Sacro Occipital Technique

Update 2007

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Introduction

Sacro Occipital Technique (SOT) is a method of chiropractic developed by Major Bertrand DeJarnette, DO, DC. SOTO-USA has attempted to gather information for the doctor, the chiropractic profession and all interested parties regarding the efficacy and substantiation of SOT: A Chiropractic Technique.

Therefore the following will discuss the issues of:

1. **SOT evidence in the peer-reviewed published literature**

2. **SOT a chiropractic technique and its considered as a standard of care for chiropractic treatment**

3. **Exploring how a research evidence base can be gathered without "blind" reliance solely on randomized controlled studies for qualification of a chiropractic technique**

Peer reviewed research and published literature is greatly important to Sacro Occipital Technique Organization – USA and SOT. Specific published literature has been gathered for our reference and help both understand and support our use of SOT as a chiropractic technique.

SOTO-USA is dedicated to bringing you the most updated and comprehensive research relating to Sacro Occipital Technique (SOT). Research is the future of chiropractic and SOT. Publishing this research sets the foundation for the future of SOT and protects its future worldwide. Understanding the published research allows us to grow, learn and modify our technique and diagnostic methods to fit our discoveries and stay current in the scientific community. The research department of SOTO-USA is goal oriented and focus on action and results. **Please consider a tax deductible donation to SOT research so SOTO-USA can help us further SOT's prominence in chiropractic healthcare**.

SOTO-USA is an organization dedicated to the advancement of SOT and the work of Major Bertrand DeJarnette, DO, DC. One of the many ways in which we at SOTO-USA contribute to the chiropractic profession is through the publishing of articles, newsletters, compendiums, and manuals relating to the art, science and philosophy of SOT (please visit our website for a complete listing of publications; www.SOTO-USA.org).

Please take time to review our landmark SOT research texts, which will eternally preserve SOT, related published research, which will also have updated volumes every 5 years.

The Compendium of Sacro Occipital Technique: *Peer-Reviewed Literature 2000-2005. (In Press)*

The Compendium of Sacro Occipital Technique: *Peer-Reviewed Literature 1984-2000.*

The SOT Collection: *To the Year 2000.*

The SOT Collection: Supplement: To the Year 2000.

Please note that all of SOT related articles can be viewed on the website **www.soto-usa.org** by going to the SOT Literature page.

Abstracts and poster presentations do show due diligence on the part of SOTO-USA and SOT to be a part of the research process and work within an evidence based system. Many of the initial stages prior to publication involve presentations at research conferences and incorporating feedback from experts in the field. Lastly, for instance, articles submitted to the Research Agenda for Chiropractic / Association of Accredited Chiropractic Conferences (RAC/ACC) all go through a blinded peer review process before being accepted for presentation at their conference.

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SOT A CHIROPRACTIC TECHNIQUE AND ITS CONSIDERED AS A STANDARD OF CARE FOR CHIROPRACTIC TREATMENT

The National Board of Chiropractic Examiners (NBCE) published a Job Analysis of Chiropractic. The **Job Analysis** was first published in 1993; 1994, 2000, and the NBCE released a companion volume that included a state-by-state statistical report on chiropractic practice. The "**Job Analysis 2005**", is considered the largest and most comprehensive as compared to all prior volumes. [1]

The project director, author and editor of all three volumes was Mark Christensen, PhD, the director of testing for the NBCE. To gather the necessary information for *Job Analysis 2005*, 2,100 U.S. doctors of chiropractic who completed the final "Survey of Chiropractic Analysis". This selection process was designed to provide reliable data at the state and national level. [1]

With regard to the section of the study entitled "the most utilized chiropractic adjustive techniques/ procedures adjustive" SOT fared as follows:

"% of DC's Utilizing SOT in 1991:	41.3%
% of DC's Utilizing SOT in 1998:	49.0%"
% of DC's Utilizing SOT in 2005:	49.6%" [1]

The Mercy Guidelines

The "**Guidelines for Chiropractic Quality Assurance and Practice Parameters,**" [2] also know as the Mercy Guidelines, was for most of the 1990s considered the accepted

guidelines for chiropractic healthcare. While the majority of the SOT related literature published in the peer review literature was published following the review of the authors, their review still came to specific determinations regarding SOT's major treatment modality, the pelvic blocks. Using Kaminsky's [3] method of analysis for chiropractic methods and techniques the Mercy review committee determined the following regarding SOT "Pelvic Blocks":

Pelvic Blocks: These paired wedges are used primarily for positioning the lumbosacral and sacroiliac joints to produce a sustained stretch. This procedure is in fairly common use, and there is reasonable rationale and expert opinion on its utility in certain situations. [2]

Rating: Promising for the care of patients with neuromusculoskeletal problems. [2]

Evidence: Class III - Evidence provided by expert legal opinion, descriptive studies or case reports. [2]

Consensus Level: 1 - Established: Accepted as appropriate by the practicing chiropractic community for the given indication in the specified patient population. [2]

There has been a great deal of literature published following the publication of the Mercy Guidelines as well as other SOT published literature that was not available at the time of review. Therefore while the consensus level could not possibly be any higher, the evidence level certainly would be.

Chiropractic Named Techniques

Chiropractic researchers have attempted to evaluate and discuss various “named” chiropractic techniques. In all efforts to evaluate named techniques, SOT is always one method that is listed, and commonly considered a major form of care in chiropractic. [4-8] While the majority of these studies have not had full access to the SOT published literature, SOTO-USA has attempted to remedy that situation recently. While the current text to be published shortly by Gleberzon and Cooperstein on “Named” Chiropractic Techniques [8] treats SOT quite favorably, even this text was written without access to all published studies on SOT related treatment.

One study performed by a review of the Applied Chiropractic Department, at Canadian Memorial Chiropractic College, completed in 1998, involving faculty, clinicians and students, “revealed that 87% of students are in favor of more exposure to named techniques.”[5] It was determined that 53% of the students had interest in learning Sacro Occipital Technique [5], which is similar to the NBCE study. [1]

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RANDOMIZED CONTROLLED STUDIES AND THEIR USE AS A SOLE QUALIFICATION OF A CHIROPRACTIC TECHNIQUE

Randomized Controlled Studies (RCTs) at this time are not considered a sole criteria to base the acceptance of SOT as an accepted chiropractic treatment. RCTs by nature are reductionistic and some researchers investigating believe that SOT does not lend itself to adequate study in this manner. While it is obvious that in the future SOT will find ways of overcoming this obstacle and find ways of performing RCTs, Cohort Studies, and other high quality levels of research, what is clear is that our methods of study will obviously need to improve. However while RCTs definitely have their value they should not be seen as a sole criteria based on the following:

1. An "evidence base" must be built on a variety of investigational methods and there can be inherent problems with RCTs.

2. If the healthcare community is going to use the criteria that **all methods of care** should be held to the standard that they need to be evaluated through "**well-designed prospective randomized controlled clinical trials in the peer-reviewed published medical literature demonstrating their effectiveness**," then:

    a. Why is there acceptance of most surgical procedures and pharmaceutical medications, which do not follow that criterion?

    b. Why is there is not general acceptance for chiropractic non-musculoskeletal treatment based on RCTs that suggest otherwise?

    c. Why is there often acceptance for antibiotics for the treatment of otitis media in lieu of manipulation?

3. Most chiropractic techniques have not been subjected to RCTs however presently in publication, there is a well designed prospective randomized controlled clinical trial, which successfully shows SOT as a positive method of chiropractic care.

RCTs and Evidence Based Study

In communication with Anthony L. Rosner, Ph.D., Past Director of Research and Education, Foundation for Chiropractic Education and Research he notes that there is an abundance of references which have been published within the past few years, which demonstrate how, the "evidence base" must be built upon a VARIETY of investigational methods (including observational studies, cohort studies, case series and the like). Many of these studies go farther and point out how meta-analyses and RCTs have been misinterpreted and become counterproductive. [1] Rosner has a paper published in September 2003 issue of he *Journal of Manipulative and Physiologic Therapeutics* that demonstrates how RCTs and meta-analyses have been misused and abused from the point of view of 7 case studies dealing with both the medical and chiropractic literature. [2]

No less than the leading epidemiologist David Sackett has gone on record saying how RCTs taken by themselves produce a distorted and misleading picture of clinical response. [3] Cooperstein and Perle suggest a solution is to "Recognize that case reports and non-controlled studies may be of redeeming value due to their clinical relevance and RCTs may have methodological flaws." [4]

RCTs and Medical Coverage by Aetna

A considerable number of covered medical services are not supported by RCTs: According to David Eddy, the list begins with many forms of surgery and extends to glaucoma treatments. [3] According to Aetna's policy, if congruent across the board, many traditional medical services would have to also not be covered. [http://www.shef.ac.uk/%7Escharr/ir/percent.html]

RCTs: SMT for Non-Musculoskeletal Condition

If RCTs are the "gold standard" for Aetna then why is chiropractic care not covered for non-musculoskeletal conditions? How can Aetna not recognize the work of Meeker and Haldeman [5,6] in which SMT is supported by no less than 75 RCTs, 46 of which are positive, 29 equivocal, and **0 negative**? Included in this list are headache, neck pain, and elbow pain for musculoskeletal conditions AND dysmenorrhea, infantile colic, premenstrual syndrome, and hypertension for non-musculoskeletal conditions.

RCTs: Antibiotics in Lieu of Manipulation for Treatment of Otitis Media

If RCT are to be used as a guideline for acceptance or non-acceptance of chiropractic treatment then it is essential to review a recent study published in the *British Journal of Medicine* by Little, Gould, Moore, Warner, Dunleavey, and Williamson they concluded, "In children with otitis media but without fever and vomiting antibiotic treatment has little benefit and a poor outcome is unlikely." [7]

RCTs: Sacro Occipital Technique

Even though RCTs can have their limitations SOT is looking toward the future with the goal of producing more studies many of them RCTs. The chiropractic research community upon evaluating our research base has recommended that it is common to have a base of 100s of case histories on a topic before a RCT is attempted for evaluation. Presently there is a study that was ongoing

A preliminary study was presented at the International Conference on Spinal Manipulation in Toronto, Canada, which included as part of the accepted techniques used in this study, **sacro occipital technique**. Selected subjects were randomly assigned to 4 groups and chiropractic treatment was carried out across 23 centers around Sydney, Australia. Their study concluded that direct chiropractic treatment (6 weeks) reduces salivary cortisol levels over the 14-week period of the trial. The results of their study strongly suggested that somatovisceral mechanisms are involved with chiropractic treatment. [8]

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SUMMARY

As scientific research attempts to grapple with healthcare one major step forward has been understanding the importance of building an evidence base to develop a consensus regarding treatments such as chiropractic and sacro occipital technique in particular. The current literature suggest that RCTs are not the only way, and sometimes "RCTs taken by themselves can produce a distorted and misleading picture of clinical response." [1] Apparently observational studies, cohort studies, case series and others are needed to reach a level of greater understanding and building a solid evidentiary base. [2]

RCTs are a stringent a form of investigation and if used by scientific community in a consistent manner to evaluate all its accepted forms of healthcare this would leave few forms of care for patient care. Therefore other factors must be taken into account for a proper evaluation of a chiropractic technique such as sacro occipital technique. These factors can be SOT's published literature in peer review journals and its acceptance within the chiropractic community. This acceptance spans all state boards of all 50 states, encompasses SOT as a viable taught method of chiropractic for over 70 years, is illustrated by the NBCE report that almost 50% of the chiropractors practice SOT [3], and that the Mercy Guideline's consensus describes SOT pelvic blocks as "Established: Accepted as appropriate by the practicing chiropractic community for the given indication in the specified patient population." [4]

While SOT has been used for over 70 years by doctors successfully, the publishing in the journals is only beginning the past 2 decades. SOT is in the forefront of chiropractic techniques in this regard. Of the various chiropractic methods of evaluating the lumbo-pelvic spine, other than palpation for pain, only SOT had a method that showed some validity. "Only tests for palpation for pain had consistently acceptable results. Motion palpation of the lumbar spine might be valid but showed poor reliability, whereas motion palpation of the sacroiliac joints seemed to be slightly reliable but was not shown to be valid. Measures of leg-length inequality seemed to correlate with radiographic measurements but consensus on method and interpretation is lacking. For the sacrooccipital technique, some evidence favors the validity of the arm-fossa test but the rest of the test regimen remains poorly documented. Documentation of applied kinesiology was not available. Palpation for muscle tension, palpation for misalignment, and visual inspection were either undocumented, unreliable, or not valid." [5]

Therefore:

1. Compared to any chiropractic technique, sacro-occipital technique (SOT) has a significant number of published articles. Admittedly SOT still has work to do improving the quality of any and all studies performed, but still compared to other chiropractic techniques, the quality and quantity of the research puts SOT is in the upper echelon.

2. SOT has been used for over 70 years by tens of thousands of chiropractors, its primary method of treatment the pelvic blocks was highly approved by the (now outdated) Mercy Guidelines [4], National Board of Chiropractic Examiners Study found that close to 50% of all chiropractors use SOT [3], and all studies ever written describing chiropractic techniques consider SOT as one of its "major" techniques [6-8].

3. There is no doubt that the health care community needs to address their acceptance of many medical procedures that have poor quality of evidence [9], that the SOT observational studies can have some merit [10], and that there is some question as to the ultimate use of RCTs [11] especially in lieu of the consistent clinical findings of SOT for over 70 years.

4. Lastly, the "grandfathering" or "off-lable" use of medications is commonly accepted in the medical field (general practice [12-13], pediatrics [14-15], psychiatry [16], dermatology [17], obstetrics [18], and oncology [19]) and Aetna often does not dispute the use of medications in this manner. This is based on the anecdotal evidence of medical healthcare practitioners weighed against the cost of needed research versus the benefit of the pharmaceutical agent used.

SOT has been a technique used for over 70 years, is widely accepted by chiropractic healthcare practitioners over that time, its *safety* has not been questioned in the literature and the literature is building consistent greater evidence for its *effectiveness*.

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Background and Objective: Bronchial asthma is a condition characterized by widespread bronchial obstruction due to muscular spasm producing expiratory wheezing with prolongation of expiration. In this multifactorial condition, a thick, white mucus is produced by the respiratory epithelium of the bronchi leading to obstruction of the airways and considerable difficulty in breathing. While individuals may be exposed to the same or very similar environments, the question of why some become asthmatics while others do not is a taxing one. We hypothesize that chronic physical and/or psychological stress is in part the answer. Stress is associated with an increase in circulating cortisol, which among other things causes a reduction in immunity and increases smooth muscle contractibility. Reduction in immunoglobulin A (IgA) associated with the respiratory epithelial lining makes an individual more susceptible to spasm of he respiratory smooth muscle due to pathogenic invasion. This is compounded by the muscles increases sensitivity to contraction due to inhibition of catecholamine uptake. The broad aims of this FCER funded study is to determine whether stress is a factor in the pathophysiology of asthma and to determine if chiropractic management of asthmatics can alleviate stress induced asthma. More specifically for this meeting, our study aims to determine whether chiropractic treatment has beneficial effects on the endocrine system through measurement of salivary cortisol and on the immune system via salivary IgA determination.

Methods : Both asthmatic and non-asthmatic patients are sourced through advertisements and press releases in state and local newspapers, bulletins of asthma interest groups, schools, community health groups and radio and television, in the greater Sydney area. Interested subjects phone a hotline and details regarding their brief medical history and treatment regimes are requested. Subjects are sent correspondence on two separate occasions detailing the trial aims and objectives and the requirements of each patient and consent forms. Subjects are further requested to attend an information seminar before they are required to take full spinal x-rays. Subjects are selected for the trial based on their medical history, age, procedural understanding, wellness questionnaire and on the outcomes of their x-rays. Selected subjects are randomly assigned to 4 groups consisting of a) chiropractic treatment at centers (3 times per week), b) no treatment at centers, c) not treatment at home and d) non asthmatics no treatment at home. Patients undergo a 14-week program consisting of a 2-week pre treatment, 6-week treatment and 6-week post treatment regime. Chiropractic treatment is carried out across 23 centers around Sydney. All clinicians are University educated and registered and all attend at least one of our research orientation seminars to ensure research standards, protocols and procedures are strictly adhered to. The accepted techniques include high velocity low amplitude spinal adjustments, diversified, passive wedge (SOT), and activator methods.

All patients are administered an asthma questionnaire, the SF-36 wellness questionnaire, and the depression, anxiety stress scales (DASS) at the commencement, midway through and completion of the 14 weeks. All patients provide saliva at 8am and 8pm three times a week on Tuesdays, Thursdays and Sundays. Saliva samples are assayed for cortisol, IgA, osmolarity, albumin and creatinine is used to check the quality of the saliva samples provided to ensure that changes in the former are specific to stress and immunity. A total of 400 patients will be involved in the trial providing over 35,000 samples and over 176,000 assays will be performed. This is the largest, most comprehensive trial of this type attempted.

Results: We report here the cortisol and IgA patterns that are emerging from the data collected and analyzed thus far. We are this stage reluctant to commence a full comprehensive statistical analysis of all the data at hand as it is not "best practice" to do so.

The results we have to date suggest a decrease in salivary cortisol over the 14-week period for patients receiving chiropractic care compared to those who are not. However we do note an initial increase in cortisol at the commencement of treatment follow4ed by a decrease over the 6 weeks post treatment period. Mean morning salivary cortisol for the A group at the commencement of the trial is 6.2 ug/dL which increases to 7.7. ug/dL in the first 2-3 weeks of treatment. Mean salivary cortisol however decreases to its lowest levels over the 14-week trial period to 4.6 ug/dL in the last two weeks of the trial. In contrast, mean salivary cortisol values remained unchanged over the 14-week trial period for group B and group C. While group B does not show an overall decrease in cortisol, we do observe a slight increase 2-3 weeks into clinic visit for some patients.

In concert with this we also note an increase in salivary IgA levels for both groups A and B but not in group C. This is in line with our hypothesis outlined above. Perhaps the most striking feature of our IgA data to date is that IgA levels in asthmatics are very erratic throughout the period of the trial suggesting repeated infections or other stressors of the respiratory system. This erratic nature of IgA by in large disappears after chiropractic treatment (group A), whereas it is maintained in groups B and C.

Conclusion: the FCER funded study aims to determine the effects of chiropractic treatment of the endocrine and immune system of asthmatic patients. We have determined from the data thus far that direct chiropractic treatment (6 weeks) reduces salivary cortisol levels over the 14-week period of this trial. We do however note an initial increase associated with the first 2-3 weeks of treatment. This could either be due to anxiety associated with visiting a clinic or due to the physical nature of the chiropractic treatment. That some patients showed a slight increase 2-3 weeks into clinic visit suggest the former. However full analysis of the data at the conclusion of the trial with respect to individual patient changes versus treatment regime received will be required to finalize this question. There is no indication at this stage that the reduction in cortisol after chiropractic treatment is due to the well characterized placebo effect as both group B and Group C cortisol values remained unchanged from the start to the end of the trial.

In support of our hypothesis outlined above we show an increase in salivary IgA levels for group A patients. We expect this to be partly responsible for the decrease in the severity and number of asthmatic attaches experienced by these patients. The most striking feature was the decrease in the erratic nature of IgA levels for group A patients. We attribute this to an increase in basal IgA levels associated with decreased cortisol and hence a better ability of patients to ward off potential pathogenic invasion (or the like) which ultimately shows the increasing /decreasing erratic IgA patterns we observe.

Whether chiropractic treatment effects both the endocrine and immune systems independently or one system through the other requires further analysis of our biochemical data and questionnaire data for individual patients. Full analysis of our data, which we plan at the conclusion of this trial, will also have the benefit of answering a large number of questions related to the efficacy of chiropractic treatment regimes. It is the comprehensive nature of this trial that will make this possible. Our results strongly suggest somatovisceral mechanisms are involved in chiropractic treatment.

Concato J, Shah N, Horwitz RI. **Randomized, controlled trials, observational studies, and the hierarchy of research designs.** *N Engl J Med*. 2000 Jun 22;342(25):1887-92. Department of Internal Medicine, Yale University School of Medicine, New Haven, Conn 06510, USA. john.concato@yale.edu

BACKGROUND: In the hierarchy of research designs, the results of randomized, controlled trials are considered to be evidence of the highest grade, whereas observational studies are viewed as having less validity because they reportedly overestimate treatment effects. We used published meta-analyses to identify randomized clinical trials and observational studies that examined the same clinical topics. We then compared the results of the original reports according to the type of research design. METHODS: A search of the Medline data base for articles published in five major medical journals from 1991 to 1995 identified meta-analyses of randomized, controlled trials and meta-analyses of either cohort or case-control studies that assessed the same intervention. For each of five topics, summary estimates and 95 percent confidence intervals were calculated on the basis of data from the individual randomized, controlled trials and the individual observational studies. RESULTS: For the five clinical topics and 99 reports evaluated, the average results of the observational studies were remarkably similar to those of the randomized, controlled trials. For example, analysis of 13 randomized, controlled trials of the effectiveness of bacille Calmette-Guerin vaccine in preventing active tuberculosis yielded a relative risk of 0.49 (95 percent confidence interval, 0.34 to 0.70) among vaccinated patients, as compared with an odds ratio of 0.50 (95 percent confidence interval, 0.39 to 0.65) from 10 case-control studies. In addition, the range of the point estimates for the effect of vaccination was wider for the randomized, controlled trials (0.20 to 1.56) than for the observational studies (0.17 to 0.84). CONCLUSIONS: The results of well-designed observational studies (with either a cohort or a case-control design) do not systematically overestimate the magnitude of the effects of treatment as compared with those in randomized, controlled trials on the same topic.

Rosner A, *Commentary:* **Fables or foibles: Inherent problems with RCTs** *Journal of Manipulative and Physiological Therapeutics* Sep 2003; 26(7) **[http://www2.us.elsevierhealth.com/scripts/om.dll/serve?action=searchDB&searchDBfor=art&artType=fullfree&id=as0161475403000940]**

For 50 years, the accepted standard by which the usefulness of a therapeutic treatment is judged has been the randomized controlled trial (RCT), building from Hippocrates' premise 2000 years ago that experience combined with reason was the therapy of choice for patients; that is, any treatment plan should both seem reasonable in theory and then be tested experimentally. Assuming that threats to both internal and external validity could be ruled out, the RCT became what is commonly regarded as the highest quality of clinical outcome study that could be mounted to allow inferences about cause and effect relationships to be drawn. The thinking was that the more rigorous and fastidious the design, the more credibility could be attached to the conclusions drawn from the outcomes of the study and the more likely the intervention was thought to have brought about those outcomes. **1**One of the strongest proponents of the RCT through the 1950s and 1960s was the British epidemiologist Archie Cochrane, who held that this type of experimental approach was essential for upgrading the quality of medical evidence. **2**In common hierarchical schemes of clinical experimental design, the RCT has been ranked the highest in rigor, as shown in Table 1 .**3**Even greater rigor has been presumed to occur with the statistical combination and weighting of the results of multiple RCTs in a meta-analysis to generate a more conclusive estimate of effect size. **4**,**5**

Hierarchy of experimental designs **3**

1. Control group outcomes study (including RCTs).
2. Single-subject experiment, replicated single-subject experiments.
3. Single-group outcome study.
4. Systematic case study.
5. Anecdotal case report.

Designs are presented in descending order of rigor.

RCT, Randomized control trial.

From the point of view of clinical practice, however, especially in areas in which physical treatments are applied, the principles of fastidious treatments and blinding begin to wear thin and in a few recent examples regarding spinal manipulation, appear to have fallen apart completely. This difficulty is by no means confined to physical treatments, as the literature pertaining to the use of medications has also suggested that the inexperienced use and/or uncritical acceptance of the results of RCTs can lead to confusion. In this presentation, a few representative samples will be introduced as 7 case studies, which ironically would be ranked among the lowest in experimental rigor by the aforementioned

hierarchy of clinical evidence. **3**

1. Reduction of meta-analyses to subjective value scales

In their efforts to compare 2 different preparations of heparin for their respective abilities to prevent postoperative thrombosis, Juni et al **6**have demonstrated that diametrically opposing results can be obtained in different meta-analyses, depending on which of 25 scales is used to distinguish between high-quality and low-quality RCTs. The root of the problem is evident from the variability of weights given to 3 prominent features of RCTs (randomization, blinding, and withdrawals), as shown in Table 2 by the 25 studies, which have compared the 2 therapeutic agents.

In 1 study, a third of the total weighting of the quality of the trial is afforded to both randomization and blinding, whereas in another study cited in the article, none of the quality scoring is derived from these 2 features. Widely skewed intermediate values for the 3 aspects of RCTs under discussion are apparent from the 23 other scales presented. The astute reader will immediately suspect that sharply conflicting conclusions might be drawn from these different studies, and these are amply borne out by the statistical plots shown in Figure 1 . Here, each of the meta-analyses listed resolve the 17 studies they have reviewed into high-quality and low-quality strata, based on each of their scoring systems.

It can be seen that 10 of the studies selected show a statistically superior effect of 1 heparin preparation, low-molecular weight heparin (LMWH), over the other but only for the low-quality studies. Seven other studies reveal precisely the opposite effect, in which the high-quality but not the low-quality studies display a statistically significant superiority of LMWH.

Depending on which scale is used, therefore, it is possible to either demonstrate or refute the clinical superiority of one clinical treatment over another. In this manner, therefore, all the rigor and labor-intensive elements of the RCT and its interpretation by the meta-analysis are simply reduced to the subjective and undoubtedly capricious human element of value judgment through the arbitrary assignment of numbers in the weighting of experimental quality. **6**

2. Occult “salami” publications

At times, authors of studies have been known to present their data in more than 1 forum in the scientific literature, resulting in what has become referred to as mass-produced or “salami” publications. Because the exclusivity of such data is unknown, it will be oversampled by the unsuspecting author of a meta-analysis or systematic literature review and thus will be given more weight than it merits. One such instance has been reported in the evaluation of nonsteroidal anti-inflammatory drugs (NSAIDs) in treating rheumatoid arthritis, in which 44 publications of 31 clinical trials were found to result in an oversampling of at least 18%. Twenty of these studies were published in 2 different sources, 10 studies were published in 3 different sources, and 1 study was published in 5

different sources. The fact that these data were published elsewhere was not noted in 32 of the 44 articles. Even more unsettling is the finding that in about half of the articles, the first author and total number of authors were different, and there appeared to be important discrepancies between versions of the same trial. **7**

Further evidence is shown in studies of risperidone, an antipsychotic agent. In this instance, 20 articles plus unpublished reports actually represented only 9 trials. **8**Finally, a report from Tramer et al **9**has described how 84 trials involving 11,980 patients using ondansetron for postoperative emesis resulted from only 70 trials employing 8645 patients. It was believed that the duplicate data led to a 23% overestimation of the efficacy of ondansetron.

Here, it is clear that the "one man, one vote" principle of systematic data review has been violated, such that clinical observations derived from the RCTs of certain authors have been given excessive credibility. Care must be taken to ensure that the data incorporated into an analysis of the effect of a particular treatment in an RCT are scored only once, a highly formidable if not impossible task.

3. Manipulation of experimental results

One of the more startling analyses of RCTs has been presented by Johansen and Gotzsche, **10** who reviewed a meta-analysis comparing fluconazole and amphotericin B, 2 antifungal agents. To begin, in 3 large trials comprising 43% of the patients identified for meta-analysis, the results from amphotericin B were combined with the results for nystatin, known to be an ineffective drug for fungal infections. Worse, 79% of the patients in these trials were randomized to receive amphotericin orally, which is perplexing and disturbing, since amphotericin B is known to be poorly absorbed and is normally administered intravenously.

When questioned more closely about the sources of their data, 12 of the 15 authors were found to be less than fully compliant, with 1 suggesting that the trial was "old" and that the primary data resided with the drug manufacturer, another claiming that sufficient time was lacking to respond, and a third professing the lack of access to the database because of a change of affiliation. The final surprise, which appeared to belie the validity of this entire undertaking, was the fact that Pfizer, the manufacturer of the superior drug, provided employment to 12 of the 15 authors in studies involving 92% of the total number of patients evaluated. It would appear that the intention all along was to manipulate the trials to favor the successful pharmaceutical product.

4. Flawed RCT no. 1: Misrepresentation of therapies and overgeneralization of results

A widely publicized study by Cherkin et al **11** , which appeared in *The New England Journal of Medicine* , represents an inaccurate depiction of the 3 treatments which are

presumably compared (chiropractic care, physical therapy, and medical intervention). These are reduced, respectively, to a single side-posture manipulation, the McKenzie method, and an education booklet. While these applications are certainly indicated in a fastidious design, there is no justification for the authors, who found little difference in outcomes between the 3 interventions with greater costs associated with the side-posture or McKenzie treatments, to then state as a conclusion: “Given the limited benefits and high costs, it seems unwise to refer all patients with low back pain for chiropractic or McKenzie therapy.”

First, one must be aware that there are several chiropractic techniques applicable to the management of low back pain; among them are low-force (the Logan Basic or Sacro-Occipital) techniques, flexion-distraction, use of a drop table, and traction. In this trial, only 1 high-velocity technique (side-posture) was applied, and it might not be equally effective for all patients. Furthermore, important ancillary procedures which are intrinsic to the chiropractic visit appear to have been denied to patients. In particular, extension exercises were forbidden, and patients were most likely not given any literature, even though these 2 options are considered to be parts of a customary chiropractic regimen for office visits. It appears that these 2 elements were permitted only in the other 2 arms of the trial. In short, the chiropractic treatment administered in this particular investigation appears to have been only a pale shadow of the actual therapy administered to patients in the real world. This would only add further irony to the inappropriate conclusion quoted from the authors above.

Additional problems with this trial surface with the examination of baseline characteristics regarding severity among the 3 groups tested, creating a bias in the outcomes. First, the percentage of patients who had prior chiropractic care for low back pain appears to be substantially lower for the chiropractic cohort (24%) than for the McKenzie and medical booklet groups (35% and 40%). This problem is only magnified by the authors' citation of another prominent investigation, noting that “the British study found the benefits of chiropractic to be most evident among patients who had previously been treated by chiropractors.” Second, the chiropractic cohort indicates the highest percentage of patients who, because of low back pain and prior to their therapy, encountered more than 1 day of best rest (35% vs 24% and 22% for the McKenzie and medical booklet cohorts, respectively), more than 1 day of work lost (39% vs 41% and 30% for the McKenzie and medical booklet cohorts, respectively], and more than a single day of restricted activity (72% vs 65% and 52% for the McKenzie and medical booklet cohorts, respectively).

Curiously, the outcomes in the figure between weeks 0 and 1 were not shown in the original article but indeed represent the bulk of improvement in the 3 patient cohorts (the change from the baseline scores to those observed at 1 week of follow-up is depicted by the dotted line). In this chart, there does appear to be a tendency for the “chiropractic” group to show greater improvement at most of the weeks of follow-up evaluated, although statistically this is not borne out. Even with these abbreviated interventions, larger group sizes in this trial might have overcome what could have been a type II error and delivered statistically robust differences in both outcomes and baseline characteristics

shown above. These are but a few of the deficiencies of this particular study, which have been outlined extensively elsewhere. **12 -14** In summary, this study is a poor representation of therapies which have been successfully applied to live patients in physicians' offices worldwide. The deficiencies in its design undercut its validity to the point of compromising the reliability of the study as a whole. Indeed, the Royal College of General Practitioners, in a recent systematic review of the literature designed to update guidelines issued by the government of the United Kingdom for the management of low back pain (which themselves conflict with the Cherkin et al **11** study by citing spinal manipulation as a treatment of choice for low back pain **15**), has concluded that this RCT under discussion neither adds to nor detracts from the evidence base regarding appropriate interventions for low back pain. **16**

5. Flawed RCT no. 2: Improper sham procedure

An equally widely publicized study appearing in *The New England Journal of Medicine* purported to add further negative evidence to the efficacy of spinal manipulation, stating that “the addition of chiropractic spinal manipulation to usual medical care for four months had no effect on the control of childhood asthma.” This statement was based on the failure of active and sham-manipulated patient groups aged 7 to 16 years in a clinical trial to be differentiated in terms of their outcomes in both quality of life and airway function. What is indisputable is that there were major improvements from baseline to follow-up observed in each of the groups. **17**

The problem arises when one considers what was actually done in the sham procedures. Prolonged applications to no less than 3 distinct anatomical areas (gluteal, scapular, and cranial) to the patient are described. Admittedly, these are not high-velocity contact procedures, but this evades the issue. Two pieces of evidence strongly suggest that simple contact with patients through sham procedures will produce a significant effect. The first indicates that with respect to the reflexive inhibition of the alpha-motoneuron pool in human subjects, sham and active manipulative procedures display little difference. This is to suggest that cutaneous receptors, muscle spindles, and joint mechanoreceptors individually or in concert are significantly affected by so-called sham procedures. **18** The second demonstrates that 2 groups of children, aged 4 to 8 and 9 to 16, display profound changes in pulmonary functions, attitude and behavior scores, and cortisol levels following massage, as compared to a noncontact control group. **19** Thus, it would appear that physical contact with the patient is sufficient to trigger a cascade of physiological changes, which seem to have been erroneously dismissed in the asthma study. What appears to have been underemphasized by both the authors and most readers of the asthma study is that chiropractic encompasses a broad range of both high-velocity and low-force techniques together with ancillary procedures, many of which have obviously been embedded in the sham procedures described. In its attempt to craft a fastidious design, this trial gives the impression of missing the forest for the trees by attempting to portray the essence of chiropractic care as the lack of differentiation between the sham and manipulated experimental groups.

6. Flawed RCT no. 3: Inconsistencies between pilot and full-scale trial and sham procedures

Another recently published RCT would have appeared to replicate the problems with the asthma trial by invoking a contact sham procedure and then failing to find a significant difference in outcomes between sham and actively manipulated patient groups—this time in women complaining of primary dysmenorrhea. **20**

What is curious in this instance, however, is that the same authors did find significant differences between the 2 experimental groups in their own pilot study published previously. **21** This is plainly apparent in Table 3 , in which both pain and prostaglandin (KDPGF2a) levels are seen to decrease significantly in the active spinal manipulative therapy as opposed to the sham low-force manipulation group in the pilot study, whereas no such pattern can be detected in the full-scale investigation.

However, a closer examination of the data explains at least what appears to have happened regarding the scales. Pain baseline levels in the full-scale study can be observed to be virtually 1.5 to 2 units less than the corresponding values in the pilot study. Since the baseline values in the full-scale study are close to the expected final outcome levels, their accurate measurement is a moot point. The reason is that the qualifying criteria for patients in the full-scale trial as opposed to the pilot were changed: instead of having to immediately report to the clinic with menstrual pain, patients were now allowed up to 48 hours to register for the trial, resulting in having many patients recording no pain at all during baseline measurements. Decreased prostaglandin levels at baseline also seem to be apparent for the patients in the full-scale trial, again raising the probability that finding a downward trend during the course of any treatment during the investigation would be less likely to occur.

As for the asthma trial discussed above, it would have been far preferable to have a control group of patients having experienced no physical contact if chiropractic procedures were to be more accurately evaluated. The fact that a much larger group of chiropractors applied the sham procedure in the full-scale trial as opposed to a single practitioner in the pilot raises questions regarding the uniformity of training and reproducibility of contact procedures, the lack of which would have created a significant scattering of patient outcome measurements. Final discrepancies between the pilot and full-scale trial which are mystifying include the application of an effleurage in the full-scale trial prior to administering either the sham or high-velocity procedure, the pretreatment obscuring the therapeutic effects being followed, and the lack of a 24-hour period of abstention from exercise in the full-scale investigation, which had been included in the pilot study. All these differences may have been related to difficulties of recruiting a sufficient number of patients for the full-scale as opposed to the pilot trial, underscoring how the constraints of an experimental procedure may carry the investigation even farther afield from what is presumed to occur in the physician's office.

To their great credit, the authors state their conclusions far more precisely and

conservatively than those seen in the previously discussed trials: “The [results of this trial] are strong evidence that either the low force mimic maneuver was an insufficient placebo treatment or, in fact, that manual therapy does not relieve the pain in women with primary dysmenorrhea.” The concern is that both sections, rather than simply the latter portion of this statement, can be carried into any future citations in research publications, as well as into the public consciousness.

7. Flawed RCT no. 4: Effects may be obscured by small samples sizes in a type II error

In comparing patient groups given either high-velocity cervical spinal manipulation or low-level laser treatments as a control, Nilsson **22** observed a tendency of the manipulated group to fare better in terms of pain experienced, headache hours per day, and use of analgesics to alleviate discomfort (Fig 3). The first trial involving 39 patients showed a trend toward improvement in all categories but failed to reach the usual level of statistical significance.

Upon increasing the total patient number to 54 with resumed recruitment, however, the investigators arrived at statistically significant differences in all 3 parameters (*P*= .04 to .03). **23** Had the aforementioned asthma **17** or low back pain trials **11** been repeated with larger patient numbers, trends which appeared in much of the data might have become statistically significant differences, overcoming a type II error. Clearly, the potential exists to misinterpret the results of an RCT if they are not reviewed from a multiplicity of viewpoints rather than accepting statistical numbers at face value.

From the preceding, we can appreciate that the following principles need to be maintained as a checklist with which to avoid being mislead by a published RCT:
Outcomes of meta-analyses depend on the scoring systems used for inputs.
A potential exists for corruption in the comparison of pharmaceutical agents.
Oversampling of data may occur from duplicate (“salami”) publications.
Fastidious interventions in RCTs must not be confused with actual clinical treatments.
RCTs which include physical methods of intervention must be checked for inappropriate sham procedures.
Trends in RCTs may be obscured by type II errors produced by small sample sizes.
The results of RCTs must be confined to the parameters expressed within the investigation and not indiscriminately generalized to clinical practice.

Further concerns about the integrity of RCTs have been stoked by a recent review of 136 research projects addressing a malignant blood disease. The authors of this particular study found a disparity of positive results, depending on the funding source of research, reporting that 74% of the trials reviewed favored a new treatment when they were funded by a for-profit source and that figure being reduced to 47% when funding was provided by nonprofit sources. Moreover, inferior controls were found in 60% of occasions when a particular trial was supported by a for-profit entity but only 21% of the time when a

nonprofit source provided funding. The authors were forced to conclude that the uncertainty principle (known as clinical equipoise) appears to have been violated, generating a bias in research. **24**

Adding to the leveling of the hierarchical playing field of experimental design discussed above in Table 1 is the intriguing observation from Benson and Hartz, **25** which suggests that observational studies since 1984 have risen sufficiently in quality to match the findings of the more lofty RCTs. In a search of both the Abridged Index Medicus and the Cochrane databases to identify 2 or more treatments for the same condition, the authors located 136 reports addressing 19 diverse treatments. They found that in most cases, estimates of the treatment effects from observational studies and RCTs were similar; in only 2 out of the 19 analyses did the magnitude of observational studies lie outside the 95% confidence interval for the combined magnitude of RCTs. Thus, there was little evidence that estimates of combined treatment effects from observational studies reported after 1984 were either consistently larger or qualitatively different from those obtained in the more fastidiously constructed RCTs.

In the rush to worship RCTs and extoll their fastidious construction, it is easy to forget what gave rise to performing the RCT in the first place, the astute clinical observation. Indeed, the epidemiologist David Sackett **26** has attempted to reconcile this dilemma by indicating that both observations taken in the doctor's office and rigorous experimental design are needed to build the evidence required for clinical treatment: “External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision.”

The problems of uncritically accepting evidence from randomized controlled trials and meta-analyses in clinical decision-making have been extensively reviewed elsewhere. **27-31** To build the proper documentation for evidence-based medicine, therefore, one needs to be able to evaluate RCTs realistically in the proper context. Some of the irregularities discussed in this report might tempt the clinical researcher to cast a jaundiced eye on RCTs per se; rather, he or she should simply be prepared to synthesize the proper design and interpretation of RCTs with sound observations gleaned from the individual patient.

Conclusion

The 7 case studies reviewed in this report combined with an emerging concept in the medical literature both suggest that reviews of clinical research should accommodate our increased recognition of the values of cohort studies and case series. The alternative would have been to assume categorically that observational studies rather than RCTs provide inferior guidance to clinical decision-making. From this discussion, it is apparent that a well-crafted cohort study or case series may be of greater informative value than a flawed or corrupted RCT. To assume that the entire range of clinical treatment for any modality has been successfully captured by the precision of analytical methods in the scientific literature, indicates Horwitz, **32** would be tantamount to claiming that a medical librarian who has access to systematic reviews, meta-analyses, Medline, and practice

guidelines provides the same quality of health care as an experienced physician.

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The Inclusiveness of Sacro Occipital Technique: A Unifying Chiropractic Technique

Sacro Occipital Technique (SOT) is a system of analysis and treatment that integrates various methodologies or treatment modalities. To Major Bertrand DeJarnette, DO, DC and SOT practitioners, SOT is considered a paradigm for health care. This SOT paradigm guides and helps us focus care directly and orderly to the patient, helping to release vertebral, visceral, extremity, and cranial distortions which affect whole body anatomy and physiology.

While SOT has various techniques novel to its care, it is not an exclusionary chiropractic technique. Rather it offers guidelines and direction to those practicing its various methods through a system of diagnostic indicators and pre and post evaluation tests. This is demonstrated in the methods used to:

- **Adjust vertebral segments**
- **Affect the musculoskeletal system through wedges or blocks**
- **Affect viscerosomatic reflexes and the viscera**
- **Adjust the extremities**
- **Affect the myofascial system of the body**
- **Affect cranial bone dynamics**
- **Affect craniospinal meningeal balance**
- **Affect treatment of the pregnant woman, neonatal and pediatric patient**

Adjusting Vertebral Segments

While DeJarnette presented some specific guides to manual articular adjustments with regards to lumbar, thoracic, and cervical vertebra, the definitive SOT method of correction is not limited to any one specific mode of osseous correction. In SOT there are various systems of diagnosis such as trapezius fibers, occipital fibers, R + C factors, and vasomotor adjustments. In each case, the system of diagnosis leads you to the vertebra and gives you an indication of the vertebral involvement and sometimes the direction of its malposition or subluxation. The method of correction is up to the doctor and can involve a diversified, Gonstead, activator, or any other possible method to affect that vertebral segment. When the specific vertebral segment is adjusted properly then the indicator will no longer be present and success of correction can be accurately determined.

Affect the Musculoskeletal System through Wedges or Blocks

DeJarnette developed the use of pelvic blocks to affect pelvic and whole body distortions in an extremely non-traumatic manner. He also developed a series of treatments using the blocks or wedges to affect the patient and by utilizing gravity as the slow force of correction. SOT orthopedic block placements can be applied under the rib cage, clavicle, lumbars, thoracics, knees, and in various directional positions. Aside from very specific manner of placement with the SOT category one, two and three distortions, the orthopedic block placement allows for the position of the blocks in any manner, which favorably affects SOT indicators.

Affect Viscerosomatic Reflexes and the Viscera

SOT has various methods of affecting the viscerosomatic and somatovisceral component of a subluxation complex. The procedures for diagnosing and treating the vertebra, viscera and its neurological reflex arch are called "Bloodless Surgery" or CMRT (Chiropractic Manipulative Reflex Technique). CMRT was originally called bloodless surgery but was updated when DeJarnette changed its name to CMRT in the 1960s. Bloodless surgery offers a multitude of treatment options and allows all types of visceral manipulation to fit into the SOT chiropractic mode of treatment. In complex conditions where the patient does not respond to CMRT procedures, other forms of treatment (including visceral manipulation and nutritional support) are indicated. Therefore, any forms of visceral manipulation can be part of SOT Bloodless Surgery (CMRT) treatment.

Adjusting the Extremities

DeJarnette developed a specific protocol for treating a whole body distortion pattern when initiated by the extremities. Not just another method of treating a single extra-vertebral joint, SOT extremity technique involves a specific formula of treatment protocol beginning with evaluation of the hip, knee, ankle and foot, then shifting to the scapula, shoulder, elbow and wrist and ends with upper cervicals. While DeJarnette presents several effective methods of treating the extremities, any other extremity technique could also be used. In the context of SOT extremity technique the goal is to determine the condition of the extremity and then make corrections as necessary.

Affect on the Myofascial System of the Body

The myofascia (soft tissue) affects and is affected by the vertebra, ribs, extremities, viscera and cranium. The fascia often reflects a historical record of the patient's entire life experience. Due to fixed patterns of distortion in the fascia, subluxations of the vertebra, ribs, extremities, viscera and cranium can persist regardless of repeated treatment to the osseous or visceral component. Therefore, SOT has various soft tissue treatments such as psoas, iliofemoral, SOTO, cervical sutural and other techniques that augment SOT osseous manipulation and treatment. All forms of soft tissue manipulation and treatment can fall into the SOT treatment protocol as long as they are appropriate for condition and SOT category receiving treatment at that time.

Affecting Cranial Bone Dynamics

There are various systems of cranial bone manipulation, the majority of which are philosophically based on Dr. William Garner Sutherland osteopathic cranial techniques. DeJarnette studied under Sutherland his osteopathic cranial techniques create the basis for SOT cranial technique. SOT cranial techniques have indicators that fit into a framework of care which relate to the SOT category diagnosis of the body. Therefore, with SOT, cranial techniques have a specific place and are used to enhance craniospinal meningeal dynamics, cranial suture mobility, and temporomandibular balance as well as a multitude of related conditions. All the various cranial techniques such as osteopathic cranial manipulation and craniosacral therapy can be used during SOT cranial manipulative treatments. SOT cranial technique incorporates any cranial technique that can safely affect the patient's anatomy or physiology. Since there are several ways that cranial bones can be influenced, there are also a multitude of effective cranial techniques, which can be used in this process. SOT cranial techniques allows for this limitless option while giving specific indicators to evaluate the effectiveness of the cranial treatments.

Affect on Craniospinal Meningeal Balance

The craniospinal meningeal system incorporates myoligamentous dural interconnections all the way from the occipital to the sacrum. Strong dural attachments are found in the cranium and sacral regions and these osseous attachments are profoundly affected by SOT category treatment and cranial techniques. Various SOT procedures affect meningeal tension and the vascular system in the spinal (vasomotor) and cranium (venous sinuses). Any technique that would reduce "twisting," "torque," or balance tension in the craniospinal meningeal system could be a part of the SOT method of care. The SOT methods of diagnosis help the doctor determine these meningeal imbalances as well as determine the effectiveness of care and need for follow up.

Affect Treatment of the Pregnant Woman, Neonatal and Pediatric Patient

Due to the non-traumatic nature of treatment offered by the pelvic blocks, SOT for the pregnant woman allows treatment of sacroiliac sprains, common in the last trimester, with little if any contraindications. There are no abrupt movements, twisting, nor strong forces generated to the pelvis or lumbar regions. SOT pediatric care is a complete method of care spanning neonatal through the early teens. Obviously, the treatment varies during the age of the child but incorporated are a myriad of SOT and SOT cranial techniques modified for use in a very gentle yet effective manner. All cranial techniques can be part of the SOT protocol and these have clinically been found to be related to conditions such as, ADHD, otitis media, craniosynostosis, birth trauma, and many others.

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