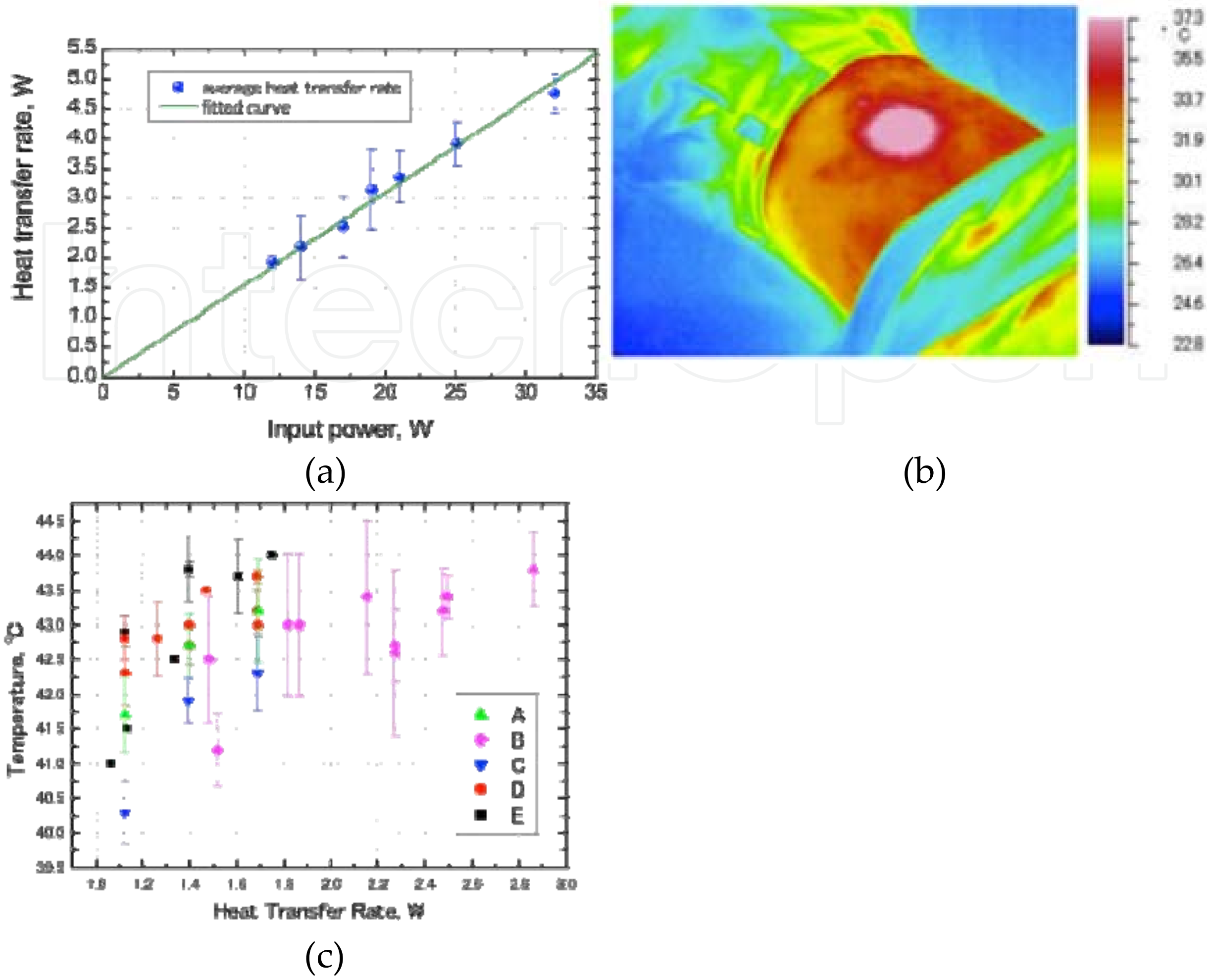

Figure 14. a) Correlation between the radiative heat conduction rate emitted by the radiation heater and input electric power. (b) Thermography snapshot of a subject's skin heated by the radiation heater. (c) Correlation between skin surface temperature and radiative heat transfer rate.

3.4.1.2. Individual difference in comfortable temperature at time of treatment with disc-shape heater

This device, which is able to precisely control the temperature, enabled us to detect the temperature at which a patient feels comfortable, as shown in Figure 16. Each individual has a different level of comfortable temperature that can even vary for the same subject. Figure 16 shows the results from an experiment conducted on 13 subjects.

3.4.1.3. The relationship between patient age and optimal heating temperature with the disc-shaped device

We measured the most comfortable temperature by applying the disc on the umbilical region of 39 healthy subjects. Figure 17 shows the ages of the subjects and the distribution of the temperature, at which they felt most comfortable. We applied the least squares method for evaluation. This graph indicates that elderly people felt most comfortable at higher tempera-

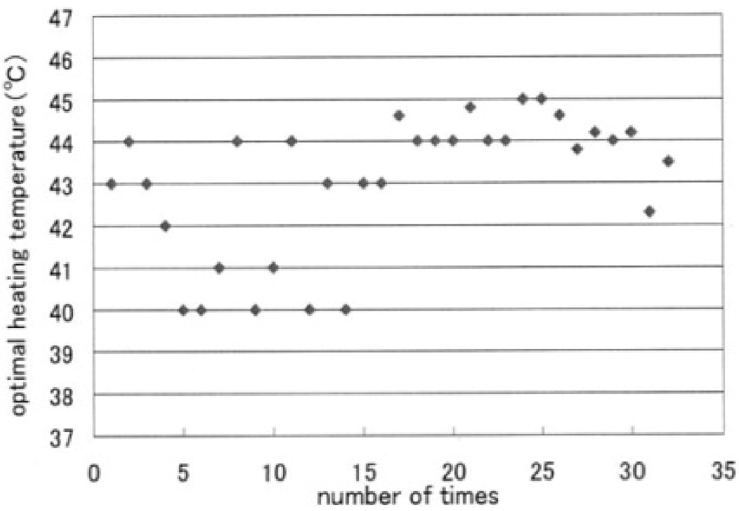

Figure 15. Statistical results of optimal heating temperature of one patient.

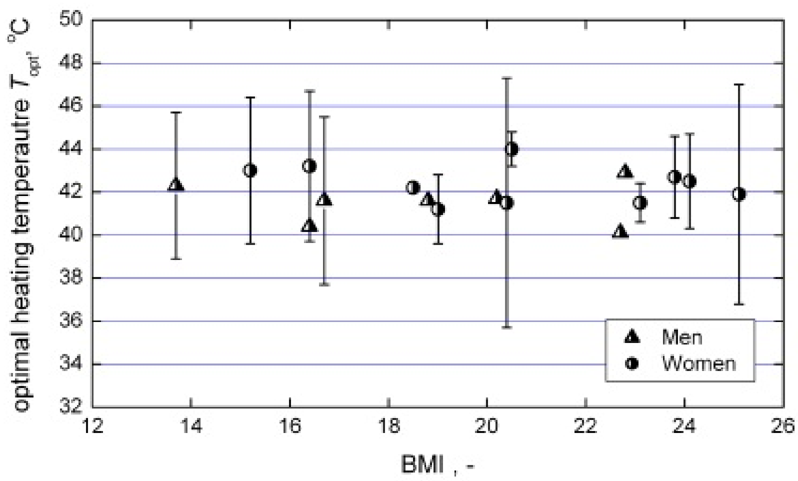

Figure 16. Body mass index (BMI) and the optimal heating temperature

tures. It is possible that an elderly person's sense of temperature is blunted, suggesting that they have a higher risk of incurring burn injury at the time of moxibustion treatment.

3.4.2. Case reports

3.4.2.1. Case of a patient who was unable to eat due to long-term vomiting after cord blood stem cell transplantation for treatment of adult T-cell leukaemia: A disc-shaped heat transfer device was used effectively as treatment

A 49-year-old Japanese woman (height of 150 cm and weight of 54 kg) was referred to our clinic because of difficulty eating. She could not eat any food because she would vomit as she ate, and she felt nauseous just looking at food. She had cacogeusia (bad taste not related to

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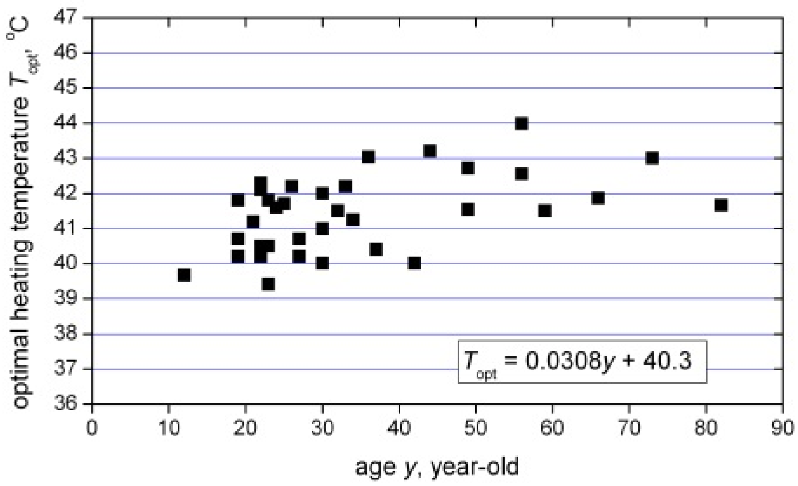

Figure 17. Correlation between subjects' age and comfortable temperature.

ingestion of various substances) and reported symptoms of fatigue, insomnia, finger tremor, and algia at the lower extremities. Medical history: She had an automobile accident 5 years ago. Family history: Father had stomach cancer; her mother had lumbar spondylolisthesis. Social history: She had worked at a supermarket; currently, she is a stay-at-home wife.

Clinical history: The patient received a cord blood stem cell transplant with a pre-treatment of total body irradiation, cytosine arabinoside, and cyclophosphamide on Day -157, due to chemotherapy resistance against adult T-cell leukaemia onset two years ago but had a rejection response. She received a second cord blood stem cell transplant with pre-treatment of fludarabine and melphalan on Day -115. Her state was regarded as remission and she was referred to our clinic from the Department of Hematology and Immunology, Tohoku University Hospital, because complications such as nausea and lack of appetite, which are common after transplantation, did not improve easily.

Internal medicine: The patient was treated with one tablet of tacrolimus hydrate 2.0 mg twice daily, one tablet of omeprazole 20 mg once daily, two tablets of Baktar® (sulfamethoxazole 400 mg, trimethoprim 80 mg) twice daily, Scopolamine butylbromide, Ethyl loflazepate, and Flunitrazepam. Medication adherence: None. Drug allergy: None. Findings of physical examination: left-sided upper abdominal tenderness and a cold lower abdomen. (In Kampo medicine, great attention is paid to the findings of the abdominal examination when determining treatment. If the patient had a cold problem, we would choose a heating treatment such herbal medicine and moxibustion.)

Course of treatment: We started the treatment by heating the umbilicus with the disc-shaped heat transfer treatment device on Day 1. At the time the patient started treatment, she was not able to take anything orally. On Day 8, she was able to eat 30% of the food provided by our hospital. She could eat 50% of the food 24 days after the start of treatment, and she could eat more than 80% of the food on the 29th day. After that, she could maintain eating 50–70% of the food.

Conclusion: The patient underwent heating treatment delivered by the disc-shaped heat transfer treatment device to her navel to treat her eating difficulty after cord blood stem cell transplantation. The patient's prolonged eating difficulty was improved.

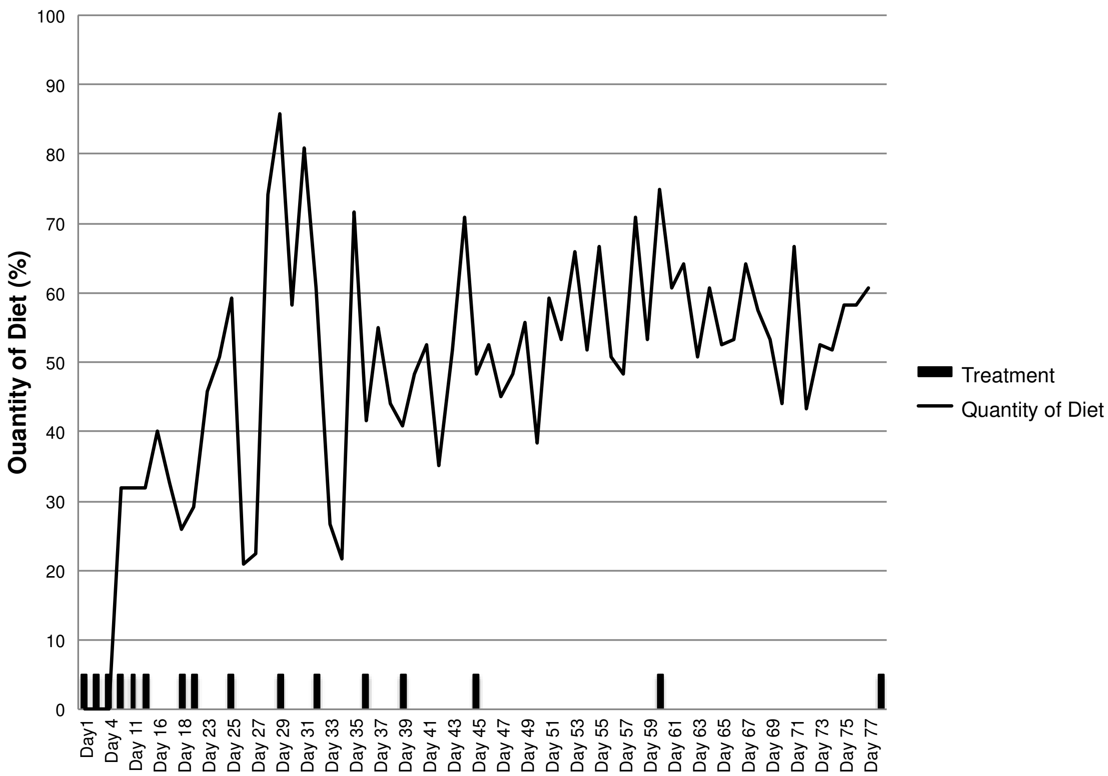

Figure 18. Course of treatment. Percent change of quantity of diet.

3.4.2.2. Case of a patient with refractory melosalgia following an allogeneic bone marrow transplant after extirpation of a granulocytic sarcoma of the lumbosacral spinal cord

A 27-year-old Japanese woman (height of 161 cm, weight of 54 kg) who had been bedridden for some time, started experiencing pain in her right hip through the lower thigh after starting to walk again. She was referred to our clinic due to the intractable nature of her condition. The pain was relieved when heated and worsened before it rained. Also, she contracted a rash on her face when she was physically fatigued or psychologically stressed. Medical history: She underwent surgery for strabismus at the age of 5 and surgery for appendicitis at Sendai Medical Centre when she was in sixth grade. She became easily tired after giving birth to a child three years ago. Family history: unremarkable. Social history: She was previously employed as a corporate worker.

Clinical history: Two years ago, she had been tired because she had to take her child to various hospitals for a cold. She used massaging tools because she felt numbness in her leg, but she had extreme pain on her left sacrum. She received a nerve block at an orthopaedic clinic, but later she experienced problems with menstrual bleeding that was difficult to stop. Last year, magnetic resonance imaging showed a tumour and the patient underwent a tumourectomy at Konan Hospital. Granulocytic sarcoma and acute myeloid leukaemia were diagnosed based on a biopsy for vertebral canal tumor. The patient had a partial response after a course of remission induction and nearly a complete response after receiving a high dose of Cytarabine. However, her prognosis was poor, which led to a bone marrow transplant from her sister with matching HLA. Pre-treatment included 12 Gy total body irradiation and 120 mg/kg Cyclophosphamide hydrate. She showed good progress after the transplant, maintained symptom relief, and completed treatment with immune suppressive medication without developing chronic graft-versus-host disease. However, she incurred prolonged pain in the back and buttocks as well as pain and numbness in the back of the thigh after the tumourectomy that interfered with her daily life if she did not take medication for pain relief. She used nonsteroidal anti-inflammatory drugs (NSAIDs) as analgesics. She was not diagnosed with sciatica, and her symptoms were assumed to be associated with the surgery on the lumbosacral spine. At the time, she was 27 years old and too young to be treated with NSAIDs on a long-term basis. Thus, she was referred to our clinic.

Internal medicine: Baktar® (Day -1), Etodolac 3–1 times/day, Loxoprofen sodium hydrate, Sodium azulenesulfonate. External medication: Hot compress (Nippo Pharmaceutical Industries Ltd.; phellodendron bark, red pepper, menthol, camphor, methyl salicylic acid). Medication adherence: None. Drug allergy: None. Dietary history: She likes fruit. Findings on physical examination: MRI scan did not reveal the cause of the pain.

Course of treatment: We initiated heat transfer treatment using the disc-shaped device on Day 1 (first visit). The treatment was conducted by maintaining the temperature of the device between 43°C and 44°C and applied the heat on her right gluteal area and acupoint GV4 (vital point on the back) for 25–40 minutes each time. We evaluated the intensity of the pain by the dose of Etodolac (oral medication) and using a verbal numeric rating scale (NRS) of 0–10 (Farrar et al., 2008). The pain was relieved after the treatment. However, one hour later, there was a gradual recurrence of the pain. On Day 15 (second visit), the dose of Etodolac 200 mg was decreased from 3 tablets/day on the first visit to 2 tablets/day, and we thereafter detected an alleviation of pain. After Day 16, only one tablet was administered each day; moreover, the frequency of the administration was reduced from every day to less than once every 2 days from the 10^{th} day to the 23^{rd} day. The NRS showed a gradual decrease in pain to 3/10 or 0/10 on Day 39 (10th visit).

Conclusion: We applied heat transfer treatment using the disc-shaped device primarily on the site of pain to treat intractable pain after surgery, which resulted in improvement of the symptom of prolonged pain.

3.4.2.3. A case of patient with intractable stomach pain due to ulceration of the colon caused by Behcet's disease: the portable disc-shaped heat transfer treatment device was used effectively for treatment

A 39-year-old Japanese woman (height of 158 cm, weight of 43 kg) was referred to our clinic because of a stomach ache. She constantly experienced stomach pain, which became most intense during the night. Her symptoms included nausea, fatigue, poor circulation in her leg, stiff shoulder, headache, eye pain, and frequent throat pain. Medical history: Unremarkable.

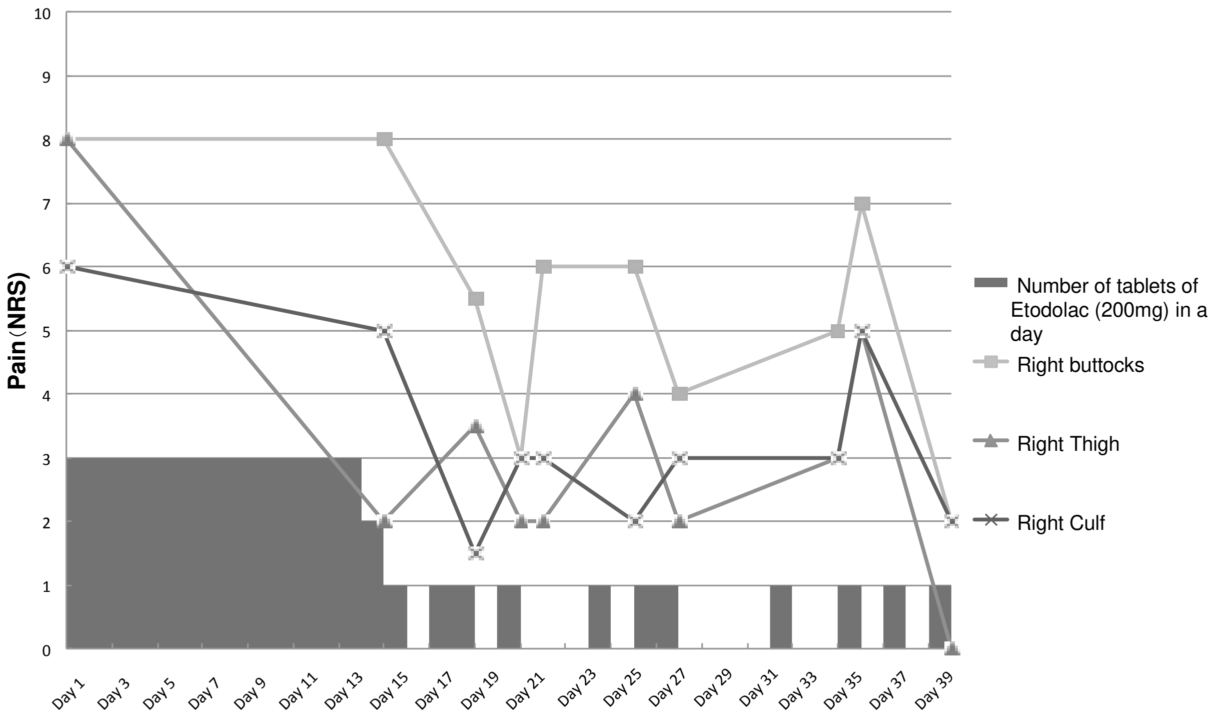

Figure 19. Course of treatment. Change of pain and dose of Etodolac.

Family history: Mother had chronic pancreatitis. Social history: She worked in an office between the ages of 30 and 35, and then became a housewife.

Clinical history: She had stomatitis since she was a child and started having it frequently around the age of 30 years. She was hospitalized due to suspected appendicitis two years ago. She was diagnosed with ulcerative colitis caused by Behcet's disease last year.

Administered medication: Rebamipide 100mg, Miya-BM fine granules 1 g, Mesalazine 250mg, Corticosteroid 9 mg/day since five months ago, and Imuran 50 since ten months ago. Medication adherence: None. Drug allergy: She had a history of an allergic reaction to an analgesic medication at the age of 23 years, when her upper lip became itchy and swollen (except when taking Bufferin®). Dietary history: She likes sweets. Findings on physical examination: Pressure pain in the lower stomach.

Course of treatment: This patient was referred to our clinic. Because her pain became more intense on Day 1, we started treatment by affixing portable disc-shaped heater to the patient's lower abdomen with a corset 1–3 times per day for 30 minutes each time. The pain was reduced after 13 days of treatment, showing that the treatment was effective, and the treatment was discontinued.

Conclusion: This patient's prolonged pain was alleviated by treatment using the portable disc-shaped heat transfer device on the lower abdomen for intractable pain due to ulceration of the colon.

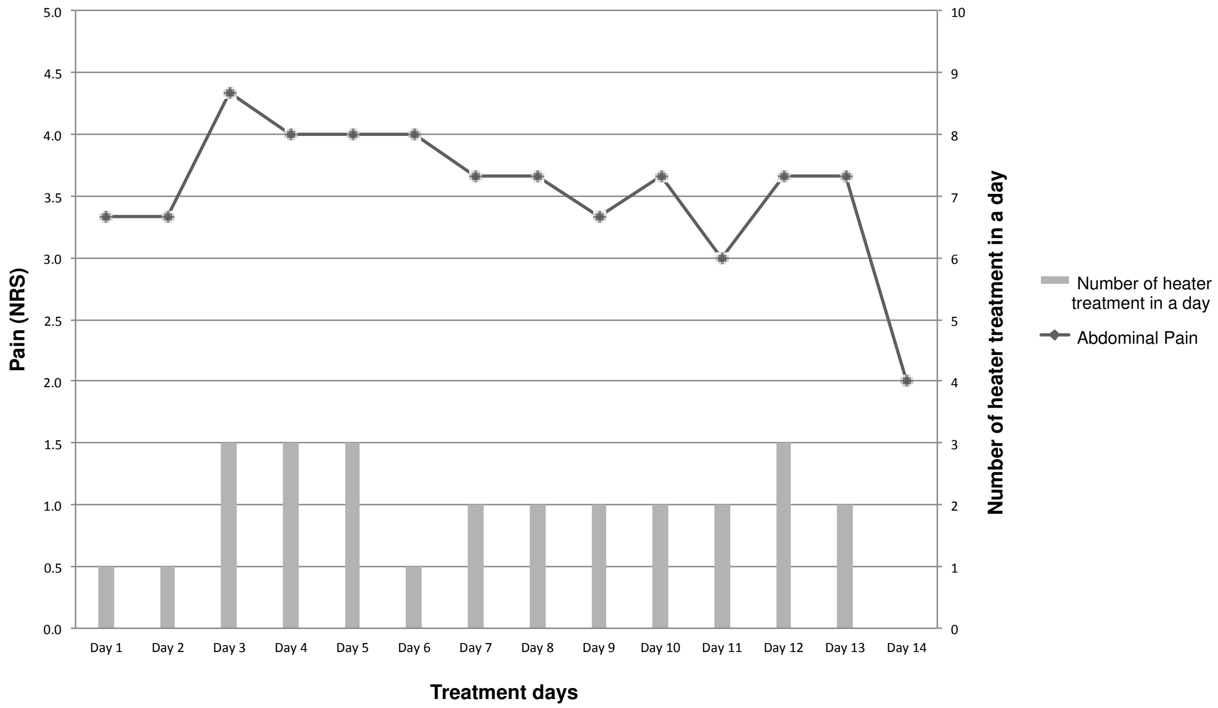

Figure 20. Course of treatment. Change of pain and the number of heater treatment in a day.

3.4.2.4. A case of a patient with cervical and occipital pain after surgery for an extradural cyst tumour in the thoracic vertebra region: Use of the pencil-shaped heater was an effective form of treatment.

A 57-year-old Japanese woman (height of 156 cm, weight of 56 kg) was referred to our clinic because of pain in her right shoulder blade and heaviness in the neck. Her symptoms included headache, shoulder stiffness, dizziness, and weight loss from loss of appetite and tongue soreness. Medical history: Whiplash injury three times in a year eleven years ago. Family history: Her husband is diabetic. Social history: She had been working as a university staff member since she was 18 years old.

Internal medication: Betahistine mesilate, Zolpidem tartrate (prescribed for difficulty sleeping due to pain in the interior shoulder blade), Neurotropin® (An extract from cutaneous tissue of rabbit inoculated with vaccinia virus), Famotidine, Eperisone hydrochloride, Diclofenac sodium capsules 37.5 mg and Bifidobacterium. External medication: Diclofenac sodium suppositories. Health food: She also consumed Barley Young Leaves Green Juice. Medication adherence: None. Drug allergy: None. Dietary history: Unremarkable. Findings on physical examination: Postoperative cicatrix inside the left shoulder blade and on the right shoulder blade.

Clinical history: Postoperative cicatrix of the right shoulder blade, which was exacerbated by coldness after surgery four months ago. From two months ago, the patient experienced heaviness of the neck, headache, shoulder stiffness, and dizziness. And she visited our clinic.

Course of treatment: The pain during the first visit was rated as 8-10 on the numeric rating scale (NRS), and the patient started general acupuncture and moxibustion treatment. She started treatment using the pencil-shaped device on the algesic region, and the pain appeared to be alleviated (Day 1). The pain (NRS) was 8-6 before heater treatment on Day 35. Pain reduction was detected after every treatments. On Day 48, she received treatment with the pencil-shaped device, which helped to alleviate the pain to a rating of 1-6.

Conclusion: The patient received treatment using a pencil-shaped heat transfer device on the algesic region for postoperative intractable pain, and her protracted pain was alleviated.

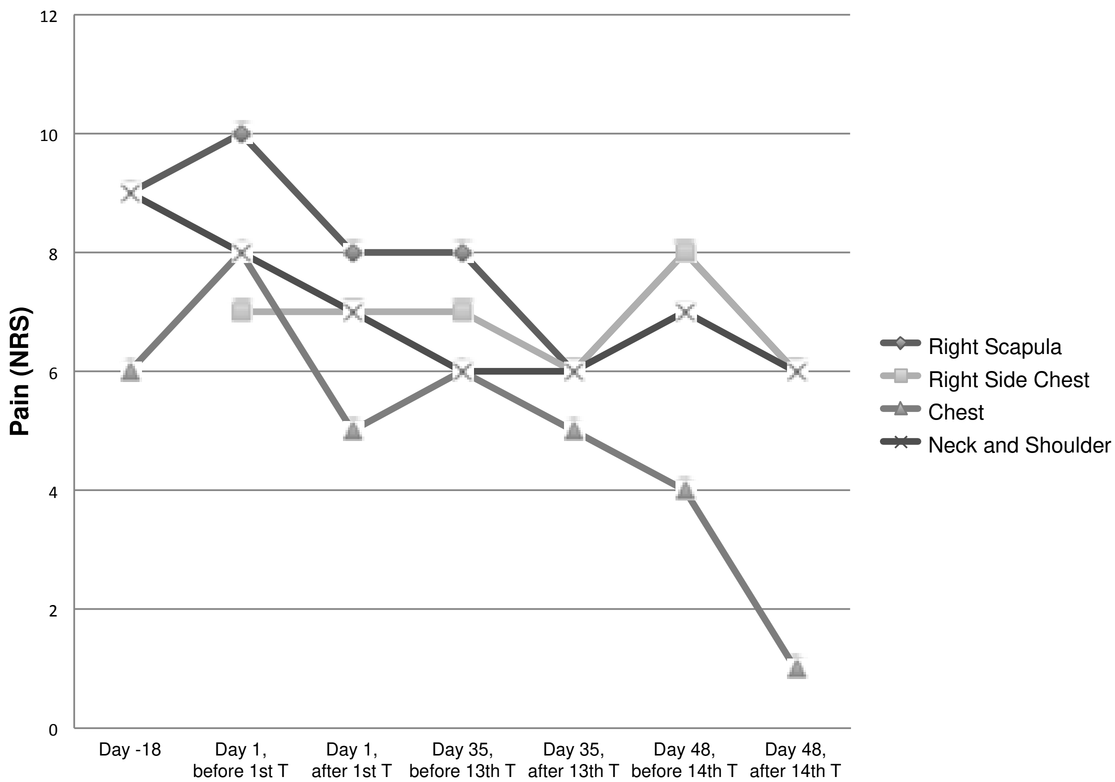

Figure 21. Course of treatment. Change of pain. T: heater treatment.

3.4.3. Adverse events

No adverse events were confirmed in any of the research or medical cases.

4. Discussion

4.1. The merits of the device

There were many comments by patients that the disc-shaped device in particular was very comfortable (data not shown). The heat transfer treatment device has certain features that

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distinguishes it from other medical devices, including patient comfort level, the capability of heating a certain area at a certain temperature, and a precise temperature controller. This device does not emit any fumes and prevents the risk of burn injury.

The portable disc-shaped device possesses the same merits as the stationary disc-shaped device; further, attaching the device with a belt enables it to heat the femoral region, buttocks, and dorsal region even when it is not in a horizontal position, which enables the patient to receive treatment without interfering in his or her daily life. It heats the local area easily and is safe and easy for general users to handle. A smaller-sized version is now in development.

The pencil-shaped device is capable of heating a specific small area using precise temperature control. It can safely heat any part of the body as long as the heater can reach it. Moreover, it can be immediately moved so as to make contact with the skin or can be removed from contact with the skin so that a stimulus similar to direct moxibustion can be achieved. Having a small area of contact with the skin enables application of different temperature stimuli to each region based on the condition of the stimulus region (sensitivity to temperature, intensity of pain). It is also capable of changing the temperature of the contact condition and making instantaneous contact with the skin under certain temperature conditions. Because it is unnecessary to use moxa or ignite it, this makes it possible to stimulate many affected areas (such acupuncture points) consecutively. As a result, it is possible to not only shorten the time for treatment but also alleviate the burden for both patients and practitioners.

The radiation heating treatment device can heat at certain temperatures without making any contact, which keeps the risk of burn injury at a minimum. This device was developed for the purpose of radiation-based treatment of the body without direct contact with or heating of the skin. Because this device is capable of treating the patient without making contact with the skin, the device can be applied to other regions of the body that are difficult to reach during and immediately after surgery.

4.2. Study limitations

This research involved only a limited number of subjects.

4.3. Future studies

We have shown that there are individual differences in the relationship between the amount of heat transfer of the radiation heating device and the temperature on the surface of the skin. Due consideration must be given to fluctuations of time in different individuals and individual differences of tissue heat. As a result, it is necessary to clarify in greater detail the mechanism of heat phenomena in tissue, such as metabolic response to tissue organization of heat transfer and heat stimulation of blood circulation within tissue. However, such individual differences are possible ground-breaking indicators capable of measuring individual health conditions, which makes it necessary to advance research related to the condition of the human body. Although the difference in temperature (as sensed by a patient) between the acupuncture point and the meridian is said to be tied to the diagnosis, it is possible to quantitatively measure this with the pencil-shaped device.

In the future, we will take steps to increase the number of subjects and conduct comparative experiments.

We are in midst of further studies to identify ways to further reduce the size and weight of the portable disc-shaped version of the contact-type heating controller.

5. Conclusion

5.1. Safety and sanitariness

The temperature distribution in moxibustion therapy is high in the centre regions. Accordingly, if no appropriate measures are taken, burn injury is a clear likelihood. We have developed a therapeutic device capable of replacing moxibustion therapy that produces no fumes, is non-invasive, is safe, and avoids burn injuries.

5.2. Effectiveness and indication

The device has proven to be effective for the treatment of protracted pain and digestive system symptoms in some cases, and it has demonstrated identical effectiveness to older techniques.

We have developed heat conduction treatment devices and radiation heating device capable of controlling temperature with a high degree of precision. Such a device makes it possible to achieve a level of effectiveness on par with moxibustion treatment as currently practiced and is capable of evaluating hyperthermia therapy quantitatively. They make it possible to undertake a scientific study of moxibustion.

5.3. Convenience

The device does not require trained skill to use, which means that many more patients can be treated because it is easier to administer than moxibustion treatment.

5.4. Characteristics of the devices

These devices make it possible to set the optimal temperature of acupuncture points for each individual patient, which promises to maximally improve the effectiveness of moxibustion without incident of burn injury.

It also optimizes stimulation of each acupoint or area for each individual by allowing precise control of the amount of stimulation possible, which results in the possibility of greater treatment efficacy.

Furthermore, this device advances scientific research of moxibustion therapy, thanks to the ability to quantify the amount of stimulation.

Because this device is capable of temperature regulation, we were able to obtain clear evidence for the first time. At the present time, we are taking steps to commercialize these devices.

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