Research Paper: Comparing Spinomed®and Elderly Spinal Orthosis Use on Kyphosis Angle, Back Pain, and Quality of Life in Elderly With Thoracic Hyperkyphosis

Zahra Rahimi[1], Seyed Mani Mahdavi[2*], Mojtaba Kamyab[3], Haleh Dadgostar[3], Samane Ataei[3]

1. Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran.
2. Department of Orthopedic Spine Surgery, Rasoul-e-Akram Hospital, Iran University of Medical Sciences, Tehran, Iran.
3. Department of Sports Medicine, Rasoul Akram Hospital, Iran University of Medical Sciences, Tehran, Iran.

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ABSTRACT

Objectives: Thoracic hyperkyphosis is one of the most common conditions in the elderly. The use of orthosis and exercise is one of the most effective treatments suggested, but unfortunately, there is little evidence to support this treatment. The study aimed to compare the effect of Spinomed® orthosis and elderly spinal orthosis with exercise and exercise alone on the angle of kyphosis, quality of life, and pain in the elderly with thoracic hyperkyphosis.

Methods: In this study, 40 older adults aged 60 years and older with a kyphosis angle of more than 50 degrees were recruited. The participants were allocated into three groups: Spinomed® orthosis and exercise (n=14), elderly spinal orthosis and exercise (n=15), and exercise only (n=11). The groups were treated for three months.

Results: There was a significant decrease in the kyphosis angle of participants in the Spinomed® orthosis and exercise groups (P=0.005). Pain score was significantly decreased in the Spinomed® orthosis and exercise group (P=0.023). There was only a significant increase in the physical component summary in the Spinomed® orthosis and exercise group (P=0.03) and the elderly spinal orthosis and exercise group (P=0.04) .

Discussion: The combination of Spinomed® orthosis with exercise is the best choice to correct the kyphosis angle, reduce pain, and increase the quality of life. Elderly spinal orthosis and exercise can also improve the quality of life scores.

*** Corresponding Author:**
Seyed Mani Mahdavi
Address: *Department of Orthopedic Spine Surgery, Rasoul-e-Akram Hospital, Iran University of Medical Sciences, Tehran, Iran.*
Tel: *+98 (912) 8331475*
E-mail: *mahdavi.sm@iums.ac.ir*

Highlights

- This study was performed on the elderly with thoracic hyperkyphosis. The purpose of this study was to compare orthosis treatment along with a supervised exercise program.

- Orthotic therapy combined with an exercise program can have an excellent therapeutic effect on reducing kyphosis angle and back pain and increasing the quality of life.

Plain Language Summary

At present, the mean age of the world population is the highest compared to the past. Preventing old-age injuries is the best way to control the health cost of society and improve the quality of life of the elderly. This study is about the hunchback complication that has adverse effects on the health of the elderly. Hunchback causes people to fall, reduces their respiratory capacity and activity, and even increases mortality in the elderly community. Exercise and the use of orthoses are two non-surgical methods in controlling and treating this complication. The purpose of this study was to investigate these treatments and their further combinations.

1. Introduction

The range of thoracic kyphosis for the average population is 20 to 40 degrees which can be measured with the Cobb method on standing lateral radiograph of the spine; when the thoracic kyphosis exceeds 45 degrees, it is called hyperkyphosis [1, 2]. This type of deformity is known as one of the most common age-related postural disorders, with a prevalence of 20%-40% in older people (people higher than 60 years old) [3, 4]. Back pain, postural imbalance in the sagittal plane, mental disorder, reduced respiratory capacity, fatigue, muscle imbalance, and low self-esteem are common complaints of older people with hyperkyphosis [5-9]. This condition may reduce their health-related quality of life [10].

Non-operative treatment of elderly participants with hyperkyphosis is a topic of ongoing research in this field. Therapeutic exercise, orthotic management, gait training, and fall prohibition programs are accepted non-operative treatments of these people [11-13]. People in this age group have limited gadget tolerance and restricted choices for orthoses. Weighted kypho-orthosis, corset support posture, Spinomed®, and Elderly Spinal Orthosis (ESO) alleviate the condition [14-16]. Each orthosis has some studies to support its effectiveness except the ESO, which is commonly used because of its affordable price.

To strengthen the effectiveness of exercise in reducing kyphosis in the elderly, it is better to combine exercise with orthosis treatment [15, 17]. A study by Raeissadat et al. on the elderly with osteoporosis showed that using a weighted kypho-orthosis with an exercise program improves posture and strengthens back extensor muscles [14]. Still, the quality of the exercises has not been the focus of previous studies, and indeed, not all practices are suitable for reducing the kyphosis angle [18, 19]. Custom-designed exercise programs, supervised exercises, and group exercising might improve the therapeutic outcome, but no published studies were found on the combined use of exercise with orthoses.

Considering the insufficient data for long-term outcomes of orthotic treatment in older adults with hyperkyphosis, a specific physical exercise routine must be designed when using orthoses for treatment. Therefore, this study aimed to answer whether the clinical effectiveness can be increased by combining orthotic intervention and therapeutic exercise in managing older people with hyperkyphosis. The hypothesis in the study states that the angle of kyphosis, pain score, and quality of life score will change in all three groups after the intervention.

2. Materials and Methods

This study was a prospective randomized controlled trial study. Data collection, interventions, and assessments were performed at the Orthopedic Clinic of Rasoul-e-Akram Hospital in Tehran, Iran, from February 2020 to June 2020. The study protocol was approved by the Ethics Committee of Iran University of Medical Sciences (IR.IUMS.REC.1398.310) and was registered in the Iran Registry of Clinical Trials (registration No. IRCT20140811018762N2). This study complies with the Consolidated Standards of Reporting Trials (CONSORT) guidance.

The sample size was calculated using G×Power software (v. 3.0.1 was used). Considering α=0.05, power=0.8, and effect size=1 (The effect size was deemed to be based on Cohen's method in similar studies [20] as 1, which has a proportionate and reasonable power), a sample of 17 participants in each group, and a total of 51 people was estimated to be sufficient. Because of the COVID-19 pandemic and ethical issues associated with inviting older people to a general hospital, the researchers were obliged to discontinue the study. Therefore, a total of 40 participants were finally included. Of these, 11 patients were under Exercise-Only (EO) treatment, 14 were under Spinomed® Combined with Exercise (SOE), and 15 were under Elderly Spinal Orthosis Combined with Exercise (ESOE).

Volunteers joined the study using either public invitations or outpatient spine clinics of the hospital. All eligible participants voluntarily signed a written consent form. The inclusion criteria were those aged 60 or over 60 years with a thoracic kyphosis angle above 50 degrees and can sit, stand, and walk at least 10 meters independently [3, 21-24]. The exclusion criteria were having physical abnormalities other than hyperkyphosis that interferes in the research process as determined by a spinal specialist, having a history of fracture or surgery in the lower limb or spine in the last 12 months, central nervous system diseases, and neuromuscular disorders [25-28]. Participants who did not follow the instruction of wearing the orthoses and performing the exercises were excluded from the study [29].

Allocation of a participant to each group was based on the sealed envelope method [30]. The participants were blinded to the randomization process and the study groups. To blind the participants, after grouping, the participants of each group went to the center on particular days to not meet other groups.

In the EO group, the specific exercises were applied to the participants under the supervision of a sports medicine specialist (Sports Medicine Physical Med & Rehab [PMM]). These exercises were prescribed for strengthening the core muscles, upper limb, and lower limb muscles. The participants were asked to take part in a session of 3 hours to learn how these exercises should be performed. After that, they did the exercises at home daily (45 minutes). A brochure was provided to participants to ensure that all movements were performed. The specialists visited the participants every fortnight to check the quality of the exercises and retrain for the new exercise prescription, which was defined based on complaints, comments, and the abilities of each particular participant individually. The strengthening part of the training was started from the second visit with 0.5 kg weight for the upper limb and 1 kg for the lower limb. Then gradually and depending on the participant's ability, the weight increased to 2.5 kg for the upper limb and 3 kg for the lower limb. The visits with the sports medicine specialist took place every fortnight for six consecutive sessions. The participants reported their compliance to the exercise program with a daily schedule.

In the SOE group, the participants were prescribed Spinomed® IV AP orthosis (Medi-Bayreuth, Bayreuth, Germany) (Figure 1) and received the exercises mentioned earlier. The Spinomed® consists of an abdominal pad, a hand-moldable metallic back part, and shoulder straps to retract the shoulders. According to the patient's anatomy, the dorsal metallic back part is flexible and shaped by the orthotist. This orthosis weighs approximately 450 g [31]. The duration of wearing the orthosis was three months, covered for 30 minutes a day in the first two weeks and two hours a day in the remaining weeks to prevent muscle cramps. They also revisited every two weeks. An experienced orthotist readjusted the orthosis on the participant's body shape in each visit. The participants reported their compliance to the exercise program and wearing the orthosis on a provided table daily.

In the ESOE group, the participants received an elderly spinal orthosis and exercise similar to the previous groups. This orthosis consists of a back part, an abdominal pad, a pelvic belt, and velcro closures. The orthosis was worn on the exact timetable as the Spinomed®. The orthosis provides pressure on the spine through its dorsal part, made of metal and covered by soft materials. According to the patient's anatomy, the dorsal frame is flexible and was shaped by the orthotist. This orthosis weighs approximately 900 g (Figure 2). The angle of kyphosis, quality of life, and pain were measured in random order at baseline, and the final assessment was carried out at the end of three months.

The kyphosis angle was measured at the baseline both using x-ray and dual digital inclinometer (Made by; JTech Medical, USA). The x-ray images were used to diagnose the complication of thoracic hyperkyphosis in the participants, and only those whose hyperkyphosis was due to osteoporosis were entered the study. For x-ray, all participants were referred to two constant radiography centers, which were obliged to follow the standard protocol of x-ray capturing for kyphosis evaluation in the elderly. The x-ray acquisition was not repeated in the final assessment to avoid unethical x-ray radiation exposure. Because of the immorality of using x-rays for

Figure 1. Spinomed® orthosis Iranian Rehabilitation Journal

Figure 2. Elderly spinal orthosis Iranian Rehabilitation Journal

less than six months, the inclinometer was used at the beginning and end of the study to obtain changes in the kyphosis angle. The dual digital inclinometer was recalibrated before each assessment based on the producer's instruction by placing the lower part of both device sensors on a flat surface with a 0 slope and pressing the associated button after showing the number 0 on the device. The participant was instructed to stand steady with arms forward, same as the position to take the x-ray. The examiner placed the device's sensors on the T1 and T12 spinous processes, which have been previously marked on the participant's body.

The pain was assessed using a 10-point visual analog scale: 0 indicating no pain and 10 most pain. The participants were asked to rate the amount of back pain on the scale. The quality of life was measured with the short form 36 health survey questionnaire (SF-36). The questions of this questionnaire are divided into two parts: physical component summary (PCS) and mental component summary (MCS). The score of this questionnaire is from 0 to 100. A higher score indicates a better quality of life [32]. The reliability and validity of the Persian version of SF-36 were already investigated [33].

SPSS v. 16 was used for data analysis. In the present study, the α and β errors were set at 0.05 and 0.2, respectively. All data were encoded to prevent any bias and blinded by the statistician. The normal distribution of the quantitative variables was compared with the Shapiro-Wilk test. When normality was assumed, a paired-sample t-test was employed to compare the means of variables in each group before and after the intervention. The Wilcoxon test was used for data that lacked normal distribution (pain in ESOE group, quality of life [PCS] in SOE group, quality of life [MCS] in EO group, and kyphosis angle in EO group). ANCOVA test was used in between-group comparisons. A 1-way ANOVA test was used to evaluate the homogeneity of the study population.

3. Results

In the initial assessments, 187 participants (162 females and 25 males) were recruited. A total of 147 people lacked the inclusion criteria. Ultimately, 40 were willing and eligible to participate in the study. During the investigation, two participants in the SOE group, one participant in the ESOE group, and one participant in the EO group withdrew from the study because of not doing an exercise program, not wearing orthoses according to the instruction (n=1), disinclination to participate in the follow-up sessions (n=2), or diagnosed with cancer (n=1). Finally, 40 participants (36 women and 4 men) with a Mean±SD age of 66.58 (5.14) years (range: 60-80 years), a Mean±SD BMI of 28.27 (4.13) kg/m^2 (range: 19.2-35.5 kg/m^2), and a Mean±SD kyphosis angle of 67.44 (1.05) degrees (range: 50-90 degrees) (Table 1). The amount of power was calculated for the study vari-

Table 1. Mean Body Mass Index (BMA), age, and kyphosis angle at baseline

	Mean±SD		
Variables	**EO**	**ESOE**	**SOE**
Age (y)	66.20±1.23	67.14±8.04	68.81±1.22
BMI (kg/m$^{2)}$	26.55±5.47	29.62±3.51	27.95±4.00
Kyphosis angle (degree)	66.30±4.25	67.14±4.97	66.17±6.11

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EO: Exercise only; ESOE: Elderly spinal orthosis, and exercise; SOE: Spinomed® orthosis and exercise.

ables and was acceptable numerically. In the kyphosis angle, this rate is 0.62, pain is 0.85, quality of life (PCS) is 0.34, and quality of life (MCS) is 0.25.

As shown in Table 1, the changes in kyphosis angle became significant only in the SOE group. In the pain variable, only a significant change occurred in the SOE group, and the changes in the quality of life variable are also substantial in SOE and ESOE groups.

Within-group comparison

Regarding the angle of kyphosis, based on the paired-sample t-test results, there was a significant decrease in the kyphosis angle of participants in the SOE group. However, no substantial reduction in kyphosis angle was observed in the ESOE and EO groups (Table 2).

Also, the paired-sample t-test results showed that the severity of the pain significantly decreased in the participant of the SOE group. This reduction was not significant in EO and ESOE groups (Table 2).

With regard to the quality of life, the paired-sample t-test for the MCS and Wilcoxon test for the PCS in the SOE group showed only a significant increase in the PCS. Similarly, in the ESOE group, based on the paired-sample t-test, there was a significant difference in increasing the PCS but no significant difference in the changes of MCS. Finally, in the EO group, contrary to the MCS group, the paired-sample t-test was applied in PCS. The Wilcoxon test was used in MCP, none of them resulted in a significant difference (Table 2).

Between-group comparison

Based on the findings of the Kruskal-Wallis test, the intergroup changes were not significant in any of the variables (Table 3).

4. Discussion

In this study, the primary purpose was to investigate the effectiveness of conventional back exercise alone, combined with Spinomed® orthosis and elderly spinal orthosis, on pain, kyphosis angle, and quality of life in the elderly. In addition to exercising under the supervision of a sports medicine specialist, an exercise program was personalized for each person. One highlight of the current study was that for the first time, elderly spinal orthosis was compared with Spinomed® orthosis com-

Table 2. Within-group comparison

Variables	Mean±SD								
	EO			ESOE			SOE		
	Before	After	p	Before	After	p	Before	After	P
Kyphosis	66.20±1.23	53.60±9.81	0.24	67.14±8.04	65.44±4.41	1	68.81±1.22	66.55±1.25	0.005*
Pain	5.40±3.62	4.50±3.88	0.09	4±3.65	2.83±2.51	0.12	5.33±3.14	2.89±2.08	0.02*
Quality of Life (PCS)	51.81±2.05	48.74±2.11	0.30	49.34±1.76	57.72±1.82	0.04*	49.58±2.28	65.93±1.84	0.03*
Quality of Life (MCS)	49.99±2.29	58.85±1.53	0.27	51.93±1.83	54.58±1.76	0.31	61.50±2.18	73.23±1.56	0.16

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EO: exercise only; ESOE: elderly spinal orthosis, and exercise; SOE: SpinoMed orthosis and Exercise; MCS: mental component summary; PCS: physical component summary.

Table 3. Between-group comparison

Variables	EO- ESOE-SOE			
	EO	ESOE	SOE	p
Kyphosis	53.60	65.44	66.55	0.57
Pain	4.50	2.83	2.89	0.57
Quality of life (PCS)	48.74	57.72	65.93	0.073
Quality of life (MCS)	58.85	54.58	73.23	0.89

EO: exercise only; ESOE: elderly spinal orthosis, and exercise; SOE: Spinomed® orthosis and Exercise; MCS: mental component summary; PCS: physical component summary.
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bined with exercise. Ultimately, the results revealed that the simultaneous use of Spinomed® orthosis and exercise had the best results in changing kyphosis angle.

Regarding the kyphosis angle, the mean angle of kyphosis decreased significantly only after using Spinomed® orthosis with exercise. Although the reduction in kyphosis angle was slight in the SOE group, the Sinaki et al. study shows that a 2-8 degrees reduction in kyphosis angle can effectively strengthen the back extensor muscles [34]. The reduction of kyphosis angle due to the use of Spinomed® orthosis is consistent with the study findings of Hosseinabadi et al. and Pfeiffer et al. However, the lack of change in kyphosis angle in the exercising alone group contrasts with the Sidi et al. and Katzman et al. studies [16, 35-37]. Fascinatingly, at the beginning of the Sidi et al. study, the mean kyphosis angle was significantly lower than in the present study. It should be noted that exercise may only work for a mild kyphosis angle, and in cases where the kyphosis is severe, a combination of orthosis and training may be needed. As reported in Aboutorabi et al. study, the amount of hyperkyphosis angle is essential in orthosis treatment's effectiveness as it happens in adolescent kyphosis [38, 39]. Therefore, it is suggested that a study be conducted to investigate the efficacy of exercise alone and combined training with an orthosis to develop an adjusted program to determine the need for exercise therapy alone or with orthoses in different kyphosis angles.

Interestingly, there was no significant difference in the mean changes of kyphosis angle in the group related to elderly spinal orthosis with exercise in the present study. The advantage of elderly spinal orthosis is the affordable cost, which is almost one-tenth of the Spinomed® cost and resulted in its widespread usages, particularly in the countries that healthcare costs need to be paid by the elderly. The ineffectiveness of the elderly spinal orthosis may be related to orthosis weight, ease of use, and appearance of the orthosis. Both orthoses initially reduce kyphosis, but the acceptance of elderly spinal orthosis is weak. Therefore, it is possible that people are less inclined to wear it and have not received its effectiveness.

Consequently, it is suggested that the acceptance of two orthoses and the factors affecting the approval of spinal orthoses in the elderly are investigated. Better appearance and its comfortable use can help improve psychological acceptance and compliance.

Regarding pain, the results are very similar to the kyphosis angle, and the arguments for the kyphosis angle seem to apply here as well.

Regarding the quality of life, the findings show a relatively similar difference in the PCS in Spinomed® orthosis and elderly spinal orthosis with exercise. This finding is still in line with the Pfeiffer study [16]. The Pfeiffer study also states that orthoses improve the quality of life, although they attribute this improvement to pain relief. The question that comes to mind is why Spinomed® orthosis and elderly spinal orthosis were equally involved in improving the physical quality of life indicators. In contrast, elderly spinal orthosis was not effective in reducing pain. Wearing spinal orthoses in neurologically intact elderly patients increases biomechanical vertebral stability and enhances postural stability, which may help improve the quality of life. Also, in Arnold's study, there was no significant difference in the quality of life of the experimental and control groups after Aquatic and land exercises, which is consistent with the present study findings [40].

It is recommended to conduct a study to develop an appropriate protocol for prescribing exercise therapy alone and in combination with orthoses in people with hyperkyphosis. Determining a range of kyphosis angles to add orthosis treatment to exercise therapy seems necessary to achieve the best results.

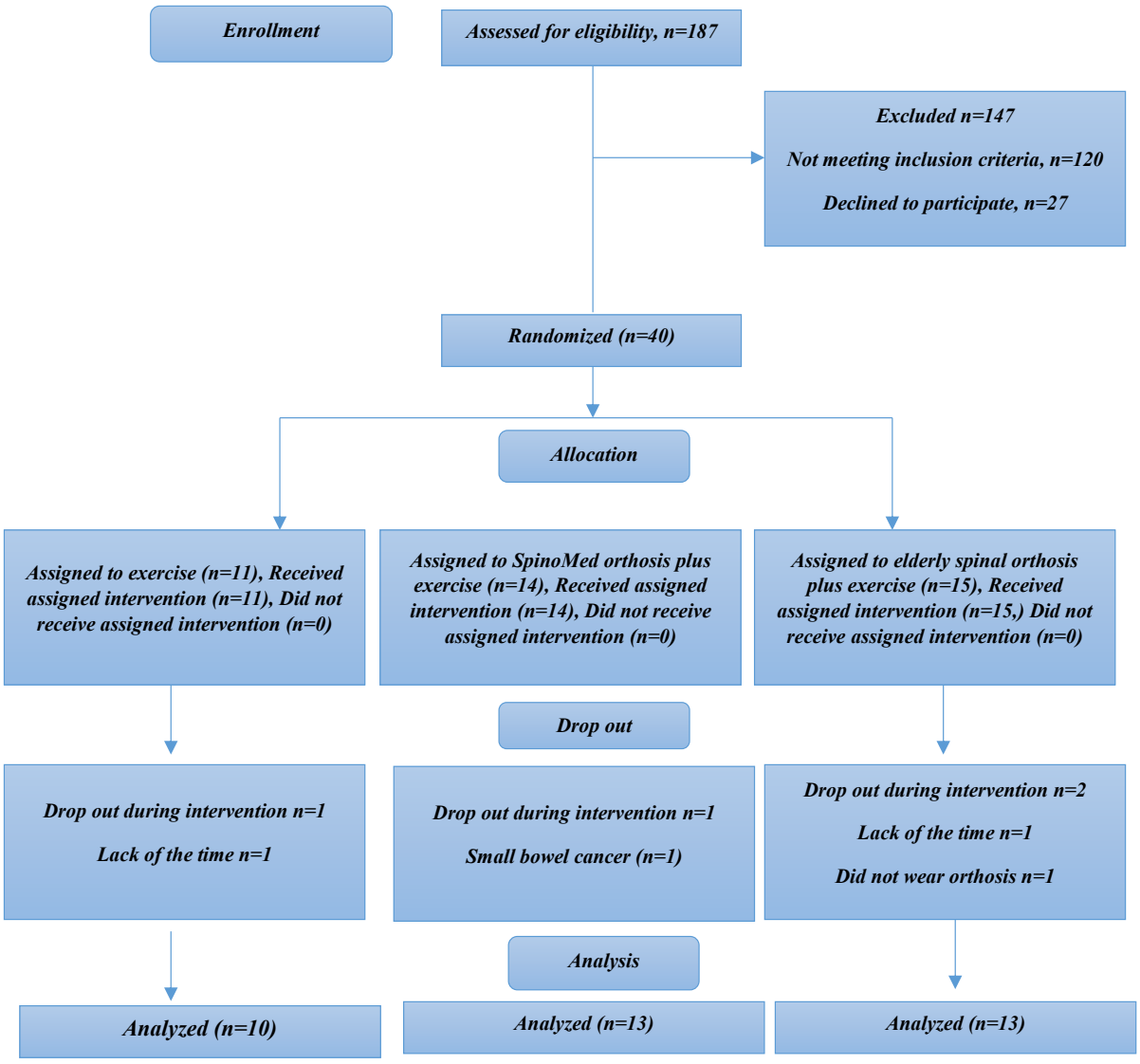

Figure 3. Flow chart of patient enrollment, allocation, and attrition

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The main limitation of this study was the onset of the COVID-19 pandemic worldwide. The spread of the disease prevented some samples from finishing the study. Because of the dangers of radiographic radiation, x-rays were taken from the participants only at the beginning of the study to assess the kyphosis angle for entering the study. Owing to the patients' self-reporting of the assigned tasks, some people might have performed their exercises incompletely or have not used their orthoses enough and not reported these deficiencies.

5. Conclusion

Based on the present study findings, combining Spinomed® orthosis with exercise to correct the kyphosis angle, reduce pain, and increase the quality of life score is more appropriate than the other options proposed. Elderly spinal orthosis along with exercise can also improve the quality of life scores.

Ethical Considerations

Compliance with ethical guidelines

The study protocol was approved by the Ethics Committee of Iran University of Medical Sciences (Code: IR.IUMS.REC.1398.310) and was registered in the Iran Registry of Clinical Trials (Registration No. IRCT20140811018762N2).

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Authors' contributions

All authors contributed equally to the preparation of this manuscript.

Conflict of interest

The authors declared no conflict of interest.

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