

**RESEARCH ARTICLE**

## **Clinical outcomes of a scoliosis activity suit worn by patients with chronic post-fusion pain: 6-month case-controlled results.**

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### Abstract

**Purpose:** Spinal fusion surgery is the recommended treatment in the United States for scoliosis measuring beyond 50°. However, pain and disability are long-term concerns many patients face. This study intended to evaluate results of wearing a scoliosis activity suit in patients with a history of spinal fusion surgery.

**Methods:** A retrospective collection of patient data was obtained and compared to data obtained from people who did not participate in the treatment. Data from both groups had been collected at 6 months following a specific list of inclusion criteria. These data included radiographic Cobb angle, quadruple numerical pain rating scores (QVAS), and SRS-22r questionnaire.

**Results:** Post-fusion patients wearing the scoliosis activity suit achieved significant improvements in Cobb angle, QVAS scores, and SRS-22r scores at 6 months as well as compared to the control group. Harrington rod fusion patients tended to improve more than patients with newer pedicle screw instrumentation.

**Conclusion:** The scoliosis activity suit may be a clinically useful therapy in adult post-fusion scoliosis patients seeking pain management strategies aside from commonly recommended pharmacological management. The scoliosis activity suit improved the Cobb angle in Harrington rod patients, and increased the quality of life for all fusion patients when compared to controls after 6 months of use.

## Introduction

Approximately 38,000 spinal fusion surgeries are performed for progressive adolescent idiopathic scoliosis annually [1]. Spinal fusion surgery is the standard of care for progressive scoliotic curves reaching or exceeding 50° [2]. While spinal fusion surgery for scoliosis has been the gold standard treatment for decades, recent evidence raises concerns over its long-term impacts [3]. In patients who had Harrington rod surgery 16.7 years prior, nearly 40% of them were classified as legally disabled [5]. Recently, it has been shown that 41% of patients who receive spinal fusion for scoliosis develop chronic or persistent pain after the surgery [6]. Given that post-fusion patients still experience pain after surgery [7], adult patients are seeking more opportunities for pain management.

Conventionally, adult post-fusion patients seeking pain management interventions may commonly receive steroid injections, opioid prescriptions, epidural injections, or medical cannabis. However, the effects of these therapies are short-lived in many cases [8]. Although infrequent, the risk of severe complications with repeated injections or epidurals may not be worth the temporary benefit [9]. Finally, the risks of dependency and increased afferent sensitization from opioids [10], as well as the unknown long-term risks of a newer therapy like medical cannabis [11] make these choices difficult for patients.

Recently, Morningstar et al have published radiographic, pain, and functional outcomes for an adult post-fusion patient who wore a scoliosis activity suit for 8 months as a pain management strategy [12]. The scoliosis activity suit is a neoprene wrap-style exercise suit. A sample setup of the suit is depicted in **Figure 1**. The activity suit is composed of 4 separate pieces: 1) the Anchor, which is fitted to the patient's thigh, 2) the Lumbar, which attaches directly to the Anchor and counter-rotates the lumbar spine; 3) the Torso, which provides counter-rotation about the thoracic spine relative to the lumbar spine, and fastens to the Lumbar piece; and 4) the tension straps, which allow for the transmission of rotational forces between the Torso and Lumbar pieces. The tension straps are what provide the majority of rotational force as the patient is ambulating. The pieces are configured based upon the patient's curve pattern, and the tension straps are applied relative to each patient's ability to react against the tension straps. The tension straps may be long or short. The longer tension straps are more elastic and provide more rotational resistance to which to resist, while the shorter straps provide more of a supportive barrier for patients who need more external support.

This present case-controlled series documents the pain, functional, and radiographic outcomes in a sample of adult post-fusion patients who wore the scoliosis activity suit for 6 months.

**Figure 1**



**A sample illustration of an adult scoliosis activity suit setup.**

### **Methods**

A series of records were evaluated from a single multidisciplinary medical center. All patients whose files were selected signed HIPAA-approved informed consents to publish their non-identifying data. In addition to radiographic Cobb angle, pain and quality of life measures were also used. These included a quadruple numeric pain rating scale (QVAS), and the Scoliosis

Research Society's SRS-22 revised questionnaire (SRS-22r).

For patient records to be chosen for the intervention group, each chart needed to satisfy the following inclusion criteria: 1) Patients must have received some version of spinal fusion for scoliosis, 2) patients were 18 years of age or older at time they started wearing the scoliosis activity suit, and 3) they must have worn the activity suit for at

least 6 months. Adhering to this inclusion criteria, a total of 39 patient files were included. A control group was created from the information collected from adult scoliosis patients with a history of spinal fusion who decided not to pursue using the scoliosis activity suit. These people either requested information, or came to the clinic to be fitted, but still opted to forego the treatment. Out of 213 adults not receiving treatment, who were asked to complete the quadruple numeric pain rating scale and the SRS-22r, baseline and 6-month data were collected from 47 of them.

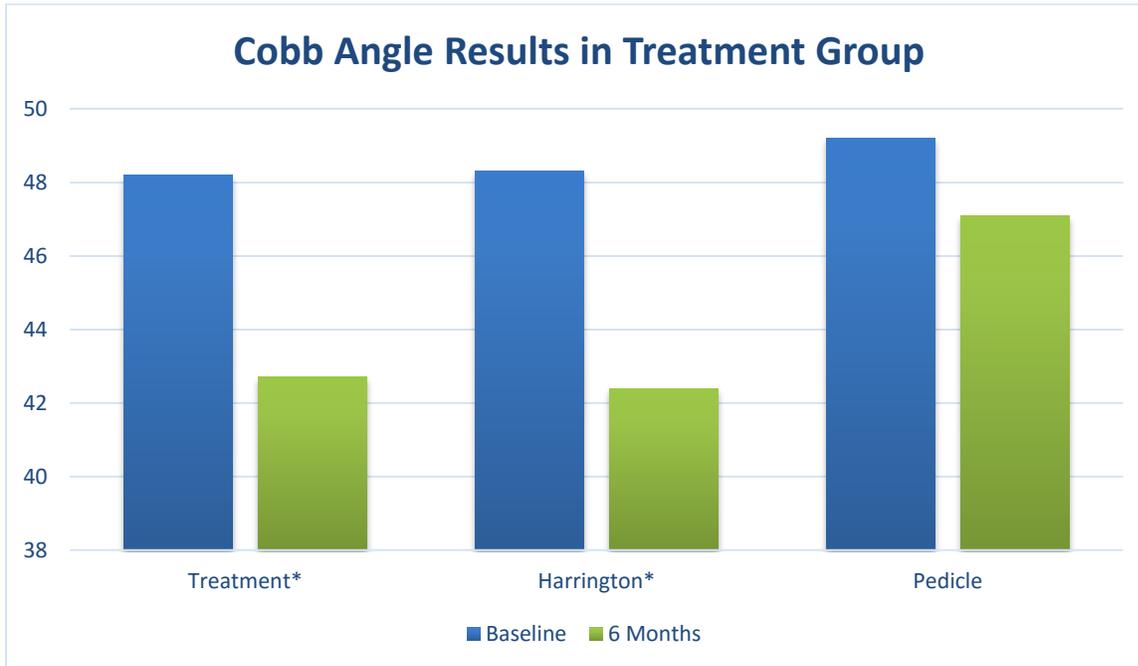
All patients in the intervention group wore the scoliosis activity suit for at least 6 months. Over the first 6 months of use, patients were instructed to slowly build the length of time they wore the suit each day from 20 minutes twice daily to 2-3 hours twice daily. Patients were encouraged to perform all of their normal daily activities while wearing the scoliosis activity suit. Since the thigh is the impetus for the counter-rotation produced by the activity suit, the patient needed to be weight bearing in order for the suit to provide a corrective anti-rotational effect. The only time patients could not count toward their total wear time was when they were lying down. At 6 months, patients returned to the office for an updated standing scoliosis radiograph, or were referred locally for the radiograph. Cobb angle measurements were obtained from these radiographs. Patients also completed an updated quadruple numeric pain rating scale and an SRS-22r for

comparison. This study was granted IRB exemption by IntegReview IRB .

### **Results**

The Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) considers a change of 6° to be clinically significant [13]. Power analysis using Power & Precision 4 software demonstrated that 32 patients would produce 80% power to show that 6° is statistically significant. Remaining statistical analyses were performed using Microsoft Excel 2010. The treatment group was composed of 39 patients (3 male, 36 female), with an average age of 47 years. The control group totaled 47 subjects, with an average age of 45 years (4 male, 42 female). The treatment group consisted of 10 patients with pedicle screw instrumentation and 29 patients with Harrington instrumentation. The control group had 16 and 31, respectively. Single factor ANOVA testing showed these groups to be similar based on surgery type ( $P=0.404321$ ). Paired t-tests and one-way ANOVA testing were used to compare within-group differences at baseline and 6 months, as well as between-group differences at the same time intervals. When comparing the before and after Cobb angle measurements, the treatment data were divided into multiple groups: 1) the entire treatment cohort, 2) the Harrington treatment group, and 3) the pedicle screw treatment group. **Figure 2** provides an illustration of their respective before and after results.

**Figure 2**



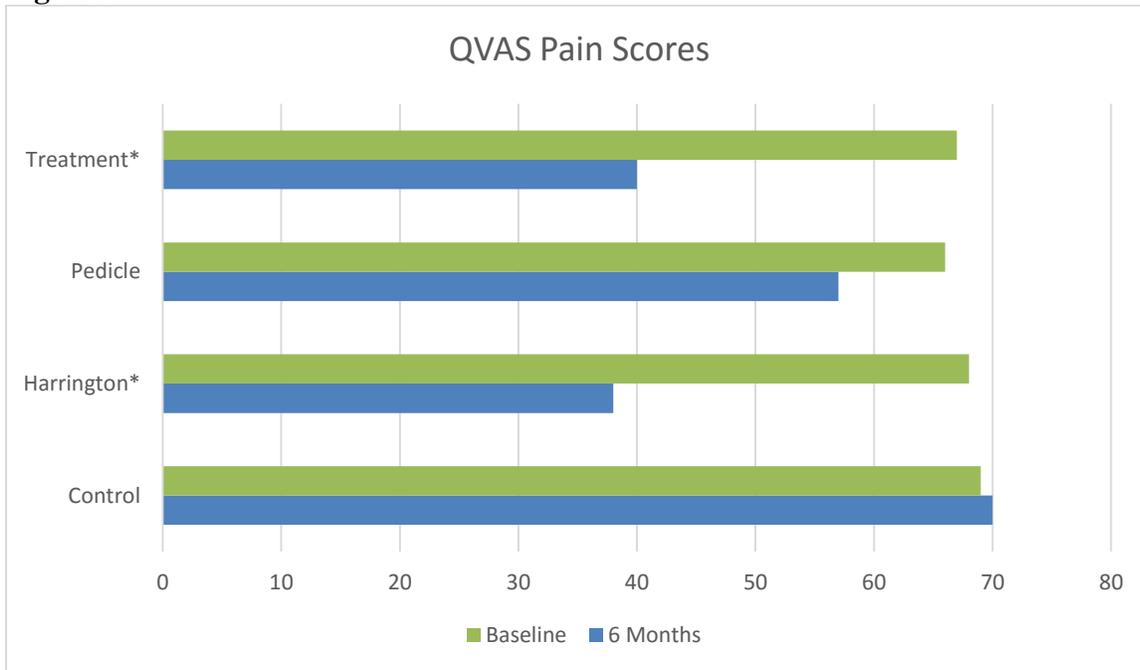
\* Difference was statistically significant at  $P < .001$

The Cobb results could not be reported for the Control group, as there was no 6-month radiographic taken to review for these people. The treatment group had statistically significantly improved Cobb angles at 6 months, decreasing from an average of  $48.2^\circ$  to  $42.7^\circ$  ( $P < .001$ ). When the treatment group was divided by fusion type (Harrington vs. pedicle screw instrumentation), the Harrington group saw their curves decrease  $5.9^\circ$  ( $P < .001$ ), while the pedicle screw patients had a change of  $2.1^\circ$  ( $P = 0.018813914$ ). Within the treatment group, there were 29 Harrington patients and 10 pedicle screw patients. In the control group, these values were 30 and 17, respectively. When rating pain on a quadruple numeric pain rating scale (QVAS), the treatment group reported a baseline average score of 67, with an average 6-month score of 40 ( $P < .001$ ). The control group had a baseline score of 69, with a 6-month score of 70.

One-way ANOVA testing showed that the baseline scores between these groups were similar ( $P = .518177$ ). The 6-month scores were statistically different between groups ( $P < .001$ ). The Harrington treatment group had a baseline score of 68, and 6-month score of 38 ( $P < .001$ ), while the pedicle screw group had baseline and 6-month scores of 66 and 56, respectively. This change was not statistically significant at  $P = 0.028211242$ . These scores are shown in **Figure 3**.

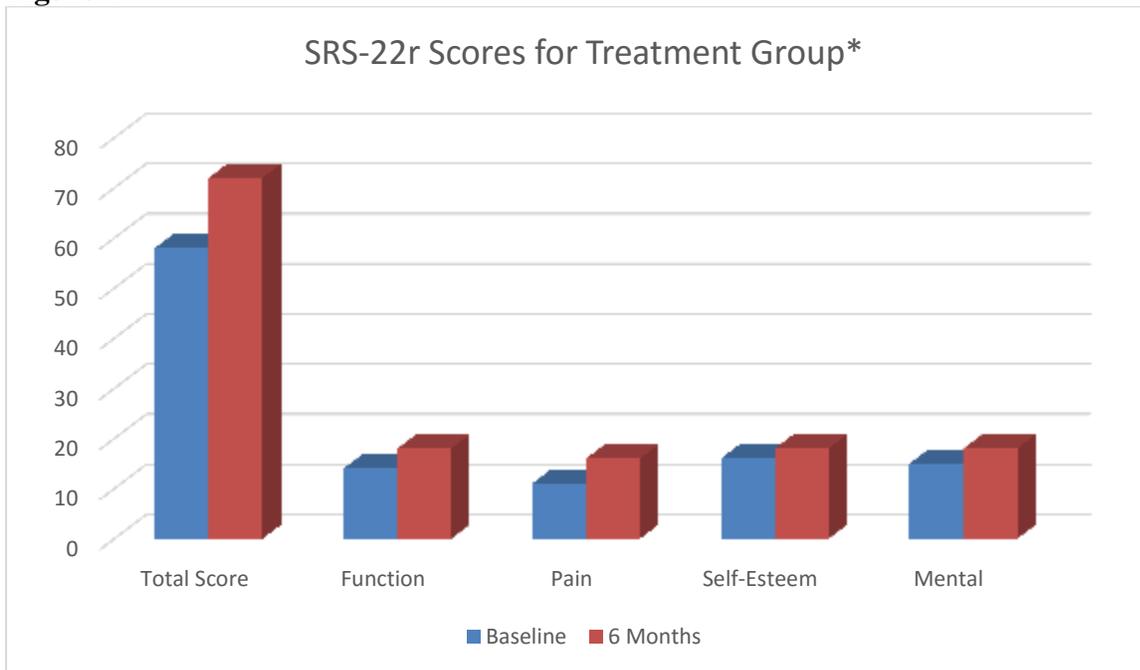
The Scoliosis Research Society-22 revised (SRS-22r) questionnaire was totaled and subtotaled for all groups. For the treatment group, whose scores for the SRS-22r are shown in **Figure 4**, the initial average total score was a 58/100, and a 6-month average total of 71/100, resulting in a P value less than .001. Baseline total SRS-22r scores for both groups were statistically similar ( $P = .002324$ ).

**Figure 3**



\* Difference was statistically significant at  $P < .001$

**Figure 4**



\* All differences were statistically significant at  $P < .001$

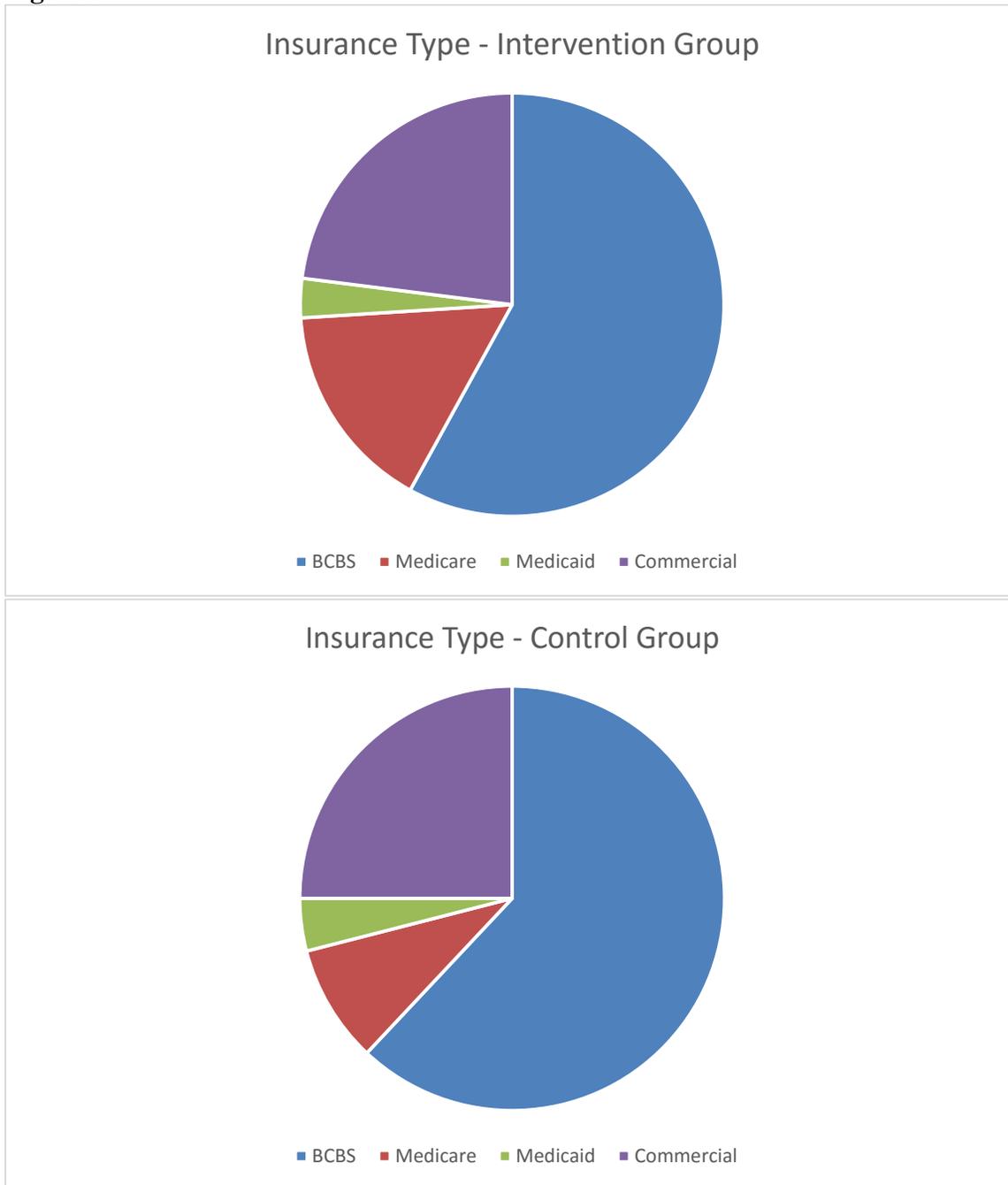
The 2 questions regarding management satisfaction were not calculated into the total score, and instead calculated separately. On the Function portion of the SRS-22r, the treatment group had average initial baseline and 6-month scores of 14 and 18, respectively ( $P < .001$ ). Treatment group scores for the Pain portion of the SRS-22r were 11 and 16. For the Self-Esteem portion of the questionnaire, the treatment group scored an average of 16 and 18, respectively. Finally, on the Mental portion of the questionnaire, they scored a baseline of 15, and a 6-month of 18. Statistically significant differences between the treatment group and control group total scores was determined by one-way ANOVA testing.

When breaking down the treatment group into the Harrington and pedicle screw groups, both groups had baseline scores of 58. The Harrington group had a 6-month total score of 72, while the pedicle screw group had a 6-month score of 68. Both 6-month values were statistically significant ( $P < .001$ ). The Harrington group achieved significant ( $P < .001$ ) improvements in all 4 SRS-22r individual categories. Function improved from 14 to 18, Pain improved from 11 to 17, 16 to 18 in Self-Esteem, and 15 to 18 in Mental Health. In the pedicle screw group, in addition to the total score, the only category to reach a statistically significant difference was the Self-Esteem section, improving from 17 to 19 ( $P < .001$ ).

The final portion of the SRS-22r has to do with the patient's satisfaction of their current management. In the treatment group, their initial average satisfaction score with prior management was a 2.9. At 6 months their satisfaction score increased to 7.3. This change was significant ( $P < .001$ ) when compared within the treatment group as well as between groups at 6 months. In the control group, their initial score was 3.4, while their 6-month score was 3.3.

The 2 groups in the present study had similar breakdowns by insurance type. **Figure 5** shows a comparison of the insurance makeup for each group. Given that insurance coverage for any medical procedure or service can be a significant barrier to patient access, this demographic was used to minimize selection bias, as the present study was a retrospective chart review. Commercial insurances accounted for 23% (9 patients) in the treatment group, and 25% (12 subjects) in the control group. Blue Cross Blue Shield insurances made up 58% (23 patients) of the treatment group, and 62% (29 subjects) of the control group. The treatment group had 16% (6 patients) Medicare patients, while the control group had 9% (4 subjects). Only 3% of the treatment group (1 patient) and 4% of the control group (2 subjects) had Medicaid or were uninsured. Single factor ANOVA testing showed that these differences were not statistically significant.

**Figure 5**



## **Discussion**

The patients selected in this study were those with a history of post-surgical fusion for juvenile or adolescent idiopathic scoliosis. This population of patients has a significant chance of becoming disabled following fusion surgery [14]. Patients in our treatment and control groups typically showed high intensity initial average QVAS scores (67 for the treatment group, 69 for the control group). All of the people in both groups initially expressed interest in treatment. Therefore, these two groups may not be reflective of all post-fusion patients, as those in less pain would not be as likely to seek treatment initially.

Given that a portion of post-fusion patients still see their curves progress over time [15], it is possible, albeit unlikely, that the observed changes in Cobb angle may have been a reduction in the amount of progression that had occurred between the initial post-operative measurement and the time at which they presented for the current treatment.

Although we were able to obtain baseline and 6-month questionnaire results from control subjects, we could not obtain 6-month radiographic results from this group. Therefore, we could not perform between-group comparisons to determine any differences. However, the purpose was primarily to use the scoliosis activity suit as a pain control device, therefore, priority was not given to obtaining follow-up radiographs at the time data were collected.

It is noteworthy to discuss the differences in the outcomes of patients receiving the

Harrington surgery as compared to the newer posterior pedicle screw instrumentation techniques. Aside from the lack of change in the Cobb angle in the pedicle screw group, only one section on the SRS-22r, the Self-Esteem section, demonstrated a statistically significant change at 6 months. However, the total score for the pedicle screw group on the SRS-22r was also statistically significant. Our only theory as to why this would happen is that the newer techniques require many more vertebral attachment points for the hardware as compared to the Harrington instrumentation, leaving less intrinsic joint flexibility to recruit during global musculoskeletal function.

## **Conclusion**

A group of patients who were status post-spinal fusion for a history of idiopathic scoliosis wore a scoliosis activity suit for 6 months. At the end of this time, radiographic Cobb angle, as well as total scores on a quadruple numerical pain rating scale and SRS-22r, were significantly improved compared to baseline. These values were also significantly different compared to a control group comprised of people with a similar insurance demographic. Patients with a history of Harrington rod instrumentation scored better overall on follow-up scales when compared to those with newer surgical techniques. Harrington rod patients also achieved significant Cobb angle reductions compared to pedicle screw patients.

## References

- [1] National Scoliosis Foundation. <http://www.scoliosis.org/info.php>  
Accessed: 03/30/2016.
- [2] Negrini S, Aulisa AG, Aulisa L, Circo AB, de Mauroy JC, Durmala J, et al. 2011 SOSORT guidelines: Orthopaedic and Rehabilitation treatment of idiopathic scoliosis during growth. *Scoliosis* 2012 7:3.
- [3] Weiss HR, Goodall D. Rate of complications in scoliosis surgery – a systematic review of the Pub Med literature. *Scoliosis* 2008; 3:9.
- [4] Sponseller PD, Cohen MS, Nachemson AL, Hall JE, Wohl ME. Results of surgical treatment of adults with idiopathic scoliosis. *J Bone Joint Surg Am* 1987; 69: 667-675.
- [5] Götze C, Slomka A, Götze HG, Pötzl W, Liljenqvist U, Steinbeck J. Long-term results of quality of life in patients with idiopathic scoliosis after Harrington instrumentation and their relevance for expert evidence. *Z Orthop Ihre Grenzgeb.* 2002;140:492-8.
- [6] Chidambaran V, Ding L, Moore DL, Spruance K, Cudilo EM, Pilipenko V, et al. Predicting the pain continuum after adolescent idiopathic scoliosis surgery: A prospective cohort study. *Eur J Pain.* doi:10.1002/ejp.1025.
- [7] Cochran T, Irstam L, Nachemson A. Long term anatomic and functional changes in patients with AIS treated by Harrington rod fusion. *Spine* 1983;8:576-584.
- [8] Manchikanti L, Helm S 2nd, Fellows B, Janata JW, Pampati V, Grider JS, Boswell MV. Opioid epidemic in the United States. *Pain Physician.* 2012 Jul;15(3 Suppl):ES9-38.
- [9] Bicket MC, Chakravarthy K, Chang D, Cohen SP. Epidural steroid injections: an updated review on recent trends in safety and complications. *Pain Manag.* 2015;5(2):129-46.
- [10] Manchikanti L, Buenaventura RM, Manchikanti KN, Ruan X, Gupta S, Smith HS, Christo PJ, Ward SP. Effectiveness of therapeutic lumbar transforaminal epidural steroid injections in managing lumbar spinal pain. *Pain Physician.* 2012 May-Jun;15(3):E199-245.
- [11] Shah A, Craner J, Cunningham JL. Medical cannabis use among patients with chronic pain in an interdisciplinary pain rehabilitation program: Characterization and treatment outcomes. *J Subst Abuse Treat.* 2017 Jun;77:95-100.
- [12] Morningstar MW, Dovorany B, Stitzel C, Siddiqui A. Radiographic, Pain, and Functional Outcomes in an Adult Post-Fusion Patient Using a Scoliosis Activity Suit: Comparative Results after 8 Months. *International Journal of Clinical Medicine,* 7, 265-269.
- [13] Negrini S, Hresko TM, O'Brien JP, Price N; SOSORT Boards; SRS Non-Operative Committee. Recommendations for research studies on treatment of idiopathic scoliosis: Consensus 2014 between SOSORT and SRS non-operative management committee. *Scoliosis.* 2015 Mar 7;10:8.
- [14] Chidambaran V, Ding L, Moore DL, Spruance K, Cudilo EM, Pilipenko V, Hossain M, Sturm P, Kashikar-Zuck S, Martin LJ, Sadhasivam S. Predicting the pain continuum after adolescent idiopathic scoliosis surgery: A prospective cohort study. *Eur J Pain.* 2017 Aug;21(7):1252-1265.
- [15] Helenius I, Remes V, Yrjönen T, Ylikoski M, Schlenzka D, Helenius M, Poussa M. Harrington and Cotrel-Dubousset instrumentation in adolescent idiopathic scoliosis. Long-term functional and radiographic outcomes. *J Bone Joint Surg Am.* 2003 Dec;85-A(12):2303-9.