

The SpineCor

Dynamic Corrective Brace



Standard Treatment Protocol



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INDEX

TREATMENT PRESCRIPTION & PROVISION	Page 3
INDICATIONS - IDIOPATHIC	Page 4
CONTRA INDICATIONS	Page 5
PRESCRIPTION EVALUATION	Page 5
SPINECOR TREATMENT PROCEDURE	Page 6
1 st Visit	Page 6
2 nd Visit	Page 6
3 rd Visit	Page 6
4 th Visit	Page 7
5 th Visit	Page 7
6 th Visit	Page 7
All Following Visits	Page 7
Weaning Procedures	Page 8
Weaning Sequence	Page 8
Restrictions	Page 9
Radiological Variables and Instruments	Page 9
Clinical Examination	Page 9
Brace Adjustment	Page 10
In Brace Control X-rays	Page 10
Patient/Parent Education (Brace Fitting)	Page 10
SPINECOR TREATMENT PROTOCOL IN TREATMENT	Page 11
SPINECOR WEANING PROTOCOL	Page 12

TREATMENT PRESCRIPTION AND PROVISION

SpineCor Treatment

Can consist of three elements, bracing, shoe lifts and physiotherapy. These should always be prescribed by a suitably qualified medical doctor. The prescribers should maintain overall responsibility for all aspects of SpineCor treatment and oversee treatment provision when delegated to any other healthcare professional (doctor, orthotist, physiotherapist, chiropractor etc).

SpineCor Brace Treatment

The provision of SpineCor brace treatment and where appropriate a shoe lift should only be carried out by a SpineCor bracing accredited professional (doctor, orthotist, physical therapist or chiropractor) or a suitably qualified professional undergoing an accreditation program.

SpineCor Physiotherapy Treatment Program

When a physiotherapy program is indicated and prescribed this should only be provided by a SpineCor physiotherapy accredited professional usually physical therapist or chiropractor.

INDICATIONS - Idiopathic

- Idiopathic Scoliosis diagnosed and confirmed
- Boy or Girl 5 years of age +
- Initial Cobb angle equal or above 15° if there is a family history of Scoliosis or proven progression >5° in last ⁶/₁₂
- Initial Cobb angle equal or below 50°
- Risser 0, 1, 2, 3 or pre-menarchial
- Curve Type: All classes including curves that are inverse to normal patterns (e.g. Left Thoracic, Right Lumbar)

In some special cases SpineCor has been shown to be effective for non-idiopathic Scoliosis. Such cases include a number of syndrome related Scoliosis where there is no specific neuromuscular deficit.

Attempting to treat such patients without significant experience of SpineCor and without very close monitoring is **NOT** advised. Advice should be sought from The SpineCorporation before attempting treatment of any non-idiopathic Scoliosis.

Any patients treated outside the above indications must be considered experimental and informed consent obtained from patients. Out of indication treatments are the responsibility of the prescribing doctor, The SpineCorporation Limited cannot accept any responsibility for such treatments.

CONTRA INDICATIONS

- Neuromuscular scoliosis resulting from abnormal asymmetric innervation or unbalanced muscle function. E.g.;
 - CP
 - Traumatic paraplegia or quadriplegia
 - Spinal Muscular Atrophy
 - Friedreich's Ataxia
 - Familial Dysautonomia
 - Peroneal Muscular Atrophy
 - Duchenne
 - Myopathy
- Postural Scoliosis when a supine Vs PA X-ray shows an almost complete reduction (cobb angle less than 5°).
- Patients who have had previous treatment except for Physio or shoe lift.
- Patients with Congenital defect

PRESCRIPTION EVALUATION

- A clinical examination (as detailed in the SpineCor Assistant Software)
- A Neuro muscular clinical examination
- An erect frontal PA, lateral and supine (AP) X-ray to determine Cobb angles, curve reducibility and Risser value.
- Erect PA and lateral X-rays should include the full Thoracolumbar spine and the iliac crests.
- Supine (AP) X-rays should be "unstretched" T1 – S1 or as much of the spine as possible within the limits of the X-ray equipment.

SPINECOR TREATMENT PROCEDURE

1st Visit (within 1 month after the recruitment/prescription visit):

- Regular clinical exam (as detailed in the SpineCor Assistant Software)
- SAS computer classification, to be validated by the Doctor, Orthotist or Therapist.
- The SpineCor Dynamic Corrective Brace will be set-up on the patient and a PA X-ray in brace will be taken immediately to control the brace actions, which must not worsen the curvature. If it is the case, there are two possibilities.
 - i The classification selected and/or the brace set-up need to be reviewed.
 - ii If it is impossible to correct the action of the brace, contact The Spine-Corporation to confirm that the brace has been properly set up.
- If the brace set-up and the immediate result are satisfactory training will be given to the parent/child on how to put on and take off the brace. Each of the following visits will include a control of the brace set-up.
- The brace will be worn 20 hours per day. (Four hours break time from wearing permitted each day. The four hours however must not be taken in one period, at least two breaks must be taken each day ideally of equal duration.)

2nd Visit (4 weeks after initial fitting)

- Regular clinical exam (as detailed in the SpineCor Assistant Software)
- The brace will be adjusted based on the Doctors, Orthotists or Therapists evaluation before x-ray control

3rd Visit (3 months after initial fitting)

- Regular clinical exam
- The brace **MUST FIRST** be adjusted and then the result controlled with a PA X-ray in brace, which must show a reduction or stabilisation of the original Cobb angle(s).

4th Visit (6 months after initial fitting)

- Regular clinical exam (as detailed in the SpineCor Assistant Software).
- The brace will be adjusted based on the Doctors, Orthotists or Therapists evaluation this **MUST BE** done prior to in brace x-ray.
- PA x-ray in brace and shoe lift if prescribed.

5th Visit (9 months after initial fitting)

- Regular clinical exam (as detailed in the SpineCor Assistant Software).
- The brace will be adjusted based on the Doctors, Orthotists or Therapists evaluation.

6th Visit (12 months after initial fitting)

- The brace will be adjusted based on the Doctors, Orthotists or Therapists evaluation this **MUST BE** done prior to in brace x-rays.
- PA X-ray in brace and shoe lift if prescribed.

Following Visits (every 3 months*)

- Regular clinical exam (as detailed in the SpineCor Assistant Software)
- The brace will be adjusted based on the Doctors, Orthotists or Therapists evaluation this **MUST BE** done prior to in brace x-ray.
- PA X-ray in brace and shoe lift if prescribed each 6 months from initial brace fitting.
- When patient is ready for weaning evaluation (not normally less than 18 – 24 months from start of treatment) the brace should be removed 72 hours prior to visit for PA x-ray out of brace.

* Follow-up visits after the first 3-4 months of treatment are advised at 3 month intervals. This review period may be extended to 4 or 5 months only in cases where the prescribing doctor is confident that the risk of progression is low. Extended review periods are not advised without great experience of SpineCor treatment.

Weaning Procedure

- The weaning procedure will be as follows:
Patients Criteria: (Patients must fulfil all three criteria before commencing weaning.)
 - i. Full Risser 4 or more
 - ii. 2 Years Post-Menarché or after voice change.
 - iii. Minimum 18 Months in Brace

WEANING SEQUENCE

1. Weaning Visit: **THE PATIENT IS ASKED TO REMOVE THE BRACE 72 HOURS BEFORE THE VISIT**

On arrival for weaning visit: Firstly, take a PA X-ray **without** brace. Then after refitting the brace take a PA X-ray **with** brace.

- 1.1 If the two x-rays show similar angles (less than 5° difference):
The patient is asked to wear the brace for **10 hours/day during the daytime**, preferably during physical activities, for a period of **6 months**.
- 1.2 If the two x-rays show more than 5° difference:
Review compliance during the last 18 months.
Continue with full time brace wearing (20 hours/24) for a period of **6 months**.

After this period, ask the patient to remove the brace 72 hours before the visit and take a new X-ray out of the brace. If the result is satisfactory, the patient is asked to wear the brace for **10 hours/day during the daytime**, preferably during physical activities, for a period of **6 months**.

2. First Follow Up Visit (After 6 months of daytime wearing)

The patient is asked to remove the brace **72 hours** before the visit.

On arrival for the follow-up visit: Firstly, take a PA X-ray **without** brace.

- 2.1 If there is no worsening: **COMPLETE DISCONTINUATION**, for a period of **6 months**.
- 2.2. If there is some worsening: **6 months further daytime brace wearing**. You may also prescribe a SpineCor physiotherapy program.

Note: If the patient is wearing a **shoe lift** and the pelvic obliquity persists, the patient is often asked to continue wearing it after weaning from the brace, with gradual decrease of the height of the lift. The effectiveness of the lift is controlled by frontal x-ray with and without the lift

Restrictions

There are no restrictions during bracing other than initiating a therapeutic treatment that can interfere with it*. All patients can participate in regular physical activities and treated patients are encouraged to do so with their brace.

*Only a SpineCor approved Physiotherapy Protocol should be followed. This should form part of a modified overall SpineCor Dynamic Corrective Brace Protocol and be pre-approved by The SpineCorporation's Scientific Director prior to use who will provide written consent only valid providing the individuals providing treatment have followed a training course provided by The SpineCorporation Limited and maintain their skills according to the SpineCor treatment accreditation program.

Radiological Variables and Instruments

A standard X-ray machine will be used with template, standard settings established for scoliosis X-rays must be respected. Analysed variables are the Cobb angle, all apexes, kyphosis and lordosis.

The Cobb angle will be measured as defined by Cobb himself. Apex is defined as the longest distance between the line drawn from the superior end plate of the upper end vertebra and the inferior end plate of the lower end vertebra. These limits must remain unchanged throughout follow-up unless they change by more than 2 levels. In such a case both the new and old limits and apexes must be measured and noted.

Whenever possible kyphosis limits should be T2 – T12 and lordosis should be T12 – L5. Should there be a junctional kyphosis, it will be measured with its own limits.

Clinical Examination

All clinical evaluations to be carried out with the patient's feet in the standardised position using the SpineCor foot template. The clinical examination will involve the patient undergoing evaluation of their back in standing and forward bending. Prominences will be noted and measured using a scoliometer. The degree of rotation, level and side of each prominence will be noted. Any Scapulae asymmetry will be noted.

Body segment rotations/tilts will be recorded in both apical and frontal planes, these will include the shoulders, thorax and pelvis using the software.

Spineous processes will be marked using a make up pencil to evaluate the curve and the effect upon it brought about by the appropriate corrective movement.

General flexibility and the ease with which the child can perform the corrective movement will also be evaluated. (These factors are most important in obtaining the most effective adjustment of the brace when fitted.)

Lateral shift measured using a plumb line or a laser from T1 to S1 and measuring millimetres of shift to either RT or LT.

The patient's height will be measured both in standing and sitting for future evaluation of overgrowth and spinal growth. Weight will also be recorded at each visit.

Where there is any pelvic tilt noted, leg length needs to be checked. All cases of true leg length discrepancy should be compensated for by a shoe lift unless they aggravate the prominence values.

Where pelvic tilt is due to the Scoliosis alone, the pelvis should be levelled using a shoe lift in cases of lumbar and thoraco lumbar curves only. Shoe lifts can aggravate thoracic curves so normally should not be given.

All shoe lifts should be sole and heel and not just heel, as this does not level the pelvis without negative rotation and version effects on the pelvis, which do not help to stabilise the spine.

Brace Adjustment

The brace corrective bands must be fastened in the positions, sequence and with the relative tensions described in The SpineCor Assistant Software (SAS V3.0 or higher) specific to the chosen classification.

It is most important that the patient understands and is able to perform and maintain the corrective movement. Band tensions are adjusted only when the patient is wearing the brace in the optimised corrective movement position.

In Brace Control X-rays

These **MUST** always be taken after adjustment of the brace.

Patient/Parent Education

All patients/parents must be shown how to perform their specific corrective movement and shown how to correctly apply their brace maintaining an optimal corrective movement position.

Patients/parents should demonstrate by fitting the brace independently 2 – 3 times that they fully understand the correct fitting procedure.

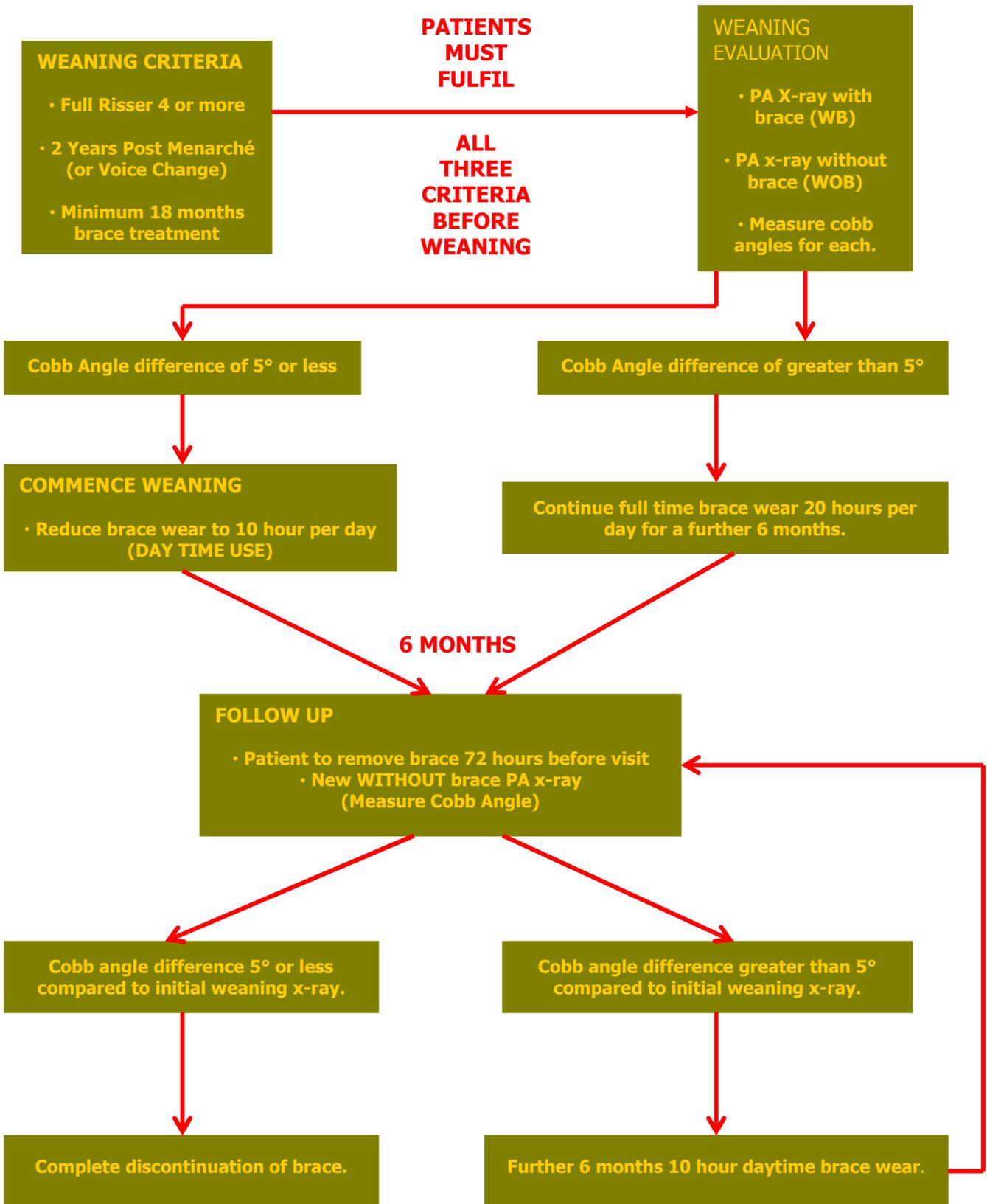
A patient manual and patient classification specific brace fitting instructions (printed from the SAS Software) should be given to the patient.

The whole process of patient/parent education in brace fitting should take no less than 20 – 30 minutes.

SPINECOR TREATMENT PROTOCOL IN TREATMENT

	Brace Initial Visit	Brace Follow-up	Brace Follow-up	Medical/ Brace Follow-up	Brace Follow-up	Medical/ Brace Follow-up	Brace Follow-up	Medical/ Brace Follow-up	Brace Follow-up	Medical/ Brace Follow-up	Brace Follow-up	Medical/ Brace Follow-up	Brace Follow-up	Medical/ Brace Follow-up
	1 st VISIT (Brace Fitting)	2 nd VISIT 1 Month after Brace Fitting	3 rd VISIT 3 Months after Brace Fitting	4 th VISIT 6 Months after Brace Fitting	5 th VISIT 9 Months after Brace Fitting	6 th VISIT 12 Months after Brace Fitting	7 th VISIT 15 Months after Brace Fitting	8 th VISIT 18 Months after Brace Fitting	9 th VISIT 21 Months after Brace Fitting	10 th VISIT 24 Months after Brace Fitting	11 th VISIT 27 Months after Brace Fitting	12 th VISIT 30 Months after Brace Fitting	13 th VISIT 33 Months after Brace Fitting	14 th VISIT 36 Months after Brace Fitting
Verification of the brace as worn by the patient		X	X	X	X	X	X	X	X	X	X	X	X	X
Clinical evaluation	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Corrective movement	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Brace fitting	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Scoliometer	x	X	x	X	X	x	X	x	x	x	X	x	X	x
P/A x-ray without brace	X													
Lateral x-ray without brace	X													
Supine x-ray without brace	X													
P/A x-ray with brace (and shoe lift if prescribed)	X		X	X		X		X		X		X		X

SPINECOR WEANING PROTOCOL



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