

# *Scoliosis Research*

## *List of Peer Reviewed Articles*

### **Sections:**

1. Bracing
2. Surgery
3. Miscellaneous/General Discussion or Opinion

Note: Highlighted sections emphasized by me

# Pulmonary restrictive effect of bracing in mild idiopathic scoliosis

Thorax 1987;42:959-961

J D KENNEDY, C F ROBERTSON, A OLINSKY, D R V DICKENS, P D PHELAN

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## ABSTRACT

The use of bracing in the treatment of mild idiopathic scoliosis is controversial. A study of 33 adolescents showed that bracing significantly decreased lung volumes. Functional residual capacity was reduced by a mean of 26%, 18% of children showing a reduction of greater than 40%. The mean reduction in total lung capacity was 16% and in forced vital capacity 18%. This restriction of lung function by bracing might have a deleterious effect on lung growth or might impose an additional risk factor in the presence of other disorders, such as asthma and diaphragmatic weakness. The use of bracing in individuals with mild scoliosis should be judiciously reassessed.

Scoliosis is one of man's earliest known physical deformities. It has been depicted in cave drawings, noted in the mummified remains of the pharaohs, and aroused fear in Victor Hugo's tale of Quasimodo, the Hunchback of Notre Dame.

Despite this long history, its treatment, particularly bracing, remains controversial. The use of bracing in the management of scoliosis began during the 1940s with the introduction of the Milwaukee brace, designed to stabilise the spine postoperatively.<sup>1</sup> During the 1950s and 1960s bracing began to be used in the non-operative management of scoliosis. During the 1970s the Boston brace was introduced.<sup>2</sup> There is continuing debate in orthopaedic publications about the indications and effectiveness of bracing programmes.<sup>3 4</sup>

Although braces have been used extensively in the past 30 years, their effect on underlying lung function and chest wall mechanics is largely unknown. We report the effect of bracing on lung volumes in 33 adolescents with idiopathic scoliosis.

## Patients and methods

We studied 33 adolescents, six male and 27 female, with idiopathic thoracic scoliosis attending an orthopaedic clinic and being treated by bracing. Eight used a Milwaukee brace and 25 a Boston brace. Their mean Address for reprint requests: Dr C F Robertson, Professorial Department of

Thoracic Medicine, Royal Children's Hospital, Parkville 3052, Victoria, Australia. Accepted 21 July 1987 age was 13-3 years and the mean thoracic Cobb angle 29.0. In five children the thoracic curve had improved with bracing and at the time of testing was less than 20 degrees. The mean age of onset was 11.7 years (range 6-16 years) and the mean duration of bracing 1.4 years (range 1 month-5 years). None of the patients had cardiopulmonary symptoms at the time of testing. Functional residual capacity (FRC) and total lung capacity (TLC) were measured in the sitting position by means of body plethysmography (Jaeger Bodyscreen 2) both with and without the brace. The order of testing—that is, whether the brace was on or off for the first measurements was randomly selected to allow for a learning effect. All spirometric volumes were corrected to BTPS. The non-deformed height was taken as equal to arm span. In our laboratory the armspan:height ratio estimated from 2368 measurements of 8-18 year old subjects is close to unity (0.999 (SD 0.023) for girls and 1.006 (0.022) for boys).

The Milwaukee brace reduces lumbar lordosis with a polypropylene pelvic girdle and attempts to correct the thoracic curve with a metal vertical suprastructure on which are mounted pressure pads. The Boston bracing system also uses a polypropylene girdle, which, unlike the former, extends to enclose the lower thorax, again attempting to correct the spinal curve by means of pressure pads mounted on the inner surface, acting on the apices of the curve.

Six children with a brace induced reduction in FRC of over 30% were further studied to assess the effect of bracing on oxygen saturation during sleep. Oxygen saturation was monitored overnight with a Nelcor pulse oximeter; studies were performed on two nights, one with and the other without the brace.

We used analysis of variance, repeated measures design,<sup>5</sup> to assess the effect of gender and brace type on reduction in lung volumes; p values of less than 0.05 were regarded as significant.

The study was approved by the hospital ethics committee and informed consent was obtained from subjects and parents.

## Results

As a group, the subjects had normal lung volumes when unbraced (table 1). Although some patients had a mild restrictive defect, this did not correlate with age of onset of scoliosis or duration of bracing.

With the brace on, there were significant reductions in all the subdivisions of total lung capacity, especially FRC ( $p < 0.001$ ). FVC and FEV<sub>1</sub> were also reduced ( $p < 0.001$ ) (table 2). The 95th centiles for coefficient of variation for lung volumes in normal subjects from our laboratory are included in the table for comparison. The mean reduction in FRC was 26%. Six children (18%), however, had a reduction of over 40% and 13 children (39%) had a reduction of at least 30%. No difference was found between the restrictive effect of the brace on boys and on girls. There was also no difference

between the restrictive effects on lung volumes of the Boston and the Milwaukee brace. All overnight oximetry studies, both with and without the brace, showed normal oxygen saturation levels of 97-100% during sleep.

## Discussion

The use of braces in the conservative management of idiopathic scoliosis has been widely practised for the past four decades. Latterly their role has been under critical review. Recent long term reviews of both Milwaukee and Boston braces concluded that the mean effect of orthotic treatment is to produce a curve which is only a few degrees better than the original.<sup>9</sup>

The effect of these restrictive braces on the underlying lung and chest wall has remained unrecognised. Sevastikoglou et al<sup>1</sup> studied the effect of the Milwaukee brace in 26 patients with idiopathic scoliosis and reported that the brace did not alter vital capacity significantly, a conclusion with which we disagree. No previous study has examined in detail the change in the subdivisions of total lung capacity associated with bracing.

In our patients there were significant reductions in FEV<sub>1</sub> and FVC and in all the subdivisions of TLC, especially FRC (table 2). The reduction in lung volumes appears to be due to a combination of factors. In an attempt to reduce lumbar lordosis the brace is fitted tightly around the abdomen, thus displacing abdominal contents into the chest, reducing lung volumes, and restricting the downward movement of the diaphragm. With the Boston brace there is also a direct pressure effect on the ribcage, which further restricts respiratory excursion.

It is important to note that there was no difference in the degree of restriction of lung volumes imposed by the two types of brace. Although the Boston brace may vary from centre to centre, depending on individual modification, the Milwaukee brace design is consistent between centres, suggesting that the restrictive effect of these braces is not due to local design practices.

During inspiration, with descent of the diaphragm the intra-abdominal pressure rises. This pressure is relieved by the outward movement of the abdominal wall and lower rib cage. If these movements are restricted by a brace the intra-abdominal pressure will rise and impose an additional load on the diaphragm, which might have important implications for a child with diaphragmatic weakness.

Normal subjects have a 20% reduction in FRC on changing from the sitting to the supine posture.<sup>2</sup> As the mean reduction in FRC for children sitting with brace on was 26% we were concerned that there might be an additional effect while the child slept. This could be a particular problem during REM sleep, when there Pulmonary restrictive effect of bracing in mild idiopathic scoliosis may be a further fall in FRC owing to relaxation of the intercostal muscles,<sup>2</sup> and thus a risk of oxygen desaturation. Overnight oxygen saturation was, however, normal in all the six children whose brace restriction was the most severe.

The effects we have found might also have implications for a child who has asthma in addition. During an attack of asthma expiratory flows at all lung volumes are reduced. This is partially offset by an increase in FRC,<sup>3</sup> achieved by braking expiratory flow with partial glottis closure, increasing the respiratory rate and persisting inspiratory muscle activity during expiration.<sup>4,5</sup> The restrictive effect of a brace would be likely to limit the child's ability to increase FRC and to breathe at higher lung volumes.

An effect of scoliosis on lung growth has been documented<sup>6</sup> but the effect of prolonged use of a restricting brace during a period of continuing alveolar growth is unknown.

Although there is general agreement that bracing may be effective in progressive curves of 30-40°, idiopathic scoliosis beginning after the age of 11 years does not appear to carry the risk of cardiorespiratory failure that was hitherto believed.<sup>7</sup> Thus if braces do not appreciably alter the natural history of adolescent curves,<sup>3</sup> their use needs to be judiciously reassessed because, as we have shown, they can have a considerable effect on lung volumes, and there may be a potential risk of impairing lung growth or aggravating underlying disorders such as asthma or diaphragmatic weakness.

We gratefully acknowledge the technical assistance of Graeme Johnstone and Andrew Young, Department of Orthotics, and Ian Howlett and Stuart Brown, Department of Thoracic Medicine.

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# Surgical rates after observation and bracing for adolescent idiopathic scoliosis: an evidence-based review

LA Dolan and SL Weinstein.

Spine 2007; 32(19 Supplement): S91-S100. [[PubMed: 17728687](#)]

## CRD summary

The authors concluded that there was insufficient evidence to recommend either observation or bracing in preference to the other for reducing the surgical rate in adolescent [idiopathic scoliosis](#). There were limitations to this review, but the authors' conclusions reflect the limited and inconsistent evidence from [observational studies](#).

## Authors' objectives

To evaluate rates of [surgery](#) after observation (untreated) and bracing for adolescent [idiopathic scoliosis](#) (AIS).

## Searching

MEDLINE, Web of Science, the Cochrane Controlled Trials Register and Clinical Evidence were searched for studies published in the English language; the search terms were reported. In addition, reference lists were screened.

## Study selection

Study designs of evaluations included in the review

Clinical evaluations were eligible for inclusion.

## Specific interventions included in the review

Studies that evaluated observation or bracing (including thoracolumbosacral (TLSO) and bending braces but not including Milwaukee, SpineCor or Triac) without any other prescribed [interventions](#) were eligible for inclusion. The included studies evaluated a variety of different braces including the Wilmington, Providence, Boston, TLSO, Charleston and Rosenberger. Studies evaluated full-time (16 to 23 hours), part-time (12 to 16 hours) and night-time bracing.

## Participants included in the review

Studies in which most patients had AIS diagnosed at, or after the age of 8 years, and meeting current indications for bracing (age less than 15 years, Cobb angle between 20 and 45 degrees, and

Risser 0, 1 or 2) were eligible for inclusion. There were exceptions to these inclusion criteria and these were discussed. Most of the included studies involved males and females; some included only females. All studies included skeletally immature patients (Risser 0 to 2); some studies included a small number of patients with Risser 3 or 4. Cobb angles at the start of bracing ranged from 20 to 49 degrees. The patients had different types of curves (including thoracic, thoracolumbar/lumbar and double major).

### **Outcomes assessed in the review**

Studies that assessed [surgery](#), recommended surgery, and curve progression beyond 50 degrees were eligible for inclusion. Studies had to follow patients until at least skeletal maturity to be eligible. Where reported, the included studies used different indications for surgery (including undefined progression, and progression to more than 40 to 50 degrees and various other reported criteria).

### **How were decisions on the relevance of primary studies made?**

One reviewer selected the studies.

### **Assessment of study quality**

The authors did not state that they assessed validity.

### **Data extraction**

One reviewer extracted the data using a standardised form and repeated the data extraction a week later. Both versions were compared and discrepancies dealt with. Attempts were made to contact authors of studies with incomplete or missing information. For each study, the rate of [surgery](#) was presented.

### **Methods of synthesis**

#### **How were the studies combined?**

Pooled [prevalence](#) rates of [surgery](#) with 95% confidence intervals (CIs) were calculated separately for untreated patients (observation) and those who had undergone bracing, by dividing the total number of surgical [interventions](#) by the number of patients.

How were differences between studies investigated?

Differences between the studies were discussed in the text. Subgroup analysis was used to examine the effect on pooled [prevalence](#) rates of Cobb angle at [baseline](#), type of brace, curve type, Risser sign and bracing dose.

### **Results of the review**

Seventeen studies (n=1,953) were included. One retrospective study compared observation with bracing; the other studies provided data for one [treatment](#) only. Fifteen studies (n=1,814) provided



data for the evaluation of bracing and 3 studies (n=139) provided data for the evaluation of observation.

The sample size ranged from 15 to 139.

Surgical rates varied from 1 to 43% after bracing and from 13 to 38% after observation.

Pooled surgical rates were similar for bracing (23%, 95% CI: 20, 24) and observation (22%, 95% CI: 16, 29).

## **Authors' conclusions**

There was insufficient evidence to recommend either observation or bracing in preference to the other for reducing the surgical rate in AIS.

## **CRD commentary**

The review addressed a clear question that was defined in terms of the participants, [interventions](#) and outcomes. Only broad inclusion criteria were specified for the study design, but this seems appropriate given the limited evidence identified. Several relevant sources were searched but no attempts were made to minimise publication or language bias. Only one author selected studies and extracted the data, and this lack of duplication by another reviewer might have led to the introduction of error and bias. Adequate details of each included study were given. The data were pooled without a formal assessment of heterogeneity. The wide range of values for [surgery](#) rates suggest that pooling might not have been appropriate. However, attempts were made to examine potential sources of heterogeneity between the studies. Although study validity was not assessed, the limitations of evidence from [observational studies](#) were taken into account in the conclusions. There were limitations to this review, but the authors' conclusions reflect the limited and inconsistent evidence from observational studies.

## **Implications of the review for practice and research**

Practice: The authors stated that patients should be informed that there is no definitive evidence about the risk of [surgery](#) in AIS, and that the best estimates are that some 20 to 24% of patients who are treated with bracing will go on to have surgery.

They should also be told that there is no evidence that bracing is better than observation at reducing rates of future surgery.

Research: The authors stated the need for long-term studies to assess the effect of 'patient-determined' [surgery](#) and 'clinically determined' surgery on health and function throughout adulthood.

## **Funding**

Not externally funded.

### **Bibliographic details**

Dolan L A, Weinstein S L. Surgical rates after observation and bracing for adolescent idiopathic scoliosis: an evidence-based review. Spine 2007; 32(19 Supplement): S91-S100. [[PubMed: 17728687](#)]

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**Centre for Reviews and Dissemination**

CRD has determined that this article meets the [DARE scientific quality criteria](#) for a systematic review.

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PMID: [17728687](#)

# Adolescent idiopathic scoliosis: the effect of brace treatment on the incidence of surgery.

Spine (Phila Pa 1976). 2001 Jan 1;26(1):42-7.

Goldberg CJ<sup>1</sup>, Moore DP, Fogarty EE, Dowling FE.

## Abstract

### *STUDY DESIGN:*

Retrospective analysis of outcome in terms of incidence of surgery for adolescent idiopathic scoliosis during a period when bracing was not practiced.

### *OBJECTIVES:*

To determine whether centers with an active bracing policy have lower numbers undergoing surgery for adolescent idiopathic scoliosis than a center where nonintervention is the practice.

### *BACKGROUND DATA:*

Two major recent publications have claimed that bracing significantly improves the outcome in adolescent idiopathic scoliosis. However, one had no control subjects and the other did not examine the final status of the subjects under review. While statistically significant differences in progression have been observed, what will convince patients to submit to an onerous treatment is the conviction that it will make a substantial difference, such as the avoidance of surgery.

### *METHODS:*

Since 1991, bracing has not been recommended for children with adolescent idiopathic scoliosis at this center. The scoliosis database was searched for patients with adolescent idiopathic scoliosis who were at least 15 years of age at last review and who had adequate documentation of curve parameters. The incidence of surgery was compared with that of published data from other centers.

### *RESULTS:*

A total of 153 children, 11 boys and 142 girls, fitted the criteria. Forty-three of these (28.1%) have undergone surgery. This was not statistically different from the surgery rate reported from an active bracing center.

### *CONCLUSIONS:*

If bracing does not reduce the proportion of children with adolescent idiopathic scoliosis who require surgery for cosmetic improvement of their deformity, it cannot be said to provide a meaningful advantage to the patient or the community. Recent studies notwithstanding, the question of the efficacy of orthoses in idiopathic scoliosis remains unresolved.

# Scoliosis: discs and vertebrae. Cobb angle: friend or foe?

Ian AF Stokes

From 7th International Conference on Conservative Management of Spinal Deformities Montreal, Canada. 20-22 May 2010

## Introduction

Both vertebral and disc deformity contribute to scoliosis deformity, but the Cobb angle measures both, without distinguishing their relative magnitudes, which are approximately equal. (The disc deformity is greater in the lumbar region than in the thoracic.) Most attention has been given to the vertebral deformity, which apparently develops because of growth disturbance, and some subsequent remodeling. Conversely, discs do not grow in height while adolescent deformity is progressing. It appears from a few studies that progression of scoliosis occurs initially in the discs and subsequently in the vertebrae. Nutritional compromise has been implicated premature disc degeneration on the concave side in scoliosis. Our rat-tail model in which a curvature is imposed along with compression develops a 'structural' disc deformity with tissue remodeling after 5 weeks, and we are studying the underlying mechanisms.

## Materials and methods

Disc tissue from discs subjected to combinations of angulation, compression and reduced mobility for 5 weeks provided measurements of composition (water, GAG, collagen and cellularity), synthesis (via incorporation of radiolabelled proline and sulphate) and gene expression of matrix proteins, and degradative enzymes (real-time RT-PCR). Radiolabel incorporation and gene expressions were also measured after 5 days.

## Results

Compression resulted in increased GAG content, but angulation did not result in asymmetrical content. Synthesis rates (tracer incorporation) were higher at 5 days than 5 weeks. After 5 days, compression was associated with greater incorporation of both proline and sulphate. Gene expression studies showed matrix degradation indicative of degeneration and/or remodeling at 5 days in all groups and declining levels of tissue remodeling after 5 weeks.

## Discussion

Measurements of disc composition and metabolism indicated relatively small changes in tissue turnover relative to large reduction in disc space and mechanical flexibility. The disc wedging structural changes in human scoliosis may result from reduced mobility as well as asymmetrical compression.

## **Conclusion**

Disc deformity is a significant contributor to scoliosis, not specifically measured relative to vertebral deformity by the Cobb angle. Prevention of progressive disc deformity may require maintenance of mobility as well as reversal of loading asymmetry.

## **Surgery**

# SRS-22r Scores in Non-Operated Adolescent Idiopathic Scoliosis Patients with Curves Greater than Forty Degrees

[Spine \(Phila Pa 1976\)](#). 2016 Dec 2.

[Ward WT](#)<sup>1</sup>, [Friel NA](#), [Kenkre TS](#), [Brooks MM](#), [Londino JA](#), [Roach JW](#).

Orthopaedic Surgery, University of Pittsburgh, Chief, Pediatric Orthopaedic Division, Children's Hospital of Pittsburgh, 4401 Penn Avenue, Pittsburgh, PA 15224.

## Abstract

### *STUDY DESIGN:*

Case control comparative series OBJECTIVE.: Describe surgical range adolescent idiopathic scoliosis (AIS) patients electing to forgo surgery and compare health related quality of life outcomes to a similar cohort of operated AIS patients by the same single surgeon.

### *SUMMARY OF BACKGROUND DATA:*

No data have been published either documenting SRS-22r scores of non-operated patients with curves  $\geq 40^\circ$  or comparing these scores to a demographically similar operated cohort.

### *METHODS:*

Individuals with curves  $\geq 40^\circ$ , age  $\geq 18$  years, and electing to forgo surgery were identified. All patients completed an SRS-22r questionnaire. This non-operated cohort's SRS-22r scores were compared to those of a large demographically similar cohort operated by the same surgeon. Group differences between the SRS-22r scores were evaluated by comparing these to published Minimal Clinically Important Differences (MCID) for the SRS- 22r.

### *RESULTS:*

One hundred ninety subjects with non-operated curves were compared to 166 individuals who surgery. The non-operated cohort averaged 23.5 years of age, averaged 7.7 years since curve reached  $40^\circ$ , and had an average  $50^\circ$  Cobb angle at last follow-up. No statistical differences were found between the groups on the Pain, Function, or Mental Health domains of the SRS-22r. Statistically significant differences in favor of the operative cohort were found for Self-image, Satisfaction and Total score. The observed group differences did not meet the established thresholds for minimal clinically important differences in any of the domain scores, the average total score, or raw scores.

## **CONCLUSION:**

There are no meaningful clinically significant differences in SRS-22r scores at average 8 year follow-up between AIS patients with curves  $\geq 40^\circ$  treated with or without surgery. These data in conjunction with an absence of long-term evidence of serious medical consequences with non-surgical management of curves  $\geq 40^\circ$  should encourage surgeons to reevaluate the benefits of routine surgical care.

*LEVEL OF EVIDENCE: 3.*

PMID:

27922579

# Adolescent Idiopathic Scoliosis: 5-Year to 20-Year Evidence-based Surgical Results

Westrick, Edward R. MD; Ward, W. Timothy MD

Journal of Pediatric Orthopaedics: [January/February 2011 - Volume 31 - Issue - p S61-S68](#)

doi: 10.1097/BPO.0b013e3181fd87d5

## [Abstract](#)

Surgical intervention for adolescent idiopathic scoliosis (AIS) should be proven to alter the natural history without introducing iatrogenic complications. The risks of surgery should be substantiated by a body of scientific research, which should show a clear superiority of surgery over observation, both in the short term and the long term. The purpose of this review was to conduct a systematic search of the literature to critically evaluate the scientific evidence on the long-term outcomes and complications of surgical intervention for AIS. Our search identified 39 distinct patient populations with a minimum average follow-up of 5 years. No long-term, prospective controlled studies exist to support the hypothesis that surgical intervention for AIS is superior to natural history. Although surgery reliably arrests the progression of deformity, achieves permanent correction, and improves appearance, there is no medical necessity for surgery based on the current body of literature. However, the surgeon must not underestimate the psychological indication that occurs when a patient is no longer able to cope with the deformity.



# Scoliosis curve correction, thoracic volume changes, and thoracic diameters in scoliotic patients after anterior and after posterior instrumentation.

[Int Orthop.](#) 2001;25(2):66-9.

[Kovac V1](#), [Puljiz A](#), [Smerdelj M](#), [Pecina M](#).

## Abstract

Thoracic volume was calculated in 50 adolescent patients operated on for severe idiopathic thoracic scoliosis. In 25, anterior instrumentation was used (group 1), and posterior instrumentation in the other 25 patients (group 2). Calculation of thoracic volume was made from measurements of pre-operative and post-operative radiographs. The mean spinal curvature in group 1 was 73 $\pm$ 12.4 degrees before the operation, and 19 $\pm$ 15 degrees after the operation, and in group 2 the curvature was 75 $\pm$ 13 degrees before the operation and 37 $\pm$ 10 degrees after the operation. The calculated thoracic volume in the group with anterior instrumentation increased from 5234 ml pre-operatively to 6043 ml post-operatively, while with posterior instrumentation it increased from 5155 ml to 5489 ml. The correlation between the change in the Cobb angle and the thoracic volume change was poor for both groups. To determine the role in the thoracic volume increase of the frontal, sagittal and vertical thoracic diameters, further correlation tests were made between these and the thoracic volume increase in each diameter. The best correlation was found between the frontal and vertical increase of diameters in group 1, whereas in group 2 the best correlation was found between the volume increase and the sagittal parameters.

# Results of surgical treatment of adults with idiopathic scoliosis.

Sponseller, P D; Cohen, M S; Nachemson, A L; Hall, J E; Wohl, M E

Journal of Bone & Joint Surgery - American Volume: June 1987

## Abstract

The outcome of surgical treatment of idiopathic scoliosis in forty-five adults was studied with special attention to pain, function, self-image, and pulmonary function. All of the patients were more than twenty-five years old at operation and had been followed for more than three years. Every patient who was operated on by one of us (J. E. H.) and who met these criteria was evaluated. The magnitude of the curves averaged 66 degrees. Standardized gradations of pain and function showed improvement over-all, but significant impairment remained. There was a reduction in the levels of peak and constant pain, but no change in the frequency of peak pain after operation. The number of patients who were pain-free after surgery was not increased. Functional impairment due to the scoliosis was lessened, and the ability to perform the common activities of daily living was improved, but no important changes in occupation or recreational activity were recorded. Correlations of pain or function, or both, and the changes in either, were found with only two parameters: age at follow-up and physical occupation. Pulmonary function, as measured, did not change. Eighteen (40 per cent) of the patients had a minor complication and ten (20 per cent), a major complication; there was one death, due to pulmonary embolism, of a patient who was excluded from the series. **In view of the high rate of complications, the limited gains to be derived from spinal fusion should be assessed and clearly explained to patients before the procedure is undertaken.**

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# SCOLIOSIS SURGERY: APPROPRIATE MONITORING

Anesthesiology Clinics of North America

Volume 15, Issue 3, 1 September 1997, Pages 573–592

Tod B. Sloan, MD, PhD\*

[http://dx.doi.org/10.1016/S0889-8537\(05\)70352-7](http://dx.doi.org/10.1016/S0889-8537(05)70352-7)

## Abstract

Correction of scoliosis is largely an elective cosmetic procedure in the young population, who account for the largest portion of the surgical population. Associated with the correction, however, is a very real possibility of major neurological injury, including paralysis. Although the incidence of spinal cord injury was estimated as 0.5% in 1979, 75 newer instrumentation methods have markedly increased the risk.

More recent reviews have reported markedly higher figures (e.g., 17% neurologic complications with 4% paralysis<sup>29; 40 ; 84</sup>). The risks are highest for patients with kyphosis, congenital scoliosis, preexisting neurological impairment, and patients in traction preoperatively. As such, there has been a major impetus to develop monitoring methods that could warn the surgeon of impending spinal damage so that the procedure could be altered to improve outcome. Electrophysiologic techniques have been developed to meet this need, and scoliosis surgery serves as an excellent model to evaluate the application of these techniques. This article reviews these techniques and the results of their application to scoliosis surgery.

# 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 Sep-Oct;140(5):492-8.

Götze C1, Slomka A, Götze HG, Pötzl W, Liljenqvist U, Steinbeck J.

Abstract

AIM:

The expert evidence of operated patients with idiopathic scoliosis is determined by functional and pulmonary restriction. The degree of deformity and the extent of fusion is crucial for grading disability. In a retrospective study on the quality of life (SF-36) and low back pain (Roland-Morris Score) of 82 patients (22 - 40 years) with idiopathic scoliosis treated with Harrington instrumentation the grading was registered.

METHOD:

An average of 16.7 years after the surgery, these data were correlated with the type and size of curve and to the extension of fusion.

RESULTS:

Compared to the age-matched healthy population, there was no significant difference in the physical SF-36 scale ( $P = 0.98$ ). Surgically treated patients showed significantly lower scores than at baseline in the psychological SF-36 scale ( $P = 0.005$ ). Sixty-five (79.3 %) of the eighty-two patients reported no or occasional back pain in the Roland Index. Five patients (6.1 %) complained of chronic back pain. 33 patients (40 %) were legally defined in their rate of disability as severely handicapped patients. The grading disability was associated with the physical SF-36 scale ( $P < 0.001$ ) and the low back pain ( $P = 0.02$ ). A significant correlation between the grading disability and the extent of fusion ( $P = 0.53$ ) or the size of curve ( $p = 0.4$ ) could not be proven.

CONCLUSION:

Despite good long-term outcomes, 40 % of operated treated patients with idiopathic scoliosis were legally defined as severely handicapped persons. The additional measurements of quality of life and low-back pain can improve legal assessment in orthopaedics.

# Health and function of patients with untreated idiopathic scoliosis: a 50-year natural history study.

JAMA. 2003 Feb 5;289(5):559-67.

Weinstein SL1, Dolan LA, Spratt KF, Peterson KK, Spoonamore MJ, Ponseti IV.

Abstract

CONTEXT:

Previous long-term studies of idiopathic scoliosis have included patients with other etiologies, leading to the erroneous conclusion that all types of idiopathic scoliosis inevitably end in disability. Late-onset idiopathic scoliosis (LIS) is a distinct entity with a unique natural history.

OBJECTIVE:

To present the outcomes related to health and function in untreated patients with LIS.

DESIGN, SETTING, AND PATIENTS:

Prospective natural history study performed at a midwestern university with outpatient evaluation of patients who presented between 1932 and 1948. At 50-year follow-up, which began in 1992, 117 untreated patients were compared with 62 age- and sex-matched volunteers. The patients' mean age was 66 years (range, 54-80 years).

MAIN OUTCOME MEASURES:

Mortality, back pain, pulmonary symptoms, general function, depression, and body image.

RESULTS:

The estimated probability of survival was approximately 0.55 (95% confidence interval [CI], 0.47-0.63) compared with 0.57 expected for the general population. There was no significant difference in the demographic characteristics of the 2 groups. Twenty-two (22%) of 98 patients complained of shortness of breath during everyday activities compared with 8 (15%) of 53 controls. An increased risk of shortness of breath was also associated with the combination of a Cobb angle greater than 80 degrees and a thoracic apex (adjusted odds ratio, 9.75; 95% CI, 1.15-82.98). Sixty-six (61%) of 109 patients reported chronic back pain compared with 22 (35%) of 62 controls (P = .003). However, of those with pain, 48 (68%) of 71 patients and 12 (71%) of 17 controls reported only little or moderate back pain.

## CONCLUSIONS:

Untreated adults with late-onset Idiopathic Scoliosis (LIS) are productive and functional at a high level at 50-year follow-up. Untreated LIS causes little physical impairment other than back pain and cosmetic concerns.

# Complications and radiographic correction in adult scoliosis following combined transposas extreme lateral interbody fusion and posterior pedicle screw instrumentation.

Neurosurg Focus. 2010 Mar;28(3):E7. doi: 10.3171/2010.1.FOCUS09263.

Tormenti MJ1, Maserati MB, Bonfield CM, Okonkwo DO, Kanter AS.

Abstract

OBJECT:

The authors recently used a combined approach of minimally invasive transposas extreme lateral interbody fusion (XLIF) and open posterior segmental pedicle screw instrumentation with transforaminal lumbar interbody fusion (TLIF) for the correction of coronal deformity. The complications and radiographic outcomes were compared with a posterior-only approach for scoliosis correction.

METHODS:

The authors retrospectively reviewed all deformity cases that were surgically corrected at the University of Pittsburgh Medical Center Presbyterian Hospital between June 2007 and August 2009. Eight patients underwent combined transposas and posterior approaches for adult degenerative thoracolumbar scoliosis. The comparison group consisted of 4 adult patients who underwent a posterior-only scoliosis correction. Data on intra- and postoperative complications were collected. The pre- and postoperative posterior-anterior and lateral scoliosis series radiographic films were reviewed, and comparisons were made for coronal deformity, apical vertebral translation (AVT), and lumbar lordosis. Clinical outcomes were evaluated by comparing pre- and postoperative visual analog scale scores.

RESULTS:

The median preoperative coronal Cobb angle in the combined approach was 38.5 degrees (range 18-80 degrees). Following surgery, the median Cobb angle was 10 degrees ( $p < 0.0001$ ). The mean preoperative AVT was 3.6 cm, improving to 1.8 cm postoperatively ( $p = 0.031$ ). The mean preoperative lumbar lordosis in this group was 47.3 degrees, and the mean postoperative lordosis was 40.4 degrees. Compared with posterior-only deformity corrections, the mean values for curve correction were higher for the combined approach than for the posterior-only approach. Conversely, the mean AVT correction was higher in the posterior-only group. One patient in the posterior-only group required revision of the instrumentation. One patient who underwent the transposas XLIF approach suffered an intraoperative bowel injury necessitating laparotomy and segmental bowel

resection; this patient later underwent an uneventful posterior-only correction of her scoliotic deformity. Two patients (25%) in the XLIF group sustained motor radiculopathies, and 6 of 8 patients (75%) experienced postoperative thigh paresthesias or dysesthesias. Motor radiculopathy resolved in 1 patient, but persisted 3 months postsurgery in the other. Sensory symptoms persisted in 5 of 6 patients at the most recent follow-up evaluation. The mean clinical follow-up time was 10.5 months for the XLIF group and 11.5 months for the posterior-only group. The mean visual analog scale score decreased from 8.8 to 3.5 in the XLIF group, and it decreased from 9.5 to 4 in the posterior-only group.

#### CONCLUSIONS:

Radiographic outcomes such as the Cobb angle and AVT were significantly improved in patients who underwent a combined transpsoas and posterior approach. Lumbar lordosis was maintained in all patients undergoing the combined approach. The combination of XLIF and TLIF/posterior segmental instrumentation techniques may lead to less blood loss and to radiographic outcomes that are comparable to traditional posterior-only approaches. However, the surgical technique carries significant risks that require further evaluation and proper informed consent.



# Cotrel-dubousset instrumentation for the correction of adolescent idiopathic scoliosis. Long-term results with an unexpected high revision rate

*Scoliosis*20127:13

DOI: 10.1186/1748-7161-7-13

## Abstract

### Background

For many years, the CD instrumentation has been regarded as the standard device for the surgical correction of adolescent idiopathic scoliosis (AIS). Nevertheless, scientific long-term results on this procedure are rare. Therefore, we conducted a retrospective follow-up study of patients treated for AIS with CD instrumentation and spondylodesis.

### Methods

A total of 40 patients with AIS underwent CD instrumentation in our department within 3 years and between 1990 and 1992. For the retrospective analysis, first all the patient documents were reviewed, and pre-/postoperative X-ray images as well as those at the latest follow-up were analysed. Furthermore, it was attempted to conduct a clinical survey using the SRS-24 questionnaire, which was sent to the patients after a preceding announcement on the phone.

### Results

Radiologically, the frontal main curvature was improved from a preoperative angle of 69.2° to a postoperative angle of 35.4°, and the secondary curvature was improved from a preoperative angle of 42.6° to a postoperative angle of 20.5°. The latest radiological follow-up at average 57.4 months post surgery showed an average loss of correction of 9.6° (main curvature) and 4.6° (secondary curvature), respectively.

Within the first 30 days post surgery, 3 out of 40 patients (7.5%) received early operative revision for the dislocation of hooks or rods.

At an average of 45.7 months (range 11 to 142 months), 19 out of 40 patients (47.5%; including 2 patients with early revision) received late operative revisions: The reasons were late infection (10 out of 40 patients; 25%) with the development of fistulae (7 cases) or putrid secretion (3 cases), which was resolved with the complete removal of instrumentation after all. The average time until revision was 35.5 months (range 14 to 56 months) after CD instrumentation. Furthermore, complete implant removal was necessary in 8 out of 40 patients (20%) for late operate site pain (LOSP). The average time until removal of instrumentation was 62.7 months (range 18 to 146 months) post surgery; and one patient received partial device removal for prominent instrumentation 11 months post surgery. Altogether, only 22 out of 40 CD instrumentations (55%) were still *in situ*.

After an average period of 14.3 years post surgery, it was possible to follow-up 14 out of 40 patients (35%) using the SRS-24 questionnaire. The average score was 93 points, without showing significant differences between patients with or without their instrumentation *in situ*.

## **Conclusions**

Retrospectively, we documented for the first time a very high revisions rate in patients with AIS and treated by CD instrumentation. Nearly half of the instrumentation had to be removed due to late infection and LOSP. The reasons for the high rate of late infections with or without fistulae and for LOSP were analysed and discussed in detail.

# Analysis of factors that affect shoulder balance after correction surgery in scoliosis: a global analysis of all the curvature types.

Eur Spine J. 2013 Jun;22(6):1273-85. doi: 10.1007/s00586-013-2697-5. Epub 2013 Mar 1.

Hong JY1, Suh SW, Modi HN, Yang JH, Park SY.

Abstract

PURPOSE:

To identify factors that can affect postoperative shoulder balance in AIS.

METHOD:

89 adolescent idiopathic scoliosis patients with six types of curvatures who underwent surgery were included in this study. Whole spine antero-posterior and lateral radiographs were obtained pre- and postoperatively. In radiograms, shape and changes in curvatures were analyzed. In addition, four shoulder parameters and coronal balance were analyzed in an effort to identify factors significantly related to postoperative shoulder balance.

RESULT:

In general, all the four shoulder parameters (CHD, CA, CRID, RSH) were slightly increased at final follow up (t test,  $P < 0.05$ ), although there was a decrease in Lenke type II and IV curvatures. However, pre- and postoperative shoulder parameters were not significantly different between each curvature types (ANOVA,  $P > 0.05$ ). Moreover, no significant differences of pre- and postoperative shoulder level between different level of proximal fusion groups (ANOVA,  $P > 0.05$ ) existed. In the analysis of coronal curvature changes, no difference was observed in every individual coronal curvatures between improved shoulder balance and aggravated groups ( $P > 0.05$ ). However, the middle to distal curve change ratio was significantly lower in patients with aggravated shoulder balance ( $P < 0.05$ ). In addition, patients with smaller preoperative shoulder imbalance showed the higher chance of aggravation after surgery with similar postoperative changes ( $P < 0.05$ ).

CONCLUSIONS:

Significant relations were found between correction rate of middle, and distal curvature, and postoperative shoulder balance. In addition, preoperative shoulder level difference can be a determinant of postoperative shoulder balance.

# Long-term clinical outcomes of surgery for adolescent idiopathic scoliosis 21 to 41 years later.

Spine 2012 Mar 1;37(5):402-5. doi: 10.1097/BRS.0b013e31823d2b06.

Akazawa T1, Minami S, Kotani T, Nemoto T, Koshi T, Takahashi K.

Abstract

STUDY DESIGN:

A case control study.

OBJECTIVE:

To determine the clinical outcome of middle-aged patients surgically treated for adolescent idiopathic scoliosis and to compare their outcomes with assessments of age- and sex-matched healthy controls.

SUMMARY OF BACKGROUND DATA:

Several long-term follow-up studies have been published on the clinical outcomes of surgical treatment for adolescent idiopathic scoliosis in patients who have reached their 20s or 30s. However, clinical outcomes in patients who have reached middle age remain unknown.

METHODS:

This study included 256 patients surgically treated for adolescent idiopathic scoliosis (AIS) between 1968 and 1988. The Scoliosis Research Society Patient Questionnaire (SRS-22) and Roland-Morris Disability Questionnaire (RDQ) were used for evaluating long-term clinical outcomes. Sixty-six (25.8%; 62 females, 4 males; mean age, 46.0 years [range 34-56]) of the 256 patients responded to the questionnaires. The mean follow-up period was 31.5 (range 21-41) years. Seventy-six healthy age- and sex-matched individuals with neither a history of spinal surgery nor scoliosis were selected as a control (CTR) group.

RESULTS:

On the basis of the SRS-22 responses, AIS patients had significantly decreased function (AIS:  $4.3 \pm 0.6$ , CTR:  $4.7 \pm 0.5$ ,  $P < 0.01$ ) and decreased self-image (AIS:  $3.0 \pm 0.8$ , CTR:  $3.7 \pm 0.5$ ,  $P < 0.01$ ) in comparison with the controls, but the 2 groups were similar with respect to pain (AIS:  $4.3 \pm 0.6$ , CTR:  $4.2 \pm 0.5$ ,  $P = 0.14$ ) and mental health (AIS:  $3.9 \pm 0.9$ , CTR:  $3.7 \pm 0.7$ ,  $P = 0.14$ ). The RDQ responses

indicated that low back pain was not significantly increased in the AIS group compared with the CTR group (AIS:  $1.8 \pm 3.5$ , CTR:  $1.4 \pm 3.1$ ,  $P = 0.36$ ).

CONCLUSION:

**Surgery had no demonstrable adverse effects on pain or mental health in these middle-aged AIS patients 21-41 years after surgery, although the AIS patients did have significantly lower function and lower self-image than the controls.**

# Adolescent idiopathic scoliosis patients report increased pain at five years compared with two years after surgical treatment.

Spine (Phila Pa 1976). 2008 May 1;33(10):1107-12. doi: 10.1097/BRS.0b013e31816f2849.

Upasani VV1, Caltoum C, Petcharaporn M, Bastrom TP, Pawelek JB, Betz RR, Clements DH, Lenke LG, Lowe TG, Newton PO.

Abstract

## **STUDY DESIGN:**

A multicenter study of changes in Scoliosis Research Society (SRS) outcome measures after surgical treatment of adolescent idiopathic scoliosis (AIS).

## **OBJECTIVE:**

To evaluate changes in patient determined outcome measures between 2 and 5 years after AIS surgery.

## **SUMMARY OF BACKGROUND DATA:**

Current surgical procedures have been shown to improve subjective measures in patients with AIS. At 2-year follow-up, AIS patients reported significant improvement in all 4 preoperative domains of the SRS questionnaire. In addition, the major Cobb angle was shown to be negatively correlated with preoperative scores in the pain, general self-image, and general function domains. Five-year SRS scores have not been evaluated previously.

## **METHODS:**

A multicenter, prospectively generated database was used to obtain perioperative, radiographic, and SRS-24 outcomes data. The inclusion criteria were: a diagnosis of AIS, surgical treatment (anterior, posterior, or combined), a comprehensive set of radiographic measures, and completed preoperative, 2-year, and 5-year SRS questionnaires. Repeated measures analysis of variance was used to compare changes in patient responses for each of the 7 outcome domains. Univariate analysis of variance was used to compare the change in pain score at 5 years to the level of the lowest instrumented vertebrae and surgical approach. A correlation analysis was used to determine the association between changes in any of the radiographic variables and changes in SRS scores. The data were checked for normality and equal variances, and the level of significance was set at  $P < 0.01$ .

## **RESULTS:**

Forty-nine patients (42 women, 7 men; 14.2 +/- 2.1 year old; 5.4 +/- 0.6 years follow-up) met the inclusion criteria for this study. Thirty-seven of 49 (76%) of these patients underwent an open or thoracoscopic anterior procedure. SRS-24 scores improved significantly in 3 of the 4 preoperative domains at the 2-year visit. At 5 years postop, a statistically significant decrease in the pain score (4.2 +/- 0.6 to 3.9 +/- 0.9, P = 0.003) and a trend toward worsening scores in 4 other domains was observed; however, Patient Satisfaction scores remained unchanged. Lowest instrumented vertebrae and surgical approach could not be correlated to changes in the pain score. In addition, no correlation was found between changes in any of the 21 radiographic measures evaluated and changes in SRS scores.

## **CONCLUSION:**

There was a statistically significant increase in reported pain from 2 to 5 years after surgical treatment; however, the etiology of worsening pain scores could not be elucidated. Given continued patient satisfaction, the clinical relevance of this small reduction remains unknown. Nevertheless, this observation deserves further evaluation and must be considered in relation to the natural history of this disease.

# Comparison of long-term functional and radiologic outcomes after Harrington instrumentation and spondylodesis in adolescent idiopathic scoliosis: a review of 78 patients.

Spine (Phila Pa 1976). 2002 Jan 15;27(2):176-80.

Helenius I1, Remes V, Yrjönen T, Ylikoski M, Schlenzka D, Helenius M, Poussa M.

Abstract

## STUDY DESIGN:

A retrospective follow-up study of adolescent idiopathic scoliosis after Harrington instrumentation and spondylodesis was conducted.

## OBJECTIVE:

To correlate radiographic parameters with the Scoliosis Research Society questionnaire in terms of patient outcome, clinical findings, spine mobility, and trunk strength measurements.

## SUMMARY OF BACKGROUND DATA:

Previous studies have shown that long-term radiologic correction can be achieved with Harrington instrumentation. It seems, however, that radiologic correction does not correlate with patient outcome. There are no previous studies on long-term results of functional outcome, including spine mobility and trunk strength measurements, after operative treatment of adolescent idiopathic scoliosis, as compared with findings in the normal population.

## METHODS:

Of 98 consecutive patients who underwent surgery with Harrington distraction rod and posterior spondylodesis in 1979, 78 (80%) (11 males; mean age, 36 years) participated in the study. The average follow-up period was 20.8 years (range, 19.1-22.4 years). Radiographs were obtained before surgery, at the 2-year follow-up assessment, and at the 20-year follow-up assessment. Additionally, physical examination was performed, and the Scoliosis Research Society questionnaire was completed. Spine mobility and nondynamometric trunk strength measurements were obtained at the 20-year follow-up assessment.

## RESULTS:



The mean Cobb angle of the instrumented thoracic curve was 53 degrees +/- 10 degrees before surgery, and 38 degrees +/- 11 degrees at the 2-year follow-up assessment. At the 20-year follow-up assessment, the mean angle was 45 degrees +/- 12 degrees. Degenerative changes in the noninstrumented lumbar spine (sclerosis of facets, endplate sclerosis, osteophyte formation) were noted in 17 patients (22%). Ten patients (13%) reported having low back pain often or very often at rest according to the Scoliosis Research Society questionnaire. No correlation was found between the Cobb angle of the thoracic or lumbar curves at follow-up assessment and the Scoliosis Research Society total score or back pain indexes. Neither was any association found between the Scoliosis Research Society total score and the spondylodesis fusion level. However, the magnitude of the thoracic curve at follow-up assessment showed a significant inverse correlation with the scores for Scoliosis Research Society questions about cosmetic aspects. The nondynamometric trunk strength measurements corresponded with the reference values, on the average, but did not show any correlation with the magnitude of the thoracic or lumbar curves or with the Scoliosis Research Society total score or back pain indexes. Spine mobility, especially trunk side bending, was diminished in 59% of the patients, and did not correlate with the Scoliosis Research Society total score or individual indexes.

## **CONCLUSIONS:**

In patients with adolescent idiopathic scoliosis who undergo surgery with Harrington instrumentation, the overall long-term clinical outcome does not correlate with the radiologic outcome. However, a significant inverse correlation was found between the magnitude of the primary thoracic curve at follow-up assessment and the scores for questions on cosmetic matters in the Scoliosis Research Society questionnaire. Spine mobility is diminished as a result of spondylodesis, but the patients perform, on the average, as well as the normal population in nondynamometric trunk strength measurements.

# Rate of complications in scoliosis surgery – a systematic review of the Pub Med literature

Hans-Rudolf Weiss and Deborah Goodall 05 August 2008

Scoliosis 2008 3:9 DOI: 10.1186/1748-7161-3-9

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## Abstract

### Background

Spinal fusion surgery is currently recommended when curve magnitude exceeds 40–45 degrees. Early attempts at spinal fusion surgery which were aimed to leave the patients with a mild residual deformity, failed to meet such expectations. These aims have since been revised to the more modest goals of preventing progression, restoring 'acceptability' of the clinical deformity and reducing curvature.

**In view of the fact that there is no evidence that health related signs and symptoms of scoliosis can be altered by spinal fusion in the long-term, a clear medical indication for this treatment cannot be derived.** Knowledge concerning the rate of complications of scoliosis surgery may enable us to establish a cost/benefit relation of this intervention and to improve the standard of the information and advice given to patients. It is also hoped that this study will help to answer questions in relation to the limiting choice between the risks of surgery and the "*wait and see – observation only until surgery might be recommended*", strategy widely used. The purpose of this review is to present the actual data available on the rate of complications in scoliosis surgery.

### Materials and methods

Search strategy for identification of studies; Pub Med and the SOSORT scoliosis library, limited to English language and bibliographies of all reviewed articles. The search strategy included the terms; 'scoliosis'; 'rate of complications'; 'spine surgery'; 'scoliosis surgery'; 'spondylodesis'; 'spinal instrumentation' and 'spine fusion'.

### Results

The electronic search carried out on the 1<sup>st</sup> February 2008 with the key words "scoliosis", "surgery", "complications" revealed 2590 titles, which not necessarily attributed to our quest for the term "rate of complications". 287 titles were found when the term "rate of complications" was used as a key

word. Rates of complication varied between 0 and 89% depending on the aetiology of the entity investigated. Long-term rates of complications have not yet been reported upon.

## **Conclusion**

**Scoliosis surgery has a varying but high rate of complications. A medical indication for this treatment cannot be established in view of the lack of evidence. The rate of complications may even be higher than reported. Long-term risks of scoliosis surgery have not yet been reported upon in research.**

Mandatory reporting for all spinal implants in a standardized way using a spreadsheet list of all recognised complications to reveal a 2-year, 5-year, 10-year and 20-year rate of complications should be established. Trials with untreated control groups in the field of scoliosis raise ethical issues, as the control group could be exposed to the risks of undergoing such surgery.

## General Discussion or Opinion:

# Spinal fusions serve as case study for debate over when certain surgeries are necessary

**By Peter Whoriskey and Dan Keating, Published: October 27, 2013**

By some measures, Federico C. Vinas was a star surgeon. He performed three or four surgeries on a typical weekday at the Daytona Beach, Fla., hospital that employed him, and a review showed him to be nearly five times as busy as other neurosurgeons. The hospital paid him hundreds of thousands in incentive pay. In all, he earned as much as \$1.9 million a year.

Yet given his productivity, some hospital auditors wondered: Was all of the surgery really necessary?

To answer that question, the hospital in early 2010 paid for an independent review of cases in which Vinas and two other neurosurgeons had performed a common procedure known as a spinal fusion. The review was conducted by board-certified neurosurgeons working for AllMed, a company accredited to audit health-care businesses.

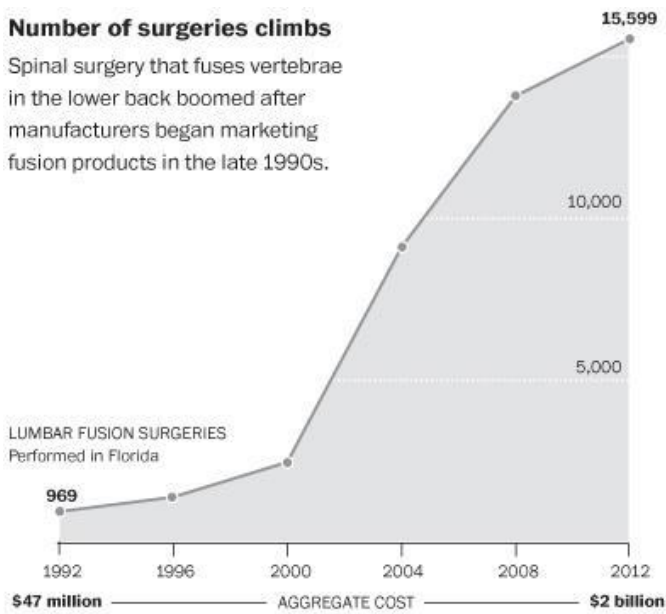
Of 10 spinal fusions by Vinas that were selected, nine were deemed not medically necessary, according to a summary of the report.

Vinas is still working at Halifax Health, and a hospital spokesman said that, after the AllMed report, the hospital conducted an internal review that validated his surgeries. Another review conducted this year in response to litigation also validated them, the spokesman said. The hospital would not answer further questions or release details of those reviews.

Vinas "has never and will never perform an unnecessary surgical procedure on any patient," his attorney, Robert H. Pritchard, said in a statement.

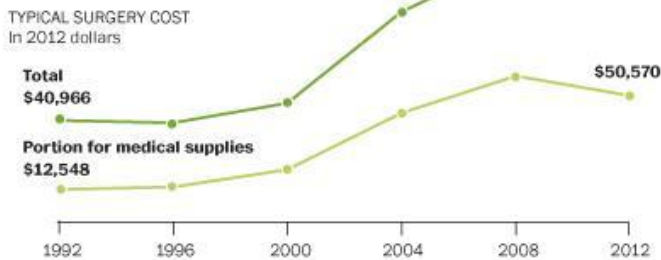
### Number of surgeries climbs

Spinal surgery that fuses vertebrae in the lower back boomed after manufacturers began marketing fusion products in the late 1990s.



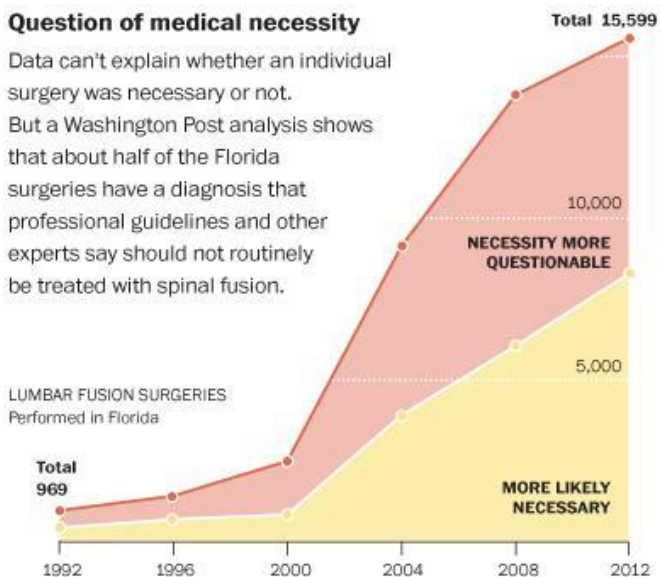
### Cost per surgery almost triples

The hospital fee does not include the cost of the surgeon or other doctors. The largest part of the fee is the medical equipment involved.



### Question of medical necessity

Data can't explain whether an individual surgery was necessary or not. But a Washington Post analysis shows that about half of the Florida surgeries have a diagnosis that professional guidelines and other experts say should not routinely be treated with spinal fusion.



unusual glimpse into these issues.

More than 465,000 spinal fusions were performed in the United States in 2011, according to government data, and some experts say that a portion of them — perhaps as many as half — were performed without good reason.

The rate of spinal fusion surgery has risen sixfold in the United States over the past 20 years, according to federal figures, and the expensive procedure, which involves the joining of two or more vertebrae, has become even more common than hip replacement.

It can be difficult, in individual cases, to get doctors to agree about when the procedure is warranted.

But at a broader level, the rapid rise of spinal fusions in the United States, especially for diagnoses that generally don't require the procedure, has raised questions from experts about whether, amid medical uncertainty, the financial rewards are spurring the boom.

Advancements in diagnostic and surgical technology may explain some of the increase in surgery. And patients may have become more demanding.

But a Washington Post analysis of 125,000 patient records also shows that roughly half the tremendous rise in spinal fusions in Florida has been on patients with diagnoses that experts and professional societies say should not routinely be treated with spinal fusion.

Questions are raised

Normally, information that might shed light on the ways that economics shape medical decisions by doctors and hospitals doesn't become public. But a wide-ranging lawsuit at Halifax Health offers an

In 2009, a former compliance official at the hospital filed a whistleblower lawsuit alleging illegal financial incentives for doctors. The court filings make available an array of documents — e-mails, testimony, audits. These and other sources allow a fuller depiction of the financial rewards and relationships that depended on treatment decisions. They also show how hospital administrators responded when suspicions arose that a doctor, who was generating millions in profits, may have been performing unnecessary surgery.

The compliance official, Elin Baklid-Kunz, couldn't determine by herself whether any of the surgeries Vinas had performed was unnecessary — she is not a doctor.

But just as the numbers of spinal fusions in the United States have raised questions about the procedure's necessity, audits she and an outside firm had conducted showed unusual productivity in parts of the hospital. Those numbers, she says, demanded further review.

Moreover, the compensation agreements the hospital had with Vinas and other doctors essentially offered large incentives for more treatment, she has alleged. The Justice Department has joined her lawsuit regarding illegal compensation.

As at many hospitals, the financial benefits of operating at Halifax Health extended to at least three groups.

- Vinas and his colleagues in neurosurgery earned as much as thousands of dollars extra — above their base salaries — for each procedure after a certain threshold. The vast majority of Vinas's earnings came from such incentive pay, according to legal filings.
- According to government estimates, each neurosurgeon at Halifax Health was generating more than \$2 million a year in hospital profits. The hospital charged fusion patients an average of about \$80,000, according to Florida records on Halifax Health analyzed by The Post, ranking the procedure as one of the more expensive.
- The companies that sell the hardware — screws and braces — already a multibillion-dollar business in the United States, also benefited. Those companies often have a representative positioned in the operating room, where the equipment for one fusion can typically amount to a \$7,000 sale, according to the Millennium Research Group. Vinas was friendly enough with his parts salesman — who, among other things, measured the length of the necessary screws — that he traveled in Thailand with him, according to a deposition.

Baklid-Kunz detected Vinas's rapid pace of work in an audit and asked for further review of his surgeries, documents show.

But she was discouraged from investigating further, she said.

"Hospital administrators didn't want to touch Dr. Vinas," she said in an interview.

Instead, they referred to Vinas and the hospital's two other neurosurgeons as "our high rollers," she said, and told her that rather than cracking down on their billing that "we need to make them happy."

More than two years would pass before the hospital pursued the further review Baklid-Kunz had recommended — the AllMed report — and it was during the wait that she decided to file the lawsuit. Even after the AllMed report, she said, the hospital did little to curb Vinas's practices.

"The hospital was caught in the act and did nothing," said Marlan Wilbanks, Baklid-Kunz's attorney. "They didn't send anyone to extra training. They didn't take any extra steps at all. They were making a lot of money."

Hospital spokesman John Guthrie said the AllMed report was "bogus" because it was based on cases that Baklid-Kunz had selected.

"The AllMed report was based on incomplete medical records that were cherry-picked," the hospital said in a statement. "For The Post to accept this unsupported report as fact is irresponsible and creates a grossly misleading perception."

Pritchard, Vinas's attorney, said his client is a well-respected surgeon, with almost 100 publications and book chapters to his credit, who takes steps to make sure that surgery is done only as a last resort.

Vinas has never had a malpractice action filed against him and, even though he has seen 15,000 patients in his career, only "a very small handful" expressed dissatisfaction with his care, Pritchard said.

Some of Vinas's patients said they are pleased with his work.

Steven Hunt, 62, a heavy-equipment mechanic, said Vinas operated on him four or five times.

"I'd have one and then another," he said. "I can't explain it, but I had to have them. Dr. Vinas said if I didn't have it, I'd have been paralyzed. Some people said to let it go, but being a mechanic, I like to fix what's broken.

"He's a gentle, kind man," Hunt said. "I don't think he ever did a surgery that was unnecessary."

What is necessary?

As U.S. medical costs have risen, questions about unnecessary treatment have become frequent. By some estimates, Americans are spending billions every year on unnecessary surgery and other medical care.

Medicare, the nation's health-care system for people older than 65, is at the center of the debate.

As the nation's largest insurer, it is critical to determining what kinds of surgeries in the United States are covered — and, therefore, performed. Many private insurers look to Medicare when making their own decisions.

Today, by its own admission, Medicare may be spending billions annually on unnecessary medical treatment.

The Medicare agency every year audits a sample of the claims it has paid and determines how many of those have “medical necessity” errors. The agency estimated the amount of money spent improperly on spinal fusions was more than \$200 million in 2011, for example, and most of that was because the treatment was deemed unnecessary, often because a more conservative course hadn't been tried, officials said.

How could this happen?

The answer, in part, is that the Medicare system is not designed to discourage doctors from performing it, according to past and present Medicare officials.

At a very practical level, the bureaucracy offers little incentive to weed out unnecessary treatment: Medicare hires contractors to issue payments to doctors, and those contractors are paid based not on how many claims they reject but on how many they approve.

“The contractors are incentivized to efficiently process claims and not to accurately evaluate clinical effectiveness” of treatment, according to a paper by three former senior officials at the Medicare agency and one current one.

Moreover, when bureaucrats try to restrict what surgeries Medicare will pay for, they sometimes face punishing political backlash.

In 1978, for example, Congress created the National Center for Health Care Technology, which among other things recommended to Medicare what procedures it should cover.

It ran on a \$4 million budget, and within just a few years of its inception, it was estimated that its advice had saved the government between \$100 million and \$200 million a year.

But two influential groups opposed the agency's mission: the American Medical Association and the Health Industry Manufacturers Association.

Medical judgements are “better made — and are being responsibly made — within the medical profession,” an AMA spokesman told Congress at the time. “The advantage the individual physician has over any national center or advisory council is that he or she is dealing with individuals in need of medical care, not hypothetical cases.”

In 1981, Congress zeroed out the agency's budget.

Again in 1989, Congress decided that there should be a government effort to review the effectiveness of medical treatments.



It was called the Agency for Health Care Policy and Research, and in its first years, it issued guidelines on how to treat hysterectomies, strokes and ulcers.

Then, in 1994, the agency published a set of guidelines on back pain, discouraging spinal fusion for some cases.

“For several low back disorders, no advantage has been demonstrated for fusion over surgery without fusion, and complications of fusions are common,” its researchers concluded.

The reaction from some surgeons was furious. The North American Spine Society suggested that the effort was a waste of taxpayer money. A letter-writing campaign was launched. A Virginia spine surgeon founded a group called the Center for Patient Advocacy, which sought to kill the agency.

Some physicians rallied to its defense. But when the dust settled in Congress, the agency’s budget was cut by 21 percent, and the agency curtailed its efforts at developing guidelines.

“The larger damage was the message sent by Congress: ‘If you get too close to actually changing how clinical or reimbursement decisions are made, Congress is going to slap you down,’ ” said Sean Tunis, formerly chief medical officer at the Medicare agency. “I think everyone took a lesson from that.”

#### A rise in spinal fusions

Even by American health-care standards, the rise of spinal fusions has been remarkable. According to federal figures, the number of spinal fusions in the United States rose from 56,000 in 1994 to 465,000 in 2011.

Advancements in technology — more refined imaging, new spinal devices to hold vertebrae in place — probably account for some of the rise.

Moreover, Americans may be demanding more mobility as they age, surgeons say.

“Patients want to be able to play tennis and golf and go surfing at much higher ages than they did in the past,” said Gunnar Andersson, chairman emeritus of the department of orthopedic surgery at Rush University Medical Center in Chicago and president-elect of the International Society for the Advancement of Spine Surgery, a professional group. “They are more likely to seek out treatment and more likely to accept surgery as an option.”

He added that some of the critics of the procedure, who believe spinal fusions are being performed too frequently, are “not wrong.”

“The problem is we don’t know what the rate of spinal fusions ought to be,” he said.

The growth in spinal fusion in the United States has been much faster than other surgeries to address wear and tear, such as knee and hip replacements. And Americans are far more likely to undergo the procedure than people from other countries.

The rate of spinal fusions in the United States is about 150 per 100,000 people, according to federal data. In Australia, it is about one-third of that; in Sweden, it is about 40 per 100,000; and in Britain it is lower still.

Or just consider the sales of spinal fusion equipment. Sales of such equipment in the United States amount to \$5.1 billion a year, nearly twice what the total sales are in the rest of the world, according to Millennium Research Group.

“My hunch is that as many as half of the spine fusions in the U.S. are unnecessary,” said Richard Deyo, a researcher at Oregon Health and Science University and a longtime critic of the procedure.

The International Society for the Advancement of Spine Surgery has sounded a note of caution in its policy statement on lumbar fusion, too.

“Increasing success and optimism may be leading some surgeons to overuse procedures beyond what the current state of medical evidence really supports,” it says. The varying rates of spine surgery suggest “a lack of collective adherence to the current state of medical evidence.”

To get a better understanding of the reasons for the boom, The Post reviewed 125,000 records of patients who underwent spinal fusions in Florida. The data included primary and secondary diagnoses.

The analysis shows that the procedure has been used more and more to treat ailments of the lower back that experts say are generally better addressed with safer and less-costly treatments.

Professional societies and other experts rule out or discourage the routine use of spinal fusion for several common problems of the lower back — stenosis, herniated discs and disc degeneration — when there are no accompanying problems of spinal instability or deformity.

Yet about half of the rise in lumbar spinal fusions has come from its use for just such ailments.

Between 2000 and 2012, the number of lumbar spinal fusions for those ailments in the state rose fivefold, from 2,014 to 9,887, according to the analysis of Florida records.

Lumbar spinal fusions to treat stenosis, an ailment caused by a narrowing of the spinal canal, rose the fastest, from 292 in 2000 to 2,565 in 2012.

Medicare and insurance companies could stop paying for such procedures, of course. When they object, however, their motivations are often viewed as profit-driven as much as scientific.

But decisions about surgery also have financial ramifications for doctors, as Eugene Carragee, a surgeon and professor at Stanford University, has noted.

He said that a simpler procedure known as a decompression often offers patients, without complications, as much benefit as a fusion and poses fewer risks. But the decompression might yield a surgeon roughly \$1,000, while a complex fusion would garner as much as \$6,000.

While insurers see a “conspiracy of escalation,” Carragee said, “surgeons are saying, ‘You can’t tell me what the appropriate thing is to do.’”

Medicare weighs in

In 2006, Medicare decided to take a closer look at spinal fusion surgery.

At the time, the number of spinal fusions had been soaring upward, rising by nearly five times over the previous decade.

An increasing number of the spinal fusions were being done to treat something called degenerative disc disease, an affliction that results in pain from a disc that has disintegrated after normal wear and tear.

Medicare officials decided to convene a panel to examine the use of lumbar spinal fusion in patients with degenerative disc disease.

The evidence that a spinal fusion was the best means of treating it was sparse.

The researchers that Medicare commissioned to summarize the evidence found only four randomized clinical trials of spinal fusion for degenerative disc disease. Three trials found no clear benefit of spinal fusion over other therapy.

The fourth found just the opposite — that there was a benefit. It was alone in another regard as well. While the others had been funded by governments or nonprofit groups, the positive study was funded by two companies that make spinal surgery equipment — Acromed and Ossano Scandinavia.

The authors of the evidence review, led by Duke University physician and researcher Douglas C. McCrory, reported that there was no conclusive evidence that spinal fusion offers “short-term or long-term benefits compared with non-surgical treatment.”

The report was then presented to a Medicare advisory committee of nine voting doctors. Three of them had worked for or owned stock in makers of spinal equipment.

Their votes were cast on a scale of one to five: A one reflected that fusion was “not likely” to benefit patients with lumbar degenerative disc disease, three was “reasonably likely” and five “very likely.”

The long-term benefit of spinal fusion was judged a 1.5 — that is, the panel had voted that it was less than “reasonably likely” that spinal fusion provides a benefit.

Yet Medicare never changed its policy: It still pays for spinal fusions for degenerative disc disease.

A Medicare spokeswoman, Kathryn Ceja, offered this statement: “By law, Medicare must cover items and services that are reasonable and necessary. Within those rules, doctors and their patients are free to make medical treatment decisions that are best for the patient.”

After the 2006 advisory meeting, the number of spinal fusions continued its rapid upward trend.

An analysis of health records published last year in the journal *Spine* showed that the number of spinal fusions for degenerative disc disease in the lumbar spine had more than tripled between 1998 and 2008, becoming the most common primary diagnosis for spinal fusions.

Like Medicare, insurers have proved tentative about restricting payment. Some insurers have put modest limits on lumbar fusion procedures, but the idea of an insurance company putting itself between a patient and a doctor's recommendation often spurs unwelcome publicity.

In late 2009, for example, Blue Cross Blue Shield of North Carolina decided to curb its use based on research and the guidelines of professional societies.

In the first year, the number of lumbar spinal fusions at the insurer dropped 32 percent.

But the insurer was also confronted with unflattering portrayals in the newspaper and on television.

A local TV station ran an investigative story about the insurer denying coverage.

"Guys, a major insurance company here in North Carolina is one of the first to deny a back surgery that some doctors love but some insurers don't," an investigative reporter on Raleigh's ABC affiliate announced one night. "Why? At least one doctor and two patients we talked with say it's all about profit margin."

Unhappy patients

Ever since the news of Baklid-Kunz's lawsuit against the hospital, some of Vinas's patients, especially those who say the surgery did nothing — or worse, harmed them — have begun to wonder whether their surgery was necessary.

Among the patients who have come to doubt the surgery they had is a dentist who says he had to sell his practice because after the surgery he could no longer stand for long periods; another is a pipe fitter who can no longer work and became unsteady on his feet; another is a retired aerospace engineer who developed cognitive problems after the surgery.

Three patients said Vinas urged them to get the surgery, too. He warned them that they were going to be "crippled" or "in a wheelchair" if they didn't, they say.

Eunice Murphy was a retiree playing tennis four times a week before the surgery; she says she has had trouble walking since then.

"I wasn't his patient," Murphy said. "I was his victim."

Vinas fused her spine after she complained of numbness in her thumb and forefinger. Vinas's medical report says she had "intractable neck pain," too. Murphy insists the problem was only in her hand. Three months later, she got a second fusion from Vinas for back pain and leg trouble, according to his report.

The hand trouble was unaffected by the fusion surgery, she says. This year, she went to another doctor for what she says is the same hand trouble. He traced it in part to carpal tunnel syndrome, an ailment of the wrist, according to that doctor's report.

She bought an \$18 brace for her forearm at the drugstore, and the numbness receded, she says.

More than a year after the second fusion surgery from Vinas, she got an appointment just to confront him, she said. She is not suing him for malpractice — the two-year window for filing such a suit has elapsed.

"I said, 'This is the cruelest thing one person could do to another. Why did you ruin the rest of my life?' "

William Scott, 62, the pipe fitter, had been having back pain for years. He was diagnosed with lumbar stenosis and degenerative problems. He was tired of taking medication for the problem and decided to see if the surgery would help him.

"Vinas told me I'd be back on my motorcycle in time for Bike Week" in a few months, he said.

But instead of curing him, the surgery has all but crippled him, he says. He can't stand for long, can't take walks because he is prone to falling and can no longer work. He had to sell his motorcycle.

"He took my life away," Scott said, his voice rising. "He took being a man and a husband away from me. And for what?"

Pritchard, Vinas's attorney, said his client was barred by law from commenting on individual patients.

But he noted that despite a surgeon's best efforts, "a small percentage may not recover as well as hoped and may be dissatisfied. That in no way means the surgery was unnecessary or should not have been performed."

Any suggestion that a fusion was performed on a patient with only carpal tunnel syndrome is "patently absurd," he said.

#### Other opinions

Another employee at Halifax Health who came to question Vinas's practice was a fellow neurosurgeon.

William Kuhn said he would no longer assist in surgeries with Vinas, at least in part because he questioned the type of surgery being done, though he said he did not reach any conclusion, according to his deposition.

"On a couple of cases I've walked into the room to assist, and looking at the films alone and hearing a brief description of the patient's symptoms . . . based only on that information, I had felt somewhat uncomfortable regarding the procedure that was being performed," Kuhn said in a deposition.

In 2007, auditors ran the numbers on Vinas — and he was exceptionally busy.

A physician's work is measured in terms of RVUs, or relative value units. Each procedure is assigned a certain number of them. By that measure, Vinas was nearly five times as busy as the average U.S. neurosurgeon, working at a rate of more than 25,000 RVUs per year, while the national average for a neurosurgeon was 5,600, according to the audit by an outside company.

The proportion of fusion procedures in his practice was about three times the national average for neurosurgery practices, the numbers showed. He told hospital officials that he was tailoring his practice to patients who required a fusion, but he declined to comment for this story.

After the big numbers in the 2007 audit, the hospital's compliance department proposed a clinical review to determine whether Vinas's surgeries were medically necessary, according to a memo at the time written by Baklid-Kunz.

In early 2010, after more than two years, the hospital hired AllMed and its independent board-certified neurosurgeons to conduct the review.

With guidance from AllMed, Baklid-Kunz, as a hospital compliance official, picked 10 of Vinas's cases between October 2008 and December 2009, as well as the five for Kuhn and five for a third neurosurgeon.

AllMed used several board-certified neurosurgeons to perform the reviews. The reviewers had the complete inpatient records and, except for "a few" cases, imaging done before the surgeries, according to a summary Baklid-Kunz prepared at the time.

Kuhn would fare only marginally better than Vinas when his cases were reviewed by AllMed. Their report found that in three of five cases reviewed the surgeries were not medically necessary. He did not return phone calls seeking comment, and his secretary directed calls to the hospital spokesman.

As for Vinas, the report found that nine of Vinas's 10 fusions were not medically necessary, according to a summary. It called into question Vinas's technique in three cases.

When presented with the results, Vinas was "pretty upset," he said in a deposition, and he prepared a written response. As part of a review, he sat with the hospital's chief medical officer, Don Stoner, who is a cardiovascular specialist, not a neurosurgeon. The hospital declined to offer any more information about this review.

"There were not any specific concerns about my practice. And we discussed that there was room to improve my documentation, that not all was perfectly complete," Vinas said in a deposition. "In some cases you have two physicians providing different opinions, and there is more than one way to treat a patient."

About three years later, the hospital decided to take another look at the AllMed report.

By then, the hospital had come under a new level of scrutiny when in late 2011 the Justice Department joined Baklid-Kunz's suit.

The hospital hired Timothy Schoettle of Kentucky, a neurosurgeon, to review the AllMed cases, hospital spokesman Guthrie said.

Schoettle found that all of those 10 surgeries were medically necessary, Guthrie said.

The hospital declined to make available a copy of Schoettle's report affirming Vinas, however, and Schoettle did not return phone calls to his office. The hospital did not answer questions about how it chose Schoettle to do the review.

"We don't want to start a trial in the newspaper, because that's not fair to a judge and jury," Guthrie said.

# Interview from Dr. Clayton Stitzl with Dr. Ian Stokes

I do disagree with Dr. Stokes in regards to bracing, as his own rat tail research suggests it have negative effects on disc wedging, which is a key component to biomechanical progression of scoliosis.

Dear Dr. Stokes, thanks for accepting this interview. If you are ready we go ahead with it:

1. At the beginning your research career you were focused on studying how forces react in the lower limbs. What made you change your research into the spine?

And more exactly to start research programs related to the scoliosis field?

Every researcher should ask the question: where is there the greatest chance to make a contribution? It is true that I started my career in biomechanics by studying foot problems, and I think we were able to make a contribution to understanding of effects of diabetes, as well as hallux valgus. But spinal problems probably represent a greater need. In the area of spinal biomechanics the risks for a researcher are high, because the two major problems – back pain and deformity - are plagued by lack of understanding of the original causes. Back pain represents a huge problem for which there are many causes including injury, degeneration, and osteoporosis. Of course biomechanics should be able to help in all of these, but actually I think that progress has been very slow. Scoliosis and biomechanics may be more directly linked if we consider that there are two stages in scoliosis development – initiation (etiology) and subsequent progression. The pattern of progression seems to be very similar after a wide range of initiating causes: neuromuscular, congenital and idiopathic.



2. In recent years you are concentrating on the intervertebral disc and many papers were published about it. What makes you focus in this topic?

A scoliosis curve results from wedging of both the vertebrae and the discs. So it is important to understand the causes of both components. In terms of the biomechanics of scoliosis progression, we probably know more about how mechanical forces influence vertebral growth, but it is also very important to understand how the discs respond to altered mechanical load too. I have been using the rat tail model to investigate how altered and asymmetrical loading as well as reduced mobility affect the loss of disc height associated with the wedging deformity of discs.

3. What did you expect before this work?

I knew it would be difficult to study how intervertebral discs become deformed in scoliosis for several reasons. The rat tail seemed to be a good platform to look at the biomechanics, since it is accessible, and the tissue changes occur quite rapidly (in weeks) relative to those in humans (time scale of years) and we expected to see either degeneration or remodelling of the discs that would represent what happens in scoliosis.

4. What was your reaction after this?

The rat tail model is pointing strongly to reduced motion (mobility) of the disc as a key factor associated with loss of disc height. But in the human context, one huge remaining question is why curve progression more or less stops with cessation of growth at skeletal maturity. We think we know why wedging deformity of the vertebrae stops progressing when growth ceases, but why would the disc deformity stabilize too?

5. How did this reorient your investigation?

Since most of the loading on the spine results from activation of muscles, it is very important to get a better understanding of how muscles are recruited, and how this recruitment pattern is altered when the spine is curved laterally. Biomechanics tells us that there is no unique pattern of muscle forces to achieve any given task – you have a choice about which muscles to recruit. This variability in muscle activation strategies may be the key to understanding how the rate of curve progression differs between individuals.

6. How is your interpretation about scoliosis changing?

The concept that there are two stages in the development of a scoliosis – an initiation (aetiology) and a progression seems very logical now. Furthermore, I think that the role of biomechanics in the second (progression) phase is widely accepted now. The pattern of progression during the period of rapid adolescent skeletal growth is very similar in all kinds of scoliosis (congenital, neuromuscular and idiopathic).

7. What can you explain to us about the growing period and its differentiation relative to the implications for the disc? And what does this imply for etiopathology theories?

The question why disc wedging stabilizes at skeletal maturity should be studied. Equally, the question why some scoliosis curves that are small at the onset of a growth spurt progress and others do not is crucial to understanding pathomechanism, as well as being the biggest challenge faced by clinicians.

8. How will this modify the clinical approach?

If biomechanics really is a key element responsible for scoliosis progression, then

this clearly supports the use of bracing and other conservative approaches to managing progressive deformity. But there are two additional components required: (1) braces as presently prescribed, perhaps because of difficulties with patient compliance, have a questionable efficacy. (2) early identification of patients at risk for progression is prerequisite for treatment approaches involving early and minimally invasive (or minimally destructive) interventions if we are to avoid overtreatment of patients who actually have benign deformity.

9. Do you think that we (basic scientists and clinicians) can really lead to understand the cause of scoliosis? Sometimes seems that this two specialties are following parallel paths and they have very few crossroads. What do you think about it?

At present the natural history of idiopathic scoliosis is very poorly understood. By this I mean that we do not know the specific phenotypes of patients who are likely to have a progressive curve. The studies showing quite low concordance of scoliosis in monozygous twins point to the huge complexity of this problem. So there should be a huge potential for collaboration to collect longitudinal data on cohorts of children, in order to identify better the risk factors for progression. Such a collection of data should not be a 'fishing expedition' – it should be designed around the best hypotheses that we have – from genetic, biochemical and biomechanical theories. Clinicians and basic scientists could collaborate to design the data collection and analysis to test plausible hypotheses. The SRS membership is accustomed to reporting all their surgical results to a central registry. Perhaps they could be encouraged to collaborate in a comprehensive natural history study too.

10. How is your opinion can we strength this link?

Of course SOSORT and other societies have a key role in attracting clinicians to study the patients they care for. Attracting basic scientists into this field may be difficult because it is often viewed as a high-risk field professionally in which it is difficult to obtain funding, and bright young researchers are under pressure also to generate results. Many scoliosis studies have produced negative findings, and these don't easily satisfy the funding and publication criteria. So the link can be strengthened by scientists and clinicians collaborating to design research studies that have a high impact and high probability of producing important new clinical insights.

Thanks again for your colaboration Dr. Stokes.

# "BrAIST" Study NOT Conclusive according to New England Journal of Medicine

Spinal Bracing in Adolescent Idiopathic Scoliosis

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Before the introduction of the poliomyelitis vaccination, paralysis due to poliovirus infection was a leading cause of spinal deformity in children and young adults. The severe, stiff spinal deformities associated with poliovirus infection were complicated by pulmonary dysfunction; spinal bracing, which was often ineffective in correcting the deformity or preventing the progression of scoliosis, also exacerbated restrictive pulmonary disease, pulmonary hypertension, and cor pulmonale. Today, coronal spinal deformity in children and young adults is nearly always adolescent idiopathic scoliosis: a flexible, three-dimensional, spinal curvature affecting primarily girls, beginning in adolescence, and very rarely leading to clinically significant cardiopulmonary disease. When children with idiopathic scoliosis reach skeletal maturity with a primary curve of less than 40 degrees, the curvature usually stabilizes and there are few or no long-term clinical effects. However, if the primary curve progresses to more than 50 degrees during adolescence, consequences include not only frequent cosmetic dissatisfaction but also increased risks of progressive deformity after maturity, accelerated disk and facet-joint degeneration, and potentially serious neurologic irritation over time. Surgical treatment, involving an instrumented fusion of 6 to 10 vertebrae, is frequently recommended when the spinal curvature approaches or exceeds 50 degrees.

Consequently, strategies to prevent the progression of scoliosis in children have aimed to prevent curve progression beyond 40 to 50 degrees when the child is still growing.<sup>1,2</sup> Several proposed interventions, including specific exercises, activity restriction, electrical stimulation, and traction, have not proved to affect curve progression during the critical adolescent years.<sup>3</sup> However, various thoracolumbar bracing strategies have been suggested to delay or prevent scoliosis progression in the growing adolescent, on the basis of observational studies.<sup>4,5</sup> Despite the widespread use of bracing in immature adolescents with curves of more than 25 degrees, the U.S. Preventive Services Task Force concluded in 2003 that its effect was "unknown."<sup>6</sup>

Weinstein et al.<sup>7</sup> now report in the Journal the results from the Bracing in Adolescent Idiopathic Scoliosis Trial (BRAIST), a multicenter study designed to determine the effectiveness of bracing in preventing scoliosis progression. Treatment failure was considered to be a progression of the primary scoliosis curve to 50 degrees or more before the patient reached skeletal maturity, as assessed radiographically. The authors concluded that brace treatment was effective, and of particular interest, they found that a longer duration of brace wear each day was associated with better outcome.

Although the authors initially intended to conduct a strict randomized trial, in practice this was not possible. Strong treatment preferences limited enrollment in the randomized trial, so the investigators added observational patient-preference groups. Of 242 patients included in the analysis, 116 had received randomly assigned care and 126 received patient-directed care (71% of the patients in this group choosing brace treatment). Furthermore, very few patients wore the brace for the recommended 18 hours per day; 27% of the patients stopped using the brace completely (see the Supplementary Appendix of the article, available at NEJM.org).

The difficulties with enrollment and compliance must be considered in interpreting the results. Because much of the data were derived from a nonrandomized cohort, the magnitude of the associations between brace wear (and its duration) and good outcome may have been inadvertently magnified if patients whose curves were more likely to progress were correspondingly less inclined to wear a brace (e.g., if they had relatively stiff curves, which resist the corrective pressure of the brace, or rapidly progressing curves, which outgrow the mechanics of the brace). The intention-to-treat analysis showed the same general trend of treatment effectiveness but with much less statistical confidence.

The decision to commit a 12- or 13-year-old patient to several years of brace wear requires careful consideration of both the benefits and the downsides. Although brace wear in adolescent idiopathic scoliosis does not have the serious physiological side effects that are apparent in poliomyelitis-related scoliosis, it carries financial, emotional, and social burdens that need to be considered. Overall, the findings of the present trial confirm the general proposition that brace treatment confers benefits for some patients with adolescent idiopathic scoliosis, but an open question is the applicability of the findings to individual adolescents with idiopathic scoliosis. Patients with adolescent idiopathic scoliosis represent a heterogeneous group, and this study does not have adequate numbers to evaluate the treatment effect for specific structural types of adolescent idiopathic scoliosis or the efficacy according to relative correct-ability or relative discomfort of bracing that requires high forces to maintain correction. With improved flexibility, especially in the lumbar spine, the probability of success with bracing is likely to be greater.

As the authors appropriately point out, 48% of the untreated patients had a successful outcome, as did 41% of the patients in the bracing group who spent little time wearing the brace. In retrospect, the bracing indications described are probably too broad, resulting in what may be unnecessary treatment for many patients. We agree with the authors that the equally important finding of this study is that so many growing children with adolescent idiopathic scoliosis seem to do just fine with no treatment at all; the challenge for the field going forward is to identify children who are most likely to benefit from bracing and those who are unlikely to benefit.<sup>8,9</sup>