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Patient-centered care or osteopathic manipulative treatment as mediators of clinical outcomes in patients with chronic low back pain

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Abstract

Context: Patient-centered care is often considered a characteristic of osteopathic medicine, in addition to the use of osteopathic manipulative treatment (OMT) in such musculoskeletal conditions as low back pain.

Objectives: This study aimed to determine if patient-centered care or OMT are mediators of the clinical outcomes of osteopathic medicine in patients with chronic low back pain.

Methods: A comparative effectiveness study was conducted within the Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry). Eligible patients met the diagnostic criteria recommended by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain and completed four consecutive quarterly encounters between April 2016 and November 2020. The Consultation and Relational Empathy instrument for patient-centered care was used at the baseline encounter and OMT use was measured at the final encounter. The clinical outcome measures included low back pain intensity on a numerical rating scale (NRS) from 0 to 10, back-related functioning on the Roland-Morris Disability Questionnaire (RMDQ), and pain impact on the National Institutes of Health Minimum Dataset for Chronic Low Back Pain (NIH-MDS). A parallel multiple mediator model was used to compute the direct and indirect effects of osteopathic medicine in achieving each of the three clinical outcomes.

Results: The 404 study patients had a mean age of 52.2 years (standard deviation, 13.1 years) and 288 (71.3%) were female. The 88 (21.8%) patients treated by osteopathic physicians reported more favorable scores for patient-centered care (mean, 41.3; 95% CI 39.0–43.5) than patients treated by allopathic physicians (mean, 38.0; 95% CI 36.8–39.3) ($p=0.02$). Fifty-six (63.6%) patients treated by osteopathic physicians used OMT. The age- and sex-adjusted outcomes for patients of osteopathic vs. allopathic physicians across all four encounters were: mean, 5.4; 95% CI 5.0–5.7 vs. mean, 5.9; 95% CI 5.7–6.1 on the NRS for pain intensity ($p=0.01$); mean, 11.3; 95% CI 10.1–12.6 vs. mean, 14.0; 95% CI 13.3–14.7 on the RMDQ for back-related disability ($p<0.001$); and mean, 26.8; 95% CI 24.9–28.7 vs. mean, 30.1; 95% CI 29.1–31.1 on the NIH-MDS for pain impact ($p=0.002$). Patient-centered care did not mediate any outcome of osteopathic medicine, whereas OMT mediated better outcomes in low back pain intensity.

Conclusions: This appears to be the first study to simultaneously address both patient-centered care and OMT as potential mediators of the effect of osteopathic medicine in treating chronic pain. Patient-centered care did not mediate the effects of osteopathic medicine and OMT only mediated outcomes relating to low back pain intensity. More research is needed to identify other aspects of osteopathic medicine that mediate its beneficial effects in patients with chronic low back pain.

Keywords: back-related disability; chronic low back pain; mediation analysis; osteopathic manipulative treatment; osteopathic medicine; pain impact; pain intensity; pain research registry; patient-centered care.

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A joint statement from the American Medical Association in conjunction with the American Osteopathic Association recently called for an effort to combat the mischaracterization of osteopathic physicians by media, celebrities, and companies [1]. It emphasized that osteopathic medicine is a distinctive branch of medical practice in the United States that involves a whole-person approach to care, including

the use of osteopathic manipulative treatment (OMT) for such musculoskeletal conditions as low back pain. Similar claims about the distinctiveness of osteopathic medicine, which also focused on the dual tenets of a holistic or patient-centered approach to care and OMT, have been widely espoused for over two decades [2]. Data from the National Ambulatory Medical Care Survey have shown that low back pain historically has been a leading reason for patients to visit osteopathic physicians [3], and continues to be so today in primary care [4]. Based largely on systematic reviews and meta-analyses [5, 6], the only clinical practice guidelines issued by the American Osteopathic Association recommend that OMT be used when somatic dysfunction is the cause of or a contributing factor in low back pain [7, 8]. The latter is defined as impaired or altered function of related components of the body framework system, including skeletal, arthrodial, and myofascial structures, and their related vascular, lymphatic, and neural elements [9]. Thus, low back pain represents an ideal condition to test the hypothesized distinctive aspects of osteopathic medicine. In particular, chronic low back pain enables a long-term assessment of the patient-centeredness of the ongoing physician-patient relationship as well as OMT. The purpose of this study was to use longitudinal data from a pain research registry to measure the clinical outcomes of patients with chronic low back pain and to determine if the effects of osteopathic medicine are mediated by either patient-centered care or OMT.

Methods

Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation

Patients in this study were selected from the Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry). The registry was established at the University of North Texas Health Science Center in 2016 to collect longitudinal data at quarterly encounters relating to chronic low back pain treatments and clinical outcomes [10]. Patients who reported being pregnant or institutionalized were not eligible to enroll in the registry. The registry transitioned to a digital research platform in 2020, which extended its reach to the 48 contiguous United States and District of Columbia using social media. The registry's platform has facilitated ongoing collection of clinical research data and the maintenance of standard operating procedures for clinical research during the COVID-19 pandemic [11], including the conduct of a randomized registry trial [12]. The registry was approved by the North Texas Regional Institutional Review Board (protocol 2015-169) and all patients provided written informed consent prior to enrollment.

Eligibility criteria

Patients were eligible for the study if they were 21–79 years of age at registry enrollment, had sufficient English-language proficiency to complete case report forms independently or with staff assistance, had a physician who regularly treated their low back pain, and had chronic low back pain according to diagnostic criteria established by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain [13]. The latter require that patients report low back pain during at least the past 3–6 months, with a frequency of at least one-half of the days during the past 6 months. All eligible patients must have completed four consecutive quarterly encounters between April 2016 and November 2020, thereby representing 12 months of observation. Patients who reported physician crossover (i.e., being treated by an osteopathic physician at the first quarterly encounter and an allopathic physician at the final quarterly encounter, or vice-versa) were excluded from the study.

Measurement of patient-centered care

Patient-centered care was measured at the first quarterly encounter with the Consultation and Relational Empathy (CARE) instrument, which is comprised of 10 items relating to physician-patient interactions during medical care visits [14, 15]. The CARE instrument has been validated as a measure of physician empathy-based consultation during the process of delivering primary care. In particular, one item specifically queries whether the physician is interested in the patient as “a whole person,” while another item addresses physician “care and compassion.” Total scores on the CARE instrument range from 10 to 50, with higher scores reflective of a more patient-centered approach that is conducive to providing high-quality medical care for patients with chronic problems. Scores on individual items of the CARE instrument were multiplied by a factor of 10 to place them on the same scale as the total score for comparative purposes.

Measurement of osteopathic manipulative treatment

The use of commonly recommended treatments for chronic low back pain [16, 17] was measured at each quarterly encounter, including use of both non-pharmacological treatments (exercise therapy, yoga, massage therapy, spinal manipulation, acupuncture, and cognitive behavioral therapy) and pharmacological treatments such as nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids. The use of OMT was determined with a trichotomous variable derived from the two items involving use of spinal manipulation and the type of physician provider. Patients who reported never using spinal manipulation at the final quarterly encounter were considered to have never used OMT (OMT=0), regardless of their physician type. Patients who reported using spinal manipulation were considered to have possibly used OMT (OMT=1) if they were treated by an allopathic physician. For example, it is possible that such patients may have received OMT from an osteopathic manipulative medicine specialist. The latter generally restrict their practices to providing OMT as a complement to primary care provided by other physicians. However, other health care professionals, such as chiropractors, may also provide such complementary spinal

Table 1: Patient sociodemographic and clinical characteristics at the first quarterly encounter by physician type (n=404).^a

Characteristic	Osteopathic physician		Allopathic physician		p-Value
	n=88		n=316		
	No.	%	No.	%	
Age, years (mean, SD)	53.2	14.3	52.0	12.7	0.45
Female sex	66	75.0	222	70.3	0.38
Race					0.06
White	73	83.0	215	68.0	
Black	13	14.8	89	28.2	
Asian	2	2.3	5	1.6	
American Indian/Alaska Native	0	0.0	6	1.9	
Native Hawaiian/Pacific Islander	0	0.0	1	0.3	
Hispanic ethnicity	10	11.4	37	11.7	0.93
Educational level					0.051
Less than college degree	44	50.0	201	63.6	
Bachelor's or Master's degree	42	47.7	106	33.5	
Professional or doctoral degree	2	2.3	9	2.8	
Ever lost work for 1 or more months due to low back pain	25	28.4	127	40.2	0.04
Ever applied for or received disability or workers' compensation benefits because of inability to work due to low back pain	14	15.9	77	24.4	0.09
Ever involved in a legal claim related to low back pain	10	11.4	32	10.1	0.74
Cigarette smoking status					0.01
Never smoked	53	60.2	158	50.0	
Former smoker	31	35.2	106	33.5	
Current smoker	4	4.5	52	16.5	
Body mass index, kg/m ² (mean, SD)	31.8	7.7	33.0	8.4	0.25
Medical conditions ever diagnosed					
Herniated disc	26	29.5	121	38.3	0.13
Sciatica	32	36.4	123	38.9	0.66
Osteoarthritis	24	27.3	110	34.8	0.18
Osteoporosis	11	12.5	32	10.1	0.52
Hypertension	32	36.4	132	41.8	0.36
Heart disease	13	14.8	23	7.3	0.03
Diabetes mellitus	16	18.2	60	19.0	0.86
Asthma	22	25.0	87	27.5	0.64
Depression	38	43.2	157	49.7	0.28
History of low back surgery					0.49
Yes, one surgery	8	9.1	24	7.6	
Yes, more than one surgery	3	3.4	21	6.6	
No	77	87.5	271	85.8	
Ever used non-pharmacological treatments for low back pain					
Exercise therapy	44	50.0	194	61.4	0.055
Yoga	25	28.4	79	25.0	0.52
Massage therapy	45	51.1	150	47.5	0.54
Spinal manipulation	58	65.9	117	37.0	<0.001
Acupuncture	19	21.6	45	14.2	0.09
Cognitive behavioral therapy	6	6.8	30	9.5	0.44
Currently use pharmacological treatments for low back pain					
Nonsteroidal anti-inflammatory drugs	55	62.5	214	67.7	0.36
Opioids	25	28.4	120	38.0	0.10

^aTable entries for characteristics are No. (%), unless otherwise specified.

Clinical outcome measures

manipulation. Patients who reported using spinal manipulation were considered to have used OMT (OMT=2) if they were treated by an osteopathic physician.

The clinical outcomes (low back pain intensity, back-related functioning, and pain impact) were measured at each quarterly encounter.

Figure 1: Flow diagram for selection of study patients.

Low back pain intensity was measured with an 11-point numerical rating scale (NRS) ranging from 0 (“no pain”) to 10 (“worst pain”) for the average pain level over the past 7 days. Back-related functioning was measured with the Roland-Morris Disability Questionnaire (RMDQ), which assessed back-related disability on the encounter date [18]. Scores on the RMDQ range from 0 to 24, with higher scores indicating greater levels of disability. Pain impact was measured using nine items from the National Institutes of Health Minimum Dataset for Chronic Low Back Pain (NIH-MDS), including scales for physical function and pain interference with activities [13]. The latter scales were derived from the Patient-Reported Outcomes Measurement Information System for health-related quality of life [19]. Higher scores represent worse outcomes on the pain impact measure.

Statistical analysis

Patient characteristics and clinical measures were summarized using the no. (%) for dichotomous or categorical variables and the mean (standard deviation [SD]) for continuous variables. Comparisons of these measures according to physician type were performed with contingency table methods and the Student's *t*-test, respectively. Repeated measures analysis of variance was used to compare each of the clinical outcomes over the four quarterly encounters by physician

type, with patient age and sex entered as covariates to control for potential confounding. Mediation analyses were performed to determine if patient-centered care or OMT mediated the effects of osteopathic medicine in achieving any of the clinical outcomes. These analyses were performed with the PROCESS program [20], a regression-based approach that enables computation of the mean effects of osteopathic medicine and 95% CIs. Physician type was entered as the independent variable and the grand mean of the four measures at each quarterly encounter was entered as the dependent variable in each of the respective analyses for the three clinical outcomes. A parallel multiple mediator model was used to compute the direct and indirect (i.e., mediated) effects of osteopathic medicine with 50,000 resamples used to compute percentile bootstrap 95% CIs for patient-centered care and OMT, while controlling for patient age and sex. All database management and other statistical analyses were performed with the IBM SPSS Statistics software (Version 25). Hypotheses were assessed at the 0.05 level of statistical significance using 2-sided tests.

Results

A total of 404 patients were included in the study, with 88 (21.8%) treated by osteopathic physicians and 316 (78.2%)

Figure 2: Measures on the Consultation and Relational Empathy (CARE) instrument according to physician type. Error bars represent 95% confidence intervals. p-values were computed using the Student's *t*-test based on 88 patients treated by osteopathic physicians (DOs) and 316 patients treated by allopathic physicians (MDs). The CARE instrument items measure the following patient perceptions of their physician: 1. Making you feel at ease; 2. Letting you tell your “story”; 3. Really listening; 4. Being interested in you as a whole person; 5. Fully understanding your concerns; 6. Showing care and compassion; 7. Being positive; 8. Explaining things clearly; 9. Helping you to take control; 10. Making a plan of action with you. Scores range from 10 to 50, with higher scores representing a more patient-centered approach.

treated by allopathic physicians (Figure 1). Overall, the mean age of patients was 52.2 years (SD, 13.1 years) and 288 (71.3%) were female (Table 1). Patients treated by either type of physician were generally comparable. However, patients treated by osteopathic physicians were less likely to report ever having a work loss of 1 or more months due to low back pain or to be current cigarette smokers, but they were more likely to report a history of heart disease and ever having used spinal manipulation. There were no differences according to physician type in ever having used exercise therapy, yoga, massage therapy, acupuncture, or cognitive behavioral therapy, or in currently using NSAIDs or opioids for low back pain. The outcome measures over all four quarterly encounters were: mean, 5.8; 95% CI 5.6–6.0 on the NRS for low back pain intensity; mean, 13.4; 95% CI 12.8–14.0 on the RMDQ for back-related functioning; and mean, 29.4; 95% CI 28.5–30.3 on the NIH-MDS for pain impact.

Patients treated by osteopathic physicians reported higher total scores on the CARE instrument (mean, 41.3; 95% CI 39.0–43.5) than patients treated by allopathic physicians (mean, 38.0; 95% CI 36.8–39.3) ($p=0.02$) (Figure 2). Osteopathic physicians received higher scores than allopathic physicians on six of the 10 CARE instrument items, including those that measured care and compassion (mean, 42.7; 95% CI 40.4–45.1 vs. mean, 38.2; 95% CI 36.9–39.6; $p=0.001$) and being interested in the patient as a whole person (mean, 40.7; 95% CI 38.1–43.2 vs. mean, 36.6; 95% CI

35.2–38.1; $p=0.007$). Overall, 211 (52.2%) patients had never used OMT. A total of 56 (63.6%) patients treated by osteopathic physicians reported having used OMT for low back pain at the final quarterly encounter, compared with 137 (43.4%) patients treated by allopathic physicians who may possibly have used OMT.

Patients treated by osteopathic physicians reported lower scores for low back pain intensity, back-related disability, and pain impact than patients treated by allopathic physicians over the four quarterly encounters (Figure 3). The corresponding age- and sex-adjusted main effects outcomes for patients of osteopathic vs. allopathic physicians during this period of observation were: mean, 5.4; 95% CI 5.0–5.7 vs. mean, 5.9; 95% CI 5.7–6.1 ($p=0.01$) on the NRS for low back pain intensity; mean, 11.3; 95% CI 10.1–12.6 vs. mean, 14.0; 95% CI 13.3–14.7 ($p<0.001$) on the RMDQ for back-related disability; and mean, 26.8; 95% CI 24.9–28.7 vs. mean, 30.1; 95% CI 29.1–31.1 ($p=0.002$) on the NIH-MDS for pain impact. There was also a significant physician type $\times$ time interaction for low back pain intensity, wherein pain decreased over time in patients treated by osteopathic physicians but remained stable in patients treated by allopathic physicians ($p=0.03$).

Patient-centered care did not mediate the effects of osteopathic medicine in achieving any of the clinical outcomes. The use of OMT was a significant mediator of the effect of osteopathic medicine on low back pain intensity (β -coefficient, -0.27 ; 95% CI -0.52 to -0.04

Figure 3: Clinical outcomes over time according to physician type. Outcomes include (A) low back pain intensity, (B) back-related disability, and (C) pain impact. Error bars represent 95% confidence intervals. p-values were computed using repeated measures analysis of variance based on 88 patients treated by osteopathic physicians (DOs) and 316 patients treated by allopathic physicians (MDs). NRS, numerical rating scale; RMDQ, Roland-Morris Disability Questionnaire; NIH-MDS, National Institutes of Health Minimum Dataset for Chronic Low Back Pain. Higher scores represent worse outcomes on each measure. A significant physician type $\times$ time interaction was observed for low back pain intensity ($p=0.03$).

Table 2: Regression coefficient estimates for the direct and indirect effects of osteopathic medicine on clinical outcomes (n=404).^a

Effect of osteopathic medicine	Clinical outcome		
	β	95% CI	p-Value
Low back pain intensity			
Total effect of osteopathic medicine	-0.54	-0.97 to -0.11	0.01
Total direct effect of osteopathic medicine	-0.24	-0.73 to 0.25	0.33
Total indirect effect of osteopathic medicine	-0.30	-0.56 to -0.06	0.02
Patient-centered care	-0.03	-0.09 to 0.02	0.34
Osteopathic manipulative treatment	-0.27	-0.52 to -0.04	0.03
Back-related disability			
β 95% CI p-Value			
Total effect of osteopathic medicine	-2.66	-4.08 to -1.25	<0.001
Total direct effect of osteopathic medicine	-2.32	-3.95 to -0.69	0.006
Total indirect effect of osteopathic medicine	-0.35	-1.15 to 0.49	0.40
Patient-centered care	-0.16	-0.38 to 0.02	0.14
Osteopathic manipulative treatment	-0.19	-0.97 to 0.61	0.63
Pain impact			
β 95% CI p-Value			
Total effect of osteopathic medicine	-3.32	-5.45 to -1.18	0.002
Total direct effect of osteopathic medicine	-2.71	-5.17 to -0.24	0.03
Total indirect effect of osteopathic medicine	-0.61	-1.80 to 0.64	0.33
Patient-centered care	-0.26	-0.64 to 0.02	0.12
Osteopathic manipulative treatment	-0.35	-1.49 to 0.84	0.56

*p-values were computed using mediation analysis based on 88 patients treated by osteopathic physicians and 316 patients treated by allopathic physicians. Clinical outcomes were measured over four quarterly encounters using a numerical rating scale for low back pain intensity, the Roland-Morris Disability Questionnaire for back-related disability, and the National Institutes of Health Minimum Dataset items for pain impact. Negative β -coefficients represent more favorable outcomes with osteopathic medicine (i.e., lower scores for low back pain intensity, back-related disability, and pain impact). The total indirect effect of osteopathic medicine is that which is attributable to the two potential mediators in the regression models.

(p=0.03) (Table 2). Osteopathic manipulative treatment mediated about one-half of the total effect of osteopathic medicine relating to low back pain intensity based on the regression model coefficients. However, OMT did not mediate clinical outcomes relating to back-related functioning or pain impact.

Discussion

There are over 150,000 osteopathic physicians and medical students in the United States [21], including almost 22,000 osteopathic resident physicians in programs accredited by the Accreditation Council for Graduate Medical Education and combined specialty programs [22]. Yet, fundamental misrepresentations of osteopathic physicians often occur, such as those involving televised mass media reports that questioned why an “osteopath” led the multidisciplinary team that treated President Trump for COVID-19 and implied that he was not an “actual doctor.” [23] This prompted the American Medical Association and American Osteopathic Association to combat such misrepresentations in their joint

statement by focusing on the distinct and equivalent training of osteopathic physicians [1]. However, relatively little research has addressed whether such distinctiveness remains after osteopathic physicians complete their training and enter the workforce. This study begins to provide evidence in response to this question by examining the osteopathic approach to chronic low back pain, which may be considered a “best-case scenario” for demonstrating its distinctiveness and corresponding effects on clinical outcomes. Indeed, patients rated osteopathic physicians more highly than allopathic physicians for overall patient-centered care and in such aspects as “care and compassion” and treating the “whole person.” Also, not surprisingly, a majority of patients treated by osteopathic physicians had received OMT for low back pain.

Virtually all previous research on osteopathic medicine for chronic low back pain has focused on the efficacy of OMT. The two largest trials, which both followed patients for only 12 weeks, found conflicting results relating to low back pain intensity. One trial involving 155 patients failed to observe significant improvements in low back pain intensity or back-related functioning with OMT [24]. A later trial

involving 455 patients found significant improvement in low back pain intensity with OMT, but not in back-related functioning or general health [25]. The most recent systematic review and meta-analysis that included these and other trials found that OMT significantly improved low back pain intensity and functional status in patients with chronic low back pain [6]. In our study, patients treated by osteopathic physicians reported significantly lower scores for low back pain intensity, back-related disability, and pain impact than patients treated by allopathic physicians. All three of these physician group differences in outcomes are clinically important based on effect size criteria [26]. Such longitudinal outcomes in a pragmatic study within a real-world setting demonstrate effects of osteopathic medicine that have not always been evident during short-term efficacy trials of OMT.

Although osteopathic physicians were reported to have a more patient-centered approach to medical care than allopathic physicians, it was not a mediator of the effect of osteopathic medicine in achieving any of the three clinical outcomes in our study. This is somewhat surprising given that the osteopathic patient-centered approach is closely aligned with the biopsychosocial model of pain [27, 28]. Perhaps more fittingly, osteopathic principles [29], and the American Osteopathic Association clinical practice guidelines in particular [7, 8], stress the importance of using OMT to treat somatic dysfunction when it is the cause of or a contributing factor in low back pain. Somatic dysfunction is characterized by positional asymmetry, restricted range of motion, tissue texture abnormalities, or tenderness, which may include pain elicited through palpation [9]. Osteopathic manipulative treatment is used to alleviate somatic dysfunction by applying manually guided forces to improve physiologic function and support homeostasis. It is unclear why OMT mediated better outcomes in low back pain intensity, but not in back-related functioning or pain impact, because OMT is more often used to treat restricted range of motion than tenderness or pain [30].

There were both advantages and limitations of this study. To our knowledge, this is the first study to simultaneously address both patient-centered care and OMT as potential mediators of the effect of osteopathic medicine in treating chronic pain. It was conducted within a pain research registry, thereby providing a well-defined population for longitudinal observation using the case definition and clinical outcome measures recommended by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain [13]. Although formal

mediation analyses were performed [20], there were limitations of this approach. First, OMT was only assessed with a categorical measure using the available registry data rather than with a more robust continuous measure. This categorical measure was sufficient to identify OMT as a mediator of the effect of osteopathic medicine on low back pain intensity; however, it may have limited our ability to detect mediation of the other clinical outcomes. Moreover, this measure based on use of spinal manipulation and physician type may not have been entirely specific for OMT (i.e., for OMT provided by osteopathic physicians vs. spinal manipulation provided by other health care professionals). Second, although our sample of 404 patients was sufficiently large to detect the significant effects of osteopathic medicine on each of the three clinical outcomes, an *a-priori* sample size was not computed for the mediation analyses because of the scarcity of relevant data on the magnitude of potential effects of the hypothesized mediators [20]. Nevertheless, based on empirical sample size estimates involving percentile bootstrap tests such as ours, the sample size was sufficiently large to achieve or surpass approximately 80% statistical power under most likely scenarios [31].

Conclusions

Patients with chronic low back pain reported that osteopathic physicians provided a more patient-centered approach to medical care than allopathic physicians and often used OMT. These patients also reported better long-term outcomes relating to low back pain intensity, back-related functioning, and pain impact. However, patient-centered care did not mediate any of the effects of osteopathic medicine. The use of OMT mediated the effect of osteopathic medicine in achieving better outcomes in low back pain intensity, but not in the other two domains. More research is needed to identify other aspects of osteopathic medicine that mediate its beneficial effects in patients with chronic low back pain.

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data, or analysis and interpretation of data; both authors drafted the article or revised it critically for important intellectual content; both authors gave final approval of the version of the article to be published; and both authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Competing interests: None reported.

Informed consent: All patients provided written informed consent prior to enrollment.

Ethical approval: The registry was approved by the North Texas Regional Institutional Review Board (protocol 2015-169).

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