

Effect of a Spinal Orthosis with Leaf Spring and Programmable Local Vibration on Kyphosis Angle and Trunk Muscle Strength in Hyperkyphosis: A Technical Note and Feasibility Evaluation.

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Abstract

Background: Application of spinal orthoses and local vibration in the treatment of hyperkyphosis is a developing concept. Further research is needed to determine the impact of leaf springs and local vibration techniques on the neuromusculoskeletal system.

Objective: To evaluate the effect of the simultaneous application of a leaf spring and a programmed local vibration system in a spinal orthosis on thoracic kyphosis angle and trunk flexor and extensor muscles' function.

Methods: We used a soft thoracolumbar orthosis as a basis for a parallel leaf spring bar made by AISI 1075 steel with (45cm×2cm×2mm) dimensions. We added and evaluated two local vibration systems with predefined force, Probe displacement and programmed frequency. Each local vibration unit was positioned alongside the spinal column, at a distance of 12 cm, while wearing the orthosis. Then one person used the orthosis. We assessed thoracic kyphosis and trunk flexor/extensor muscle function (isometric, isotonic, and isokinetic) before and after a four-week intervention.

Results: Results indicated that each vibration unit caused an on-body displacement of 3 to 6 mm and a free displacement of 1 cm, operating at 8 Hz with a force of 20 N, current of 300 mA, and voltage of 12 V over an area of 12.56 cm². Each session lasted 10 seconds with a 5-minute rest, totalling 12 repetitions. After 4 weeks, the thoracic kyphosis angle decreased from 47.24 to 45.81 degrees. In isometric tests, extensors improved strength by 22.2% to 50%, while flexors decreased torque by -24.1% to -26.5% but achieved faster force generation (-50% half-peak time). Isotonic concentric tests showed extensors improving power by 66.7% to 100% and efficiency, with flexors experiencing reduced power output (12.5-14.3%) but better control (40% decay time). In isotonic eccentric tests, flexors increased peak power by 44.4% and decreased average power (-16.7%), while extensors maintained baseline power but improved efficiency by 20%. Isokinetic tests revealed flexors improved peak torque by 233% and work capacity by 200%, while extensors increased by 66.7% with efficient torque development (55.2% time to peak).

Conclusions: This study demonstrated the feasibility of a semi-rigid thoracolumbar orthosis with integrated programmable vibration in the management of hyperkyphosis. This system achieved good user acceptance and a reduction in thoracic kyphosis. Extensor muscle performance and modified flexor activation patterns improved. Muscle-specific responses warrant targeted rehabilitation approaches, and the solenoid system delivers effective mechanical stimulation while maintaining comfort. These results support further development of combined biomechanical-neuromuscular orthotic interventions for spinal rehabilitation. Clinical Trial: This study was the first phase of the first author thesis project protocol that received approval from the ethics committee of the University of Social Welfare and Rehabilitation Sciences in January 2023. The approval code was (IR.USWR.REC.1401.217). This thesis project protocol received approval from the ethics committee of the University of Social Welfare and Rehabilitation Sciences, with an approval code (IR.USWR.REC.1401.217) in January 2023. The protocol for RCT of this thesis was subsequently approved by the Iranian Registry of Clinical Trials on February 14, 2023, with the registration reference code IRCT20190811044505N2.

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Keywords: Spine, Orthotic Devices, Muscle Strength, Kyphosis, Vibration.

Introduction

Spinal orthoses have been developed over decades to enhance their functionality and effectiveness as soft exoskeletons[1]. Early designs primarily focused on rigid structures that applied limiting or corrective forces. These designs provided protection in post-surgical or post-injury conditions, as well as in cases of scoliosis and kyphosis[2]. However, over time, the adverse effects of immobilization on muscle integrity and bone mineral density revealed the limitations of rigid immobilization techniques[3]. By the late 1990s, the first orthosis designs based on biomechanical principles incorporated semi-rigid and soft structures for the treatment of kyphosis[4].

Today, semi-rigid thoracolumbar spinal orthoses represent a conservative therapeutic intervention prescribed to reduce thoracic kyphosis and improve muscle strength in postural and age-related hyperkyphosis[1]. Although these orthoses demonstrate statistically and clinically significant effectiveness, they are not the most efficient conservative intervention for reducing thoracic kyphosis or enhancing back muscle strength[5].

Orthotic interventions continue to evolve. Initial improvements in design were reported in a 2004 study by Pfeifer et al., which introduced the Spinomed (medi) orthosis[6]. Throughout the

development of semi-rigid spinal orthoses, the application of leaf springs has shown notable clinical and statistical effectiveness[7, 8]. However, research has primarily focused on therapeutic outcomes rather than the specific material properties of the springs[1].

In our previous study, we examined the effects of leaf springs constructed from AISI 1075 carbon steel—a widely available and commonly used material—to determine their efficacy[8]. The mean reduction in thoracic kyphosis angle achieved with AISI 1075 carbon steel leaf springs was 8.14 degrees[8], which was lower than the 11.76-degree reduction observed with the Spinomed orthosis[6]. Both results were inferior to those achieved through supervised exercise training, as demonstrated in a meta-analysis[5].

To enhance the effectiveness of semi-rigid thoracolumbar orthoses in treating hyperkyphosis, we incorporated a programmable local vibration system. Previous studies have explored vibration as a postural reminder in young individuals with hyperkyphosis[9]. However, given the negative correlation between age-related hyperkyphosis and back extensor muscle strength[10], our focus extended to both kyphosis angle correction and muscle strengthening.

Local vibration is a beneficial intervention for mitigating muscle soreness, fatigue [11] and hypertrophy[12]. Among the various vibration systems used in muscular rehabilitation, displacement probes are the most commonly employed. However, there is no certainty in evidence[13] and concerns exist regarding muscle weakness resulting from unsupervised or improper use of local vibration. Therefore, we developed a programmable system to ensure user safety, protecting both muscle and skin tissues during orthosis use.

This study aims to develop a semi-rigid thoracolumbar spinal orthosis equipped with two leaf springs and a programmable local vibration system to reduce thoracic kyphosis angle and improve trunk muscle strength.

Application of Leaf Springs in Spinal Supports

Leaf springs can assist or resist specific trunk functions to reduce loads on bony and soft tissue structures or enhance muscular performance. Their positioning and attachment method depend on the intended support objective. Additionally, the type of metal, thickness, and length of the leaf spring determine the magnitude of force applied. These parameters explain their use in both exoskeletons and orthotic devices for protection or rehabilitation purposes[14].

In exoskeletons, leaf springs help reduce lumbar spine loading during lifting or minimize strain on muscles and the spine during repetitive bending or overhead tasks. Their primary function is protective, providing mechanical assistance[15]. Thus, leaf springs are positioned at a predefined distance from the body's surface to ensure proper center of rotation alignment, generating corrective momentum while reducing mechanical stress on anatomical structures[16, 17]. This design also minimizes skin irritation caused by friction against rigid components.

In lower limb orthotics, leaf springs serve similar purposes as in exoskeletons—assisting lost or diminished functions[18]. However, in spinal orthoses, leaf springs are primarily used to induce corrective positioning, applying resistive or assistive forces to improve muscle function and, consequently, spinal curvature[6, 8]. These springs are positioned parallel and posterior to the spine. Unlike exoskeletons, spinal orthotic leaf springs maintain direct contact with the body, though spacing may be adjusted to facilitate corrective forces or allow postural adjustments without immobilization.

Application of Local Vibration in Spinal Supports

To date, local vibration in spinal supports or orthoses has primarily served as a postural reminder or neuromuscular stimulator in young and healthy subjects[9, 19, 20]. No prior studies on spinal orthotics have explored local vibration with the explicit goal of improving muscle strength, before results derived of this studies data[21]. In this article we report the technical information and result of feasibility evaluation of the newly developed orthosis.

Our work

Methods: This study was the first phase of a project protocol that received approval from the ethics

committee of the University of Social Welfare and Rehabilitation Sciences in January 2023. The approval code was (IR.USWR.REC.1401.217). The initial part of the study focused on assembling and programming the orthosis, as well as assessing its functions for each specific feature. The second part involved a pilot study that evaluated the comfort of the orthosis, its impact on muscle function, and the angle of thoracic kyphosis in a single participant over a four-week intervention period.

Part one (design of the orthosis): In this study, the semirigid thoracolumbar orthosis was include four structures that produced three different actions with the aim of reducing thoracic kyphosis angle and muscle strength improvement including:

1. Support structure: The support structure consisted of a conventional soft thoracolumbar orthosis, serving as a wearable base for the leaf springs and vibration system. This structure included two shoulder straps, each 70 cm in length, constructed from a dual-layer elastic fabric. The straps originated at the level of the C7 vertebra (seventh cervical vertebra) and extended anteriorly and inferiorly over the shoulders, crossing each other posteriorly at approximately the level of the first lumbar vertebra (L1). They were then secured anteriorly over the abdomen via stitching to the lumbar elastic bands.

The lumbar bands provided spinal coverage through a two-step fastening system comprising wide elastic straps. These straps enveloped the lumbar region posteriorly and extended anteriorly between the 10th ribs and the prominent bony landmarks of the anterior superior iliac spine (ASIS). The two-step fastening mechanism consisted of:

- a. Primary Fastening: Two 40 cm-wide elastic straps ("wings") originating posteriorly and secured anteriorly using Velcro.
 - b. Secondary Fastening: A central 10 cm-wide transverse strap that crossed horizontally from the right to the left side of the primary 40 cm-wide strap (see Figure 1, Sections A and B).
2. Leaf springs configuration: The orthosis incorporated a single leaf spring measuring 2 mm in thickness, 2 cm in width, and 50 cm in length, positioned along the posterior aspect of the device. The proximal end of the spring was aligned with the C7 vertebral level, while the distal end terminated adjacent to the coccyx surface landmark.

The leaf spring was custom-contoured to match the user's thoracic and lumbar spinal curvature using two wrenches for precise shaping. In accordance with semi-rigid orthosis alignment protocols, the proximal portion was formed with a 4 cm offset from the spinal column. This strategic spacing served dual purposes. (1) permitting adequate range of motion for trunk movements, and (2) facilitating thoracic kyphosis angle reduction during therapeutic intervention.

The maintained distance between the spring and spine was intentionally designed to minimize immobilization effects while simultaneously promoting activation of trunk musculature (see Figure 1, Section C). This configuration aligns with contemporary orthotic principles that emphasize functional rehabilitation over rigid immobilization.

3. Local Vibration System: The vibration system was controlled by an Arduino microcontroller, programmed to administer vibrations according to a predefined protocol specifying activation durations and rest intervals. The system incorporated four vibration units, each featuring:

- A displacement range of 3-6 mm during body contact
- 1 cm of free movement capability
- An operational frequency of 8 Hz
- Vertical force generation of 20 N
- Power requirements of 300 mA at 12 V

- A contact surface area of 12.56 cm² per probe

The vibration probes were strategically positioned over the paraspinal musculature between the T6 and T12 vertebral levels (Figure 1, Section D). This placement was selected to optimally target the erector spinae muscle group while avoiding direct vertebral column contact.

4. Vibration Protocol: The intervention protocol consisted of:

- 10-second vibration bursts
- 5-minute rest intervals between activations
- 12 complete cycles per session

This protocol was developed through synthesis of existing literature, as no established guidelines currently exist for vibration application to trunk extensor musculature (Germann et al., 2018). The parameters were derived from:

- a. Safety recommendations for prolonged vibration exposure (Wu et al., 2020)
- b. Previous studies examining erector spinae muscle response (Bosco et al., 1999)

Control System Implementation: The Arduino-based control system operated as follows:

1. Button Configuration
 - Digital pin 2 connection
 - INPUT_PULLUP setting (HIGH at rest, LOW when depressed)
2. Operational Logic
 - Button press initiates relay control sequence
 - 10-second relay activation period
 - Cycle counter increment after each activation
3. Timing Control
 - 300,000 ms (5-minute) inter-cycle interval
 - Automatic termination after 12 cycles
 - System lock (while (true);) until manual reset

This implementation ensured precise protocol adherence while maintaining user control over session initiation. The extended rest periods between activations were designed to prevent neuromuscular fatigue while allowing for optimal therapeutic response.

Outcomes of Design Evaluation

Functional Characteristics Assessment: Prior to clinical implementation, the orthosis was evaluated by the research team for its functional performance, comfort, and aesthetic acceptability.

Vibration System Analysis:

1. Free Displacement and Vibration Frequency:

- o The free displacement of probes and baseline vibration frequency (measured without external pressure) were assessed via high-speed video recording.
- o Video playback was slowed to quantify oscillations per second.

2. Pressure Measurement:

- o Vibration-induced pressure was evaluated under two conditions:

- *Free vibration*: The system was placed in a stabilizing box to maintain solenoid perpendicularity.
- *On-body vibration*: Measured while participants wore the orthosis.
 - o A 16 × 16 cm force-sensing resistor integrated with the *Pliance*® system (Novel GmbH) was used to record pressure and force distribution.

3. Weight Assessment:

- o The orthosis was weighed both with and without the vibration system.

Comfort and Usability Evaluation

Ten middle-aged participants with hyperkyphosis were recruited to assess wearability and design acceptability. Three orthosis sizes (based on C7-coccyx spine length) were fabricated. Each participant wore their size-matched orthosis for 30 minutes before providing feedback.

Assessment tool: Two questions were administered via a 10-point numerical scale (0 = *extremely unpleasant*; 10 = *extremely pleasant*):

1. "Rate the orthosis's appearance."
2. "Rate the orthosis's user-friendliness."

Responses were documented in a standardized checklist for analysis.

Part Two: Feasibility evaluation

Following validation of the orthosis's functional characteristics, a single-subject pilot study was conducted. The participant, recruited through the University's Orthotics and Prosthetics Department, underwent the following evaluation and intervention protocol:

Initial Assessment and Fitting:

1. Baseline thoracic kyphosis angle (TKA) measurement was performed
2. A certified orthotist performed patient-specific adjustments to the semi-rigid spinal bars
3. A 30-minute orientation session was conducted to ensure proper orthosis use
4. Participants received:
 - o A wear-time log for daily documentation
 - o An instruction manual with the principal investigator's contact information for reporting adverse effects or technical concerns

Intervention Protocol:

- Week 1: Gradual adaptation period (initial wear time: 10 minutes, progressively increasing)
- Weeks 2-4: Maintenance phase (1-2 hours daily wear time, self-scheduled in segments)
- Vibration protocol (administered every other day):
 - o 10-second vibration bursts
 - o 5-minute rest intervals

- o 12 cycles per session

All outcome measures were reassessed after the 4-week intervention period[21].

Outcome measures: Primary outcomes were Thoracic kyphosis angle (TKA) and Isometric function of trunk flexor and extensor muscles. Secondary outcomes were Isotonic eccentric and concentric trunk flexor and extensor muscle function, and Isokinetic concentric performance of the trunk flexor and extensor muscle.

All assessments followed standardized protocols as previously published in our prior work, including:

Thoracic kyphosis angle: We assessed TKA using photogrammetry, which demonstrates high reliability in test-retest scenarios (ICC = 0.97; SEM = 1.67; MDC = 4.62) [22]. This method is effective for evaluating spine curvature in adults and has been safely utilised in elderly populations [23]. In this research, participants positioned themselves on a marker while a calibrated camera (Canon 8 Mpixel MV150i) captured three digital images of the markers located on the seventh cervical and twelfth thoracic spinous processes [24]. We analysed the images using AutoCAD to compute the angles based on the markers, with the average of the three angles documented as the TKA.

Isokinetic Dynamometer: We assessed the function of trunk muscles using isometric, isotonic, and isokinetic tests within the trunk muscle evaluation framework of the HUMAC-Norm isokinetic dynamometer system (CSMi, Stoughton, MA, Software HUMAC 2014, v.12.001.0005: NORM) while the subjects were in a standing (orthostatic) position. The reliability of this system for measuring trunk muscle strength in the standing position is 0.98[25]. The isokinetic setup was calibrated for each assessment within a 30-degree range of motion for both trunk flexion and extension, utilising a defined 5-degree extension and a defined 30-degree flexion, which was selected based on the trunk kinematics observed in older adults [26]. Data processing included gravity correction and was performed at a speed of 60 degrees per second [27]. We considered the positions of the anterior superior iliac spine and the seventh thoracic vertebra for each participant according to the mechanical axis of the dynamometer. Body weight, height, and adjustments for leg height, along with the positioning of pelvic, thoracic, and knee pads, were documented for each evaluation [28]. After ensuring that all stabilisers were firmly secured, the examiner verified the participant's comfort before commencing any tests.

Isometric function of trunk flexors and extensors: The procedure included a submaximal warm-up followed by assessments of trunk extension and flexion. The warm-up and assessment protocols were comparable [29]. Following the warm-up, the assessment lasted for 60 seconds. Each assessment comprised three one-minute trials with a 30-second interval. We set no torque threshold with 15 degrees of flexion. The participants did not receive any visual feedback and were encouraged with the phrase, "Go as fast and as hard as possible." After finishing six extension trials, a one-minute rest period followed before starting the flexion assessments, which followed the same protocol. After all trials, we considered a 10-minute rest period. The HUMAC software logged various metrics, including peak torque, average torque, peak torque slope, time to half peak torque, and time to peak torque.

Isotonic function of trunk flexors and extensors: The trunk extensor and flexor isotonic test consists of a familiarisation trial and an actual test, conducted in concentric and eccentric modes with brief rest periods. The protocol involves setting the trunk's range of motion and using a level 1 cushion with an evaluation torque of ten. Participants first perform three consecutive trunk flexions and extensions starting from 30 degrees of flexion, followed by a rest period and then the test. After another rest, they transitioned to eccentric mode, which started from a 5-degree extension. During

the tests, participants receive no visual feedback and execute movements on the examiner's request. HUMAC software reports variables such as torque, peak power, work per repetition, and time parameters.

Isokinetic function of trunk flexors and extensors: The isokinetic test protocol for trunk extensors and flexors involves two concentric protocols: a submaximal familiarisation phase and the test. Evidence supports the equivalence of concentric and eccentric evaluations, leading us to choose the concentric mode to reduce evaluation time. High intra-rater (ICC = 0.89 to 0.95) and inter-rater (ICC = 0.95 to 0.98) reliability has been established for these evaluations [30]. Familiarisation included three trials of trunk flexion and extension at 60 degrees per second from a 30-degree flexed position, with 30 seconds of rest between trials and a 1-minute break before the test. The participant has no visual feedback. The HUMAC software recorded variables like peak torque and average power. The reliability analysis of this protocol shows a high intraclass correlation coefficient (0.89 for flexion and 0.86 for extension). Isokinetic trunk settings were recorded for future sessions.

Statistical Analysis: All study data were systematically presented using tabular formats to facilitate comprehensive interpretation. Descriptive statistics, including measures of central tendency and dispersion, were calculated where appropriate to characterize the dataset.

For comparative analysis, we evaluated the observed changes in outcome variables against established clinically significant thresholds derived from previous studies employing comparable interventions and assessment methodologies. This comparative approach enabled contextual interpretation of our findings within the existing evidence base.

Results:

Results of design related outcomes: The mechanical stimulation component affixed to the orthosis has a total weight of 300 grams, consists of two boxes weighing 20 grams each and four solenoids, each weighing 60 grams. To evaluate the frequency of 8 Hz video recording techniques utilised. The footage captured from the mechanical stimulation component of the orthosis underwent analysis via specialised software (DaVinci Resolve Studio 20.0.1.6 Win), which involved slowing the recording for one second and isolating it from the segment that commenced with the movement of the probe. It confirmed that the probe reaches its maximum distance from the solenoid a total of eight times per second.

The force exerted by the probe was measured using the force plate of the Pliance® system. To carry out this measurement, we fixed the Pliance® system sensor on a table. The mechanical stimulation units were then placed directly on top of the sensor, while it remained in its box (Figure 1D). The local stimulation system activated and recorded the maximum force that the sensor detected. Next, we evaluated the mechanical force applied to the subject's body by placing the sensor between the mechanical stimulation system's probe and the subject while they used the orthosis. At this stage, the Pliance® system sensor recorded the maximum force. The pressure sensor displayed a reading of 20 Newtons per square centimetre in the free state and 9.5 Newtons per square centimetre in the wearing state against the subject's body. Additionally, we measured the displacement of the solenoid probe inside the box using a ruler. For this measurement, we connected the solenoids to a battery and gauged the probe's movement with a ruler. We observed the displacement one centimetre.

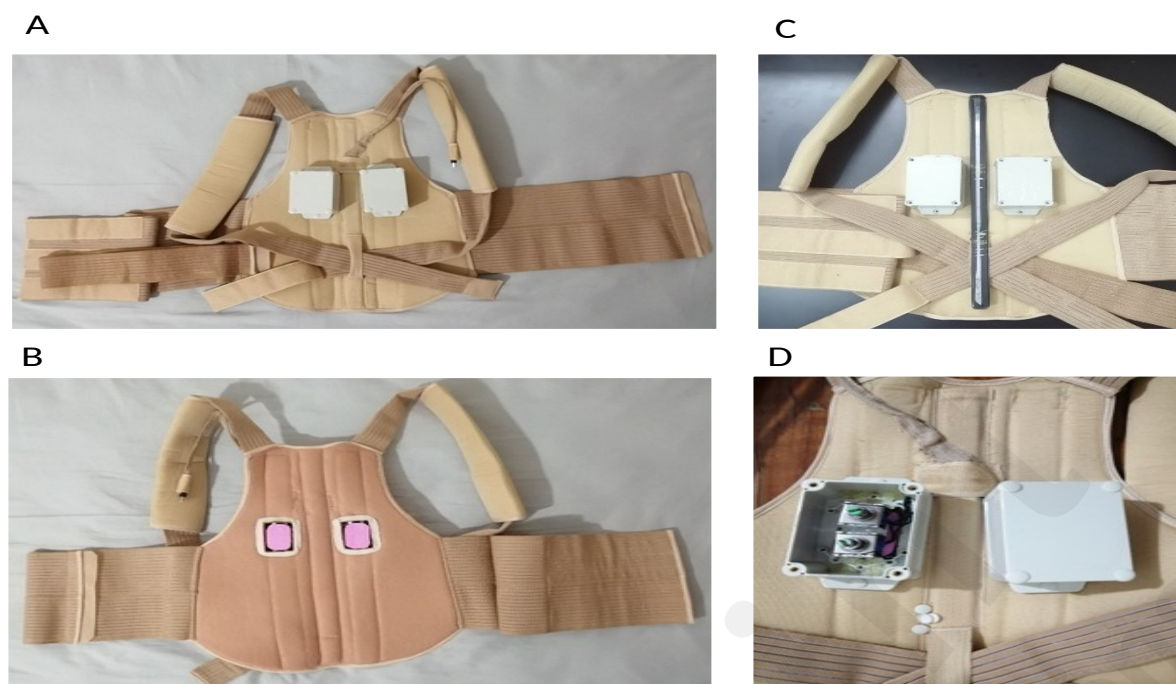


Figure 1: Sections A and B demonstrate the support structure. Section C demonstrate the leaf spring position. Section D demonstrate the vibration units' placement in the orthosis.

Ten senior participants with hyperkyphosis evaluated the orthosis for appearance and comfort. Their mean age was 62.2 ± 7.83 years, and their mean thoracic kyphosis angle was 55.53 ± 1.69 degrees. The average score for appearance was 7.95 ± 0.83 , and the average score for comfort was 7.6 ± 0.07 . The details of participants' demographic data, their responses on appearance and user-friendliness, and their kyphosis angles were reported in (Table 1).

Results of pilot study outcome: The orthosis with a local vibration system was evaluated by a 45-year-old woman during four weeks of use every other day. Before using the orthosis, we measured the kyphosis angle in the thoracic region through a photogrammetric method.

Table 1: Demographic data of participants in part one that answered the questions of comfort.

N	age	sex	Height	weight	TKA	Appearance	Comfort	Mentioned unpleasant characteristics
1	64	W	1.70	69.00	49.3064	9.5	8	-
2	60	W	1.63	60.00	56.8915	9	8	-
3	60	W	1.65	67.00	56.0748	8	8	-
4	62	W	1.57	55.00	61.2558	8	7	Heavy
5	62	W	1.52	58.00	57.4112	8	8	-
6	62	W	1.49	66.00	53.3264	8	6	-
7	63	W	1.55	69.00	50.4129	7	8	-
8	67	W	1.50	70.00	63.2491	8	8	-
9	77	M	1.76	90.00	60.1117	7	7	Hard to wear
10	45	W	1.50	51.00	47.2400	7	8	-
Mean $\pm$ SD	62.2 ± 7.83	-	1.59 ± 0.09	65.5 ± 10.82	55.53 ± 1.69	7.95 ± 0.83	7.6 ± 0.07	-

W: Woman, M: Man, TKA: Thoracic Kyphosis Angle, SD: Standard Deviation

We also conducted tests on trunk muscle function with an isokinetic device and assessed pain levels utilising the visual pain index. We repeated these assessments after four weeks of use. We also evaluate the functional characteristics, comfort, and appearance of the orthosis before and after intervention. Details of the results reports are in Tables 2 to 5. The kyphosis angle of the thoracic region of the prototype orthosis user was 47.24 degrees before using the orthosis and 45.81 degrees after four weeks.

In the results of the isometric test of the extensor muscles, four weeks of using the orthosis with a local vibration system increased maximum torque (+5 Nm, 26.3%), average torque (+4 Nm, 22.2%), maximum torque slope (+9 Nm/s, 50%), and time to reach half maximum torque (+0.07 s, new onset). In the isometric test of the flexor muscles, maximum torque (-9 Nm, 26.5%) and average torque (-7 Nm, 24.1%) decreased, and the maximum torque slope remained constant. The "time to maximum torque" increased (+0.08 s, 7%), and the "time to half maximum torque" decreased (-0.06 s, 50%). (Table 2)

Table 2: Isometric tests results for trunk extensor and flexor muscle before and after 4 weeks of intervention.

Isometric tests	Extensors			Flexors		
	before	After	% change	before	After	% change
Peak Torque (Nm)	19	24	increase 26.3%	34	25	26.5% decrease
Average Torque (Nm)	18	22	increase 22.2%	29	22	decrease 24.1%
Peak Torque Slope (Nm/s)	18	27	increase 50%	33	33	0%
Time to Peak Torque (s)	2.27	1.36	decrease 40.1%	1.14	1.22	increase 7%
Time to Half Peak Torque (s)	0.0	0.07	new onset	0.12	0.06	decrease 50%

The isotonic concentric test of the extensor muscles, conducted after four weeks of using the orthosis, demonstrated an increase in maximum power (+4 W, 66.7%), work done per repetition (+1 J, 14.3%), average power per repetition (+5 W, 100%), and time to decline of maximum power (+0.03 s, 150%). Additionally, there was a decrease in the joint angle at maximum power (-1°, 9.1%), the time to reach maximum power (-0.05 s, 8.3%), and the reciprocal delay (-0.57 s, 36.3%). The concentric isotonic flexor test showed a decrease in maximum power (-1 W, 12.5%), work per repetition (-1 J, 14.3%), average power per repetition (-1 W, 14.3%), joint angle at maximum power (-2°, 11.1%), reciprocal delay (-0.24 s, 18.2%), and increase in time to peak power decay (+0.04 s, 40%). (Table 3)

Table 3: Isotonic concentric tests results for trunk extensor and flexor muscle before and after 4 weeks of intervention.

Isotonic concentric	Extensors			Flexors		
	before	After	% change	before	After	% change
Peak Power (W)	6	10	increase 66.7%	8	7	decrease 12.5%
Work Per Repetition (J)	7	8	increase 14.3%	7	6	decrease 14.3%
Average Power (W)	5	10	increase 100%	7	6	decrease 14.3%
Joint Angle of Peak Power (°)	11	10	decrease 9.1%	18	16	decrease 11.1%
Time to Peak Power (s)	0.60	0.55	decrease 8.3%	0.46	0.30	decrease 34.8%
Time to Peak Power 2 (s)	1.15	0.55	decrease 52.2%	1	1.04	increase 4%
Peak Power Decay Time (s)	0.02	0.05	increase 150%	0.10-	0.06-	improve 40%
Reciprocal Delay (s)	1.57	1	decrease 36.3%	1.32	1.08	decrease 18.2%
Delay Time (s)	0.0	0.0	-	0.0	0.0	-

The isotonic eccentric test of the extensor muscles showed an increase in the average power per repetition (+1 W, 20%). This test also showed a decrease in the joint angle at maximum power (-2° , 8%), although the maximum power was stable. Also, there was a reduction in the time to the decline of maximum power (+0.01 s, 12.5%) and reciprocal delay (-0.56 s, 47.1%). The eccentric isotonic flexor test showed an increase in maximum power (+4 W, 44.4%). The test also showed a decrease in average power per repetition (-1 W, 16.7%), joint angle at maximum power (-5° , 38.5%), time to peak power decay (-0.02 s, 66.7%), and reciprocal delay (-0.10 s, 11%). (Table 4)

Table 4: Isotonic eccentric tests results for trunk extensor and flexor muscle before and after 4 weeks of intervention.

Isotonic eccentric	Extensors			Flexors		
	before	After	% change	before	After	% change
Peak Power (W)	9	9	0%	9	13	increase 44.4%
Work Per Repetition (J)	5	5	0%	5	5	0%
Average Power (W)	5	6	increase 20%	6	5	decrease 16.7%
Joint Angle of Peak Power ($^\circ$)	25	23	decrease 8%	13	8	decrease 38.5%
Time to Peak Power (s)	1.30	1.01	decrease 22.3%	1.01	0.83	decrease 17.8%
Time to Peak Power 2 (s)	0.20	0.31	increase 55%	0.24	0.30	increase 25%
Peak Power Decay Time (s)	0.08-	0.07-	improve 12.5%	0.03	0.01	improve 66.7%
Reciprocal Delay (s)	1.19	0.63	decrease 47.1%	0.91	0.81	decrease 11%
Delay Time (s)	0.0	0.0	-	0.0	0.0	-

The extensor isokinetic test showed an increase in maximum torque (+8 Nm, 66.7%), joint angle at maximum torque ($+2^\circ$, 11.8%), force decay time (+0.50 s, 217%), reciprocal delay (+0.12 s, 9.5%), and delay time (+0.04 s, 25%). The test also showed a decrease in the time to peak (-0.53 s, 55.2%) and half-maximal torque (-0.01 s, 100%). The flexor isokinetic test showed an increase in maximum torque (+14 Nm, 233%), work per repetition (+4 J, 200%), joint angle at maximum torque ($+4^\circ$, 25%), time to peak torque (+0.39 s, 75%), and force decay time (+0.19 s, 67.9%). Average power per repetition was stable. The test reported a decrease in the time to half-maximal torque (-0.01 s, 100%), reciprocal delay (-1.35 s, 43.1%), and delay time (-0.05 s, 35.7%). (Table 5)

Table 5: Isokinetic tests results for trunk extensor and flexor muscle before and after 4 weeks of intervention.

Isokinetic concentric	Extensors			Flexors		
	before	After	% change	before	After	% change
Peak Torque (Nm)	12	20	increase 66.7%	6	20	increase 233%
Work Per Repetition (J)	2	2	0%	2	6	increase 200%
Average Power (W)	4	4	0%	4	4	0%
Joint Angle Peak Torque ($^\circ$)	17	19	increase 11.8%	16	20	increase 25%
Time to Peak Torque (s)	0.96	0.43	decrease 55.2%	0.52	0.91	increase 75%
Time to Half Peak Torque (s)	0.01	0.0	decrease 100%	0.01	0.0	decrease 100%
Force Decay Time	0.23	0.73	increase 217%	0.28	0.47	increase 67.9%
Reciprocal Delay	1.26	1.38	increase 9.5%	3.13	1.78	decrease 43.1%
Delay Time	0.16-	0.12-	decrease 25%	0.14-	0.19-	increase 35.7%

The user of the orthosis with a local vibration system assigned 8 points out of a total of 10 points to the ease of wearing the orthosis, 7 points to the ease of using the orthosis, 7 points to the weight of the orthosis, and 5 points to the appearance of the orthosis. Free and on body force was stable.

Discussion:

This research presents the outcomes of the technical advancement of an orthotic device featuring a programmable local vibration system that was part of the PhD thesis of the first author. We reported the effects of this orthosis through a recently published randomised controlled trial in age-related hyperkyphosis. Nonetheless, the assessment of technical features requires clarification in a technical note study.

The unit for electromechanical stimulation consisted of four push-pull solenoids linked to a movable pad that delivered force to the body surface, as part of the semi-rigid thoracolumbar orthosis. Batteries, relay, and Arduino microcontroller were connected during stimulation, and positioned in a separate box to reduce the weight of the orthosis and guarantee the user's safety.

We defined the protocol of vibration with seven parameters, including the program, the frequency of vibration generation, the amount of displacement of the moving part in the free state, the force generated in the free and worn states, the duration of mechanical stimulation, and the site of stimulation based on previous studies on effective local vibration therapy in wearables [31] and vibration therapy for pain reduction [32].

The placement of the solenoids was determined through a study that explored the length of spinal manipulation therapy using localised vibration at a force of 20 Newtons across four distinct frequencies applied to the spine on the paraspinal muscles adjacent to the sixth to eighth thoracic vertebrae [33]. In this study, the solenoids were placed in a standard box on the orthosis, positioned about two inches below the inferior angle of the scapula to avoid contact with the bone. Considering that the length of each box was 12 cm and each vibration-generating unit was about 1 cm away from the walls of the box, the location of the mechanical stimulation section was located around the ninth to twelfth thoracic vertebrae [34]. The findings of our study suggest that we made an excellent choice in the location for local stimulation.

Considering the purpose of using local vibration in the present study, the duration of mechanical stimulation is critical. The duration of stimulation consisted of 10 10-second stimulations with five-minute rest intervals. A study found that shorter durations of mechanical vibration applied to the thoracic paraspinal muscles positively correlated with increased electromyographic responses [33]. In another study in 2017, a group of researchers evaluated electromechanical manipulation using a gun massager (solenoid force) for short durations of less than 10 seconds with force of 15, 22, 44, and 67 Newtons using the Hoffman reflex of the paraspinal muscles of the thoracic spine (paraspinal muscle spindle response) in an animal model (cat) [35]. The results of this study reported that, in general, mechanical stimulation drives resulted in reduced muscle spindle discharge, with the majority of afferents requiring periods (>6 seconds) to return to pre-drive levels of activity based on the average frequency of muscle spindle depolarisation. This neurophysiological response to mechanical stimulation persisted for a duration of 2 to 7 milliseconds. Given that the maximum value of the Hoffmann reflex indicates the activation of all motor neurons that carry the action signal to the muscle [36] and that mechanical stimulation can activate the Hoffmann reflex [37], the report of the existence of this reflex with a mechanical stimulation duration of 10 seconds suggests that this intervention duration can not only lead to the stimulation of motor neurons but also provide us with sufficient time for the polarization and depolarization of muscle spindles. We determined the duration necessary for mechanical stimulation to induce a physiological response in the thoracic spine muscles [33]. Consequently, this intervention period appears to be appropriate.

Force generated in the free and covered state: Normally, the force exerted by the moving component when working with a handheld massager is regulated to some extent by the amount of pressure exerted by the user. Typically, in handheld local vibration systems, the force differences are controlled using a weight influenced by gravity [31]. Using a constant force allows control over the varying levels of pressure generated by the users. This study utilised the constant force generated by the orthotic straps. Most research on local vibration in the spine has focused on mechanical stimulation to enhance proprioception, balance, or posture [38-40]. In this study, we utilised manipulation interventions and the average pressure applied by the fingers to determine the force exerted by the orthosis in a manner that promotes muscle function. The average controlled force applied by the fingers during multi-finger manipulation is about 3 to 4.5 N per finger [41]. We used a stimulation unit with a vertical displacement and a constant force, equivalent to about 10 N, relying on the force of two fingers without reciprocal force from an adjacent finger. The maximum vertical force for all fingers in extension averages between 50 and 268 N on a smooth metal surface [42]. Since the thumb generates more force than the other fingers, we used the index finger as the standard [43]. The maximum force that can be exerted by the index finger on a smooth metal surface in different positions of finger joint flexion, similar to that used in manipulation, is 15–30 N [44]. Because in the presence of tissue interaction and the placement of the stimulation units in an orthosis, the displacement of the moving part and the force applied in the covered position will be reduced [31], the use of solenoids with a capacity to exert 20 N of vertical force in the free position seems to be a suitable choice.

Most studies that employ vibration systems to enhance muscle strength use various types of vibration gun devices with adjustable frequency settings and defined protocols [13]. Based on displacement measurements from prior research [13], the present study implemented a local mechanical vibration system using 12 V solenoids with a fixed displacement of 10 mm. A microcontroller regulated the vibration frequency within the mechanical limits of these lightweight solenoids.

Therapeutic mechanical vibration frequencies typically range from 5 Hz to 300 Hz, depending on the aim of intervention [45]. Higher frequencies often target proprioception improvement and employ vibration motors [40, 46]. Previous applications of vibration motors in spinal orthoses aimed to correct posture through mechanical vibration [9]. However, this study focused on enhancing muscle function.

Research comparing four frequencies (15, 30, 45, and 60 Hz) for upper limb muscle strength demonstrated significant improvements within the 30–60 Hz range [47]. Another study found that local vibration at 15, 30, and 45 Hz (36 N force) reduced Hoffmann reflex suppression during muscle fatigue and aided muscle volume recovery during rehabilitation [48]. A study compared 1 Hz and fifteen Hz vibrations on muscle strength in older adults. They found significant effectiveness after 8 weeks and muscle hypertrophy after one year in both groups. It shows no difference between the frequencies. It suggests that low frequencies may be a safer option for geriatric rehabilitation [49]. A local vibration intervention on upper limb muscles applied 8 Hz and 26 Hz local vibration during isometric contraction over four weeks, yielding significant strength improvements in both groups without a notable difference between frequencies [50]. In the current study, participants held a therapist-guided seated posture while receiving local vibration delivered through orthoses. Since

this also occurred during isometric contraction, 8 Hz emerged as a safe and effective frequency for muscle function improvement while minimising solenoid overheating.

The solenoids in this study had a free displacement of 1 cm, which we estimated would reduce to 6–7 mm when covered [31]—a range previously validated for efficacy [50]. We programmed the system to deliver ten 10-second local vibration intervals interspersed with 5-minute tissue rest periods using a conditional loop command. The solenoids generated an applied force of approximately 20 N/cm² (200 kPa) in the unconstrained state. Following the local vibration protocol, users first donned the orthosis and then activated the microcontroller by pressing two buttons on the control box. The solenoids subsequently operated according to the programmed sequence. The Arduino's predefined program automatically deactivated the vibration system upon completion of the treatment cycle.

We previously assessed the effectiveness of the semi-rigid thoracolumbar orthosis in this study on age-related hyperkyphosis [8]. This orthosis consisted of a two-layer elastic lumbar corset, woven elastic shoulder straps, and custom-made spring metal bars tailored to each individual's thoracic and lumbar spine lengths and waist circumference. The metal bars in this semi-rigid thoracolumbar orthosis were typically positioned parallel to the paraspinal muscles, following the Night Taylor orthosis design[2]. In this study, we incorporated an orthosis featuring a local vibration system. To achieve this, two bars were placed parallel to each other along the spine at the centre of the back. This design not only preserved the overall structure of the original orthosis but also ensured proper space for the vibration unit installation. The use of an integrated spring metal bar has also been used previously in orthoses to correct hyperkyphosis [51].

The results of the evaluation of the functional indices showed that the local vibration system, with a frequency of 8 Hz, a displacement of 10 mm and a free force of 20 Newtons, vibrated while connected to the orthosis. However, the amount of force generated in the worn state was equal to 9.5 Newtons, which was lower than our expectations. The padding and the integrated probe, which connected both solenoids, likely reduced the force. It could also stem from the softer body tissue compared to the surface utilised for assessing the free force.

A prototype user under 60 initially rated the local vibration system's usability as 10/10. However, after four weeks of use, the combined orthosis system received lower scores for ease of use (7/10) and appearance (5/10), with comfort and weight rated 8 and 7, respectively. This decline in usability likely stems from the system's seated, spine-aligned requirement, which induced fatigue. Unlike pain patients who find orthoses supportive [52], this user's mild kyphosis (<52°) limited the functional benefit and long-term acceptance, contrasting his initial high score that reflected technology acceptance [53] rather than clinical need.

The prototype users' thoracic kyphosis decreased from 47.24° to 45.81° after four weeks. We selected this duration based on previous local vibration studies [50], which suggests it adequately assesses system effectiveness and safety. However, this 1.5° reduction in mild kyphosis (<52°) may derive from multiple factors: the orthosis alone, the vibration system alone, their combined effect, or participation in the hyperkyphosis treatment program [54].

The dynamic orthosis used an integrated spring load to generate extensor torque while allowing controlled spinal movement [55]. The orthotist adjusts the movement range to match the patient's spinal alignment. It uses a functional reminder mechanism characteristic of semi-rigid orthoses.

When the user bends unintentionally, tension from the shoulder straps creates underarm pressure that promotes conscious postural correction.

In a study, application of an orthosis with a vibrating reminder for four consecutive days, four hours daily, resulted in an 8-degree reduction in the kyphosis angle [20]. Whereas our system combines mechanical feedback (through shoulder straps) with therapeutic vibration, we didn't reach this reduction. The observed improvement in kyphosis angle may be influenced by the study population's specific enrolment criteria, as reported in previous studies [8, 54].

We assessed muscle function in isometric (constant joint angle), isotonic (constant force) and isokinetic (constant speed) before and after four weeks. Based on the results of this section, the values reported for isometric muscle function are higher than those reported in isotonic and isokinetic tests. The common variance between the three methods of measuring muscle function suggests that all three assessment techniques describe different dimensions of the same goal, namely maximal voluntary strength; however, within a given muscle group, this correlation is reduced due to the presence of various speeds and joint angles [56]. Therefore, it is not surprising to report better results in favour of one of the three methods: isometric, isotonic, and isokinetic.

The orthosis structure and local vibration protocol jointly influenced the isometric strength of trunk flexor and extensor muscles. After four weeks, maximum extensor torque increased by 26.31% while flexor torque decreased by 26.47%. The extensor group showed improvements in mean torque, torque slope, and time-to-torque parameters, whereas the flexor group demonstrated reductions in these metrics.

Local vibration targeted the extensor muscles. It may cause torque improvement. Although semi-rigid orthoses haven't been shown to improve muscle strength within four weeks, studies suggest vibrations are effective during similar interventions[50]. Our protocol (8Hz vibration every other day) increased upper limb muscle maximum voluntary contraction by 23.2%, consistent with our extensor findings.

Pre-intervention, the female office worker participant exhibited greater flexor than extensor strength - atypical for healthy adults with age-related hyperkyphosis [57] but expected in sedentary individuals [58]. The extensor torque increase aligns with combined orthosis-vibration effects, but the flexor reduction contradicts previous semi-rigid orthosis studies [1].

Notably, the torque development rate (maximum torque/time to maximum torque) remained stable in flexors but increased 75% in extensors. Both muscle groups showed prolonged time-to-maximum torque. In young adults, such isometric torque increases typically correlate with faster power achievement, suggesting improved motor unit activation rates, torque development velocity, or reduced electromechanical delay [59].

The isotonic tests revealed significant changes following four weeks of orthosis use with local vibration. Maximum eccentric power increased in flexor muscles, while extensor muscles showed increased maximum concentric power. However, extensor eccentric tests demonstrated only average power improvement, and flexor concentric tests showed reduced maximum power. These changes reflect alterations in peak muscle output during isotonic contractions with constant tension.

Our semi-rigid orthosis combined metal spring loading with a local vibration system. Previous research indicates isotonic contraction typically improves after resistance training [60]. The

observed power increases may stem from enhanced muscle endurance due to orthosis use [8]. Local vibration may improve extensor muscle function [61-63].

The prototype user exhibited reduced average power and work output in flexor muscle tests. This aligns with studies showing that local vibration of agonist muscles decreases immediate performance while optimizing antagonist muscle's contractions [64, 65]. The angle for maximal power application decreased across tests, indicating earlier peak power, possibly due to vibration-induced neuromuscular adaptations [66].

Both muscle groups demonstrated reduced maximal power decay time and reciprocal delay. Since power decay time correlates with muscle endurance [67], these improvements may indicate enhanced neuromuscular efficiency from mechanical vibration stimulation [66]. Local vibration can affect isotonic performance significantly [64].

After four weeks, maximal torque more than doubled in the flexor muscle group and increased by 50% in extensors. Extensor muscles showed changes in average power and work output, while flexors maintained constant average power despite a two-unit increase in work. Isokinetic testing revealed increased maximal torque decay time, reciprocal delay, and delay time in extensors, whereas flexors exhibited only prolonged decay time with reductions in the other two variables.

In isokinetic assessments, maximal torque serves as the primary metric, with work and average power derived computationally from this value. The increased extensor torque corroborates prior local vibration research. These results reflect the combined effects of conventional orthosis design and vibration therapy. Systematic reviews support the potential of vibrations in improving muscle strength, while highlighting methodological weaknesses in current research [13, 45]. Concurrent vibration and resistance training yields comparable strength gains [68, 69]. Our results demonstrate measurable isokinetic torque enhancement, contradicting a 2015 study that found vibration only increased isometric performance [70]. The observed increases in decay time, reciprocal delay, and latency likely reflect vibration-induced neuromuscular adaptations [66].

Flexor muscle torque changes may stem from cross-activation effects. Vibration equally reduces excitability in antagonist and agonist muscles immediately after intervention [71]. Agonist muscle vibration also induces neuromuscular changes in antagonists [65], with agonist strengthening potentially improving antagonist performance[72].

Prototype user outcomes align with intervention expectations. As this analysis evaluates individual results, we need to compare the statistical significance with group findings in the thesis's second phase.

Limitations and Future Directions: This prototype represents a viable foundation for developing orthotic systems that combine biomechanical correction with neuromuscular stimulation. The single-subject design precludes broad generalizations, though the consistent quantitative improvements across multiple biomechanical parameters suggest biological plausibility. A randomized controlled trial was conducted based on this PhD thesis to standardize wear-time protocol and examine its long-term effects on spinal alignment and muscle adaptation, using the minimum acceptable sample size. However, the results of published RCTs opened new questions[21]. Integrating programmable vibration with semi-rigid spinal support presents a multimodal hyperkyphosis management strategy warranting further evaluation via large, randomized clinical trials with diverse outcome measures.

Conclusion: A semi-rigid thoracolumbar orthosis with integrated programmable vibration (8 Hz, 20 N/cm² free/9.5 N/cm² worn) is feasible for managing hyperkyphosis. The 300 g system was well-received (comfort/appearance >7.5/10) and reduced thoracic kyphosis by 1.43°. Improved extensor muscle performance and modified flexor activation patterns. Muscle-specific responses warrant targeted rehabilitation approaches, and the solenoid system delivers effective mechanical stimulation

while maintaining comfort. These results support further development of combined biomechanical-neuromuscular orthotic interventions for spinal rehabilitation.

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This study was conducted without any external financial support.

Conflicts of Interest

None declared.

Data Availability

All data generated or analyzed during this study are included in this published article.

Abbreviations

TKA: Thoracic Kyphosis Angle

N: newton

Mm:

Cm:

Hz:

mA:

V:

cm²:

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