Least potential harm with treatment for adolescent idiopathic scoliosis patients

K Moramarco*

Abstract
Introduction
Recent reviews discussing risks and benefits of spinal fusion surgery in patients with scoliosis have lead to the conclusion that evidence for spinal fusion is lacking. Long-term follow-up studies have shown a high rate of complications due to surgical intervention. A long-overdue debate has ensued about the pros and cons of spinal fusion surgery. The aim of this paper was to discuss treatment options for adolescent idiopathic scoliosis patients.

Short Communication
Untreated adolescent idiopathic scoliosis results in limited physical impairment during adulthood. Typical primary complaints of concern in adults with scoliosis are back pain and emotional distress over one’s postural appearance. As a result, spinal fusion surgery should not be regarded as mandatory upon achieving a certain Cobb angle.

The reality is, until recently, very few have ever challenged surgery for adolescent idiopathic scoliosis in a field dominated and managed by spinal surgeons. Most of the patients and parents have a natural aversion to surgery for scoliosis, yet many spinal surgeons lead patients to believe that there is no other choice when it comes to scoliosis.

Full disclosure about the potential unknowns of surgery in the short-and long-term should be mandatory, so families may weigh the myriad of unknowns against the perceived benefits of surgery. Examples of the risks of surgery include, but are not limited to, post-surgical pain, hardware failure including breakage, corrosion, advanced degeneration, late infections, and the potential for one or more revision surgeries.

Conclusion
In the field of adolescent idiopathic scoliosis, certainly most of the physicians would agree that there are still many unknown factors. A few ideal treatment protocols exist for the scoliosis, especially from the perspective of the adolescent patient and his/her parents. It is for this reason that a dialogue is essential and must be kept with the goal that treatments should always incur the least potential harm and maximum potential benefit in both the short- and long-term.

Introduction
Recent reviews discussing the risks and benefits of spinal fusion surgery in patients with scoliosis have lead to the conclusion that evidence for spinal fusion is lacking. At the same time, long-term follow-up studies show a high rate of complications due to surgical intervention. A debate has ensued about the pros and cons of spinal fusion surgery based on a critical review published recently. A response to Weiss and Moramarco letter to the editor entitled ‘Indication for surgical treatment in patients with adolescent Idiopathic Scoliosis – a critical appraisal’ May 24, 2013 has been published and reveals the arguments of surgeons in defence of their work.

The response by Dr. Shay Bess regarding a recent letter to the editor is appreciated. Obviously, there is substantial disagreement regarding the treatment of scoliosis among factions. Concerns of those in favour of more conservative management practices are about surgery, when it is warranted, and unknown or negative long-term implications for patients. The results of recent long-term studies or lack thereof must be considered. It is essential to stimulate dialogue for the benefit of the long-term health and awareness of patients with AIS.

The overzealous use of surgery as a treatment for scoliosis is a concern because of potential complications in the short- and long-term. Surgery for scoliosis is routinely indicated primarily to address cosmetic appearance and prevent progression. Surgery is not performed to improve ventilatory function.

In the treatment of AIS, it is problematic that many in the surgical community have chosen to ignore the general conclusions of studies on the natural history of scoliosis. Perhaps, in the field’s most well-known study on natural history, the conclusion by Weinstein et al. specifically states that ‘Untreated adults with 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’. Such conclusions have lead to the use of the term ‘relatively benign’ assigned to AIS by Weiss and Moramarco and others previously. However, choice of terminology is no way meant to downplay the very real effects of living with scoliosis.

In the aforementioned response by Bess, he objects to citations authored by Weiss as anti-surgery in tone and content; yet conclusions drawn are...
from the current literature. In fact, Hawes also pointed out a lack of evidence for surgery\textsuperscript{11}. The sad reality is, until recently, very few have ever challenged the surgeon-dominated protocols for the management of AIS illustrated by the common practice that upon suspicion of scoliosis, even of a mild curvature, an adolescent is sent, usually by a paediatrician, to a surgeon often only to order the X-rays necessary to confirm scoliosis. This paper discusses how treatments should incur the least potential harm for adolescent idiopathic scoliosis patients.

**Short Communication**

The author has referenced some of his/her own studies in this short communication. These referenced studies have been conducted in accordance with the Declaration of Helsinki (1964) and the protocols of these studies have 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.

Most of the patients and parents naturally have an aversion to surgery, yet most of the spinal surgeons make patients believe that there is no other choice. Dr. Bess’s response calls for an ‘open-minded view’ regarding treatment options for scoliosis. This has been the position of those advocating the nonsurgical management of scoliosis for years. Having an ‘open-minded view’ should also include a commitment to full disclosure about the potential unknowns of surgery in the short- and long-term, so families may consider the myriad of unknowns against the perceived benefits. Examples of surgical risks include, but are not limited to, pain, hardware failure including breakage, corrosion\textsuperscript{12}, advanced degeneration, late infections\textsuperscript{13}, and the potential for one or more revision surgeries. Dr. Bess takes issue with the Weiss and Moramarco interpretation of Mueller and Gluch\textsuperscript{4} and calls the study an ‘outlier’ because the conclusions do not satisfy his agenda or those of his cited affiliates. Outlier or not, at the very least, the Mueller and Gluch article raises the point that additional long-term follow-ups are necessary before subjecting patients to the potential risks associated with surgery, and maybe it is time for the surgical community to stop and consider the practice of recommending surgery for scoliosis at 45–50° and higher.

Risks must be disclosed to families of patients so that they are aware that after two to five decades, unintended consequences or additional surgeries could be required. Dr. Bess states that Weiss and Moramarco have a ‘single-sided view’, implying bias and refers to their ‘zealous rejection of surgery for AIS’. A similar counter-accusation can be made with equal justification.

As conservative care physicians, Weiss and Moramarco work to empower patients to manage scoliosis nonsurgically. If that results in a bias, then perhaps guilty as charged is in order. Although practitioners of conservative methods are at odds with surgeons, their ultimate goals should be the same, i.e. to help patients lead the highest quality of life possible while living with scoliosis. It is acknowledged that there are cases when surgery may be warranted.

Avoiding bias is indeed a challenge for all physicians who are passionate and dedicated to their field, or niche along a spectrum within a field. Doctors must constantly strive to that end for the benefit of the patient. Unfortunately, when prominent spinal surgeons have affiliations with medical device companies, as Dr. Bess reveals he has, that raises a red flag. When relationships exist with Depuy Spine, Medtronic, K2M, Allosource and Pioneer Spine, it could lead a reasonable person to believe that perhaps those relationships instil bias. Questionable relationships between other spinal surgeons and medical device companies have been reported in *Wall Street Journal*\textsuperscript{13} and *New York Times*\textsuperscript{14,15} also. Moreover, there are hundreds, probably thousands, of published works by SRS surgeons, and others, with stated conflicts of interest with regard to device patents and affiliations which trigger the question of bias.

Spinal fusion surgery is a lucrative procedure. Patient testimonials in the online forum of the National Scoliosis Foundation report surgeon fees which could be considered astronomical. As a result, in ‘Scoliosis and the Human Spine’, Dr. Martha Hawes devotes a chapter to ‘the appearance of a conflict of interest’.

‘Zeal’ for treating scoliosis conservatively puts Weiss and Moramarco in the minority and in direct opposition with surgeons. However, Dr. Bess’s states that each holds beliefs which are jaded could cause one to surmise that certain surgeons also possess a jaded view. If not, how is it responsible to inform patients with little remaining growth and balanced spinal curves that nothing can be done short of surgery? One could easily conclude that this advice indicates a bias for surgery in light of the natural history studies, ignored by so many.

Advocates for the conservative management of scoliosis are merely calling for informed consent, in every sense, to ensure that the adolescent patients and their families understand the potential long-term complications of scoliosis surgery and the potential for revision surgery or surgeries. Those complications may, and for many do, result in consequences far worse than living with idiopathic scoliosis itself.

Anecdotally, the clinical experience of Weiss and Moramarco reveals that those living with the negative long-term effects of surgery are perhaps underestimated due to the number of patients who report doctor hopping to desperately try to resolve post-surgical problems attributed to scoliosis.
up to two or more decades later. Numerous patients report being told to learn to live with the pain. These topics are discussed publically on the NSF online forum and are the source of great frustration for many who feel like they have nowhere to turn. Post-surgical patients present with descriptions of lives spent in pain and X-ray images confirming advanced degeneration. Few long-term studies exist, but one cites the likelihood of early disc degeneration post-surgically in the non-fused segments due to hypermobility. Surgical procedures are constantly evolving, but if anything; this underscores the point that patients should be made aware that the long-term results are unknown.

Dr. Bess cites several health-related quality of life (HRQOL) studies as a support for the necessity of surgery. Improving HRQOL is a virtuous effort, but those measures are subjective measures and fail to take into account the effects of cognitive dissonance. No one will ever argue against wanting to improve HRQOL scores for the scoliosis, whenever possible, or that HRQOL for adolescents with AIS differs from those who are unaffected by the condition. Certainly, surgeons should present parents with more definitive and qualitative evidence before requesting consent for such a dramatic procedure with potential consequences which may linger for decades.

Discussion

Recent information pertaining to HRQOL states that self-image is the sole area that differs from a clinical perspective. The important questions are—is a procedure as invasive as spinal fusion really necessary for small improvements in HRQOL? Will long-term outcomes actually result in improved HRQOL? Should postsurgical complications occur after a period of time?

The HRQOL studies cited by Bess do not assuage concerns about surgery and contribute little to discussion about evidence-based medicine on behalf of patients in the long-term. For example, one of the studies presented as evidence about the benefits of surgery is a patient–patient questionnaire. The study states that ‘Based on SRS-24 data, parents typically scored higher than their children in the operative treatment of idiopathic scoliosis in total score, self-image, and overall satisfaction’. In the end, does it really matter what the parents’ perceptions are? Concern should be with the patients in the long-term. Using this type of evidence to support claims for surgery does little to strengthen the argument for surgery.

A final note on HRQOL is, after surgery, problems can arise in both the short- and long-term. Bess seems to have missed that point because HRQOL citations presented as evidence in favour of surgery are primarily for 6–12 months post surgery with the longest having a mean of 24 months. This evidence only serves to emphasise how few studies exist on long-term follow-up for scoliosis surgery.

For the scoliosis patient and their parents, this ultimately raises the question, are minimal statistical changes in HRQOL a reason to expose oneself or one’s child to the unknown risks and effects over a lifetime for a surgical procedure not supported by any prospective controlled trial. Indeed, it is a fact that surgery for AIS is the only treatment option not supported by any prospective controlled study.

Cochrane reviews of physical methods exist concluding there is a lack of high-quality evidence, and on bracing, low-quality evidence. Furthermore, it should be noted that there is a Cochrane review of surgery, not for AIS, but for neuromuscular scoliosis. This review fails to show the necessity of surgery.

Finally, Dr. Bess takes issue with the citation of the work of Westrick and Ward, specifically the statement, ‘no long term, prospective controlled studies exist to support the hypothesis that surgical intervention for AIS is superior to natural history’. His response: to cite limitations in the literature - exactly the point - limitations do exist. Bess also dismisses the natural history studies as ‘poorly performed historical studies with incomplete follow-up and poor metrics’.

At this juncture, it must be agreed upon to disagree; but foremost, all parties must consider the long-term safety of patients.

Conclusion

In the field of AIS, most agree that there are still many unknowns. There are few ideal treatment protocols available for scoliosis, especially from the perspective of patients. For this very reason, a dialogue must continue and be in kept with the goal that treatments should always incur the least potential harm.

Conflict of Interests

The author declares to have a personal interest in Scoliosis 3DC offering programs for the conservative management of scoliosis and the Chêneau Gensingen brace.

Acknowledgement

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Abbreviations list

AIS, adolescent idiopathic scoliosis; HRQOL, health-related quality of life.

References