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Health-related Quality of Life Improvements in Adult Patients with Chronic Low Back Pain under Low-force Chiropractic Care: A Practice-based Study

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ABSTRACT: Background: Chronic Low Back Pain (cLBP) costs the United States over $100 billion annually. Primary Study Objective: This study reports pain intensity, general health and functional disability outcomes after 4-weeks of chiropractic care for cLBP patients. Methods/Design: A prospective case series, nonrandomized, non-controlled, practice-based study. Setting: 22 private chiropractic practices in the US. Subjects: 131 adult cLBP patients, 68 males (53.5%), mean age of 46.75 with chief complaints of cLBP (LBP ≥ 3 months) with mean duration of 11 years. Intervention: Each patient received 6 office visits over a 4-week period with doctors following Directional Non-Force Technique (DNFT) chiropractic protocols. Outcome Measures: The Dartmouth COOP charts (general health), Modified Oswestry Disability Questionnaire (MODQ) (functional disability), and an 11-point Pain Intensity Numerical Rating Scale (PI-NRS) for pain. Results: The pre and post-care mean scores of COOP were 13.16 (95% CI 9.33 – 16.99, P < 0.01) and 10.52 (CI 6.98 – 14.06, P < 0.01) respectively, 20.06% improvement. The MODQ were 17.72 (CI 11.02 – 24.42, P < 0.01) and 8.92 (CI 2.30 – 15.54, P < 0.01), 49.66% improvement in functional disability. The PI-NRS was 18.18 (CI 12.26 – 24.10, P < 0.01) and 10.60 (CI 3.80 – 6.80, P < 0.01), improving 41.69%. Conclusions: Improvements appeared to be significant on general health, functional disability, and pain intensity after an intervention of 4-weeks with 6 visits of DNFT chiropractic care. These findings merit a randomized control trial of chiropractic versus a control group or other treatment modalities in the future.

INDEX TERMS: (MeSH): CHIROPRACTIC; COMPLEMENTARY THERAPIES; LOW BACK PAIN; MANIPULATION, CHIROPRACTIC. (Other): CHRONIC LOW BACK PAIN; PRACTICE-BASED RESEARCH; RECURRENT LOW BACK PAIN.

Low back pain (LBP) is the second leading symptom-related reason to seek medical care and the most common spinal pain.1 Patients suffering low back pain longer than 3 months are conventionally categorized as chronic low back pain (cLBP) sufferers.2 Freburger et al5 reported that chronic low back pain prevalence rose from 3.9% in 1992 to 10.2% in 2006. While it is commonly accepted that most LBP cases resolve quickly,6 a growing number of studies challenge this belief.7,8 Among them, Croft et al8 reported 25% of the 463 patients that sought primary care still suffered low back pain after 12 months.

Katz7 reported cLBP with associated disability makes up 5% of the cases with low back pain yet it accounts for 75% of the total costs related to the disorder. The same study reported the total cost being over $100 billion annually in the United States with two-thirds coming from indirect costs, which include lost wages and reduced productivity.

In 2007, the American College of Physicians and the American Pain Society published clinical guidelines regarding the diagnosis and treatment of low back pain including seven recommendations.8 One of the recommendations under consideration was “nonpharmacologic therapy with proven benefits” which included spinal manipulation for patients with unresolved chronic low back pain after an initial trial of self-care and medications; but the recommendations were rated as weak due to only moderate quality of the evidence available in current literature.

Evidence for effectiveness of chiropractic adjustments for cLBP is inconclusive or weak.9 Some studies have positive outcomes10,11 while others cannot conclude that spinal manipulation is more effective than placebo, exercise, massage, and other non-invasive procedures.12-15 A 2011 systematic review of interventions for cLBP concluded high-quality evidence suggests no clinical relevant difference between spinal manipulative therapy and other interventions for reducing pain and improving function.16

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CONFLICT OF INTEREST STATEMENT:
Dr. Kim Khuuv has received speaking and consultation fees from DNFT chiropractic.
Dr. Chris John is the proprietor of DNFT® chiropractic.

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The distinctions between the Directional Non-Force Technique (DNFT) chiropractic\textsuperscript{17,18} and “conventional chiropractic” SMT thrust must be drawn so that any statistical results from this study would not be considered to be a repetition of similar existing studies.

- The DNFT thrust does not involve rotary torque of the spine as part of a thrust setup, at any level.
- The pre-thrust tension is less than that of traditional chiropractic.
- Only the thumb or disc plexor described below is utilized, and not the traditional diversified doctor contact points such as pisiform, tenar, etc.
- The magnitude of the DNFT thrust, although in the “low amplitude” range, must be considered generally less than that of traditional chiropractic.
- With the DNFT thrust, there are typically no joint cavitations with articular sounds, such as those that often occur with the traditional chiropractic thrust.
- DNFT disc adjustments are delivered as described above except that for certain levels and directions where the impulse is delivered with a “disc plexor” (a 3/8” modified wooden dowel) instead of the thumb. Whether a “modified thumb” or “disc plexor” is utilized to correct a “disc subluxation,” the thrust is lighter than that delivered upon most other structures.

Due to the many difficulties associated with randomized clinical trials (RCTs) and the study of cLBP and chiropractic care (ie, patient recruitment, randomization, and the length of time for base-line evaluations),\textsuperscript{19} the authors choose to report on a practice-based research network (PBRN) study. Dr Larry A Green\textsuperscript{20} defined PBRN as “a group of practices devoted principally to the care of patients.” While practice-based research networks have been around since 1970s in the US,\textsuperscript{21} it only experienced a resurgence over the past few years within family medicine,\textsuperscript{22} pediatrics,\textsuperscript{23} dental,\textsuperscript{24,25} and nursing.\textsuperscript{26,27} Within chiropractic, published studies have demonstrated the feasibility of PBRNs for collecting descriptive epidemiology, utilization patterns and patient outcomes,\textsuperscript{28} a feasibility study of chiropractic care for acute neck pain,\textsuperscript{29} the safety and effectiveness of pediatric chiropractic care,\textsuperscript{30} and the chiropractic care of adults 55 years or older.\textsuperscript{31} We report on a practice-based research network study of chiropractic practitioners improving health-related quality of life in chronic low back pain patients.

**METHODS**

**Design**

A prospective, nonrandomized, non-controlled, multicenter, practice-based research network study with chronic low back pain patients entering DNFT chiropractic care for 6 office visits over approximately a 4-week period was conducted. A total of 22 chiropractors volunteered to participate each with a minimum of 3 years of clinic practice of DNFT chiropractic utilizing the technique according to DNFT protocol.\textsuperscript{16,17} Each chiropractor was instructed to enrol 6 new adult cLBP patients that met the inclusion and exclusion criteria described below and have the patient complete a total of seven forms (one intake form and three outcome questionnaires on the first and sixth visit). The forms were completed in the adjusting room but not in the presence of the chiropractor and turned into the front desk person. The chiropractors and their assistants were instructed not to read the forms and mail them to the research coordinator. Every patient completed consent forms as part of standard intake in each practice. The practice-based trial was conducted in accordance with the principles of the Helsinki Declaration as revised in 2000.

None of the chiropractors or patients involved with this study received any payment for their participation. All the patients received their care pro-bono. No funding source supported this study.

**Inclusion Criteria**

The subjects selected for the study were from a convenient sample entering chiropractic care that met the following criteria:

1. Be a new patient with a chief complaint of chronic low back pain (low back pain lasting 3 months or longer) determined from their history and confirmed by physical examination.
2. Have no prior experience with DNFT chiropractic care.
3. Be 18 years of age or older.
4. Be ambulatory, cognizant, in good health, and literate in the English language.
5. Have access to transportation to the clinics.

In addition, each subject:

1. Completed the patient section on each of the following forms; consultation, consent, privacy policy notification, and neurologic and orthopedic examination.
2. Completed the COOP charts, PI-NRS, and MODQ on the first visit
3. Completed 6 visits of DNFT chiropractic care within approximately 4 weeks.
4. Completed the COOP charts, PI-NRS, and MODQ after receiving chiropractic care on the sixth visit (generally 4 weeks after enrollment).

**Criteria for DNFT care**

All patients completed a history intake form, a consent form, a privacy policy notification, and received an examination prior to receiving DNFT chiropractic care. The history intake form collected the following information: date of the first visit, date of last visit, weeks of care, and the patient’s age, gender, chief complaint, and duration of low back pain. Each practitioner provided his or her own standard consent forms and privacy policies for each patient to complete. To protect the patient’s private health information, each patient was assigned a non-identifiable patient ID number, which consisted of the chiropractor’s initials and a 2-digit number (ie. TK01, TK02, etc). This ID number was recorded on every research form pertaining to this study. The standard examinations included standard orthopedic, neurological, and chiropractic tests. DNFT challenging and
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reactive leg reflex protocols in prone and supine positions were utilized to detect subluxations.16,17

Exclusion Criteria

Subjects were excluded from the study if the examining chiropractors discovered evidence of skeletal fractures, severe sciatica resulting from large disc bulges that would warrant surgical intervention, central nervous system diseases or other contra-indications to chiropractic adjustments. Patients that could not commit to one month of gratis treatments were also excluded.

INTERVENTION

Each of the new cLBP subjects received the following care plan: 2 visits for the first week, 2 visits for the second week, 1 visit for the third week, and 1 visit for the fourth week. This treatment plan consisted of 6 total visits within approximately 4 weeks.

Intervention consisted of analysis and correction of subluxations on each patient visit as per Directional Non-Force Technique® chiropractic protocol.16,17 The diagnostic part of this protocol consists of a structural challenge immediately followed by the DNFT "Reactive Leg Reflex" test that, according to protocol, indicates presence or absence of subluxation, as well as directions of correction. The challenge is a test consisting of a gentle push or pull of an osseous or soft tissue structure. It is theorized that the Reactive Leg Reflex is elicited by the combination of challenge and a proprietary foot eversion maneuver; if the test is positive, it produces a temporary shortening of one leg by approximately 3/4 inch.

The corrective part of DNFT protocol consists of a thumb thrust which, although it has sometimes been included in the general category of "high velocity, low amplitude thrust," differs significantly from the traditional chiropractic thrust that also shares this categorization.

OUTCOME ASSESSMENTS

Outcome measures to assess a variety of interventions for cLBP include the Original or Modified/Revised Oswestry Low Back Pain Disability Questionnaire (MO/D)25,23 for functional disability, the Dartmouth Primary Care Cooperative Information Project (COOP) charts24 for general health, and an 11-point pain intensity numerical rating scale (PI-NRS) for pain assessment.25

The three subject-reported outcome measurements were utilized to measure present pain intensity and functional status on the first visit and at the end of the sixth visit within approximately 4 weeks of care. The Dartmouth COOP charts (25 points total) measure physical fitness, social activities, daily activities with difficulties, feelings, and overall health.24 The COOP charts have demonstrated ease of usage, sensitivity to change, reliability and validity.25,26

The PI-NRS form (44 points total) is a measure of pain intensity representing varying episodes distinguished by 4 questions:

1. What is your low back pain level RIGHT NOW?
2. What is your TYPICAL or AVERAGE pain level in your low back?
3. What is your low back pain level AT ITS BEST (How close to "0" does your pain get at its best)?
4. What is your low back pain level AT ITS WORST (How close to "10" does your pain get at its worst)?

Below each question was an 11-point pain numerical rating scale with a score of "0" (no pain) to "10" (worst possible pain). The PI-NRS has demonstrated predictive validity and is used to measure chronic low back pain intensity.25

The MODQ (50 points total) has been shown to have high reliability and construct validity in the measure of functional disability with cLBP.29 The MODQ contains 10 questions pertaining to Pain Intensity, Personal Care, Lifting, Walking, Sitting, Standing, Sleeping, Social Life, Traveling, and Changing Degree of Pain. Each response is scored from a scale of "0" to "5" with a score of "5" equating to the highest level of disability from low back pain.

Data Analysis

Data from each subject was entered into SPSS 17.0 (SPSS Inc, Chicago Ill) for analysis. A paired sample t-test was used for comparing the pre- and post-intervention total scores of the COOP charts, the Pain Intensity scales, and the Modified Oswestry. A significance level equal to 0.05 was applied to the statistical analyses.

RESULTS

A total of 131 (68 males, 59 males, 4 missing) adult patients suffering from cLBP with an average age of 46.75 years (range 19 to 99 years), met the inclusion criteria and were included in this study. The chief complaint of cLBP (LBP ≥ 3 months) had a mean duration of 132.08 months (range 3 months to 576 months). The patients were under care with a mean number of weeks at 3.19 ± 0.56 weeks, which also represents the average time between data collection.

The patients were treated by 22 DNFT chiropractors between April 2004 and September 2005. Of the 22 chiropractors, 14 of them treated exactly 6 patients as requested totalling 84 subjects (64% of total patients). The remainder of the chiropractors treated various numbers of subjects giving a mean of 5.95 patients per chiropractor.

Paired samples t-tests were used to analyse pre- and post-treatment scores on the COOP, MODQ, and PI-NRS. Only data from subjects that completely filled-out both the pre-and post-treatment forms were included in data analyses.

The mean baseline total COOP score was 13.16 (± 3.83, n=130, 99.2% response) and post-intervention was 10.52 (± 3.54). The 2.64-point average improvement (20.1% decrease in score) was statistically significant (p < .01). The baseline for the total MODQ score was 17.72 (± 6.70, n=120, 91.6%) and post-intervention was 8.92 (± 6.62) representing an 8.8-point (49.7%) statistically significant improvement (p < .01). The baseline mean PI-NRS was 18.18 (± 5.92, n=128, 97.7%) and post-intervention was 10.60 (± 6.80) resulting in a 7.58-point (41.7%) statistically significant improvement (p < .01).

There were no adverse reactions to care reported.

DISCUSSION

In the current study, a statistically significant improvement in all three valid outcome measures was observed after 4 weeks (6 adjustments) of DNFT chiropractic care. This is
### Table 1
Modified Oswestry Disability Questionnaire (MODQ) scores at baseline and at 4 weeks for *current study and current literature.*

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>P value</th>
<th>Baseline MODQ</th>
<th>4-week MODQ</th>
<th>Net Change</th>
<th>Net Change %</th>
<th>Number of Adjustments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Study *</td>
<td>120</td>
<td>0</td>
<td>17.72</td>
<td>8.92</td>
<td>-8.8</td>
<td>49.66%</td>
<td>6</td>
</tr>
<tr>
<td>Haas et al 10†</td>
<td>527</td>
<td>0</td>
<td>19.25</td>
<td>10.95</td>
<td>-8.3</td>
<td>43.12%</td>
<td>Missing</td>
</tr>
<tr>
<td>McMorland &amp; Suter 11‡</td>
<td>14</td>
<td>No sig.</td>
<td>27.1</td>
<td>21.73</td>
<td>-5.37</td>
<td>19.80%</td>
<td>12</td>
</tr>
<tr>
<td>*Zapraudina et al 10 §</td>
<td>59</td>
<td>0.069</td>
<td>9.95</td>
<td>6.15</td>
<td>-3.8</td>
<td>38.19%</td>
<td>3 to 5</td>
</tr>
<tr>
<td>Giles &amp; Muller 32 §</td>
<td>25</td>
<td>0.01</td>
<td>12</td>
<td>6 (9 wks)</td>
<td>-6</td>
<td>50%</td>
<td>18</td>
</tr>
</tbody>
</table>

* Used Modified or Revised Oswestry Disability Questionnaire
† Chronic pain was defined as a current episode 7 weeks or longer
‡ Chronic pain was defined at > 6 months
§ Used Original Oswestry Disability Questionnaire, Converted to 50 points scale

supported by a number of studies that use either the Original or Modified/Revised Oswestry Disability Questionnaire (ODQ) to report on chiropractic care and cLBP patients.10,11,12 Table 1 illustrates the results of the current study and current articles found on PubMed. When the other studies utilized the 100-point Oswestry scale, their scores were converted (by dividing the scores by 2) to a 50-point scale to be consistent with the current study.

From Table 1, there are three differences found in the other studies and the current study: the number of subjects, the percentage of net change of Oswestry scores, and the number of adjustments. The current study had 117 subjects, making it the second highest number of subjects behind Haas11 with 527. Zapraudina10 had the third highest at 59 subjects while the other followed in the twenties and teens. The current study and Haas11 were able to achieve a high number of participants by incorporating multi-center, practiced-based research. The current study achieved the highest net percentage change among the Modified or Revised ODQ with 49.66% (P < .01) as compared to 43.12% (P = .000) by Haas,11 and a non statistical significant 19.80% by McMorland and Suter.32 While the current study only offered DNFT chiropractic care for their subjects, Haas11 described chiropractic care in the study as “spinal manipulation, physical therapy, exercise plan, and self-care advice.” Giles and Muller32 did achieve a 50% (P = .01) reduction in the Original ODQ after a 9-week intervention of 2 treatments per week.

### Study Limitations
While the results from this study appear positive, there were limitations that need to be addressed. There was no randomization or use of a control group. The study also lacked the comparison to other treatment modalities such as exercise, medication, massage, physical therapy, or self-care education to compare the results against. Social desirability on self-reported questionnaires is an important bias to address with chronic pain research,10 especially when the subjects completed the pre-and post-questionnaires within the practice setting at which they received care but not in the presence of the chiropractor. The use of the Marlowe-Crowne Social Desirability Scale 41 should be included in future studies with cLBP and the use of the MOPD, the COOP charts and the PI-NRS. The use of the randomized controlled trial (RCT) study design, reducing social desirability by study design, and performing sensitivity analysis of “non-completers” would minimize many of these biases and improve these findings.

### CONCLUSION
This study supports the few other studies in current literature suggesting that chiropractic care can improve cLBP by decreasing pain intensity and functional disability while improving overall health. DNFT chiropractic care achieved these results with 6 adjustments. The study is not without limitations that can be addressed in a study design with RCT. Future RCT studies with DNFT chiropractic care against a number of different modalities and placebo would be desirable to confirm these findings.

### ACKNOWLEDGEMENTS
We would like to acknowledge Dale Johnson, PhD and Nadine Kadey for critically revising and editing the manuscript and the librarians at Life Chiropractic College West, Barbara Delli Gatti, Annette Osenga and Patricia Brack, for their countless hours of literature research support.

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