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Effect of conservative management on the prevalence of surgery in patients with adolescent idiopathic scoliosis

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Summary

Study design: Retrospective analysis of outcome in terms of prevalence of surgery for adolescent idiopathic scoliosis in patients receiving conservative management.
Objectives: To determine whether a centre with an active policy of conservative management has fewer patients who eventually undergo surgery for adolescent idiopathic scoliosis than a centre where the practice is non-intervention.
Background data: The efficacy of orthoses for the treatment of idiopathic scoliosis was called into question in a recent publication. Because the prevalence of surgery in an untreated group of patients (28.1%) was not significantly different from that in a braced group (22.4%), the authors concluded that bracing appears to make no difference. Based on prior experience, this conclusion is questioned.
Methods: Since 1991, bracing and physical therapy have been recommended for children with adolescent idiopathic scoliosis at a centre in Barcelona, Spain. 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 the Cobb angle. The prevalence of surgery was compared with that of published data from a centre where the practice is non-intervention.
Results: From a total of 106 braced cases out of which 97 were followed up, six cases (5.6%) ultimately underwent spinal fusion. A worst case analysis, which assumes that all nine cases that were lost to follow-up had operations, brings the uppermost number of cases that could have undergone spinal fusion to 15 (14.1%). Either percentage is significant statistically when compared to the 28.1% reported surgeries from the centre with the policy of non-intervention.
Conclusions: If conservative management does reduce the proportion of children with adolescent idiopathic scoliosis that require surgery, it can be said to provide a real and meaningful advantage to both the patients and the community. It is contended that conservative methods of treatment should never be ruled out from scoliosis management, because they can and do offer a viable alternative to those patients who cannot or will not opt for surgical treatment.

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Introduction

How effective is the conservative management of scoliosis? Whether the treatment provided is physical therapy (figure 1) or bracing, the problem has been investigated continually. As early as 1958, Blount *et al.* [1] appeared to provide a solution and the Milwaukee brace soon became the standard treatment of scoliosis worldwide. Other brace designs introduced in the US, e.g. the Boston [2] and the Wilmington braces [3], were reported in the literature to have been effective treatments [4–7]. A study by Nachemson and Peterson [9] corroborated the effectiveness of bracing. Despite this and other documented support for the efficacy of certain orthoses [8, 9], their validity has generally been

Figure 1 Asymmetric exercise for an asymmetric condition. Patient with lumbar hump on the left side and pelvic prominence on the right both corrected in the 'Schroth' exercise.

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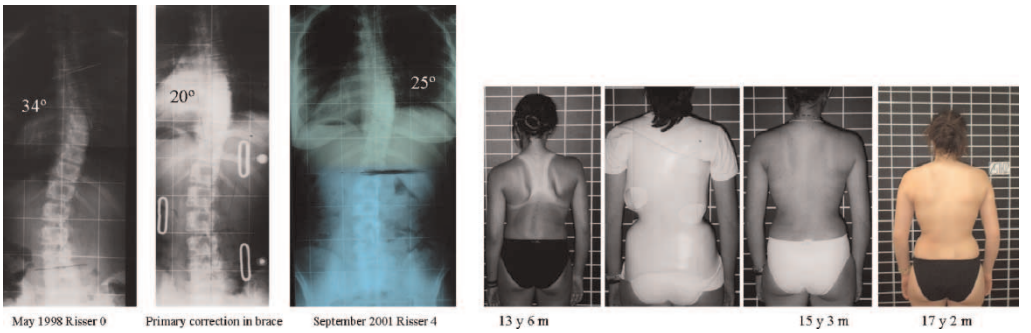

Figure 2 Case 2: Girl, 13 years 6 months. Scoliosis was first noticed 2 months before. Initial thoracic curvature of 34° Cobb and 10° Perdriolle was combined with a lumbar minor curve of 21° Cobb and 5° Perdriolle, with a Risser sign of 0. The girl had a pre-menarchial status. She started to wear the Rigo-System Chêneau brace (RSC-brace), a pattern specific modification of the original Chêneau brace, and had her first intensive rehabilitation programme immediately. The x-ray with the brace was taken afterwards. Correction with the first brace was 23° Cobb, 5° Perdriolle (thoracic) and 16° Cobb, 10° Perdriolle (lumbar). A second brace was built 1 year later correcting the thoracic curvature to 20° Cobb, 5° Perdriolle and the lumbar curvature to 18° Cobb, 5° Perdriolle. When she was 15 years 3 months, she judged her own cosmetic appearance as impressively good. She left the brace at 16 years 6 months. A new x-ray was taken at 16 years 9 months. The last picture shows her cosmetic aspect months later. She still does her exercises regularly.

denied, and the treatments themselves widely rejected [10, 11].

Although conservative methods of treatment with physical therapy and bracing are generally accepted in Central Europe [12, 13], they are largely discounted in the US. Different perceptions of the effectiveness of conservative treatment coincide with differences in the definitions of success across regions. Whereas, in Central Europe, treatment is regarded as effective if a curvature either shows no further progression, even when growth is expected, or shows a decrease in Cobb angle; in the US, treatment has been regarded as successful when an increase in curvature does not exceed 10° Cobb [14].

Two factors have emerged as the main parameters of successful brace treatment. Goldberg *et al.* [11] cite two references [4, 5] in which good patient compliance with bracing corresponded with favourable outcomes. However, the actual extent of the corrective effect is also described as an essential criterion in successful bracing [8, 15, 16]. Based on a review of the literature, Weiss [16] confirmed that there exists a direct positive correlation between the primary corrective effect of an orthosis and the end result. The importance of this effect is supported by a study from Mellerowicz *et al.* [15] and by a study from Landauer [8], in which he independently concludes that compliance and the primary correction effect in the brace are the two most important variables associated with good brace outcomes.

The Chêneau brace is currently the most practiced conservative treatment in Spain. It is defined as a thermoplastic brace modelled on a hypercorrected positive plaster mould of the patient. Specific pad areas are designed to provide detorsional forces through the trunk. Expansion rooms are also built, in order to allow active correction by breathing movements. Clinical histories of individuals enjoying excellent corrective effects (figure 2) and favourable outcomes with the Chêneau brace are encouraging its use in Spain as well as in Germany [17] and other places in Central Europe.

It must now be emphasized that, no matter how well adjusted an orthosis may be, it cannot be effective in every case; there are curvatures whose progression cannot be halted. Furthermore, Thulborne and Gillespie [18] are right in saying that even if the progression can be reduced by bracing, cosmetic appearance and the rib hump may not always be influenced positively, which may be distressing to some patients. However, self-image and other psychological factors can no more be affected by surgical treatment [19, 20]. Bettany *et al.* [21] conclude that, after surgery, levels of pain and emotional problems associated with scoliosis often remain unaltered, while a good initial cosmetic result may deteriorate and a rib hump may again become clearly evident [21]. Another important consideration for the patient is that conservative management generally brings with it a much higher incidence of routine radiological investigations than would a non-interventionist management protocol [11]. To prevent children from being subjected to unnecessary follow-up radiographs, the centre has, since 1994, employed a surface topography system to track spinal deformity (Formetric, DIERS International, Wiesbaden, Germany). Thus, patient exposure to radiation during interventionist management can be greatly reduced.

In order to provide patients with the most comprehensive and accurate information possible regarding their treatment options, a study of the outcomes of conservative scoliosis management was undertaken including observation, outpatient physical therapy or brace treatment plus outpatient physical therapy. The study was designed to address the following questions: Are one's efforts reasonable and worthwhile, involving as they do the time-consuming education of patients, moulding techniques and follow-ups and the strain put on patients by all the conservative methods? Conversely, is non-interventionist management; i.e. waiting until the scoliosis must be corrected surgically, a justifiable and reasonable option? In short, is there enough evidence that conservative management prevents surgery in a sufficient number of cases as to promote it as a rational policy?

In a recent study, Goldberg *et al*. [11] analysed the prevalence of surgery in patients with adolescent idiopathic scoliosis at several centres in which a comparison between the prevalence of surgery in braced and non-braced patients was made. Based on the number of surgical interventions in each group, the authors concluded that patients who used a Milwaukee brace in the years between 1950–1970 did not differ significantly from untreated patients in the 1990s. Unfortunately, the authors failed to match their sample closely to the controls with regard to Cobb angles. Despite the lack of properly matched samples in the Goldberg *et al*. [11] study, one was able to employ their database as the control group for this retrospective study.

Materials and methods

Patients were identified from the scoliosis database that was built up during the 1990s at the centre (treatment group) and comprised all patients who fulfilled the inclusion criteria delineated in the Goldberg *et al*. [11] study (controls):

(1) Diagnosis of adolescent idiopathic scoliosis ('AIS') (minimum age of 10 years at initial evaluation);
(2) Must have a minimum age of 15 years at last check-up; and
(3) Documentation of the Cobb angle without the brace at initial evaluation (at least 10°).

All patients from the database who were included in the study (treatment group) were under supervision of the senior author. The conservative management of scoliosis was implemented using the following guidelines: Immature patients with curvatures of less than 20° Cobb are observed for signs of progression. Patients who have initial curvatures of between 20–25° Cobb or have initial curvatures of less than 20° that subsequently exhibit one or more non-standard signs of progression, i.e. their Scoliometer and/or Formetric measurements increase, are prescribed outpatient physical therapy. Physical therapy consists of a specific set of individualized postural corrections in three dimensions that are internalized by the patient through a method developed in Germany by Schroth [22, 23]. At the clinic in Barcelona, the Schroth method of rehabilitation comprises a total of 40 2-hour sessions that usually take place three times per week over a period of 3–4 months. At the end of the training, the patients are asked to undertake an individualized home exercise programme and to attend the clinic one-to-four times per month to monitor how they are performing it. After 1 year of such close supervision, most patients come in once every 3–6 months for home programme monitoring. Patients with curvatures of $\geq 25°$ or who have a true progression, defined as an increase of $\geq 10°$ in patients with an initial curvature of less than 20° or an increase of $\geq 5°$ in patients with an initial curvature of $\geq 20°$, are treated with a Rigo-System Chêneau brace (RSC-brace), a pattern specific modification of the original Chêneau brace, plus outpatient physical therapy. Some patients reject the brace and accept just the physical therapy.

The guidelines for a recommendation of surgery are the same at the centre in Spain as at other centres worldwide [11, 12, 21, 24]. It is generally accepted that curve size alone is not a sufficient indication for spinal surgery in patients with AIS. The probability of further progression and the cosmesis, maturity and wishes of the patient must all be taken into account [11].

One hundred and fifty-seven patients (three males, 154 females) met the above criteria and were included in the study. Mean age was 12.6 years $\pm$ 1.1 (10–14). Seventy-nine cases had a pre-menarchial status (50.3%). Mean initial Cobb angle was 26.7° $\pm$ 12.3 (11–65). The curve pattern distribution for the entire sample of 157 patients was as follows: 33.7% thoracic, 42% double major, 9.5% thoracolumbar and 14.6% lumbar. Eight cases were under observation (5.1%), 43 cases had outpatient physical therapy (27.4%) and 106 patients were wearing a brace combined with outpatient physical therapy (67.5%).

One hundred and six patients (two males, 104 females) out of 157 in the study (67.5%) were under brace treatment combined with outpatient physical therapy. To be closer to the Cobb angle reported by Goldberg *et al*., these cases were analysed separately. For the braced group, mean age was 12.5 years $\pm$ 1.1

Table 1 Comparison of surgery rates at different centres

Author	n	*Mean Cobb angle*	*Prevalence of surgery*
Matched groups (diagnosis AIS, age at last visit minimum 15 years)			
Rigo *et al.* (conservative treatment)	157	26.7°	3.8% (12.1% worst case)
Rigo braced (conservative treatment)	106	34°	5.6% (14.1% worst case)
Weiss *et al.* [24] (conservative treatment)	179	32.2°	7.3%
Goldberg *et a*l. [11] (non-intervention)	153	33°	28.1%
Unmatched samples			
Lonstein and Winter (Milwaukee brace) [27]			22.4%
Noonan *et al.* (Milwaukee brace) [28]			31%
Fernandez-Feliberti *et al.* (TSLO) [5]			25.9%

(10–14). Forty-two had a pre-menarchial status (39.6%). Mean initial Cobb angle was $34^\circ \pm 10.3$ (14–65). The curve pattern distribution for the braced group was as follows: 42.4% thoracic, 42.2% thoracic-lumbar or thoracolumbar double major, 6.6% thoracolumbar and 4.7% lumbar. Twenty-four patients wore the brace part time; i.e. less than 16 hours per day, and 82 wore it full time; i.e. more than 20 hours per day.

The *Z*-test for independent proportions was used to compare the prevalence of surgery in the treatment [25] and control [11, 26] groups.

Results

Thirteen cases were lost for follow-up (8.3%). Six known cases out of 157 had an operation, yielding a prevalence of surgery of 3.8%. The worst-case analysis (all dropouts = failures) brought the prevalence of surgery to 12.1% (19 out of 157 cases).

Nine out of 106 cases in the braced sub-group were lost for follow-up (8.5%). Six of the remaining 97 were operated on, yielding a surgery prevalence of 5.6%. Worst-case analysis (15 out of 106 cases) brought the total surgery prevalence to 14.1%.

The mean Cobb angle of the operated sample as of when the operation was decided upon was $61.5^\circ \pm 10.1$ (55–78). Unfortunately, neither Goldberg *et al.* [11] nor two of the three studies with which they compared their data [5, 27] reported the average Cobb angle of their operated samples. The remaining study, by Noonan *et al.* [28], reported a mean operated Cobb angle of 50°, which coincides with a recommended threshold for surgery at their centre [28].

The prevalence of surgery as found in this study was significantly lower than in the controls [12]. There were also significant differences from braced control groups of other studies; i.e. prevalence of surgery in a braced group studied by Noonan *et al.* [28] was 31%, by Fernandez-Feliberti *et al.* [5] was 25.9% and in the Milwaukee braced group of Lonstein and Winter [27] was 22.4%. The results of the different studies are compared in tables 1–3.

Table 2 Comparison of the prevalence of surgery following conservative management vs non-intervention [11] (critical *z*-value = 1.645)

	Goldberg et al. *[11]* n = *153*
Rigo ($n = 157$)	$Z = -5.870$ (significant)
Rigo worst case ($n = 157$)	$Z = -3.524$ (significant)
Rigo brace ($n = 106$)	$Z = -5.151$ (significant)
Rigo brace worst case ($n = 106$)	$Z = -2.657$ (significant)
Weiss *et al.* [24] ($n = 179$)	$Z = -5.042$ (significant)

Discussion

A 1995 controlled brace outcome study sponsored by the Scoliosis Research Society [29, 30] was criticized on the grounds that the groups were not as well matched as they might have been [31]; unfortunately, neither were the groups in the study by Goldberg *et al.* [11]. Thus, the conclusion drawn could also have been that there was a medically relevant difference between the Goldberg sample and the braced population [25]. Nevertheless, the same inclusion criteria was adopted as Goldberg *et al.* [11], as if the different outcomes could be compared.

The outcome of the Spanish study is comparable to that of a German sample presented at the 2002 IRSSD meeting in Athens [24]. Both centres use a standardized protocol for conservative management that includes outpatient physical therapy via the Schroth method [22] and the Chêneau brace [17]. Thus, this study appears to support the premise that comparable management regimens result in comparable outcomes.

Questions arise as to why conservative management at different locations has different end results and why

Table 3 Comparison of the prevalence of surgery following conservative management in Central Europe vs different braces in the US (critical z-value = 1.645)

	Lonstein and Winter (Milwaukee brace) [27] (n = 1020)	*Noonan* et al. *(Milwaukee brace) [28] (n = 88)*	*Fernandez-Feliberti* et al. *(TLSO) [5] (n = 54)*
Rigo ($n = 157$)	$Z = -5.439$ (significant)	$Z = -5.965$ (significant)	$Z = -4.787$ (significant)
Rigo worst case ($n = 157$)	$Z = -2.951$ (significant)	$Z = -3.628$ (significant)	$Z = -2.421$ (significant)
Rigo brace ($n = 106$)	$Z = -4.058$ (significant)	$Z = -4.678$ (significant)	$Z = -3.690$ (significant)
Rigo brace worst case ($n = 106$)	$Z = -1.976$ (significant)	$Z = -2.840$ (significant)	$Z = -1.813$ (significant)
Weiss *et al.* [24] ($n = 179$)	$Z = -4.646$ (significant)	$Z = -5.086$ (significant)	$Z = -3.742$ (significant)

the prevalence of surgery in the Milwaukee-braced population is more than twice as great as when modern concepts of conservative management are applied [17, 23, 32].

Admittedly, one possible answer is different thresholds for surgery. At 61.5°, the mean Cobb angle of the operated sample is higher than that reported in the study by Noonan *et al.* [28]. However, the mean Cobb angle is comparable not only to that of a similarly managed sample in a study by Weiss *et al.* [24], but also to those of operated samples in other international studies [20].

Another answer could be different qualities of treatment (figure 3). However, how can one measure the quality of a brace? As there is a direct positive correlation between the primary correction effect in the brace and the end result [4, 8, 16], one has a good guideline with which to compare the outcomes of studies when the primary correction effects are documented. Unfortunately, there have been and there continue to be [33] many papers about bracing that have not taken the primary correction effect into account [9, 11]. Because such studies include no measure of the quality of treatment, the conclusions drawn from them are assumptions. This may also be true for the application of physical therapy [34].

Conclusions

Conservative methods of treatment with outpatient physical therapy on an intensive basis and the application of high-correction braces are effective in reducing the prevalence of surgery in patients with AIS. The compliant use of an orthosis may result in fewer degrees of a final Cobb angle and is appreciated by the patient when offered all information available regarding the relative risks and benefits of surgery or conservative management [24].

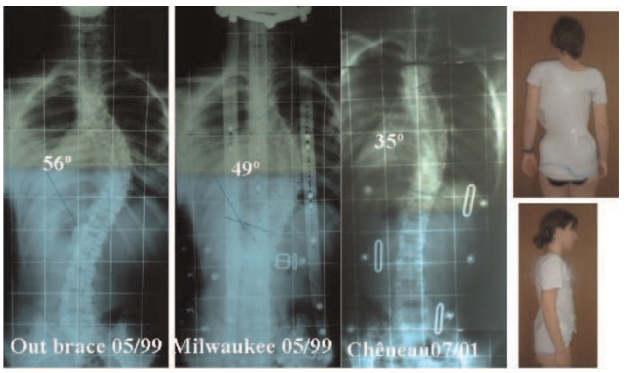

Figure 3 Comparison of the primary correction effect of the Milwaukee vs the Rigo-System Chêneau brace (RSC-brace).

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