Osteopathic research: The needed paradigm shift

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Among the osteopathic medical profession's most conspicuous achievements of the past 20 years has been the threefold expansion of its very source—the colleges of osteopathic medicine—from 5 to 15, 10 of them university-affiliated and publicly funded. As a result, the osteopathic medical profession has been recognized as the nation's fastest growing profession. No less important is the fact that in the process it has succeeded in recruiting a corps of competent scientists, *more* than three times larger than that of 20 years ago, to serve as teachers of osteopathic physicians and as researchers in the basic medical sciences. This has presented the osteopathic medical profession with the opportunity for a proportionate increase in the scale and scope of its research productivity.

There *has* been such an expansion of research under osteopathic auspices, much of which has brought wide recognition to the investigators and their institutions. There has been little increase of research, however, in areas most relevant to osteopathic theory and practice, and designed to test and refine the theory and improve the effectiveness of practice. There are valid reasons, of course, why scientists are loathe to depart—and should *not* depart—from fields for which they prepared, in which they have established themselves and become productive, widely recognized, and successful in procuring grants in order to seek answers to osteopathic questions. Nevertheless, it has been both disappointing and perplexing that so few have found challenge and excitement in the hundreds of questions waiting to be asked and addressed that have arisen from osteopathic thought, prior research, and a century of clinical observation and experience.

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Two main reasons (aside from the prior commitments just identified) have emerged from inquiries of many colleagues over many years. First is the misperception that "osteopathic" research is limited to investigation of the "distinctive" modality, manipulative treatment; and that if one's skills are in areas not directly related to the musculoskeletal system, one has no contribution to make.

Second is the general impression that osteopathic principles, as customarily presented—the body is a unit; the body has inherent self-regulatory, defensive, and recuperative powers; structure and function are reciprocally related, etc—are so self-evident, axiomatic, implicit, and pervasive in biomedical research as to be too platitudinous to raise new questions for research.

This article is addressed to these misperceptions. Its purposes are as follows: (1) to restate and elaborate the familiar osteopathic principles from my viewpoint as a physiologist in such a way as to make more evident their theoretical implications and to evoke the latent questions; (2) to identify, on the basis of the elaborated principles, some of the areas awaiting exploration; and (3) to indicate the kinds of investigative strategies—paradigms—that seem to be called for. In the concluding section, I shall more briefly examine the implications of these principles, as restated, to the testing of the effectiveness of osteopathic medical care.

(continued on page 161)

My offerings, in this context, are products of 54 years of experience in medical education and research, 45 of those years in intimate and broad acquaintance with osteopathic physicians as teacher, researcher, curious observer, grateful patient, and persistent asker of questions. The offerings therefore are unavoidably a mixture of documentable "facts" and less objective perceptions, insights, and opinions. I have tried, throughout, to distinguish the objective from the subjective, but given the inevitable coloring of interpretation of objective data by subjective viewpoints, I cannot claim total success. I hope that the reader will assume that there is an experiential, substantive basis for my perceptions.

A heuristic interpretation of osteopathic principles

The unity of the person

Extending unity from body to person has theoretical and clinical implications far more fundamental than they may appear. This is not to deny that the earlier osteopathic emphasis on the unity of the *body* in clinical practice has been an important contribution to human health. But, it is a remnant of the mechanistic and dualistic Cartesian viewpoint that the body is a machine (and that the physician is a mechanic) and that the mind is quite a separate, and superimposed, entity. The premise underlying research and practice guided by this perspective is that total understanding of the person, as well as the body, can be achieved by study of body parts and processes.

The mechanistic biomedical philosophy that I refer to (and perhaps caricature) has guided medical research for many decades. Its basic premise, whether articulated or not, is that the way to understand *anything*, including humans, their illnesses, and the origins of their vulnerability, is to take them apart; that is, to reduce them to their components, and to study these and their interactions as minutely as possible. Thus, to understand each human disease, seek the part or the process that has gone wrong, the way it has gone wrong, and what (the cause) has made it go wrong; then find the chemical or physical agent to set the part right and thereby restore the patient to health. The disease is seen as that of the component—the kidneys, the heart, the skin, etc. For obvious reasons, this research paradigm is described as "reductionist."

Having in this critical manner characterized research in the reductionist mode, I hasten to point out that such research is essential to scientific progress and that it has been enormously productive of knowledge about biological structure and process, about the things that go wrong with this or that kind of cell, tissue, or organ, the causative factors and the functional and clinical manifestations of these departures from normal. Many of the medical advances of this century can be ascribed to such analytical research. The growing reservations about the reductionist paradigm are not that it has been unproductive or misguided, but that it is *incomplete*, most particularly with respect to the human species.

It is incomplete in that it gives little importance or attention to the organismic context. Discounted are the facts that (1) the organism is the environment—the context—in which the parts operate; (2) that human contexts are different from those of the various species from which most of the knowledge about component parts and processes is acquired (that is, that they function in totally different kinds of organisms, living vastly different kinds of lives, in vastly different kinds of environments); (3) that each human provides a context distinct from that of every other human; and (4) that everything about each person, from conception on, subjective as well as objective, enters into determining how well every part functions, for how long, and how it may go wrong.

Reductionism is incomplete in that, in effect, it regards the organism—the person—as merely the sum of body parts. By reducing the organism to its component parts, reductionist research conceptually demolishes the very entity it seeks to understand. It sees too little need to take into account that at each higher level of organizational complexity, properties emerge that cannot be understood or predicted from the properties of the components, and that the components may even be governed by the emergent phenomena. I mean this in the sense that the properties of water cannot be

predicted from the properties of hydrogen and oxygen, and that once incorporated in water hydrogen and oxygen are constrained by the very molecules that they comprise.

In its drive for universal, all-encompassing laws, reductionism ignores the diversity of expression of these laws from person to person. Valuable as is our knowledge about *the* heart, it remains an abstraction. There are only *hearts*, each different from all others according to who the person is and his or her entire history, from conception on. Materialistic in its orientation, reductionism dismisses as irrelevant, the circular interplay between the material (the body) and the impalpable—mind, feeling, belief, past conditioning, etc. Subjective experience is seen as too "soft" for scientific attention. Only that which can be *objectively* demonstrated, quantified, and replicated is admissible to its realm.

Reductionist biomedical research clings, although somewhat less tenaciously in recent years, to the concept of linear causality—one-way cause-effect relationships—and pursues the quest in medical research and practice for the specific cause and specific cure. In doing so, it overlooks the role of the patient, and of the immense and unique constellation of factors in and around the patient, in both pathogenesis and recovery. Even in infectious disease, in which "specific etiology" seems established, the pioneer in that field, Louis Pasteur, reminded us that the microbe proliferates only when the host has become too hospitable because of preexisting illness.[1] Finally, reductionist, mechanistic medical research fails to see that when illness occurs, whatever the affected part, it is illness of the *person*.

It is in this incompleteness that the reductionist paradigm does not meet the requirements of osteopathic research. From the osteopathic viewpoint, nothing can be understood *except* in relation to something else, and especially to the totality of which it is a part and which it serves. While the knowledge yielded by reductionist research is essential to osteopathic research, the latter requires, in effect, that the knowledge about the component structures and processes be reinserted into the total person whom it serves, where it is subject to the influences of all other parts through the communication systems of the body, and where it is affected by all the factors—physical, chemical, mental, emotional, social, and environmental—that render the human distinct from all other species, and each human different from all other humans. *The reinsertion of the parts into the human context accomplishes the needed completion.* What is more, when the human is restored to its context, new light is cast on each part: Properties, functions, interactions emerge that are not evident in isolation and out of that context.

This is my personal interpretation and elaboration of "the body is a unit."

The patient's health-maintaining and health-restoring powers

Osteopathic medical practice is predicated on the patient's inherent "healthcare system." That system comprises all the homeostatic, defensive, and healing functions, including the numerous reflex and humoral self-regulatory mechanisms, the enormously complex immune system and its nervous and humoral control and feedback, the detoxifying mechanisms, the capacities for self-repair and regeneration, and the integrative role of the nervous system, and others well known to biomedical scientists. Included also are the "body's own medicines," more recently called "endocoids," now known to compose a large and diverse pharmacopeia.[2]

The osteopathic physician sees it as his or her major responsibility to evoke and support those mechanisms, to remove all possible impediments to their functions, and, above all, to do them no harm in the course of treatment. The osteopathic physician is aware that it is the patients who *get* well and not the procedure or the medication that *makes* them well; that cure comes from within. It is never forgotten that while the physician's care is often crucial to recovery, *all* treatment ultimately depends on, and would be valueless without, those indwelling mechanisms. They are the ultimate source of health and the means for recovery of health.

This, for me, is the essential meaning of the "body's healing power."

The musculoskeletal system

Osteopathic thought and practice seek to integrate the musculoskeletal system into the community of organs and systems and to give it its rightful place in the total organismic scheme.

- More than just the locomotor system, the musculoskeletal system is seen as the instrumentality through which we express every aspect of our humanity and of our individuality. It is the means through which thought, emotion, belief, and moral, ethical, and religious principles find their expression in behavior. It is our means of communication, whether by spoken or written word, signal, gesture, or facial expression. It is the instrument through which intellect and creativity are manifested.
- The most massive of all the body systems, the musculoskeletal system is also metabolically the most demanding on all the other systems to meet its logistic requirements, which vary widely from moment to moment according to what the person is doing, how he or she is responding to the environment and his or her circumstances. As the major "consumer" in the body economy, the musculoskeletal system therefore is the major source of perturbation and of continual and varying challenge to the homeostatic mechanisms of the body.
- Through its rich efferent and afferent connections with the central nervous system and through the large volumes of blood that perfuse it, the musculoskeletal system both influences and reflects what goes on in all other systems and therefore in the person as a whole.
- Much, perhaps most, illness fundamentally may be viewed as discrepancy between musculoskeletal requirements and the meeting of those requirements by other systems, whether the discrepancy is due to (1) inappropriate or excessive behavioral and musculoskeletal demand; (2) musculoskeletal dysfunction; (3) visceral dysfunction, or (4) miscommunication among the systems. The larger the discrepancy, the less able is the musculoskeletal system to serve as the means for body support and motion. Therapeutic rest is automatically imposed.
- Unlike the quadruped, the human musculoskeletal system is peculiarly vulnerable to gravitational and other external forces because of its vertical configuration and its narrow bipedal base. Research (to be cited later) and clinical experience show that resulting dysfunction is communicated to other tissues and organs with deleterious effects, especially to those innervated from related parts of the spinal cord. As has also been shown (and will be cited later), musculoskeletal dysfunction, through the central and autonomic nervous systems, focuses and magnifies the impact of other negative factors in the person's life on neurologically related organs. Somatic dysfunction therefore is a frequent source of impediment to the person's health-maintaining and health-restoring mechanisms.
- Because of its intercommunication with all other systems, thereby both reflecting and influencing what goes on in them, and because of its accessibility, the musculoskeletal system provides a basis both for diagnosis and for the introduction of favorable influences on the other systems and on the person as a whole. Osteopathic manipulative treatment (OMT) of the ill patient is not treatment of the disease but rather treatment of the patient's ability to deal with the disease.

These six features and their clinical and theoretical implications are an interpretation and elaboration of the original principle that "structure determines function" and its more recent version that "structure and function are reciprocally interrelated." Review of the older osteopathic literature indicates that "structure" was not intended as a universal concept but as *musculoskeletal* structure, as in "structural diagnosis."

The questions

What kinds of questions are suggested by these expanded versions of osteopathic principles? A few are identified here for consideration by biomedical scientists in osteopathic institutions. Included, also, are some questions that were the products of prior investigations and that have remained unanswered. In research, as in other areas of human endeavor, "It is better," as author James Thurber said in *The Fable of Our Times*, "to know some of the questions than all of the answers."

Questions related to the human context

In what ways have fundamental biological structures, such as heart, lungs, and reticuloendothelial tissues, and processes, such as respiration, metabolism, thermoregulation, and blood circulation, that are shared by all mammals, been adapted to the unique demands of *human* life? To the upright stance and bipedal locomotion? To the enormous cerebral development and the accompanying new capacities and to the new kinds of demands that they created? To the diverse manmade environments? To the trappings of culture and civilization? Which structures, processes, responses, behavior patterns have remained *un*modified and ill-adapted or inappropriate to the requirements of human life? How are all these factors related to human susceptibility to illnesses that are uniquely common in humans, such as the chronic degenerative diseases, and rare in other species (except in domesticated ones)? That is, to what degree is the human capacity for health and human illnesses as much a product of evolution as humans themselves?

Questions related to individual human contexts

Why do some hearts (stomachs, kidneys, brains, immune systems, etc) go on serving their owners well for 80, 90, 100 years or longer, while others succumb much sooner? What resources do the healthy, disease-resistant, long-lived people have that others do not? Aside from heredity, what factors account for their good fortune that can be taught or conveyed to others? Instead of focusing almost exclusively on the causes of this or that disease, should we not seek the "cause" of *non*-disease—of health as a phenomenon in itself?

In this connection, the entire field of body-mind interplay, exemplified in the emergence of psychoneuroimmunology as a distinct discipline[3] is most relevant to osteopathic theory and practice. How are stress, psychic tension, and emotional conflicts somatically expressed, for example, in organ function, in posture, and patterns of muscle tensions? To what extent do the sites of somatic dysfunction determine which parts of the body will be most affected by disturbed mental and emotional states? Conversely, do somatic dysfunctions have mental and emotional repercussions? What kinds of somatic dysfunction, in which parts of the musculoskeletal system?

Questions about the place of the musculoskeletal system in the organismic scheme

- How have the functions that are shared with other mammals been adapted to or been affected by assumption of the erect posture and by the altered relation to gravitational forces? Circulation to the head? Venous return from the lower parts of the body? Pulmonary ventilation and drainage of bronchial secretions? Lymphatic drainage and immune functions? Postural and righting reflexes? Fetal development and parturition? Others? How are these adaptations to upright posture related to clinical problems common to humans?
- What are the implications of the fact that the autonomic innervation of all of the musculoskeletal system is exclusively sympathetic? That sympathetic preganglionic neurons and motoneurons are located in adjoining columns of the spinal cord, where they are subject to the same or similar presynaptic inputs of somatic, visceral, and cerebral origin?
- Earlier research demonstrated that both motor and sympathetic reflex thresholds are lowered in cord segments related to areas of somatic dysfunction.[4-11]
- This facilitation manifests itself in exaggerated and prolonged responses in those segments to incoming impulses from any source, including the brain. What changes in afferent input or in the cord itself (or both) are responsible for lowering the thresholds? One theory implicated muscle spindles and their gamma-fiber control as a facilitating factor,[12] another, "garbled" collective input from proprioceptors.[13] Although compatible with clinical observations, these hypotheses await experimental testing. What *maintains* those segments in the facilitated state? Does the spinal cord have the capacity for learning and memory, as has been strongly suggested by experimental studies?[14]
- In view of evidence from earlier research

of facilitation of sympathetic pathways segmentally related to somatic dysfunction,[6-10] what are the effects of sustained stimulation of the sympathetic innervation of various organs and tissues, including the nervous system itself? Since the exaggerated responses include those to impulses descending from the higher centers, to what extent does facilitation of segmental sympathetic pathways play a role in the visceral and vasomotor manifestations of mental and emotional disturbances?

- Electromyographic recording from the paraspinal musculature in standing subjects has shown that the patterns of sustained and intense muscular activity vary from individual to individual and are constant for each.[15,16] What factors determine the location of the hyperactive areas? What is their relation to somatic dysfunction and other clinical problems?
- On empirical as well as theoretical grounds, the fascias have long been implicated in somatic dysfunction and are the focus of attention in such manipulative techniques as myofascial release. What functions does fascia have beside its "connective" role? If, indeed, "release" occurs, does this signify that fascia has contractile properties? If the answer is in the affirmative, what are the functional implications?
- Another important area, one that can, according to one's research specialty, be extended to every tissue, organ, and function, is the two-way communication between the musculoskeletal system (and other somatic tissues) on the one hand, and all the remaining systems, including their vasculature, on the other. The mechanisms to be examined are not only those acting via the nervous system, that is, somatoautonomic integration and control,[17] but also the diverse chemical means of communication and the direct mechanical influence of musculoskeletal activity on viscera and on flow of blood and lymph.

One of the fundamental problems in the context of neural control is the abrupt shift in pathways that occurs in the presence of pathologic alteration. In normal function, efferent neurons are recruited according to what their *effectors* do, without regard for their location in the neuraxis. When, however, a viscus or somatic structure innervated from the same segment is injured or becomes dysfunctional (especially if nociceptors are excited), then they are suddenly on a "party line," and their segmental relationship is suddenly conspicuous. ("A segment in view is a segment in trouble."[13]) Clinically, this phenomenon is widely known in the form of referred pain, in which pain of visceral origin is felt, not in the viscus, but in segmentally related somatic structures (skin, bone, and muscle) in which functional changes, such as muscular contraction, also occur. The phenomenon of newly established "party lines," initiated in both visceral and somatic structures, have also been demonstrated experimentally.[9,10,18-20]

The heart, for example, does not directly participate in any way in the activities of dermatomes, myotomes, or sclerotomes that also receive their innervation from upper thoracic segments of the spinal cord. Similarly, the paraspinal musculature of the upper thoracic segments and the corresponding areas of skin make no contribution to cardiac function. Cardiac systoles and diastoles are totally independent of paraspinal muscle contractions and relaxations. But, given myocardial ischemia or severe intervertebral dysfunction or paraspinal muscle spasm in upper thoracic levels of the spine, then viscus and soma are immediately linked in a self-sustaining circuit of autogenic impulses of which each is both source and victim. What is the mechanism by which that circuit is created? How is it maintained? Can it be prevented? How can it be interrupted noninvasively?

- Although somatovisceral interchange predominantly involves the peripheral sympathetic nervous system, the participation of the parasympathetic division of the autonomic nervous system in the visceral expression of somatic dysfunction remains largely unexplored.
- Under what circumstances and in which musculoskeletal structures does compression of blood and lymphatic vessels occur, and with what effects?
- What are the effects of osteopathic manipulative treatment on aberrant functions and processes, for example, cardiac arrhythmias, uterine inertia, pulmonary ventilation, or various

aspects of immune, gastrointestinal, or sensory function?

Questions about nonimpulse-based neural functions

Research has shown that of the many proteins that are synthesized in peripheral neurons and that are axonally transported, only a few selectively cross the junctions with innervated tissues and enter their cells.[21-24] The transferred proteins, at least in the case of striated muscle, are those not synthesized by muscle cells themselves. The hypothesis was proposed that the transfer of neuronal proteins to innervated tissues is the basic mechanism of long-term, nonimpulse-based trophic functions of nerves.

It was further postulated[25] that impairment of this function, such as would occur when the nerve is sufficiently compressed to impede axonal transport or when the quality or quantity of neuronal proteins is altered (as in facilitated neuron pools in sustained hyperactivity), could account for some of the remote pathologic effects of somatic dysfunction. It would be of enormous theoretical as well as clinical value to identify the transferred proteins, and to ascertain their loci and functions in the recipient cells.

Do all tissues receive neuronal proteins? Which, if any, do not? How do they differ from those that do? What are the mechanisms of transfer? Would neuronal proteins, known to be essential for regeneration of extremities in certain lizards and amphibia,[26] have applicability to the human in support of wound healing, for example? That this is a possibility is suggested by the remarkable degree of limb regeneration that was achieved in a mammal, the opossum, by the same technique that succeeded in amphibia, namely hyperinnervation.[27]

Since retrograde axonal transport (*to* the neuron) also occurs, carrying such items as nerve growth factor, chemical feedback from the innervated structure, neurotoxins, and neurotrophic viruses,[28] could this mechanism be used to administer therapeutic agents to selected neuron pools that have been injured, infected, or affected by toxins?

Questions about cranial mechanisms

Another rich area awaiting further exploration at the basic science level is that related to cranial biomechanics. What, for example, is the origin of palpable and recordable[29] movements of the cranial bones (apparently around the sutures that join them?[30] In humans, these movements are usually maintained at quite regular rates of about 8 to 12 per minute, and are independent of the respiratory rate and arterial pulse rate. They seem to be synchronous, however, with the plethysmographic (volume-fluctuation) rhythm in peripheral tissues. Are these cranial movements related in any way to fluctuations in volume or pressure of the cerebrospinal fluid, or rhythmic contractions and relaxations of large veins? Is impaired cranial motion or rhythm related to malfunction elsewhere in the body?

Questions about endocoids

A great contribution to biomedical science that would have broad applicability would be the design of methods and measures by which to evoke, as necessary, the "body's own medicines." These include the numerous neuropeptides, the prostaglandins, various hormones, interleukins, interferons, and others yet to be discovered.

Other questions

These are but a few of the questions related to osteopathic theory and practice that, it seems to me, offer research opportunities for anatomists, physiologists, biochemists, neuroscientists, pharmacologists, immunologists, psychologists, and others. Bioscientists need hardly be reminded that in addition to the preceding questions much remains to be learned about all of the inherent self-regulatory, homeostatic, defensive, healing, recuperative, and regenerative mechanisms that are so important to the maintenance and restoration of health and factors that affect them favorably as well as unfavorably.

Clinical research

This section is limited to research the purpose of which is to assess the effectiveness of osteopathic medical care. Having had little experi-

ence in this area, I can claim no personal authority, and must rely totally on the contributions of those who have demonstrated competence in such research. I have learned also from the mistakes of others who have sought to use experimental designs inappropriate to osteopathic medical practice. It is my purpose in this section only to emphasize that in designing and undertaking such studies, investigators must keep in mind that osteopathic medical practice and methodology, a central component of which is OMT, are derivatives of osteopathic philosophy; and, therefore, that *assessment of effectiveness must be tested in that context and with criteria consonant with that context and no other.* I also offer some research designs that appear to be eminently suitable or adaptable to this purpose.

Designs are required that assess the effect of treatment not merely on the presenting complaint, dysfunction, or disease, but the impact of treatment on the total person and the person's ability to carry on, with adequate reserve, the functions that are important to him or her. The designs should also make possible comparisons with other systems of care. Other qualifications will become clear as we examine the ways in which conventional clinical trials are usually inappropriate to assessment of osteopathic practice and especially OMT.

Most clinical trials are designed to assess the effects of a given medication, physical agent, or therapy on a given clinical problem. With few exceptions, the therapy is so uniform or standardized that its effect is hardly, if at all, influenced by the person who prescribes or administers it. It matters a great deal, however, who administers OMT (as well as who receives it), by his or her training, prior years of manipulative experience, choice of diagnostic cues, technique preferences, and so forth. (My own experience over many years as recipient of osteopathic medical care is that "style" and effectiveness are as diverse and idiosyncratic as the personalities of the physicians.)

This variability is further compounded by variation in response, not only from patient to patient and from visit to visit, but also from moment to moment as the (skilled and discerning) osteopathic physician assesses tissue and patient response to each maneuver, and then selects and applies succeeding ones accordingly. In effect, physician and patient are linked in a cybernetic loop —a "wordless dialogue"—in which each responds to the other's changing input.[31]

Conventional clinical trials require large randomized populations that are divided into experimental and control groups to compensate statistically for unavoidable sources of ambiguity, such as the variations in the "effects" of the therapy. (In the osteopathic perspective, the variations are in the patients' *response to* therapy.)

The second source of error or ambiguity to be compensated for is the "spontaneous" recovery, remission, or improvement that would occur in unknown percentages of patients in the absence of treatment. Compensation is made by administering a placebo or sham treatment to the members of the control group, who are matched (age, sex, clinical status, etc) as closely as possible to the experimental group, who receive the real treatment. Both patients and evaluating physicians are "blinded," that is, not permitted to know who receives the placebo and who, the treatment under test.

The placebo is "medication" or "therapy" that is inert and that looks and tastes like the "real" thing. A favorable response to such treatment is regarded as the "placebo effect," which must be taken into statistical consideration in assessment of efficacy of the treatment being tested.

The osteopathic physician, however, is aware that spontaneous recovery or the placebo effect is a *response*—an active response of the patient's recuperative mechanisms and a demonstration of their potency. The response is evoked, not by the sugar pill or nontreatment, but by such factors as confidence in the treatment, positive beliefs, expectations, and attitudes with respect to the illness and its outcome or even by desperation—"this has *got* to work!"

The osteopathic physician knows that whatever the treatment and however great its role in favorable clinical outcome, that role is made possible only through the patient's own heal-

ing resources. Hence, the osteopathic physician not only does not wish to suppress or "rule out" their role, but he or she also *relies* on those resources, and seeks in every way to evoke, encourage, disencumber, and support those mechanisms and to call on the body's own medicines. The physician does this not only by the treatment, but also by touch, word of mouth, tone of voice, body language, and confidence expressed in the patient's ability to get well. *Therefore, that which is regarded as nuisance and source of error from one perspective is essence and source of clinical results from the osteopathic perspective.*

It is essential, therefore, that assessments of effectiveness of OMT be of OMT *as it is practiced,* as an integral part of the total interaction between physician and patient, and not as an isolated, contrived, and standardized procedure which, though nicely amenable to statistical analysis, is totally unrelated to clinical reality. "As it is practiced" means that experimental designs must be such as to accept as given (1) that OMT, unlike medications, and their dosages, cannot be made standard and uniform; (2) that the placebo response is an integral, inseparable part of the patient's total response to osteopathic medical care. Also, criteria of change in clinical status must be chosen that are consonant with osteopathic perspectives and practice.

Given these constraints, what kinds of clinical assessment designs are already available or can be devised that are appropriate to osteopathic medical practice?

Almost ideally suited to this purpose is the so-called Medical Outcomes Study (MOS). Highly refined and rigorous versions of the MOS have been described in a recent series of papers.[32-38] The criteria of clinical outcome employed in these studies were in five categories, each of which includes a number of quantitatively assessable items, which, despite the subjective nature of some of them, are collectively amenable to a high degree of reliability of statistical analysis:

- physical functioning (ability to perform a variety of physical activities);
- role (ability to carry out daily activities such as housework, vocational work;
- socialization (ability to conduct social and group activities, visiting with friends);
- mental health (general mood or affect, sense of well-being);
- health perception (self-rating of current health in general); and
- bodily pain.

Osteopathic clinical researchers would find study of these papers and of others cited therein highly rewarding, as they would the book *Measuring Health.*[39] The basic design of these studies is readily adaptable to the assessment of the effectiveness of osteopathic medical care that includes OMT and to its comparison with other medical systems.

In view of the two-way, dialoguelike relation between osteopathic physician and patient and the patient's involvement in OMT, consideration should also be given to adopting, or adapting as necessary, designs successfully used in the behavioral and social sciences and in psychotherapy. Of special interest are the intrasubject (so-called N of 1) and intersubject designs involving individuals and small groups.[40-49]

Finally, another approach would be to take advantage of ready-made patient populations, such as in health maintenance organizations and in industrial plants, in which some people are under osteopathic medical care, the others under allopathic medical care. Longitudinal studies on comparative outcomes, such as incidence of minor illnesses and disabilities (headaches, backaches, colds, dysmenorrhea) and of various diseases and degrees of recovery, length of convalescence, absenteeism, and so forth, in the two populations would be of enormous value.

Summary

The purposes of this article are twofold: (1) To assist scientists on the faculties of colleges of osteopathic medicine in the design of research projects relevant to osteopathic medical theory and practice; and (2) to assist clinical investigators in the development of research protocols that are best suited to the assessment of clinical outcomes of osteopathic medical practice. Toward this end, the central osteopathic medical principles are heuristically inter-

(continued on page 170)

preted and elaborated, with the intention of facilitating the formulation of fundamental questions by researchers in the various biomedical disciplines and the design of clinical research projects by osteopathic physicians. A few of the questions evoked by such elaboration of the osteopathic medical principles and awaiting study are suggested for consideration by researchers. Such research questions require and, in part, compose a research paradigm that differs basically from, yet complements and "completes," the prevailing and highly productive reductionist paradigm. It is, in the original sense of the word, a "holistic" paradigm that places emphasis on the organismic context in which the biological mechanisms exist and operate.

Conventional clinical research protocols for the assessment of efficacy of most chemical and physical therapeutic agents are ill-suited for the assessment of osteopathic medical care, of manipulative treatment in particular. It is emphasized that osteopathic medical care must be evaluated as it is practiced and not as a contrived, unreal version; and that it must be tested as a derivative of, and in the context of, that philosophy by criteria consonant with that philosophy. Arguments are presented that conventional correction for the so-called placebo effect would render invalid the testing of osteopathic medicine *as it is practiced.*

Alternative designs and models are suggested. Most of them have been tested and reported in the clinical literature; others await careful trial and development under osteopathic auspices.

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