

Summary of the Latest Clinical Results - 2006-01

1. SPINECOR PATIENTS PROSPECTIVE OBSERVATIONAL COHORT

At Ste-Justine Hospital in Montreal 472 patients have been treated with the SpineCor system since 1993. For this group of consecutively treated Idiopathic Scoliosis patients the average age at the beginning of treatment was 12 years (SD: 2 years), with 438 female and 34 male subjects. The average initial major Cobb angle was 29° (SD: 8°, n = 472). The initial Risser sign was 0 for 293 patients, Risser 1 for 59 patients, Risser 2 for 59 patients, Risser 3 for 56 patients, Risser 4 for 3 patients and 2 patients had a Risser 5. The initial cohort characteristics by curve amplitude and curve type as well as the last available Cobb angle during treatment with the SpineCor brace are presented in Table 1.

Table 1 : Initial Characteristics of Idiopathic Scoliosis Patient Population

	Initial Cobb Angle (Degrees)		Cobb Angle During Treatment (With Brace)	Percent Reduction
	n	Mean	Mean	Mean
All Patients	472	29	23	23
Thoracic	197	32	28	21
Thoraco-lumbar	174	25	16	41
Lumbar	32	25	18	31
Double	69	31	23	8

At the last available visit there were 167 patients still under treatment and 225 have terminated treatment with a post-treatment follow-up time ranging from 0 to 6 years with a mean bracing time of 2.3 years (SD: 1 year). From this cohort of 472 patients, there were 69 patients who progressed to surgery (15 %). The patients who progressed to surgery had an initial mean Cobb angle of 35° (SD: 8°). There were also 16 patients who withdrew from treatment.

2. Outcome for Idiopathic Scoliosis Patients who completed treatment by the SpineCor brace

There are 225 patients who have completed treatment with the SpineCor brace with an average duration of treatment in brace of 2.3 years (SD: 1.1). The initial mean Cobb angle for this sub-cohort of patients was 28° (SD: 8°). At the weaning point, there was an overall correction in reference to the patient's initial state of greater than 5° for 40% of the patients (mean: 11°; range: 6° to 22°), there was a stabilisation for 47% (mean: 1°; range -5° to 5°) and 13% of the patients worsened (mean: -11°; Range: -6° to -23°. Success (correction or stabilisation of the Cobb angle) was achieved in 87% of the case.

3. Outcome for Idiopathic Scoliosis Patients with a Minimum 5-year Follow-up after Treatment with the SpineCor brace

There are 45 patients who have a minimum of 5 years post-treatment follow-up with the SpineCor brace with an average duration of treatment in brace of 2.2 years (SD: 0.9). The initial mean Cobb angle for this sub-cohort of patients was 27° (SD: 8°).

- Comparing the initial Cobb angle to the angle at the end of bracing, there was an overall correction of greater than 5° for 48% of the patients (mean: 11°; range: 6° to 22°), there was a stabilisation for 49% (mean: 1°; range -3° to 5°) and 4% of the patients worsened (mean: -2°; Range: -10° to -14°).
- If we now compare the Cobb angle at the initial state and 5 years after the end of bracing, there was an overall correction of greater than 5° for 53% of the patients (mean: 11°; range: 6° to 26°), there was a stabilisation for 38% (mean: 2°; range -3° to 5°) and 9% of the patients worsened (mean: -7°; Range: -6° to -9°).
- Finally, if we compare the Cobb angle at the end of bracing and 5 years after weaning of the brace there was an overall correction of greater than 5° for 27% of the patients (mean: 7°; range: 6° to 13°), there was a stabilisation for 66% (mean: 1°; range -5° to 5°) and 7% of the patients worsened (mean: -9°; Range: -8° to -10°).

THESE RESULTS DEMONSTRATED THAT 27% OF THIS COHORT OF PATIENTS STILL CORRECTED THEIR COBB ANGLE AFTER WEANING OF THE BRACE.