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One-Year Follow-Up of a Randomized Clinical Trial Comparing Flexion-Distraction with an Exercise Program for Chronic Low-Back Pain

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ABSTRACT

Objective: Flexion distraction is a commonly used form of chiropractic care with chiropractor utilization rates of 58%. However, no previous randomized clinical trial has assessed the effectiveness of this form of care. The objective of this investigation was to compare the pain and disability during the year after active care based on treatment group allocation (Flexion Distraction versus Exercise Program).

Study design: Randomized clinical trial, follow-up.

Subjects: Two hundred and thirty-five (235) subjects who were previously randomized to either chiropractic care (flexion distraction) or physical therapy (exercise program) within a clinical trial.

Outcome measures: Subjects were followed for 1 year via mailed questionnaires to assess levels of pain (Visual Analog Scale) and dysfunction (Roland Morris).

Results: Study subjects had a decrease in pain and disability after intervention regardless of which group they attended ($p < 0.002$), however, during the year after care, subjects who received chiropractic care (flexion distraction therapy) had significantly lower pain scores than subjects who received physical therapy (exercise program) ($p = 0.02$).

Conclusions: In this first trial on flexion distraction care, flexion distraction was found to be more effective in reducing pain for 1 year when compared to a form of physical therapy.

INTRODUCTION

Conservative care for back pain is common these days. On an annual basis, 26%–74% of patients with chronic low-back pain visit a general practitioner, whereas 30%–35% visit a chiropractor, and approximately 9% visit a physical therapist.[1–3] A series of conservative care treatments may last several weeks to a few months, at which time the patient is typically released from care with resolution of the back pain. However, not all back pain is resolved after a course of care, and patients may be left with residual symptoms. Most clinical trials have focused on the

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change in pain and dysfunction only during the course of conservative care, whereas only a few studies have explored the long-term benefits after trial intervention is complete. The purpose of this study was to assess the 1-year follow-up outcomes of pain and dysfunction after 4 weeks of either a form of physical therapy (exercise program) or a form of chiropractic care (flexion distraction).

Postacchini et al.[4] were the first investigators to assess the long-term follow-up of chiropractic care versus physical therapy for low-back pain. Using a composite score of subjective and objective parameters, they concluded that 3 weeks after treatment was completed *acute* low-back pain patients showed greater improvement with chiropractic care, whereas *chronic* low-back pain patients showed greater improvement with physical therapy; however, there were no differences in the outcomes between the treatment groups at 6 months.

Koes et al.[5] completed a clinical trial comparing four different treatment groups for persistent back and neck complaints. Manipulative therapy and physiotherapy produced greater patient improvement in subjects' pain than general practitioner care and placebo treatment did, and there was a greater trend toward improvement in pain and physical functioning with manipulative therapy than with physiotherapy after 12 months of follow-up. An explorative subgroup analysis further determined significantly better results in the manual therapy group (manipulation) than the physiotherapy group in both chronic patients (pain $\geq$1 year) and in patients younger than 40 years old.[6] Differences in other subgroups were not as clear.

Skargren et al.[7,8] compared chiropractic care with physical therapy for low-back pain and followed patients for 1 year while continuing to assess pain (visual analog scale; VAS) and disability (Oswestry Disability Index). In this study, both treatments significantly decreased subjects' pain and disability immediately after treatment, at 6 months, and at 12 months. However, there were no significant differences in outcomes between groups. A subgroup analysis revealed that, at both 6- and 12-month follow-up, subjects with a higher degree of disability had greater improvement with chiropractic care, whereas subjects with lower disability had greater improvement with physical therapy.

A similar study conducted by Hurwitz et al.[9] assessed the change in pain (VAS) and disability (Roland Morris disability questionnaire) in managed care patients who were randomized to one of four treatment groups: chiropractic, chiropractic with physical therapy, medical care, or medical care with physical therapy. After 6 months of follow-up, chiropractic care and medical care were comparable in their effectiveness and the added benefit of physical therapy in either group was nonsignificant (9–10).

Most recently, Aure et al.[11] compared manual therapy (which included spinal manipulation, mobilization, and stretching exercises) with physical therapy (stretching and strengthening exercises) for chronic low-back pain. As in other studies, significant improvements were observed in both groups in terms of pain (VAS) and disability (Oswestry Disability Index). However, the manual therapy group showed significantly larger improvements than the physical therapy group on all outcome variables throughout the entire follow-up period of 4 weeks, 6 months, and 12 months.

Of all the previous clinical trials with long-term follow-up, it appears that the chiropractic care included high-velocity, low-amplitude manipulation, which is only one form of chiropractic care available. The results presented in this paper are the first to describe the long-term follow-up after subjects underwent a commonly used treatment method of chiropractic care called Flexion Distraction (FD) therapy. No other clinical trial has utilized this form of chiropractic care for treatment of low-back pain.

FD care is a form of slow, controlled, manual traction rather than the high-velocity, low-amplitude maneuvers that chiropractors typically utilize.[12] A survey conducted by the National Board of Chiropractic Examiners in 1993 indicated that 53% of the chiropractors surveyed routinely employed FD in the management of low-back pain.[13] A more recent estimate indicates that this percentage has increased to 58%.[14]

A 4-week trial comparing changes in low-back pain and dysfunction after either a 4-week course of FD therapy or a specific form of physical therapy called an Active Trunk Exercise Program (EP) was documented in a previous publication.[15] The short-term outcomes for this study demonstrated a significant decrease in pain (VAS) and disability (RM) in both treatment groups independently ($p < 0.01$ for both) after 4 weeks of care, however, subjects in the FD care group demonstrated a significantly greater reduction in pain compared to the exercise program ($p = 0.01$). A subgroup analysis also noted that FD treatment appeared superior to EP therapy in patients with radiculopathy (pain in leg) as well as in chronic patients with moderate to severe symptoms that remain constant, whereas EP therapy appeared to be superior for moderate to severe pain patients with chronic–recurrent symptoms (symptoms that return periodically over time).

The purpose of this paper is to compare the pain and disability *during the year of follow-up* in patients who were randomized to either a 4-week interval of chiropractic care (FD therapy) or physical therapy (exercise program) for chronic low-back pain.

METHODS

Participants

Consecutive new patients with chronic low-back pain were recruited from two chiropractic clinics and two allopathic clinics in a major metropolitan area. Additional recruitment efforts included media advertising such as radio

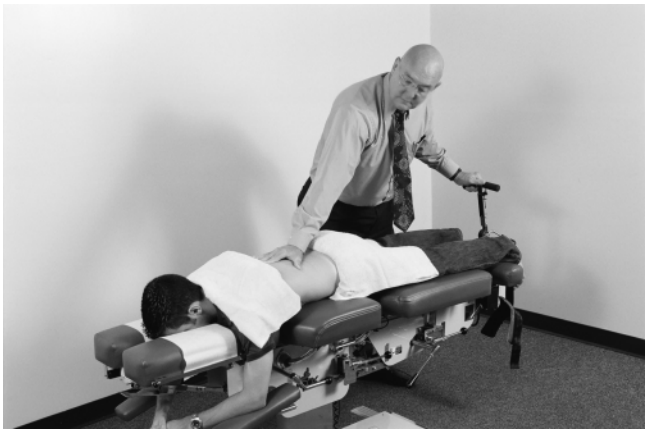

FIG. 1. Flexion distraction procedure.

and newspaper advertisements, press releases, cable television advertisements, local posters, and a local electronic sign advertisement. Prior to enrollment, subjects viewed a 3-min video demonstrating treatments and assessments, and were presented with an Institutional Review Board–approved informed consent. Subjects enrolled in the study were at least 18 years old, had a primary complaint of low-back pain for more than 3 months, and had no contraindications to manual therapy. A more thorough description of inclusion and exclusion criteria is presented in a previous publication.[15]

Demographics and baseline characteristics of the two groups were compared using chi-square tests for categorical variables and *t*-tests for continuous measures. Groups of subjects who did or who did not withdraw from the study were similarly assessed for baseline differences. Reasons for individual subject withdrawal during care and during follow-up were investigated and described. To assess pain and disability based on withdrawal status, we created variables to define withdrawal status during care (yes/no) and during follow-up (yes/no) and tested these variables for significance in all models. If the subject discontinued participation and completed no more questionnaires, then withdrawal status was coded as affirmative. To assess pain and disability based on missingness of data (not necessarily withdrawal from participation), a variable tallying the number of missing data points (baseline, week 5, week 13, week 25, and/or week 53) was developed (ranging in value from 0 to 4) and tested for significance in all models.

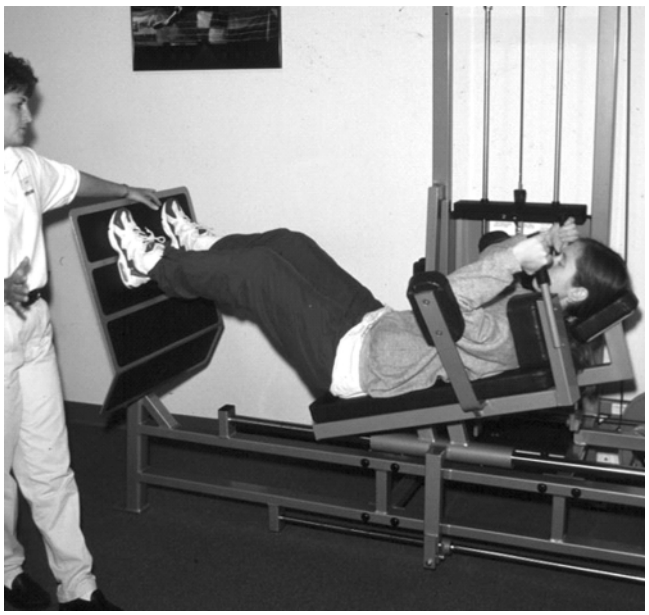

FIG. 2. Exercise program.

Interventions

Subjects were randomized to one of two forms of treatment including: a series of flexion distraction procedures (FD) administered by chiropractors[12] and an active trunk exercise program (EP) administered by physical therapists. The FD technique was performed on a specially constructed table with a moveable headpiece, a stationary tho-

Table 1. Baseline Characteristics of Study Population by Treatment Status

	Flexion distraction (n = *123*)	*Exercise program* (n = *112*)
Age; years (mean, SD)	42.2 ± 11.4	40.9 ± 12.8
Gender (*n*, %)		
Female	42 (34.2%)	46 (41.1%)
Male	81 (65.9%)	66 (58.9%)
Race (*n*, %)		
White	102 (82.9%)	91 (81.2%)
Hispanic	5 (4.1%)	7 (6.3%)
African American	8 (6.5%)	7 (6.3%)
Asian	8 (6.5%)	4 (3.6%)
Other	0 (0.0%)	2 (1.8%)
Marital (*n*, %)		
Never married	26 (21.1%)	24 (21.4%)
Married	74 (60.2%)	66 (58.9%)
Divorced	20 (16.3%)	19 (17.0%)
Widowed	3 (2.4%)	3 (2.7%)
Education (*n*, %)		
<HS diploma	3 (2.4%)	4 (3.6%)
High school diploma	53 (43.1%)	53 (47.8%)
Trade/technical school	18 (14.6%)	16 (14.4%)
Bachelors degree	32 (26.0%)	31 (27.9%)
Graduate/advanced degree	17 (13.8%)	7 (6.3%)
Employment (*n*, %)		
Manual labor	42 (34.2%)	32 (28.6%)
Nonmanual labor	66 (53.7%)	63 (56.3%)
Unemployed, retired	15 (12.2%)	17 (15.2%)
Income (*n*, %)		
Less than $20,000	6 (5.0%)	16 (15.1%)
$20,000–$39,999	28 (23.1%)	25 (23.6%)
$40,000–$59,999	36 (29.8%)	27 (25.5%)
More than $60,000	51 (42.2%)	38 (35.9%)

racolumbar piece, and a moveable lower extremity piece (Fig. 1). With the subject lying prone, the clinician placed one hand over the lumbar region at the approximate spinal level of interest and used the other hand to flex, laterally flex, and/or rotate the lower extremity section of the table. The FD intervention was administered by chiropractors with postgraduate certification in this technique. Application of treatment protocols was assessed, and consistency between clinicians in administering the FD treatment was confirmed by routine patient file checks by the supervising clinician along with weekly meetings to discuss patient procedures.

EP was administered by licensed physical therapists and consisted of strength exercises (Fig. 2), flexibility exercises, and cardiovascular exercises. The aim of this program was to strengthen the muscles surrounding the spine and increase trunk flexibility. The physical therapists maintained treatment consistency through weekly group meetings.

Study participants in both study groups were treated for 4 weeks, two to four times per week at the discretion of the treatment provider. There was no significant difference in the number of treatments administered between the two treatment groups. More information on these forms of care is located in a previous publication.[15]

Objectives

The objective of this randomized clinical trial follow-up was to compare the pain and disability during the year after active care based on treatment group allocation (EP versus FD). Our null hypothesis was that there was no difference in pain or disability measures between groups during the year after active care.

Outcomes

Perceived pain was measured by a 100-mm VAS.[16–20] Subjects were asked to place an "X" on the line indicating their level of current pain, with the indications of "no pain" and "worst pain imaginable" at either end of the continuum. Each VAS measured 100 mm.

Physical disability was measured using a 24-question Roland Morris disability questionnaire (RM).[21–23] Subjects were asked to place a check next to the statement(s) that apply, with each checkmark equaling one point. The RM was

Table 2. Baseline Characteristics of Study Population Related to Low Back Pain by Treatment Status

	Flexion distraction (n = *123*)	*Exercise program* (n = *112*)
Onset (*n*, %)		
Gradual onset	85 (69.1%)	78 (69.6%)
Sudden onset	38 (30.9%)	34 (30.4%)
Previous pain (*n*, %)		
No prev back pain	29 (23.6%)	17 (15.2%)
1 previous episode	10 (8.1%)	4 (3.6%)
2 or 3 previous episodes	20 (16.3%)	19 (17.0%)
4 or more previous	64 (52.0%)	72 (64.3%)
Radiculopathy (*n*, %)		
No radiculopathy	101 (82.1%)	89 (79.5%)
Radiculopathy	22 (17.9%)	23 (20.5%)
Depression (*n*, %)		
None	94 (77.1%)	79 (70.5%)
Mild	22 (18.0%)	23 (20.5%)
Moderate	6 (4.9%)	10 (8.9%)
Severe	0 (0%)	0 (0%)
Pain: VAS of 100 (mean, SD)	38.0 ± 22.3	35.7 ± 20.8
Disability: RM out of 24 (mean, SD)	6.6 ± 4.8	6.8 ± 4.5
Short Form 35 (mean, SD)		
Physical function	69.9 ± 19.4	69.8 ± 22.3
Role function, physical problems	45.8 ± 37.7	50.0 ± 39.0
Bodily pain	47.4 ± 15.5	45.0 ± 15.6
General health	70.7 ± 18.7	69.9 ± 19.4
Vitality/fatigue	51.4 ± 20.3	48.6 ± 21.3
Social functioning	77.5 ± 20.7	74.2 ± 26.2
Role function, emotional problems	75.0 ± 36.2	71.1 ± 38.4
Mental health[a]	75.9 ± 14.7	71.2 ± 18.5
Physical component score	41.8 ± 8.2	42.7 ± 8.8
Mental component score	51.2 ± 9.1	48.5 ± 12.5″

[a]Treatment groups significantly different at $P < 0.05$ level.
VAS, visual analog scale; RM, Roland Morris disability questionnaire; SD, standard deviation.

Table 3. Reasons for Withdrawal During Active Care or During Follow-Up

Reason		*FD group (n = 123)*	*EP group (n = 112)*
During care			
	Refused care in randomized group	0	3
	Scheduling conflicts	3	5
	No longer interested in participation	7	14
	Too much pain to continue	1	2
	Injury or surgery unrelated to LBP	2	1
	Total withdrawn during care[a]	13	25
During follow-up			
	No longer interested in participation	8	7
	Unknown reason	6	2
	Total withdrawn during follow-up	14	9

[a]Treatment groups significantly different at $p < 0.05$.
FD, flexion distraction; EP, exercise program; LBP, low-back pain.

scored by adding the number of checkmarks, which ranged from 0 to 24. A higher score indicated a higher degree of disability.

Pain and disability were measured at baseline (week 0), upon completion of the 4-week intervention period (week 5), and by mail at weeks 13, 25, and 53. Subjects were asked not to take any pain-reducing medication prior to data collection at weeks 0 and 5; however, no such restriction was placed on subjects for data collection at weeks 13, 25, or 53.

Analysis

Observed means and standard deviations were calculated for the pain (VAS) and disability (RM) measures at baseline, immediately after treatment (week 5), and at the week 13, week 25, and week 53 follow-up time points. Means and standard deviations were calculated for each treatment group, and within each treatment group analysis of variance models were developed for the (1) difference in mean pain (VAS) at baseline versus week 5; (2) versus week 13; (3) versus week 25; and (4) versus week 53. Similar models were developed for the baseline and subsequent disability (RM) measures.

To test the group differences and group differences over time, separate longitudinal analysis models were developed for pain (VAS) and disability (RM) measures at the five time points using mixed effects regression models (implemented using SAS PROC MIXED) allowing for random-subject intercepts and slopes. The models characterized the pain and disability measures based on treatment group (Group) and the pain and disability time-related changes (Group*Week). The dependent pain variable (VAS) was continuous, ranged from 0 to 100, and was normally distributed; and the dependent disability variable (RM) was continuous, ranged from 0 to 24, and was normally distributed after square root transformation. Both time (Week) and time squared (Week*Week) were included in all analyses, along with the group by time interactions (Group*Week and Group*Week*Week). Covariates tested for significance included (1) SF36 mental health subscale score at baseline (because of significant group differences), (2) gender, (3) age, (4) presence of radiculopathy, (5) presence of recurrent pattern, (6) withdrawal status during care, (7) withdrawal status during follow-up, (8) number of missing data points, (9) interaction between treatment and presence of radiculopathy, and (10) interaction between treatment and presence of recurrent pattern. Nonsignificant covariates

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Table 4. Numbers and Percents of Participants at Each Time Point Based on Treatment Group

	FD group VAS data (n, %)	*EP group VAS data (n, %)*	*FD group RM data (n, %)*	*EP group RM data (n, %)*
Baseline (week 0)	123 (100%)	112 (100%)	122 (99.2%)	112 (100%)
End of care (week 5)	108 (87.8%)	86 (76.8%)	110 (89.4%)	87 (77.7%)
Week 13	87 (70.7%)	76 (67.9%)	87 (70.7%)	76 (67.9%)
Week 25	90 (73.1%)	74 (66.1%)	91 (74.0%)	78 (69.6%)
Week 53	96 (78.0%)	78 (69.6%)	96 (78.0%)	78 (69.6%)

FP, flexion distraction; EP, exercise program; RM, Roland Morris disability scale; VAS, Visual Analog Scale for pain.

Table 5. Means and Standard Deviations of Pain and Disability Measures at Each Time Point Based on Treatment Group

	FD group		*EP group*	
		p-*value (difference from week 0)*		p-*value (difference from week 0)*
Pain (VAS out of 100)				
Baseline—week 0	38.0 ± 2.0		35.7 ± 2.0	
Week 5	14.6 ± 1.7	<0.001	19.7 ± 2.0	<0.001
Week 13	19.3 ± 2.1	<0.001	22.1 ± 2.2	<0.001
Week 25	19.2 ± 2.0	<0.001	23.8 ± 2.4	0.002
Week 53	20.6 ± 1.9	<0.001	21.6 ± 2.0	<0.001
Disability (RM out of 24)				
Baseline—week 0	6.6 ± 0.4		6.8 ± 0.4	
Week 5	3.6 ± 0.4	<0.001	3.8 ± 0.4	<0.001
Week 13	2.7 ± 0.4	<0.001	2.9 ± 0.4	<0.001
Week 25	2.6 ± 0.4	<0.001	3.4 ± 0.5	<0.001
Week 53	2.9 ± 0.4	<0.001	3.2 ± 0.4	<0.001

FD, flexion distraction; EP, exercise program; VAS, visual analog scale.

($p \geq 0.05$) were removed from the model and nonsignificant interaction terms were removed from the model in a backwards manner (i.e.: Group*Week*Week first, and then Group*Week). If both Group*Week and Group*Week*Week terms were nonsignificant, the model was refit to include only the main group effect (i.e.: group difference averaged over all time points).

Mixed effects regression models do not mandate that subjects have complete data at all data points; therefore, subjects with missing data were not excluded from analysis. Consequently, model parameter estimates were based on all available data.

An alternate analysis was performed to assess the pain and disability outcomes between treatment groups during the follow-up portion of the study only. This form of analysis allowed us to determine whether there was a significant group difference during follow-up only, while including the baseline pain and disability measures as covariates rather than main effects. Including the baseline measures in the analysis of group effects minimizes the likelihood of finding significant group effects because the baseline pain and disability are expected to be equal because of randomization. These analyses followed the above modeling structures using the same covariates; however, the analyses only included data from the follow-up portion of the study (VAS and RM outcomes from week 5, week 13, week 25, and week 53) controlling for the baseline pain and disability measures (week 0) and other significant covariates.

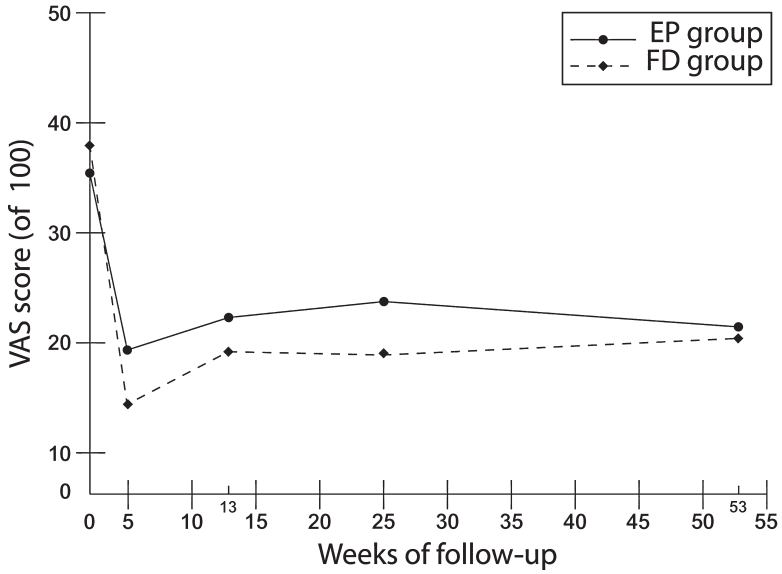

FIG. 3. Average pain (visual analog scale; VAS) levels over time per group.

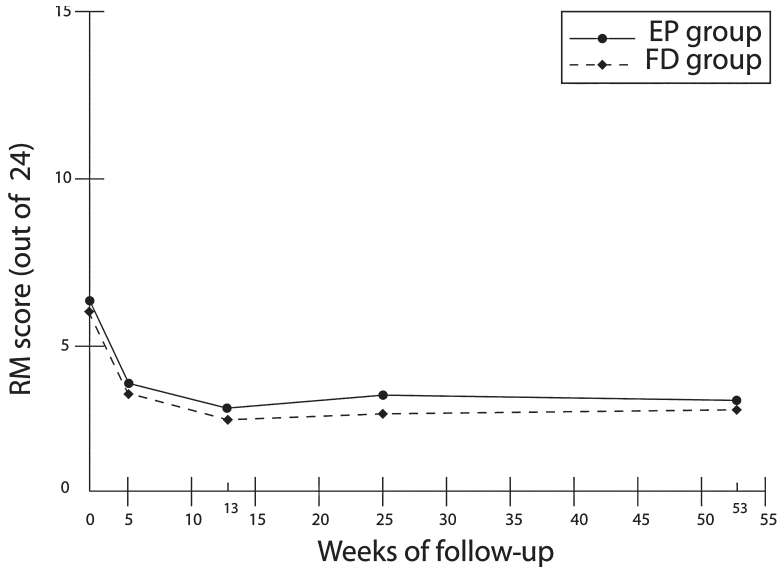

FIG. 4. Average disability (Roland Morris disability questionnaire; RM) levels over time per group.

All analyses were performed by using the Statistical Analysis System (SAS), Version 8.02 (SAS Institute, Inc., Cary, North Carolina).

RESULTS

Participant flow

Recruitment of study participants began in August 1998, was completed in December 1999, and study participant follow-up was completed in February 2001. Number of people screened and reasons for exclusion are found in a previous publication.[15]

Patient demographics and baseline characteristics of the two groups were compared (Tables 1 and 2). Only the SF36 mental health component scores were found to differ between the groups at baseline (subjects in the EP group had lower/worse scores); therefore, this variable was tested for significance in all models. Even though no other statistically significant group differences were found, gender, age, presence of radiculopathy (pain in leg), and presence of recurrent pattern of back pain were also tested for significance within the analyses as potential prognostic factors.

Two hundred and thirty-five (235) subjects were randomized into the study, 123 subjects were allocated to FD and 112 to EP. Of the 235 subjects randomized, 197 (83.8%) subjects successfully completed the 4 weeks of active care (week 5 outcomes) and were sent outcome questionnaires at 13, 25, and 53 week time points. Questionnaires were sent at each time point regardless of previous questionnaire completion, unless the subject requested to be withdrawn from the study. Subjects who were included in the long-term follow-up (n = 197) were also tested for significant differences in baseline characteristics, and no characteristics (including the SF36 Mental Health score) were found to differ between the groups.

Overall, 61 subjects withdrew from the study: 38 during the trial intervention (13 FD and 25 EP) and 23 during the follow-up (14 FD, 9 EP) (Table 3). Withdrawal patterns were significantly different in the intervention phase; however, these patterns were not different in the follow-up. The main reason for withdrawal was "no longer interested in participation." Groups of subjects who did or who did not withdraw from the study were assessed for baseline differences, and again the SF36 mental health component was found to differ between groups (subjects who withdrew had lower/worse scores). No other baseline variables significantly differed by withdrawal status.

The response rates were higher in the FD group than in the EP group (Table 4), with the majority of the overall responses at the baseline visits (week 0) and at the end of care (week 5). Response rates decreased at weeks 13 and 25, and then increased again at week 53. Increased percent of participation at the end of follow-up was most likely because

Table 6. Mixed Regression Modeling Outcomes for Pain (VAS) (n = 235)

	Coefficient	p-*value*
Intercept	31.42	<0.0001
Group (0 = EP, 1 = FD)	−1.80	0.37
Week	−30.80	<0.0001
Week*Week	24.45	<0.0001
Gender (0 = F, 1 = M)	−4.93	0.02
Missing data (0 to 4 possible)	3.07	<0.0001

VAS, visual analog scale; EP, exercise program; FD, flexion distraction.

Table 7. Mixed Regression Modeling Outcomes for Disability (RM) (n = 235)

	Coefficient	p-*value*
Intercept	1.91	<0.0001
Group (0 = EP, 1 = FD)	−0.13	0.23
Week	−3.14	<0.0001
Week*Week	2.44	<0.0001
Gender (0 = F, 1 = M)	−0.36	0.002
Radiculopathy (0 = N, 1 = Y)	0.46	0.001

RM, Roland Morris disability scale; EP, exercise program; FD, flexion distraction.

subjects were compensated for their follow-up participation at the completion of the week 53 measures.

Outcomes and estimation

The average pain (VAS) and disability (RM) scores for each treatment group at each time point are documented in Table 5 and visual representations are demonstrated in Figures 3 and 4. No pain or disability differences were noted at baseline between the two treatment groups. Overall, the average pain scores initially decreased at week 5 (after 4 weeks of treatment) and then gradually increased over time to approximately half of the original scores. The average disability scores also demonstrated a decrease at week 5, but then continued to drop at week 13, and remained approximately stable until the end of data collection. In each of the groups, there were significant differences between the average baseline pain score (VAS) and the average score at each subsequent time point (weeks 5, 13, 25, and 52), demonstrating a significant pre–post change in pain in both treatment groups individually. Likewise, there were significant differences between the average baseline disability score (RM) and the average score at each subsequent measure, demonstrating a significant change in disability within each treatment group.

Table 6 presents the results of the mixed model analysis for the pain measures (VAS) across all time points (week 0 to week 53) between the two treatment groups. In this model, the Group*Week and Group*Week*Week interaction terms were nonsignificant, indicating no significant differences in the pain trends between treatment groups and were therefore removed from the model, leaving only main effects (Group, Week, and Week*Week) and significant covariates in the model. There were also no treatment (Group) effects meaning there was no evidence that either treatment group had significantly lower pain scores when averaging scores from baseline forward. As the negative linear (Week) and positive quadratic (Week*Week) time trend variables indicate (and as we noted in Fig. 3), the overall pain scores initially decreased and then gradually stabilized over time. As covariates, we determined that at baseline males had significantly lower pain scores than females and that increases in missing follow-up data coincided with significantly higher pain. No other covariates were significant in this model.

The results of the mixed model analysis for the disability scores (RM) over all time points (week 0 to week 53) are documented in Table 7. Again, the interaction terms of Group*Week and Group*Week*Week were nonsignificant, indicating no significant difference in disability scores over time per treatment group. Likewise, there was no overall treatment effect (Group) meaning the overall disability scores did not differ based on group throughout all time points. There were negative linear (Week) and positive quadratic (Week*Week) time trends demonstrating an overall decrease in disability and then stabilization of the scores. In this model, we also noted that males had significantly lower disability scores than females and that subjects with radiculopathy (pain down the leg) had significantly higher disability scores. Missing data were not significantly associated with higher or lower disability in this model. No other covariates were significant within this model.

The results of the analyses assessing pain and disability outcomes between treatment groups during follow-up only are documented in Table 8. Again, the group-by-time interaction terms (Group*Week and Group*Week*Week) were not significant; however, the treatment effect variable (Group) was significant, indicating that the FD group had significantly lower pain scores during the follow-up portion of the study ($p = 0.02$), when compared to the EP group scores. These results differ from the previous analysis because the VAS measures at baseline, which were not significantly different between groups due to randomization, were removed from the group effect assessment, allowing us to compare only group effects for the follow-up portion of the study between the treatment groups. Also, within this model we determined that the linear time trend (Week) was significant; however, the quadratic trend (Week*Week) was not, indicating that there was only a significant positive linear effect during the follow-up period. Other significant covariates in this model included the pain scores at baseline, indicating that higher pain at baseline corresponded with higher pain during follow-up, and that more missing data during follow-up corresponded with higher pain scores during the follow-up assessments. No other covariates were significant within this model.

Outcomes for the disability scores (RM) during the fol-

Table 8. Mixed Regression Modeling Outcomes for Pain (VAS) for Follow-up Only (n = 197)

	Coefficient	p-*value*
Intercept	10.45	<0.0001
Group (0 = EP, 1 = FD)	−5.09	0.02
Week	4.52	0.001
VAS-baseline	0.27	<0.0001
Missing data (0 to 4 possible)	2.76	0.046

VAS, visual analog scale; EP, exercise program; FD, flexion distraction.

Table 9. Mixed Regression Modeling Outcomes for Disability (RM) for Follow-up Only (n = 197)

	Coefficient	p-*value*
Intercept	1.03	<0.0001
Group (0 = EP, 1 = FD)	−0.15	0.20
Week	−0.14	0.054
RM at baseline	0.11	<0.0001
Gender (0 = F, 1 = M)	−0.31	0.01

RM, Roland Morris disability scale; EP, exercise program; FD, flexion distraction.

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low-up period (week 5 to week 53) can be found in Table 9. Based on only follow-up data, again there were no significant group by time interactions (Group*Week and Group*Week*Week), nor were there significant treatment effects (Group) indicating that there were no differences in group means during the follow-up portion of the study. A negative time slope (Week) indicated that the disability scores significantly decreased during the follow-up period, without a significant quadratic shift (Week*Week). The baseline disability scores were significantly correlated with the follow-up scores, indicating that higher baseline disability scores led to higher scores during follow-up. Also, as in the previous analysis, males had significantly lower disability scores. No other covariates were significant within this model.

No adverse outcomes occurred within either of the treatment groups during this study.

DISCUSSION

The results of this study demonstrated that study subjects had a decrease in pain and disability after both conservative treatments; however, subjects who received chiropractic care (flexion distraction therapy) had significantly lower pain scores than subjects who received physical therapy (exercise program) during the year after care but no significant group differences in disability were noted. Based on these results, our hypothesis of no group difference in pain was rejected, but our hypothesis of no group difference in disability was upheld.

This study is consistent with previous studies demonstrating a significant decrease in pain and/or disability in both the chiropractic and physical therapy groups.[5–11] However, previous studies conflict on which form of treatment is more beneficial. One main issue causing such conflict might be utilization of differing treatment styles and parameters within both the chiropractic and physical therapy groups; however, it is assumed that all previous chiropractic studies utilized high-velocity, low-amplitude manipulative (HVLA) thrusts. Unlike the previous studies, this trial utilized a different form of chiropractic care called FD. FD differs from the conventional form of chiropractic care in that it utilizes a slow stretch to the low back, rather than the HVLA thrust. FD has been taught to chiropractors and was utilized in their clinics for decades, yet no experimental evidence existed of the effectiveness until now.

The implications of this study are twofold. First, we determined that both FD and EP treatments decrease pain and disability in subjects with low-back pain, again demonstrating that conservative care is a viable option for treatment of low-back pain with no adverse outcomes. Second, we determined that in this setting there was a significantly greater decrease in pain after FD treatment compared to EP. It is noteworthy that we demonstrated a significant group effect with a sample size powered only for the primary outcome analyses.[15] In our view, it will be advantageous to conduct more studies, which are appropriately powered, to verify these results.

As in any clinical trial, we recognize our study limitations. First of all, the term "chronic low-back pain" has various definitions, making the results difficult to generalize to all subjects with this disorder. It is probable that there are various diagnoses blended together within the population of subjects with "back pain." Because of this, we attempted to assess differences in back pain presentation by using recurrence of pain and radiculopathy (pain down the leg) as covariates in the models. Neither treatment group was significantly associated with previous recurrences nor with radiculopathy; however, this does not rule out the possibility that there are a variety of diagnoses within the disorder of "back pain" and that one form of treatment may benefit a specific disorder more than another.

As a second limitation within this study, this group of subjects had relatively moderate baseline scores for pain and disability compared to previous studies. Pain scores in previous trials were initially between 45 and 69 out of 100,[6,7,9,11] whereas our subjects' baseline pain scores averaged only 37 out of 100. For disability, we may have run into a floor effect, meaning the outcomes decreased to a point where no further effects were likely. This might have limited our ability to determine which form of treatment was more beneficial in terms of decreasing disability measures. In this study, 7 of the 235 subjects (3.0%) had a baseline RM score of zero, indicating no disability at the start of this trial. The number of subjects with a zero RM score increased to 44 (18.7%) at the end of the 4 weeks of intervention and remained high throughout the follow-up period with 53 subjects (22.5%) at week 13, 48 (20.4%) at week 25, and 42 (17.9%) at week 53. Future studies may limit intake to subjects with a higher pain or disability measure. Likewise, missing data were a significant problem in this study, possibly leading to imprecision of the final outcomes. When tested within the model, missing data were significantly associated with pain but not disability, leading us to believe that subjects with more pain were less likely to return their questionnaire. Future studies may implement more incentive to return follow-up questionnaires.

Future research in the area of chronic low back pain

should include studies that focus on the FD treatment. Because this study was the first clinical trial to investigate this mode of care, more studies are needed to determine effectiveness. Studies involving a different population with a more specific diagnosis, such as lumbar disc herniation or lumbar stenosis, would be of value.

CONCLUSIONS

Subjects with chronic low-back pain who were treated with 4 weeks of either FD therapy or an exercise program and followed for 1 year demonstrated a decrease in low-back pain and disability, with the FD group demonstrating significantly greater pain reduction.

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