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EFFECTIVENESS OF GENSINGEN BRACE TREATMENT FOR ADOLESCENT IDIOPATHIC SCOLIOSIS: A PROSPECTIVE COHORT STUDY

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ABSTRACT

Objective: The efficacy of brace treatment for patients with adolescent idiopathic scoliosis (AIS) remains controversial. This study aimed to evaluate the effectiveness of Gensingen brace treatment in patients with AIS (identified using the Scoliosis Research Society inclusion criteria) and explore factors affecting treatment success rates.

Materials and Methods: This study included twenty-five patients diagnosed with AIS and treated using a Gensingen brace between April 2015 and February 2018. Initial brace correction rates and progression of the main curves were evaluated. Treatment outcomes were classified into a) progression if ⩾6° increase in curvature was observed and b) improvement in case of ⩾6° decrease in curvature. The association between treatment success rate and age, gender, Lenke classification, Risser grade, initial Cobb angle, and rotation grade was examined.

Results: The spinal curvature was seen to progress in 13 cases, improve in two cases, and remain unchanged in 10 cases, yielding a success rate of 48% (12/25). Moreover, only three out of 25 cases exhibited progression of the Cobb angle above 45° requiring surgery. The mean pre-brace Cobb angle of the main curves was 27.9°±6.7° (range: 20° to 37°) and the mean duration of brace treatment was 37.2 months (range: 6-76 months). The mean Cobb angle at the end of treatment was 32.1°±8.2° (range: 15° to 45°). Successful treatment outcomes were correlated with initial Cobb angle (r=0.680; p=<0.001), rotation grade (r=-0.458; p=0.028), and main thoracic Lenke classification (r=0.481; p=0.020), although no such association with age and Risser grade was observed.

Conclusion: The patient's age, Risser grade, and gender showed no significant association with successful treatment outcomes, although initial Cobb angle, rotation of apical vertebra, and Lenke classification did.

Keywords: Brace treatment, Gensingen brace, adolescent idiopathic scoliosis, conservative treatment

INTRODUCTION

The ideal treatment plan for patients with adolescent idiopathic scoliosis (AIS) and Cobb angles between 10-25° is still unclear, with several studies suggesting rehabilitation and bracing as a viable conservative treatment option[1-3]. Bracing is usually suggested for patients with spinal curves of 20-30°, and a curvature improvement of 5° or more may be observed between subsequent visits. It can also be suggested as the treatment of choice in skeletally immature (Risser grade 2 or lower) patients with spinal curvatures of 30-45°[4]. To date, a wide range of braces, such as Boston, Milwaukee, Wilmington, Osaka Medical College, soft braces (SpineCor/TriaC), and night-time braces (Providence/Charleston) have been developed[3]. Orthopaedic braces, when used for the treatment of scoliosis, may prevent curvature progression in patients with AIS[5]. However, braces should be assessed individually as treatment outcomes often depend on various factors such as the percentage of in-brace correction, patient compliance, and duration of treatment[6-8]. As previous studies have reported increasing popularity of the Gensingen Brace due to greater patient satisfaction, the current study aims to evaluates its effectiveness in the treatment of AIS and explores the factors influencing treatment outcomes.

MATERIALS AND METHODS

This prospective clinical cohort study was conducted at our clinic between April 2016 and February 2018, and patients diagnosed with progressive idiopathic scoliosis were asked if they wanted to volunteer to partake. Ethical approval was acquired from the Research Ethics Board at the University (24.10.2018), and written informed consent was collected from all participants and their guardians.

Inclusion criteria: This study included all patients who met the Scoliosis Research Society (SRS) inclusion criteria, as follows: age >=10 years at the time of brace prescription; Risser stage 0-2; primary curvature angles between 25-40°, no

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prior treatment for AIS; either pre-menarchal or <1 year post-menarchal[9]; and available for a minimum follow-up period of two years.

Exclusion criteria: Patients with a history of brace treatment and co-morbidities that could change the course of AIS (such as genetic defects, neuromuscular disorders, metabolic disorders, and severe trauma) were excluded from this study.

Gensingen Boston type braces were fabricated and placement of the pressure pads were checked by the same certified orthopaedist. Standing anteroposterior (AP) X-rays were used to confirm in-brace correction as well as the patient's full spinal alignment, including the pelvis, while wearing the brace (Figure 1). The correction magnitude threshold was >50% reduction of the initial Cobb angle, and patients were instructed to wear the brace for a minimum of 23 hours per day at the start of treatment. Skeletal maturity was defined as fulfilment of the following three criteria: a) Risser stage equal to 4; b) completion of at least two years since the onset of menstruation (for girls); and c) two consecutive visits over at least one year where no more than 1 cm increase in height was observed. Brace treatment was stopped one year after skeletal maturity.

This study included twenty-five patients (22 girls and 3 boys) diagnosed with AIS, and the mean age of the cohort was 11.4±1.19 years (range: 10-14) at the start of treatment. X-rays were taken before commencement of treatment, at the start of treatment while wearing the brace, before and after each subsequent brace, and at skeletal maturity (after wearing the brace). In-brace X-rays were taken six weeks after the start of treatment, and again six months after completion of treatment

Figure 1. Patient treated using Gensingen type brace

or achievement of "skeletal maturity". All analyses of changes in Cobb angle were carried out by the senior author T.A. Patients were grouped into two main curvature types, main thoracic (Lenke I, II, or III; n=10) and main lumbar (Lenke V or VI, n=15). Rotation of apical vertebrae was measured using the Nash & Moe method, which is based on the relationship between the vertebral pedicles and the centre of the vertebral body in an AP X-ray[9]. Rotation was grouped into five degrees based on the position of the pedicles, with 0° representing no vertebral rotation where the pedicles were located halfway to the lateral margins of the vertebral bodies. The rotational degree progressed as the pedicles of the apical vertebrae moved towards the median line in the AP X-rays, with the highest value (4°) being reached when the pedicle crossed the median line.

Clinical outcomes were assessed using the SRS criteria. The Cobb angle was measured in patients (without the brace) using standing AP spine X-rays, and outcomes were classified into the following groups: (1) improved: Cobb angle decreased by 6° or more; (2) stable: no more than 5° progression or improvement; (3) progressed: increase in the Cobb angle by 6° or more; and (4) surgical: progression of the Cobb angle beyond 45° requiring surgical intervention.

Statistical Analysis

All statistical analyses were carried out using SPSS version 24.0 (IBM Corp, 2011, Armonk, New York). Descriptive statistics, including mean, standard deviation, median, frequency, ratio, and minimum and maximum values, were generated for the cohort. Quantitative comparisons were carried out between the two groups using Student's t-test for normally distributed data and Mann-Whitney U test when the distribution was not normal. Pearson chi-square test, Fisher Freeman Halton Exact test, and Fisher's exact test were used to compare qualitative data. The significance level was set at $p<0.05$ a priori.

RESULTS

This study included 25 patients, of which three were male and 22 were female. Three patients underwent surgery for scoliosis, and the curvature distribution in the cohort was as follows: main thoracic curvature (n=8), thoracolumbar curvature (n=10), lumbar curvature (n=5), double major curvature (n=1), and double thoracic curvature (n=1). The distribution of Risser stages was as follows: grade 1 (n=8 cases), grade 2 (n=8), and grades 2-3 (n=9). The apices of the main curves were at T6 in four cases and below T7 in 11 cases (T8 in four cases, T9 in three cases, T10 in one case, T11 in one case, T12 in two cases, L1 in two cases, L2 in five cases, and L3 in three cases). The mean pre-brace Cobb angle for the main curve was 27.9°±6.7° (range: 20° to 37°) and the mean duration of brace treatment was 37.2 months (range: 16-76 months). The mean Cobb angle at the end of treatment was 32.1°±8.2° (range: 15° to 45°). The distribution of rotation, as per the Nash Moe classification, in the cohort was as follows: grade 1 (n=12), grade 2 (n=6), grade 3 (n=2), and grade 4 (n=4).

The last follow-up consultation after completion of treatment showed that curvature had progressed in 13 cases, improved in two cases, and remained unchanged in 10 cases (Figure 2 A, B and 3 A, B). Only three cases exhibited progression of the Cobb angle beyond 45° and were recommended for surgery. Therefore, a success rate of 48% (12/25) was accomplished.

No correlation between age, Risser grade, and brace treatment outcome was observed. However, successful treatment outcomes were seen to be significantly associated with initial Cobb angle (r=0.680; p=<0.001), rotation grade (r=-0.458; p=0.028), and main thoracic Lenke classification (r=0.481; p=0.020).

DISCUSSION

Using age and simple morphologic classifications (Cobb, Lenke classification, and Risser grade), we definitively demonstrated a success rate of Gensingen brace treatment in AIS and the relationship between the uncomplicated parameters and brace benefit[10]. Thompson et al.[11], in their study examining treatment of 168 patients using thoraco-lumbosacral orthosis braces, reported that curvature improvement of ≥50°(p=0.0383) was observed in 35.8% (43 of 120) of patients with persistent main thoracic curves, 20.0% (6 of 30) of patients with persistent main lumbar curves, 12.5% (1 of 8) of patients with main thoracic curves that converted into main lumbar curves, and 0% (0 of 9) of patients with main lumbar curves that became main thoracic curves[10].

Thoracic curves are associated with a higher risk of brace failure than lumbar curves, independent of primary curve magnitude and the average duration of daily brace wear. This was corroborated by the findings of the current study, where patients with main thoracic curves exhibited a higher success rate than those with main lumbar curves. Additionally, rotation also exhibited correlation with successful treatment outcomes. While some clinical studies reported an association between

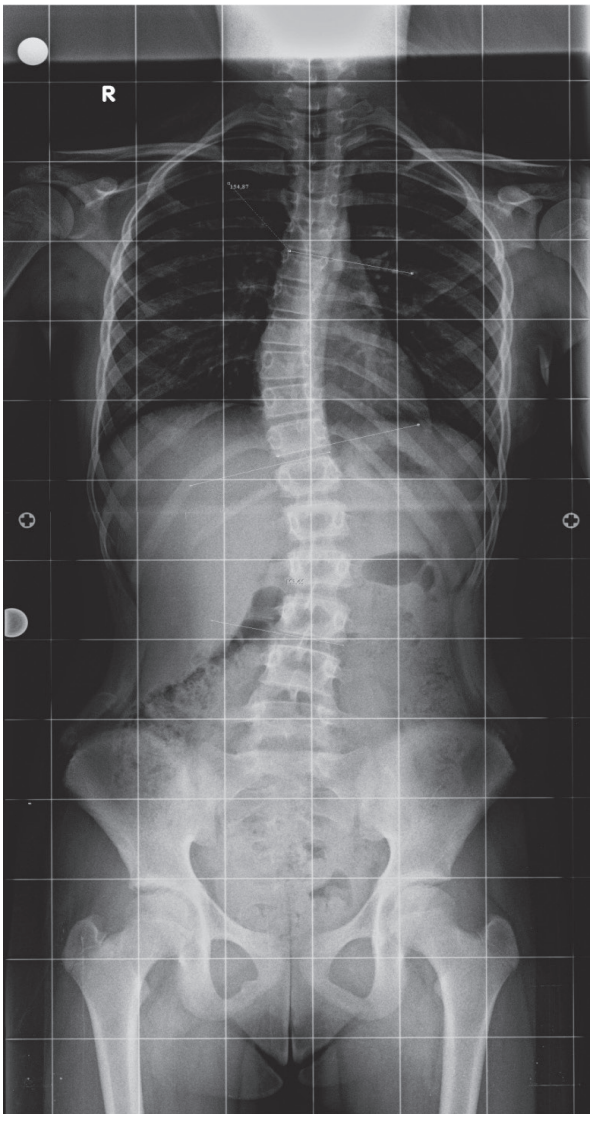

Figure 2. A) Standing anteroposterior radiograph of patient before commencement of treatment with Gensingen brace

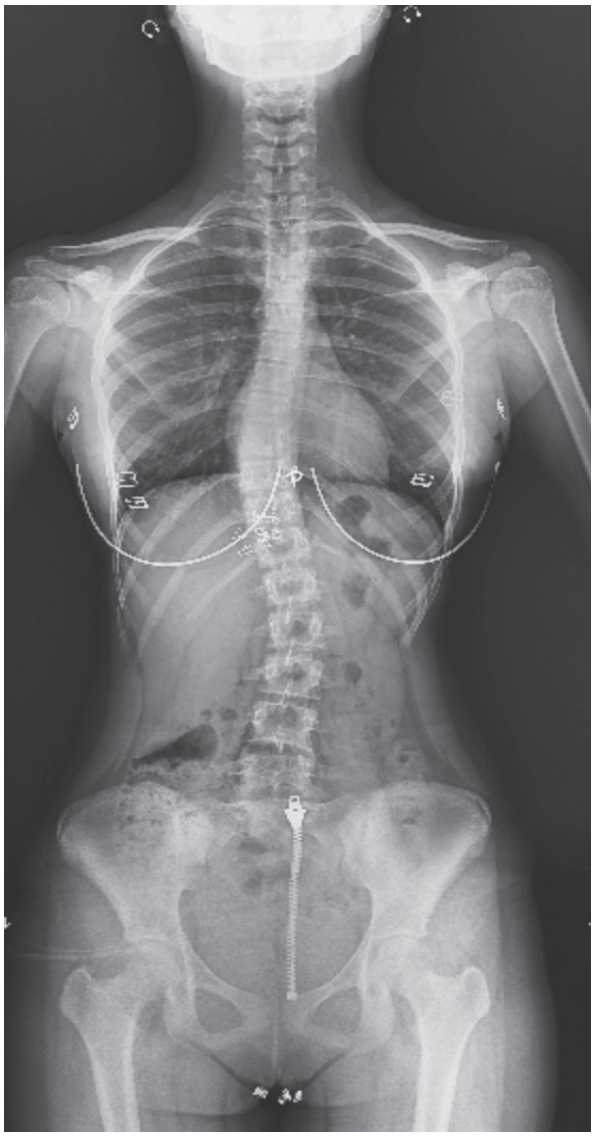

Figure 2. B) Successful treatment outcome observed upon removal of Gensingen brace

curve progression and younger age[11,12], others reported no evidence of a relationship between curve improvement and age. Cheung et al.[13], in their study consisting of 586 patients (mean duration of wearing brace: 3.8±1.5 years, mean post-bracing follow-up duration: 2.0±1.1 years), found that curve progression exhibited an association with younger age (Odds ratio: 0.71; 95% confidence interval: 0.55 to 0.91; p=0.008) [12]. Yrjönen et al.[14], in their study examining treatment of 102 patients with AIS using a Boston brace, reported no statistically significant association between the risk of curve progression and the patient's age, curve pattern, or curve magnitude[13]. Similarly, Peltonen et al.[15] examined 107 patients diagnosed with idiopathic scoliosis who were treated using a Boston brace (mean post-treatment follow-up duration of 3 years) and found no correlation between the patients' age at the start of the treatment and the treatment outcome[14]. The findings of the current study were in agreement with this, with no relationship between the patient's age and curve progression being observed.

Another key factor that affects treatment outcome is the initial spinal curvature exhibited by patients with AIS. Emans et al.[16] suggested that a Boston brace stated that higher primary curve magnitude enhanced the potential for surgery[15]. Katz and Durani[17]. reported that double curves with an initial thoracic curve >35° were more likely to exhibit progression, although this was contradicted by Ovadia et al.[18] who found that lower baseline Cobb angles were associated with limited progression rates, although their findings were not statistically significant. Kuroki et al.[19] observed lower success rates in patients with Cobb angles between 20° and 30° compared to those with Cobb angles above 30° (although this was not statistically significant), and concluded that there was no association between curve magnitude and treatment success. The systematic review conducted by Van Den Bogaart et al.[20] found moderate scientific evidence supporting no association between initial Cobb angle and treatment failure and inadequate evidence on treatment success. The present study

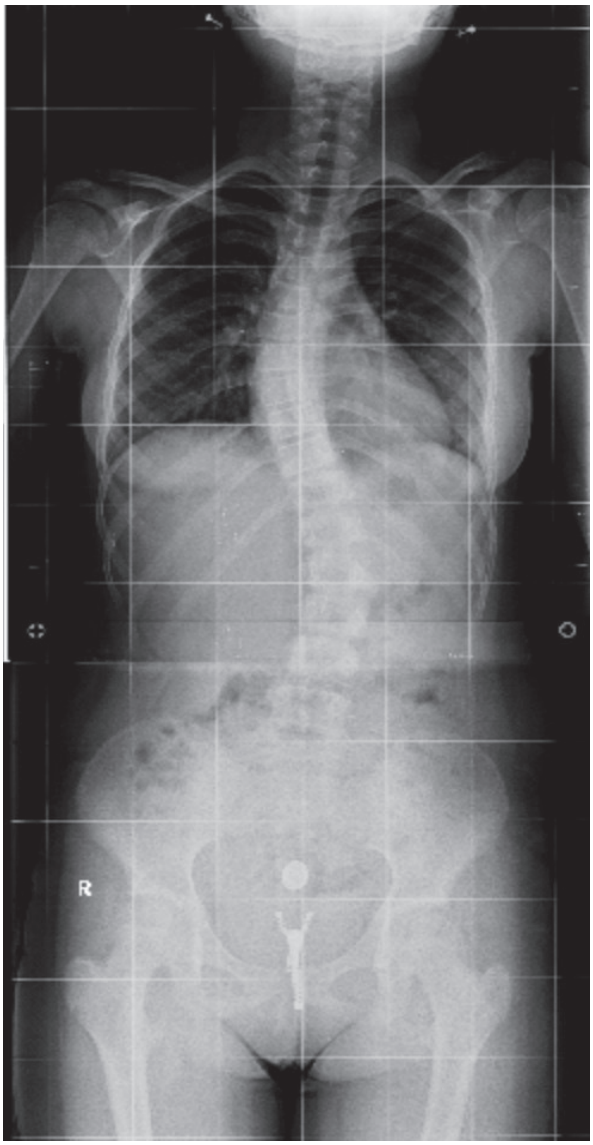

Figure 3. A) Standing anteroposterior radiograph of patient before commencement of treatment with Gensingen brace

Figure 3. B) Curve progression observed upon removal of Gensingen brace

showed a notable correlation between the primary Cobb angle and treatment success.

Study Limitations

This study has several limitations including small sample size, relatively short follow-up period, and limited number of male patients, thus preventing examination of any associations between sex and treatment outcome. The small sample size also prevented accurate measurement of the Risser stage, which has been previously shown to influence brace success. Finally, the mean duration of daily bracing was not assessed, preventing examination of its effect on compliance and treatment success.

CONCLUSION

Treatment of AIS in skeletally immature patients using a Gensingen brace can significantly decrease risk of curve progression to the threshold requiring surgical intervention. This study found that the initial Cobb angle, rotation of apical vertebra, and Lenke classification were significantly associated with treatment success, while no such association was observed with the patient's age, Risser grade, and gender.

Ethics

Ethics Committee Approval: Ethical approval was provided by the institutional review board (24.10.2018).
Informed Consent: Informed consent was collected from all patients.
Peer-review: Internally peer-reviewed.

Authorship Contributions

Concept: Ş.K., Design: M.A.Ö., Data Collection or Processing: M.A., Analysis or Interpretation: S.B., Literature Search: S.B., Writing: T.A., S.B.
Conflict of Interest: No conflict of interest was declared by the authors.
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