Study design. To find the value of the radiological changes to the spine of 400 children suffering from scoliosis who were treated with a special physiotherapy treatment for a year.

Objectives. To evaluate the reduction of the Cobb angle and the vertebra rotation, the averages, and the improvement percentage of 400 scoliosis cases who were treated with the F.E.D method for 12 months.

Background. The conservative treatment of spine deviations is often met with little enthusiasm and conviction. We have recently finished this study which started at the end of 1989, after having been encouraged by the results of our investigations which consisted in applying the conservative treatment to scoliosis- first in animals (rabbits), then in humans, during their growth period.

Material and Methods. Four hundred scoliosis cases aged between 4 and 42. The average age at the start was 13.5 and the Risser was 1.805. 13% were under 10 years of age; 63% between 10 and 15 and 24% were over-15 years. 64% were girls/women and 36% boys/men.

Progressive Idiopathic Scoliosis 368 cases (92%); 9 Congenital (2.25%); 8 Neurogenics (2%); 5 Myogenics (1.25%); 4 Osteogenics (1%); 3 Post Traumatic (0.75%); 2 Postural Acquired (0.5%) and 1 Post Surgery (0.25%).

The rachis alterations were measured by physical and functional tests and by an antero-posterior X-ray, in standing position, of the general spine with vision of the Iliac crests and femoral heads. An X-ray was taken of them every 6 months. The curves ranged between 10° and 66°, with an average Cobb angle of 20°, and a vertebra rotation of 12° in 117 cases. 248 cases had curves under 20° Cobb. 94 cases had between 20° and 30° Cobb. 31 cases had 31° to 40° Cobb. 27 cases had curves above 41° Cobb.
All patients had special physiotherapy treatment for 12 months. The treatment consisted in preparing the thoracic-lumbar back area, using electrotherapy and thermo therapy; then applying external corrective forces on the scoliosis curves. These were generated by a designed, experimented and patented system (F.E.D.) This system allows the rachis to be elongated and set three-dimensionally while applying a pressure (of between 1 and 100 kg) to the apex of the scoliosis curve, de-rotating and inflecting it intermittently (15 seconds of pressure and 10 of relaxation) for 30 minutes. Every session ended with analytical kinesitherapy and PNF.

Results. At the end of 12 months, the radiological study showed a significant reduction in the average Cobb angle, from 20º to 9º, with a relative recuperation percentage of 67%. The vertebra rotation was reduced from 12º to 4º, with a relative recuperation percentage of 74%. There was a significant improvement as a result of this treatment. The scoliosis curve and the vertebra rotation were significantly less after 12 months of F.E.D treatment.

Conclusions. The results blatantly contradict the negative concept that many specialists have of the effectiveness of physiotherapy in treating scoliosis. These experiments and results prove the effectiveness and value of physiotherapy and its therapeutic effects. It should be a top option for treating spinal curves.

Key words. idiopathic scoliosis; conservative treatment; scoliosis correction; the value of physiotherapy; spine; spinal deformities; spinal curvatures; physical therapy techniques; vertebra de-rotation; inflection of the scoliosis curve; three-dimensional setting of the rachis; orthopaedic procedures; F.E.D.

Introduction

The dynamic forces generated by the daily activities of the individual suffering from scoliosis, kyphoses or lordosis exert a continual unilateral pressure on the hemi vertebrae, discs and cartilages which are subjected to greater compression, leading to alterations in their trophy and their imbibition system. Studies on the effects generated by a derangement of the imbibition mechanism of the vertebrae and cartilage, have shown that they can cause a de-stabilization effect to the spine and cause scoliosis. (1,5,7,11,46,47,52,61,63). Through similar mechanisms, the vertebral growth nuclei and the neurocentral cartilages may also be affected (28,31,46,47,61). Compression of the neurocentral cartilage in pigs and rabbits caused scoliosis (16,38). Surgical interventions in animals affecting the vertebral growth nuclei also caused scoliosis (13,15,21,34,35). Unilateral epiphysiodesis of the epiphysis cartilage, in dogs and rabbits, caused wedging with vertebral deformation and scoliosis (1,38). The lesion of several epiphyseal cartilage plates of the vertebrae in young pups of 2 to 3 months caused scoliosis and kyphosis (20). The resection of the sacrospinatus and interspinatus muscles and ligaments in animals resulted in an asymmetrical chondrogenesis due to unequal compression, causing kyphosis and scoliosis (3,43,57). Alterations in the transport of calcium to the cellular membrane in the back muscles have been pinpointed as a cause of scoliosis as well. (69). From these experiments, we’ve learned that unilateral and asymmetrical pinching, cutting and chearing cause repeated micro trauma to the cartilaginous tissues and bone, resulting in ischemic disorders and morphological changes which enhance the curves. (2,11,39,46,49,66). Nutritional imbalances of the spine were studied. The coagulation of the proximal segments of the intercostal arteries in rabbits induced scoliosis (12). Unilateral, vascular alterations of the metameric artery nourishing hemi vertebra, the
growth cartilages and the neurocentral cartilages caused scoliosis in rabbits during their growth period (6). The unilateral intervertebra compressive factors worsen the curves; without these compressive factors, scoliosis wouldn’t form (30,34,46,49,59,60,68).

The FED system of tridimensional spine Fixation, in Elongation with graded corrective and De-rotating pressure and postural self-control by the patient was postulated on the basis of our daily practice experience, which led us to the following hypothesis:

“If asymmetrical, dynamic compressive forces are able to cause and worsen a deformation of the bone during the period of bone growth, then other greater forces applied in the contrary direction should stop the primary deforming effects and normalize the situation »

Our research started more than 20 years ago based on this hypothesis. It consisted in creating experimental scoliosis in forty 25-day old rabbits. Twenty animals had physiotherapy treatment. Compressive, dynamic and asymmetric forces generated by adequate manual techniques were applied to oppose the causes aggravating the deformity. The other twenty rabbits were not interfered with. After the four-month experiment, the results were significant when comparing the treated and non-treated animals. The miotendinous-ligamentous forces elicited by vertebral manipulation, with their mechanical effects on the scoliotic incurvation, achieved a remodelling of the bone, cartilaginous and muscular tissues of the treated rabbits. The study showed, with a 99.99% certainty, the effectiveness of therapy in those treated when compared to the non-treated. The significant difference between the two groups could only be attributed to the techniques of the treatment used in our research (46,62). In December 1989, we designed an experiment prototype of the FED system to achieve the same therapeutic effects in humans as in the rabbits. For about 15 years, we’ve been treating patients, as much as possible during their growth period, who have spinal curvature, mainly idiopathic scoliosis. Our results are compiled below.

**Material and Methods**

Four hundred patients suffering from scoliosis, aged between 4 and 42.
The initial average age was 13.5; the initial Risser average was of 1,805 and at the end of twelve months, of 2,359. The distribution in function of the age gap for 280 cases was: < 10 years old, 13%; [10-15 years old], 63%; > 15 years old, 24%.

64% of the patients were girls/women 36% were boys/men. Table 1.

Before starting the treatment, all the patients underwent a physical and functional test and a measurement of the spine alteration by X-ray, antero posterior, in standing position, of the spine with vision of the Iliac crests and femoral heads.

There were clinical, physical and functional tests done every 6 weeks and X-rays done every 6 months.

The initial X-ray showed curves ranging from 10º to 66º, with an initial average Cobb angle of 20º and the Raimondi (40,41) vertebra rotation of 12º in 117 of the cases, .

The characteristics and frequency distribution of the curve size is given in Table 1.

During 12 months, all the patients regularly had special physiotherapy, which consisted in preparing the thoracic-lumbar back area using electrotherapy and thermotherapy. This was followed by applying external corrective forces to the scoliosis curve using the FED system, to achieve the same therapeutic results that were achieved with the rabbits. Figure 1.

The FED system is fundamentally a chassis formed by profile members. These can be adjusted vertically and horizontally and support the means for holding up the patient as well as other therapeutic means to immobilise the patient. This system allows the tridimensional fixation of the spine in elongation, with a de-rotary corrective pressure
which is adjustable and exerts between 1 and 100 kg to an area of 2.000mm² on the apex of the scoliotic curve, de-rotating and inflecting it intermittently (15 seconds of pressure and 10 of relaxation). These traction-elongation forces, de-rotating, inflecting and/or reversing the scoliosis curve with the patient’s posture auto control, while in an ortostatic position, is done repeatedly during 30 minutes.

The correction of the deformity is thus possible due to the therapeutic effects on the various tissues from the traction, elongation, pressure, detraction and de-rotation forces as well as the control of correction by the patient himself. All this stimulates the proprioceptive system – the interoceptors of the capsules, tendons and muscles -, which, when placed under stress, begin transmitting afferences to the upper centres that register the correct position and improves the postural self-control.

Each session ends with a half hour of analytical kinessitherapy and PNF.

**Results**

*Effectiveness of the treatment*

**Scoliosis according to King-moe I, II, III, IV and V**

Table 2.

In scoliosis patients with more than one curve, only the most pronounced curve was taken into account. If the two curves were the same, we elected the dorsal scoliosis, which is, in double scoliosis cases, the one with the least relative recuperation. Figures 2, 3 and 4.

**Statistical comparison of two observational means in large populations (n = 400) with paired data.**

1. A change of variables is made. We define a new variable \( z = x - y \), where 
   - \( x \): initial curve;
   - \( y \): curve at the end of the 12 months;
   - \( z \): each individual’s difference.
2. \( \bar{Z} = 11.52 \quad S_z^2 = 27.83 \)
3. \( H_0 \): the treatment has not produced significant improvement; the curve before and after the treatment is the same, \( \bar{Z} = 0 \)
   \( H_1 \): the treatment has produced significant improvement; the curve after the treatment is less \( \bar{Z} > 0 \)
   (This is a comparison test of an observed average \( \bar{Z} = \frac{\sum (x - y)}{400} \), with a theoretic average \( m = 0 \)).
4. \( Z = \frac{|Z|}{\sqrt{\frac{S_z^2}{n}}} = \frac{11.52}{\sqrt{\frac{27.83}{400}}} = 43.6555 \)
   If \( Z \leq Z_{0.01} \), we accept the \( H_0 \)
If $Z > Z_{0.01}$, we reject the $H_0$

As $Z_{0.01} = 2.576 < 43.6555$, we reject the $H_0$ (with a $x = 0.01$ risk).

The treatment produces a significant improvement. The scoliosis curve is significantly less after the 12-month treatment.

Table 2.

Rotation

Statistical comparison of two observational means in a large population ($n = 117$) with paired data.

1. $z = x - y$, where $x$ : initial rotation; $y$ : rotation after 12 months; $z$ : each individual’s difference.
2. $\bar{Z} = 8.25 \quad S^2_x = 29,007$
3. $H_0$ : the treatment has not produced significant improvement; the rotation after the treatment is the same, $\bar{Z} = 0$
   $H_1$ : the treatment has produced significant improvement; the rotation after the treatment is less. $\bar{Z} > 0$
   (This is a comparison test of an observed average $\bar{Z} = \frac{\sum(x - y)}{117}$, with a theoretic average of $m = 0$).
4. $Z = \frac{\bar{Z}}{\sqrt{\frac{S^2_x}{n}}} = \frac{8.25}{\sqrt{\frac{29,007}{117}}} = 16.5758$
   If $Z \leq Z_{0.01}$, $H_0$ is accepted
   If $Z > Z_{0.01}$, $H_0$ is rejected
   As $Z_{0.01} = 2.576 < 16.5758$, we reject $H_0$ (with a $x = 0.01$ risk).

Figure 4.

The treatment produces a significant improvement. The scoliosis curve rotation is significantly less after the 12-month treatment.

Table 2.

Locating the post treatment improvement.
Test to determine whether the treatment has a different effect on the lumbar scoliosis and the dorsal scoliosis.

Analysis of the variance: factorial plan of two unrelated factors.
Factor A: Type of scoliosis, dorsal or lumbar in patients with scoliosis King-Moe I, II and V.
- Factor B: Patients (factor not relevant)

According to the $F$ distribution:
$F(1,161,0.05) = 3.89$
$F(1,161,0.01) = 6.79$
the factor is significant at the 1% level.

There are differences in the results of treating dorsal scoliosis and lumbar scoliosis in patients with double scoliosis: lumbar scoliosis recuperates better. This significant difference is due to the obstacle of the ribs to the other scoliosis curve.

The average recuperation degree of scoliosis King-Moe I dorsal is of $X = 10^\circ$, and the lumbar is of $X = 13^\circ$.
The average recuperation degree of scoliosis King-Moe II dorsal is of $X = 9^\circ$, and the lumbar is of $X = 10^\circ$.
The average recuperation degree of scoliosis King-Moe V dorsal is of $X = 12^\circ$, and of the lumbar is of $X = 11^\circ$.

Table 3.

Recuperation percentage in relation to the degree of bone maturity

1. The value of the Risser. The average value of Risser for the 12 months was calculated; the equivalences can be found in Table 4.

2. The recuperation percentage. Since all the individuals improved, the measurement of relative improvement was recorded.

$$P_{r,cobb.} = \frac{(Curva \cdot inicial) - (Curva \cdot tras \cdot n \cdot meses \cdot trat.)}{Curvatura \cdot inicial} \times 100$$

$$P_{r,rot.} = \frac{(Rotación \cdot inicial) - (Rotación \cdot tras \cdot n \cdot meses \cdot trat.)}{Rotación \cdot inicial} \times 100$$

The average Risser at the start was of 1,805 and at the end, was of 2,359. Table 5 shows the total averages of recuperation of Cobb and the rotation in function of the
average Risser after 12 months of treatment. In individuals with double scoliosis, the Cobb was only taken for the bigger scoliosis curve. If the curves were the same, the recuperation percentage of the dorsal scoliosis curve was taken, since it is the one of less relative recuperation.

**Correlation**

Variables:

\[ x = \text{Average Risser of the 12-month treatment.} \]

\[ y = \text{Recuperation percentage after the 12-month treatment.} \]

\[
\begin{align*}
    r_{xy} &= \frac{\sum xy - \frac{1}{N} \sum x \sum y}{\sqrt{\frac{1}{N} \sum x^2 - \left(\frac{1}{N} \sum x\right)^2} \sqrt{\frac{1}{N} \sum y^2 - \left(\frac{1}{N} \sum y\right)^2}} \\
    &= -0.6689
\end{align*}
\]

**Test of independence between the variables \( x \) and \( y \)**

\( H_0 : \text{Independence between the variables } x \text{ and } y \), if \( |r_{xy}| \leq r(398, 0.01) \).

The hypothesis of independence between variables with \( x = 0.01 \) risk is rejected; the variables \( x \) and \( y \) are related.

**Regression line**

Variables:

\[ x = \text{Average Risser of the 12-month treatment.} \]

\[ y = \text{Recuperation percentage after the 12-month treatment. Figure 5.} \]

We can conclude that:

- The variables \( x : \) [average Risser of the 12-month treatment] and \( y : \) [recuperation percentage after the 12-month treatment], are independent variables, with a correlation coefficient = -0.6689.

- The negative coefficient indicates that they are proportional inverse variables (regression lines with a negative gradient): when the variable \( x : \) [average Risser of the 12 month treatment] increases, the variable \( y : \) [recuperation percentage after the 12 month treatment] decreases.

**Discussion**

The results clearly show, beyond any doubt, the therapeutic effects of the FED system on the bone, cartilage, disc, ligaments, muscles, vascular system sensorimotor network, neuromuscular system and orthostatic postural control of the patient with spine deformity. There is a logical, rational and scientific explanation for this. In fact, there
was no reason apart from the technical difficulty to think that we would not be able to obtain the same results with humans as we got some years earlier in rabbits treated exclusively with physiotherapy (46,62).

These results from 15 years of evaluating, treating and following scoliosis patients, blatantly contradict the negative concept that many specialists have of the effectiveness of physiotherapy in treating spinal curves. (8,9,19,22). It is probable that the results of the conservative treatment, as Willers states (67), have not been clearly documented in the past. Now, however, more therapeutic preponderance must be conceded to physiotherapy when it comes to spinal curvatures since the results from the experiments prove its efficiency and therapeutic effects (4,10,23,29,46,47,49,50,51,55,56,62,65).

Cotrel (10) and Stagnara (56) have combined systematic exercise programmes, which have reduced the seriousness of idiopathic scoliosis.

In the USA, however, they have opted for the “benefits” of surgery and braces, namely the Milwaukee brace and the lumbosacral orthosis. They have openly spoken out against physiotherapy. Today, we know that the Milwaukee brace is only recommended for kyphose and scoliosis cervico-thoracic, which represent approximately 1% of all scoliosis cases. On the other hand, there are also questions over the long-term effects and complications of surgery on curvature of the spine. More and more specialists are choosing the conservative treatment and applying the new active and effective methods early on. (4,10,13,23,25,26,32,42,46,47,49,50,51,54,55,56,62,64,65).

We know that spinal deformities have their genesis, independently of the etiology, in alterations of the vertebra or of the systems and elements of the rachis called extra vertebral alterations.

All these alterations become apparent through morphological and anatomopathological changes of the bone and cartilage. They can vary in seriousness if they are not treated and can even start to be noticed by the naked eye. These structural changes will end up unbalancing the perfect symmetry of the spine and chest, which in turn, will accelerate the deformation, especially in scoliosis cases with a Cobb angle above 30° and a high rotation component (36,53,58). In order to reduce the deformation once it is structured in the spine, external forces are needed to achieve the orthostatic position of the spine. The most important factor, which also conditions the others, is that the rachis has not yet finished growing. The recuperation percentage is always higher, the younger the patient. The younger the patient, with Risser at around zero, the higher the recuperation percentage when using the FED method, and fewer are the difficulties that could arise when rectifying the pathological curves of the spine.

Mccarthy (26) states that early diagnosis and treatment at an early age is the best way to prevent later scoliosis complications. According to Viladot (64) the best scoliosis treatment is early diagnosis.

In fact, some authors pinpoint the risk of scoliosis progression at puberty and associate it to the menarche presence and the secondary sexual characteristics (14,24,37,56,70). This is the reason for the insistence on early diagnosis and treatment, before the growth spurt. There has been enough research made to know the risk of scoliosis progression. (14,17,24,26,27,45,54,56,70).

The FED method is a global treatment which mainly corrects the pathological curves of the spine during the growth period. It reduces and appeases the painful symptomology in children and adults (4), showing an effectiveness index (IE) (8,18) significant and superior to all existing conservative methods (23,50,65). Figures 6 and 7.

The FED method, although investigated and put into practice from another angle, with methodology and different techniques of applying non-comparable external forces, is
similar to Cotrel and Morell’s (10) “E.D.F” technique. Although the abbreviations FED – EDF, are in a different order, they mean the same: F = Fixation (Setting); E = Elongation, and D = De-rotation and inflecting or inverting the scoliosis curves. The Cotrel and Morell technique consists of a system similar to a rectangular stretcher which elongates, rotates and finally sets the spine in plaster cast.

The FED system sets the spine three dimensionally. It then elongates and rotates it at the same time as it inflects it, which in many cases, reverses the scoliosis curves in a dynamic and active way rather than passively. The monitored forces applied are generated by an electro-pneumo-mechanic system to rectify the rachis curves. The intensity and intermittence is regulated by a computer which guarantees efficiency and security. The FED unit is a very versatile system that can be applied to any type of spinal deformities, be it scoliosis kypohses or lordoses.

**Conclusion. The benefits of the F.E.D Method.**

1.- The early diagnosis and treatment by FED Method during the child’s growing spurt are logical and rational interventions which can correct spinal deformities and avoid personal, social, and economic problems which she or he may experience in the future.

2.- The F.E.D. method structurally shapes and rectifies wholly or partially the alterations of the vertebrocostals, discs, cartilages, muscles, vascularisation, the proprioception and the awareness of the orthostatic position, normalising and improving posture. All this is done during the patient’s growth period.

3.- The external forces applied by the FED method firmly push on the growing spinal structures inhibiting the hyperactive asymmetric bone generation, as well as soft tissue alterations and sensorimotor network. At the same time, it stimulates and favours the tissue activity in the hypoactive side which is the cause of asymmetry.

4.- The FED method, accelerates the awareness and volitive correction process of the spinal curves of people suffering from scoliosis, kiphoses or lordoses.

5.- The FED method avoids the slave-like assistance of the physiotherapist in teaching and correcting patients’ spinal curvature.

6.- Through F.E.D, we are able to monitor the control the amount of force applied in the opposite direction to the one causing the deformation on the spine of the patient. It has an efficiency very rarely obtained by other procedures.

7.- The F.E.D. method is easy to apply when compared to other procedures such as plasters, tractions, stretchers, braces...

8.- In serious, advanced spinal curvature, the F.E.D method allows the use of orthopaedic systems, out of treatment hours, which compliment and improve the achieved results.

9.- In symptomatic spinal curvature, applying the F.E.D method reduces and/or appeases the symptomatology, mainly the pain, the stiffness and the instability...both in children and adults, given that it avoids medicine (51), (which is inefficient since it does not solve the cause of the symptomology).

10.- The F.E.D method, when applied early on, rectifies the rachis during the growth spurt making the need for surgery, really very exceptional. In the worst of the cases, it makes the surgeon’s intervention easier when there is no other option, as long as the criteria of the specialists are met. (9,22,44).

A conservative method such as the F.E.D method, is extraordinarily good value, as much for the individual as for the society because it avoids any further suffering, health problems and absences from work of those suffering from spinal deformities. More
importantly, it improves their potential life span and their quality of life as well as avoiding the aggression and implants of foreign material that surgery entails.

References

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258-278. IOS Press (A. Tangay and B. Peuchot).
Table 1. Classification, seriousness and distribution of the scoliosis curves

<table>
<thead>
<tr>
<th>Type of curve</th>
<th>Average Cobb</th>
<th>Distribution of the Curves (400 cases)</th>
<th>Average rotation (117 cases)</th>
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<tr>
<td></td>
<td>n cases</td>
<td>Initial Grade</td>
<td>&lt;20º</td>
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<tr>
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<td>112</td>
<td>18</td>
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<tr>
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<tr>
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<td>64</td>
<td>17</td>
<td>52</td>
</tr>
<tr>
<td>King-Moe IV</td>
<td>117</td>
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<tr>
<td>King-Moe V</td>
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Total of the general table 400 20 248 94 31 27 117 12

Table 2. Percentage improvement of the Cobb and Rotation.

<table>
<thead>
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<th>Type of curve</th>
<th>Average Cobb</th>
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<th>Average rotation</th>
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<tr>
<td>King-Moe V</td>
<td>27</td>
<td>37</td>
<td>63</td>
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</table>

Total of the general table 9 67 81 50 35 31 4 74

PR: Relative recuperation percentage

Table 3. Analysis of the variance with a 1% level of significance

<table>
<thead>
<tr>
<th>Origins f the variations</th>
<th>Sum of the squares</th>
<th>Grades of freedom</th>
<th>Average of the cuadrados</th>
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</table>

Total 10913 323
Figure 1. FED system. A Manual techniques used in research with animals to correct the experimental scoliosis. (46,47,48,49,62) B The FED unit inspired the research and experiments. C Sketch of the overall corrective forces on the rachis generated in the FED unit. D Sketch –detail of the incidence of the corrective forces on the anatomical enclaves rib-vertebrae, neurcentral and epiphyseal cartilages -
Treatment of scoliosis. FED Method – Results of 400 cases - Sastre et al.

Figure 2. Average of the percentage of recuperation of the Cobb in function of the initial curve.

Figure 3. Average of the percentage of recuperation of the Cobb in function of the initial King-Moe.

Figure 4. Average of the percentage of recuperation of the rotation in function of the initial King-Moe (n=117 patients).

Figure 5. Regression line. We note a dependence between the recuperation average and the average Risser after 12 months of treatment using the FED method.
Figure 6. X-ray of a 12 year old girl with progressive idiopathic scoliosis. She had two sessions a week of the FED method and the rest of the week analytical kinesitherapy at home. Evolution:

X-ray: A 06/2003: T11-L4 26º Risser 0 Raimondi L2 10º  
B 01/2004: T11-L4 19º Risser 1,5 Raimondi L2 8º  
C 11/2004: T11-L4 15º Risser 2,5 Raimondi L2 3º  

Figure 7. X-ray of a 5 year old boy with progressive idiopathic scoliosis. Sessions from Monday to Friday using FED method. Weekends he had analytical kinesitherapy at home. Evolution:
Treatment of scoliosis. FED Method – Results of 400 cases

Sastre et al.

X-ray:

- A 10/2000: T6 – L1 55° Risser 0 Raimondi T9 19°
- B 06/2001: T6 – L1 48° Risser 0 Raimondi T9 15°
- C 01/2003: T11-L4 23° Risser 0 Raimondi L2 3°