Flawed trials, flawed analysis: why CBP should avoid rating itself

Robert Cooperstein, MA, DC*
Stephen M Perle, DC, MS**
Brian J Gleberzon, DC†
David H Peterson, DC††

The views expressed in this editorial are in part derived from discussion that took place during March, 2006, among the individuals who make up the Technique Consortium. This is an intercollegiate group, consisting of technique department chairs and technique instructors, that meets once a year under the auspices of the Association of Chiropractic Colleges. Despite the benefit provided by the in-depth group discussion at our meeting, the authors of this editorial take full responsibility for the views expressed.

Flawed throughout

Oakley et al.[1] summarize the research status of CBP (Clinical Biomechanics of Posture) Technique, in part by accomplishing a systematic review that compares its evidence base to that of Diversified Technique, as they define it, and also to general spinal manipulation. We do not think the novel methodology employed in their systematic review marks any type of advance on those who have preceded them in such undertakings. In addition, we do not feel their definitions of the other techniques allow them to extract the type of information from the literature they would need to execute their project. We have serious concerns about the research methodology CBP investigators have used in their 6 controlled clinical trials, so much so that we do not think they would satisfy the inclusion criteria for a rigorous, unbiased systematic review. Not surprisingly, after having taken exception with their methods and their interpretation of previous studies, we can not agree with Oakley et al. that the protocols they describe for structural rehabilitation are evidence-based or defensible in some other way.

The article begins with a simplistic discussion of the place of randomized clinical trials in studying chiropractic treatment, clearly intended to justify the later inclusion of previous CBP non-randomized clinical trials in their systematic review. Oakley et al. can't seem to decide whether "the RCT is unarguably the best research design," as they say it is, or whether it isn't, by the time they wind up awarding equal value to their non-randomized clinical trials, at least under certain circumstances. Their discussion does not reflect awareness that there is no best research design; the real question is whether a study design is capable of addressing the question at hand, in the clinical situation at hand.

CBP is the "7th most utilized technique": Does that mean it is heavily utilized?

After justifying their general interest in evidence-based care, Oakley et al. tell us why they feel the specific need to justify their own "protocol for structural rehabilitation": even though according to Hawk the Clinical Biomechanics of Posture technique is the "7th most utilized technique in chiropractic practices," there is only one preliminary manuscript in support of its protocols. On a minor note, it should be noted that Hawk did not refer to their technique, the technique formerly known as Chiropractic Biophysics (CBP), as the "Clinical Biomechanics of Posture" technique. More importantly, it is very misleading for Oakley et al. to give the impression that being the 7th most-practiced technique means that a lot of people use the technique. Hawk et al.[2] take the trouble to warn us that there is no reason to even suppose their data on technique system utilization can be safely projected to

* Palmer West
** University of Bridgeport Chiropractic College
† Canadian Memorial Chiropractic College
†† Western States Chiropractic College

chiropractic practice in general, since their participants were specially selected by the investigators, rather than being randomly chosen. Hawk concludes: "PBR [practice-based research] is conducted among volunteer practices and their consenting patients; data collected from these sources might or might not be generalizable to the general population."[2]

However, even leaving Hawk's warning aside, it turns out that CBP was identified as the primary technique used by only 1.9% of the survey respondents. Moreover, CBP was tied with 3 other techniques at 1.9%, which means that among this non-representative group of chiropractors, CBP was tied with 3 other techniques at the bottom of the 10 most-utilized list, at a mere 1.9%. Although the utilization rate of CBP is hardly the thrust of their article, it remains true that the interest we might have in Oakley et al.'s opinions on CBP, especially in comparison to other techniques, entirely depends on our confidence in their neutrality, their lack of bias. Clearly, the spin that Oakley et al. would put on the utilization of CBP is at odds with reality, as is further suggested by the fact that CBP was not even included by the NBCE in its job analysis,[3] which listed 15 technique systems in order of usage. Our impression is that there is no burning need, and least not based on utilization rates, for CBP protocols of care or structural rehabilitation.

Study design

Oakley et al. eventually inform readers what they are going to do: (1) compare the evidence for CBP vs. spinal manipulative therapy (SMT) vs. Diversified for pain relief; and (2) derive an evidence-based protocol for structural rehabilitation using CBP methods. Some of the problems inherent in this project are immediately apparent. First, the term SMT cannot be neatly distinguished from the set of procedures commonly conveyed by the term Diversified. Second, the investigators have coined what we believe to be a new category of health care – "structural rehabilitation." They have done this without providing a reference or clear definition of what structural rehabilitation is and what distinguishes it from other forms of rehabilitation. In one fell swoop the authors have generated a new branch of therapy and set up their own standards and guidelines without any external comparisons for validity. Third, even though the unique engine they develop for systematic review is flawed, more importantly, serious flaws in their own clinical studies ought to exclude them from consideration by any systematic review as anything other than enhanced practice-based research.

Inadequate literature retrieval

Even if the project had made sense, the authors do not demonstrate the requisite ability to execute it. They were only able to retrieve 73 clinical trials on SMT using their search strategy. It was clearly deficient since Meeker and Haldeman[4] were able to retrieve 73 clinical trials in their article published several years ago, in 2002. Even a superficial search on our part between 1990 and 2005 retrieved 261 trials. (Search strategy: ("Manipulation, Spinal" [MeSH] OR "Manipulation, Osteopathic" [MeSH] OR "Manipulation, Chiropractic" [MeSH] OR "Manipulation, Orthopedic" [MeSH] OR "Musculoskeletal Manipulations" [MeSH]) AND "Low Back Pain" [MeSH] OR "Neck Pain" [MeSH] AND Randomized Controlled Trial[ptyp] AND ("1990" [PDAT] : "2005" [PDAT]). As a case in point, we note Oakley et al. missed the UK BEAM II study,[5,6] one of the largest studies on SMT conducted over the past five years.

CBP vs. Diversified vs. SMT for pain relief?
Can't be done.

Oakley et al. want to compare CBP to what they label "Diversified Technique." It doesn't take long for their methodology to collapse. Their non-referenced definition of Diversified appears in Table 1. Briefly, it says Diversified is a technique system where the doctor uses x-ray and motion palpation to obtain a listing, then delivers a "specific line of drive opposite the spinal listing." Problem is, whether this is a good or a bad definition, it remains *their* definition. Apparently, Oakley et al. did not notice that the CBP definition of Diversified would apply just as well to Gonstead Technique. Thus, the strategy of searching for studies on "Diversified" exactly as they define it will not locate the many studies where Gonstead Technique was used, which the investigators would have to admit would be relevant. By comparison, a Gonstead Technique website[7] includes some relevant research involving *Gonstead-like* methods.

Leaving aside the issue that several chiropractic colleges do not concern themselves with listings at all, this definition of Diversified is completely arbitrary, unsupported by historical and contemporary fact, and is used by Oakley et al. to make Diversified a straw man that would be shown to be inferior to CBP. Not only is the definition in Table 1 *ad hoc* in relation to the diverse usages deployed by others in chiropractic, it is inconsistent with CBP's own usage, as in a 1994 publication concerning one of their clinical trials. In it, they write: "treatment group 1 consisted of diversified spinal manipulations in lateral flexion and or axial rotation."[8] This contradicts the comment in their Table 6 that Diversified was not used in this study.[1] More importantly, if CBP researchers and practitioners have been using the terms spinal manipulation and diversified adjusting more or less interchangeably over the years, what's the point of drawing a distinction at this time, other than their current need to hammer down a straw dog?

The more narrowly a treatment method is defined, the less information will be retrievable in a literature search. Two of us had to deal with this problem when we and our collaborators studied the literature and clinical evidence for specific chiropractic procedures, stratified by specific low back conditions.[9–11] We had to collapse the plethora of chiropractic adjustive methods available down to only 10. Only one-third of the chiropractic data (exclusive of the Journal of Manipulative and Physiological Therapeutics) was retrievable through electronic searching, since chiropractors do not excel in choosing the best keywords, and many of the publications we consulted were not indexed anyway. It is very likely that many researchers doing studies in which the treaters might have defined their adjustments as "Diversified" did not use that keyword, which is not even available in the MeSH system.

What happens if we apply Oakley et al.'s type of search strategy to their own technique? Doing a search for CBP clinical trials using the search term "Clinical Biomechanics of Posture" does not result in a single citation, since that term has just been invented. Although "CBP Technique has over 80 publications in Index Medicus Journals"[12] only 17 show up searching using the former name of the technique, Chiropractic Biophysics. Of those 17 only 5 are labeled in MEDLINE as clinical trials and only one is classified as a nonrandomized clinical control trial.

Since it is unlikely that most chiropractors distinguish Diversified adjusting from manipulation, just as Oakley et al. may not have until this current publication, it makes no sense to classify literature as pertinent to one or the other. Oakley et al. state: "Surprisingly, there is [sic] little data existing on Diversified technique (as defined in Table 1)." Given how limited their classification of Diversified is, the CBP investigators should not be surprised by the result. If, as they state in the abstract, the evidence for SMT exceeds that for CBP, the difference would appear even more pronounced were studies they classify as Diversified combined with SMT studies in their review, as they should have done. Actually, we don't think this is much of a problem, since we don't think (however paradoxically) the CBP studies should be included in their own systematic review, or any other, for reasons discussed below.

Cooperstein,[13] Cooperstein and Gleberzon[14] (p.143-9), and Peterson[15] (p.495) have written extensively on the historical roots of Diversified Technique; as have Green and Johnson.[16] What becomes apparent is that Diversified has a dual nature, in which "Diversified" (capitalized) denotes a brand-name technique system and "diversified" (lower case) denotes a more eclectic grouping of diagnostic and therapeutic procedures used by any and all practitioners throughout the chiropractic profession. There are reasons to believe that Diversified developed in part as a response to the rigidity and dominance of the Palmers. Cooperstein and Gleberzon wrote: "Ironically, as the years went by, DT, which originated as a liberating, eclecticizing response to the myriad of narrowly defined and often cultistic technique systems of the day, found itself more than just occasionally arranged alongside of, rather than alternative to them – as yet another technique system. However paradoxically, it appears that modern DT is chiefly distinguished from all of the others by its poor distinction from any one of them"[14] (p.147). Indeed, "Diversified is too global to describe succinctly, whereas as a named technique, it too eclectic to describe distinctly"[14] (p.143). The data from the NBCE Job Analysis[3] also support a very broadscope sense of Diversified in the chiropractic profession, very much at odds with Oakley et al., in that 96.2% of chiropractors claim to use Diversified some of the time, on 71.5% of their patients.

The comment that the CCE mandates the teaching of Diversified, however defined, is entirely inaccurate. The word "diversified: does not appear in the CCE Standard.[17] Although we would prefer to not speculate about Oakley et al.'s motivations in writing their paper, a major error of fact like this suggests a possible wish to demonstrate CBP procedures are superior to the eclectic and integrated methods of chiropractic technique taught at many of the chiropractic colleges. This would in turn have potential implications for third party payment, not warranted by the facts as we see them.

Flawed systematic review

Just as we find the CBP studies flawed (discussed below), we are not confident in Oakley et al.'s experience and neutrality as systematic reviewers. What are we to make of comments like "Bronfort et al. deleted any RCTs with 10 subjects or less while in this manuscript, we deleted any RCTs if ... there were 11 subjects or less ..."[1] Any particular reason we should trust the judgment of these particular systematic reviewers, over that of a Bronfort, who has conducted many RCTs and published systematic reviews before? Any reason to suppose 11 is preferred to 10, other than the possible desire to exclude a couple of SMT studies the CBP'ers find competitive with their own?

In Table 3, where Oakley et al. reveal their own unique rating scale, we encounter some very questionable propositions. For some reason we find the points awarded to an RCT with less than 30 subjects to be the same as those awarded to a non-randomized controlled clinical trial with more subjects. We think it most arbitrary to decide that a non-controlled trial with 30 patients is worth more than an RCT with 29 subjects. Especially indefensible is their consideration of the data base which located manuscripts as a factor for evaluation and rating them. To take into account the "indexing data base of manuscript publication" (as if databases published manuscripts), means awarding more points to studies that show up in Index Medicus than in in CINAHL, and more for those in CINAHL than those in MANTIS. Shouldn't studies be judged on their merits, as determined by a non-biased reviewer, rather than the search engine that includes them?

Disabling conflict of interest

We agree with Oakley et al. that "systematic reviews of available published evidence are required. The value of these literature reviews, however depends on the quality of the review ..."[1] That is why we don't think it is a very good idea that individuals involved in marketing a trademarked, proprietary technique system get involved in writing systematic reviews comparing their own product to other technique systems or procedures. Readers must be very certain that the reviewers are unbiased; we must know that their rating decisions are not purely or largely self-serving, as they appear to be in the case at hand. At a minimum, there should be a stipulation affixed to the publication to the effect that the authors have a commercial interest in the technique being evaluated, and provided funding for some of the studies and publications they chose to rate. We are very surprised this manuscript made it through the peer review process without such a disclosure in the final publication. We recommend that journal editors strictly interpret existing stipulations that require disclosure of such conflicts of interest. A reader naïve to the associations of these authors to CBP, who only looked at the affiliations shown in the paper, would never know that some or all of them have a pecuniary interest in CBP.

Flawed supportive clinical evidence for CBP

In our opinion, serious design flaws in the CBP clinical studies summarized in Table 6[1] would prevent inclusion in quality evidenced-based systematic reviews comparing chiropractic techniques. To cut to the chase, the so-called CBP clinical trials, to the extent we can make sense of their under-developed methods sections of their publications, commingle the effects of SMT, Diversified, and CBP care. Since their experimental subjects get several weeks of spinal manipulation prior to even undertaking CBP care, there is no way to tease out the patient benefits due to SMT/Diversified from those due to CBP. Having made their research bed, they must now sleep in it: they cannot include their own studies in a systematic review of CBP vs. either SMT or Diversified. Had they at least administered pain scales after the manipulation phase of care, and before the initiation of specific CBP care (why didn't they?), they might have been able to determine the pain reduction they claim accrued as a result of CBP procedures. Certainly, CBP researchers are already aware of this flaw, and we need only cite their own acknowledgment: " ... cervical spinal manipulation may be responsible for pain relief in many of our subjects".[18] We agree.

We are also very troubled by the lack of information supplied about the control groups. Of the six papers we examined,[8,19–22,18] in only one do we learn anything about how the controls were recruited: in this case, they were "chosen from family members of patients at the clinic."[8] Although we don't know if this method was used in all the studies, this is a crippling defect; so much so, that it can be safely said the control group was useless, at least as far as pain comparisons are concerned. One might conjecture that a control subject, knowing a family member had bought into several dozen patient visits, might be expected to exaggerate their post-check pain levels, lest their treated family members develop a sense of having wasted money. Failure to describe and disclose anything about the control groups other than their basic demographics is just as disabling in a non-randomized clinical trial as failure to describe the randomization process in a randomized trial. We also don't know if the study personnel involved in obtaining pre and post-treatment pain scores were masked as to whether the study participants were experimental subjects or controls. We might also add that across the several studies, post-checks on the experimental subjects and controls were not always performed at the same intervals. No information is supplied about the Institutional Review Board(s) that approved the studies, nor what measures were taken to protect the rights and interests of the non-treated controls. Research designs requiring controls to endure months of pain without treatment are not highly regarded at this time.

The fact that the controls' pain levels stayed at about the same relatively high level for several months in each of the CBP trials that reported on pain is very puzzling, since pain levels tend to decline due to the passage of time alone. This is a red flag alerting us that there is something very strange about these control groups. We need to know why they declined care, how long they had had pain, whether they sought other treatments while they did not receive CBP care, and if not, why did they not seek such other care?

The conclusions of the Oakley study: largely irrelevant

We can not comment on the implications for patient care that Oakley et al. would derive from either their CBP studies themselves or their systematic review, since neither the studies nor the review merit serious consideration as demonstrating anything at all about the relative value of CBP vs. SMT/Diversified in changing pain levels. Thus, we have no comment on their structural rehabilitation protocol, except that it is not very evidence-based. Their penchant for extrapolating their study data to even more extended care regimens also fails to impress, since the studies themselves are not convincing. We don't see how anyone can make sense of the following: After telling us that the trial data are *not* linear on p.274,[1] Oakley et al. declare in the very same sentence that this "is exactly the kind of average data that can be extrapolated to another time period." The proposition that if 38 CBP treatments can effect a 17.9 degree change in the cervical lordosis, then it is hypothetically the case that it would take 114 visits to effect three times that curve change[1] is most unconvincing.

The algorithm in Figure 1, besides not conforming to conventions for such algorithms as described by Hansen,[23] is very confusing; just about each box raises questions that would take us off-point to enumerate in this editorial. Although the ability to change spinal structure was not one of Oakley et al.'s two stated areas of focus, their data suggest CBP procedures may change measured parameters of spinal curves. We can not rule out that there may be some clinical value in that, at least for certain patients. For the average patient, we remain unable to determine whether the time and expense required of patients for this CBP goal of care is indicated, nor whether such protocols are consistent with what many have called "patient-centered chiropractic." Changing curves just because you can may not be warranted; we remain unconvinced that moving patients towards CBP-defined normal values, the midpoints of ranges with huge variance, is good chiropractic.

Oakley et al. round out their article with a few odds and ends extolling the virtues of CBP. We agree with them that their radiographs appear to be reliable. We are relieved to see in their paragraph on the "Ideal and Average Spinal Model"[1] that the CBP folk have finally come to the same conclusion as Cooperstein, who questioned long ago whether a CBP spinal "model" based on a mathematical average of the spinal measurements of pain-free subjects could be considered a model at all in the usual sense of the term.[24,25] The discussion of the health hazards of CBP radiographic procedures is very troubling, in that we are asked to take comfort in the fact that CBP doctors take less x-rays than an orthopedic surgeon in surgery cases. Shouldn't they be comparing how many x-rays they take compared to an orthopedic surgeon who does *not* perform a surgery in non-surgical cases?

In conclusion, we find neither support for the CBP protocols of care, nor merit in the technique comparisons drawn in this study. We recommend that the CBP investigators be more careful in their implementation and more forthcoming in their description of their research methodology; in particular, the selection, characterization, processing, and protection of the control groups. Lacking that information, we must reclassify their studies as either seriously flawed controlled clinical trials, or perhaps spiffed up practice-based research, which should be included or excluded from systematic reviews as such. On the other hand, as preliminary studies they certainly have some role to play in weighing all the evidence. We would also recommend that future systematic reviews involving CBP or any other technique system use conventional systematic review standards and not be undertaken by anyone with a vested interest in the outcome. When the reviewers can look forward to more sales of chiropractic equipment and supplies, and more seminar attendees to the extent readers are favorably influenced by their judgments, they cannot avoid the appearance of impropriety, and worse, they may take advantage of this obvious conflict of interest.

We do not think the public interest is best served by the proprietors of trademarked technique systems implying the protocols they think best for their own methods applies more generally, fay, to "structural rehabilitation". We do expect these proprietors to conduct the clinical research demonstrating the safety and effectiveness of their procedures, but independent reviewers should be entrusted with the responsibility of reducing evidence like this to clinical guidelines and best-practices protocols. When and if technique system proprietors take issue with the opinions and methods of independent reviewers, they retain the right to make their own views known, just as Oakley has recently done.[26]

References

1 Oakley PA, Harrison DD, Harrison DE, Haas JW. Evidence-based protocol for structural rehabilitation of the spine and posture: review of clinical biomechanics of posture (CBP®) publications. J Can Chiropr Assoc 2006; 49(4):270–296.
2 Hawk C, Long CR, Boulanger KT. Prevalence of nonmusculoskeletal complaints in chiropractic practice: report from a practice-based research program. J Manipulative Physiol Ther 2001; 24(3):157–69.
3 Christensen MG. Job Analysis of Chiropractic. A Project Report, Survey Analysis and Summary of the Practice of Chiropractic within the United States. Greeley, Colorado: National Board of Chiropractic Examiners; 2005. p. 135.
4 Meeker WC, Haldeman S. Chiropractic: a profession at the crossroads of mainstream and alternative medicine. Ann Intern Med 2002; 136(3):216–27.
5 United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: cost effectiveness of physical treatments for back pain in primary care. BMJ 2004; 329(7479):1381.
6 United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: effectiveness of physical treatments for back pain in primary care. BMJ 2004; 329(7479):1377.
7 http://www.gonstead.com/research/
8 Harrison DD, Jackson BL, Troyanovich S, Robertson G, DeGeorge D, Barker WF. The efficacy of cervical extension-compression traction combined with diversified manipulation and drop table adjustments in the rehabilitation of cervical lordosis: a pilot study. J Manipulative Physiol Ther 1994; 17(7):454–464.
9 Cooperstein R, Perle SM. Condition-specific indications for low back chiropractic adjustive procedures for the low back: Literature and clinical effectiveness ratings of an expert panel. Topics in Clinical Chiropractic 2002; 9(3):19–29.
10 Cooperstein R, Perle SM, Gatterman MI, Lantz C, Schneider MJ. Chiropractic technique procedures for specific low back conditions: Characterizing the literature. J Manipulative Physiol Ther 2001; 24(6):407–24.
11 Gatterman MI, Cooperstein R, Lantz C, Perle SM, Schneider MJ. Rating specific chiropractic technique procedures for common low back conditions. J Manipulative Physiol Ther 2001; 24(7):449–56.
12 http://www.idealspine.com/pages/research.htm
13 Cooperstein R. Diversified technique, historically considered: core of chiropractic, or "just another technique system"? In: Cleveland III C, Gibbons R, editors. Conference Proceedings of the Chiropractic Centennial Foundation; 1995 September 14–16, 1995; Davenport, Iowa: Chiropractic Centennial Foundation; 1995. p. 21–22.
14 Cooperstein R, Gleberzon B. Technique Systems in Chiropractic. Edinburgh: Churchill Livingstone; 2004.
15 Peterson DH, Bergmann T. Chiropractic Technique. 2 ed. Saint Louis, MI: Churchill Livingstone Inc.; 2002.
16 Green BN, Johnson CD. Unveiling an enigma: The origins and development of Diversified chiropractic technique. In: Cleveland III C, Gibbons R, editors. Conference Proceedings of the Chiropractic Centennial Foundation; 1995 September 14–16, 1995; Davenport, Iowa: Chiropractic Centennial Foundation; 1995. p. 34.
17 http://cce-usa.org/2006%20January%20STANDARDS.pdf
18 Harrison DE, Harrison DD, Betz JJ, Janik TJ, Holland B, Colloca CJ, et al. Increasing the cervical lordosis with chiropractic biophysics seated combined extension-compression and transverse load cervical traction with cervical manipulation: nonrandomized clinical control trial. J Manipulative Physiol Ther 2003; 26(3):139–51.
19 Harrison DE, Cailliet R, Betz J, Haas JW, Harrison DD, Janik TJ, et al. Conservative methods for reducing lateral translation postures of the head: A nonrandomized clinical control trial. J Rehabil Res Dev 2004; 41(4):631–9.
20 Harrison DE, Cailliet R, Betz J, Harrison DD, Haas JW, Janik TJ, et al. A non-randomized clinical control trial of Harrison mirror image methods for correcting trunk lits (lateral translations of the thoracic cage) in patients with chronic low back pain. Eur Spine J 2005; 14(2):155–162.
21 Harrison DE, Cailliet R, Harrison DD, Janik TJ, Holland B. Changes in sagittal lumbar configuration with a new method of extension traction: nonrandomized clinical controlled trial. Arch Phys Med Rehabil 2002; 83(11):1585–91.
22 Harrison DE, Cailliet R, Harrison DD, Janik TJ, Holland B. A new 3-point bending traction method for restoring cervical lordosis and cervical manipulation: a nonrandomized clinical controlled trial. Arch Phys Med Rehabil 2002; 83(4):447–53.
23 Hansen DT, Mootz RD. Understanding and utilizing clinical algorithms. Topics in Clinical Chiropractic 1994; 1(4):44–57.
24 Cooperstein R. Letter to the editor on A normal sagittal spinal configuration: a desirable clinical outcome. J Manipulative Physiol Ther 1996; 20(2):136–137.
25 Cooperstein R. Spinal graffiti: the rise and fall of the Harrison Spinal Model. Dynamic Chiropractic 1996; 14(22):18, 29.
26 http://www.idealspine.com/pages/ajcc_october_2005_its_pauls_opinion.htm.