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Critical review

Spinal Surgery

Risks and long-term complications of adolescent idiopathic scoliosis surgery versus non-surgical and natural history outcomes

HR Weiss[1]*, M Moramarco[2], K Moramarco[2]

Abstract

Introduction

Recently, a paper was published containing the long-term results of the first 'modern' double rod instrumentation, the Cotrel–Dubousset instrumentation. Results showed an unexpected high rate of reoperation of nearly 50% due to late infections or chronic back pain occurring after surgery.

Further research into the long-term complications of spinal fusion surgery in adolescent idiopathic scoliosis (AIS) patients is necessary, with special attention to more recent instrumentations. This critical review discusses risks and long-term complications of AIS surgery versus non-surgical and natural history outcomes.

Materials and methods

The previous systematic review on long-term complications, as they might develop over a lifetime, was published in 2008. The first author conducted a PubMed search to locate additional studies related to long-term outcomes of AIS surgical complications published after August 2008. Target publications were prospective or retrospective papers on complications in spinal fusion surgery for AIS with a minimum follow-up of 10 years and prospective or retrospective papers on reoperation rates in spinal fusion surgery for AIS with a minimum follow-up of 10 years.

Results

No paper with the topic on complications and a long-term follow-up of at least 10 years was found. Two papers were found with the topic of reoperation rates and a long-term follow-up of at least 10 years. Reoperation rates were reported between 12.9% and 47.5%.

Discussion

In the relatively benign population of AIS patients, according to the findings within this review, it may be concluded that the long-term outcome of surgery for AIS is worse than the long-term consequences of the condition itself.

Conclusion

A medical indication for AIS spinal fusion surgery does not exist, except in extreme cases. The rate of complications of spinal fusion surgery appears to increase with time. The risk/reward relationship of spinal fusion surgery is unfavourable for the AIS patient, except in rare cases. There is no evidence that spinal fusion surgery improves quality of life for AIS patients versus natural history. The risks and long-term costs, in terms of pain and suffering, after spinal fusion surgery exceeds what is reasonable for AIS patients, putting the common practice of surgery in question, except in extreme cases.

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Introduction

Scoliosis is a three-dimensional deformity of the spine and trunk, which may deteriorate quickly during periods of rapid growth[1–4]. Although scoliosis may be an expression or a symptom of certain diseases (e.g. neuromuscular, congenital, due to certain syndromes or tumours), the majority of the patients with scoliosis (80%–90%) are 'idiopathic' because an underlying cause has not been determined[5]. The treatment of symptomatic scoliosis should be determined by the underlying cause, whereas, treatment of idiopathic scoliosis is determined by the deformity itself. Most scoliosis progresses during growth, some in later life; therefore, the main aim of any intervention should be to stop curvature progression[1,2].

While children grow until they have fully matured, there are times of more or less growth during childhood and adolescence. Curvature progression is probable during these different phases of growth[1,2].

In principle, the diagnosis of adolescent idiopathic scoliosis (AIS) describes a spinal curvature in an otherwise healthy individual. According to the Scoliosis Research Society (SRS), the prevalence of AIS is 2%–3% in the general population. Nearly 10% of AIS patients require some form of treatment and up to 0.1% will eventually require surgery[6]. AIS is more commonly found in females (female:male ratio of 7:1) and usually AIS does not cause any health problems during growth.

Long-term follow-ups of untreated patients with AIS indicate that the consequences of AIS over a lifetime are minimal except for the cosmetic deformity, sometimes moderate in more severe cases, but never life threatening. The curvature in this AIS population will usually not exceed 80°. This degree of curvature will not

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affect vital capacity (VC) or breathing mechanics in the same way that other severe health conditions that compromise the cardiopulmonary system may in the long term[3–7].

Treatment of AIS, when necessary, consists of physiotherapy, bracing and spinal fusion surgery. While there is limited documented evidence, to date, for physiotherapy[8,9], documented evidence is promising. Moreover, there is a substantial body of evidence for bracing[10,11].

For spinal fusion surgery, no prospective controlled or randomized studies have been found[12–14]. Westrick and Ward[14] state: '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'.

The numerous, substantial risks of spinal fusion surgery in both the short- and long-term are: the typical risks of surgery, but also pseudoarthrosis, a myriad of neurological complications including full or partial paralysis, implant breakage or movement, pulmonary complications and more[15]. Many of these potential complications warrant reoperation, perhaps numerous times. Furthermore, although it is an implied goal when surgery is recommended, there is little evidence of an improvement in VC or exercise capacity as a result of spinal fusion for AIS[15].

Therefore, it is concluded from what is available in international literature, the medical necessity for AIS fusion surgery, commonly at Cobb angles of 45°[15,16] and above, is not medically indicated considering the extensive risks and long-term complication rates unveiled during the last decade.

Although the short-term complications may be minimal, long-term complications were estimated to exceed 50% with a rate of salvage surgeries of up to 25%[16]. Granted, these results were from populations treated with 'older' instrumentations such as Harrington rod or VDS procedures that are no longer applied today. However, in consideration of the recently published long-term results of the first Cotrel–Dubousset (CD) 'modern' double rod instrumentations, which also revealed an unexpectedly high rate (nearly 50%) of reoperation due to late infections or chronic back pain[17], long-term results are not in the best interest of the AIS patient.

The common practice of surgical intervention at Cobb angles of around 45° is highly questionable, especially in consideration of recent research regarding long-term complications. Further research into the long-term complications of spinal fusion surgery in 'AIS' patients, with special attention to more recent instrumentations, is needed. The aim of this paper is to assess the risks and long-term complications of modern and traditional methods of idiopathic scoliosis surgery.

Materials and methods

The last systematic review on long-term complications, as they might develop over a lifetime, was published in 2008[16]. The first author conducted a PubMed search to locate studies related to long-term outcomes of AIS surgical complications published after August 2008.

Target publications

- Prospective or retrospective papers on complications in spinal fusion surgery for AIS with a minimum follow-up of 10 years.
- Prospective or retrospective papers on reoperation rates in spinal fusion surgery for AIS with a minimum follow-up of 10 years.

Search terms

By title and abstract for key word 'complications'.

Keywords used

- adolescent idiopathic scoliosis, scoliosis surgery, long-term complications,
- scoliosis, surgery, complications,
- adolescent idiopathic scoliosis, surgery, complications,
- scoliosis surgery, long-term outcomes,
- adolescent idiopathic scoliosis, reoperation rates.

Date of PubMed review

November 1, 2012.

Results

Seventeen papers displayed for the keywords 'Adolescent idiopathic scoliosis, scoliosis surgery, long-term complications', 900 papers displayed for the keywords 'scoliosis, surgery, complications', 183 papers displayed for the keywords 'adolescent idiopathic scoliosis, surgery, complications', 44 papers displayed for the keywords 'scoliosis surgery, long-term outcomes', and 5 papers displayed for the keywords 'adolescent idiopathic scoliosis, reoperation rates'.

No paper has been found with the topic on complications and a long-term follow-up of at least 10 years.

Two papers were found on the topic of reoperation rates with a long-term follow-up of at least 10 years[17,18]. Reoperation rates were between 12.9%[18] and 47.5%[17].

Other papers were located supporting the position against surg ery for most AIS patients. These papers, reviewed by abstract, discuss complication rates to surgery and are a matter of discussion in the next section.

Discussion

The authors have referenced some of their own studies in this review. These referenced studies have been conducted in accordance with the Declaration of Helsinki (1964) and the protocols of these studies have

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been approved by the relevant ethics committees related to the institution in which they were performed. All human subjects, in these referenced studies, gave informed consent to participate in these studies.

Although the problem with post-surgical complications is highly relevant[15–17], reporting of long-term outcomes does not seem to be of utmost importance, as evidenced by the lack of published literature. One red flag is reporting a complication is not mandatory[15]. As a result, in the literature there are a variety of non-standardized studies with various follow-up times prohibiting proper comparison.

Based on the experience of the authors in Germany and the United States, the majority of surgeons continue to inform otherwise healthy AIS patients (and their parents) that surgery is necessary at a given Cobb angle even when the patient is near or at bone maturity. However, for most of the AIS population, there is no medical indication for such spinal fusion surgery. Signs and symptoms of scoliosis cannot be changed in the mid-term and cosmetic improvements initially achieved with surgery are not necessarily stable[15]. When one considers that the long-term course of AIS is far from being disastrous, according to natural history[7], we may conclude that the consequences of scoliosis surgery are far more dangerous and detrimental than the condition itself (Figures 1 and 2).

Although no paper on long-term complications was discovered when reviewing recent literature, it is worthwhile to consider the papers located in the search.

Low rates of complications (<20%) have been reported in two papers on the long-term outcome of two different instrumentations, and low back pain has been an issue in the population undergoing the CD instrumentation[19,20].

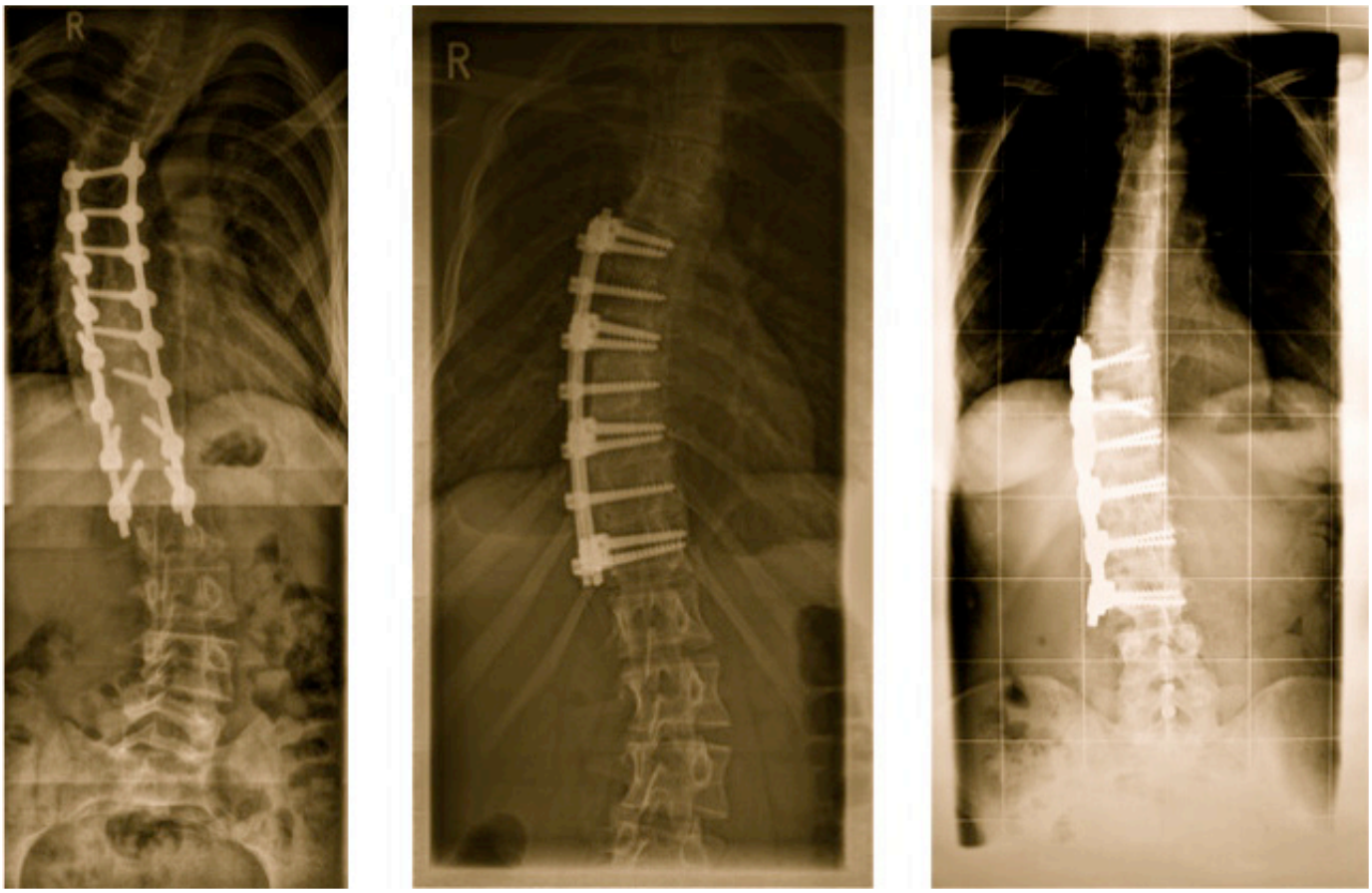

Figure 1: Three AIS patients with problems post-operatively. Left, modern dorsal double rod instrumentation with pedicle screws. This patient had severe pain in the upper thoracic spine after surgery while no pain was present prior to surgery. In the X-ray, bending of the thoracic spine proximal to the instrumentation can be seen. Middle, modern ventral double rod instrumentation with the same problems as in the patient on the left, however, radiologically the proximal bending of the upper thoracic spine is not pronounced, yet. Right, modern ventral double rod instrumentation for a thoracolumbar curve with chronic back pain due to functional costotransversal problems without any radiological sign of complication.

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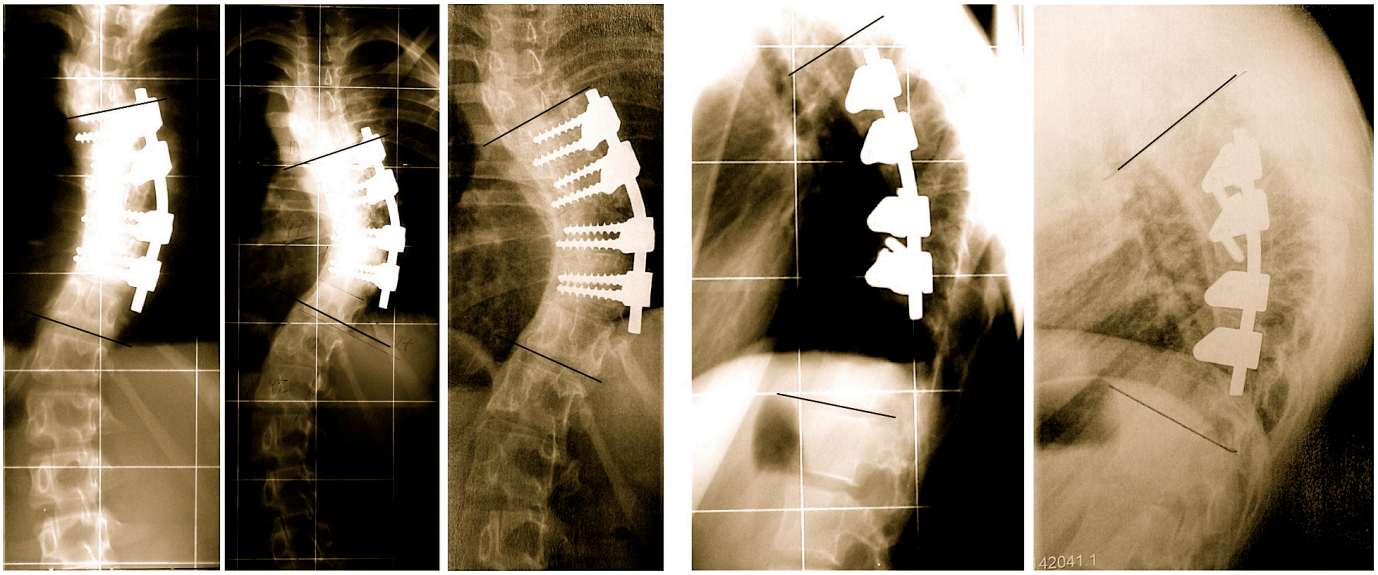

Figure 2: Short modern ventral double rod instrumentation with deterioration of the Cobb angle and of kyphosis after surgery. This indicates curve instability, perhaps due to a procedural error or misjudgement.

Other papers seem to reveal low rates of complication, and reoperation rates <10%[21–23]. Reoperation rates were between 3.9% at 2-year follow-up[22] and 9.2% at 8.3 years follow-up[23]. Therefore, it appears with AIS, reoperation rates increase with time.

In conditions other than AIS, complication rates have been found to be rather high[24–32]. After <3 years, a complication rate has been found between 26% (follow-up 14.3 months[26]) and 42%[24] (follow-up 28 months).

Obviously, post-operative back pain is an issue[33,34] in the AIS population, and also disc degeneration, which increases after surgery[35]. Patients reported increasing post-surgical back problems as time elapsed after AIS surgery[34].

Furthermore, a selection bias seems to exist in AIS post-surgical studies. The population 'lost to follow-up' had more pain and less function in the specific SRS-22 domains than the 'follow-up' populations in the studies. This most likely means patients with a negative outcome after surgery are more likely to seek advice from another healthcare provider and do not return to the surgeon who performed the initial operation[36]. From this, two conclusions can be drawn:

1. The long-term outcome papers on surgical treatment are underestimating complication rates and/or failures.
2. Future studies on the outcome of surgery should add the 'lost to follow-up' group to the failure/complication population.

Since there is no evidence indicating surgical correction in patients with AIS[12–14] and post-surgical complications are estimated around 50% over a lifetime[15–17], no claims should be made for the medical indication for such surgery. In the relatively benign population of AIS patients, according to the findings within this review, it may be concluded that the long-term outcome of surgery for AIS is worse than the long-term consequences of the condition itself.

With the bracing technology available today, a success rate exceeding 90% may be expected according to the SRS inclusion criteria for scoliosis bracing[37]. With the utilization of high correction braces, the patient can expect a pain-free experience, even a comfortable treatment, provided there is a trained professional of appropriate skill administering brace adjustments. In this light, it seems questionable when new surgical techniques are applied, which do not halt progression in curves exceeding 50° and no long-term experience is evident in the range of the general bracing indication, for curves between 25° and 41°[38].

There are numerous papers basing conclusions on quality of life questionnaires, mainly the SRS-22, claiming a high patient satisfaction after scoliosis surgery[12,13,35]; however, the results or conclusions derived from these studies are questionable when the 'dissonance' effect is considered, as referenced in a discussion of post-surgical interviews[12,13]. Cognitive dissonance occurs most often in situations where an individual must choose between two incompatible beliefs or actions and there is a tendency for individuals to seek consistency among their cognitions. Unable to face an inconsistency, such as being dissatisfied with a surgical procedure, a person will often change his/her attitude. Surgery is impossible to reverse, but subjective beliefs and

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attitudes can be altered more easily. As a result, a patient not satisfied with a surgical procedure may not necessarily admit this[12,13].

Spinal fusion in AIS should only be considered when it is the rare curve that has progressed to a very severe degree, or in patients with substantial psychological trauma due to the deformity presented by scoliosis.

An indication for spinal fusion surgery may present itself when socialization is self-restricted because of the deformity. However, this is rarely the case in a population treated conservatively according to the latest standards. In a recent paper (with a sample of patients fulfilling the SRS inclusion criteria for studies on bracing), after completion of brace treatment, no patient considered a surgical intervention[37].

Moreover, in a patient requiring surgery, informed consent must be obtained for patient awareness and a surgeon's liability. The patients must be aware of the high percentage of long-term complications of fusion surgery and the extent of long-term complications to expect[15–17]. Additionally, the stress the patient experiences due to the deformity must be documented. Therefore, the first author developed a brief questionnaire (BSSQ) in 2006[39], which has been implemented and validated in several languages[40–44]. It is highly recommended that patients complete the preoperative patient awareness documentation regarding possible complications, sometimes presenting more than 20 years post-operatively[15–17]. This documentation, in conjunction with the deformity-related stress level questionnaire, should be read carefully for full disclosure of long-term effects. A documentation sheet to fill this gap is proposed within this paper (Supplementary files 1 and 2).

A few published studies compare surgical to non-surgical treatment of adult scoliosis patients[45–47], however, none included an untreated control group. In spite of the limitations of these studies, conclusions may be drawn. In one study, the authors[45] state, 'An important caveat of this study was that the treatment was not randomized and therefore the treatment group might have deteriorated if not for the treatment they received'. Bridwell et al.[46] had dropout rates of >50% in the non-operative group; so, no conclusions are justified because a 'worst case' analysis could lead to the opposite conclusions.

A similar paper was published in 1995[48] in the American edition of the Journal of Bone and Joint Surgery, even though the conservative sample who refused surgery had a return rate of only 50%. Scientifically, these papers are questionable as was discussed in a recent review[49].

Finally, to come back to the title, 'Risks and Long-Term Complications of Adolescent Idiopathic Scoliosis Surgery vs. Non-Surgical and Natu ral History Outcomes,' there are two aspects worth looking at more closely: the risk/reward relationship for the patient and the cost to the community.

1. Since proof is lacking that health-related issues can be solved by spinal fusion surgery[15] in AIS patients and the long-term risks of such surgery are more detrimental to the patient than the consequences of the deformity itself,[16,17] the risk/reward relationship of surgical treatment is unfavourable for the AIS patient. A high resurgery rate[16,17], long-term complications[17] and regular returns of the deformity[15] should normally cause patients to reject this form of treatment.

Today, favourable results can be achieved with a skilled practitioner through modern bracing concepts (Figures 3 and 4) and cosmetic results can be estimated at least as good as post-surgical or even better (Figure 4) without a lifetime of surgical hardware implanted and the long-term complications that result in approximately 50% of cases. Currently, it is not possible to prove whether the effects of modern bracing concepts are long-lasting; however, the surgical effects on sustainability of improvement in cosmetic appearance are also not proven in the long-term. Therefore, an indication for spinal fusion surgery with respect to cosmetic issues should not be indicated.

As shown recently, high-quality bracing can prevent the need for undergoing spinal fusion surgery in nearly all AIS patients[37,50].

2. The cost of AIS surgical treatment for the community is critical as well. In a paper comparing the costs of modern conservative treatment versus surgical intervention in patients with AIS (in Germany), modern conservative treatment is clearly favourable, and cost-effective, with respect to claims paid by insurers[51]. This may differ in countries where there is no public health insurance available, but then the patient must handle the burden of excess costs related to surgery, subsequent reoperation(s) or re-treatment.

Conservative treatment rarely results in complications and is beneficial and cost-effective for AIS patients and the community.

Evaluations of the problems arising from spinal fusion surgery are just beginning. The search for adverse effects of AIS surgery is compromised because there is no mandatory reporting of complications and implant failures[15]. As time passes, more problems seem to emerge for the post-surgical patient. The recent study on the long-term effects of CD instrumentation[17] must be viewed as a warning. Many issues have not yet been investigated, and later in life various problems occur, which are not necessarily attributed to spinal fusion surgery[16].

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Figure 3: Immature AIS patient with a thoracic curve of 56° at the start of treatment. The treatment with a modern high correction brace has led to a rebalancing of the curve so as to allow a drastic clinical and radiological improvement as well. Finally, the patient had a well-balanced spine with a residual curve of 43°. This shows that also in curvatures exceeding 50°, bracing success is attainable. This picture has first been published in: Weiss HR, Moramarco M. Remodeling of trunk and backshape deformities in patients with scoliosis using standardized asymmetric CAD/CAM braces. Hard Tissue 2013 Feb 26;2(2):14.

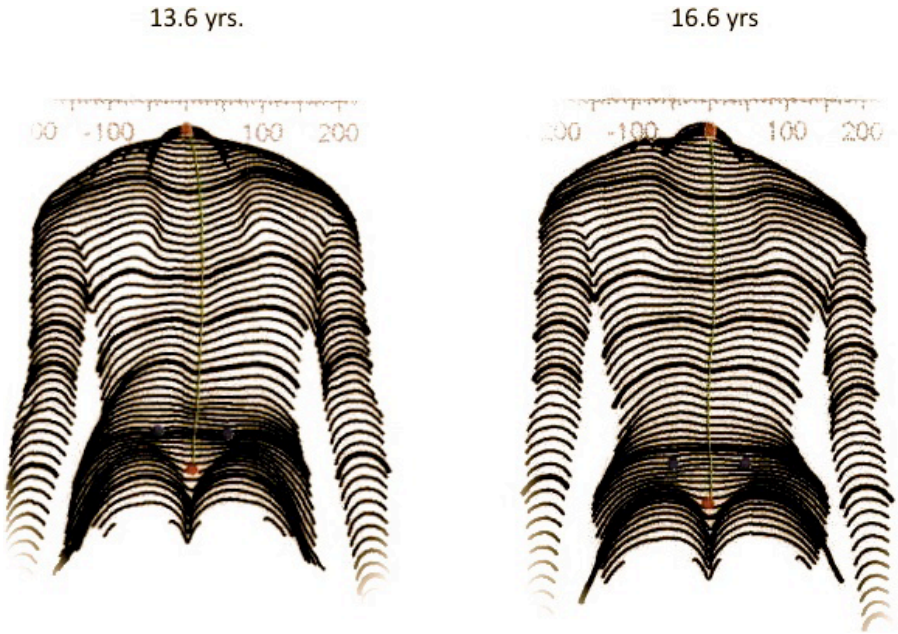

Figure 4: A 13.6-year-old patient with a thoracic AIS curve of 54°. Left, at the start of treatment and right, at the age of 16.6 years with a clinical recompensation obviously not needing surgical intervention with a high patient satisfaction. This shows that clinical improvement is possible with high-quality bracing. The risks associated with AIS surgery seem unjustified, considering that more conservative treatments now offer the potential for improvement.

Furthermore, in a recent article, the problem of 'metallosis' was described. It was stated that the consequences of the findings of 'metallosis' are not yet clear[52]. According to Cundy et al., 'A significant and rapid rise in serum titanium and niobium levels was observed within the first post-operative week, after which elevated serum levels persisted out to 12 months. Conclusions of this study: We report abnormally elevated serum titanium and niobium levels in patients with titanium-based spinal instrumentation out to 12 months. The long-term systemic consequences of debris generated by wear and corrosion of spinal instrumentation is unclear but concerning, particularly as these implants inserted into the paediatric population may remain in-situ for beyond six decades'.

Finally, a recent article published in Spine, February 2013[53] addresses mortality and morbidity following

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early onset scoliosis spinal surgery. The complication rate is 84% with a mortality rate of 18%. The authors conclude, 'The high mortality rate is alarming, suggesting that further study is needed in this area'.

Conclusion

- A medical indication for AIS spinal fusion surgery does not exist, except in extreme cases.
- Complications of AIS spinal fusion surgery in the long-term exceed what is reasonable for AIS patients.
- The risk/reward relationship of spinal fusion surgery is unfavourable for the AIS patient, except in rare cases.
- The rate of complications of spinal fusion surgery appears to increase with time.
- There is no evidence that spinal fusion surgery improves quality of life for AIS patients versus natural history.
- In the small number of patients with AIS who cannot tolerate the deformity, written informed consent must be obtained after full disclosure regarding the extent of complications one can expect and the rate of reoperation in the long-term.
- Due to the resulting health complications of AIS surgery, patients, due to no fault of their own, place an unnecessary burden on public health systems as the patient is forced to seek recourse, remedy or reoperation from surgeries with unintended consequences.

Competing interests

MM and KM declare to have no competitive interest. HRW is advisor of Koob GmbH & Co KG, Abtweiler, Germany.

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All authors abide by the Association for Medical Ethics (AME) ethical rules of disclosure.

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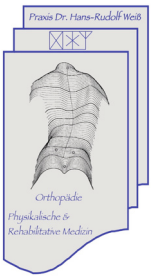
Critical review

 1

BSSQ - Bad Sobernheim Scoliosis Questionnaire



.....

Last name: Surname (First): DOB: No:

Please read this questionnaire carefully and answer honestly. These questions are designed to reveal (or depict) how you feel about your scoliosis. Following the evaluation of this questionnaire, we will be able to better estimate or recognize any stress caused by your scoliosis (deformity). This information will enable us to better advise you in respect to future treatment options.

1. I feel self-concious about the appearance of my back
- Δ completely true
- Δ nearly true
- Δ hardly true
- Δ not true at all

2. It is difficult for me to openly show my back (eg. public swimming pool).
- Δ completely true
- Δ nearly true
- Δ hardly true
- Δ not true at all

Supplementary files 1 and 2: The BSSQ (English, not validated version) and an additional consent for scoliosis surgery. In a patient requiring surgery, full consent must be obtained for both the patients and the surgeon's safety. It is highly advisable to complete the preoperative documentation for patient awareness of possible problems arising sometimes more than 20 years post-operatively[15–17] together with the deformity-related stress level questionnaire before surgery is performed.

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 2

3. I feel uncomfortable in situations where my back is visible to others.	Δ	completely true
	Δ	nearly true
	Δ	hardly true
	Δ	not true at all
4. I don't feel embarrassed when people see my back.	Δ	completely true
	Δ	nearly true
	Δ	hardly true
	Δ	not true at all
5. I avoid body contact (close dancing, ect.) which would allow others to recognize I have scoliosis.	Δ	completely true
	Δ	nearly true
	Δ	hardly true
	Δ	not true at all
6. Hiding my back is a large factor in deciding what kind of clothing to wear or how to wear my hair.	Δ	completely true
	Δ	nearly true
	Δ	hardly true
	Δ	not true at all
7. Scoliosis is part of me, people have to accept me the way I am.	Δ	completely true
	Δ	nearly true
	Δ	hardly true
	Δ	not true at all
8. Because of my back I avoid activities/hobbies, which I otherwise love to do.	Δ	completely true
	Δ	nearly true
	Δ	hardly true
	Δ	not true at all

Original version:

[1] Weiss HR, Reichel D, Schanz J, Zimmermann-Gudd S. Deformity related stress in adolescents with AIS. Stud Health Technol Inform. 2006;123:347-51.

Validated international versions:

[2] Kotwicki T, Kinel E, Stryla W, Szulc A. Estimation of the stress related to conservative scoliosis therapy: an analysis based on BSSQ questionnaires. Scoliosis. 2007 Jan 3;2:1.
[3] Misterska E, Glowacki M, Harasymczuk J. Polish adaptation of Bad Sobernheim Stress Questionnaire-Brace and Bad Sobernheim Stress Questionnaire-Deformity. Eur Spine J. 2009 Aug 11.
[4] D'Agata E, Testor CP, Rigo M. Spanish validation of Bad Sobernheim Stress Questionnaire (BSSQ (brace).es) for adolescents with braces. Scoliosis. 2010 Jul 15;5:15.

Supplementary files 1 and 2: (*continued*)

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Critical review

Consent for spinal fusion surgery in patients with Adolescent Idiopathic Scoliosis

I have been informed that for this type of surgery, about 50% of patients may eventually expect long-term complications. This includes various complications, which have been outlined by the advising surgeon (1,2,3,4).

Complications occurring as a result of surgery include chronic back pain (3), late infection (3), implant failure or other issues, which may lead to a reoperation in more than 25-50% of patients over a lifetime (2,3,4).

I have difficulty coping with my deformity which is apparent from my poor score values in the BSSQ (<12 / 24).

In spite of the immediate and long-term complications, which may occur as a result of surgery, I definitely want to undergo the procedure.

I am aware that the instrumentations used in spinal fusion surgery, as available today, have not yet been tested in the long-term.

I see spinal fusion surgery as the only way to improve my quality of life, although I do know that signs and symptoms of a scoliosis will not necessarily be improved in the long-term (1).

Date:

....
(Patient's signature) (Parent's signature)

.....
(Physicians signature)

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Supplementary files 1 and 2: (*continued*)

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Critical review

BSSQ - Bad Sobernheim Scoliosis Questionnaire (scale)

1. I feel self-concious about the appearance of my back	0 completely true 1 nearly true 2 hardly true 3 not true at all
2. It is difficult for me to openly show my back (eg. public swimming pool).	0 completely true 1 nearly true 2 hardly true 3 not true at all
3. I feel uncomfortable in situations where my back is visible to others.	0 completely true 1 nearly true 2 hardly true 3 not true at all
4. I don't feel embarrassed when people see my back.	3 completely true 2 nearly true 1 hardly true 0 not true at all
5. I avoid body contact (close dancing, ect.) which would allow others to recognize I have scoliosis.	0 completely true 1 nearly true 2 hardly true 3 not true at all
6. Hiding my back is a large factor in deciding what kind of clothing to wear or how to wear my hair.	0 completely true 1 nearly true 2 hardly true 3 not true at all
7. Scoliosis is part of me, people have to accept me the way I am.	3 completely true 2 nearly true 1 hardly true 0 not true at all
8. Because of my back I avoid activities/hobbies, which I otherwise love to do.	0 completely true 1 nearly true 2 hardly true 3 not true at all

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