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Original Article

Effectiveness of the Osaka Medical College Brace for the Treatment of Idiopathic Scoliosis: A 1-Year Outcome Analysis

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The Osaka Medical College (OMC) brace is an underarm spinal orthosis for the treatment of scoliosis. It consists of a plastic pelvic section with a pad extended from the lateral bar to correct the convexity of the curve. The plastic cover on the trunk is minimized, and thus perspiration under the plastic contour is reduced. This is favorable for people who are heat intolerant or for those living in a hot and humid climate. In Taiwan, the use of the OMC brace has been increasing because it allows for good ventilation, is light, and has a less-restrictive design, yet its effectiveness has not been described adequately in the literature. In the present study, we analyzed the change in the Cobb angle 1 year after bracing in 81 patients fitted with an OMC brace for the treatment of idiopathic scoliosis. During the study, 23 patients (28.4%) were lost to follow-up and were regarded as dropouts. Among the 58 patients remaining for analysis, 13 (22.4%) belonged to the brace failure group (curve progression $>$ 5° at 1 year after bracing) and 45 (77.6%) belonged to the brace success group (curve progression $\leqq$ 5° at 1 year after bracing). No statistically significant difference existed between these 2 groups in terms of gender, curve type, side of curve vertex, and major curve level ($p > 0.05$). There was a significant difference in the mean age at which the need for bracing was presented between the brace failure group (10.7±3.2 years) and brace success group (12.4±2.1) years) ($p = 0.028$); this indicates that patients who present with symptoms at a young age have poor prognosis. We suggest the OMC brace is an effective spinal orthosis for the treatment of idiopathic scoliosis, and further research is needed to investigate what kind of brace will be suitable for individuals with early onset of scoliosis in the future. (Tw J Phys Med Rehabil 2011; 39(1): 9 - 16)

Key Words: Osaka Medical College, brace, idiopathic scoliosis

INTRODUCTION

Idiopathic scoliosis is a structural deformity of the spine in which the frontal plane curve is greater than 10°, the cause of which is unknown. It accounts for 80-90% of all cases of scoliosis and is one of the most common spinal disorders in adolescents.[1-4] According to Chung et al screening of children in a primary school revealed that the prevalence of scoliosis in the school was estimated to

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be 3.76%, the most prevalent type of scoliosis being idiopathic scoliosis.[5] This result is comparable to that of previous studies, which reported the prevalence of idiopathic scoliosis as 1.8-4% elsewhere in the world.[6,7]

Scoliosis may cause musculoskeletal imbalance, cardiopulmonary compromise, and negative self-body image due to unpleasant cosmesis. Early intervention is important to prevent these complications. For skeletally immature patients with idiopathic scoliosis with the Cobb angle in the range of 20°-40°, the use of spinal orthosis remains the treatment of choice to arrest curve progression.[8,9] The Milwaukee brace was the first modern brace for the treatment of scoliosis.[10,11] This type of cervico-thoraco-lumbo-sacral-orthosis (CTLSO) is now less frequently prescribed because of its bulky and conspicuous appearance, though it is still used in scoliosis patients with the curve apex at or above T8. For treating a curve with the apex below T8, the thoraco-lumbo-sacral-orthosis (TLSO) is preferred because it can be placed under the arm and has a removable cervical component.[12-14]

A variety of underarm TLSOs are available now. They can be hidden underneath one's clothes and are therefore preferred to the Milwaukee brace. On the basis of the traditional Boston brace, which is a prototype of TLSO made from polypropylene, modifications are made to increase the patient compliance.[12] The Wilmington brace is a custom-made plastic brace with an anterior opening. It was originally fashioned from low-temperature plastic (Orthoplast), which made the brace more lightweight.[13] The Charleston bending brace overcorrects the scoliotic curve in recumbent position, and is worn only at night.[14]

The Osaka Medical College (OMC) brace is also a TLSO-type brace developed in Japan.[15] It is composed of a plastic pelvic section with a pad extended from the lateral bar to correct the convexity of the curve (Figure 1). It can be placed under the arm, like the other types of TLSOs; this significantly decreases its impact on daily activities such as sitting and squatting. The plastic cover on the trunk is minimized, and therefore perspiration under the plastic contour is reduced. This increases chances of patient compliance in heat-sensitive individuals.

In Taiwan, the summers are humid and hot. Considering that the effect of bracing will be largely influenced by patient compliance, the use of the OMC brace for the treatment of idiopathic scoliosis has been increasing in Taiwan. However, the efficacy of the OMC brace has not been adequately described in the literature. In the present study, we aimed to investigate the effectiveness of the OMC brace for the treatment of idiopathic scoliosis and to determine the influencing factors.

MATERIALS AND METHODS

Subjects

Patients diagnosed with scoliosis by a physiatrist or orthopedic surgeon between June 1998 and July 2008 were referred to our orthotic department for fabrication of a scoliosis brace. The inclusion criteria were as follows. (1) The individual should have scoliosis confirmed by whole spine radiography in the posteroanterior (PA) view showing the frontal plane curve as >10°. (2) The age of diagnosis should be >3 years. (3) The patient should not have made any previous attempts at bracing and should not have undergone surgery before treatment with the OMC brace was initiated. (4) The patient should be diagnosed with idiopathic scoliosis. (5) The patient should visit the outpatient clinic for at least 1 year. The status of serial clinical examinations and radiographs was recorded by chart review. The exclusion criteria includes (1) an age of <3 years at the time of diagnosis, (2) history of secondary scoliosis, (3) history of wearing a spinal orthosis other than the OMC brace, and (4) dropping out of the study within 1 year.

Orthotic management program

The OMC braces were fabricated by the same orthotist. Patients were instructed to wear the brace for at least 16 hours per day, and to undergo follow-up examinations entailing PA radiography in the standing position every 6 months. Once skeletal maturity (Risser 4) was reached, the patients were weaned off the brace by decreasing the bracing time to wearing the brace only in the evenings. During this period, the patients were requested to undergo yearly follow-up examinations, which entailed obtaining a PA radiograph of the brace when in the standing position, until they discontinued wearing the brace. If the curves progressed to beyond 50°, surgical treatment with instrumentation and arthrodesis was indicated. Individuals who refused surgery were asked to follow up with

radiographs at 1-2-year-intervals after they discontinued wearing the brace.

Radiographic analysis

The whole spine PA radiograph, ranging from the distal iliac crest to most of the cervical spine, was obtained with the patient in the standing position. Radiographs from each patient were reviewed by the same physician to determine the curve pattern, which took the shape of an "S" (double curve) or a long "C" (single curve). The upper end vertebrae and lower end vertebrae of all curves were recorded, and the curve magnitude was measured by the Cobb method. The level and side of the scoliosis were determined by the apex of the convexity of the curve or by that of the major curve for the double curve type. Radiographic assessment was recorded at the initial evaluation and at all follow-up examinations performed after the brace was removed. The Risser grading system was used to evaluate skeletal maturity. As in the literature reviewed, patients with curve progression of $>5°$ after bracing for 1 year were included in group A (brace failure group); and those with curve progression of $\leqq 5°$ after bracing for 1 year, in group B (brace success group).[8,9,11,15,16]

Statistical analyses

Statistical analyses were performed by the statistics software SPSS 10.0. Categorical variables such as gender, curve pattern (single curve or double curve), side of the curve vertex (left or right), and level of the curve (thoracic or lumbar) were compared by using the Chi-square test or Fisher's exact test. Numerical data such as age at which the patient started wearing the brace and the Cobb angle were analyzed by the independent *t* test. Significant difference was defined as a *p* value that is <0.05.

RESULTS

Data of 81 patients were obtained; however, complete data of only 58 patients was available for further analysis, and 23 patients were lost within 1 year of follow-up. Of these 58 patients (6 men and 53 women), 38 (65.5%) showed a single curve; and the remaining 20 (34.5%), a double curve. Regarding the side of the curve vertex, 22 patients (37.9%) had left-side curve vertex, and 36 patients (62.1%) had right-side curve vertex. As for the curve level, 41 patients (70.7%) had a major curve in the thoracic spine, and 17 patients (29.3%) had a major curve in the lumbar spine.

Depending on curve progression at a 1-year follow-up examination, the 58 patients were divided into group A (brace failure group with a curve progression of $>5°$ after bracing for 1 year; Figure 2) and group B (brace success group with a curve progression of $\leqq 5°$ after bracing for 1 year; Figure 3). There were 13 patients in group A and 45 patients in group B. No significant difference existed between the 2 groups in terms of gender, curve type, side of curve vertex, and major curve level ($p > 0.05$, Table 1).

The mean age of presentation for bracing was 10.7 (3.2) years in group A, and 12.4 (2.1) years in group B. The *p* value was 0.028, indicating a significant difference between these 2 groups (Table 1).

The apex of the major curve was analyzed. We classified the apex of the major curve as above T8, T9~T11, T12~L1, and below L2. There were 20 patients with the apex above T8 (group A, 35%; group B, 65%), 20 patients with apex at T9~T11 (group A, 15%; group B, 85%), 15 patients with apex at T12~L1 (group A, 6.7%; group B, 93.3%), and 3 patients with apex below L2 (group A, 66.7%; group B, 33.3%). The OMC brace was inclined to be more effective in patients with the apex of scoliosis below T8 and above the L2 level (Table 2).

The average initial Cobb angle was 28.1° (7.7°) in group A and 28.8° (7.2°) in group B ($p > 0.05$). At a 1-year follow-up examination, the curve magnitude increased to 40.1° in group A, whereas it slightly decreased to 25.0° in group B. The independent *t* test however showed that the curve regression in group B had no statistical significance ($p = 0.76$) (Figure 4).

DISCUSSION

Patients with scoliosis not only have a cosmetic problem due to asymmetric appearance but also decreased cardiopulmonary function, arthralgia, back soreness, poor perception of body image, and awareness of being less healthy.[16,17] Other issues that have been reported include decreased vital capacity, tachypnea, impaired exercising capacity, and reduced working capacity by as much as

14%.[18-20] The ultimate goal of bracing in patients with scoliosis is to prevent the need for surgery rather than to correct the curvature. To assess the bracing efficacy, however, majority of the literature uses curve progression of more than 5° as a benchmark for bracing failure.[8,9,11,15,16] Katz et al compared the use of the Charleston brace to the Boston brace in the treatment of idiopathic scoliosis in adolescents. In subjects with smaller curves, i.e., between 25° and 35°, more than 5° of progression was noted in 47% and 29% of the Charleston and Boston groups, respectively. The difference was significant in patients with larger curves, i.e., in the range of 36° to 45°; of these patients, 83% of those in the Charleston group and 43% of those in the Boston group had a curve progression of more than 5°.[21] In a 25-year retrospective study on 1,020 cases of idiopathic scoliosis in adolescents, Lonstein and Winter reported a 40% rate of Milwaukee brace treatment failure, which was defined as a curve progression of ≥5°.[11] Our study showed a 22.4% failure rate (13 in 58 cases) after the patients used the OMC brace for 1 year. The OMC brace is an effective orthosis for the treatment of idiopathic scoliosis as reflected by improvements in the curve progression rate.

Table 1. Scoliosis curve and age at which bracing was initiated

	Total	Group A	Group B	*p* value
Patient Number	N = 58 (100%)	N = 13 (22.4%)	N = 45 (77.6%)	
Gender, N (%)				
Male	6 (10.3%)	1 (7.7%)	5 (11.1%)	
Female	52 (89.7%)	12 (92.3%)	40 (88.9%)	$p = 0.59$
Curve type, N (%)				
Single curve	38 (65.5%)	8 (61.5%)	30 (66.7%)	
Double curve	20 (34.5%)	5 (38.5%)	15 (33.3%)	$p = 0.73$
Side, N (%)				
Left	22 (37.9%)	5 (38.5%)	17 (37.8%)	
Right	36 (62.1%)	8 (61.5%)	28 (62.2%)	$p = 0.96$
Level, N (%)				
Level T	41 (70.7%)	9 (69.2%)	32 (71.1%)	
Level L	17 (29.3%)	4 (30.8%)	13 (28.9%)	$p = 0.57$
Age at which bracing was initiated (mean (SD))	12.0 (2.5)	10.7 (3.2)	12.4 (2.1)	$p = 0.028$*

Group A, brace failure group. Group B, brace success group. No statistically significant difference exists between groups A and B in terms of gender, curve type, side of curve vertex, and major curve level ($p > 0.05$). There is a significant difference between the 2 groups with respect to the age at which bracing was initiated ($p < 0.05$).

Abbreviations: N: number; Side: side of the scoliosis convexity; Level: spinal level of the curve vertex (or vertex of the major curve for the double curve).

*Statistically significant difference

Table 2. Apex of major curve

	Group A	Group B
Above T8	7 (35%)	13 (65%)
T9-T11	3 (15%)	17 (85%)
T12-L1	1 (6.7%)	14 (93.3%)
Below L2	2 (66.7%)	1 (33.3%)

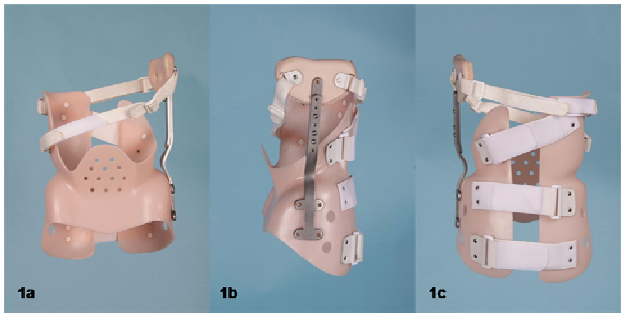

Figure 1. Osaka Medical College (OMC) brace in anterior (1a), lateral (1b), and posterior (1c) views.

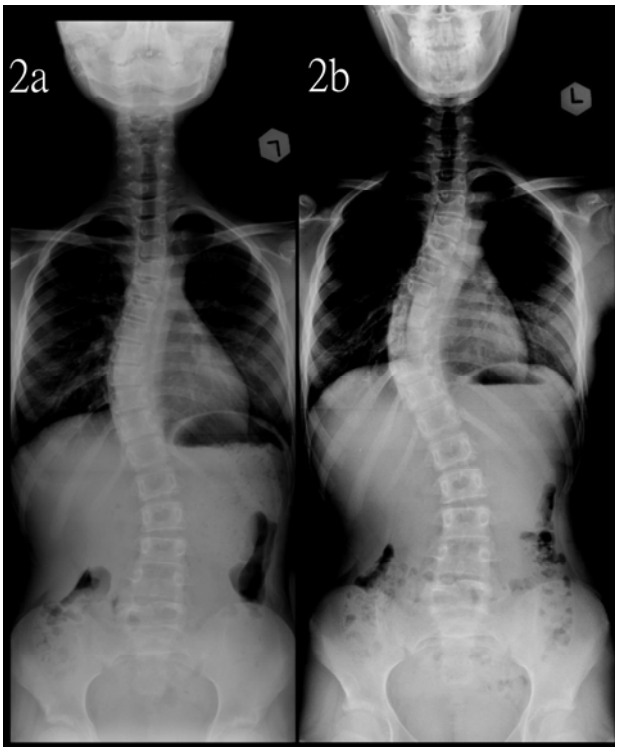

Figure 2. Curve progression in the brace failure group. One of the cases in the brace failure group (group A) shows a curve progression of >5° on the radiograph at 1 year after bracing was initiated. (2a, before bracing; 2b, 1 year after bracing was initiated)

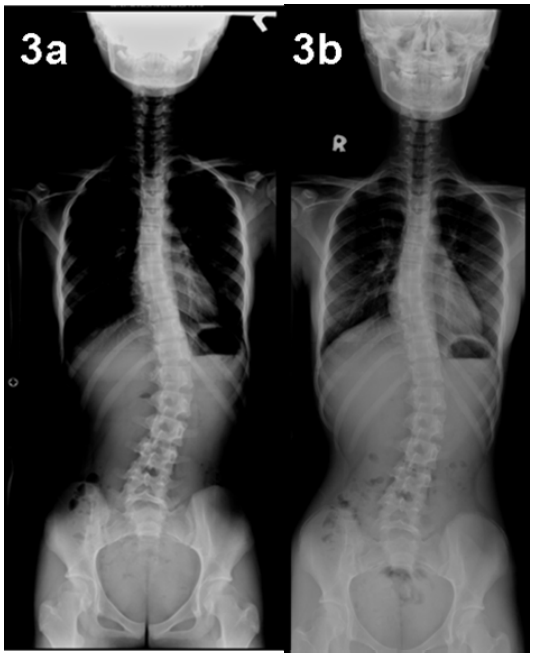

Figure 3. Cessation of curve progression in the brace success group. The radiograph illustrates cessation of curve progression after bracing for 1 year in the brace success group (group B). (3a, before bracing; 3b, 1 year after bracing was initiated)

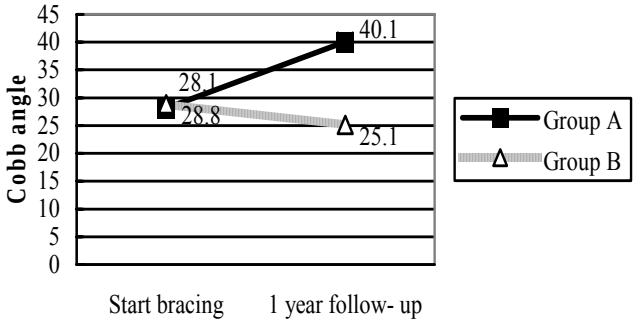

Figure 4. Cobb angle at the time when the need for bracing was presented and at the 1-year follow-up examination. No significant difference exists in the average initial Cobb angle at the time when the need for bracing was presented between groups A and B (28.1° vs. 28.8°, p >0.05). At the 1-year follow-up examination, the curve magnitude increased to 40.08° in group A and slightly decreased to 25.01° in group B.

In the literature, reports on the OMC brace are few. Wang et al first described treatment with an OMC brace in patients with idiopathic scoliosis in Taiwan. However, this was a preliminary report on 6 cases, and focused only on the immediate corrective effect it had on the spinal curve.[22] Lin et al reported an average reduction of 19%

in the curvature magnitude in 22 adolescent patients with scoliosis who were treated by the OMC brace, but the overall success rate of bracing was not reported.[23] In Japan, Kuroki et al analyzed the outcome of treatment with the OMC brace in 66 patients with idiopathic scoliosis. They judged bracing successful when the curve progression was controlled within 5°, and reported a success rate of 76% at a 1-year follow-up examination.[15] Our study involving 58 patients demonstrated a similar result, with the success rate touching 77.6%. These findings suggest that the OMC brace is beneficial for some patients with idiopathic scoliosis. In the present study, we obtained a similar result as that in the study conducted by Kuroki et al. The present study also demonstrates a 22.4% failure rate. The time of onset of scoliosis plays a major role in the success of the treatment. The results of the present study showed that the need for bracing when presented at an early age resulted in poor prognosis when the OMC brace was used ($P < 0.028$).

According to Bunnell, scoliotic patients who are younger than 12 years are at a 3 times higher risk of curve progression than older patients.[24] In the present study, the only significant difference between groups A and B was the age at which the need for bracing was presented ($p = 0.028$). Patients who were young at the start of bracing presented with poor prognosis. Both groups had comparable degrees of the Cobb angle at presentation (29.12° and 28.63° in groups A and B, respectively). Our results support the finding that the age of diagnosis is negatively correlated with the prognosis of the scoliosis.[25]

The potential advantage of the OMC brace is that it allows for good ventilation, is light, and has a less-restrictive design. It is assumed that the OMC brace is better than the traditional types of TLSOs in terms of patient acceptability. In spite of this, 23 of 81 patients were lost to follow-up and were regarded as dropouts. The dropout rate was 28.4% (23 of 81), which is higher than the 14% dropout rate reported by Nachemson and Peterson[26] and 15% reported by Maruyama et al.[27] Some of the dropouts in our study were contacted by telephone, and they stated that functional discomfort and cosmetic concerns were the major causes for discontinuing the use of the brace. Further large scale prospective and long- term studies are needed to investigate the factors contri- buting to a high dropout rate.

Patient compliance is a major determinant affecting the prognosis of scoliosis.[12,28] The principle of the OMC brace is based on the traditional three-point control theory. Forces are applied to the concave side above and below the level of the vertex of the curve, with a countered force applied to the convex side at the vertex of the curve.[1] Pressure applied to the trunk may be a source of discomfort, leading to poor compliance or even dropout among patients. In these cases, modifications of bracing systems or diversified options of braces, such as the dynamic SpineCor brace, may be alternatives to help improve the outcome of bracing.[29]

CONCLUSIONS

The choice of a brace for patients with idiopathic scoliosis is complex and not conclusive yet. The present study indicated that the use of the OMC brace is an effective treatment. Individuals who present with the need for bracing at a young age may have poor prognosis. Future studies should investigate whether other bracing systems have better therapeutic effects in young individuals.

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大阪醫科大學背架治療原發性脊椎側彎之效果：穿戴一年結果分析

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大阪醫科大學背架爲治療脊椎側彎之腋下型背架，它由塑膠骨盆基座延伸之側邊金屬連桿固定上端墊片，藉以矯正脊椎曲度。其包覆在軀幹之塑膠面積比例較低，因此可減少軀幹皮膚與塑膠材質因接觸悶熱所造成之流汗，而這有利於怕熱或生活在濕熱環境之病患穿著。由於大阪醫科大學背架具有透氣、重量輕、與拘束少的特點，在台灣的使用日漸普及，然而其治療脊椎側彎之效果，在國內外之文獻報導都很有限。本研究收集了 81 位在本院訂作大阪醫科大學背架之原發性脊椎側彎病患，分析他們穿著背架一年後之效果。81 位病患中有 23 位(28.4%)在一年後失去追蹤，被歸入流失組。在剩下 58 位中，13 位(22.4%)爲背架失敗組(一年後側彎角度的增加大於 5 度)，45 位(77.6%)爲背架成功組(一年後側彎角度的增加小於或等於 5 度)，兩組間無論在性別分佈、側彎型態、側彎方向、與側彎位置上，均無統計差異存在($p>0.05$)。背架失敗組開始穿戴背架之平均年齡(10.7±3.2 歲)明顯低於背架成功組開始穿戴背架的平均年齡(12.4±2.1 歲)(p =0.028)，顯示較小年紀就達到須以背架治療脊椎側彎的條件而開始穿戴背架，其預後較差。根據此研究，我們認爲大阪醫科大學背架不失爲治療原發性脊椎側彎的有效方法，但仍需進一步研究發展更爲有效的脊柱側彎背架治療策略，並降低病患追蹤流失率。（台灣復健醫誌 2011；39(1)：9 - 16）

關鍵詞：大阪醫科大學(Osaka Medical College)，背架(brace)，原發性脊椎側彎(idiopathic scoliosis)

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