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Different exposure times of flexion distraction technique in the L5-S1 distance and local pain of patients with chronic low back pain: A feasibility study

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ABSTRACT

Background: Low back pain (LBP) is a worldwide public health problem. The flexion-distraction technique (FDT) has been considered to treat LBP. However, the adequate dosage and the treatment effects are not clearly understood. This feasibility study aimed to assess the effects of different exposure times with 5 and 10 min of the FDT on the L5-S1 distance and pressure pain threshold (PPT) of patients with chronic LBP.
Methods: A two-arm, examiner-blinded, randomized controlled feasibility trial with participants with chronic LBP enrolled in an outpatient clinic. Participants were randomly assigned to FDT-T5 (5 min) or FDT-T10 (10 min). The distance between the L5 lamina and the sacral promontory, and the PPT at the L5 spinous process was measured before and immediately after FDT. Ultrasound imaging was used to measure L5-S1 distance, and the pressure algometry examined the PPT. Pre- and post-intervention data were compared between two groups by two-way analysis of variance (ANOVA) for repeated measures. We also calculated the intra- and inter-rater reliability of the L5-S1 measurement.
Results: Seventeen participants [10 (58.8 %) females, mean age 45 (±12) years] completed all procedures. Improvements in the intervertebral space [FDT-T5 mean change = 2.65 (95 %CI 1.45, 3.85) mm; FDT-T10 mean change = 1.88 (95 %CI -1.86, 5.63) mm] and decreases in PPT values [FDT-T5 mean change = −0.55 (95 %CI -1.35, 0.26) Kgf; FDT-T10 mean change = −0.79 (95 %CI -1.92, 0.34) Kgf] were observed, although there was no significant difference between the two groups for the distance between the L5 lamina and the sacral promontory ($p = 0.595$) or the spinous process L5 PPT ($p = 0.672$) after the intervention. Good reliability values were found for inter- and intra-rater measurements ranging between ICC = 0.81 to ICC = 0.88).
Conclusion: In this feasibility trial, both groups showed an increased distance between L5-S1 and decreased the PPT in the L5 spinous process, indicating greater pain sensitivity after the intervention. These quantitative methods may measure distance and pain in definitive studies.
Implications for practice:

- This is the first study to compare the distance between the L5 lamina and the sacral promontory after the flexion-distraction technique (FDT) using ultrasound imaging (USI).
- The present study could not determine the effect of a particular time of exposure to FDT (FDT-T5 or FDT-T10 min).
- Both groups (FDT-T5 and FDT-T10 min) increased the lumbar distance, corresponding to mobilization of the lumbar region.
- Both groups presented decreased values of PPT in the L5 spinous process immediately after the technique.

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- A single session of FDT showed improvements in the distance between L5 and S1 and reduced L5 pressure pain threshold in the feasibility study.

List of abbreviations

LBP	Low back pain
FDT	Flexion-Distraction Technique
USI	Ultrasonography Imaging
PPT	Pressure pain threshold
FDT-T5	5 min group
FDT-T10	10 min group
ANOVA	two-way analysis of variance for repeated measures
M	mean
SD	standard deviation
%	percentage
Kg	kilogram
M	meters
Kgf	kilogram-force
Mm	millimetres
CT	computed tomography

1. Introduction

Low back pain (LBP) is a worldwide public health problem. LBP affects approximately 80 % of people with at least one episode during their lifetime [1]. Patients with LBP had socioeconomic impairments and motor disabilities [2,3]. The Brazilian Population National Health Survey revealed that LBP had a higher prevalence if aged up to 55 years old, had low education levels, undertook intense physical activity at work and home, had a smoking history, or were overweight or obese [4,5]. Biomechanical, psychological factors, psychiatric comorbidity and worse general health status before the onset of pain represent prognostic factors for the chronicity of LBP [6]. Therefore, LBP affects the economically active population and can be persistent, meaning that we must investigate the effects of new therapeutic approaches.

Conservative treatments for LBP aim to reduce pain intensity, improve functionality and prevent chronicity. Several professionals, including physiotherapists, osteopaths and chiropractors, use the Flexion-Distraction Technique (FDT) to mobilize the lumbar region. Chiropractors widely use FDT in the United States [7] and Australia [8]. Few available studies have described the effectiveness of these techniques for pain and disability in symptomatic participants [9–12]. Nearly one-third of chiropractors choose FDT in cases of lumbar disc syndromes associated with radiculopathy, as well as 26 % in central lumbar stenosis, with about 18 % selecting this approach as their first treatment option [8]. Some studies measured disc height [9,13] and changes in the cross-sectional area of the sciatic nerve in healthy participants [14]. The lack of recent literature on the effect on the intervertebral disc and the perception of pain intensity represents a knowledge gap in the clinical use of this procedure.

There are different types of automated FDT equipment available today [12]. Many studies have used FDT with short exposure times in non-automatic protocols, of around 5 min [10,13,15,16]. However, longer exposure times may lead to additional biomechanical improvements with more prominent spine joint spaces or clinical benefits such as pain relief. Thus, comparing different exposure times could shed light on the FDT effects for patients with chronic low back pain.

Several instruments are available to objectively measure lumbar impairment. Ultrasonography imaging (USI) is a portable device used in real-time, with low risk for the participants. USI has been shown to locate lumbar structures [17] and measure intersegmental lumbar flexion movement in asymptomatic participants [18]. Also, USI presented excellent intra-examiner reliability for distance measurements of the space between the lumbar spinous processes in flexion, extension and neutral positions in asymptomatic patients [19]. Therefore, the USI is considered an appropriate surrogate measure to monitor clinical effects, visualize soft tissues and bone surfaces and measure intervertebral movements in a manner that is non-invasive, affordable and clinically available [20,21]. Likewise, the pressure pain threshold (PPT) is the quantitative way to measure an abnormal sensitivity to touch or pressure from musculoskeletal dysfunction and chronic pain22. PPT correlates with the visual analogue scale in patients with LBP [23]. Pressure algometry is a valid and reliable measure used in pain research and clinical practice [24], evaluating the effects of different treatments and quantifying soft tissue sensitivity [22].

In the current feasibility study, we aimed to verify the potential effectiveness of the FDT on the lumbar vertebral space and local symptoms of patients with chronic low back pain. Also, we investigated the success of recruitment, ability to retain participants, tolerability of the intervention, completeness of data collection and participants' safety. We explored quantitative methods to measure the distance at L5–S1 (USI) and the L5 pressure pain threshold (pressure algometry) after an FDT intervention. Also, we hypothesized that 10 min of FDT would be superior to 5 min of FDT for patients with chronic LBP.

2. Methods

2.1. Study design

A two-arm, examiner-blinded, randomized controlled feasibility trial design was reported following a tutorial for pilot studies [25]. This study was approved by the Research Ethics Committee (number 10519719.6.00005259). All patients met the eligibility criteria and signed the informed consent before the study procedures were started.

2.2. Study participants

Participants were recruited for convenience through an advertisement on social media, between April and July 2019. Twenty-one participants were included, all older than 18 years, with a history of persistent or recurrent chronic LBP for at least three months. The study excluded participants with a history of acute incapacitating pain maintained for at least a week or self-reported tumor, neurological, infectious, inflammatory spine or autoimmune rheumatic diseases, spine surgery, fracture, spondylolisthesis, signs and symptoms of the spinal compression, congenital anomalies, pregnant women, psychiatric illnesses, or lack of cognitive skills and participants who were treated for FDT in the previous six months.

2.3. Procedures

The participants completed the demographic and clinical data questionnaire. Participants were randomly allocated in a 1:1 distribution into one of two groups: the 5-min group (FDT-T5) and the 10-min group (FDT-T10) (1:1 allocation) by an independent examiner (M.S.M.). The allocation sequence was generated using random numbers (available online at https://www.randomizer.org/), using opaque envelopes sealed with a numbered card containing a sentence that will inform the participants of their group allocation: FDT-T5 (Group 1) or FDT-T10 (Group 2) in which the participant would be enrolled. The distance between L5–S1 and L5 local pain was evaluated before and after the intervention. Also, adverse events were assessed after the

interventions. Due to the nature of the interventions, physical therapists and participants were not blinded to treatment allocation.

2.3.1. Intervention

All participants received FDT, one group with a protocol lasting 5 min (FDT-T5) and the other lasting 10 min (FDT-T10). The participants were instructed to take the prone position on the flexion-distraction table, with their head in a neutral position, their upper limbs extended forward and supported, the thoracic and lumbar spine supported on the stationary platform, pelvis and lower limbs on the moveable lower extremity platform, with the feet outside the table, with both ankles fixed with straps. The intervention was conducted on the FlexTrac 500z model (TechMec, Araras, São Paulo, Brazil). For all interventions, the table's moveable platform was engaged to an inclination function, set to a flexion of approximately 13°, and subsequently restored to its neutral position, with 30 % power, repeatedly for 5 (Group 1) or 10 min (Group 2), without any manual contact on the lumbar spinous process by the examiner. At the end of the intervention, the participants returned to the left lateral position and the USI and the algometry were reassessed. Adverse events during the intervention were assessed by a self-reported questionnaire developed by the researchers to register symptoms and/or adverse events with duration and intensity details.

2.4. Outcomes

The primary outcomes were the distance between the L5 lamina and the sacrum promontory and the PPT at the L5 spinous process. An independent examiner (M.A.M.P.) with more than ten years of experience in using USI equipment performed the acquisition of images and pressure algometry.

L5–S1 distance. The participants were positioned in the left lateral position for the tests, with an angle of 90° of hip flexion. The examiner was set behind with free access to the lumbopelvic region, applied the gel and used the oblique sagittal paramedian orientation [26] to locate the sacrum promontory, which appears as a horizontal hyperechoic line and the right lamina of L5 (Fig. 1). The USI was obtained using the Ultrasound MDuo portable equipment (Mobissom, São Paulo – Brazil), in mode B, 5.0 MHz convex transducer and visualized, recorded and stored by a Mobissom application software installed on the iPad (iPad Air model – iOS 12.4.5 – Apple). A conductive gel was placed on the posterior lumbar surface to couple the transducer and facilitate image acquisition. The USI of the sacrum promontory and L5 lamina were saved, stored in the equipment and later transferred to the researcher's file.

The saved images were measured using the ImageJ software (version 1.43, National Institutes of Health, Bethesda, Maryland, USA). Two anatomical areas visualized in the image were considered for the analysis to measure the L5–S1 distance. The hyperechoic upper margin of the sacrum promontory and the hyperechoic lower margin of the L5 lamina were marked. Then, we used the straight and freehand line tools in ImageJ to trace the lower part of the margins represented by the yellow line in Fig. 2. Distance measures were recorded in millimetres (mm). An average of three measurements were taken for each image. Intra- and inter-examiner reliability of the mean measurements of the L5 lamina and the sacral promontory distances were estimated.

Pressure Pain Threshold (PPT). The PPT was measured using a digital algometer (Wagner FDX 25 - Wagner Instruments), which is a mechanical device formed by a piston with a rubber tip (1 cm^2 area) coupled to an electronic device that records in kilogram-force (Kgf) and offers a gradual increase in pressure that can be read on the device's display. To investigate the hypoalgesic effects of interventions, PPT was assessed at predetermined locations on the L5 spinous process, pressed with constant force and speed until the participant asked the assessor to "stop" when realizing that the pressure sensation became a sensation of pain, registered the value. Values closer to 0.01 kgf mean stronger pain, while values closer to 10 kgf indicate lower pain. The mean of two times was used for the primary analysis. We used the USI to confirm the location of the spinous process of L5.

2.5. Simple size calculation

We estimated the need to include 10 participants per group based on a large effect size of 0.8 using repeated-measures analysis of variance (ANOVA) to detect the within-between interaction groups for the distance between the L5 lamina and the sacrum promontory and the PPT at the L5 spinous process, with a statistical power of 90 % and an alpha of 0.05 (5 %), two groups and two evaluations (pre and post). The sample size calculation follows the recommendations of Whitehead et al. for feasibility studies [27]. The sample size calculation was performed *a priori* using the G*Power software version 3.1 (Heinrich-Heine-Universität, Düsseldorf, Germany).

2.6. Statistical analysis

A descriptive analysis of the participants' sociodemographic data was performed. Continuous variables were presented as mean (M) and standard deviation (SD). Categorical variables were presented in counts and proportions (%). L5-S1 distance and PPT were analyzed using absolute change values from baseline with 95 % confidence intervals (CI). Pre- and post-intervention data were compared between two groups by two-way analysis of variance (ANOVA) for repeated measures. We used the group × time interaction to compare the effect of the two treatments (5-min group and 10-min group) over two-time points (pre- and post-intervention) on the distance at L5–S1 and the L5 pressure pain threshold. The intra- and inter-rater reliability of measurements were calculated using the mean of the three measurements, with a 2-way random-effects model of the intraclass correlation coefficients ($ICC_{2,1}$), with the consistency type [28]. The analysis was performed using JASP software (version 0.12.2 for Mac open-source, free license) and the GraphPad Prism software (Version X7. Oa, San Diego, CA, USA). All significant tests were two-tailed, with an alpha of 0.05 ($p < 0.05$).

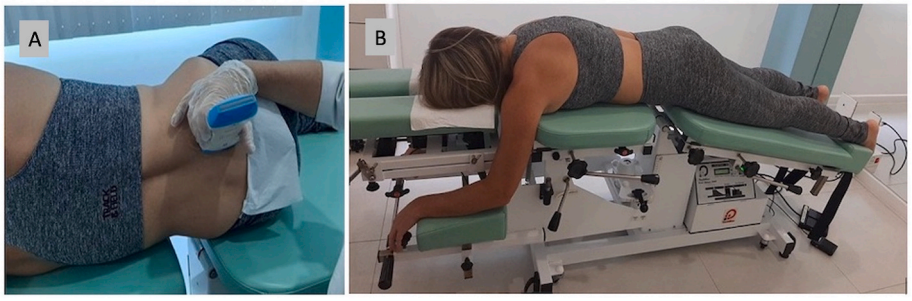

Fig. 1. (A) The transducer was placed on the posterior lumbar surface with oblique sagittal paramedian orientation. (B) The participant was positioned in the prone position to perform the flexion-distraction technique.

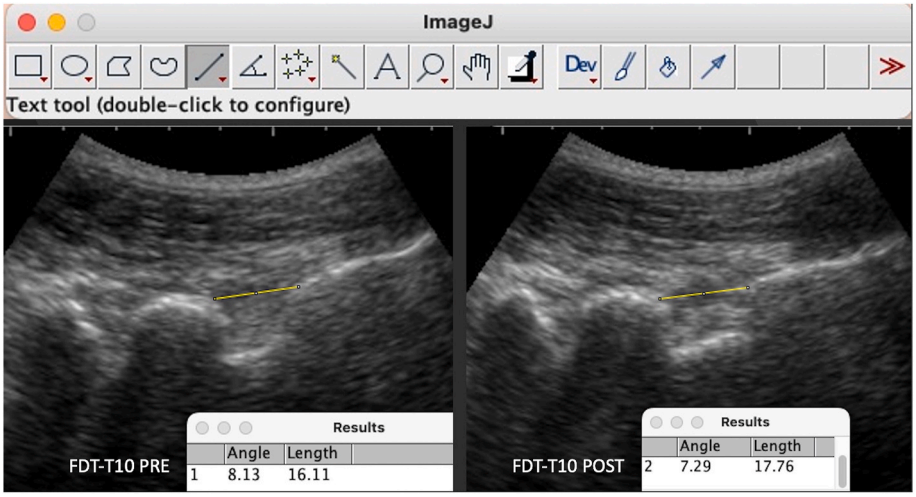

Fig. 2. ImageJ measurements (yellow line) showing the L5-S1 space of hyperechoic upper margin of the sacrum promontory and the hyperechoic lower margin of the L5 lamina, with lengths results pre- and post-intervention, respectively. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

3. Results

Twenty-five participants were recruited, but four were excluded because they had a self-reported diagnosis (systemic lupus erythematosus, fibromyalgia, spine surgery and spondylolisthesis). Four participants (25 %) were lost due to failures in the USI procedure, leaving twenty-one eligible participants remaining. A participant flow diagram is shown in Fig. 3.

Seventeen participants had complete data, including 10 (58.8 %) females, with a mean and standard deviation (M ± SD), for age of 45 ± 12 (years), weight of 83 ± 17 (Kg) and height of 1.68 ± 0.1 (m). No adverse events were associated with interventions or tests and there were no changes to assessments or measurements during the study. Table 1 presents the descriptive analysis of demographic data and group pain characteristics.

After the intervention, the two groups presented an increased distance between the L5 lamina and the sacrum promontory (ANOVA time: $p = 0.006$). Moreover, the L5 spinous process PPT was reduced in the

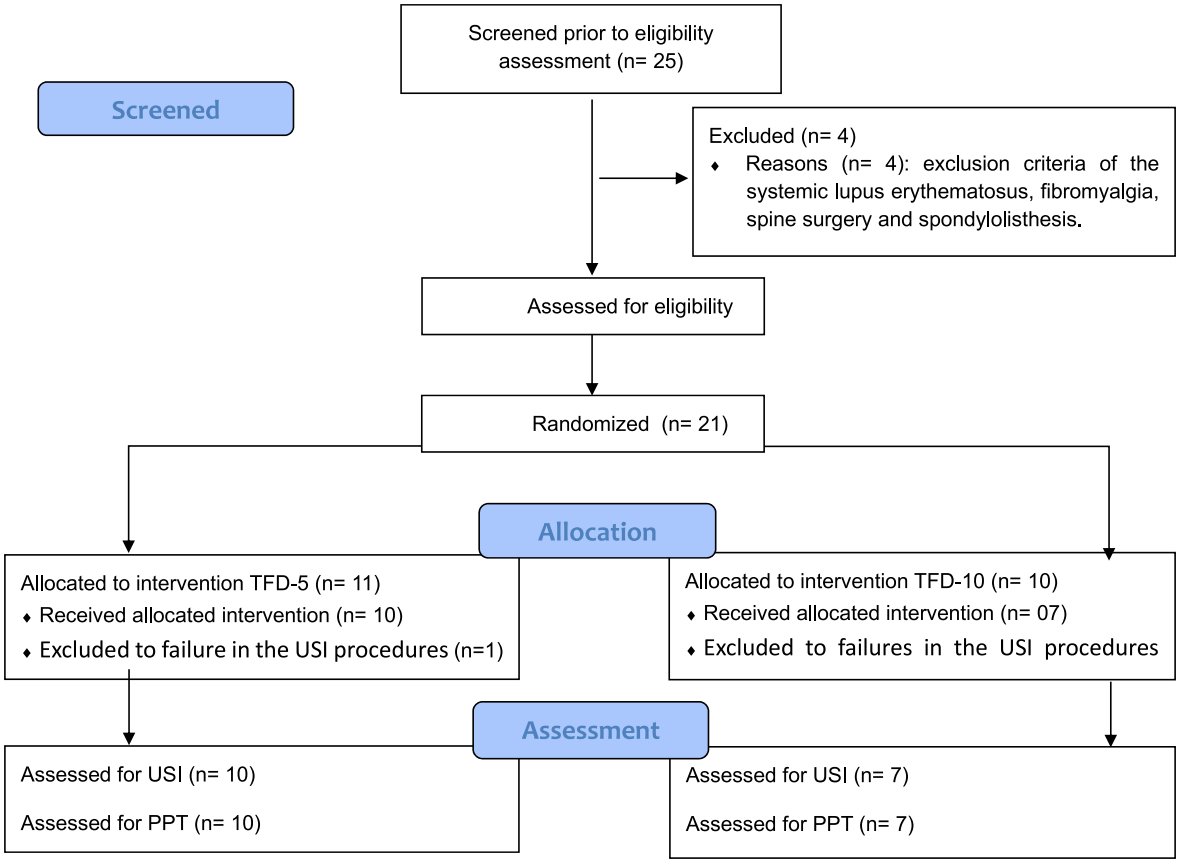

Fig. 3. Flowchart of the study.

Table 1
Demographic data and characteristics of pain.

Characteristic	FDT-T5 group (n = 10)	FDT-T10 group (n = 7)
Sex (Female), n (%)	6 (60 %)	4 (57 %)
Age (years), M ± SD	44 ± 16	46 ± 12
Weight, M ± SD	84 ± 17	80 ± 17
Height, M ± SD	1.7 ± 0.1	1.7 ± 0.1
Body Mass Index (kg/m^2), M ± SD	30 ± 5	28 ± 5
Pain duration > 6 (months), n (%)	9 (90 %)	7 (100 %)
Pain duration < 6 (months), n (%)	1 (10 %)	0 (0 %)
Local low back pain, n (%)	8 (80 %)	5 (71 %)
Radicular low back pain, n (%)	2 (20 %)	2 (29 %)

Note: Data presented for continuous variables were mean and standard deviation M ± (SD). Categorical variables were presented in absolute values and proportions (%).

two groups (ANOVA time: p = 0.034). There was no significant difference between the two groups for the distance between the L5 lamina and the sacrum promontory (time × group interaction: p = 0.595) and the L5 spinous process PPT (time × group interaction: p = 0.672) (Table 2).

The intra-rater reliability was calculated using the mean of the three measurements of the distance between the L5 lamina and the sacral promontory from the examiner A (M.A.M.P.) using the first, second and third measurements (A1, A2 and A3) and examiner B (M.S.M.) using the first, second and third measurements (B1, B2 and B3). The inter-rater reliability was calculated using the mean of the three measured distances between the L5 lamina and the sacral promontory for each examiner (A and B). Good reliability values were found for inter-rater measurements (ICC = 0.81; 95 % confidence interval from 0.67 to 0.90), intra-rater examiner A (ICC = 0.86; 95 % confidence interval from 0.77 to 0.93) and intra-rater examiner B (ICC = 0.88; 95 % confidence interval from 0.81 to 0.94).

4. Discussion

This feasibility study assessed the acute effects of different exposure times in the FDT on the L5–S1 distance and L5 spinous process PPT of patients with chronic LBP conducted on a smaller scale. Both groups (FDT-T5 and FDT-T10 min) increased the lumbar distance, corresponding to mobilization of the lumbar region. Also, the two groups presented decreased values of PPT in the L5 spinous process immediately after the technique, showing an increase in pain perception, which is an unwanted response to clinical objectives when local relief of symptoms is preferred. Our findings revealed similar outcomes when comparing the two different exposure times. We expected to find large effects in the group submitted to 10 min of FDT since the outcomes would be time-dependent. Nonetheless, our preliminary hypothesis was not confirmed, although testing for effectiveness is not recommended in feasibility studies and should be interpreted with caution.

This study has strengths and limitations. This is the first study to compare the distance between the L5 lamina and the sacral promontory after FDT using USI. A single session of FDT showed improvements in the distance between L5 and S1 and reduced L5 pressure pain threshold in the feasibility study. Thus, a definitive clinical trial may show more consistent results. On the other hand, there was a problem measuring L5-S1 distances from the USI in some cases. As there was a delay between obtaining the images and getting measurements from them, it was not possible to repeat the measurement, as the intervention had already occurred. Accordingly, we had the challenge of measuring the L5–S1 distance in some cases, causing data loss since the intervention had already happened. Trialists must be aware that the USI is a therapist-dependent instrument and an intensive training program is required to obtain accurate measures. Furthermore, specific participant features (i.e., obesity) may limit the accuracy of USI through the deep and thick layer of fatty tissue, which results in a loss of resolution in the image [29]. In addition, we used the lateral decubitus position to measure the L5–S1 distance, which may differ from the space in a prone position utilized in the intervention. Despite not finding significant results in the different times of exposure to FDT, we must consider that the times of 5 or 10 min are within the range found in the literature (from 1 to 15 min) [9–11,13,16], with variations in the protocols both in time and the number of repetitions, limiting the generalization of the study results.

We observed increased lumbar distance and local pain after FDT, showing the potential applicability of the USI and PPT in measuring the effects of the FDT. The effect of a particular time of exposure to FDT (FDT-T5 or FDT-T10 min) could not be determined in the present study due to the underpowered nature of the feasibility study. Although we conducted a randomized controlled trial on a small scale, feasibility studies may assess potential effectiveness using surrogate outcomes [30]. Thus, our findings suggest that the USI and PPT are proper measuring instruments to investigate the effects of FDT on the lumbar vertebrae distance and pain perception. Investigating the effects of FDT isolation is relevant to understanding the specific response of this intervention.

The distance between the L5 lamina and the sacral promontory before and immediately after FDT was measured for the first time in this work. Previous imaging lumbar research with different radiological modalities was conducted. Computed tomography showed an increased cross-sectional area of the lumbar spinal canal with lumbar flexion in cadavers [31,32]. Lumbar flexion also increases the foraminal height and width of cadavers in the computed tomography exam [33]. Besides, X-ray measurements showed an increase in lumbar disc height [9,13] and a decreased Ferguson's angle [16] of patients with low back pain after the FDT. We found increased lumbar distance after the lumbar flexion movement, even with different radiological modalities. Therefore, our findings highlight the potential use of the USI to measure immediate changes in lumbar vertebrae space.

The higher pain perceptions immediately after the FDT found in the current study are not a desired effect and contradict previous works. FDT associated with a broader program in chronic LBP showed greater pain relief after the intervention than those allocated to the exercise program [10]. Cambron et al. found that the perception of improvement in LBP was maintained in a one-year follow-up [11]. Another study found pain perception relief in patients with chronic LBP with a more significant effect size on PPT values after modified FDT compared with a high-velocity low-back spinal manipulation protocol [12]. Notably, these studies recruited a greater number of participants, a higher

Table 2
Pre-and post-intervention values, within- and between-group comparison for USI in the distance between L5-S1 and PPT of L5 spinous process.

	FDT-T5 (n = 10)			FDT-T10 (n = 07)			Two-way ANOVA *P*-values		
	Pre	Post	Mean change	Pre	Post	Mean change	Group	Time	Interaction
L5-S1 distance (mm)	15.40 ± 6.95	18.05 ± 7.10	2.65 (1.45, 3.85)	14.95 ± 4.75	16.83 ± 6.39	1.88 (−1.86, 5.63)	0.793	0.006	0.595
L5 pain pressure (kgf)	4.09 ± 1.50	3.54 ± 1.55	−0.55 (−1.35, 0.26)	3.72 ± 1.57	2.93 ± 1.45	−0.79 (−1.92, 0.34)	0.488	0.034	0.672

Note: Values are expressed as mean ± standard deviation for pre- and post-intervention. Mean changes are expressed as mean and 95 % confidence intervals. Significant differences within-and between-groups were tested using the two-way repeated measures analysis of variance (ANOVA). Abbreviation: PPT, pressure pain threshold; USI, ultrasonography imaging; mm, millimetres; Kgf, kilogram-force.

number of FDT sessions and different FDT protocols than the current feasibility study, which may have contributed to the clinical improvement in pain perception that could not be demonstrated here. Both groups demonstrated higher pain perception after the FDT in the current study, which may be related to the lack of manual contact during the treatment rather than the dosage of the intervention.

The effect of the FDT on the lumbar space may vary according to the intervention scheme, the participants' features and the measuring instruments. Cox Flexion Distraction Technique uses manual contact in the spinal process of a given vertebral segment and a manual or automated flexion distraction adjusted depending on the patient characteristics [34]. Likewise, other researchers used manual contact with the spinal process during the FDT [15,35]. Our protocol did not use this manual contact, which may interfere with the study findings. The number of sessions likely influenced the results since the current study performed only one session and other studies used multiple sessions [12,15,35,36]. In the same way, joining FDT with other treatments potentially impacts the outcomes. We tested the use of FDT solely, while previous research analyzed FDT in combination with other modalities. Also, the health condition could interfere with the results. We recruited patients with chronic LBP, similarly to Choi et al. [9] and Carrasco-Martínez et al. [12], while other studies investigated patients with spinal stenosis [15, 35,36]. Ultimately, Choi et al. observed an improvement in disc height after FDT plus other modalities in patients with chronic LBP [9]. Our findings showed an improvement in the L5–S1 distance for both groups submitted to FDT solely in patients with chronic LBP. Thus, the FDT may help to increase lumbar space and the USI has the potential to reveal its mechanism of action.

A large-scale study to measure the effects of FDT on the lumbar vertebral space and local symptoms of patients with chronic LBP is feasible. Our findings suggest that groups with different exposure times may not be necessary for the definitive study. The results of this feasibility study show the need for modifications to be implemented. An FDT program combined with other interventions or comparing FDT with other therapeutic options should be planned for clinical purposes. Adding clinical tools and physical tests is desirable to best approximate to clinical practice scenarios and compare surrogate outcomes (i.e., ultrasound imaging) to self-reported instruments (i.e., Numeric Pain Rating Scale). Moreover, our findings estimate that a future definitive trial should include a recruitment rate of at least 25 % higher than the estimated sample considering the loss due to failures in the processing.

5. Conclusion

In this feasibility trial, both groups showed an increased distance between L5–S1 and decreased the PPT in the L5 spinous process, indicating greater pain sensitivity after the intervention. These quantitative methods may measure distance and pain in definitive studies.

Ethical Approval

This study was approved by the Research Ethics Committee of the Pedro Ernesto University Hospital (number 10519719.6.00005259), in accordance with the Helsinki Declaration for human research. All patients met the eligibility criteria and signed the informed consent form before the study procedures.

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CRediT authorship contribution statement

Maria Alice Mainenti Pagnez: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing. **Maria Silveira Mello:** Conceptualization, Investigation, Methodology, Writing – original draft. **Juliana Valentim Bittencourt:** Formal analysis, Methodology, Writing – original draft, Writing – review & editing. **François Ricard:** Formal analysis, Methodology, Supervision, Writing – original draft, Writing – review & editing. **Leandro Alberto Calazans Nogueira:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing.

Declaration of Competing interest

The authors declare that they have no conflicts of interest.

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