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Review Article

Intervention studies on scoliosis - Review of the reviews

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ABSTRACT

Introduction: The treatment of scoliosis is still a matter of debate. Although certain systematic reviews exist, neither the surgical nor the conservative community seems to acknowledge the evidence which has been gained thus far.

Aim: The aim of this review was to highlight the knowledge concerning the conservative and the operative approach in order to provide the clinician with a clear view concerning the current alternatives.

Materials and methods: A PubMed search for outcome papers and reviews concerning the treatment of scoliosis has been performed in order to detect approaches with beneficial outcomes with respect to the Cobb angle, trunk deformity and other signs and symptoms of scoliosis.

Results and discussion: Real outcome papers (beginning of treatment in immature samples, and final results after the end of growth) have been found for brace treatment only. Some papers investigated mid-term effects of exercises, most were retrospective, few prospective and many included patient samples with questionable treatment indications. The papers on surgery do not seem to provide evidence enough to establish a beneficial cost and benefit relationship for the patient.

Conclusions: Physiotherapy in the treatment of scoliosis does not seem to be of evidence enough in the treatment of patients at risk for being progressive. Brace treatment is supported by Level II evidence with studies providing end-growth results and long-term results as well. Surgical treatment cannot be regarded as being evidence based.

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1. Introduction

Scoliosis is a three dimensional deformity of the spine and trunk. This deformation may deteriorate quickly during periods of rapid growth.^{2,25} Although scoliosis may be the expression or symptom of certain diseases, e.g., neuromuscular, congenital, due to certain syndromes or tumors, the majority of patients with scoliosis (80–90%) are called

"idiopathic" because a specific underlying cause has still not been found. The treatment of the so called idiopathic scolioses is determined by the deformity itself. As most of the scolioses progress during growth, the main aim of any intervention is to stop curvature progression.^{2,25}

While children grow until they have fully matured, there are certain periods with more or less growth during childhood and adolescence and curvature progression is more or

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less probable during different phases of $\operatorname{growth}^{2,25,36,69}$ (Fig. 1). The "baby growth spurt" ends at the age of 5.5–6 years and is followed by a "flat phase" which lasts until the first signs of maturation. With the first signs of breast development or the appearance of pubic hair, the pubertal

growth spurt starts (P1) and in its ascending phase 2/3 of progression may happen.^{25,69} Shortly after the growth peak (P3), menarche in girls and voice change in boys appear and indicate the onset of the descending phase of growth until its cessation (P5).

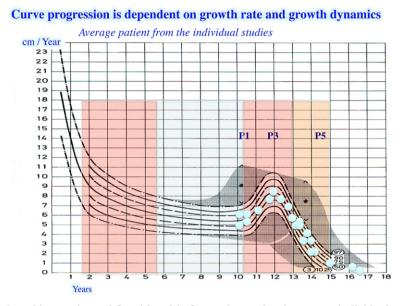
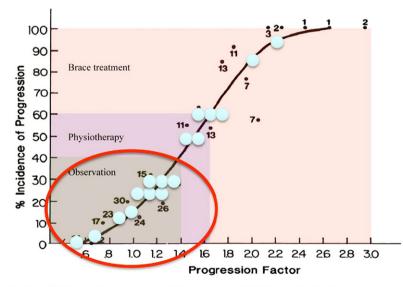


Fig. 1 – Growth rate (body length) as estimated for girls. This figure shows that immature individuals experience two phases of growth with higher velocity. One may be called the baby spurt with descended characteristics (0 to approx. 6 years of age). The other is the pubertal growth spurt (approx. 10–13 years). Between these two phases with higher growth velocity a flat phase of growth with little risk for progression occurs (figure modified from Weiss and Weiss⁷³). With kind permission of Pflaum, Munich.⁶⁹



Graph showing the incidence of progression according to the progression factor, which is calculated by the formula:

Cobb angle - (3 x Risser stage) Chronological age = Progression factor

Fig. 2 – Incidence (risk) of progression can be calculated according to the formula by Lonstein and Carlson.³⁶ According to the indication guidelines (Weiss et al.⁷⁰) we have to distinguish between: indication for observation only – incidence (risk) of progression 40%; indication for physiotherapy – incidence (risk) of progression 40–60%; indication for bracing – incidence (risk) of progression 60% and more. The average patient from the majority of the papers on physical therapy has no indications for treatment, but for observation only (blue spots). With kind permission of Pflaum, Munich.⁶⁹

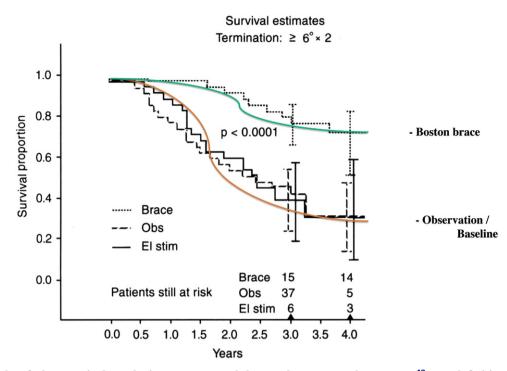


Fig. 3 – Graph of the survival analysis as presented by Nachemson and Peterson.⁴³ By definition, each patient being progressive is eliminated from the count of the study and, therefore, has not survived. Thus, at the start of the observation period there are 100% of patients in the study and at the end of the observation period there are 30% left (non-progressive) in the observation group and 70% left (non-progressive) in the patient group treated with a Boston brace (figure modified according to Nachemson and Peterson.⁴³) With kind permission of Pflaum, Munich.⁶⁹

In patients with idiopathic scoliosis during growth the risk for being progressive can be calculated using the formula by Lonstein and Carlson.³⁶ Based on this formula, the treatment indications of scoliosis patients during growth have been determined⁷⁰ (Fig. 2).

The guidelines derived from this knowledge have been established by the leading members of the Society of Scoliosis Orthopeadic and Rehabilitation Treatment (SOSORT) in order to avoid both over- and undertreatment.

A 10-year old girl with 20° and the first signs of maturation before the onset of menarche is usually Risser 0. Therefore, the progression factor is 2, indicating a risk for being progressive at a level of 90%.

A 15-year old girl with 20° is usually 2.6 years postmenarchial with Risser 4. Therefore, the progression factor in this case is 0.53, indicating there is no more risk for being progressive and that there is no more treatment indicated.

Physiotherapy, corrective bracing and spinal fusion surgery are the treatment modules currently applied in the treatment of scoliosis.³⁰ While – according to the reviews^{60,68} – there are prospective controlled studies for the use of the Boston brace^{10,43} (Fig. 3) and for the Chêneau brace⁷³ as well and prospective controlled studies, but also one randomized controlled trial (RCT) on physiotherapy,^{46,59} no papers have been found to support spinal fusion surgery at a higher level.⁶⁸

While the few Level II studies concerning bracing started in immature patient samples and ended after the cessation of growth,^{10,43,73} the studies on physiotherapy published thus far seem to have variable study designs.⁶⁸

2. Aim

The purpose of this systematic PubMed review was to analyze more closely the actual 2011 data provided by PubMed on physiotherapy, braces and surgery as well as those materials already presented in systematic reviews as found in literature.^{22,46}

3. Materials and methods

A PubMed and (incomplete) hand search for outcome papers concerning all acknowledged treatment options was performed in order to detect study designs and inclusion criteria used for studies on physiotherapy, bracing and surgery. Retrospective controlled studies (Level III), prospective controlled studies (Level II) and randomized controlled studies (Level I) were taken into account, but also other study designs were recorded.

The search (November 16th, 2011) was performed as regards manuscripts using the mesh terms "scoliosis AND physiotherapy/ exercises/ exercise," "scoliosis AND bracing/ brace/ orthosis," "scoliosis AND surgery/ spinal fusion/ instrumentation." The inclusion criteria were as follows:

- Patients: diagnosis of adolescent idiopathic scoliosis (AIS), confirmed by X-rays; we focused on patients in growing age.
- Experimental intervention: patients treated exclusively with physiotherapy and/or correcting braces and/or surgery.

- Control group: any kind of patients, either observed or treated.
- Outcome measures: only Cobb degrees results could be reported in absolute terms or as the percentage of patients improved/worsened; trunk deformity, when measures available.
- Study design: any controlled study design.

4. Results

In total, 193 papers were displayed when the phrase "Idiopathic Scoliosis AND physiotherapy" was entered; 167 papers when the phrase "Idiopathic Scoliosis AND exercises" was entered, and 139 papers when the phrase "Idiopathic Scoliosis AND exercise" was entered. Moreover, 1264 were displayed for the phrase "Idiopathic Scoliosis AND brace," 457 for "Idiopathic Scoliosis AND bracing," 1173 for "Idiopathic Scoliosis AND orthosis," 8102 for "Idiopathic Scoliosis AND surgery," 3333 for "Idiopathic Scoliosis AND spinal fusion," and, finally, 3368 for "Idiopathic Scoliosis AND spondylodesis." For the majority of these papers, physiotherapy, bracing or surgery was not the main or the only focus. Many papers were found concerning bracing; most, however, were devoted to surgery. Others were no outcome papers where the Cobb angle was used as the outcome parameter.

Real outcome papers (beginning of treatment in immature samples and final results after the end of growth) were found neither for physiotherapy nor for surgery (spinal fusion), few were found for bracing. Some papers concerning physiotherapy investigated mid-term effects of exercises, most were retrospective, few prospective and many included patient samples with questionable treatment indications. Most papers concerning bracing were cohort studies^{1,6,17,19,20,23,31,33,34,50,52,57,78,81,82} and reviews;^{26,37,55,68,71} few papers provided patient samples followed until skeletal maturity. Only three papers^{30,73,79} compared soft brace treatment to hard braces in a prospective controlled design; one of them was randomized showing no effect of soft braces during the pubertal growth spurt and no compliance difference with regards to hard braces, which is contradictory to the RCT performed by the developers.9

4.1. Studies on physiotherapy

Most of the studies concerning physiotherapy involved patient samples not meeting the treatment indications as proposed within the SOSORT indications guidelines.⁷⁰

Some studies investigated immature patient samples with curvatures of less than 15° not yet in the range of requiring treatment (see Fig. 1), many of them were already mature at the beginning of the study, not needing any treatment at all (see Fig. 2).

One study compared two different unproven concepts against each other. 48

4.2. Studies on bracing

Four prospective controlled end-result papers were found concerning hard braces, two on the Boston brace and one

on the Chêneau brace with a small, but most homogeneous sample of patients at risk for being progressive.^{10,43,73,79} One RCT was found concerning the use of a soft brace;⁹ however, the results from independent studies differ significantly from the results presented in this paper.^{73,79}

Some high quality cohort papers should be listed here as well: there are old papers on the Chêneau brace³¹ and the Cuxhafen brace¹⁹ from Germany, and most recently also another long-term study on the Boston brace³⁴ and on the Chêneau brace.^{81,82}

It has been shown in two papers,^{8,33} one of them experimental,⁸ that the outcome of bracing is correlated with the in-brace correction achieved.

4.3. Studies on surgery

Prospective controlled papers that would compare surgery to observation only were not found. In some prospective controlled papers from the Swedish series no real differences have been recorded between patients treated surgically and those treated by brace with respect to health related issues and pain in the long-term.^{11,12,13,14,15}

Other studies comparing surgical treatment to conservative management were retrospective with return rates of sometimes less than 60%.^{3,16,24,35}

On the other hand, the long-term rate of complications may be higher than 40–50% over a lifetime.^{2,67}

The short-term rate of revision surgery has to be estimated to exceed 30%.⁷

5. Discussion

5.1. Papers on physiotherapy

No paper was found with respect to patients at risk for being progressive followed until skeletal maturity under physiotherapy treatment alone.^{4,18,21,22,29,38,39,40,41,42,44,45,46,48,49,53,56,59,72,74} Claims made to regard physiotherapy as an evidence based method of treatment are, therefore, not justified scientifically.^{22,46}

The only evidence on Level II is found in the immature sample (subgroup) from the prospective controlled study from our group.⁷⁴ However, this group of patients has not been followed until skeletal maturity.

Other papers involving two unproven groups treated with physiotherapy and compared against each other do not seem to provide any evidence as this study design does not make sense^{44,48} because the differences found between the two groups cannot be regarded as leading to the conclusion that one of the therapies might be of any benefit to the patients treated. When one method is not effective and has no better results than observation only, the other method could also lead to deterioration and, therefore, be statistically different (Fig. 4). This is why only controlled studies with an untreated control group can be regarded as a valid source of scientific information.

Let us, for example, consider the material in the following study with respect to the maturity of the patient group and treatment indications: "Seventy-four consecutive outpatients with AIS, mean 15° (standard deviation 6) Cobb angle, 12.4

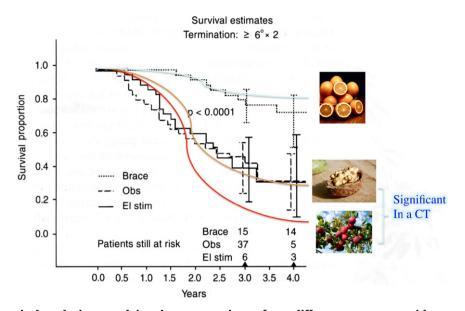


Fig. 4 – Fictitious survival analysis to explain why a comparison of two different treatments without an untreated control group does not make sense: when one group of patients undergoing the "nuts" treatment does not benefit from this, but is compared to the "plums" treatment increasing the curvature angle, there surely may be differences in controlled studies (randomized or not). But it does not show that any one of these interventions is really beneficial to the patient ("orange"). So, a controlled study design without an untreated control group does not provide any evidence for an intervention as investigated with the help of this study design. With kind permission of Weiss H-R, Best practice in conservative scoliosis care. 4th edition, in press. Pflaum, Munich⁶³; (pictures of fruits – open source, Wikipedia).

(standard deviation 2.2) years old, at risk of bracing who were not treated previously".⁴⁸

Italian girls with an average age of 12.4 years can surely be estimated as being postmenarchial with Risser 1 at least. When calculating an average patient from this sample using the Lonstein and Carlson formula^{36,70} having a curvature of 15°, we can estimate a risk factor of less than 1 and, therefore, this patient sample is not at risk at all. Instead, it is a benign sample not needing any treatment. This is only one example of a documented malpractice and, unfortunately, literature is rich in samples not requiring treatment, but claims have been made from these studies that physiotherapy would be of benefit.

A retrospective study including a "worst case analysis" with a patient sample of 13.2 years and the Cobb angle of 23.4° has also been published. This sample also lacks any indications for treatment.⁴⁵

The Chinese RCT⁵⁹ has a patient sample at the start of the follow-up period of 15 years and a follow-up time of 6 months on average. Generally, 15-year old girls (girls are the main population in samples with AIS) do not have significant residual growth left and do not necessarily need any treatment. So this study, even with the most important study design (RCT), cannot contribute to the search for evidence for physiotherapy in scoliosis.

Only 7 out of 19 samples published had a risk of progression exceeding 40% and consequently had an indication for treatment (38%).⁷² Three other papers involved a patient sample that was (nearly) outgrown and would not require any treatment.^{39,40,59}

The studies by Mollon and Rodot,⁴¹ Ducongé¹⁸ and Weiss et al.⁷⁴ were not homogeneous with respect to the materials included, had a wide range of materials and also included many prepubertal patients not yet at risk.

According to the findings from this review, studies on physiotherapy in scoliosis patients have the following shortcomings:

- wrong treatment indications,
- lack of risk for progression,
- lack of comparability,
- lack of homogeneity.

The only paper presenting at least some evidence is the prospective controlled paper from my previous working group;⁷⁴ however, this patient sample has not been followed until the end of growth (maturity). Within this study, there was a subsample of patients at a higher risk for being progressive. The controls from this study were non-progressive in 30% without any treatment which compares well to the controls in the Scoliosis Research Society (SRS) brace study⁴³ (see also Fig. 6).

5.2. Studies on bracing

The problem of treating mature patients and claiming beneficial outcomes is also evident in bracing⁴⁴ (Fig. 5). Nevertheless, Level II papers were found with patient samples at risk for being progressive and treated until the end of growth.

Thus, brace treatment can be regarded as an evidence based treatment. 10,43,51,54,73,79

However, there is still a wide range of braces available, some of them obviously useless, some with contradictory

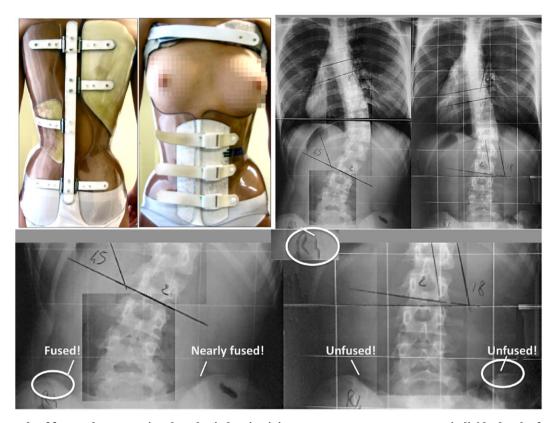


Fig. 5 – A sample of figures demonstrating that also in bracing it is not uncommon to treat mature individuals. The female patient in the upper left picture is clearly mature (breast staging: Tanner 5). The X-rays as published within the same figure, together with the clinical picture,²⁵ at first glance seem to show a drastic improvement of the curve as claimed by the authors. First of all, a permanent result like this cannot be achieved in a mature patient and, therefore, is not credible (on the left side X-ray Risser 4 has been estimated with fusion of the right iliac crest apophysis). Secondly, the Risser sign on the right X-ray seems more immature when compared to the left, which could lead to the assumption that the right X-ray was the first and the left one was the last one and, consequently, demonstrates a drastic curve progression. With kind permission of Weiss H-R, Best practice in conservative scoliosis care. 4th edition, in press. Pflaum, Munich.⁶³

results in different studies.^{6,9,23,57,61,63,64,65,66,68,71,73,75,76,77,79} Soft braces do not alter the natural history^{73,79} and do not really improve compliance as claimed by the developers.⁹ Therefore, soft braces cannot be proposed as being indicated (Fig. 6). Consequently, presently we do know that hard braces may be successful; however, the rate of success may vary significantly (Fig. 6). The end-result seems to be dependent on the in-brace correction achieved and, therefore, the brace should be applied with the best possible in-brace correction achievable. As the Boston brace corrects on average up to 30%, the Chêneau brace of the old standard 40%, and the most recent Chêneau brace should be suggested in the first place (Figs. 7–9).

There is no need for other "new" symmetric braces (Fig. 5) as proposed by the Milan working group.⁴⁴ No in-brace corrections have been reported thus far for this brace and there are no credible case reports published as well.

So the Chêneau brace should be used as today's gold standard; however, this brace may also vary significantly with respect to reliability, quality and in-brace correction. Therefore, the new CAD/CAM series^{64,71,80} seem preferable with brace libraries available which can be adjusted easily,

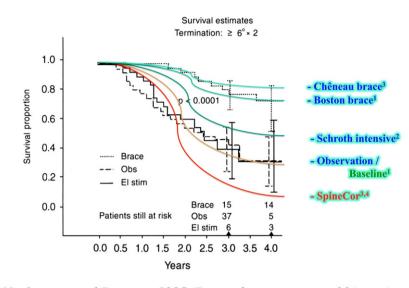
with braces of highest comfort, and at the same time, highest possible in-brace correction (Figs. 7–9).

An incomplete paper has been published discussing a patient sample nearly at the end of growth using the Chêneau light system and following the SRS inclusion criteria.⁵⁸ No patient from this sample has been operated on thus far. However, this study has to be used with caution as not all patients were outgrown at the time the study was performed.⁷⁸

5.3. Studies on surgery

A few studies comparing conservative treatment of adult scoliosis patients with operative management have been published recently.^{3,24,35} Although the limitations of these studies have been discussed, the authors dare to draw conclusions even though their studies have major short-comings. Bridwell et al.³ had return rates of less than 50% in the non-operative group, thus no conclusions are justified from this paper, because a "worst case" analysis would probably come to the opposite conclusions.

A similar paper was written by Dickson et al.¹⁶ in 1995 and was also accepted for publication in the American edition of the Journal of Bone and Joint Surgery, although the



1. Nachemson and Peterson 1995 (Boston brace vs. natural history)

- 2. Weiss, Weiss and Peterson 2003 (Schroth intensive vs. natural history
- 3. Weiss and Weiss 2005 (Chêneau brace vs. SpineCor)
- 4. Weiss 2008 (Boston brace vs. Chêneau brace vs. SpineCor vs. natural history)

Another independent study not recommending SpineCor: Wong et al. 2008 (Symmetric CAD / CAM brace vs. SpineCor)

Fig. 6 – Synopsis of the survival proportions of the different studies available for comparison. For the treatment of an immature patient the SpineCor seems worthless with a survival rate (8%) of less than observation, only (30%). The immature Schroth (physiotherapy) sample has a survival rate of 50% (estimated from the premature end-results as the sample was not followed until skeletal maturity), the Boston brace 70% and the Chêneau brace of the 1999 standard 80%. As the Schroth sample was not followed until skeletal maturity (more than 30 months only) this graph for physiotherapy is fictitious as it shows a follow-up of 4 years. The other limitation of the Schroth sample is the lack of homogeneity, also including patients not at an actual risk. On the other hand, the prospective controlled study on Schroth seems the one providing the highest evidence for physiotherapy at this stage. With kind permission of Weiss H-R, Best practice in conservative scoliosis care. 4th edition, in press. Pflaum, Munich.⁶³

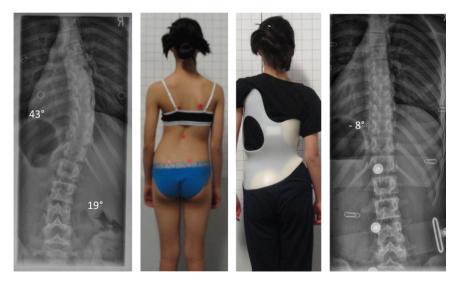


Fig. 7 – Overcorrection of a thoracic curve in the Gensingen brace from 43° to -8° in an immature 12-year old Chinese girl with a premenarchial status.⁶⁹

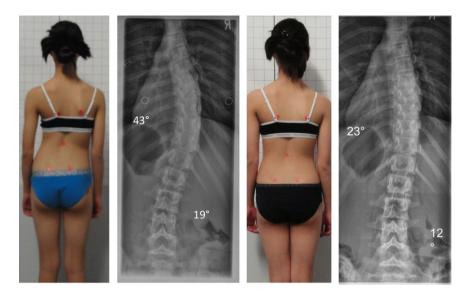


Fig. 8 – The girl from Fig. 7 after 6 months of treatment, the first brace being outgrown. This girl enters the second brace with 23°, while the initial curvature was 43°.⁶⁹

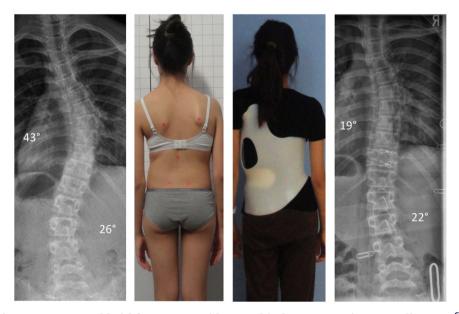


Fig. 9 - A 13-year old girl from Korea with a good in-brace correction exceeding 50%.⁶⁹

conservative sample had a return rate of 50% only. These papers seem to exemplify surgical bias, because scientifically these studies do not merit being published because material included in them is poor and the conclusions drawn invalid.

A study design may be prospectively controlled; however, because the problems (complications) of spinal surgery arise after many years mostly with a lifetime risk of 40–50%,^{2,27,28,67} a follow-up of two years seems very questionable and, therefore, not all these papers seem to be valid sources of information.

The Swedish series of papers with a prospective long-term design does not unveil any substantial evidence that surgery is superior to conservative management.^{11,12,13,14,15} Reviews indicate that spinal fusion surgery has no beneficial effect on health related issues.^{27,28,61,68} Deviations of the trunk and the rib hump may reappear one year after surgery^{27,28,61} and, therefore, the indication for surgery in the treatment of scoliosis has to be questioned, especially when considering the high rate of long-term complications as reported in literature.^{2,27,67} Recently papers have been published discussing cervical complications due to scoliosis surgery,³² a small rate of revision surgeries necessary in AIS patients,⁵ and a big rate of complications after revision surgery;⁷ however, the latter studies were not of a long-term design.

Although there is a large body of studies on "Health Related Quality of Life" in patients treated surgically, these studies do not provide any substantial evidence because the dissonance effect that patients usually experience when treated

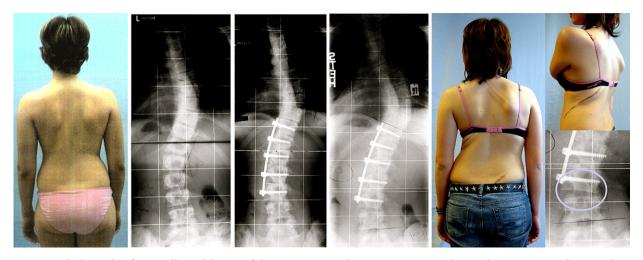


Fig. 10 – Surgical result of an Italian girl treated in a German Spine Center. Cosmetic result was worse than at the start with a high risk for low back pain in the future. Considering the fact that surgery in patients with AIS is indicated for cosmetic and/or psychological reasons only, this kind of treatment has to be regarded as being a malpractice.⁶¹

surgically cannot be ruled out leading to a high number of "false" positive results.^{61,67,68}

It has to be acknowledged that in patients with AIS there is no medical indication for surgery.^{27,28,61,66,67,68} Therefore, the only indication for this group of patients might be cosmetic. However, clinical improvements cannot be guaranteed (Fig. 10); even though such improvements are obvious directly after surgery, they might be a matter of deterioration within a year when a rib hump initially corrected very well might become visible again.^{27,67}

From the scientific data available, it has to be acknowledged that brace treatment is primary, supported by at least four papers with a prospective controlled study design and immature samples followed to the end of growth.^{10,43,73,79} As we do know that the results of brace treatment are correlated with in-brace correction,^{8,33} the postural correction should also play a major role in physiotherapy. There should be no room for unspecific methods such as Yoga, Pilates, SEAS or DOBO MED as presented by Fusco et al.²²

A significant postural correction can only be achieved with exercises relying on certain classifications aiming at a maximum pattern specific postural correction such as Side Shift exercises.^{39,40,74}

Scientifically, no claims can be made that physiotherapy is effective to halt progressive curves (in immature samples with significant Cobb angles) and, therefore, we rely on the curve corrections of modern high correction braces in the first place.

We apply physiotherapy additionally to brace treatment or alone in patients not at actual risk for progression during growth or in outgrown patients and aim at an improvement of postural control during the activities of daily living. Therefore, we do need the postural experience of pattern specific curve correction in order to allow avoidance of uncorrected postures in activities of daily living loading the spinal curve over many hours per day.

The major aim of these exercises is not curve correction; however, with pattern specific correction of the curve we can teach the patient to achieve an optimum postural control enabling one to avoid loading the spinal curve all day long.⁶⁹ Surgery should be performed only in cases with vast deformities to improve the cosmetic appearance and to foster

the (social) participation of these patients.

6. Conclusions

- Most of the studies found on physiotherapy included patients not yet or no more at risk for being progressive and, therefore, no claims can be made based on such papers.
- There is no outcome paper on physiotherapy in scoliosis with a patient sample at risk for being progressive followed from the premenarchial status until skeletal maturity.
- 3. Brace treatment is based on evidence and, therefore, has a real indication in the treatment of scoliosis patients during growth.
- There is evidence that the amount of in-brace correction, besides compliance, is the main predictor for the outcome of brace treatment.
- Surgery is not supported by prospective or randomized controlled studies and, therefore, has a very limited indication.
- Additionally, papers concerned have a follow-up period too short to draw any conclusions because complications of surgery in most cases appear more than 5 years after surgery.

Conflict of interest

The author is advisor of Koob-Scolitech, 55564 Abtweiler, Germany.

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