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Base on concept of traditional Chinese medicine: Experimental studies on efficacy of BIOCERAMIC Resonance to alleviate drug withdrawal symptoms

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ABSTRACT

Those who are challenged by dependency on prescription drugs or suffer drug addictions have few options available to them for recovery, such as psychotherapy and physiotherapy. Here we present a new approach with clinical examples involving stimulant addiction or overdose of hypnotic drugs that were received BIOCERAMIC Resonance, which was developed based on concept of 12 meridian channels of traditional Chinese medicine, and has successful withdrawal or dose reduction benefits. We describe the whole process and the clinical outcome. And by help of our previous publication on functional MRI, we discuss the possible brain locations response to BIOCERAMIC Resonance that may be corresponding to the beneficial effects of relief of depression, sleep deprivation and other mental symptoms that associate with substance abuse and withdrawal effects. We suggest this could be potentially widely application on substances abuse.

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1. Introduction

Drug dependence are both involved physical or psychological, and depends on individually with different chemical, intensity and duration of abuse. As to abstinence from drug abuse, it is always a frustration to the patients that not able to tolerate the withdrawal symptoms. As we know, there are psychological symptoms of drug withdrawal, include depression, anxiety, sleep disturbances, mania, panic attacks, and so on.

In this study, we used BIOCERAMIC Resonance to observe the possibility of alleviate psychological symptoms during the process of drug withdrawal. About BIOCERAMIC material, it has been proven to have weakening effects on hydrogen bonds and can alter the characteristics of liquid water.^{1–3} Furthermore, significant findings of the effects of BIOCERAMIC in different cell experiments, animal experiments and human trials, particularly in the promotion of microcirculation, beneficials to diabetics, myofascial neck pain, as well as ischemic cerebral infarction, were also found and reproduced.^{4–7} Since BIOCERAMIC material produces a weak

biological field radiation effect and has been hypothesized as a new concept in physics (Fig. 1),^{8–14} one of the effects we observed was that the corresponding biological field can be transmitted via sound waves propagation. 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 of BIOCERAMIC technology.^{4–14}

According to the experiment conducted by Wang et al., different harmonic frequencies of individual's original heartbeat produce coupled oscillation to different internal organs, which suggested a resonance pattern occurring between specific organs and vascular bed.^{11–14} Wang also proposed that the function of resonance frequencies is to help blood enter the specific organs.^{11–14} Our previous publications were demonstrated, for example, harmonic frequencies are found in the range of 1.2 Hz–13.2 Hz (Table 1) if the heart beat remains constant at 72 beats per minute (bpm).^{11–14} These harmonic frequencies are single frequency resonance channels that could indeed correlate with the Traditional Chinese Medicine (TCM) concept of the “meridians” (Table 1).^{11–14} Described in our previous publication, candidates received BIOCERAMIC Resonance with rhythmic sound frequency set at different tempo output may experienced “Propagated Sensation along Meridians” (PSM), our results seem to suggest that BIOCERAMIC Resonance stimulates the twelve main meridian channels

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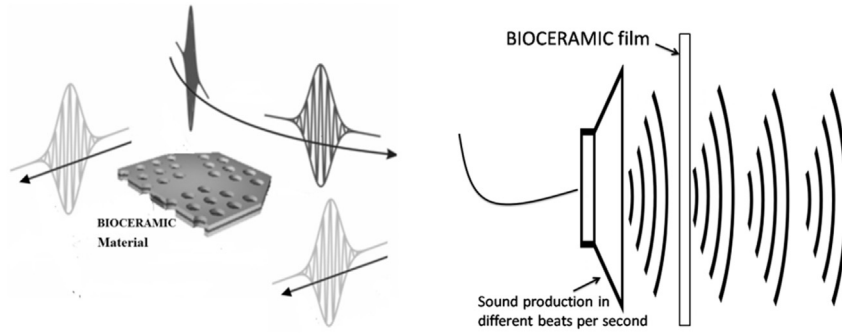


Fig. 1. Conceptual drawing of BIOCERAMIC material activated by sound(a,left); BIOCERAMIC Resonance production and propagation(b, right).

Table 1
Harmonic frequencies(HF) based on standard heartbeat baseline of 72bpm.

Number of harmonic frequency (HF)	1 st HF	2 nd HF	3 rd HF	4 th HF	5 th HF	6 th HF	7 th HF	8 th HF	9 th HF	10 th HF	11 th HF	12 th HF
Corresponding Meridian Channels of TCM	Liver	Kidney	Spleen	Lung	Stomach	Gall Bladder	Urinary Bladder	Large Intestine	triple energizer	Small Intestine	Heart	Pericardium
Hz estimated by heart rate at 72 bpm	1.2	2.4	3.6	4.8	6.0	7.2	8.4	9.6	10.8	12	13.2	14.4

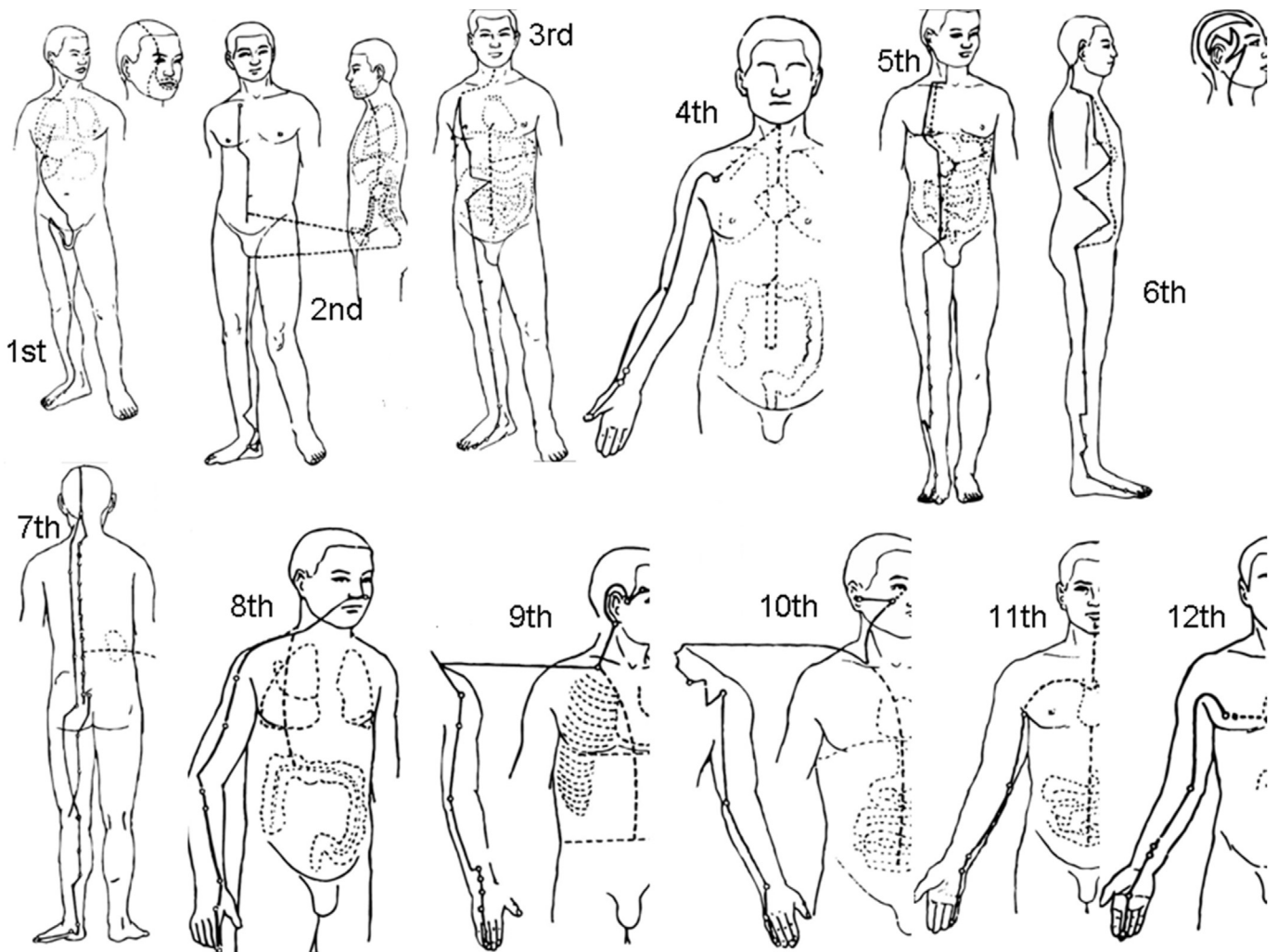


Fig. 2. Harmonic frequencies of heart beat(1st to 12th) with their corresponding road maps on body, corresponding to 12 meridian channels.

according to TCM (Fig. 2) (Table 1).^{11–14} BIOCERAMIC Resonance can objectively improve sleep disorder due to psychological causes, which can transiently alter brain wave activity. By using fMRI imaging,¹⁴ we also demonstrate the brain's regions of stimulation under the operation of BIOCERAMIC Resonance, include left temporal pole, left parahippocampal gyrus, left rolandic operculum, left inferior frontal gyrus, left precentral gyrus, left hippocampus, left middle frontal gyrus, left insula, left thalamus, left cerebellum and left gyrus insula.¹⁴

In this study, we present two case studies of the use of BIOCERAMIC Resonance on a female patient with substance abuse. We describe the clinical benefit and efficacy of BIOCERAMIC Resonance on both physiological and psychological factors.

2. Material and methods

2.1. BIOCERAMIC material and BIOCERAMIC Resonance

The BIOCERAMIC powder used in this study (obtained from the Bioenergy laboratory, Bioenergy Development Ltd, Taoyuan, Taiwan) was composed of micro-sized particles produced from several ingredients, mainly different elemental oxides. BIOCERAMIC material possesses a weak energy field with the aforementioned functions^{1–14} that can be enhanced and transmitted by wave of sound^{11–14} (Fig. 1). The concept of BIOCERAMIC Resonance, is a modified tempo sound input to human body. By using 10% of the BIOCERAMIC material powder^{1–14} and mixed with silicone rubber to produce sheet membrane having a spongy density, which is capable of sound transmission. We also used BIOCERAMIC Resonance to produce different beats of tempo measured in beats per second (bps), which help to amplify the effect of the BIOCERAMIC material. Based on technology of BIOCERAMIC with its effects described in our previous publications,^{1–14} we developed the instrument of BIOCERAMIC Resonance for human trials capable of producing a biological field with rhythmic tempo associated with average sound power level at 100 dB.^{11–14} The vibration source would contact the skin surfaces of the subject's posterior trunk of thoracic-lumbar spine levels and bilateral ventral feet (Fig. 3). BIOCERAMIC Resonance with pulsed sound output is set at one cycle of 1–12 beats per second (bps), and the subject is given a treatment session of one cycle lasting 45 min. The subject can choose to repeat specific bps settings based on intensity of the sensation experienced.^{11–14} The study protocol was approved by the Human Subjects Committee (approval number: TH-IR-0014-0001 and TYGH-106015).

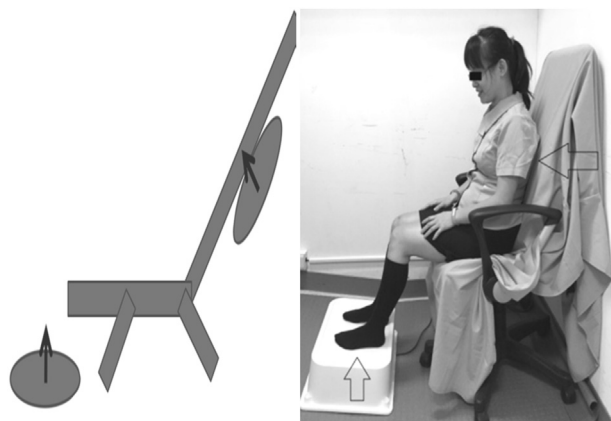


Fig. 3. Conceptual drawing of BIOCERAMIC Resonance platform (a, left) with BR outputs on skin surface of posterior trunk of thoracic-lumbar spine levels (solid arrows) and the picture of corresponding experimental BR outputs (hollow arrows) (b, right).

2.2. Clinical examples of stimulant addiction and overdose of hypnotic drugs for BIOCERAMIC Resonance treatment

Two clinical examples of drug overdose candidates with past history of suicide attempts, are selected in this study. The first case is a 48-year-old female, right handed, high school graduate patient in relatively good health and without past records of any major physical disease or a family history of psychiatric disorders. She came to visit our open patient department seeking help for substance abuse, chronic insomnia and emotional problems. According to her statement, she suffered a major and severe head injury in 1990, which caused subsequent intracranial hemorrhage leading to a comatose state for several weeks. Although she recovered and discharged from hospital, she thereafter became despondent, suffered depression and attempted suicide several times. For the past 24 years since 1992 she came to rely on amphetamine (0.7–1.5 gram per day) to ameliorate her depression, fatigue, anxiety and emotion instability. She sought and received medical treatment for amphetamine withdrawal several times, but they were all unsuccessful. In 2008, she was admitted in hospital after being diagnosed with schizophrenia and depression. In addition, she also suffered from strong dependence upon flunitrazepam after administering 2 mg of it nightly over a period of ten years. Even though dependent on heavy doses of such a hypnotic drug, her sleep was of poor quality with many dreams and she was easily awakened. After consulting with us at out-patient department of our Hospital in 2016, we arranged for her to receive our BIOCERAMIC Resonance protocol of daily treatment sessions lasting 45 min scheduled routinely before noon time. The second case is a 62-year old female, right handed, high school graduate patient who was in good health until she found her only son death in an accident ten years ago. The tragedy was deeply affecting her and she was committed suicide for several times. Within this ten years period, she became sedative overdose to help sleep. However, her sleep problem was aggravated for this year and her usual dose of Zolpidem was at least 70 mg per night. Although high dose of hypnotic using, she was easily awakened, even though a small sound was produced outside the bedroom. After the consultation at out-patient department of our Hospital in 2016, she was arranged for her to receive our BIOCERAMIC Resonance protocol as 2 times in a week lasting 45 min scheduled in the morning.

3. Results

3.1. Clinical outcome of BIOCERAMIC Resonance treatment on clinical example one

During the BIOCERAMIC Resonance treatment, she initially experienced drowsiness, continual yawning, hiccupping and sensed the air quality to be heavy and stagnant. She also had a decrease of muscular tone and a transient pain sensation in her head in the parietal region. Under specific frequencies (bps) during the BIOCERAMIC Resonance treatment session, this woman also experienced episodes of stimulation moving at a slow speed along different sections of her skin. At the end of every treatment, she regained her spirit, recovered muscular strength and felt like she breathing fresh air once again. She felt less dependence on her hypnotic drugs after the first treatment and therefore decreased the dosage. Within the first 7 days of treatment, her amphetamine abuse was remarkably decreased to less than 0.2 gram per day. And by the end of 12 treatments she was able to abstain from ingesting amphetamines altogether. Moreover, her sleep pattern was improved; she reported deep, restful slumber even though she had reduced the daily dose flunitrazepam to 0.5 mg. Subsequently, since being treated with BIOCERAMIC Resonance, this subject has

Table 2
Comparison (1) Clinical outcome, social and psychological problem and (2) dosage of drugs, before and after BR treatment.

	Clinical outcome, social and psychological problem(s) before treatment	Clinical outcome, social and psychological benefit(s) after treatment	Dosage of drug before treatment	Dosage of drug after treatment
Case one: 48-year-old female	(1) Depression, fatigue, anxiety and emotion instability (2) Poor relationship with family members (3) Re-built a good family relationship	(1) Regained her spirit, recovered muscular strength and felt like breathing fresh air. (2) Improved of sleep pattern, with deep, restful slumber	(1) Amphetamine(0.7 –1.5 gram per day) (2) Flunitrazepam(2 mg per night)	(1) Amphetamine(after 7 days, decreased to less than 0.2 gram per day; and then complete withdraw) (2) Flunitrazepam(reduced to 0.5 mg per night)
Case two: 62-year-old female	(1) Severe sleep difficulty (2) Severe depression that aggravated by remember the tragedy of the death of her only son.	(1) Have deep sleep at night (2) Became sleepy before mid-night (3) Improved of overwhelming feeling of sadness. (4) Improved of her depression and poor spirit in the morning	Zolpidem was at least 70 mg per night.	Decrease of zolpidem to 30 mg per night.

Table 3
Comparison on the brain locations activated by BIOCERAMIC Resonance to locations of brain functional change with different mental conditions or disorders that might related to drug overdose and withdrawal.

Brain location activation by BIOCERAMIC Resonance	Locations of brain function change in generalized depression ^{26,27}	Locations of brain function change in unipolar depression ²⁸	Locations of brain function change in bipolar depression ²⁸	Locations of brain function change in Sleep deprivation ^{29,30}	Locations of brain function change in panic disorder ³¹	Locations of brain function change in anxiety disorder ³²
Left temporal Pole				Positive		
Left para-hippocampal gyrus		Positive		Positive	Positive	
Left rolandico-perculum						
Left inferior frontal gyrus	Positive		Positive	Positive	Positive	Positive
Left precentralgyrus		Positive			Positive	
Left hippocampus	Positive			Positive		
Left middle frontal gyrus	Positive		Positive	Positive	Positive	Positive
Left insula				Positive		
Left thalamus			Positive	Positive		
Left cerebellum						
Left gyrus insula				Positive	Positive	

gradually re-built a good family relationship. All these positive outcomes have further strengthened her resolve to complete the withdrawal therapy (Table 2).

3.2. Clinical outcome of BIOCERAMIC Resonance treatment on clinical example two

Within the first month of treatment, she was started to have deep sleep at night and became sleepy before mid-night that rarely happened on her for the past ten years. Until the end of second month of treatment, she was begun to decrease her dose of zolpidem to 30 mg per night, and she claimed she was improved of overwhelming feeling of sadness. According to her statement, she was obviously improved of her depression and poor spirit in the morning due to sleep disturbance (Table 2).

4. Discussion

Our previous publication has already proven that the BR device can facilitate microcirculation and elicited 'propagated sensation along meridians' (PSM), under the concept of traditional Chinese medicine (TCM). PSM is a phenomenon characterized by the subjective sensation of slow movement or stimulation traversing along the meridian channels. In the past, this phenomenon occurred only in 1.3% of the subjects undergoing an acupuncture treatment, but

which cannot be satisfactorily explained by either neural or blood transmission.¹⁵ BR-induced PSM was also associated with successful treatment of many illnesses.^{11–14} A past review study failed to conclusively report the effectiveness of acupuncture and electro-acupuncture therapies in drug addiction treatment, however, acupuncture and electro-acupuncture may be effective in decreasing psychological distress and increasing confidence during the withdrawal process.^{16,17} In our opinion, the beneficial clinical effect of BIOCERAMIC Resonance (BR) on substance dependence may be founded on the concept of TCM.

Furthermore, it also has the merits of being noninvasive and an easy approach. It can be implemented independently or act as an adjunct therapy or alternative therapy to strengthen the function on other medical methods, such as other minimum invasive alternative brain stimulation treatments for mental disorder were include neuromodulation with transcranial direct current stimulation (tDCS)¹⁸ and transcranial magnetic stimulation (TMS).^{19,20} The tDCS treatment had been shown to increase beta power during and after stimulation.²¹ TMS had shown consistently evoked beta-band oscillations (13–20 Hz) in the parietal cortex.²¹ One of an example belongs to this technology, is a 1-Hz TMS system (-NeuroStar), which produces brief duration and pulsed magnetic fields.²² It provides rapidly alternating fields induce electrical currents within localized, targeted regions of the cortex which are associated with various physiological and functional brain changes.

By knowing TMS stimulation associated with increased specific locations of brain activity, include left prefrontal cortex, left hippocampus, left dorsolateral prefrontal cortex.^{23,24} It is routinely placed and localized the magnetic coil of TMS over the scalp close to left frontal-temporal region, to target on the aforementioned locations. It was found more effective in acute treatment of major depression. It was showed a statistically significant improvement on the medication free patients with major depression, assessed by Montgomery-Asberg Depression Scale and the Hamilton Depression Rating Scale.²⁴ However, these two kinds of so called 'non-invasive' brain stimulation is not absolutely non-invasive, although the operation associate with no incision or insertion is made into the body. It is because it has been suggested that TMS and tDCS might be used to enhance brain function, but also more or less disrupt brain activity.²⁵ As a kind of new developing technology, BIOCERAMIC Resonance provide only low energy field modified tempo sound output, which has the merit of both safety and effectiveness. In this study, we demonstrated our clinical examples of drug abuse who were received BIOCERAMIC Resonance that successful on drug withdrawal with benefits on mental symptoms, including relief of depression, sleep deprivation and other mental symptoms. To explain the possible mechanism, we used fMRI to demonstrate the brain locations that may activated by BIOCERAMIC Resonance.

By review publication, we compare the brain activating locations of BIOCERAMIC Resonance and the functional change of brain locations of those mental disorders that related to drug overdose and corresponding process of drug withdrawal, such as generalized depression, unipolar depression, bipolar depression, sleep deprivation, panic disorder and anxiety disorder (Table 3). We found a high degree of correlations to the locations that activated by BIOCERAMIC Resonance. The locations are include left temporal pole, left para-hippocampal gyrus, left inferior frontal gyrus, left precentral gyrus, left hippocampus, left middle frontal gyrus, left insula, left thalamus and left gyrus insula. The finding may help us to explain the mechanism. Similarly, acupuncture may also provoke functional change of cerebral regions on healthy volunteers.³³ As a pilot study, the limitation of this study is still small case number on heavy drug abuse cases and clinical assessment is not abundant.

5. Conclusion

As far as we know, this is the first clinical study with preliminary data that proving a modified sound tempo generating device of BIOCERAMIC Resonance can objectively provide beneficial effect on drug withdrawal process by alleviating some of the related mental symptoms. In the future, this technology should be intensified evaluated by more clinical observations and assessment of questionnaires on patients with drug abuse.

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