Original Papers

Resolution of Cavitational Osteonecrosis Through NeuroModulation Technique, a Novel Form of Intention-Based Therapy: A Clinical Case Study

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Abstract

Objectives: This study evaluated the possibility of using NeuroModulation Technique (NMT), a form of intention-based medicine, to induce osteogenesis and healing of cavitational osteonecrosis, a common progressive form of ischemic disease of the alveolar arch.

Design: Eleven (11) adult patients were enrolled based on the presence of lesions in the jawbone. Ten (10) subjects underwent NMT therapy for up to 10 months, while 1 subject received no treatment.

Outcome measures: A sensitive analysis of bone density in the alveolar processes of maxilla and mandible was performed before and after therapy using the U.S. Food and Drug Administration–approved Cavitat system of through-transmission ultrasonography and computer imaging.

Results: All subjects presented between one and six cavitational lesions at the first scan, most of which (92%) were associated with sites of previous tooth extraction. NMT-treated patients demonstrated significant improvement in bone density in 27 of the 34 lesions analyzed (79%). The median number of lesions per patient was 4 pretreatment and 0 post-treatment (p < 0.01). One NMT-treated patient, 1 surgically treated patient, and the control subject were also imaged at later time points, showing a durable healing of the lesions through NMT comparable to that of surgery, as opposed to disease persistence in the untreated control.

Conclusions: NMT therapy provides a safe and potentially effective treatment for jawbone osteonecrosis. Preclinical placebo-controlled trials are encouraged to investigate in depth the potential of NMT for treating inflammatory and degenerative pathologies.

Introduction

Cavitational osteonecrosis is a very common progressive pathological condition of the alveolar arches that is frequently encountered in dental practice. Described as early as 1920 by G.V. Black, "the father of modern dentistry," these kinds of lesions are commonly referred to as "jawbone cavitations." Cavitations present as a progressive death of bone, characteristically producing softening of the structure and develop into large "hollowed out" areas of bony tissue. Black already observed the cavitation's unique ability to produce extensive destruction without redness or swelling, and without significant increase in the body's temperature.¹ Recent studies summarized the classic features of the problem:² intrabony cavity formation (cavitation), and bone tissue death (osteonecrosis). When the condition is associated with facial

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Most aspects of the development of cavitational osteonecrosis lesions remain unclear. There is a greater likelihood of development of these lesions in patients who had infections or dry sockets following a tooth extraction, or who have undergone root canal therapy. Contributory factors include trauma, microorganisms, heavy metals associated with dentistry, endodontic and periodontal procedures, extraction, or the use of local anesthetics and procoagulants.^{5–12} Shankland¹³ reported that in 476 of 500 (95.2%) consecutive cases, cavitational osteonecrosis lesions were directly attributable to ischemia in the bone and/or tooth, and spontaneous resolution has not been observed.

Whatever the particular contributing factors, patients with cavitational lesions are left with a chamber of dead tissue that may or may not be painful.^{14–17} The biggest risk that such lesions present may be that they serve as a reservoir of anaerobic pathogens and their various protein and nonprotein toxins. These toxins paralyze body enzyme systems, challenge the vitality of tissues, directly inhibit osteogenesis, and may contribute to neurodegenerative and other systemic diseases.^{18,19}

Cavitational osteonecrosis has been diagnosed in patients as young as 18 years of age, but a typical patient is a 40–60year-old woman. Bone sites most frequently involved in decreasing order of prevalence are mandibular molars, maxillary molars, maxillary cuspids, and lateral incisors. Third molar extraction sites (wisdom teeth) account for over 45% of all jawbone cavitations. Diagnosis generally involved a clinical examination and the review of x-ray films, while additional information was gained from diagnostic injections as well as noninvasive techniques such as neurokinesiologic muscle response testing (MRT) and electrodiagnostic screening (i.e., electroacupuncture according to Voll).^{13,14} X-rays do not reveal the lesions well because cavitations involve the cancellous bone that resides between layers of cortical bone. The 2002 advent of the U.S. Food and Drug Administration (FDA)-approved Cavitat CAV 4000 through-transmission ultrasonography (TTU) imaging has resolved much of the problem in precise imaging of these lesions within the alveolar process.^{15,20,21} FDA submission data for the Cavitat documented over 97% agreement in 3500 cases between the results of Cavitat-based detection of cavitational osteonecrosis and that of surgical biopsy.²² In our experience of over 200 cavitation surgeries performed within the last few years, we confirmed in all cases, by surgical biopsy performed within a year from the scan, the presence of osteonecrotic lesion identified prior by Cavitat imaging.

These lesions can be both nonsurgically and surgically treated. Nonsurgical procedures may include the use of cold laser, ozone, the injection of antibiotics, or homeopathic preparations. Complete resolution of cavitations by these therapies is, in our experience, not seen and improvement with these methods over 1 year of such treatments is in the range of 10%–20%. Surgical treatment of these lesions involves the removal of the infected and/or necrotic bone tissue and is currently the therapy of choice. For these reasons, there is a need to investigate new, more durable, and less invasive treatments for this serious degenerative condition.

In this study, we investigated the effectiveness of Neuro-

Modulation Technique (NMT) therapy for the treatment of cavitations. NMT is a form of complementary and alternative intention-based therapy that may be referred to generically as "informational medicine" or "consciousness medicine." Using Cavitat imaging as a sensitive and reliable measure, we demonstrate successful resolution of jawbone cavitations in patients treated exclusively with NMT.

Materials and Methods

Study design

A total of 11 subjects with cavitation lesions of the jawbone, as identified on the basis of clinical examination and on positive neurokinesiologic testing, were enrolled in this study. Cavitat imaging confirmed the presence of osteonecrotic lesions in all these subjects. Patients were informed of the surgical alternative and gave their informed consent to undergo exclusively NMT therapy for a maximal duration of 10 months, while one patient chose to not undergo any treatment strategy. All treated subjects received a Cavitat scan before and after NMT therapy. As outcome measure, we evaluated the differences in total bone density between the two scans. The interscan interval was determined based on the patient's subjective evaluation and on a new medical examination. The NMT practitioners (LSF, KPF, LV) were blinded to this outcome analysis. The study protocol was consistent with the Helsinki Declaration and patients received no compensation.

High-resolution diagnostics of the alveolar process

A sensitive analysis of bone density in the alveolar processes of maxilla and mandible was performed using the FDA-approved CavitatTM CAV 4000 (Cavitat Medical Technologies, Inc., Aurora, CO) system of TTU and computer imaging according to the manufacturer's test protocol. This device uses a specially designed ultrasound transducer to detect diminished bone density in the jawbone. It is capable of detecting such lesions with high accuracy down to 1 mm in diameter. Acquired signal data are sent to the computer and converted to a high-resolution digital three-dimensional perspective color image with reference measurement scales. The images are color coded to distinguish varying degrees of ischemic changes throughout the volume of the alveolar process.

NeuroModulation Technique therapy

A detailed description of the rationale and clinical algorithms underlying NMT therapy are beyond the aim of this paper, and more information can be found elsewhere.²³ Briefly, NMT therapy is based upon the proposition that all physiologic processes occurring in the patient are a reflection of the informational state of regulatory data-processing systems of the mind–body. NMT postulates that the mind–body represents an intelligent self-correcting system that always seeks homeostasis. When the mind–body engages in pathophysiology, this may be interpreted as some combination of diminished self-awareness and/or corruption of the informational status. NMT is a therapeutic intention-based system consisting of 70 or so clinical algorithms, called NMT Clinical Pathways, each of which comprises two

| Patient ID | Sex | Age | Months NMT | <i># NMT</i> treatments | <i># Lesions</i> assoc. w/extract. | # Lesions before NMT | # Lesions after NMT |
|------------|-----|-----|---------------|----------------------------|--|----------------------------|---------------------------|
| P1 | F | 58 | 6 | 10 | 2 | 2 | 2 |
| P2 | F | 54 | 6 | 10 | 4 | 4 | 0 |
| Р3 | М | 78 | 5 | 8 | 6 | 6 | 1 |
| P4 | F | 54 | 9 | 9 | 1 | 2 | 2 |
| P5 | F | 56 | 5 | 7 | 1 | 1 | 0 |
| P6 | F | 52 | 5 | 8 | 4 | 4 | 0 |
| P7 | F | 55 | 6 | 8 | 2 | 4 | 2 |
| P8 | F | 34 | 2 | 5 | 3 | 3 | 0 |
| Р9 | М | 68 | 6 | 5 | 4 | 4 | 0 |
| P10 | F | 56 | 5 | 5 | 4 | 4 | 0 |
| C1 | F | 85 | 19 | 0 | 2 | 2 | 2 |

| TABLE | 1. | Patient | Cohort ^a |
|-------|----|---------|---------------------|
|-------|----|---------|---------------------|

^aThis table summarizes data for each patient (P1–P10) and control (C1) involved in the study by listing patient identification codes, sex, age, number of months of NeuroModulation Technique (NMT) therapy, total number of NMT therapy sessions, the number of cavitations associated with sites of tooth extraction, and the total number of lesions before and after NMT therapy as determined by Cavitat scan. The great majority of lesions (33 of 36) were associated with sites of tooth extraction. The comparison between the total number of cavitations before (34) and after (7) NMT therapy shows a high degree of disease resolution in 8 of 10 patients.

phases: first, a test phase in which the practitioner mentally or verbally applies a selection of clinically relevant query statements structured upon some clinical topic for the purpose of identifying the patient's subconscious informational basis of pathophysiology. NMT recognizes that the aggregate neurologic and energetic components that regulate body processes function at a subconscious or "other than conscious" (OTC) rather than conscious level. The OTC level is considered intelligent and can comprehend meaningful dialog/intention that is directed to it, and can respond in a binary manner to this dialog by producing fluctuation in some body process that the OTC regulates. MRT, also known as "applied kinesiology," is a method of eliciting a subconscious yes/no response of the patient's mind–body to the presentation of some stimulus and has commonly been used in the field of complementary medicine for nearly 50 years.¹⁴ The MRT test stimulus in the context of the NMT protocol allows the therapist to measure the degree of coherence of the patient's OTC to the various diagnostic queries that comprise the therapeutic dialogue, in order to identify the underlying OTC information processing faults. In the subsequent therapy phase, the practitioner mentally projects

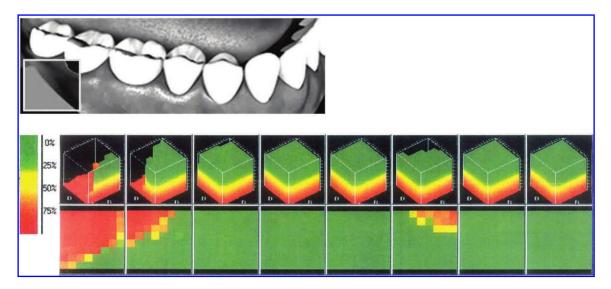


FIG. 1. A representative image produced by through-transmission ultrasonography imaging. The upper image indicates graphically the area of alveolar bone analyzed by Cavitat scan. Bone of full density for each alveolus is represented in the images below as a fully filled three-color cube. A scale correlates the percentage of density loss with the three-color layers of the cube, indicating areas of 0%–33% bone density loss (in green), 33%–66% loss (in yellow), and 66%–100% loss (in red). (Shown in black and white; for color see online version of this paper.) This image exemplifies significant loss of bone density associated with the tooth in position #1 and less severe loss associated with #2, and clinically insignificant compromise of bone density associated with #6. For clarity, each three-dimensional density-cube is further exemplified below in a two-dimensional representation seen from above.

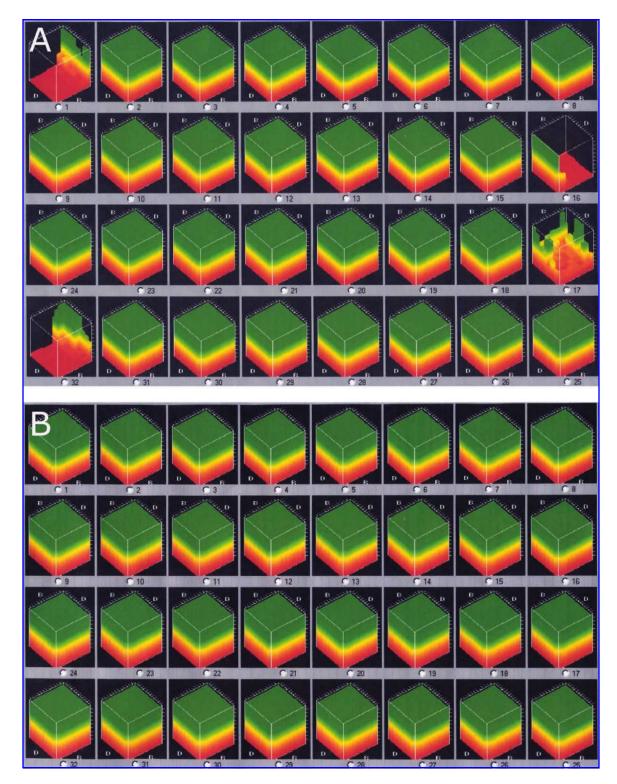


FIG. 2. Pre- and post-therapy Cavitat scans of patient P2 provide a representative example of complete lesion resolution in response to NeuroModulation Technique treatment. The pretherapy scan (**A**) showed four areas of severe bone density loss (#1, 16, 17, 32), one in each quadrant (rows from top to bottom: upper left, upper right, lower right, lower left), and all associated with old sites of third molar extraction. As shown in (**B**), the post-therapy Cavitat scan shows complete restoration of normal bone density at all four sites.

specific therapeutic intentions to the patient's OTC level to correct such faults.

The goal of this study was to induce better mind-body awareness of the jawbone cavitations, to increase angiogenic activity there, to improve immune system response to pathogens in the lesioned areas, and to increase osteogenesis in the alveolar bone. MRT was used to determine specific combinations of NMT Clinical Pathways to be applied and the

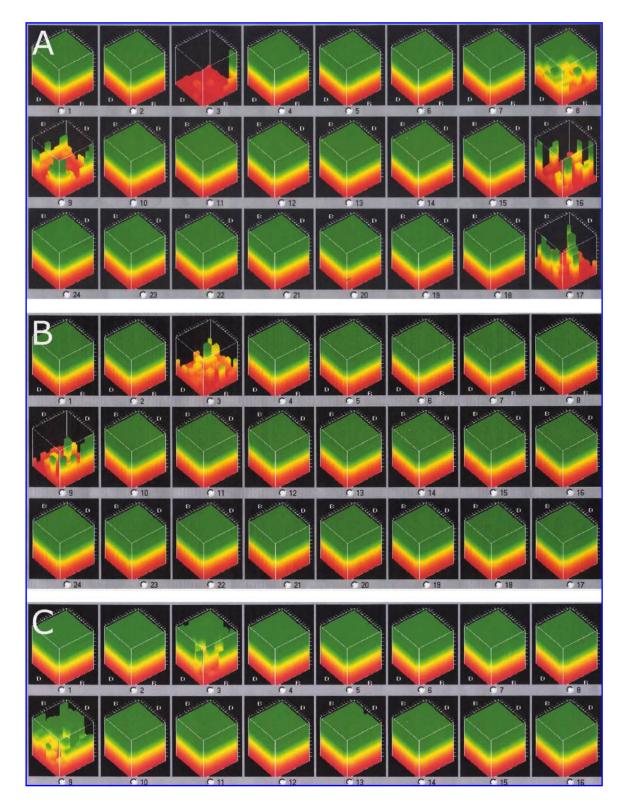


FIG. 3. The pretreatment (**A**) Cavitat scan of patient P7 demonstrated four prominent areas of diminished bone density (#3, 9, 16, 17), two of which were associated with old root canal–treated teeth (upper right first molar #3, and upper left first incisor #9) and the other two with extractions (upper right third molar #16, and lower right third molar #17). A second Cavitat scan performed after 6 months of NeuroModulation Technique (NMT) therapy (**B**) demonstrated complete restoration of normal bone density in two of the lesions (#16 and #17), little improvement in #3, and no apparent change in #9. A third scan performed after 12 more months (seven more treatments) of NMT (**C**) demonstrated a significant increase in bone density in #3 and in #9. It is also noted that the lesion that improved by the second scan (#16) remained normal in the third scan.

frequency of treatment. Treatment frequency was about once every 3–4 weeks for a maximum of 10 months. Table 1 summarizes patient demographics. One (1) NMT treated, 1 untreated, and 1 surgically treated patient were also imaged at later time-points, up to 23 months after the initial scan.

Surgical procedure

An incision was made through the anesthetized mucosa and a flap was reflected to expose the jawbone. A small hole was drilled in the bone locating the area of necrosis under the cortical bone. A window was then cut open into the lesion; the necrotic tissue in the alveolar process was cleaned with a large round bur to fresh clean bone, and the surgical site was then closed.

Statistical analysis

The significance of changes in alveolar bone density after treatment was assessed by means of a two-tailed Wilcoxon signed-rank test and 95% confidence intervals.

Results

General example of Cavitat scan

A representative image produced by the Cavitat scan demonstrates the status in alveolar bone in one quadrant of the mouth (Fig. 1). Bone of full density is represented in these images as a fully filled three-color cube. A scale correlates the percentage of density loss with the three-color layers of the cube, highlighting areas of 0%–33% bone density loss (in green), 33%–66% loss (in yellow), and 66%–100% loss (in red). (Shown in black and white; for color see online version of this paper.) This image exemplifies significant loss of bone density associated with the tooth in position #1 and less severe loss associated with #2, and clinically insignificant compromise of bone density associated with #6.

Patient cohort

Table 1 lists patient information and summarizes the outcome of our study. All subjects presented between one and six cavitational lesions at the first Cavitat scan. Importantly, we found that the great majority of lesions (33 of 36; 92%) occurred at sites where teeth had been extracted 20 or more years earlier, which further supports the idea of a natural progression of untreated cavitations toward a chronic condition. NMT-treated patients received a median number of eight treatment sessions (range from five to ten) over a median duration of therapy of 5.5 months (range from two to ten). Post-therapy Cavitat imaging showed a high percentage of lesion resolution in 8 of 10 patients (79% of the total number of lesions analyzed). The median number of lesions per subject was 4 pre-treatment and 0 post-treatment, a statistically significant decrease (p < 0.01).

Complete bone restoration after NMT

Patient P2 provides a representative example of complete lesion resolution in response to NMT therapy (Fig. 2). The pretreatment Cavitat demonstrated four areas of severe bone density loss (#1, 16, 17, 32), all associated with old wisdom tooth extractions. NMT therapy involved a total of 10 sessions completed over a period of 6 months. As indicated by the post-treatment Cavitat scan performed 1 month after the last session, this patient demonstrated complete restoration of normal bone density at all sites.

Incomplete resolution after NMT

Patient P7 is a patient whose pretreatment Cavitat demonstrated four prominent areas of diminished bone density (#3, 9, 16, 17), two of which (#3 and #9) were associated with old root canal-treated teeth and the other two with extraction (Fig. 3). As shown, this patient demonstrated complete

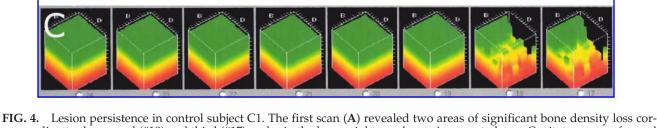


FIG. 4. Lesion persistence in control subject C1. The first scan (**A**) revealed two areas of significant bone density loss corresponding to the second (#18) and third (#17) molar in the lower right quadrant. As expected, two Cavitat scans performed after 19 months (**B**) and after 42 months (**C**) both demonstrated persistence of these lesions.

NMT THERAPY FOR CAVITATIONS

restoration of normal bone density in two of the lesions (#16 and #17), little change in #3, and no apparent change in #9 after eight NMT treatments over a period of 6 months.

This patient elected to continue after the second Cavitat scan with NMT therapy for another seven sessions over a period of 12 months. The third Cavitat scan demonstrated significant increase in bone density in positions #3 and #9. It is also noted in this figure that the lesion in position #16 that improved by the second scan remained normal bone density at the third scan (which was also true for position #17, data not shown), suggesting durable resolution in this patient by NMT therapy.

Lesion persistence in the untreated control subject

In contrast, Figure 4 shows data from subject C1, a control patient who elected to receive no treatment of any kind for the two lesions demonstrated on her first Cavitat scan (#17 and #18). She received the first scan, a second scan 19 months later, and a third scan approximately 2 years thereafter. As expected from prior observations, she demonstrated persistence of pathologic bone density loss between scans #1, #2, and #3.

Lesion persistence after NMT therapy

Figure 5 shows data from P1, a patient whose first scan demonstrated two cavitation lesions (#16 and #17), which were sites of old wisdom tooth extraction. The second scan performed 7 months later demonstrated only a slight improvement of these lesions with NMT, and the patient elected to undergo surgery, which was performed shortly after the second scan. Of importance, we found that the sur-

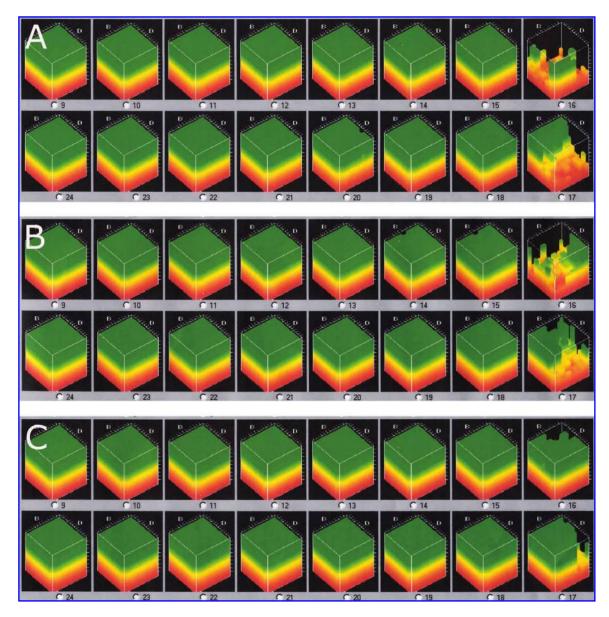


FIG. 5. Pretherapy Cavitat scan (**A**) of patient P1 demonstrated two cavitation lesions (#16 and #17) in the upper right and lower right quadrants, which were sites of wisdom tooth extraction. A post–NeuroModulation Technique Cavitat scan (**B**) demonstrated no significant improvement of bone density at these sites, and the patient elected to receive surgery. A third scan (**C**) performed 10 months postsurgery revealed good healing of both lesions.

gical sites contained a greasy black substance that represents unabsorbed medicament that was added concomitantly with the extraction, probably with the intention of promoting healing, but which might have behaved as a foreign substance that precluded osteogenesis. The third scan performed 10 months postsurgery revealed good healing of both lesions.

Discussion

This study analyzed an alternative healing modality to induce resolution of jawbone cavitations, a progressive condition of the mouth that can affect as many as 80% of all people who have had a wisdom tooth extraction. We show that treatment with the intention-based healing system Neuro-Modulation Technique induces regression of osteonecrotic lesions with an efficacy that is comparable to that known of surgery.

For diagnosed cases of cavitation, surgery has been the preferred intervention in dental practice. Unfortunately, surgery itself can be a painful procedure associated with health risks for the patients. Surgery also inevitably produces new physical trauma to the already distressed tissue, which in turn predisposes the area for more inflammation. This might explain why at least one third of cavitation surgeries present post-treatment complications or recurrence of the lesions. One important factor underlying the power of NMT therapy for the observed disease resolution may be that no biological trauma is produced.

Notably, in patient P7, the two lesions associated with wisdom tooth extractions healed completely, while the two lesions associated with teeth that had root canals demonstrated little improvement on the second scan and required NMT treatment another 12 months before bone density approached normal range. Root canal-treated teeth no longer have the intact vasculature to deliver immune system cells to the body of the tooth, and this may permit a toxic environment around such teeth that slows bone restoration. Since jawbone osteonecrosis produces an extremely toxic microenvironment associated with increased burden on the patient's immune function and lymphatic system, this condition may well predispose to other insidious systemic disease. Interestingly, patient P2 had long-standing complaints of chronic fatigue syndrome and fibromyalgia that resolved completely over the course of his first 6 months of treatment, possibly reflecting a relationship between cavitations and systemic disease.

The clinical effect of NMT is solely that of highly structured therapeutic intention. As background support for this effect, the work of Tiller and his associates has provided both a solid experimental and theoretical framework to demonstrate that mind/emotion action by humans can manifest as significant property changes in physical reality.^{24–27} Carefully controlled scientific research proved that focused human intention can, for example, modulate the chemical properties of water molecules, increase the speed of biochemical reactions occurring in living biological tissues, alter the subconscious arousal-state of other human beings, or even skew the data processing activity of computerized random number generators (reviewed in Radin and McTaggart^{28,29}). In NMT therapy, the purpose of the pathway language is to assist the practitioner in bringing clearly to mind the conceptual meaning of the various pathway query and corrective intentions so that he/she may iconographically project this meaning to the patient at an OTC level. This process is believed to raise the patient's OTC level to a higher state of awareness about its present internal state and to initiate a process of self-reorganization that will spontaneously lead to more correct body regulation.

Conclusions

Based on the very promising results of this study, larger placebo-controlled trials are encouraged to investigate in depth the potential of NMT for treating cavitational osteonecrosis. Our results also encourage exploring potential applications of NMT in other inflammatory and degenerative pathologies.

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Disclosure Statement

No competing financial interests exist.

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