

# Research Paper: Comparing In-brace Correction, Compliance, and Quality of Life Between Milwaukee and Lyon Braces in Adolescents With Thoracic Hyperkyphosis



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## ABSTRACT

**Background:** The thoracic curve degree greater than 45° leads to thoracic hyperkyphosis, and common treatment is orthosis treatment. The acceptance rate of orthosis depends on in-brace correction, compliance and patient's quality of life.

**Purpose:** We aimed to determine the comparison between in-brace correction, compliance and quality of life in Milwaukee group with Lyon group

**Methods:** In this case-evidential study, we retrospectively analyzed data for 23 adolescents who wore Milwaukee brace (n=15) and Lyon brace (n=8). In brace correction was assessed by the comparison between Cobb angle before wearing brace and two months after wearing. Compliance was determined by the percentage of actual hours worn in accordance with the prescribed regimen. Quality of life profile for spine deformity questionnaire is used which shows the quality of life in spinal deformity and mental/psychological functions. Data normality was assessed by K-S. Other sampling methods, moreover, included T tests (pair T-test, in depended T-test).

**Results:** We recruited 23 individuals with thoracic hyper kyphosis with 55 and 75 degree and aged between 10-17 years old. They were divided into two groups [Milwaukee group (n=15), mean age: 14 years old, and mean first Cobb angle: 67.9 degree, and Lyon group (n=8), mean age: 13.75 years old, and mean first Cobb angle: 61.7 degree]. No significant differences are found between in-brace correction of two groups (P=0.073), while the compliance of participants who wore Lyon brace is better, and findings depicted significant differences between quality of life (P=0.018), and quality of life was improved for Lyon groups.

**Conclusion:** The finding indicates that the Lyon brace had less detrimental impacts on quality of life in comparison with the Milwaukee ones, take this into account, the compliance rate illuminates that Lyon brace is far more preferred, but surprisingly identical in-brace correction is achieved by both braces. Therefore, consideration and integration of significant factors in the treatment plane are capable to revolutionize the outcome correction.

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## Highlights

- Supplying data on the crucial items impacting the outcome of brace treatment (in-brace correction, QOL and compliance);
- Comparison of two group braces (Milwaukee, Lyon), the results illuminated that the appearance of brace is able to boost the range of compliance and QOL;
- The overall in-brace correction would be improved which it was seen in Lyon brace in comparison with Milwaukee brace.

## Plain Language Summary

This manuscript is determined the influential factors on brace treatment and comparison them between two spinal brace (Milwaukee brace, Lyon brace) in thoracic hyperkyphosis. The effective factors on orthotic treatment were categorized in three variables: in-brace correction, compliance, and quality of life and this paper also discusses patients' mental and physical situation when they wear spinal brace. Our result introduced apt treatment protocol which is established appropriate features for the structure of brace, with concentration on psychological field, and it also provide highly chance to improve brace treatment. The knowledge of comparison between effective factors in two brace groups can provide an appropriate selection of spinal braces in thoracic hyperkyphosis among teenagers and the less of clear research, we believe that the findings presented in our paper will be appeal to medicines, orthotist, physical therapist and even psychologists. Given the mentioned comparison has been crucial to diagnose the success of treatment thus our findings will allow researchers to identify the principles of brace wearing in hyperkyphosis as team work and consider physical and mental patient's situation clearly to improve outcome treatment.

### 1. Introduction

**T**he Scoliosis Research Society has defined the normal value of thoracic kyphosis to range from 20°-40° in growing adolescents [1, 2]. The thoracic kyphotic curve >45° leads to hyperkyphosis deformity [3]. Furthermore, it is the most prevalent disorder in patients with a deformed spine after idiopathic scoliosis [4, 5]. Several conditions result from hyperkyphosis; Scheuermann's disease is a common reason with an incidence of 4%-8% in this respect [6, 7]. In general, if no scientific reason can explain an existing hyperkyphosis, the term "idiopathic hyperkyphosis" is used [3].

Treating hyperkyphosis is crucial in growing children. Untreated kyphosis may lead to increased deformity, back pain, restricted motion, pulmonary disease, and neurological disorders [8-10]. The most common treatment approaches are surgical and non-surgical methods [10-13]. Surgical treatment is prescribed to patients with a curve of >75°; however, it may cause postoperative neurological deficits, infections, vertebra fixator failure, pseudarthrosis, the loss of correction, kyphosis progression, a pulmonary disorder, and the risk of death [14]. Non-surgical treatment is often prescribed for patients

with 45°-75° thoracic kyphosis [15]. It comprises casting, physical therapy, and orthoses; orthotics treatment is the most effective non-surgical treatment for 55°-75° hyperkyphosis deformity [16, 17]. Tribus and Lowe conducted independent studies implemented by an orthotic correction in hyperkyphosis. They concluded that bracing could achieve approximately 50% correction [1, 18]. Different orthoses were prescribed for hyperkyphosis treatment, such as Milwaukee brace [10, 12, 16, 19], Boston brace [13, 20], DuPont brace [21], and Kyphologic brace [22]. Milwaukee brace is widely used to treat hyperkyphosis in adolescents [10, 12, 16, 19]. It typically includes pelvic girdle (pelvic mold), bars (superstructures), and the combination of corrective sling and pads attached to the superstructures [16, 19]. Another brace is called Lyon, which was evaluated in this study for hyperkyphosis treatment. It contains two central bars and collateral shells. Central bars are located in the anterior and posterior parts of a brace from sternal notch to symphysis pubic. The collateral shells apply corrective forces and their function is identical to kyphotic pads in Milwaukee brace [23-25].

The effectiveness of orthotics treatment depends on the evaluation of in-brace correction; it is the best guideline for predicting treatment outcomes [26-28]. Spinal orthoses can provide 50% correction in the brace, and

approximately two-thirds of cases may maintain partial correction in the long term [1, 18]. Other factors which significantly impact brace treatment outcomes are compliance and patient's Quality of Life (QoL) [26, 27]. The Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) revealed that brace compliance should not be ignored because corrective bracing yields a favorable outcome when the patient is compliant [28, 29]. Weinstein also detected a significant association between the average hours of daily brace wear and the odds of a successful treatment outcome [30]. In-brace correction, compliant brace, and patient's QoL are the main factors in curve correction outcomes. Typically, wearing spinal brace impairs QoL in patients with spinal deformity [31]. Moreover, various braces have different effects on the impairment extent [32]. They might create mental health disorders, such as increased stress, psychological disorders, disturbed body image, and a poor self-esteem [33].

Therefore, comparing the effective factors in the two brace groups can provide data on the appropriate brace selection. The current study assessed in-brace correction, compliance, and QoL between patients using Milwaukee brace and Lyon brace

## 2. Materials and Methods

The study population has been extracted from the entire database of a single orthotist and physician based on their records in a spinal clinic in Iran. Inclusion criteria were as follows: the diagnosis of thoracic hyperkyphosis, Cobb angle between  $55^\circ$  and  $75^\circ$ , the age range of 10-17 years, Risser sign 0-2 at the beginning of treatment, full-time brace prescription, no previous treatment received, and the use of Milwaukee and Lyon braces. Exclusion criteria were diagnosed congenital spinal disease, identified scoliosis of  $>10^\circ$ , and any disorder in the shoulder, hip, and lower limbs. In total, 23 patients participated in the study [Milwaukee brace group (n=15), and Lyon brace group (n=8)].

This was a retrospective comparative study regarding the effectiveness of orthosis (in-brace correction), compliance, and the QoL between two brace treatment groups of hyperkyphosis patients. The applied braces were made by the standard procedures of casting, fabrication, and fitting. Kyphotic pads in Milwaukee brace and shells in Lyon brace were the main structures to apply corrective forces. The obtained data were collected using the Quality of Life Profile for Spinal Deformities (QLPSD) scale and the Persian Adaption of Personal Self-Care Assessment Questionnaire [34].

The in-brace correction refers to changing the curve angle, resulted from orthotic treatment, and focused on the effectiveness of treatment. It was assessed by the angle differences in two consecutive X-rays conducted before and two months after brace treatment [22].

All patients were prescribed with full-time bracing (max: 22 hours daily, min: 18 hours daily). In the present study, compliance was subjectively measured via in-person interviews. The study subjects were requested to report the hours spent wearing the brace per day. The compliance rates were determined by the following formula:  $(\text{wearing time} \times 100) / \text{prescribed time}$ .

QoL refers to the psychosocial aspects of orthotic treatment. QoL measurement instruments, including the QLPSD questionnaire [34], were applied. It contains 21 items and 5 groups of variables describing 5 factors in terms of labeled psychosocial functioning, sleep disturbance, back pain, body image, and back flexibility. Administering QLPSD averagely lasts 10 minutes. Each item is allocated a score of 5 (strongly agree), 4 (agree), 3 (undecided), 2 (disagree), to 1 (strongly disagree). Higher scores indicate highly impaired QoL. Additionally, the maximum obtained score was 105. Scoring time also took about 2 minutes [35].

The relevant data were summarized by descriptive statistics, including mean and standard deviation. An in-brace correction was defined as the difference between the mean scores of Cobb angles in the two X-ray phases. Data normality was assessed by the Kolmogorov-Smirnov (K-S) test. In addition, all collected data were evaluated using the Paired Samples t-test. The Independent Samples t-test was used to compare in-brace correction as well as compliance between the two groups. To determine the patients' QoL, the mean scores of QLPSD were measured, and an Independent Samples t-test was used.

## 3. Results

The present study investigated 23 patients; among whom, 15 (6 females and 9 males) wore Milwaukee brace, and 8 subjects (2 females and 6 males) were prescribed Lyon brace. The mean age and initial Cobb angle of the Milwaukee group were  $14 \pm 0.65$  years, and  $67.9 \pm 6.3^\circ$ , respectively. These variables in patients treated with Lyon brace were  $13.75 \pm 0.88$  years, and  $61.7 \pm 6.6^\circ$ , respectively. Then, the significant variables in brace therapy (baseline characters) were matched between the two groups. They included age, height, weight, Body Mass Index (BMI), and initial Cobb angle. The rel-

**Table 1.** Subject characteristics at baseline (N=23)

| Variables                | Mean±SD                |                  | P     |
|--------------------------|------------------------|------------------|-------|
|                          | Milwaukee Group (n=15) | Lyon Group (n=8) |       |
| Age (y)                  | 14±0.65                | 13.75±0.88       | 0.449 |
| Height (cm)              | 166.2±8.68             | 161.5±11.05      | 0.273 |
| Weight (Kg)              | 74±7.51                | 50.38±5.47       | 0.095 |
| BMI (Kg/m <sup>2</sup> ) | 26.7±2.30              | 20.34±1.74       | 0.892 |
| Initial Cobb angle       | 67.9±6.3               | 61.7±6.6         | 0.291 |

PHYSICAL TREATMENTS

**Table 2.** The overall data of both brace treatments

| Variables                | Mean±SD                |                  | P     |
|--------------------------|------------------------|------------------|-------|
|                          | Milwaukee Group (n=15) | Lyon Group (n=8) |       |
| Initial Cobb angle       | 67.9±6.3               | 61.7±6.6         | 0.291 |
| Secondary Cobb angle     | 42.9±10.5              | 42.4±7.9         | 0.282 |
| Compliance               | 65.60±18.40            | 76.25±7.50       | 0.044 |
| Overall QoL              | 62.8±11.97             | 51.13±6.08       | 0.018 |
| Psychosocial functioning | 20.07±3.61             | 15±2.72          | 0.002 |
| Sleep disturbance        | 11.8±4.09              | 9.75±1.7         | 0.192 |
| Back pain                | 8.53±2.7               | 6.50±1.51        | 0.061 |
| Body image               | 11.67±3.67             | 12.38±1.06       | 0.603 |
| Back flexibility         | 10.73±3.28             | 7.50±1.30        | 0.015 |

PHYSICAL TREATMENTS

evant data were compared by the Independent Samples t-test. Accordingly, there was no difference between the two groups in terms of the characteristics mentioned above (Table 1).

The in-brace follow-up visit was conducted approximately 2 months after the brace fitting session. The in-brace correction was measured by the Cobb angle differences before starting brace therapy and 2 months later by comparing the X-ray images in two phases. Cobb mean values were 67.9°±6.3° and 61.7°±6.6° at the study onset in Milwaukee and Lyon groups, respectively. However, there was no significant difference in this regard (P=0.291). Moreover, both groups were identical in terms of initial Cobb angles. Overall, X-ray images suggested correction in all patients 2 months after wearing the brace (P=0.001). Thus, both brace types created correction with a similar outcomes. However, Cobb mean values were 42.9°±10.5° and 42.4°±7.9° at follow-

up phase in Milwaukee and Lyon groups, respectively. Therefore, there was no significant difference between the groups (0.282) (Table 2).

The prescribed braces were advised to be worn for 18-22 hours per day. Diary time was calculated by manually aggregating daily worn time from the patient diary. The compliance reported as the percentage variable of reported hours brace wear by patients versus the prescribed hours. The adherence determined from the hours reported in the Lyon group was 76.25±7.50. This value was higher than that of the Milwaukee group (65.60±18.40). Additionally, a difference was detected in the mean score of compliance between the two groups (P=0.044). The obtained results suggested that patients prefer to wear Lyon brace (Table 2).

In the present study, QoL was measured by the QLPSD questionnaire. The collected overall and subset scores

are presented in Table 2. The overall obtained score was higher in the Milwaukee group ( $62.7 \pm 9.7$ ), compared with the Lyon group ( $51.13 \pm 6.8$ ). Significant differences were observed in this regard ( $P=0.018$ ). Furthermore, QoL was more impaired by the Milwaukee brace, in comparison with the Lyon brace. Using the same model, significant differences were found between the two groups regarding the QLPSD domains' mean scores on psychosocial functioning ( $P=0.002$ ), and back flexibility ( $P=0.015$ ). Psychosocial functioning was related to the mental situation; however, back flexibility was related to the physical region. Therefore, comparing the mean score of two subsets revealed more biopsychological impairment of Milwaukee brace, compared with Lyon brace (Table 2).

#### 4. Discussion

The current study explored the most significant factors in Milwaukee and Lyon brace to approach appropriate orthotic treatment. As a result, we assessed in-brace correction, compliance, and effects of braces on the study patients' QoL. An in-brace correction could predict the success rate of brace treatment [36]. Landauer et al. [27] suggested that an initial correction of  $>40\%$  and in compliance had significant effects on treatment outcomes. In the present study, orthotic treatment with a Milwaukee brace had almost the same treatment outcome as Lyon brace. The obtained results also indicated that Lyon brace, as TLSO, surrounds the low surface of the trunk which was identical to Milwaukee brace (as CTLSO and high surroundings). Moreover, a positive impact on in-brace correction in TLSO, compared with the Milwaukee brace, was observed by Uden and associates [37]. However, Gutowski and Renshaw [16] reported reverse results in terms of comparing TLSO and Milwaukee braces. Besides, the age of their study population (juvenile 3-9-year-olds) also differed with the present study. Patients are interested in wearing a brace with the most possible comfort that encompasses the low surface of the trunk.

Surrounding all of the trunk and having cervical ring is an annoyed factor in Milwaukee brace that prevent wearing it as per the prescribed time; it also revealed similar treatment outcomes as TLSO. The low compliance of spinal bracing with hyperkyphosis is an ongoing problem with the orthotic treatment. In the present study, such compliance was reported subjectively by the study participants. The achieved results indicated that highly compliant patients wore the Lyon brace as per the prescribed hours. The possible explanation for higher compliance in the Lyon group is related to its appearance and

the lack of cervical rings that provide better compliance. Moreover, the appearance and construction of brace significantly affect the patient's compliance. Patients' cooperation in the brace design process helps reduce negative emotions. The co-design by patients concept can be introduced in the first patient-orthotist meeting; it could provide an opportunity for patients to select their favorite color and design.

Brace therapy affects emotional situations, social relations, and psychological reactions. These behaviors are related to QoL. The present study measured the QoL using the QLPSD instrument. This instrument measured psychosocial functioning, sleep disturbance, back pain, body image, and back flexibility. Such data were compared between the Milwaukee and Lyon brace user groups. The QLPSD is a useful instrument to test patients' mental (psychosocial function, body image), and physical (sleep disturbance, back pain, back flexibility) states.

Both brace groups reported the braces' negative impacts on their overall QoL. We observed different QoL scores in the two groups, and the impairment was higher with the Milwaukee brace. Milwaukee group also indicated more impairment in psychosocial functioning, compared to the Lyon group. The brace's appearance significantly impacts individuals' mental state. Setting a counseling session in the treatment plane can provide education to patients and their parents regarding brace therapy concerning the psychological aspect and a safe environment. The present study indicated that the back flexibility of the physical aspect was different between the two brace groups.

Moreover, the back was more restricted in the Milwaukee group. The possible explanation for such difference is that the Milwaukee brace contains superior (cervical ring) and inferior ends (pelvic basket). It also surrounds patients trunk stiff by supra structural. Therefore, this brace decreases the flexibility and motions of the trunk. However, the lack of cervical ring and pelvic girdle in Lyon brace provides more space for patients' physical state, especially back flexibility according to the similarity of in-brace correction between the two brace groups.

#### 5. Conclusion

This study provided data on the factors affecting brace therapy, such as in-brace correction, compliance, and QoL in thoracic hyperkyphosis participants. Lyon brace, compared to the Milwaukee brace, is more preferred among patients. The two groups demonstrated compa-

rable results in brace correction. However, high compliance and low impaired QoL were observed in the Lyon group. Evaluating significant factors in the treatment plan can improve brace treatment outcomes. Further investigations are essential to design a plan for brace treatment, considering the structure and appearance of brace, patients' cooperation, and co-design in construction processes. Moreover, they should pay more attention to patients' mental aspects.

## Ethical Considerations

### Compliance with ethical guidelines

Research involving human participants. All ethical principles were considered in this article. The participants were informed about the purpose of the research and its implementation stages; they were also assured about the confidentiality of their information; moreover, they were allowed to leave the study whenever they wish, and if desired, the results of the research would be available to them.

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### Authors' contributions

Conceptualization and Supervision: Reza Vahab Kashani, Farhoud Saeid Ershadi; Methodology: Masoud Karimlo; Investigation: Sara Rahimi; Writing-original draft and Resources: Reza Vahab Kashani, Farhoud Saeid Ershadi, Masoud Karimlo, Sara Rahimi; Writing-Review & editing: Reza Vahab Kashani, Farhoud Saeid Ershadi, Masoud Karimlo.

### Conflict of interest

The authors declared no conflict of interest.

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