

Early intervention versus standard of care for mild idiopathic scoliosis: A case-controlled series based on SOSORT criteria evaluating the impact of a scoliosis activity suit

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Abstract

In the present study, a group of adolescent patients diagnosed with mild adolescent idiopathic scoliosis wore a scoliosis activity suit instead of maintaining the recommended observation only strategy. These patients wore the scoliosis activity suit for up to 60 minutes twice daily while performing normal daily activities. These patients were followed through until end of growth. Their end of growth results were compared to a group of adolescent idiopathic scoliosis (AIS) patients who only participated in observation. The group who wore the scoliosis activity suit maintained their curve measurements through skeletal maturity, while the observation group saw their curves increase an average of 7 degrees. This study showed that a group of AIS patients were able to prevent their curves from progressing during growth, while those participating in an observation-only strategy saw their curves progress to beyond threshold where rigid brace prescription is recommended. These changes were statistically significant in intergroup comparison, as well as intragroup before and after comparison.

Introduction

Scoliosis is defined as a rotatory lateral curvature of the spine measuring 10 degrees or more by Cobb's angle.¹ Idiopathic scoliosis affects approximately 3-5% of children ages 9-14. Of these, roughly 10% will see their scoliosis progress to the point where treatment is recommended.¹ The standard of care for scoliotic curves measuring 25-50 degrees in growing children is rigid bracing. Recent reviews² have shown a variability in bracing effectiveness, based upon compliance,³ prescribed wear time,⁴ and amount of initial radiographic in-brace correction.⁵ This has resulted in a wide range of outcome percentages based upon the type of

brace studied.² Given the social impact of full-time bracing,⁶ along with concerns over its effect on intrinsic pulmonary function,⁷ technologies that can avoid these drawbacks have been created, such as dynamic bracing.⁸

With these concerns in mind, Morningstar *et al.*⁹ reported using a scoliosis activity suit in patients with idiopathic scoliosis. However, these patients were adult patients with a past history of adolescent idiopathic scoliosis, who primarily sought treatment for pain management purposes. Although the scoliosis activity suit is prescribed for both adolescents and adults alike, results of using this suit in adolescent patients have not been previously reported. The scoliosis activity suit is a neoprene wrap suit that is applied according to each patient's curve pattern. What is different about the suit compared to rigid or dynamic orthoses is that it is utilized in an attempt to increase postural muscle effort, particularly those muscle groups opposing the abnormal scoliosis rotation. From this perspective, it is more accurately thought of as exercise equipment as compared to an orthosis. In this study, the cases of 9 patients with juvenile or adolescent idiopathic scoliosis are reported. All 9 patients were initially seen at Risser 0-1 of growth. The results of all 9 patients at Risser 4, or end of growth, are reported as recommended by the Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) guidelines.¹⁰ The present study was granted IRB exemption by IntegReview IRB.

Materials and Methods

Patient selection

All patients whose charts were selected for the present study presented to a medical office for evaluation of idiopathic scoliosis. Since the purpose of the present study was to report the outcomes based on established SOSORT criteria,¹⁰ our inclusion criteria were developed in accordance with these criteria. These criteria included the following: i) initiation of treatment began at Risser 0-1; ii) status pre-menses at treatment initiation; and iii) patients completed at least 1 follow-up radiographic study at Risser 4 or 5. As a final criteria to better homogenize both groups, in an effort to increase intergroup comparability, only patients with a right thoracic curve pattern (Lenke type 1¹¹) were selected. Based upon these criteria, a total of 9 charts were consecutively identified and selected for analysis. Once the treatment group was identified, a second group of 9 patients was also consecutively

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selected. This second group, based upon the recommendation of the orthopedic surgeon, decided to participate in an observation-only, standard of care, treatment approach. Their parents forwarded copies of their subsequent x-rays as they were completed in the event that curve progression occurred to a point at which further intervention would be indicated. In an effort to minimize selection bias, all patients in both groups were required to meet to independent criteria: i) they all had the same major medical insurance, to homogenize coverage costs and limitations; and ii) they had to initially consult with pediatric orthopedics prior to presenting for therapy. In all cases, the recommended initial orthopedic management was observation.

All of the patients in the treatment group were evaluated and fitted for a right leg setup of the scoliosis activity suit (SAS), based upon their Lenke type 1 curve pattern. Once the patient was fitted, he/she was instructed on correct placement and setup, so that it could be consistently replicated at home. A subset of the control patients were also evaluated and fitted for the scoliosis activity suit, but decided not to proceed with wearing the suit. They opted for the observational management already in place. These patients who declined to use the scoliosis activity suit were given the option to report back if the curve progressed, or if they decided to use the suit in the future. All patients who began using the suit were instructed to maintain observational follow-

ups with their respective orthopedic surgeon, and to provide digital copies of subsequent radiographs as they were completed. In multiple instances, the patient performed a follow-up at the author's clinic for the 6-month radiographic study. Patients who wore the SAS were instructed to wear it for 30-60 minutes twice daily. During wear time, the patient was instructed to maintain normal activities of daily living. At each follow-up, all SAS patients completed a self-rated compliance scale. This scale provided a 0-10 wear rating, where 0 was never and 10 was 100% compliant with the prescribed wear time.

Scoliosis activity suit description and biomechanics

The activity suit is a neoprene wrap-based core activation suit for scoliosis. The activity suit is composed of 4 separate pieces. The Leg piece is the wrap that fits around the patient's thigh. The Belt attaches directly to the Leg piece, and their respective configuration is dependent upon the location of the lumbar or thoracolumbar curvature apex. The third piece is Vest piece, and looks like a half-tank top shirt that acts upon the thoracic curvature. The fourth and final piece, or set of pieces, are the tension straps. The tension straps connect each of the first three pieces together in a rotational pattern, which introduces a rotational force into the patient, to which he or she must react. These tension straps are positioned obliquely according to the direction of force the clinician seeks to introduce. Figure 1 depicts each of the activity suit pieces. The right leg setup of the SAS, as shown in Figure 1, is the setup used by all patients in the treatment group.

The scoliosis activity suit is thought to utilize leg and shoulder drive, which then transmits that force throughout the spine. As the patient wears the suit, movement increases the amount of force transmitted. At rest, the suit does not provide any appreciable resistance. This is in contrast to a rigid scoliosis brace, which provides sustained force regardless of activity level.

Results

The average age for all patients at baseline was 9 years, 8 months. The breakdown of the group was 15 females and 3 males. The average baseline Cobb angle was $20^{\circ} \pm 2$ in both groups. In accordance with SOSORT criteria, results are reported at Risser 4 or 5, depending upon when the patient received his/her last imaging study. Both groups were followed for approxi-

mately 4 years total. In both groups, patients with curves that progressed to 25° or more were referred for scoliosis bracing treatment and/or scoliosis-specific exercise treatment. This was based upon the SOSORT Guidelines.¹⁰

Paired, two-tailed t-tests were performed for each group's baseline and follow-up measurements, as well as for inter-group comparison. Table 1 shows the results of this comparison. In the treatment group, the baseline and follow-up values were unchanged ($P=0.538605386$). For the control group, the baseline Cobb angle averaged 20° , while their follow-up averaged 27° , a statistically significant increase ($P<0.05$). Figure 2 shows the results for each group.

In the control group, 5 of the 9 patients progressed beyond the 25° threshold, where bracing and scoliosis-specific exercises are recommended.¹⁰ This was in contrast to the treatment group, where 1 of the 9 SAS-treated patients had a curve reach that magnitude.

The SOSORT Guidelines also recommend reporting results based upon the percentages of patients who improve by $>5^{\circ}$, stay within $\pm 5^{\circ}$ of baseline, and progress by more than 5° .¹⁰ The treatment group had 7 of the 9 patients (78%) remain within $\pm 5^{\circ}$, 1



Figure 1. This figure illustrates a sample configuration of the scoliosis activity suit.

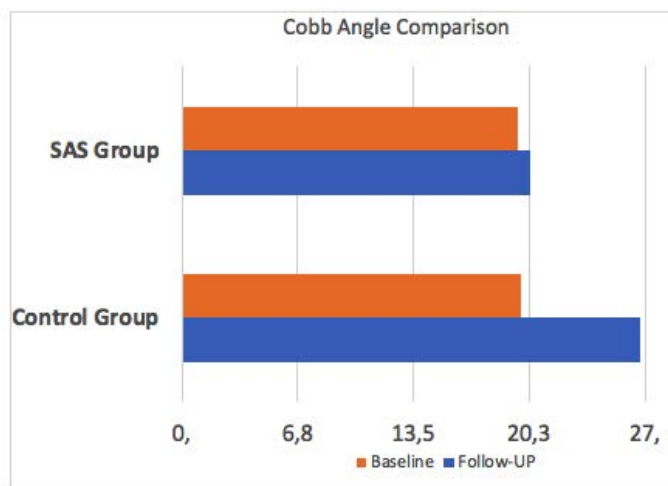


Figure 2. This figure shows the Cobb angle differences during both inter- and intra-group comparisons at baseline and follow-up.

Table 1. The results of the comparison.

	Cobb1	Cobb2 (P value)	Age1	Age2
Treatment Group	$20^{\circ} \pm 2$	$20^{\circ} \pm 5$ ($P=0.538605386$)	9 yrs, 8 mos.	13 yrs, 6 mos
Control Group	$20^{\circ} \pm 2$	$27^{\circ} \pm 4$ ($P=0.008225257$)*	9 yrs, 5 mos.	13 yrs, 9 mos.
Intergroup	$P = 0.870538639$	$P=0.006276816$ *	$P=0.74575146$	$P=0.594264016$

*Statistically significant at 95% confidence interval ($P<0.05$).

of 9 improved by >5° (11%), and 1 of 9 worsened by >5° (11%). In the control group, 4 of 9 patients remained within 5° of baseline (44%), while the remaining 5 of 9 worsened by more than 5 degrees (56%). None of the control patients improved more than 5°. Individuals in the SAS treatment group self-rated their compliance as an average of 7.2 out of 10 across the 4-year management period.

There were 2 males within the treatment group, and 1 male in the control group. Both males in the treatment group were managed for a total of 5 years. Both males in the treatment group had stable curves at end of growth when compared to their baseline values. The lone male in the control group was followed for 8 years. A curve increase of 9 degrees during that time was observed.

Finally, in an effort to evaluate outcomes based upon the age of initial diagnosis, each group was subcategorized into two groups: those classified by SOSORT¹⁰ as juvenile idiopathic scoliosis (JIS), ages 3-9, and adolescent idiopathic scoliosis (AIS), ages 10-17. There were 4 patients in both groups with JIS. There were 5 patients in each group with AIS. The 4 JIS treatment patients were statistically unchanged at end of growth (P=0.808781492). The JIS control patients curve measurements were significantly increased at end of growth (P=0.009084785), despite being similar at baseline to the JIS treatment group (P=0.207142844). Comparatively, their values were also significantly different at end

of growth (P<0.05). In the AIS subgroup, the treatment did not alter the curve measurements compared to baseline (P=0.256043606), nor when compared to the control group (P=0.500252343). Table 2 shows the complete raw data file.

Discussion

The neuromotor rehabilitation concepts behind the scoliosis activity suit are based upon the known spinal somatosensory and sensorimotor pathways governing postural control relative to gravity.¹¹ Rigid bracing is based upon a guided growth principle, where full-time brace wear hopes to alter vertical growth and minimize spinal compressive forces, in order to stabilize the scoliotic curvature.¹² Rigid bracing is predominantly a passive procedure, where muscle strengthening and activation are not inherent goals. The scoliosis activity suit, in contrast, was designed with the goal of creating a rotational resistance to which the postural reflexes and associated axial musculature must adapt. These rotational adaptations are measurable via visual posture analysis as well as comparative radiography. It is not a passive support device.

In recent data published by Weinstein,¹³ children ages 10-12 with curves between 10-18 degrees have a 25% chance of experiencing curve progression (>5 degrees). In children of the same age with curves of 20-

29 degrees, the chance of curve progression increases to 60%.¹³ Weinstein's data would predict that both groups in the present study would carry a 60% chance of curve progression if left untreated. At follow-up, the control (untreated) group had a curve progression occurrence of 56%, while the SAS treatment group had an 11% rate of curve progression. Given the homogeneity of the two groups, and using an independent variable to minimize selection bias, it can be concluded that the scoliosis activity suit had a significant impact on stabilizing mild idiopathic scoliosis throughout pubertal growth in this small cohort of patients. It should be noted, however, that due to the small sample size, the results observed in the present study may not be applicable to broader patient populations, including those with double major and primary lumbar scoliosis curve patterns.

The compliance with any prescribed therapy is an important predictor of the outcomes associated with that treatment. In the present study, the self-rated compliance was 72% over the course of therapy. However, it is possible that the actual compliance rate is lower. Although the compliance rate with rigid bracing may be as low as one-third of the prescribed wear time¹³, wear time of rigid bracing is longer than the SAS wear time. This is due to the difference in proposed mechanisms of each respective treatment. Future studies involving the scoliosis activity suit may consider more objective means of quantifying wear time compliance, such as a temperature logger.¹⁴

In the control group, the 5 patients who progressed were referred for additional standard of care management, including exercises and bracing. Those therapies were not provided by the author. Therefore, it is unknown how those interventions impacted the end of growth results in those patients. Given the reported end of growth results for those patients, the therapies stabilized the curves below surgical threshold. However, those results cannot be reported relative to the SOSORT criteria because it is unknown as to what exact measurement at which each of those patients started the additional therapy/bracing. Therefore, it cannot be speculated as to what type of outcome was received from participating in the subsequent exercise/bracing intervention. However, the chief purpose of bracing is to prevent curve progression to surgical threshold,¹⁰ so it seems plausible that patients in the control group whose curves reached 25°, and were subsequently referred for conventional management, received bracing and/or exercises that could be considered successes for those therapies. The only applicable data for the present

Table 2. The complete raw data file.

Patient	Cobb1	Cobb2	Age1	Age2	Gender	Risser1	Risser2
A1	15	17	9	13	F	0	4
A2	19	22	11	14	F	0	4
A3	14	16	9	14	M	0	4
A4	17	11	8	13	F	0	4
A5	16	17	10	15	M	0	4
A6	21	20	10	13	F	1	4
A7	20	20	11	14	F	1	5
A8	18	26	10	13	F	0	4
A9	22	22	9	13	F	1	4
B1	18	24	11	14	F	1	5
B2	17	26	8	16	M	1	4
B3	22	28	11	13	F	1	4
B4	23	24	10	14	F	0	4
B5	20	17	10	13	F	0	4
B6	19	22	11	13	F	0	4
B7	11	33	8	14	F	0	4
B8	13	30	9	14	F	1	5
B9	15	32	9	13	F	1	4

*Patients with 'A' prefix are the SAS treatment patients. Control group patients have the prefix 'B.'

study, in the case of these control group patients, was their respective baseline and end of growth measurements. Because of this, although they are in the control group, they did end up performing a more intensive physiotherapy or bracing routine, which may have improved the outcomes of the AIS subgroup controls when compared to the AIS subgroup SAS patients. This may possibly account for the statistical similarity in the AIS subgroup outcomes, but that remains unknown.

The analysis of the present data suggests that early stage intervention may lead to improved outcomes at end of growth. Interestingly, the SOSORT Guidelines¹⁰ recommend beginning physiotherapy scoliosis-specific exercises (PSSEs) at curves below the 25° threshold currently recommended in the United States in primary care guidelines.¹⁵ The outcomes of the current study support the findings of other PSSEs previously published.¹⁰

Conclusions

Adolescent patients with mild idiopathic scoliosis who wore a scoliosis activity suit through end of growth achieved a stabilization and/or improvement in 89% of cases, compared with 44% of control patients. The majority of control patients progressed and required bracing intervention in accordance with SOSORT treatment guidelines. With the established risk of progression for both groups at baseline at 60%, it is reasonable to conclude that the scoliosis activity suit had a significant impact on minimizing the chance of progression in the current sample. Juvenile idiopathic scoliosis patients responded more favorably to the scoliosis activity suit when compared to

adolescent idiopathic scoliosis patients. This management strategy may be effective for juvenile patients with mild cases of idiopathic scoliosis. More investigation is needed to determine if these results are more broadly applicable.

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