Challenges for Preclinical Investigations of Human Biofield Modalities

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ABSTRACT

Preclinical models for studying the effects of the human biofield have great potential to advance our understanding of human biofield modalities, which include external qigong, Johrei, Reiki, therapeutic touch, healing touch, polarity therapy, pranic healing, and other practices. A short history of Western biofield studies using preclinical models is presented and demonstrates numerous and consistent examples of human biofields significantly affecting biological systems both in vitro and in vivo. Methodological issues arising from these studies and practical solutions in experimental design are presented. Important questions still left unanswered with preclinical models include variable reproducibility, dosing, intentionality of the practitioner, best preclinical systems, and mechanisms. Input from the biofield practitioners in the experimental design is critical to improving experimental outcomes; however, the development of standard criteria for uniformity of practice and for inclusion of multiple practitioners is needed. Research in human biofield studies involving preclinical models promises a better understanding of the mechanisms underlying the efficacy of biofield therapies and will be important in guiding clinical protocols and integrating treatments with conventional medical therapies.

HISTORY OF WESTERN BIOFIELD STUDIES

The foundation of Western biofield research can be traced to the pioneering work of the late biologist Grad at McGill University, Montreal, Canada, in the 1960s. Bernard Grad, PhD, and colleagues reported that a biofield practitioner was able to influence the germination of plant seeds and wound-healing in mice. Since then, numerous other biofield modalities have been studied, including external qigong, Johrei, Reiki, TT, healing touch, polarity therapy, and pranic healing, among others. The experimental models tested have also been expanded to include cells and even molecules. For example, results have been reported indicating that external qigong treatment can reduce phosphorylation of the protein molecule myosin in a cell-free system. Much of the appeal of preclinical models is that they presumably exclude psychosocial elements. Thus experimentation using these models has the potential to dispel the prevailing consensus within the academic medical community that the power of suggestion or expectation underlies the efficacy of biofield therapies. This report offers perspectives on challenges facing scientists and physicians in biofield research and develops strategies to more effectively realize the potential of preclinical models for advancing the scientific understanding and exploration of biofield modalities. We will first briefly address previous research, then begin to address questions that remain unanswered in preclinical investigations, and finally discuss some of the current challenges in the field.
recipient of the intended healing. Benor discusses healing action on the following: enzymes, cells in the laboratory, fungi/yeasts, bacteria, plants, single cell organisms, and animals that have been subjected to controlled study.\(^5\) Often, these early preclinical studies presented unresolved issues of reliability. For example, Snel\(^6\) reported significant growth inhibition of mouse leukemia cells in tissue culture but not on attempted replication. Even Grad found that a practiced healer whom he used for his preclinical studies was unable to reproduce significant effects on trypsin in vitro when he was personally not at ease.\(^7\) This pattern of unreliability led skeptics to argue that claims regarding the efficacy of biofield modalities should await reliably repeatable experiments by multiple independent laboratories.

Biofield studies can be demarcated as “modern” by a seminal 2003 issue of *Alternative Therapies in Health and Medicine*. That issue published the results from a Samueli Institute (Alexandria, Virginia) conference intended to systematically assess the quality of biofield research to that date and to recommend standards for future research. In the same vein as earlier reviews, Crawford et al\(^8\) published a systematic review of the quality of both clinical and laboratory peer-reviewed biofield research performed between 1955 and 2001. After reviewing 45 laboratory and 45 clinical studies, they concluded that distant healing studies were of higher quality than hands-on healing studies and that laboratory studies were of higher quality than clinical studies. They also concluded that the main deficiencies in the field were the lack of independent replication, inadequate blinding, reliability of outcome measures, and an inadequate use of power estimations and confidence intervals.\(^8\)

In the same issue of *Alternative Therapies in Health and Medicine*, Schlitz et al\(^9\) summarized replicable effects of biofield healing on enzymes,\(^10\) fungi,\(^11\) yeast,\(^12\) bacteria,\(^13\) cancer cells,\(^14\) and hemolysis of red blood cells under osmotic stress.\(^15\) Schlitz et al made 38 specific recommendations regarding experimental protocols for studying biofield healing, addressing issues of proper randomization, sensory shielding, blinding, and fraud prevention. The authors suggest that standardized experimental protocols accompanied by systematic variations of selected parameters would increase chances of replication along with increased possibility of developing useful theoretical models.

Works published since the 2003 Samueli conference have increased the proportion of studies that might be termed "second order." That is, instead of a simple first-order demonstration of the phenomenon of biofield healing, there have been more studies looking for significant correlates to the healing, including the use of multiple simultaneous targets and dose responses. For example, Gronowicz et al\(^16\) assessed the dose-dependent effects of TT on the proliferation of different types of human cells in culture. Fibroblasts, tendon cells (tenocytes), and bone cells (osteoblasts) were treated with TT, sham treatment, or no treatment for 10 minutes per treatment with varying frequencies of treatment each week. They found that tenocytes and fibroblasts but not osteoblasts demonstrated significant increases in cell proliferation in the first week of treatment while osteoblasts did only after 2 weeks of treatment. All 3 cell types responded to 2 TT treatments per week for 2 weeks, suggesting a threshold for treatments that affect proliferation in multiple cell types.\(^16\)

Multiple targets were also used by Abe et al\(^17\) to explore the effect of Johrei on the viability and proliferation of cultured human cancer cells. Loss of cancer cell viability was significantly higher than in control groups, even though the responsiveness to Johrei varied with 7 different cancer types. The human gastric cancer cell line AGS and the uterine cervix epithelioid carcinoma HeLa proved most susceptible to Johrei, while the prostate carcinomas PC-3 and PCC-1 were the least susceptible. Somewhere in between were the human malignant lymphoma U937, the prostate carcinoma ALVA-41, and the mouse melanoma B16. These second-order phenomena of healing variability by cell line may provide the kind of promise for theoretical development hoped for earlier by Schlitz et al.\(^9\) For example, genetic mutations or differing expression patterns of ion channels unique to a particular cell type and associated with altered responsiveness to biofield therapies might provide clues regarding molecular pathways mediating the effects. Another multiple target study was published by Radin et al,\(^18\) who measured the effects of Johrei healing on both cultured cells and random event generators simultaneously. The authors found evidence supporting the notion that healing intention occurring within a given space can alter or condition the space such that the effect of healing intention on the growth of cell cultures is enhanced and that there is also an associated increase in statistical order for otherwise random events. Preclinical models have also been used to examine devices purported to harness or recreate aspects of biofield therapies, and those studies are discussed elsewhere in this issue.

In summary, general acceptance by the scientific community of human biofield research has been limited without recognition of its therapeutic potential. More than a half-century of preclinical research into the efficacy of human biofield modalities has effectively demonstrated significant results, but there remains great reluctance on the part of conventional biology and medicine to embrace biofield research. At this point, this reluctance appears to stem from a lack of interest or sometimes outright antagonism rather than in any presumed dearth of data. In addition, the paradigmatic assumptions of conventional biology and medicine may often seem at odds with some aspects of biofield research. Thus this disciplinary reluctance sometimes originates on a pretheoretical level rather than in the inability of biofield researchers to conform to acceptable scientific standards. A great deal of the past 50 years of biofield research has been devoted to demonstrations of very basic questions: Are the phenomena real? What might
be efficacious models for study? Left relatively unexamined are second-order questions, which are beginning to attract more attention.

**Methodological Issues, Practical Solutions, and Unanswered Questions**

Researchers are turning attention to questions such as dose response. What is the effect of dosing on biological outcomes? Do more biofield treatments increase efficacy, and if so, do they do so in a linear manner? Do short doses compound to equal longer doses? For example, does a 2-hour biofield treatment produce the same effect as 4 half-hour treatments? Is there a maximum dosage that can be utilized in any particular application? Do repeated biofield applications combine in effect to create a critical mass that produces something analogous to a phase transition, and how long does this effect last? Do different biofield modalities yield different effects, and what might these differences tell us about the underlying mechanisms? When a biofield practitioner successfully applies a modality to produce significant changes in cell cultures or to experimental animals, what might be the mechanism?

**Variable Effects and Statistical Solutions**

As discussed previously, one challenge facing researchers is the variability reported from well-designed studies on the biofield. This particular challenge can be addressed in part by the use of appropriate sample-size calculations and rigorous statistical methods. Sample-size calculations are essential for assuring biofield studies are properly powered to detect statistical significance and avoid type II errors. Often biofield studies require a larger population size to truly determine statistical significance. For cellular and molecular biological studies, a general rule is to repeat exactly the same experiment at least 3 independent times to ensure reproducibility of results. Ideally, at least 3 experimental groups for biofield experiments should be included: biofield treatment, sham and/or mock treatment, and no-treatment control.

A relevant approach developed specifically for studying variable biological effects is to include systematic negative controls in the protocol. The systematic negative control design randomly alternates between experiments in which the experimental treatment is compared to sham treatment (treatment/sham) and experiments comparing sham treatment to another sham treatment (sham/sham) as a way to continually assess potential variability within the model system. This stringent experimental protocol allowed Wallaczek and colleagues to convincingly describe an approximate 1.8-fold increase in the mutation frequency of a gene under specific conditions combining magnetic-field exposure and ionizing radiation.\(^{19}\) In one study assessing the influence of external qigong on cultured human brain cells, inclusion of systematic negative controls proved crucial for interpreting results that included an outlier in the experimental data set.\(^{20}\)

One of the experiments in this study comparing external qigong treatment to sham treatment yielded a data point indicative of an exceptionally strong effect. If this outlying data point were considered only within the treatment/sham dataset, it could have been interpreted as an exceptional performance by a particular practitioner in that particular experiment. However, 2 data points from sham/sham experiments were also outliers to a similar degree. Thus the outlying datapoint in the treatment/sham experiment fell within the range of variability associated with the experimental model and did not sway the results into spurious significance.

Another important aspect of designing preclinical studies is describing and enacting protocols that insure that the experimenters are “blinded” to any information that could conceivably lead to bias in the results. For example, all information regarding which experimental group is the control or sham/mock or biofield-treated group must be concealed from the experimenters involved in handling of the experimental targets and analyses of the results. Such procedures protect against both intentional and unconscious bias. Standardization of protocols for blinding, as well as for biofield and sham/mock treatments, is also an important aspect of experimental design that requires careful attention from experimenters in the field so that results can be compared across studies.

**Choice of Model Systems**

No standards exist regarding the appropriate preclinical targets for treatment by biofield practitioners for experiments in this area of scientific study. It remains an open question whether in vitro or in vivo approaches to biofield healing hold the most promise. Strickland and Boyland\(^{21}\) investigated the use of enzyme folding to explore the mechanism of TT with mixed results. Shah et al\(^{22}\) examined the effect of healing on tumor cell growth using cell culture models similar to those used by oncologists to assess the effect of chemotherapeutic agents, only to conclude that the assays were limited in their ability to demonstrate efficacy. Yount et al\(^{23}\) came to the conclusion that to achieve optimal effects, biofield therapies may rely on intact and interconnected organ systems and that in vivo models may likely be more appropriate. They acknowledge that in vitro models might provide better insight into understanding the underlying mechanism but that in vivo models offer better opportunities for evaluating biofield treatment efficacy. In that same article, Yount and colleagues also reported a problem with reliability, which is an all too common frustration among biofield researchers. While these researchers produced results that were among the first indicators of a biofield treatment dose response, their data were inconclusive because of a failure to replicate.

Gronowicz and colleagues found evidence of variable responsiveness among in vitro models (Figure). Panel A of the Figure shows an example of osteosarcoma cells that do not appear to be responsive to biofield...
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Treatment. TT treatment had no significant effect on the proliferation of SaOs osteosarcoma cells when assayed by tritiated thymidine incorporation into the DNA. However, parallel experiments with another human osteosarcoma cell line, HOS, yielded a significant decrease in proliferation with this same treatment and assay (panel B). In both cases, values associated with a placebo/mock (P) treatment were similar to control levels (C). It is possible that genetic differences between these 2 osteosarcoma cell lines render them differentially responsive to TT treatment. Interestingly, significant results were observed with both cell lines in this same experiment when the outcome measure was calcification of the bone matrix (panels C and D). Taken together, these results suggest that the choice of system and assay is important in designing experiments evaluating human biofield therapies. Additionally, experience with the scientific system and protocol to be used in the biofield study is essential to troubleshoot any issues that may arise that might increase variability and obscure significant effects.

Some evidence supports the idea that in vivo models offer the opportunity for both increased reliability and efficacy. Bengston and Krinsley demonstrated that inexperienced skeptical volunteers taught a novel biofield therapy involving visualizations were able to cure mice that were injected with a lethal dose of mammary cancer cells. Injected mice treated by the volunteer healers all developed tumors, which then ulcerated and imploded to full lifespan cure. At all stages of remission until full cure, there were viable cancer cells found. Further, cured mice were reinjected with the cancer at various times during their lives, and none developed the cancer again. Nor was a cell line that has been treated in vivo able to seed tumors going forward. By this publication, there have been 5 replications with consistent results in 4 independent laboratories of this in vivo mammary model using a wide variety of volunteer healers. Also of note was the apparent mimicking of placebo-like curing of tumors in some of the untreated control animals.

Data reported by several groups suggest that the immune system may be a particularly useful target of biofield studies in both humans and animals. The immune system appears to play an important role in the progression of some cancers, especially breast and ovarian cancers. Recent studies have shown that yoga for human breast cancer subjects and biofield treatments of animals with breast cancer can affect inflammatory signaling specifically, reducing interleukin-related inflammatory responses. In human studies, natural killer cell activity and numbers have been affected. In mouse studies, human biofield therapies also appear to target macrophage numbers and activity and reduce metastasis. An interesting possibility suggested by these apparent effects on inflammatory molecules and cells is that biofield therapies promote healing by returning systems to homeostasis or homeodynamic state in which the immune system is optimal for responding to biological threats. These tantalizing results will require further study and should be a consideration in future studies on cancer and human biofield therapies.
Characteristics of the Biofield

Perhaps the most fundamental challenge facing biofield researchers is the uncharacterized nature of the biofield itself, which makes determining experimental conditions difficult. Without definitive knowledge on the nature of the human biofield, determination of the length and frequency of biofield therapies for particular preclinical models can be complicated. Many biofield modalities are based on the premise of complex and interconnected energy fields operating in the body as a whole. Therefore approaches that examine cells separated from the body may not be ideal for studying the effects of biofield therapy.

Another open question is whether biofield treatments may cause persistent alterations in the local physics of the laboratory space that would influence subsequent experiments. Such a lingering effect could affect a control specimen placed in the same area after a biofield treatment occurred. This could conceivably work to obviate or minimize differences between treated and control groups. On the other hand, such an effect might be leveraged to enhance the ability to see the effects of treatments. Some experimental evidence supporting this possibility has been published, as mentioned above. The uncharacterized nature of the biofield also presents unique challenges to scientists regarding the design of appropriate sham and control conditions. As one example, Bengston and colleagues questioned whether their protocol for a no-treatment control group was adequate because mice in the control group still experienced remission of the cancer when they were simply observed by a practitioner. These observations underscore the importance of controlling for physical parameters associated with the proximity of a human body (the practitioner) that could potentially influence biological targets. In cases when separate spaces are used for any experimental group, it is important to verify that the environmental conditions of the spaces are as close to identical as possible.

There is mounting evidence from preclinical studies demonstrating a dose-dependent response to human biofield therapy that needs to be considered when designing biofield studies. One treatment may be adequate if rapid effects such as calcium exchange across cell membranes are studied but not if cell processes such as proliferation or differentiation are assessed. In general, there is evidence indicating that multiple treatments over 1 week are required for most cell types to respond to different dose administrations, and in some cases, multiple treatments for more than 1 week are necessary. For animal models, multiple treatments over several weeks may be required. In a preclinical study with healthy humans, 3 treatments, each lasting 15 to 20 minutes, at 3-day intervals were required to produce statistically significant effects in blood hemoglobin and hematocrit levels.

Involvement of Practitioners in Study Design

Appropriate engagement of practitioners in the design of biofield studies is essential because of tacit knowledge they possess regarding parameters associated with their practice, especially duration of treatments from their previous clinical experiences. However, since many practitioners are accustomed to working with patients, preclinical studies can be difficult for practitioners since the initial step of centering and setting an intention for the treatment is complicated by relating to animals or a dish of cells. This issue was addressed in experiments with Reiki practitioners treating bacterial cultures. Rubik et al found that a 30-minute patient treatment that provided a healing context was necessary for the practitioners to elicit significant effects in subsequent experiments on bacterial cultures. Another group of practitioners found that journaling on their treatments throughout the experiments was particularly helpful for enhancing consistency in treating cell culture dishes and led to better outcomes in preclinical studies.

Another aspect of the experimental design left unaddressed in most studies to date is the role of healer intention and if different intentions set by the practitioner, such as wanting to kill cancer cells while treating the cells, can influence the results of experiments in preclinical biofield studies. Practitioner engagement is also important because there may be conditions that seem appropriate from the scientific perspective but would interfere with a particular practitioner’s ability to perform optimally. For example, it is unclear whether it is appropriate for scientists to ask practitioners to try to kill cancer cells, and healers differ in their attitudes to this request. Perhaps the intentions for these studies should be for the “highest good” instead. At the same time, it is also important to exercise caution when incorporating input from practitioners. For example, a study evaluating the accuracy of practitioners’ perceptions of energetic fields demonstrated that there can be significant “noise” in such perceptions. The study evaluated whether practitioners could distinguish without visual cues a flask containing water from one containing human cancer cells. Not only were the practitioners unable to make this distinction, they also conveyed extensive information that was apparently erroneous with a high level of confidence.

Assessment of Practitioner Effectiveness

The development of standardized methods for assessing the quality of practitioners and ensuring uniformity in practice is another unique challenge facing biofield researchers, particularly as some biofield modalities do not have certificate programs or any standardization. A few investigators led the way in this regard. In the experiments mentioned above with Reiki practitioners treating bacterial cultures, for example, Rubik and colleagues found that higher scores in overall social and emotional wellbeing of the practitioners, as determined by the Arizona Integrated Outcomes Scale, were correlated with more robust effects on bacteria cultures. In another study, TT practitioners...
were selected for participation in cell and human studies based on a screening test. All practitioners were required to have had at least 3 years of experience in TT, be educated at the basic or intermediate level in the Kreiger-Kunz method of TT, and to have elicited at least 3 of 5 objective measures of effectiveness in treating a person. Two of the measures required interviewing the recipient after the treatment and assessment based on a visual analogue scale. The other 3 measures were associated with visible changes in the patient. Two judges for each of the 5 measures made independent assessments and then practitioners were selected for the studies based on the average of the total scores. These and other standardized screenings techniques require further development and should be included in the methodology of future studies.

**FUTURE RESEARCH**

Significant challenges face researchers using pre-clinical models to study human biofield therapies. The inclusion of human intentionality as one of the experimental variables and the close proximity of a human body makes some of these challenges unique to this area of investigation. To rise to these challenges, researchers need to employ increased scientific rigor, including strategies with strong experimental design and statistical analyses, incorporation of practitioner perspectives, and examination of alternative explanations. Ultimately, pre-clinical models have the potential to powerfully inform future research aimed at understanding and exploration of biofield modalities. Moreover, these models promise a better understanding of the mechanisms underlying the efficacy of biofield treatments, which will have important implications for guiding clinical protocols and integrating treatments with conventional therapies.

**REFERENCES**

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