

# Thermomechanical Massage Devices used in China and South Korea: A Preliminary Report of Health Outcomes and Side Effects

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## ABSTRACT

**Purpose:** To provide a preliminary evaluation of health outcomes for a type of thermomechanical massage device used in Asia, Middle East, and Europe and now in the United States. The device under study is manufactured by Migun Medical Instruments International (Taejeon, Korea) and has an estimated usage of 24-35 million client-sessions per year worldwide.

**Methods:** findings were obtained from unpublished clinical evaluations of 76 patients (47 female, 29 male; age 16-78 years) across four hospitals in China, and a survey of 238 clients from a Migun demonstration center in Seoul, Korea.

**Findings:** Health professionals in the four Chinese hospitals rated thermomechanical massage as effective among 75-95% of their patients with a variety of musculoskeletal, gastrointestinal, neurological and other disorders. Similarly, 91% of clients from the Migun demonstration center in Seoul reported an improvement of 91% overall. The most common health problems of the clients were musculoskeletal (40%), gastrointestinal (20%), and nervous system (14%). There were also side

effects reported; the most common involved the gastrointestinal (15/41), integumentary (12/41), musculoskeletal (5/41), nervous system symptoms (5/41), urogenital and endocrine systems (2/41), cardiovascular system (1/41), and respiratory (1/41) systems. Side effects were generally mild in severity and short term in duration.

**Conclusions:** Although these findings are preliminary, and based upon limited clinical evaluations and self-reported client data, they suggest that thermomechanical devices may offer major health benefits with moderate numbers of relatively minor side-effects. The next phase of the research will be to confirm these findings in a large, representative sample of thermomechanical massage clients using a new standardized self-reported health and wellness survey before initiating further studies to assess effectiveness of the device under controlled clinical conditions.

**Key words:** *Health and Wellness outcomes measures, cross-cultural health, alternative therapies, thermomechanical massage devices.*

## Introduction

There are a large number of devices on the market, domestically in the United States and internationally, which provide thermal and/or mechanical stimulation of the body. A number of these devices were specifically developed for use in chiropractic. Perhaps the oldest device on the market is the so-called "Spinalator," first trademark registered in 1938, with a number of more recently developed devices arriving on the market in 1954 ("Anatomotor") and 1992 ("Spinalign"); other devices on the market for intersegmental traction, spinal mobilization and back massage include, for example, the Chattanooga ErgoWave, Model CBR Massage Table from Williams Healthcare systems, AME Quest Intersegmental Traction Table

ATT-300 (or IST-300), or the Quantum 400 devices sold by several different manufacturers. These mechanical treatment tables are remarkably similar in design and consist of an upholstered table with a central opening or slot over which a patient lies prone. Operating through the slot, and depending upon the particular device, is a series of rollers or blunted and/or heated or vibrating probes operated by an electric motor; also depending on the device, the patient is alternatively raised or lowered with respect to the probes, or the patient remains stationary and the probes move longitudinally up and down the spine to provide passive motion relief of muscle tension, ligamentous rigidity, vascular stasis, edema and general relaxation.

Recently, another group of devices has emerged, primarily in Asian countries, with considerable anecdotal evidence of health benefits, but these devices lack supporting documentation. This latter group of devices has increasingly been used for self-directed health care in the United States, and is sold through a variety of commercial and web-based outlets.

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In an effort to explore the health effects surrounding this latter category of devices and examine the cross-cultural aspects of self-directed health care, the present study targets a large group of users who are presently utilizing the electromechanical and thermal massage machines manufactured by Migun Medical International, Taejeon, South Korea. This preliminary report summarizes the basic findings of several unpublished clinical evaluation in China and a survey conducted in South Korea. The preliminary data indicate that these electromechanical massage beds were helpful in reducing musculoskeletal pain, improving digestion, appetite and bowel function (i.e., decreased constipation), and relieving neurological symptoms including improved insomnia, headaches, and dizziness. Additionally, this paper also attempts to document the adverse events (side effects), reported by users. Finally, the findings of this study have been also used to construct a client demographic and symptom reporting form, which together with a standardized health and wellness outcomes survey,<sup>1</sup> are currently being administered at randomly selected Migun demonstration centers throughout South Korea and the United States. Results from this larger survey will be reported in the near future.

*Innovative Promotion Strategies for Thermomechanical Devices:* Financial barriers are often cited as limiting access to medical services for those without medical insurance coverage, or covered patients with limitations on outpatient services.<sup>2</sup> We were, therefore, particularly interested in the innovative promotional strategy used to market the Korean thermomechanical devices. Accordingly, the corporation has established about 400 "Demonstration Centers" in the United States and internationally in regions with large Korean populations. Although ownership and management of Demonstration Cen-

ters is not restricted, the overwhelming majority of centers are owned and operated by Korean nationals. Moreover, access to the centers is unlimited. Community residents are allowed access to the devices at the demonstration centers free of charge, and for as long as they like, without undue pressure to purchase the equipment for home or office use. In terms of utilization, some clients use the equipment several times daily, whereas others only 3-4 times per week. The centers are heavily utilized averaging from 200-500 clients per day/center, 6 days per week, with the average sessions requiring 25 min. The total utilization is estimated at 24 - 35 million-client visits/year to Migun demonstration centers worldwide.

The innovative promotion strategy has also promoted support groups for users. Access to the equipment is in a non-clinical setting, whereas as many as 20-40 thermomechanical massage beds are utilized by clients at one time for synchronized sessions lasting 25 minutes each. This group atmosphere is also relaxing and friendly for users, where they can also share their health problems and outcomes with others at the demonstration centers. The demonstration center also provides a transitional environment for the users to become owners. Eventually, about 10% of the demonstration center clients go on to purchase the equipment for home or office use.

The demonstration centers also provide culturally appropriate services, including Korean magazines, newspapers and folk music. Not surprisingly, these demonstration centers have served as social gathering places. As a consequence, this corporate marketing strategy, free access and multinational ownership, creates a unique age, gender and ethnic demographics. According to the Migun marketing data, elderly females with multiple health problems have been the predominant group of users dur-

**Table 1: Number of patients by clinical disorder and by hospital: unpublished data from China.**

Type of disorders/ ailments	Percent	Number of patients	Sources of patients
Spondylosis	33%	25	4
			6
			6
			9
Herniated lumbar disc, sciatica	36%	27	3
			7
			4
			13
Back pain	9%	7	2
			3
			2
Joint pain (osteoarthritis)	16%	12	7
			5
Sever menstrual pain	1%	1	1
Muscle ache from cold	1%	1	1
Chronic gastric disorders	4%	3	1
			2
			1
	100%	76	

ing the initial few years the thermomechanical devices were marketed. There has been an increase in younger users such as younger females who seek help with menstrual pains and improvements in complexion, and middle age professionals seeking reduction from stress. One of the long-term goals of our research is to document the trends in self-directed Complementary and Alternative Medical (CAM) care and the shift from disease care to prevention and wellness care: There has been a major trend towards more CAM utilization in the United States,<sup>3-5</sup> but this trend has not been documented in Asia.

*Migun Thermal-Mechanical Stimulating Devices:* There have been three principal models of the Migun thermal-mechanical stimulating device designated as models HY-700, HY-3000 and HY-5000. The HY-700 device is the smallest and is a hand-carried model consisting of 4 helium bulbs in a hand-held probe. The HY-3000 model is used with a Migun Bed and consists of a hand-held 5 helium bulb probe, and a bed on which another 5 helium bulb probe is moved horizontally to massage the back, from occiput to sacrum, of the recumbent client. The Migun HY-5000 model is the largest, and this model includes 2 mounted probes each consisting of 5 helium bulbs moving along the spine and another 5 helium bulbs on the hand-held probe. The HY-5000 model, like the HY-3000 model, is used in conjunction with the Migun Bed; but the HY-5000, unlike the HY-3000 model, is intended for the treatment of two regions of the body at the same time. There is a fourth model (HY-7000) that is newer and has additional options to massage the legs and calves.

According to the manufacturers, these devices were designed based on acupuncture theory originating in China more than 2,500 years ago.<sup>6</sup> According to the principles of Oriental Medicine, energy circulates throughout the body along well-defined pathways, or meridians. Points on the skin along these pathways are connected to specific organs, body structures, and organ systems. There are two major meridians on the back targeted by the thermomechanical probes: the midline "Governing Meridian" overlying the spinous process of the vertebrae and the "Bladder Meridian" situated 1 in. paramedian, running along the distal parts of the transverse processes of the vertebrae. According to acupuncture theory, acupoints along these meridians are used to treat the *Zang* and *Fu* organs. *Zang* organs include the liver, heart, spleen, lung and kidney. *Fu* organs include the gall bladder, small intestine, stomach, large

intestine and bladder. Through needling (acupuncture) or focal pressure (acupressure) along spine, practitioners of Oriental medicine hope to stimulate energy (Qi) balance on these organs to restore health in these organs. Developers of the device argue that the heating probes act upon the acupoints and meridians, similar to moxibustion, to influence health but there are no research studies to support these claims, hence, the need for this report and several other studies to follow.

## Materials and Methods

This preliminary report summarizes the findings of several clinical reports from China and patient-centered survey data collected in South Korea.

*Data and Clinical Evaluative Criteria from China:* The unpublished reports, completed June-August 1998, were written in Chinese and were translated by one of the authors of this paper for further analysis. Four Hospitals in China provided reports on clinical observation of effectiveness of thermal treatment device, Migun stimulation bed (HY-700) in 1989. These four hospitals were Beijing Tongren Hospital, Beijing Medical University; China-Japan Friendship Hospital, Beijing Chemical Industrial Hospital. Total number of patients treated was 76 and 47 of them were female.

Evaluation criteria for treatment effectiveness of disorders and ailments with Migun stimulation bed (HY-700) used in three hospitals (Beijing Medical University; China-Japan Friendship Hospital, and Beijing Chemical Industrial Hospital) were consistent. Evaluative criteria were: (a) *Completely recovered:* pain disappeared and function restored, (b) *Effective:* clear signs of improvement, pain reduced significantly and basic function restored, (c) *Somewhat effective:* Pain somewhat reduced and partial function restored, and (d) *Ineffective:* Symptoms remain the same and functional abilities restricted.

*Data and Clinical Evaluative Criteria from Korea:* A second data set was collected in 1998 from a Migun demonstration center in Seoul, Korea utilizing the newer thermomechanical (HY-3000, HY-5000) devices that combines the hand-held heating probe (HY-700) evaluated above with a bed on which the client lies while a second heated probe is mechanically moved up and down the spine from the occiput to the sacrum. Clients were asked to complete a short survey with the open-ended questions: "What was the status of your health before Migun;

**Table 2: Number of patients by clinical disorders and effectiveness of improvement:**

"Specified" indicates subsample of Chinese hospitals (Beijing Chemical Industry Hospital, China-Japan Friendship Hospital) reporting outcomes by category. The other two Chinese hospitals surveyed, "unspecified", (Beijing Medical University, Beijing Tongren Hospital) did not report effectiveness by category.

Type of disorders/ ailments	Completely recovered	Effective	Somewhat Effective	Ineffective	Specified	Unspecified
Spondylosis	1	4	4	1	10	15
Herniated lumbar disc, sciatica	5	5	5	1	16	11
Back pain	1	1			2	5
Joint pain (osteoarthritis)	1	3	2	1	7	5
Sever menstrual pain	1				1	0
Muscle ache from cold	1				1	0
Chronic gastric disorders		1	1		2	1
SUB TOTAL	10	14	12	3	39	37
Percent	26%	36%	31%	8%	100%	

what is the result after using Migun?" The survey was voluntary, and clients were provided ample time and space to complete this questionnaire.

Survey forms were collected from 238 users; 76% were females, 24% were males. The survey participants ranged in age from 26-91 years (average age = 65.3 ± 12.5 years). This represents an estimated 32% of those users attending the center during the two one-month survey periods (February, 1998; August, 1998). The average duration of utilization for this population was 15.7 ± 13.4 weeks (range 1-88 weeks).

For comparative purposes with the data from China, a similar effectiveness scale was constructed to score the client responses, with the exception that the two effectiveness categories in the hospital trials ("effective," and "somewhat effective") were collapsed into one category termed "effective". A final category was extracted from the open-ended questions—namely, any patient self-report of initial reaction (undesirable health outcomes) from use of the device. The resulting four categories were: (a) *Completely recovered*: pain disappeared and/or function restored, (b) *Effective*: clear signs of improvement; pain reduced significantly and basic function or partial function restored, (c) *Ineffective*: Symptoms remain the same and activity restricted, and (d) *Undesirable*: Side-effects (or initial reactions) that were defined as a new health problem or exacerbated presenting complaint thought by the patient to be linked to use of the device.

## Results

*Findings Based on the Chinese Clinical Reports:* Results from the clinical pilot studies in China are summarized in Tables 1-2. Beijing Medical University reported a total effectiveness rate of 75% among the 20 patients evaluated, and considered clinical treatment outcomes with the Migun stimulator devices as "satisfactory". Clinical effectiveness was defined as the number of patients reporting "favorable" or "somewhat favorable" results divided by the total number of patients. China-Japan Friendship Hospital reported a total effectiveness rate of 90% among the 20 patients evaluated. Beijing Chemical Industrial Hospital reported the highest effectiveness rate, 95%. In the report from the Beijing Tongren Hospital, patient satisfaction was noted and clinical effectiveness of the Migun stimulator bed was rated as "pronounced". However, only two hospitals (the China-Japan Friendship Hospital and the Beijing Chemical Industry Hospital) classified patients with the evaluation

criteria for treatment effectiveness. Table 2 summarizes total number of patients by types of disorders, sources of patients and reported outcomes.

*Findings Based on the preliminary survey conducted in Korea:* The clients from the Demonstration Center in Seoul reported an overall effectiveness score of 91%. That is, among the 238 clients there was a total of 766 reported symptoms before starting care (i.e., average 3.2 conditions/person) (Table 3), and of these there was a self reported improvement in 694 health conditions (i.e., 91% effectiveness) across the group (Table 3-4).

Self-reported health outcomes were divided among eight categories (Table 3-4), including: musculoskeletal, gastrointestinal, nervous system, cardiovascular, integumentary, urogenital and endocrine, respiratory, and other major organ systems. By far the most commonly reported presenting complaint (Table 3), representing 40% of the total, was among the musculoskeletal ailments (e.g., back pain, arthritis, leg spasm, restricted range of motion, etc), followed by gastrointestinal (20%) (dyspepsia, gastritis, constipation, appetite, etc.), and nervous system (14%) (insomnia, headaches, dizziness, tinnitus, etc.). The remaining complaints each constituted less than 3-8% of the total.

As summarized in Tables 4, Migun technology was reported as producing "complete recovery" in 11% of reported health problems, was "effective" in 80%, and "ineffective" in only 9% of the patient-reported health concerns. Additionally, the 238 clients reported a total of 41 side effects attributed to the use of thermomechanical massage beds, corresponding to an average side-effect rate of 0.17 side effects/person. The most commonly reported side effects involved the gastrointestinal (15/41), integumentary (12/41), musculoskeletal (5/41), nervous (5/41), urogenital and endocrine (2/41), cardiovascular (1/41), and respiratory (1/41) systems as shown in Tables 3-4. Most of the adverse events were short-term and hence we use the term "initial reactions". The new symptoms consisted either of general health concerns (flatulence, constipation, diarrhea, abdominal pain) which resolved within several days of continued use, or rashes or itchy skin which came in contact with the heated probe—these latter skin conditions required longer (1-2 weeks) to resolve. Other adverse events included an initial increase in severity of back pain before showing improvement with time, or transient pain in the ribs, posterior chest wall, and knee or gluteal region. The nervous system and cardiovascular complaints consisted of dizziness, insomnia, sleepiness, or one case

**Table 3. Self reported Health Outcomes by body system. Unpublished data from Korea**

Health problems reported by body systems	Complete		Effective		Ineffective		Side effects	
	Count	%	Count	%	Count	%	Count	%
Musculoskeletal system	20	6%	254	82%	34	11%	5	12%
Gastrointestinal system	20	13%	126	82%	8	5%	15	35%
Nervous system	22	20%	76	68%	13	12%	5	12%
Cardiovascular system	6	10%	46	77%	7	12%	1	3%
Integumentary system	9	20%	37	80%	0	0%	12	29%
Urological and endocrine systems	2	5%	32	84%	4	11%	2	6%
Respiratory system	3	10%	21	70%	6	20%	1	3%
Other	1	5%	19	95%	0	0%	0	0%
<b>Total</b>	<b>83</b>	<b>11%</b>	<b>611</b>	<b>80%</b>	<b>72</b>	<b>9%</b>	<b>41</b>	<b>100%</b>

of conjunctival bleeding in a 68-year-old hypertensive female, whereas the other endocrine complaints were one reported case of painful menstruation as a rebound from dysmenorrhea, and one reported increased incidence of common cold. All initial reactions disappeared with continued use, and occurred in subjects reporting good results with other symptoms.

## Discussion and Conclusion

This preliminary report suggests major self-reported health benefits of the hand-held and thermomechanical massage beds. The major areas of health outcomes reported by clients using the device in the hospital trials or demonstration centers were: reduced musculoskeletal pain, improved digestion, appetite and bowel function (i.e., decreased constipation), and neurological symptoms including improved insomnia, headaches and dizziness. The client-reported undesirable health outcomes or side effects, were also documented. They were relatively minor and of short duration.

Effectiveness scales are used extensively in medicine to measure patient improvement across a number of outcome measures, e.g., verbally administered numerical (or visual analog) scale for acute pain,<sup>7</sup> self-reported medical status,<sup>8</sup> quality of life,<sup>1,9</sup> psychological status,<sup>10</sup> cognitive and behavioral changes in neurodegenerative diseases,<sup>11</sup> psycho-educational and medical interventions in specific diseases such as adolescent diabetes.<sup>12,13</sup> Such scales are evaluated by the practitioner, the patient or a suitable third-party (e.g., parent, caregivers, school teacher). And, although such measures have been criticized as being subjective, they play an important part in clinical practice, particularly in evaluating clinical treatment progress and during early phases of evaluating new interventions and techniques. In the present report, effectiveness scales were evaluated in two formats; one involving third party evaluation of effectiveness by a physician (the hospital results in China), and another involving self-reported effectiveness by the patient (patients in demonstration center). The professional judgment of the practitioner adds to the credibility of the findings in the third-party assessment effectiveness. On the other hand, the data obtained from Seoul on patient self-report is important because it provides valuable information on health belief and behaviors across multiple bio-psycho-social domains of health,<sup>1,4-5</sup> information that is typically not part of the medical assessment process.

The practitioners in China reported a high level of clinical effectiveness of the thermal therapy relative to a variety of musculoskeletal complaints. The overall effectiveness rating for complete recovery was 26%, and for partial effectiveness (36% + 31% = 67%; Table 2) and in only 8% was thermotherapy ineffective. Similar results have been obtained in a variety of physical therapy settings where heat was administered (see below). Similarly, the overall effectiveness from patient self-report in Seoul was 91% and only 9% ineffective. One must keep in mind that the first set of results from Chinese Hospitals were obtained by the smaller hand help thermal devices only (HY-700), whereas the latter from Seoul were obtained with the thermal devices incorporated into the massage table (HY-3000, HY-5000).

*Thermotherapy:* Warmth is associated with pain-relief and relaxation. In physical therapy, locally applied heating agents are used not only to promote relaxation and provide pain relief, but they are also used to increase blood flow, to facilitate tissue healing, and to prepare stiff joints and tight muscles for exercise.<sup>14-18</sup> The many thermotherapy devices fall into one of two broad categories, surface heating (e.g., heat packs, paraffin, infra-red lamps) and deep heating modalities (e.g., ultrasound, short-wave, microwave diathermy). Superficial heating agents such as hot packs, paraffin wax, fluidotherapy and presumably the thermomechanical massage devices provide heat to superficial structures to a depth of only several centimeters.<sup>19</sup> Deep-heating agents, including short-wave diathermy and continuous-wave ultrasound, can increase tissue temperature at depths ranging from 3-5 cm without overheating the skin and subcutaneous tissues.<sup>20</sup> Because it employs a modified infra-red thermal source, and has a measured wavelength of  $.75-1.0 \times 10^{-3} \text{ M}$  produced by a ceramic/nephrite heating chamber containing a helium and jade stone media,<sup>21</sup> heat from the Migun device should penetrate to greater depths than conventional superficial heating agents but this assumption has not been evaluated experimentally.

Temperature is the critical variable determining the effectiveness of thermotherapy, but studies show that heat applied to skin has a complex influence on the temperature of deep target tissues. Therapeutic effects and reduced muscle spasm were reportedly optimal with temperatures of 40° – 45° C at the deep target sites;<sup>14</sup> substantial analgesia effects were obtained with slightly lower values of 38° – 42° C. In terms of vascular effects, minimal changes in blood circulation were achieved with 41° C and maximum circulatory changes with 45° C.<sup>22</sup> However, to achieve these temperatures in the depths, the skin temperature must be correspondingly higher. With conventional surface heating (infra-red lamp or hot packs) devices, research shows that the temperature of surface skin rises to peak temperature of +8° C within 10 minutes, stabilizes at around +7° C, and gradual decreases to +2° C above pre-treatment temperature within 30 minutes after removing the heat source.<sup>23</sup> Similarly, subcutaneous fat (1.1 cm below skin) gradually rises and stabilizes to a peak temperature of +3° C within 15 minutes and, gradually decreases to +2° C above pre-treatment values when the heat source is removed. In contrast, the temperature of muscle (2.0 cm below skin) shows a gradual rise to peak and stabilized at only +1° C. Upon cessation of radiation, it generally decreases to +0.5° C above pre-treatment. The penetration of surface heating modalities is relatively low, and there is generally no measurable temperature change greater than 2.0 cm below the skin surface.<sup>16,24</sup> Interestingly, if the blood supply to the muscle is compromised (by application of a tourniquet to the limb), the temperature can rise an additional 3° C with surface heat application or a fall of 3° C fall in temperature with cold application to the skin surface.<sup>25</sup> These added thermal effects with compromised circulation are likely to occur because the tourniquet blocks deep tissue circulation with the result that the heat sink effect of circulating blood is lost.

To the extent that the bodies normal core temperature is around 37° C, and skin temperature varies between 28° - 31° C, the temperature of subcutaneous and other deep structures vary

**Table 4. Self reported Health Outcomes, Data from Korea**

Health outcome measure	Complete recovery	Effective	Ineffective	Side effects
<b>MUSCULOSKELETAL SYSTEM</b>				
Pain in extremities	8	96	14	2
Pain in back, neck, & thorax	8	88	13	2
Pain in joints	3	38	6	0
Difficulties walking, restricted range of motion	1	23	1	0
Lordosis and kyphosis	0	7	0	0
Sciatica	0	2	0	1
<b>GASTROINTESTINAL SYSTEM</b>				
Dyspepsia, gastritis, ulcers	6	55	3	0
Constipation, diarrhea, flatulence	8	39	4	8
Appetite	3	12	0	0
GI pain, nausea, vomiting	3	18	1	7
Inflamed gums	0	2	0	0
<b>NERVOUS SYSTEM</b>				
headache, general stress	1	27	1	0
insomnia	11	17	2	2
blurred vision, excess tearing, dry eye, tinnitus	1	16	2	0
dizziness (vertigo)	6	6	0	3
depression	2	4	0	0
tremor, festination	1	2	5	0
facial pain, weakness	0	2	2	0
paralyzed arm from CVA	0	2	1	0
<b>CARDIOVASCULAR SYSTEM</b>				
blood circulation (numbness, tingling)	0	24	0	0
blood pressure, palpitation, angina	6	20	7	0
atherosclerosis, cholesterol	0	2	0	0
conjunctival bleeding	0	0	0	1
<b>INTEGUMENTARY SYSTEM</b>				
skin rash, fungal infections, itching, painful skin	7	21	0	12
rough skin, scar revision	0	5	0	0
bruising, general skin circulation	0	5	0	0
hair loss, nail growth, warts, age spots, eczema	2	6	0	0
<b>UROLOGICAL AND ENDOCRINE SYSTEMS</b>				
diabetes	0	11	3	0
frequent urination (polyurea), retention, incontinence	1	9	0	0
menstrual (dysmenorrhea, discomfort)	1	4	1	1
urinary tract infection (kidney, bladder)	0	4	0	0
immune status (e.g., incidence colds)	0	2	0	1
thyroid anemia	0	2	0	0
<b>RESPIRATORY SYSTEM</b>				
dyspnea	2	12	5	0
allergy and sinuses	1	7	1	1
respiratory ease (general)	0	1	0	0
rhinorrhea	0	1	0	0
<b>OTHER</b>				
fatigue, general health (relaxed state)	1	10	0	0
obesity	0	9	0	0
<b>Sub total</b>	<b>83</b>	<b>611</b>	<b>72</b>	<b>41</b>
<b>Percent</b>	<b>11%</b>	<b>80%</b>	<b>9%</b>	<b>100%</b>

between these limits; the deeper the tissue, the closer the temperature to actual core temperature. Therefore, to raise the target tissues to the therapeutic range between 40–45° C, the temperatures applied to the skin must be slightly higher to provide the required temperature gradient. However, the upper limit of skin surface temperature for the clinical effect is very close to the side effect range. There are reports of thermogenic pain with

skin temperatures of 44.5° ± 1.3° C, and skin damage has been reported with surface temperatures of 46° – 47° C.<sup>26,27</sup>

**Deep tissue massage (mechanotherapy):**

A large number of studies have evaluated the effectiveness of massage in a variety of conditions including depression, attention disorders, pain syndromes,<sup>cf. 28</sup> menstrual discomfort,<sup>29</sup>

hypertension and blood glucose regulation in Diabetes Mellitus,<sup>30</sup> migraine headaches,<sup>31</sup> Bulimia,<sup>32</sup> and among preterm infants, where they are shown to sleep better, show greater weight gain and develop optimal cognitive and motor development.<sup>33-38</sup> Other studies have shown that the massage effects are likely mediated by improving immunity and increasing the activity levels of the bodies natural "killer" cells,<sup>39-41</sup> promoting general stress relief,<sup>39</sup> improving circulation, decreasing blood pressure, promoting lymph drainage<sup>29</sup> and a number of favorable psychological changes (e.g., fosters peace of mind, promotes relaxed state of mental alertness, fosters feeling of well-being, reduces social aggressiveness, anxiety and increases awareness of mind-body connection).<sup>28,42</sup> Various mechanical methods have appeared to complement the traditional manual techniques and have been evaluated in a variety of circumstances.<sup>cf. 43</sup>

Manual therapy techniques are different from mechanical massage beds under study, thus it is difficult to compare these two modalities directly. Not surprisingly, however, many of the reported benefits are similar to those well-documented changes in patients undergoing massage therapy, e.g., pain reduction, improved circulation and digestion, etc. Moreover, the overall effectiveness rating of 91% obtained with the hand-held lights (Studies from Chinese Hospitals, Table 1-2) are virtually identical with the effectiveness scores with the combined heating probes and thermomechanical massage bed, as self-reported by Migun users (Korean study, Tables 3-4). Thus, it is difficult to discern if there are additional benefits from the mechanical massage. Carefully designed controlled experiments will be required to evaluate the therapeutic advantage of the thermomechanical devices, i.e., are the effects attributable to the mechanical and/or thermal properties of the intervention, and is there an additional benefit to its regular use in a relaxed social setting such as in the demonstration centers. Certainly, to the extent that health and wellness contain bio- psycho- and social components,<sup>1</sup> each contributing substantially to a state of patient belief about their health, i.e., wellness,<sup>4,5</sup> it is reasonable to conclude that the social components of Migun thermotherapy as practiced in the demonstration centers adds to the overall health outcome. Clinical studies on this topic will be conducted in controlled, randomized clinical trials.

### **Principles of Oriental Medicine:**

The thermomechanical massage probes provide pressure and heat to the paraspinal region with a second probe applied locally to the front of the body on the thorax, abdomen and other regions. These regions of the body generally correspond to the acupuncture meridians of Oriental Medicine, treatment of which produces local changes and effects on the deep organs. Although this correlation has been made largely on historical reference, there is modern scientific evidence to support the correlation between clinical application (acupuncture, pressure, etc.) to the back and anterior meridian points and clinical changes in the Zang-Fu organs. As pointed out in the Introduction, the acupuncture points along the back traveled by the probe belong to the Governing Meridian (GB) and Urinary Bladder (UB) meridian. Activation of these points by needling, pressure (acupressure) or heating elicit positive changes in deep organs.<sup>44</sup>

<sup>46</sup> For example, chronic neck pain was compared in a random-

ized clinical trial comparing acupuncture, laser acupuncture and massage.<sup>47</sup> These authors found that acupuncture of the spine (UB10, UB60, GB20, GB34) and other distal points on the limbs (SI3, L3, TB5) produced greater reduction of neck pain short-term than massage therapy. Studies in animals and man show that the antinociceptive effect of acupuncture is blocked by naloxone,<sup>48-51</sup> suggesting that the antinociceptive effects of acupuncture derive from central release of naturally occurring opioids.<sup>52</sup> Indeed, recent fMRI studies in humans by Hui and colleagues<sup>53</sup> found that acupuncture stimulation producing pain relief also decreases activity in limbic nuclei (nucleus accumbens, amygdala, hippocampus, parahippocampus, hypothalamus, ventral tegmental area, anterior cingulate gyrus) in all subjects treated. Modulation of these structures may be important mechanism by which acupuncture exerts its complex effects on pain and related sensory perception and may be one mechanism by which thermomechanical massage alters pain thresholds.

Side-effects with use of thermomechanical beds: A frequent complaint of new users of thermomechanical massage devices is local pain and discomfort as the probe passes slowly over various parts of the spine. Often, these sensations outlast the treatment and can persist for several hours or days, the deep joint discomfort and pain for even longer. However, pain and discomfort appear transient and in most cases, resolve with continued use. Parenthetically, deep tissue pain and discomfort is a common side effect of rekindled use of a neglected muscle group or joints being worked outside their usual range of motion

Some spinal pain from use of the thermomechanical bed is understandable given that the devices under study and many similarly designed devices produce a systematic rocking of the intervertebral joints as the probes slowly move along the spine from the cranium to the sacrum. In the fields of osteopathy, Tui Na (Chuna), and, of course, chiropractic, it is known that restricted range of motion of the spinal joints can have long-term health consequences.<sup>54</sup> Thus, in design of the clinical trials we will need to assess spinal abnormalities and vertebral subluxation correction as a possible mechanism of health benefits with thermomechanical massage beds. However, given the rather high force applied by the probes during mechanical massage, it will be important to incorporate similar guidelines for the massage beds as currently applied with use of the chiropractic intersegmental traction devices; i.e., Precautions- use with caution on elderly patients, patients with acute pain or those weighing over 300 pounds; Contraindications- Phlebitis, fractures or suspected fractures, common skin problems such as sunburn, bruises, boils or shingles that may be irritated by heating probes, or in patients with fused discs, implanted scoliosis rods or diagnosed osteoporosis.

Soft tissue manipulations are also problematic and can produce pain and discomfort. Muscle strains are well-documented in sports injuries and sedentary individuals asked to perform novel movements or exercise. Some of these soft tissue injuries such as myofascial syndrome result from deep fascial adhesions,<sup>55</sup> that trigger long term holding patterns treatable only by intensive intervention. Because most patients using the thermomechanical devices report a lessening of the muscle pain with time, it can be assumed that the stretching event is within

the normal range tolerated by seasoned athlete, Yoga enthusiasts, and others.

Urticaria (rashes) results from a myriad of conditions from ordinary "heat rash", prevalent during the summer, through "drug-induced photo-reactivity" to "exercise-induced anaphylaxis." These side effects of skin rashes and itching with thermomechanical massage beds are probably the result of the body adapting to heat application to skin areas, keeping in mind that the temperature of the heat probes is adjustable between 40-70° C. Many of the reactive skin disorders, e.g., heat rash, photoallergic dermatitis, prickly heat, exercise allergy or the more severe exercise-induced anaphylaxis are caused by heat or sun exposure and, interestingly, are co-morbid with other conditions. For example, photoallergic dermatitis is initiated by sun or heat in the presence of certain chemicals such as soaps, cosmetics or perfumes.<sup>56,57</sup> There are frequent reports of drug-induced photosensitivities in combining sun/heat exposure with medications such as birth control pills, blood pressure medications, antibiotics and nonsteroidal anti-inflammatory drugs.<sup>58,59</sup>

Generally speaking a rash is the outcome of a dilatation of capillaries in the dermis of the skin, and the underlying hypodermis, resulting from everything from mechanical injury to the skin to allergic reactions including immune responses. The finding of skin rashes found away from pressure points during Migun usage is interesting and unexpected, but it might be explained by blood circulatory and/or autonomic neuronal mechanisms. Although unproven, a likely explanation is that pressure and/or heat imposed by the heating probes cause the release of opioids, histamine and/or other vasoactive molecules into the dermis with subsequent paracrine or endocrine release of vasoactive or immuno-active molecules into the blood stream targeting distant sites and an increased density in the capillary beds of the dermis.<sup>60</sup> Alternatively, the sensory nerve endings at the contact sites may trigger reflex discharge of postganglionic nerve fibers innervating sweat glands, sebaceous glands, and the smooth muscle component of the tunica media of arterioles irrigating the dermatomes stimulated and resulting in skin rash.<sup>61</sup>

It is thought that the rise in body temperature triggered by muscle exertion, is what produces the itching, swelling and small hives that some people experience with exercise-induced allergies. People who have this condition may also experience the same reaction in hot tubs, saunas, and see that they are more likely to get it on hot days or in combination with underlying food allergies.<sup>62</sup> It may be that individuals using these thermomechanical massage beds for the first time should be screened for such symptoms so that they might avoid such initial reactions with the device. Heat-sensitive individuals often control their symptoms in other situations by using antihistamines, avoiding exercising on warm or humid days, reducing the intensity of the work-outs, or stopping the heat-producing activity at the first sign of flushing, itching skin or hives. Furthermore, it is recommended that good hydration can reduce the severity of such symptoms, so drinking plenty of water is also recommended. Finally, other screening questions might be employed to exclude overly sensitized individuals, especially if they have a history of allergies, food allergies, environmental sensitivities, use of sensitizing medications (aspirin, antibiot-

ics, hormone replacement therapy, contraceptive pills, synthetic products such as deodorants, perfumes, talcum powder, cosmetic products, or extreme emotional issues) which may cause direct or indirect susceptibility to develop a tendency towards urticaria.

In conclusion, the present data from previously unpublished technical reports suggest that thermomechanical massage beds may provide health benefits across a wide range of health conditions. Adverse events were also documented for the first time, but these were relatively minor and resolved with continued use. The challenge for the next study will be to utilize standardized outcome measures, such as the Self-Reported Health and Wellness survey developed for use in the chiropractic field<sup>1</sup> and a custom inventory of self-reported health benefits across a large statistical population of Migun thermomechanical massage bed users. This is currently underway and will help to define study parameters for controlled clinical trials to evaluate the health benefits of the device.

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