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Safety and Efficacy of Spinecall Spinal Fixation System for Adolescent Idiopathic Scoliosis

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Abstract

Study design: Retrospective case series including patient outcome assessment.

Objective: To study the safety and the efficacy of the Spine call spinal fixation system in comparison with similar series.

Background: The purpose was to determine the safety and the efficacy of a system which has been widely used in Brazil for over 15 years.

Methods: A total of 76 consecutive patients were treated by posterior instrumentation and arthrodesis from 2011 through 2017. Safety was evaluated by complications, reoperation type and occurrence. Efficacy was studied by the incidence of deformity corrections.

Results: There were no deaths, spinal cord or nerve root problems, or acute posterior wound infections. Proven pseudo-arthrosis occurred in one patient (1.3%) and in two cases was necessary debridement to remove infected tissue (2.6%). The implant-related reoperation rate was 1.3%, where an increased curvature was observed. The break of one screw (0.07% per screw) was reported, which did not lead to the need for reoperation. The largest Cobb angle averaged 57° pre-operative and 20.7° at latest follow-up, which means a 63.3% correction ($p<0.001$).

Conclusions: Spinecall spinal fixation system seems to be at least as safe and effective as other instrumentations as used for the surgical treatment of adolescent idiopathic scoliosis.

Keywords: Idiopathic scoliosis • Posterior instrumentation and arthrodesis • Safety • Efficacy • Spinecall spinal fixation system

Introduction

Idiopathic scoliosis is the most common spinal deviation of unknown etiology and is defined as a frontal plane spinal deviation [1]. Diagnosis and treatment have been paying particular attention to the development of orthopedic surgery as a specialty. In its milder forms, scoliosis may only cause a change in trunk shape, but when severe, it may develop with cardiac and pulmonary involvement [2].

The classification of the Scoliosis Research Society (SRS) recommends that idiopathic scoliosis should be classified at the age of onset of deformity due to different subtype evolution. Infant scoliosis occurs between birth and three years of age; juvenile idiopathic scoliosis between the ages of four and ten; and adolescent idiopathic scoliosis, the focus of this study, between ten years of age and skeletal maturity [3].

Characteristics of adolescent idiopathic scoliosis include a three-dimensional spinal deformity with lateral curvature plus rotation of the vertebral bodies. Most idiopathic curves are lordotic, on the lumbar region, or kypokyphotic in the thoracic region, which may represent an important factor in its etiology [4].

Posterior fusion with instrumentation has been a standard of the surgical treatment for scoliosis since first introduced by Paul Harrington [5]. In his system, correction force was applied with distraction along the concavity of the curve. In the second generation instrumentation, the system developed by Cotrel and Dubousset [6], attempted correction by the rod-rotation maneuver. In modern instrumentation systems, more anchors are used to connect the rod and the spine, resulting in better correction and less frequent implant failures [7].

Radiographic and clinical results of procedures involving instrumentation using pedicle hooks and screws show that instrumentation using pedicle

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screws leads to greater correction of the main and the compensatory curves, show better parameters of respiratory function and allow lower levels of arthrodesis when compared to previous methods. In addition, there is no difference regarding loss of correction, trunk decompensation, junctional kyphosis, bleeding, neurological complications and length of surgery [8]. An example of the wide use of this type of instrumentation in the correction of idiopathic scoliosis, especially in Brazil, is the Spinecall spinal fixation system (Spine Implantes Importacao e Exportacao Ltd, Brazil). This instrumentation has been available in the Brazilian market for 15 years, with wide use, and despite the importance of the referred material, there is still no information available on its performance. Therefore, the present exploratory study aims to investigate the safety and the efficacy levels of the Spinecall spinal fixation system in the surgical treatment of adolescent idiopathic scoliosis.

Materials and Methods

In the 6-year period from 2011 through 2017, 76 consecutive patients, with adolescent idiopathic scoliosis were treated by a team of surgeons at two hospitals (Children's Hospital Dr. Jeser Amarante Faria - Joinville - SC - Brazil "HJAF" and University Hospital Ciencias Medicas, Belo Horizonte, MG, Brazil) with primary posterior instrumentation and arthrodesis using Spinecall spinal fixation system (Spine Implantes Importaçao e Exportaçao Ltd, Brazil). Minimum 2-year follow-up results have been reported earlier for all patients.

A relatively conservative philosophy was followed. The indications for the operation in the thoracic spine were coronal plane curves that were unlikely to be corrected to 30° or less and hyperkyphosis not correcting on supine cross-table lateral radiograph, or in some cases both. Indications in the thoraco-lumbar spine were curves that were unlikely to be corrected to less than 20°, and end vertebrae with likely residual coronal angulation of 10° or more and transverse plane angulation of 5° or more. This retrospective study was approved by the Human Subjects Committee of the Faculty of Medicine, University of São Paulo (Brazil), with the document number 3.156.788.

As part of routine care, follow-up was attempted at 6 months, 1 year, and 2 years. It was also encouraged at 4 and 6 years.

The office charts and radiographs were reviewed by two senior authors (C.H.M) and (R.G.G.), and most were reviewed by another two authors (R.A.S.) and (R.F.L.). Four junior authors (F.L., V.O.M., C.H.A.C., S.T.G.) reviewed office and hospital charts. Discrepancies, when found, were discussed, and a joint decision was made as to their meaning.

The demographic variables recorded were sex, age at surgery, height, weight, and reason for follow-up. The latest follow-ups that were necessary due to symptoms (PRN follow-ups as noted) were included. Body mass index (BMI) was calculated using the formula: weight (kg)/height $(m)^2$.

Pseudo-arthrosis was determined by follow-up radiographs and reoperation. Patients with visible lack in continuity of fusion mass and those reoperated with findings of pseudo-arthrosis were considered to have a definite pseudo-arthrosis. Those with an increase of the scoliosis curve of more than 15°, an increase of 10°, or more, in proximal or distal kyphosis that included a portion of the instrumented region, or an implant breakage at less than a 2-year follow-up, were considered to have possible pseudo-arthrosis.

Safety was evaluated by complications and reoperations. Complications that could in any way be related directly to the implants were considered implant complications and those associated with any major surgery as non-implant complications. Reoperations were categorized as implant or non-implant related and the interval to reoperation determined.

Statistical Analysis

First, the data normality parameters were verified by the Kolmogorov-Smirnov test. In addition to the descriptive statistics, the significance of the differences between preoperative, postoperative and follow-up measurements was verified using a repeated measures analysis of variance that was performed along with post hoc analysis (adjusted for multiple comparisons, Bonferroni approach). A significance level of $p<0.05$ was adopted and the analyzes were conducted using the PASW statistics 23.0 (SPSS®) statistical package.

Operative Technique

The procedure was performed with the patient under general anesthesia and with intra operative electrophysiological neuromonitoring. It began with posterior midline access and subperiosteal exposure to allow visual inspection of the deformity. Pedicular screws were placed according to previous surgical planning and a rod applied with derotation maneuvers at the apex of the curve to progressively realign the spine andrelocate the apical vertebrae towards the sagittal plane (Figure 1).

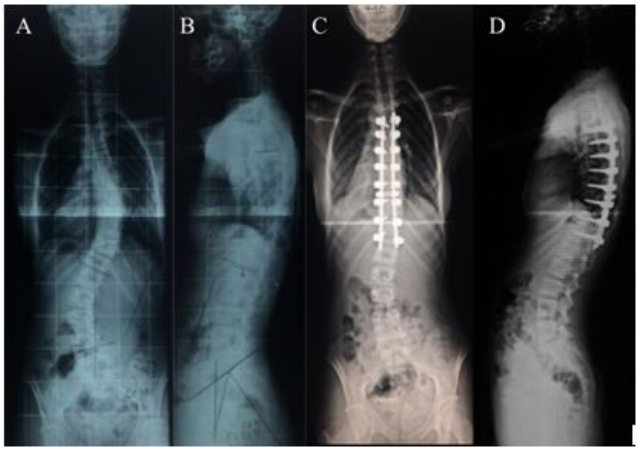

Figure 1. A 15-year-old female patient with adolescent idiopathic scoliosis, right main thoracic curve, classified as Lenke 1AN. Radiograph in preoperative anteroposterior (A) and lateral (B) standing. Postoperative X-rays after 6-month follow-up in anteroposterior (C) and lateral (D) planes show good T4-L1 correction from a previous 44° to 13° (70.45%).

Study group

A total of 76 patients met study inclusion criteria; 65 were female and 11 were male, with a mean age of 14.3 years (± 1.8 years; range, 10 - 18 years). BMI averaged 21.7 for females (± 3, range, 17.6–30.1) and 22.3 (± 0.4, range, 21.8–22.8) for males. The mean largest Cobb angle was 57° (± 15.6°, range, 32° - 112°). Curve pattern distribution was 34 double (44.7%), 25 thoracolumbar/lumbar (32.9%), 12 thoracic (15.8%) and 5 triple (6.6%). An average of 9 (± 3.5, range, 2 - 20) vertebral segments were instrumented and arthrodesed. The upper instrumented vertebra was C4 in 1 (1.3%), C6 in 1 (1.3%), T1 in 3 (3.9%), T2 in 5 (6.6%), T3 in 4 (5.3%), T4 in 13 (17.1%), T5 in 18 (23.7%), T6 in 13 (17.1%), T7 in 1 (1.3%), T8 in 2 (2.6%), T9 in 1 (1.3%), T10 in 6 (7.9%), T11 in 5 (6.6%), T12 in 2 (2.6%) and L2 in 1 (1.3%). The lower instrumented vertebrae were T8 in 1 (1.3%), T9 in 1 (1.3%), T10 in 3 (3.9%), T11 in 2 (2.6%), T12 in 6 (7.9%), L1 in 6 (7.9%), L2 in 3 (3.9%), L3 in 19 (25%), L4 in 24 (31.6%) and L5 in 11 (14.5%). A total of 1424 pedicle screws were inserted.

Results

Safety of the procedure

There were no deaths, spinal cord or spinal nerve injuries. From the study group, a total of four patients (5.2%, 4 of 76) had a total of 4 post-surgery complications. Two patients (2.6%, 2 of 76) presented no-implant-related complications that required debridement to remove infected tissue. The other

two cases (2.6%, 2 of 76) were implantrelated, and in one case (1.3%, 1 of 76), one screw (0.07%, 1 of 1424) that was inserted into the sacrum was broken and no reoperation was necessary to remove it. However, in the other implant-related case (1.3%, 1 of 76), reoperation was required due to increased curvature after the first year of follow-up (pre surgery T6 - T12 Cobb = 63° and T12 - L4 Cobb = 45°, postsurgery T5 - T12 Cobb = 53° and T12 - L5 Cobb = 39°, 1 year follow up T5 - T10 Cobb = 87° and T11 - L4 Cobb = 54°, 2 year follow up T5 - T12 Cobb = 55° and T12 - L5 Cobb = 35°).

Efficacy of the procedure

For the 76 patients with radiographic follow-up exceeding 2 years, the largest Cobb angle averaged 57° (± 15.6°, range: 32° - 112°) preoperative, 20.4° (± 12.7°, range: 0° - 60°) postoperative and 20.7° (± 12.1°, range: 0° - 60°) at the latest follow-up. The average correction after surgery is 64.6% (± 18.4%, range: 15.9% - 100%) and at the latest follow-up is 63.3% (± 17.8%, range: 12.7% - 100%).

Postoperative Cobb, as well as the latest follow-up Cobb, were significantly different (Figure 2) from the preoperative Cobb ($p<0.001$ and $p<0.001$ respectively), and there were no differences between the postoperative and last follow-up values ($p=0.981$).

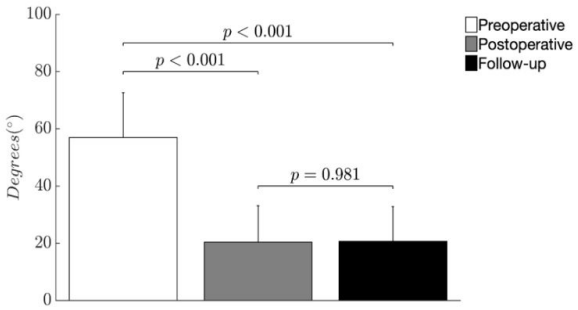

Figure 2. Cobb angles at preoperative, significantly reduced in the postoperative period and the correction maintained during follow-up.

Discussion

The Spinecall spinal fixation system consists of devices that when implanted establish a construct with a mechanical structure that provides stabilization of the segment affected in the spine. The Spinecall is among the most used systems in Brazil. Thus, this study aims to compare the performance of Spinecall with other implant systems in the treatment of adolescent idiopathic scoliosis.

A limitation of our study is that it consists of a retrospective study in which the data were generated by the team that conducted the procedure. To counteract this, the hospital and clinic data have been reviewed by two senior residents and most of the charts and radiographs by two junior staff. Statistics have been done on completely de-identified data by another member of the research team.

The first comparison that can be made is the absence of deaths in our series, while the mortality reported in the period between 2009 and 2012 ranged from 0.21% to 0.08%, respectively [9]. Also the absence of spinal cord and nerve complications in our series is a good indicator when compared with the reported data in literature during the same period (2009: 0.41%; 2012: 0.48%) [9].

The number of cases with infections found in our series (2.6%, 2 of 76) is below the range (3% to 6.9%) reported in other series [10-12], but it should be pointed out that our cases were superficial, not implant-related and solved with debridement.

The lower rate of cases presenting pseudo-arthrosis (1.3%) classified by the increase of the curvature compares positively with the range (5.5% to 9.2%) reported in the literature [13,14]. In addition, the unplanned reoperation rate for the compared series was 9.2% [14], and limited to curve/implant-related indications, thus, our 1.3% overall reoperation rate compare very favorably.

The rate of cases with screw breakage in our series (1.3%) is favorably comparable with the range reported in literature (0.4% to 24.5%), and it is noteworthy that our series features only one screw was broken in 1424 placed, representing a rate of 0.07% per screw, extremely low number compared to other data series (1% to 11.2%) [15-17]. With respect to the efficacy of the procedure, our retained Cobb correction at follow-up of 63.3% is inside of the range presented in the compared series: ranging from 61.4% to 69.6% [18,19].

Conclusion

Of the 76 consecutive patients, 100% were followed by radiographic outcome for a minimum period of two years and maximum of six years. There were no deaths, spinal cord or nerve root injuries, or acute deep wound infections. Implant related reoperation was 1.3%. The mean preoperative curve of 57° was corrected at follow-up by 63.3%. After comparing the data with other series reported in the literature, we conclude that the Spinecall spinal fixation system has similar or better efficacy and safety results than other systems on the market.

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