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Comparing Outcome Measures in Lumbar Spine Manipulations: Dynamic X-Rays and Oswestry Index

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Abstract

Background: Outcome measurements are used to validate chiropractic adjustments, and they have not always been compared to each other under the same treatment conditions and trials.

Methods: Twenty-one participants were non-randomly assigned to a treatment or a control group. The Oswestry index questionnaire was completed, and lateral bending lumbar radiographs were collected. Treatment group participants received nine treatments in two weeks, the control group was untreated, and both groups were re-evaluated after two weeks.

Results: The average number of segments manipulated per day went from 8.3 ± 1.0 (day 1) to 3.0 ± 2.6 (day 9), with a standardized effect size of 2.69. The Oswestry disability index for the treatment group was 29.8% ± 11.8% disability pre-treatment and 14.20% ± 11.5% disability post-treatment, with a standardized effect size of 1.34. In the radiograph analysis, the number of dysfunctional segments changed from 6.8 ± 2.3 pre-treatment to 1.8 ± 5.2 post-treatment, with a standardized effect size of 1.24.

Conclusion: A significant correlation was found between pre- and post-treatment measurements of the Oswestry index and dynamic radiographs.

Keywords: Manipulation; Diagnostic technique; Oswestry index; Activator

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Introduction

Outcome measures have not always been compared to each other under the same treatment conditions and trials [1-3]. This study is needed to evaluate the relative value of comparing two patient evaluation methodologies and determining if one methodology which is less invading to the patient could be used as a reevaluation tool and on-going measurement of patient improvement.

The present evaluation utilized available tools, namely the Oswestry index questionnaire and lateral bending radiographs. Our aim was to determine how the Oswestry index and lateral bending radiographs are affected by treatment, whether either outcome measure could be used as a reevaluation tool, and whether there is a correlation between these two tests. The site of interest for the spinal manipulation was defined as the lumbar spine, defined as the level from T-12 to L-5 according to Maigne [4,5]. Spinal manipulations were done using the Activator Method™ lumbar spine protocol [6,7].

Methods

This study was registered with clinicaltrials.gov, registration number NCT00739570.

Participants

Anthropometric characteristics of the participants are shown in **Table 1**. The research protocols for the evaluation and adjustment were approved by the Université du Québec à Montréal ethics committee. Written informed consent was obtained from all participants.

Control group

A total of ten participants, four females and six males, were recruited in early June 2008 from a chiropractic clinic located at 7655 Newman Boulevard, LaSalle, Quebec. The inclusion criterion was that all participants were receiving maintenance chiropractic care and would not have any treatment during the two-week span of the research project. All participants were examined, x-rayed, and evaluated for all the same outcome measures.

Table 1 Anthropometric measurements of the participants.

Variables	CTRL	TR
Weight (kg)	74.9 ± 16.9	80.3 ± 16.5
Height (m)	1.7 ± 0.1	1.7 ± 0.1
BMI	25.3 ± 3.6	28 ± 3.7
Age (Years)	47.5 ± 16.2	45.6 ± 8.9
Values are mean ± SD. CTRL: control group, TR: treatment group		

Treatment group

All participants were recruited via an announcement in the newspaper, Le Messager de LaSalle, during the period from July 6th to July 20th 2008. Forty-five subjects called the telephone number at the university and left a message indicating their interest in the project. Eleven participants who met the criteria were selected; the others were thanked for their interest. The eleven participants recruited consisted of four females and seven males. The participants were suffering from a chronic lower back condition at least three months in duration. Chronic back pain can be described as:

"Low back pain that comes and goes over weeks to months. The severity of the pain is always the same. The character of the pain is always the same, cramping pain, sharp or stabbing pain, burning pain and pain that travels to the back".

All participants were examined, x-rayed, and evaluated for all the same outcome measures. The evaluating chiropractor used static and dynamic palpation, range of motion, physical, neurological, orthopedic, and chiropractic examinations in conjunction with radiographs and the Oswestry index. Those administering the intervention were not blinded to the group assignment.

Materials and Methods

Activities of daily living questionnaire

The modified Oswestry disability index was utilized [8]. It is comprised of ten questions that evaluate the capacity of the patient to function during daily activities and how the patient rates himself on a scale from A to F. The value of A=0, and each subsequent letter has an ascending numerical value, B=1 to F=5. The maximum total score for all ten questions is 50. The total for all the answers is tabulated and multiplied by two to give a percentage of dysfunction due to lumbar pain.

X-ray analysis

X-rays were performed on the participants' lumbar spine. Anterior-Posterior (AP) lateral bending films in the left and right lateral bending position [9-11] were taken at the end position of the movement, as the patient reached the end position and stopped; the central ray was positioned seven to eight centimeters above the top of the iliac crest. The lateral bending analysis is considered reliable [12]. The lateral film was performed with the central ray at the level of L-5. The radiographs were analyzed by two independent chiropractors. One chiropractor did the pre-treatment analysis, and the other chiropractor did the post-treatment analysis. Both chiropractors were blinded to the group assignment of the participants. The chiropractors would draw lines at the inferior and superior vertebral plates of each vertebra. The lines between the superior aspect of one vertebra and the inferior aspect of the vertebra above it should merge on the side of flexion. If the lines drawn between the superior aspect of one vertebra and the inferior aspect of the vertebra above remained parallel or diverged, this was considered a vertebral dysfunction. The treating chiropractor was allowed to view the radiographs, for treatment, after the initial analyses were completed.

Interventions

A control group was included to isolate the effect of time in the absence of treatment. The participants of the control group received no treatment, only the evaluation of the outcome measures at a two-week interval. In the treatment group, the participants received the previously described chiropractic evaluation and the Activator Method™ evaluation to determine their pelvic deficient (PD) side, which is explained as follows:

"Traditionally, the short leg has been designated the Pelvic Deficient, or PD leg. It is referred to as the reactive leg because of its tendency to appear shorter or longer during different testing procedures. The PD leg is visually observed during the initial leg check following placement of the patient in the prone position on the adjusting **Table**" [6].

The Activator Method™ basic scan protocol for the lumbar spine was used, and the participants received a chiropractic adjustment.6 The instrument used for the treatment of all patients was an Activator IV Signature (Activator Methods International, Phoenix, Arizona), at the number four setting (176 N),6 and the lumbar area from T-12 to L-5 was treated according to the PD side. The treating clinician held an advanced proficiency rating in the Activator Method™ [13]. The duration of the treatment schedule was two weeks [14].

Experimental Protocol

When the participants arrived for a recording session, they completed the Oswestry index questionnaire. They were asked to remove their clothing except underwear, provided with a cotton gown that had an open slit in the back, and proceeded to the radiology room were the x-rays were taken. This marked the end of the recording session. At the end of the recording session, participants of the control group were instructed to get dressed and made an appointment for the next evaluation in two weeks; the participants of the treatment group then proceeded to make nine appointments to receive chiropractic treatments over the next two weeks [14]. When the patient arrived for a treatment session, they were shown to the treatment room and treated as previously described [6]. After the treatment they would make an appointment for the next day. The participants were treated from Monday, July 28th to Friday, August 1st and then from Monday, August 4th to Thursday, August 7th. Friday, August 8th was the last visit, which consisted of a complete reevaluation where the initial evaluation procedure was repeated. Participant 2109 did not come for the reevaluation. This was the only protocol deviation, and there were no adverse events for all participants throughout the experiment. Our final count for participants was

10 per group. On the last day of recording, all the participants were thanked for their participation and received a $30.00 payment for their travel expenses.

Statistical Analysis

Descriptive statistics (mean ± SD) were computed for all conditions. We also performed a Pearson's correlation between the different outcome measures [15]. Standardized effect-size calculations were also performed [16,17]. Cohen described an effect size of 0.2 as indicative of a small effect, 0.5 as medium, and 0.8 as a large effect [16]. A general linear model represented by a factorial ANOVA model with repeated measures [15] was used to compare all main effects and interactions (SPSS 15.0, SPSS Inc. Chicago, IL, United States) followed by the student-Newman Keuls test; $p < 0.05$ was considered as the threshold of statistical significance.

Results

The Activator Method ™ analysis revealed the following pelvic deficiency patterns: eightLPD and two RPD in the control group, and four LPD and six RPD in the treatment group. The average number of total segments adjusted per day, from a possible total of 11, decreased from 8.3 ± 1.0 pre-treatment to 3.0 ± 2.6 post-treatment **(Table 2)**, resulting in a standardized effect size of 2.69 for the treatment group.

The overall average Oswestry disability index score upon initial and evaluation and reevaluation of the control group were 10.2% ± 10.6% disability and 8.6% ± 10.8% disability, respectively (**Figure 1**). For the treatment group, the overall average Oswestry disability index score pre- and post-treatment score were 29.8% ± 11.8% disability and 14.20% ± 11.5% disability, respectively (**Figure 1**). The standardized effect size is 0.15 for the control group and 1.34 for the treatment group.

The dynamic x-ray analysis of the control group revealed a total of 27 and 26 dysfunctional segments, respectively, upon radiological initial and reevaluation, from a possible 176 total dysfunctions. The average number of dysfunctional segments in the control group was 2.7 ± 1.4 at initial evaluation and 2.6 ± 1.3 at reevaluation (**Figure 2**), representing a standardized effect size of 0.07. In the treatment group, the dynamic x-ray analysis revealed a total of 68 dysfunctional segments at the pre-treatment radiological evaluation and a total of 18 at the post-treatment radiological evaluation, from a possible 176 total dysfunctions. The average number of dysfunctional segments decreased from 6.8 ± 2.3 pre-treatment to 1.8 ± 5.2 post-treatment (**Figure 2**), representing a standardized effect size of 1.24. We found a Pearson's correlation (0.446, $p = 0.004$) (**Table 3**) between the number of dysfunctional segments and the Oswestry index. We also found a correlation between the groups (0.324, $p = 0.042$) and the pre- and post-treatment measurements of dysfunction (-0.500, $p = 0.001$). The ANOVA analysis (**Table 4**) resulted in significant findings for the change in the number of radiological dysfunctions for the treatment group ($F_{1,38} = 4.445$, $p = 0.042$) as well as for the

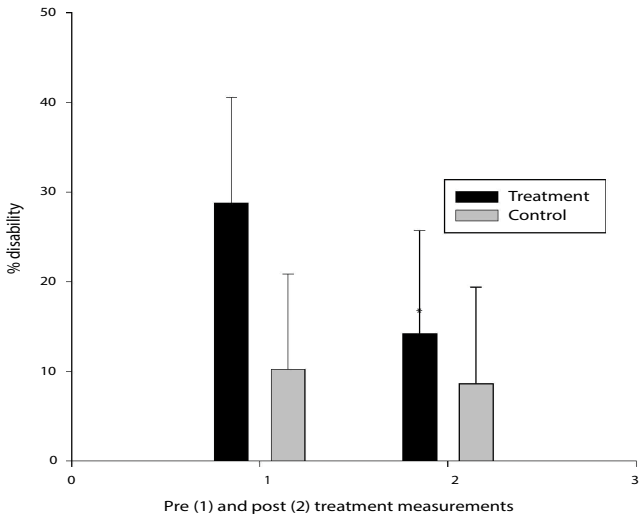

Figure 1 Pre- and post-treatment average score of the Oswestry Index in the treatment and control groups. * $p = 0.002$ Treatment vs. Control.

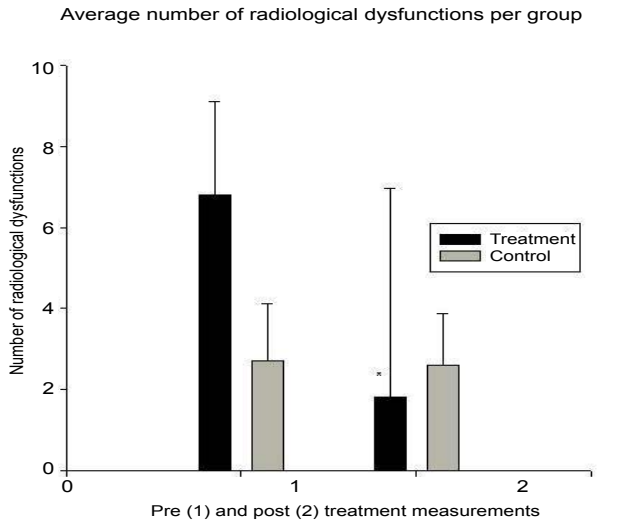

Figure 2 Pre- and post-treatment average of the number of radiological dysfunctions in the treatment and control groups. * $p = 0.042$ Treatment vs. Control.

Table 2: Spinal levels and the number of adjustments (maximum = 11) per day from day 1 to day 9, (n = 11 participants).

level/days	1	2	3	4	5	6	7	8	9
L5	9	9	9	10	9	10	10	9	6
L4	7	6	8	10	9	10	7	6	2
L2	9	8	4	2	3	0	1	0	0
D12	8	9	10	10	10	10	9	9	4
average	8.3	8	7.8	8	7.8	7.5	6.8	6	3
SD	1	1.4	2.6	4	3.2	5	4	4.2	2.6

Average number of segments adjusted per day.

Oswestry index (F1,38 = 10.487, p = 0.002). The Neuman-Keuls test results are illustrated in **Figure 3** and reveal that the final Oswestry index measurements between the different groups are similar.

Discussion

Patient 2108 from the treatment group had no change in his Oswestry score (30 pre- and post-treatment), but he had only 1 dysfunctional segment remaining at the end of treatment from the initial 9 dysfunctions. The participant mentioned that he felt improvement in his back and had pain in the morning for about 30 minutes upon awakening that then subsided. He wondered if his pain could be related to an inflamed colon, which he had not mentioned initially when asked about additional diseases. The participant said he had been constipated for the last week of treatment. This incident highlights the importance of reevaluation; other diseases may produce pain and mask physical changes related to treatment. Reevaluation is an opportunity to observe and detect other possible painful factors that can affect the patient.

In this experiment the control group demonstrates no real effect and the treatment group demonstrates a very large standardized effect size well above 0.8, the threshold for a large effect [16]. The treatment group revealed the following effect sizes: 1.24 using dynamic x-ray measurements, 1.34 using the Oswestry index, and 2.69 using the number of manipulated segments from the first treatment to the last in the series.

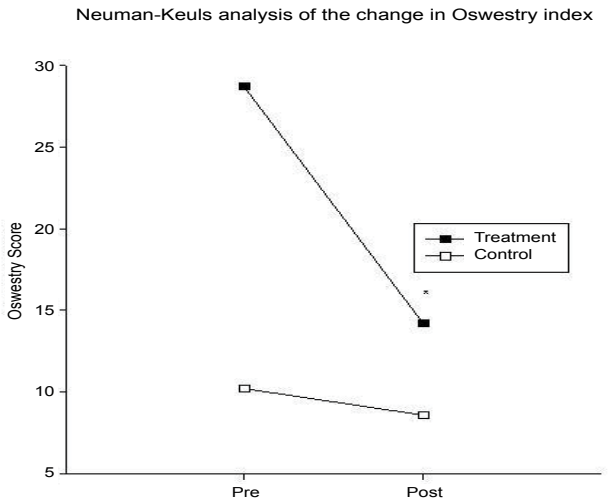

Figure 3 Graphic representation of the Neuman-Keuls test.
* p = 0.002 Pre vs. Post.

Table 3 Pearson's Correlation between X-ray dysfunction and Oswestry index initial and reevaluation measurements.

	Dysfunction	Oswestry
Dysfunction	1	0.446 (**)
Oswestry		1

Table 4 ANOVA between Outcome measures and groups.

		SS	DF	Ss	F	p
Dysfunction	Between Groups	27.225	1	27.225	4.445	0.042
Oswestry	Between Groups	1587.6	1	1587.6	10.487	0.002

SS: Sum of Squares, DF: Degree of Freedom, MS: Means of Squares, F: F-value, p: probability of significance.

The correlation between the Oswestry index and the functional radiological evaluation (**Tables 3 and 4**) indicates that this approach could be used as a reevaluation tool. Thus, if the Oswestry index is used as an outcome measure at the beginning of care, re-evaluating the patient with follow-up x-rays is not necessary. This would reduce the expense to the patient or third-party payer in addition to reducing radiation to the patient.

The strength of our ANOVA (**Table 4**) for the Oswestry index at p = 0.002 in combination with an effect size of 1.34 indicates that this tool can be used clinically as an assessment tool and as a reassessment tool if included in the initial evaluation. The radiological dysfunction ANOVA is not as strong but still significant (p = 0.042); in combination with its effect size (1.24), this finding indicates that radiological evaluation could also be used as a reassessment tool.

The improvement demonstrated by these results is similar to those obtained by Quon et al. upon treating a patient with side posture manipulation [18]. They report that "the patient improved considerably during only two weeks of treatment," and "it is emphasized that manipulation has been shown to be an effective treatment for some patients with lumbar disc herniation" [18]. The correlation between different chiropractic techniques' style of manipulation has often been disputed; however, recently many researchers have demonstrated that different technical approaches produce similar results, in agreement with earlier researchers [3,18-25]. Finally, we can see that without treatment, neither the Oswestry index nor motion x-ray analysis change spontaneously or with time.

Conclusion

Dynamic radiographs and the Oswestry index appear to be sensitive enough to detect a strong effect size after a 9-treatment course of therapy. In addition, a significant correlation was found between pre- and post-treatment measurements of the Oswestry index and dynamic radiographs which could help validate the necessity of continued care.

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