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## Original Article

# A technology developed from concept of acupuncture and meridian system, the clinical effect of BIOCERAMIC resonance on psychological related sleep disturbance with findings on questionnaire, EEG and fMRI

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## ABSTRACT

Under the concept of meridian channels that belongs to traditional Chinese medicine, BIOCERAMIC Resonance (BR) has already been applied to many clinical medical research projects with functions mimicking of traditional acupuncture. Forty-five patients were recruited with chronic sleep disorders; 36 patients were given, applied to the device with BIOCERAMIC material and sound rhythm on chest skin surface; 9 patients were included as controls. All study participants completed a sleep pattern and quality of life questionnaire (assessment on psychological and physical causes of sleep disturbances), which was repeated before, during and after treatment. Electroencephalograph (EEG) recordings were analyzed before, during and after treatment. Functional MRI (fMRI) was also used for demonstration of BR effect for another 8 candidates. During the first 3 days of treatment, sleep quality improved in all 36 patients especially to psychological reasons; in 91.7% (33/36) treatment was associated with an elevation in the beta spectrum of the EEG (at 15–27 Hz). The result of fMRI found corresponding cerebral and cerebellar areas of activation and deactivation. BIOCERAMIC Resonance can improve sleep disorder due to psychological causes, with transient alter brain wave activity and functional activation on specific locations of brain.

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## 1. Introduction

The rationale to conduct this research is due to our clinical observation and impression of beneficial effect on sleep quality,

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when our candidates were received BIOCERAMIC treatment. Thus, we were decided to perform a study to assess the possible improvement of sleep disorder by BIOCERAMIC Resonance.

Sleep disorder, such as disrupted and restricted sleep, is a common problem for many people worldwide. Sleep disorder may be related to disturbances of the autonomic nervous system, can affect mental and physical wellbeing and the ability to work and interact in social relationships.<sup>1,2</sup> Insomnia may be a symptom of other diseases, but untreated insomnia can lead to psychological distress, it may also cause clinical conditions of anxiety and depression.<sup>3</sup> Sleep disorder may also be a risk factor for

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cardiovascular disease and increased mortality.<sup>4</sup> In Asian countries, insomnia is one of the most prevalent health disorders, reported by 21.4% of the total population in Japan,<sup>5</sup> 17% of the population in Korea,<sup>6</sup> and more than 25% of the Taiwanese adult population.<sup>7</sup> Difficulty of initiating sleep is the most common type of insomnia (14.6%), followed by early morning awakening (13.9%) and difficulty maintaining sleep (13.4%).<sup>7</sup> The prevalence of use of any drug treatment for sleep disorders (including antidepressants, mood stabilizers, and anxiolytic-hypnotic drugs) has increased to more than 12.0% of the population in Taiwan for the past decade.<sup>8</sup> The overuse of anxiolytic, hypnotic and sedative medications leads to side effects that cause public health problems.<sup>9,10</sup>

Alternative treatments for insomnia in Chinese populations include Chinese herbs and acupuncture, whereas in Western countries psychological and behavioral approaches are more likely to be used.<sup>11,12</sup> Stimulation of acupuncture points or meridian channels, is a form of complementary medicine, includes several procedures to stimulate defined anatomical points. Although usually associated with the use of needles, acupuncture techniques can also include the use of magnets, low-power lasers, heat, ultrasound, manual pressure and electrical stimulation (electro-acupuncture). The application of BIOCERAMIC material includes an unexplained phenomenon of biological effect can be transmitted by sound wave and light propagation.<sup>7</sup> In the past, we had conducted preclinical and clinical studies on the properties and applications of LED emitted light to pass through BIOCERAMIC material, including change of skin's electricity conductance properties, when applied to traditional acupuncture points.<sup>13–15</sup> We have previously undertaken preclinical and clinical studies which have shown that the application of BIOCERAMIC materials promotes the microcirculation in patients<sup>13</sup> and upregulates calcium-dependent nitric oxide and calmodulin in cell lines *in vitro*<sup>16</sup> through calcium-dependent nitric oxide synthase.<sup>16,17</sup> In a series of recent clinical studies, we found the application of BIOCERAMIC materials reduced neck muscle stiffness, relieved musculoskeletal disorders, and improved the recovery of resting cardiac and respiratory rates following exercise.<sup>18,19</sup> The application of BIOCERAMIC materials has been shown to increase parasympathetic activity.<sup>20,21</sup>

About BIOCERAMIC material, it is produce a weak energy field with no ionized radiation, which is enhanced and propagated through sound wave. BIOCERAMIC material was proven to have weakening effects on hydrogen bonds and can alter the characteristics of liquid water.<sup>22–24</sup> Furthermore, significant findings of the effects of BIOCERAMIC in different cell experiments, animal experiments and human trials, particularly in the promotion of microcirculation, were also found and reproduced.<sup>16</sup> Based on Wang's deduction, the energy of a twelfth frequency is the sum of the energies of the eleven harmonic frequencies.<sup>21,25</sup> According to series of publications by Wang et al, the harmonic rhythmic sound frequencies of the heartbeat are the main frequency components of the propagated pressure wave and correspond to the twelve meridian channels of TCM. Acupuncture points and meridian channels are thought to be closely related to microcirculation.<sup>16,21</sup> BIOCERAMIC Resonance is the technology of combining sound waves using specific frequency beats in conjunction with our proprietary BIOCERAMIC material which offers a new kind of clinical application on traditional Chinese medicine.<sup>21</sup> Described in our previous publication, candidates received BIOCERAMIC Resonance with rhythmic sound set at different tempo output that designed for resonance with aforementioned harmonic rhythmic sound frequencies of the heartbeat that corresponding to three dimension standing waves that what we believed as twelve meridian channels of TCM.<sup>14,15,21,26</sup> During the rhythmic sound tempo being resonance with the specific standing wave arise from harmonic rhythmic sound frequency of heartbeat, it intensify the energy propagation of

energy field of BIOCERAMIC. Under operation BIOCERAMIC Resonance, candidates may experience "Propagated Sensation along Meridians" (PSM), our results seem to suggest that BIOCERAMIC Resonance stimulates the twelve main meridian channels according to TCM.<sup>14,15,21,26</sup>

Our previous publication has already proven that the BIOCERAMIC Resonance device can facilitate microcirculation and elicited 'propagated sensation along meridians' (PSM), under the concept of traditional Chinese medicine (TCM). Beside, candidates with insomnia, migraine, anxiety, benign facial tremor, low back pain, muscular paralysis, lower leg edema and poor wound healing of lower extremity, were clinical improved.<sup>14,15,21,26</sup> The purpose of this study is to find the possibility of clinical benefit of BIOCERAMIC Resonance on sleep disturbance, assess by questionnaire, EEG and fMRI.

## 2. Methods

### 2.1. Characteristics and use of BIOCERAMIC Resonance (BIOCERAMIC material with sound rhythm)

The BIOCERAMIC powder used in this study (obtained from the Bioenergy Laboratory, Bioenergy Development Ltd, Taoyuan, Taiwan) was composed of microscopic particles produced from several types of elemental oxides. BIOCERAMIC powder<sup>13–21</sup> was used as 10% of a mixture with silicone rubber (Bioenergy Development Ltd, Taoyuan, Taiwan) to produce a membrane with a sponge-like density, capable of sound transmission. To choose the suitable frequency for our experiment, we reviewed previous articles and studies on the effects of different frequencies. A study by G. Rasmussen found that sound rhythm from 1 to 20 Bps are the most effective.<sup>27</sup> We selected 10 Bps (mean value of 1–20 Bps) as the first sound rhythmic setting to prove our BIOCERAMIC Resonance device for this study to investigate the effects on patients with poor sleep quality.

BIOCERAMIC Resonance is the device sound rhythm generator producing 10 Bps with 10% BIOCERAMIC material mixed with silicone rubber and was capable of producing BIOCERAMIC Resonance effect. The rhythmic vibration source was at about 30 cm above the skin surface of the chest and the average sound level was 50 dB.<sup>21</sup>

### 2.2. Patients studied

The participants we wish to collect were patients who suffer sleep disturbance, not limited to insomnia, narcolepsy, cataplexy or sleep walking & night terrors. Patients were excluded who were being medications (eg. sedative or hypnotics). All patients signed informed consents to participate in this study. The study protocol was approved by the Human Subjects Ethics Committee at the Taipei Hospital (Ministry of Health and Welfare), New Taipei City, Taiwan (approval number: TH-IR-0014-0001). Because of limitation on funding resource, we allowed 45 participants in this study, who were claimed of suffering sleep disorders. There were 30 female and 15 male, with an average age of 47.4 years old (range from 25 to 68 years old), were basically suffered of insomnia. We decide the ratio of 'experimental group to control group' as '4 to 1'; thus, 36 patients underwent BIOCERAMIC with 10 Bps and 9 control subjects received sound rhythm (SR) at 10 Bps without BIOCERAMIC. They were arranged to perform sleep-quality assessment and electroencephalography (EEG) data recording. Eight male participants were received functional Magnetic Resonance Imaging (fMRI), but because of technically limitation, he was treated without and with BIOCERAMIC under circumstance of 'pulse sequence' sound vibration created by MRI device.

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