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Pain and Radiographic Changes in Adult Scoliosis Patients Using a Scoliosis Activity Suit: Case-Controlled 10-Year Follow-Up Results

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Abstract

Scoliosis in adult patients is known to increase across the lifespan and increases the chance of chronic pain in later adulthood. Non-surgical scoliosis treatment options for adults are not widely recommended, largely due to lack of research in this area. Pain management options for adults are focused primarily on treating scoliosis-related pain, and not necessarily the scoliosis itself, such as epidural injections, prescription pain medications, and general physical therapy. Recent studies reporting non-surgical, scoliosis-specific treatment methods in adults are encouraging, but their study designs limit extrapolation. The current study reports the self-reported pain and radiographic outcomes in adult patients wearing a scoliosis activity suit for at least 10 years. A total of 22 patient charts that fulfilled the inclusion criteria were selected for review. Cobb angle radiographic measurements and self-rated quadruple numerical pain rating scale (QVAS) at baseline and 10-year follow-up were used as the outcomes. Cobb angle measurements were compared at baseline and 10 years and subdivided according to scoliosis curve pattern. At 10 years, 68% of patients had improvements in their Cobb angle > 5˚, with an overall average of approximately 9˚. Significant differences were also observed in the 10-year Cobb angle measurements when compared to the predicted 10-year Cobb angles based on the established rate of linear progression in adults. A statistically significant change was also observed in the 10-year QVAS scores. These results suggest a potential role of the scoliosis activity suit for improving Cobb angles in adults and reducing scoliosis-related pain.

Keywords

Chiropractic, Pain, Rehabilitation, Scoliosis, Spine

1. Introduction

The incidence of scoliosis in adulthood steadily increases over the lifespan, occurring in 2% - 3% of young adolescence [1] and 68% of adult females aged 60 and older [2]. Given the impact on quality of life in adult scoliosis patients [3], scoliosis treatment options for adults are warranted. Although surgical treatments for adult scoliosis appear to provide improvements superior to non-operative therapies such as prescription pain medications, epidural injections, and physical therapy [4], the relative health and comorbidities in adult patients make surgical decisions more complicated [5]. Since it is well known that scoliosis continues to progress in adulthood [6], with a reported linear rate of approximately 1 degree per year [7], non-operative therapies that can at least halt this natural progression are desirable. Although many of the surgical studies previously published for adult scoliosis show good clinical outcomes, the rate of peri-operative and post-operative complications ranges from 17% - 80% [4].

Various risk factors may contribute to the progression of scoliosis in adulthood. Radiographically, Ren *et al.* [8] found that apical vertebra translation and the apical vertebral tilt angle were risk factors for adult degenerative scoliosis. Left-convex thoracolumbar and lumbar curve types are also risk factors for the onset of gastroesophageal reflux disease (GERD) [9]. Additional risk factors for adult scoliosis progression include intervertebral disc degeneration [10], disc rupture, and lumbar facet hypertrophy [11].

Scoliosis-specific exercise therapies have been shown to positively impact the adult curvature. For example, Jung *et al.* [12] showed that a short-term intervention consisting of Schroth exercises led to improvements in balance, foot pressure, and the Cobb angle. Negrini *et al.* [13] showed that scoliosis-specific exercises for adults were superior to natural history in maintaining Cobb angle measurements longitudinally.

The effectiveness of rigid bracing for adult scoliosis patients is largely unknown. Zaina *et al.* [14] showed that adults with severe scoliosis wearing a prefabricated brace improved their self-rated pain scores but did not change their quality-of-life outcomes. Another study by Zaina *et al.* showed a similar outcome [15]. A systematic review by McAviney *et al.* [16] found only low-quality evidence to support rigid brace use to improve pain and function in adult patients with thoracolumbar or lumbar curves. Morningstar *et al.* reported positive outcomes in both post-fusion [17] and non-fused [18] adult scoliosis patient populations wearing a flexible scoliosis activity suit for 6 and 18 months, respectively. Previous short-term data suggest [18] that this suit may help self-rated pain and Cobb angle measurements in adult scoliosis when compared to a control group.

The purpose of the present study is to report the outcomes obtained in a cohort of adult non-fused scoliosis patients who were prescribed a scoliosis activity suit and followed up clinically after 10 years.

2. Methods

2.1. Patient Selection

Patient files from the same medical center were pulled for retrospective analysis. Patients had previously reported to the clinic with past medical history of idiopathic scoliosis. All patient files for patients who presented for scoliosis management were analyzed, totaling 259. The inclusion criteria used for patient file selection were: 1) Cobb angle measuring at least 30˚ at baseline; 2) patient had a follow-up at 10 years after being prescribed a scoliosis activity suit to wear; 3) all patients must have completed a quadruple numerical pain rating scale (QVAS) at baseline and 10-year follow-up; 4) patients reported a minimum self-assessment of 70% average compliance with their recommended wear schedule, 5) patients were 18 years or older at baseline; and 6) patients did not receive concurrent scoliosis-specific therapy elsewhere during the 8-year period. Patient files were excluded for past histories of non-idiopathic scoliosis (*i.e.*, congenital, or neuromuscular), spinal fusion, or vertebral body tethering. A total of 22 patient files were selected based upon these selection criteria. **Figure 1** shows a diagram of the patient selection process using these criteria. Multistage sampling was performed to match the demographic and descriptive data of the previously published control group patients [7] as much as possible.

2.2. Scoliosis Activity Suit Fitting Process

The scoliosis activity suit is a neoprene, rotation-based exercise suit, comprised of 4 separate pieces. It creates a rotational resistance into the torso as the patient moves and ambulates, which is thought to counteract the rotational displacement of the scoliosis. This rotational stimulus is thought to elicit a corrective reflex that de-rotates the scoliosis curvature.

Patients had participated in a fitting visit, where the focus was on teaching each patient to properly put on his/her scoliosis activity suit based upon his/her curve pattern. Patients gradually increased their wear time over the first 6 months, from a starting time of 30 minutes daily up to approximately 2 - 3 hours twice daily. The 2 - 3 hour wear time was to be maintained ongoing. **Figure 2** shows a sample illustration of a typical scoliosis activity suit configuration for adult patients. Patients were scheduled for regular follow-ups, ranging from every 6 - 12 months. Patients whose data were selected gave their written consent to publish their non-identifying data. Advarra Institutional Review Board (IRB) provided an advisory opinion that the current study was exempt from IRB approval given the study design.

2.3. Data Collection

This study collected the data reported and obtained at each patient's 10-year follow-up. All follow-ups occurred between March of 2018 and December of 2021. Demographic data collected were patient age and gender. Descriptive data collected were scoliosis curve patterns as classified by SOSORT [19]. Quantitative data was collected for baseline and 10-year follow up visits and included Cobb angle measurements for all curves (thoracic curve was measured for patients with double curves) as well as self-reported scores on a QVAS. The QVAS

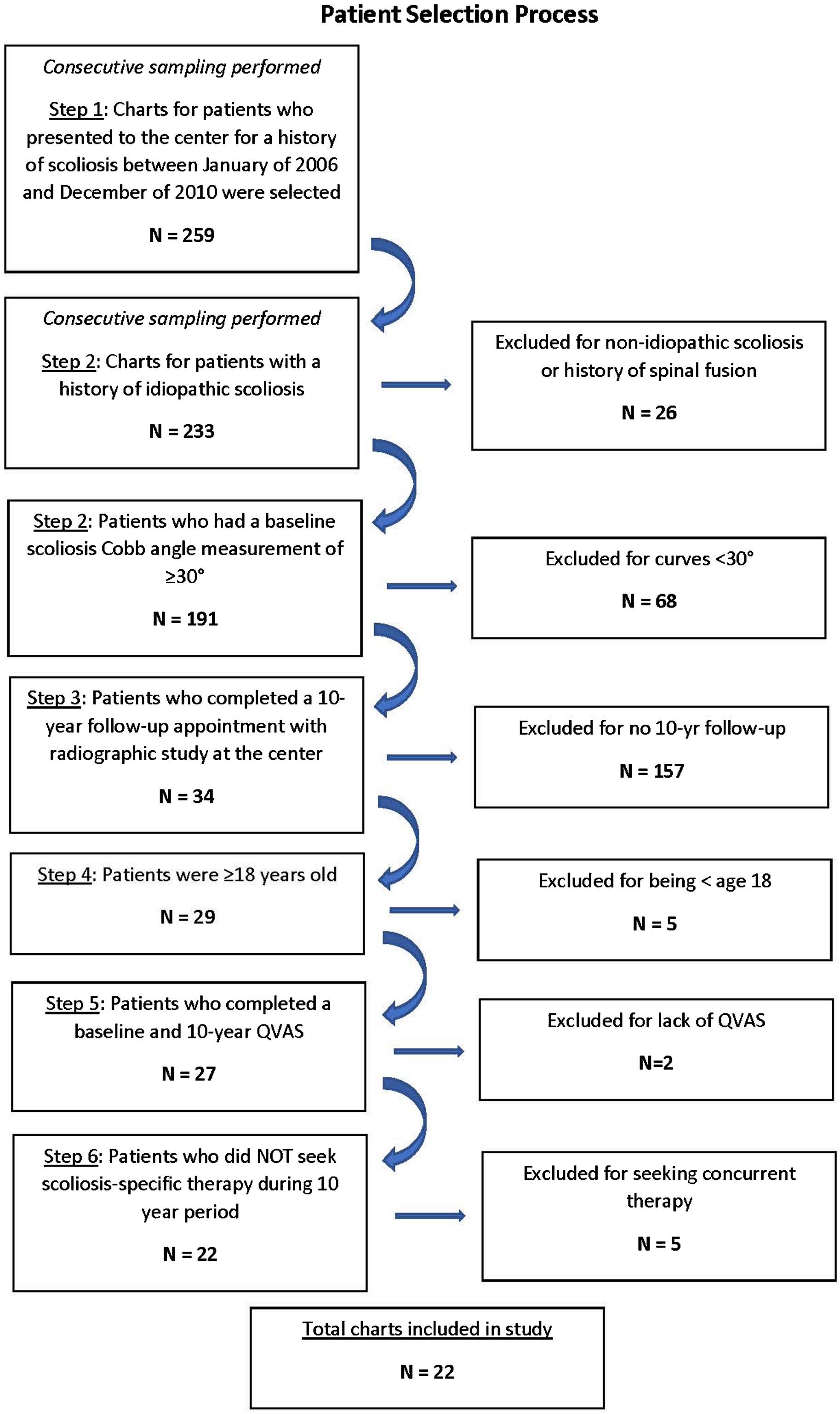

Figure 1. SAS 10-year follow-up.

Figure 2. Scoliosis activity suit configurations. (a) Right leg setup for right thoracic, left lumbar, left thoracolumbar, and double major curve patterns; (b) Left leg setup for right lumbar and right thoracolumbar curve patterns.

instrument asks about pain level at the time the questionnaire is completed, average pain level, as well as pain levels at their best and worst. The present pain level score, the average pain level score, and the worst pain level score are added together and divided by 3 to calculate the total score. Radiographic Cobb angle measurements were verified by a physician not involved in the care of the selected patients. There were 19 females and 3 males among the 22 total patient files selected. The average age at baseline was 32 years, 6 months.

3. Results

The baseline Cobb angle measurement was 43˚ ± 9˚ for the entire cohort. Their average initial QVAS score was 52˚ ± 12˚, where scores greater than 50 are consistent with moderate to severe pain. In accordance with SOSORT reporting criteria (14), 15 of the 22 patients (68%) had curve improvements of 6˚ or greater, 5 patients (23%) remained stable within ±5˚ of their initial measurements, and 2 patients' curves (9%) increased 6˚ or more. At 10-year follow-up, the average curve for the cohort was 34˚ ± 14˚, and their QVAS scores were 34˚ ± 13˚. Paired t-tests were used to compare outcomes. Both outcomes were statistically significant ($P < 0.001$). Table 1 shows all the data for the entire cohort.

The cohort was subsequently categorized based upon curve pattern. There were 7 patients with double major curves, 7 patients with single lumbar curves, 5 with single thoracic curves, and 3 with single thoracolumbar curves. Table 2 & Table 3 show the data for each curve pattern. For double major curves, the thoracic curve component was used for analysis. The baseline Cobb angle was 42˚ ± 10˚, while the initial QVAS was 45˚ ± 7˚. At 10 years, the Cobb angle was 33˚ ± 17˚, and the QVAS score was 30˚ ± 11˚. The QVAS difference at 10 years was statistically significant ($P < 0.001$). In patients with a single lumbar curve, the average initial curve was 47˚ ± 11˚, while the QVAS score was 57 ± 4. Follow-up Cobb angle measured 40˚ ± 13˚, and the QVAS was 41˚ ± 6˚ ($P < 0.001$). The baseline Cobb angle and QVAS score for the single thoracic curve pattern group were 43˚ ± 10˚, and 48˚ ± 17˚. The 10-year follow-up Cobb angles was 26˚ ± 8˚ ($P < 0.001$), and the QVAS score was 22˚ ± 13˚. Finally, the average initial Cobb angle for the thoracolumbar group was 40˚ ± 7˚, and their average starting QVAS score was 67˚ ± 12˚. Figure 3 and Figure 4 show intragroup comparisons of Cobb angle and QVAS outcomes among the individual curve patterns.

The Cobb angle differences in the Thoracic and Lumbar groups were statistically

Table 1. Patient cohort.

Patient	Gender	Age	CurveType	Cobb1	Cobb2	CobbDiff	QVAS1	QVAS2
1	m	33	D	32	20	12	47	30
2	m	31	T	52	31	21	73	43
3	m	40	TL	47	54	7	53	43
4	f	19	L	55	48	7	63	47
5	f	22	L	36	22	14	60	47
6	f	31	TL	34	28	6	70	43
7	f	44	T	42	24	18	40	10
8	f	37	T	35	25	10	33	13
9	f	26	L	40	32	8	57	30
10	f	29	D	46	25	21	43	23
11	f	18	D	33	19	14	37	13
12	f	18	D	32	28	4	43	33
13	f	34	D	47	31	16	43	27
14	f	51	L	65	60	5	60	37
15	f	49	T	54	36	18	57	23
16	f	42	D	58	68	10	43	37
17	f	33	TL	39	23	16	77	57
18	f	35	L	53	49	4	53	37
19	f	30	D	46	41	5	60	47
20	f	30	L	43	38	5	50	43
21	f	34	T	32	16	16	37	23
22	f	29	L	39	32	7	57	43
Avg				**43.63636**	**34.09091**		**52.5454545**	**34.04545**
		#Corr	15		%Corr	68		
		#Stab	5		%Stab	23		
		#Prog	2		%Prog	9		

Cobb1: Baseline Cobb angle; Cobb2: 10-year Cobb angle; CurveType: Double Major (D), Thoracic (T), Thoracolumbar (TL), Lumbar (L); QVAS1: Baseline pain rating; QVAS2: 10-yr pain rating.

Table 2. Patients classified by curve pattern.

	Patient	Gender	Age	CurveType	Cobb1	Cobb2	CobbDiff	QVAS1	QVAS2
	1	m	33	D	32	20	12	47	30
	10	f	29	D	46	25	21	43	23
	11	f	18	D	33	19	14	37	13
	12	f	18	D	32	28	4	43	33
	13	f	34	D	47	31	16	43	27
	16	f	42	D	58	68	10	43	37
	19	f	30	D	46	41	5	60	47
Avg			**29.14286**		**42**	**33.14286**		**45.14286**	**30**
STD DEV					9.949874	17.06291		7.174691	10.75484
T Test						**0.062031**			**0.00058**
	2	m	31	T	52	31	21	73	43
	7	f	44	T	42	24	18	40	10
	8	f	37	T	35	25	10	33	13
	15	f	49	T	54	36	18	57	23
Avg			**40.25**		**45.75**	**29**		**50.75**	**22.25**
STD DEV					8.883505	5.597619		17.93274	14.90805
T Test						**0.005743**			**0.00244**
	3	m	40	TL	47	54	7	53	43
	6	f	31	TL	34	28	6	70	43
	17	f	33	TL	39	23	16	77	57
Avg			**34.66667**		**40**	**35**		**66.66667**	**47.66667**
STD DEV					6.557439	16.64332		12.34234	8.082904
T test						**0.531021**			**0.061275**
	4	f	19	L	55	48	7	63	47
	5	f	22	L	36	22	14	60	47
	9	f	26	L	40	32	8	57	30
	14	f	51	L	65	60	5	60	37
	18	f	35	L	53	49	4	53	37
	22	f	29	L	39	32	7	57	43
Avg			**30.33333**		**48**	**40.5**		**58.33333**	**40.16667**
STD DEV					11.41928	14.11028		3.444803	6.705719
T test						**0.003359**			**0.000494**

Cobb1: Baseline Cobb angle; Cobb2: 10-year Cobb angle.

Table 3. Calculated linear progression.

	Patient	CurveType	Cobb1	Cobb2	Cobb3*	CobbDiff	QVAS1	QVAS2
	1	D	32	20	39	12	47	30
	10	D	46	25	53	21	43	23
6.8 deg	11	D	33	19	40	14	37	13
	12	D	32	28	39	4	43	33
	13	D	47	31	54	16	43	27
	16	D	58	68	65	10	43	37
	19	D	46	41	53	5	60	47
Stats			42	33.14286	49		45.1428571	30
STD DEV			9.94987437	17.06291	9.949874		7.17469097	10.75484
T Test				0.062031	0.006372			0.00058
	2	T	52	31	59	21	73	43
6.8 deg	7	T	42	24	49	18	40	10
	8	T	35	25	42	10	33	13
	15	T	54	36	61	18	57	23
Stats			45.75	29	52.75		50.75	22.25
STD DEV			8.88350531	5.597619			17.9327447	14.90805
T Test				0.005743	0.002085			0.00244
	3	TL	47	54	63	7	53	43
16 deg	6	TL	34	28	50	6	70	43
	17	TL	39	23	55	16	77	57
Stats			40	35	56		66.6666667	47.66667
STD DEV			6.55743852	16.64332			12.3423391	8.082904
T test				0.531021	0.087531			0.061275
	4	L	55	48	71	7	63	47
	5	L	36	22	52	14	60	47
16 deg	9	L	40	32	58	8	57	30
	14	L	65	60	81	5	60	37
	18	L	53	49	69	4	53	37
	22	L	39	32	55	7	57	43
Stats			48	40.5	64.33333		58.3333333	40.16667
STD DEV			11.4192819	14.11028			3.44480285	6.705719
T test				0.003359	1.75E−05			0.000494

*Cobb3: Hypothetical Cobb angle 10 years according to Marty-Poumarat *et al.* linear progression [7].

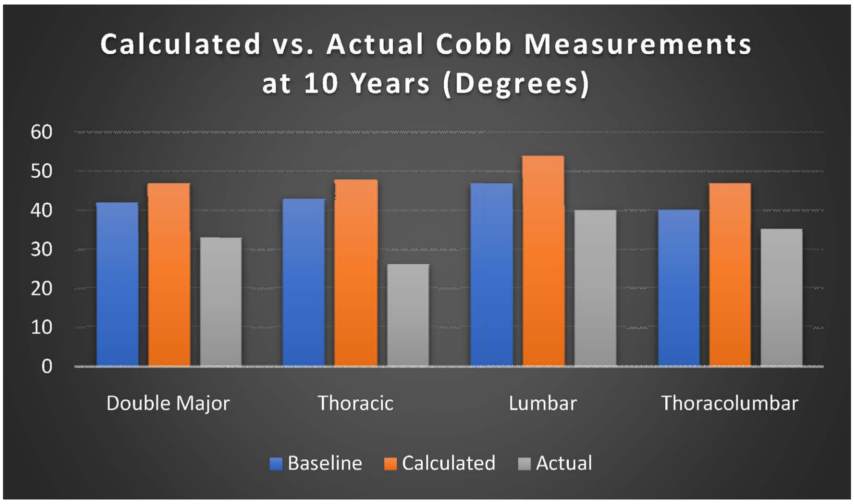

Figure 3. Intragroup comparisons of Cobb angle.

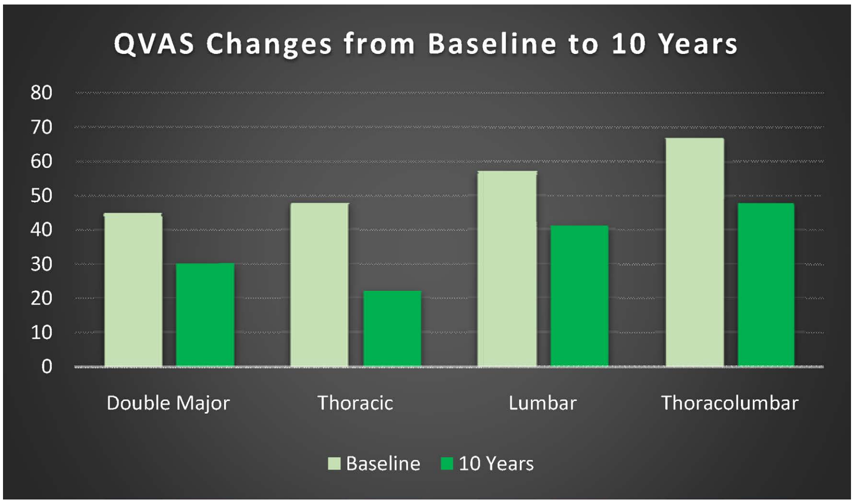

Figure 4. QVAS outcomes among the individual curve patterns.

significant, while the Thoracolumbar and Double Major groups did not reach that threshold. The Thoracolumbar group was the only group whose QVAS changes did not reach statistical significance (P = 0.061275).

Additional comparisons were made to the published control group by Marty-Poumarat *et al.* [7]. Their data was selected for comparison based upon similar patient demographics at baseline. They also reported their data by scoliosis curve type, like the current study. In their data using a total of 51 patients, the average baseline age of their entire cohort was 37 years; the cohort in the current study was 32. The average starting thoracic Cobb angle in their cohort was 44˚, while current single Thoracic and Double Major groups were 43˚ and 42˚, respectively. The current baseline Cobb angle for the Thoracolumbar group was 40˚, and 47˚ for the current Lumbar group. In the Marty-Poumarat *et al.* data [7], they combined the lumbar and thoracolumbar Cobb angle measurements, and reported a baseline measurement of 30˚. Pain-based outcomes were not reported in their data.

Using linear regression analysis, Marty-Poumarat *et al.* [7] reported an average annual curve increase of approximately 0.68˚/year for thoracic curves, and an entire cohort average increase for lumbar curves of 1.45˚/year. However, they further subclassified their Lumbar/Thoracolumbar curve group data according to age of scoliosis onset. In their group with a history of adolescent onset, the average curve increase was 0.82˚/year. In the subgroup with an adult or de novo onset, the average increase was 1.64˚/year. Therefore, for current comparative purposes, the adult-onset group's rate of progression was applied, since the age of adolescent onset does not apply to the current data set.

For the current Thoracic curve group, as well as the Double Major curve group, the average amount of curve increase would be calculated at approximately 6.8 degrees (10 years × 0.68˚/yr). The current Thoracic group's average 10-year Cobb angle was decreased by approximately 16˚ ($P < 0.001$), while the Double Major group's thoracic curves were an average of 11 degrees improved. Both measurements were statistically significant. Applying the average linear rate of progression for the lumbar and thoracolumbar curves would yield a calculated curve increase of about 16˚ (10 × 1.64˚/yr). For the current Lumbar group, the average curve measurement was reduced 7˚ ($P < 0.05$), while the Thoracolumbar group change was about 5˚ less compared to baseline. The Thoracolumbar measurement was not statistically significant. **Table 3** shows a comparison of the group's theoretical 10-year curve measurements using the data published by Marty-Poumarat *et al.* [7]. A post-hoc power analysis was calculated using this data. Using the average observed difference between the actual 10-year follow-up Cobb angle across all curve types, compared to the natural history Cobb angle as predicted by Marty-Poumarat *et al.*, which was 21˚, this difference was statistically different at $P < 0.001$ with 99% power. After omitting Cobb angles outside of two standard deviations, the change remained statistically significant with 94% power to show a significance of $P < 0.05$.

4. Discussion

Since adult scoliosis patients are more likely to experience chronic back pain compared to non-scoliotic adults [20], it is logical to evaluate those methods that seek to accomplish this goal, even if curve correction is not the primary objective.

Our control group was composed of a previously published cohort by Marty-Poumarat *et al.* [7]. Our present cohort is similar in demographics and curve characteristics to their cohort, which is why it was chosen. Since Marty-Poumarat *et al.* provided a detailed, linear rate of progression for adult scoliosis patients, it gave us a realistic comparative by which to evaluate if the scoliosis activity suit could potentially alter the course of natural history of this musculoskeletal deformity.

5. Study Limitations

It is important to discuss the limitations of this study. While we did attempt to control the study, it was retrospective in nature, which invariably provides for some degree of selection bias, although we attempted to minimize this by selecting our inclusion criteria before reviewing and selecting patient charts. We also did not perform an intent-to-treat analysis, which would have accounted for the subjects who did not report for follow-up at 10 years. Future studies should include this analysis.

Although this treatment was primarily performed at home, the present study does not consider the percentage of compliance within our study population, beyond a subjective self-rated estimate. It is possible that our outcomes could be correlated to the rate of compliance, as well as for those we lost to 10-year follow-up.

Although the average patient age at the start of treatment was 32 years, apical rotational instability doesn't often occur until around age 45. Even with our 10-year follow-up data doesn't evaluate through that age. Therefore, it is possible that results observed in the present study could be impacted as the patient group continues to wear the scoliosis activity suit into the future. The current study group will continue to be monitored, if possible, longitudinally.

Finally, while pain is a reasonable outcome assessment for this patient population in particular, the quadruple visual analog scale was not specifically designed for scoliosis patients. However, it does provide an easy-to-collect dataset from which to evaluate treatment impact on pain levels. Future studies should include quality of life indices specifically designed for the scoliosis patient population.

6. Conclusion

Based upon the comparative data, adult scoliosis patients wearing the scoliosis activity suit for 10 years did not see their curves increase as expected according to previously published natural history. Those with single thoracic and single lumbar curve patterns achieved a statistically significant reduction in their curves. Patients with single thoracic, single lumbar, and double major curves all reported significant reductions in self-rated pain. These results warrant further prospective trials in adult scoliosis patients.

Author Contributions

The author is solely responsible for the preparation of this manuscript and approved the manuscript in its current form.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

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