Other Posterior Growth-Friendly Systems

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Key Points

- The key to successful management of EOS is the prevention of curve progression while maintaining spinal growth with the least amount of complications.
- Self-guided growth surgical techniques have been developed to negate the need of repetitive lengthening required for the classic posterior distraction-based techniques (vertically expandable prosthetic titanium ribs [VEPTR] and traditional growing rods [TGR]).
- Implantation of self-guided growth Modified Luque Trolley (MLT) construct is technically demanding and is best done in patients with flexible curves where the apex can be translated to midline, slightly older age group

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(6–10 years old) with underlying diagnosis of flaccid neuromuscular scoliosis such as spinal muscular atrophy.
- The modern Luqué trolley construct consists of rigidly capturing the proximal and distal segments of the spine, while the apex of the deformity is translated and captured by gliding anchors.
- Achieving apical translation is crucial to maximizing spinal height while minimizing the risk of curve regression as it realigns the axial forces of the spinal growth.
- The gliding spinal anchors on the MLT technique are inserted through muscle-sparing extraperiosteal “keyhole” dissections to avoid spontaneous fusion. At the apex of the deformity, gliding anchors are placed for maximal apical translation and deformity correction.
- The growth-guided techniques avoid repeated procedures but do not provide an anti-collapse effect of the spine that is useful for better control of the deformity.
- The bipolar technique of the One-Way Self-Expanding Rods (OWSER) consists of a telescopic construct bridging the spinal deformity inserted through a minimally invasive approach. The construct is modular and solid enough to be hold indefinitely, hopefully avoiding the need of a final fusion procedure in many cases secondary to progressive stiffening of the spine over time.
- The OWSER maintains a permanent tension between the two ends of the bipolar construct. It expands spontaneously secondary to the spinal growth or daily motion of the patient, which may be enhanced by external trunk elongation maneuvers in rigid cases. This device preserves the bone growth and allows for a postoperative gradual correction of the residual spinal or pelvic deformities.
- The OWSER combines the advantages of both the growing rod techniques, distracting rod technique and the growth-guided technique. It offers a potential of rod expansion up to 80 mm. The rod may be contoured over its entire length on demand.
- The Spring Distraction System (SDS) concept is close to the ideal system by relying on a permanent internal distraction force. The key component of such a system is a (pre-tensioned) longitudinal helical spring that can deliver a continuous distraction force.
- The rods on SDS including the spring and buttress can be inserted less invasively, similar to TGR.
- The spine in between the proximal and distal anchors on SDS can remain untouched to minimize spontaneous fusion and the connections between the rods allow motion, especially in the axial plane, which may prevent auto-fusion

46.1 Introduction

The management of early onset scoliosis (EOS) carries significant challenges. Knowing that severe spinal deformities or early spinal fusion leads to poor lung development [1], new growth-friendly surgical techniques have evolved. The key to successful management of EOS is the prevention of curve progression while maintaining spinal growth [2, 3] with the least amount of morbidity. These new growth-sparing surgeries have been classified into three broad categories: distraction based, guided growth, and convex compression growth inhibition [4]. When deciding which of these growth-friendly procedures should be used, one must take into account the patients’ underlying etiologies and their comorbidities. The most studied surgical options that have provided some hope for successful management of these challenging patients are the spine-based dual growing rods or traditional growing rods (TGR) [5–8] and rib-based vertical expandable prosthetic titanium ribs (VEPTR) [1, 9–11]. These two techniques carry a high complication rate with one major drawback: once implanted, the patients need to be returned to the operating room approximately every 6 months for lengthening procedures.

Recent literature revived interest in the previous concepts of Luqué of a spinal construct that allowed self-lengthening with growth [12–14]. The obvious advantage of this guided growth technique is that patients do not need repetitive surgical interventions to lengthen the implants. The Modern Luqué Trolley (MLT) consists of capturing the spine in such a way that gliding spinal anchors travel along fixed rods, preventing further spinal deformity while still allowing relatively normal spinal growth. The modern Luqué trolley consists of one pair of rods fixed proximally and one pair of rods fixed distally while the apex of the spine is translated and captured by the four rods. As the spine grows, the overlying rods glide away. The modern Luqué trolleys take advantage of modern spinal implants and of a better understanding of the physiology of the young growing spine. Patient selection is crucial when using the modern Luqué trolley treatment modalities to optimize successful management.

46.2 Philosophy of Growth Guidance Techniques

There is a general consensus among treating surgeons that nonoperative treatment consisting of serial casting, plus or minus bracing, is warranted as an initial treatment in all EOS cases [3]. It is true that casting can be successful in treating

EOS in very young patients, particularly with small flexible curves [15]. It has been demonstrated that casting is also useful as a delay tactic buying time until the child is older to proceed to either a final fusion surgery or a growth-friendly procedure using TGR or VEPTR [16]. It has been demonstrated that by adopting such an approach, the overall complication rates in managing EOS will be decreased. By delaying the initiation of classic growth-friendly surgeries, one decreases the overall number of surgeries, delays the law of diminishing return [17], and decreases the overall potential for complications that have been quantified to be as much as 24% for each additional surgery [5]. Currently, nonoperative treatment is just not feasible for certain patients (respiratory compromise, neuromuscular etiology) or it is simply not successful (malignant curve progression despite casting). For such patients, only then, is surgery recommended.

When adopting growth guidance surgery, one must take a more proactive approach. Early surgical intervention is recommended rather than waiting until there are severe rigid spinal and/or chest wall deformities. However, such a philosophy must be based on strict guidelines as not to initiate unnecessary surgery. One needs to document curve progression in a child that remains skeletally immature and where there is a high likelihood that the curve will continue to progress. Thus, knowing that both the nonoperative treatment (serial casting) and classic posterior-based growth-friendly procedures require repetitive surgical intervention every 6 months, it is preferable to initiate self-growing rods to avoid these repetitive procedures, which carry a significant impact on the overall physical and mental health of the children. Pratt et al. concluded that the use of braces or plaster jackets for prolonged periods for EOS leads to an emotional scar [18]. They advocated the use of a self-lengthening construct as a favorable option for EOS. They believed that the surgical scar could be more easily hidden and forgotten, in contrast to casting that is continually reminding the child of their abnormality. Therefore, they felt that the total physical and psychological trauma to the patient was smaller in children undergoing passive-guided growth surgery compared to bracing. Such surgery needs to be performed on curves that remain flexible and where the apex can be translated to midline. By achieving such correction, the axial forces of spinal growth will be "harnessed," maximizing spinal height while minimizing the risk of curve regression.

In addition to the benefit that the children do not need to be operated on serially, this growth-friendly surgery avoids the spinal elements (e.g., vertebral growth plates, disks, facets, and the spinal musculature) to be subjected to cyclical distractive and fixed constraints. Such unnatural loads across the spine during the classic repetitive lengthening may well contribute to the law of diminishing return seen with TGR [17]. Another physiological benefit of this guided growth surgery is that there are no posterior-based distractive force-inducing junctional kyphotic moments leading to sagittal imbalance. As the gliding anchors can travel up and down the rods matching the sagittal profile, there is also no set sagittal segment that needs to be straight for the growth to occur.

These self-guided growth constructs are especially well adapted for patients with early onset neuromuscular scoliosis, particularly patients with spinal muscular atrophy (SMA). Type 2 SMA patients are at risk of precocious severe spinal deformities, seeing the onset of the disease between 6 and 18 months of age and the onset of the spinal deformity by 3 years of age [19]. These curves are at high risk of rapid progression resulting in significant deformity by 7 years of age [19, 20]. The rationale for early surgical intervention in early onset neuromuscular scoliosis is to provide a straight and stable spine in order to allow proper-guided growth of the spine. Corrective spinal surgery also protects the normal development of the lungs. In addition, it can help these patients to achieve a stable sitting balance and improved head control and overall posture, thus facilitating their caregivers' handling and improving their quality of life.

Patients with infantile or juvenile idiopathic scoliosis, congenital scoliosis, and to a lesser extent, spastic neuromuscular scoliosis are all candidates for guided growth. A key limitation behind this surgical technique is that if the spinal deformities require significant forces to straighten and maintain the spine straight, it will most likely not do well. For example, the spastic severely rigid neuromuscular patient may not grow as much as the flaccid collapsing neuromuscular scoliosis and its spinal deformity may return faster than the latter. Certain deformities require active distraction to ensure spinal growth, hence should be treated with TGR or with VEPTR to maintain spinal correction and persistent spinal growth.

46.3 Modern Luque Trolley

The original Luqué trolley was described by Luqué and Cardoso in 1977 [21]. They developed the first self-growing rod construct consisting of two L- or U-shaped rods fixed to the spine in a segmental fashion using sublaminar wires. Patients were selected for rigid internal fixation without fusion on the basis of young age (<11 years), severe long curves (e.g., wanting to avoid early long fusion), difficulty in casting (neuromuscular curves), and progressive curves [21]. As the spine grew, these rods were able to glide and "guide" the spine during longitudinal growth while maintaining the spinal correction. The short-term results at 2-year minimum follow-up were promising with mean major curve correction from 72° to 22° and spinal growth across the instrumentation of 2.5 cm. However, the use of the Luqué trolley has been abandoned as long-term result showed poor maintenance of spinal growth (range, 32–49% of expected growth) [18, 22], high spontaneous fusion (range, 4–100%) [22], and a high implant failure rate of 32% [18].

Pratt et al. in 1999 published the long-term results of the Luqué trolley for the management of infantile and juvenile idiopathic scoliosis that were previously performed by Webb [18]. This retrospective study compared the Luqué trolley fixation with ($n = 18$) and without ($n = 8$) apical convex epiphysiodesis. In the Luqué trolley group without epiphysiodesis, the mean age was older (7 years of age); the mean preoperative major curve was 48°, and decreased immediately to 25° postoperatively (47% less). Over the next 5 years, all major curves worsened. Six of the seven patients underwent a second procedure consisting of the definitive spinal fusion with segmental spinal instrumentation. The major curves were corrected from 56° (range, 46–67°) to 43° (range, 24–55°), with a final major curve of 43°. With respect to spinal growth of the instrumented spinal segment at the 5-year follow-up (FU), it was 2.9 cm, representing 49% (range, 31–71%) of the expected growth for age- and gender-matched reference. For the other group of patients treated with the Luqué trolley with apical convex epiphysiodesis, the mean preoperative major curve was 65° (range, 40–95°). The mean major curve was 26° (range, 8–66°) after the combined anterior–posterior surgery and 32° (range, 0–86°) at the 5-year postoperatively. Over a mean of 5 years postoperatively, the major curve worsened in seven patients, remained unchanged in four patients, and improved in two patients. While achieving better curve control (mean loss of correction of only 6°), spinal growth across the instrumented spinal segment at 5-year FU was only 2 cm, which represents only 32% of that expected for age- and gender-matched norm groups. In the entire study group, there were three patients with broken rods and wires, two patients with broken wires alone, and three patients with rod prominence. A distal junctional kyphosis developed at the caudal end of two Luqué trolleys. At surgical revision, the instrumented vertebrae were found to be fused. One patient developed a postoperative pneumonia. There were no neurological complications. The authors concluded that there was a need for improved instrumentation and for new surgical measures to allow better curve control and spinal growth.

When choosing a growth guidance system, one needs to properly understand the shortfalls of the classic Luqué trolley. Patients who did poorly with the classic Luqué trolley were those with large rigid curves preoperatively and/or patients who had large residual postoperative curves. The usage of wires as the spinal instrumentation contributed directly to the causes of the high complication rates, including spontaneous fusion, implant failure, and poor deformity control. The dissection required to pass sublaminar wires at every level, and the binding of the rod down onto the lamina obviously led to a high rate of spontaneous fusion leading to growth inhibition. This posterior fusion, in turn, may have also contributed to a certain amount of curve progression in the form of crankshaft phenomenon. Despite such spontaneous fusion, previous authors have observed spinal growth across such extensive dissected spines [18]. Our belief is that the fusion mass is thin and does not impede the anterior spinal growth as long as proximal and distal foundations are well anchored. Having converted Luqué trolley to final fusion, we have noted that these spontaneous fusions are generally thin and may explain persistent spinal growth. With respect to implant failure, it is not surprising that there was a high rate of implant failure as the main implants used were simple wires. Rods could not be held in place solidly with only the wires; hence these had a tendency to migrate. With the use of wires, there was no ability to capture and control the anterior spinal column. Despite having every level "captured," the construct had to be loose to allow the rods to glide. With such fixation, the spinal stabilization was relatively poor, leading to poor curve control and therefore contributing to the gradual loss of deformity correction. The patients in the study by Pratt et al. with the apical epiphysiodesis illustrated that curve control was improved significantly. However, it resulted in significant loss of spinal height, thus illustrating that apical control is indeed important for deformity control as long as one does not cause fusion across the apex.

In 2011, Ouellet published a small series of 17 patients with EOS of which five were treated with a modern Luqué trolley construct (Fig. 46.1) [12], reintroducing the concept of self-lengthening growth guidance systems [4]. The surgical technique consisted of using off-label modern spinal implants allowing for gliding spinal anchors and taking advantage of muscle sparing minimally invasive exposure to instrument the spine. The case series compared 12 patients treated with conventional growth-friendly treatment (four patients treated with serial casting, four with TGRs, and four with VEPTRs) to five patients treated with a modern Luqué trolley. The etiologies of the deformities in these five patients were two patients with idiopathic EOS, two patients with syndromic scoliosis (Prader-Willi syndrome, and one patient each with dysmorphic feature with global hypotonia of unknown etiology), and neuromuscular scoliosis (cerebral palsy). The mean age of the serial casting and distraction-based patients was 4.5 years old (range, 0.9–8.5 years) compared to 6.5 years old (range, 3–8.6 years) for the modern Luqué trolley group. Mean preoperative major curves were 61° (range, 38–94°) and 60° (range, 45–75°) and decreased to a mean of 21° (range, 10–33°) and 35° (range, 23–46°), respectively. Mean follow-up was 4.5 years (range,

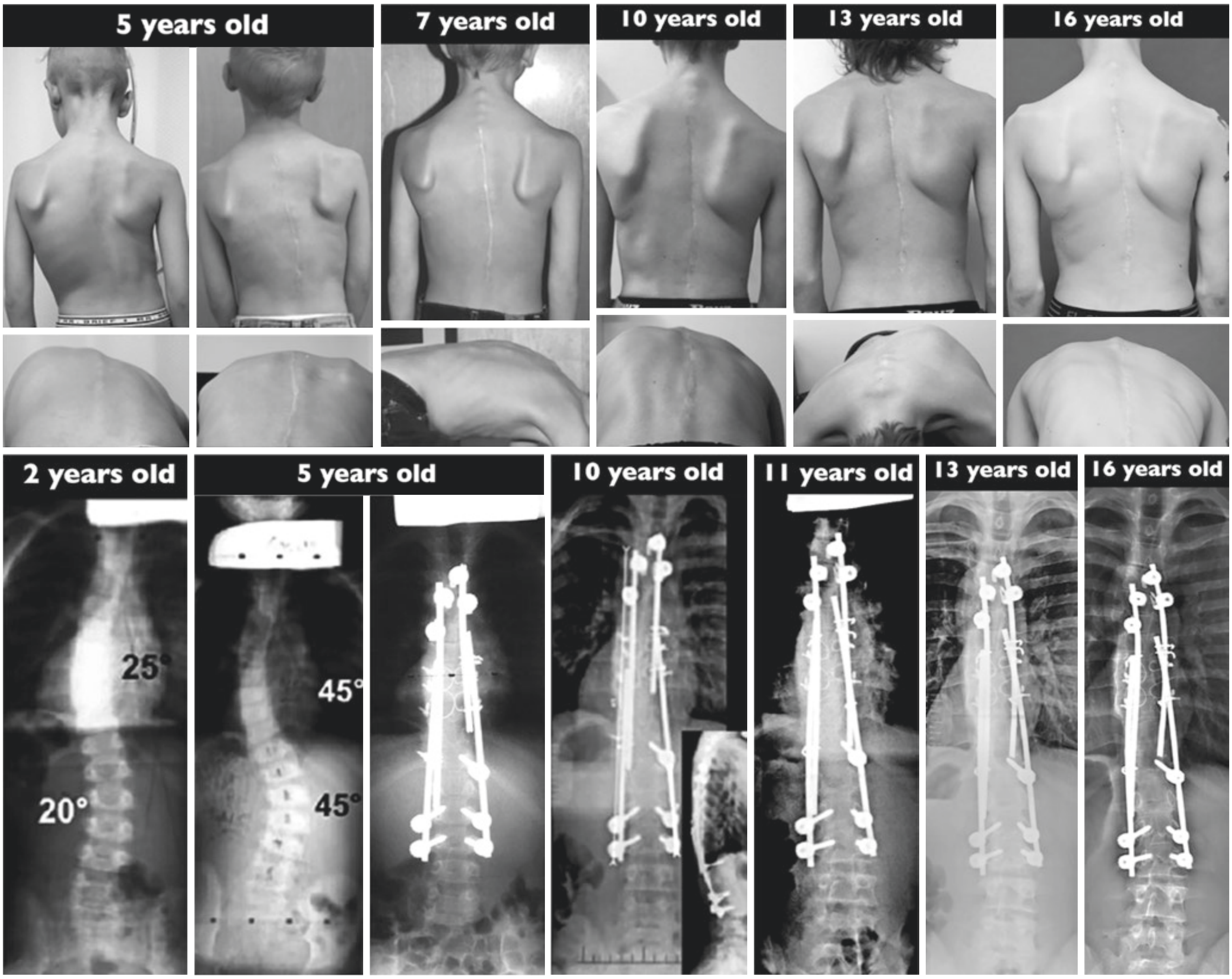


Fig. 46.1 Clinical example of a 2-year-old male with a progressive idiopathic EOS undergoing a self-guided growth surgery. Despite serial casting from 2 to 5 years of age, the deformity progressed. He was treated with a modern Luqué trolley construct, which grew over the next 10 years. He required only one revision surgery at 5 years of age as he outgrew the guided growth construct

2.5–6 years) and 5 years (range, 3–8 years) for the two groups. At the last follow-up, the mean major curve had increased to 31° (range, 14–54°) in both groups. At 5 years postoperatively, four out of five subjects (80%) had required revision surgery. Three had their initial self-guided growth implants converted to new distraction-based implants as they had outgrown the initial construct. A fourth patient, with syndromic scoliosis, required final spinal fusion before reaching skeletal maturity because the curve had progressed (54°) and had minimal remaining spinal growth (26% expected). The fifth patient was still immature and growing. Comparing the two groups, the first treatment group had a total of 89 procedures over a 4.5-year period, with a mean of 7 procedures per patient and 1.7 procedures per year, per patient. In contrast, the modern Luqué trolley had a total of 9 procedures over a 5-year period, resulting in 1.8 procedures per patient and 0.3 procedures per year. In respect to spinal growth, after the mean follow-up of 5 years, the spine grew on average 67% (range, 26–91%) of expected growth.

More recently, in 2020 the main author's group gathered preliminary data from seven patients that had surgery using the MLT technique that used "gliding" implants which have the CE mark in Europe and that are also available in Canada (Video 46.1) [23]. These implants have not been submitted to the FDA at this time. The data was collected prospectively between 2014 and 2018 and analyzed retrospectively. The mean follow-up in this cohort was 3 years. Mean number of instrumented segments was 11. The percentage of expected growth was 52%. Mean major curve preoperatively was 68° (range, 40–97°) and the immediate scoliosis correction postoperatively was 28° (range, 5–46°). The immediate percentage of curve correction was 55% and the final maintained correction at 3 years was 35% (Table 46.1).

Table 46.1 Descriptive table of the latest series of cases followed up for 3 years by the senior author. Mean (range) values

Pt number	Age	Dx	FU	Non-fused segments	Growth	% Expected growth (%)	Scoli pre	Immediate post op	Immediate correction (%)	Final scoli	Final correction (%)	Complications
1	11	Neuromuscular	28	10	0	0	53	5	81	25	52	–
2	14	Neuromuscular	25	11	18	80	40	31	22	46	−15	–
3	7	Neuromuscular	47	13	20	38	97	26	73	57	41	–
4	13	JIS	43	11	9	23	63	21.2	66	37	41	–
5	6	Neuromuscular	27	10	26	117	65	30	54	32	51	–
6	5	Neuromuscular	38	11	24	70	84	39	54	29	34	–
7	10	Neuromuscular	56	12	23	42	74	46	38	44	40	Wound infection
Results	*9*		*37 m*	*11*	*17 mm*	*52 (0–117)*	*68° (40–97)*	*28° (5–46)*	*55 (22–81)*	*34° (−6–57)*	*35*	

46.3.1 Surgical Technique (Video 46.2)

For the MLT, patients are positioned prone on a radiolucent table under a total intravenous general anesthetic compatible with multimodality spinal cord monitoring. Preoperative planning is mandatory to plan the skin incision as well as the location of the gliding anchors. Classic midline incisions are to be made ensuring that no prominent spinal implant will be directly below the skin incision. Either one single skin incision is made spanning the entire planed instrumented spine (Fig. 46.2). Two or three separate skin incisions can be made over the proximal, apical, and distal segments (Fig. 46.3). The MLT trolley-gliding vehicle that is currently only available in Europe and special access in Canada captures the rod with a PEEK belt mechanism allowing for gliding. Other implants can be used in such a fashion allowing for certain gliding properties. The oldest segmental fixation is a sublaminar wire and it can be used as a gliding anchor. The other possibility is to purposely use a smaller diameter rod (5 mm) in a pedicle screw-based system designed to capture a larger diameter rod (6 mm). For example, the pedicle screws of the AO universal spine system (AOUSS) can be used with its small stature 5-mm rods. Obviously, using spinal instrumentation in this way is off-label and is not recommended by any of the manufacturers.

The MLT construct consists of fixed proximal and distal anchorage points. A classic subperiosteal dissection is performed at the proximal and distal segment, as these segments need to be fused to achieve long-term solid anchors. Fixed spinal anchors such as standard screws or hooks locked to the rods are inserted. The gliding spinal anchors (either gliding screws or sublaminar wires free to travel along the rods) are inserted through muscle-sparing “keyhole” dissections (see Fig. 46.2a, b). At the apex of the deformity, gliding anchors are placed for maximal apical translation and deformity correction. The dissection at the gliding anchors must be kept to a minimum using extraperiosteal and muscle-sparing techniques to avoid spontaneous fusion. In the lumbar spine, the gliding pedicle screws are inserted through a Wiltse approach sparing the joints and minimizing bony exposure. In the thoracic spine, the gliding pedicle screws are inserted laterally to the midline erector spinae, dissecting directly onto the transverse process avoiding exposure of the lamina (see Fig. 46.3a, c). Pedicle screw insertion should be done with the use of intraoperative imaging. Fluoroscopy can be used to confirm the pedicle entry point, and using a freehand technique, the gliding screws can be inserted at strategic points allowing for maximal apical translation. These gliding screws capture a 5-mm rod with a locking cap belt that glides over a peek surface (see Fig. 46.3 a-h). At segments where sublaminar titanium cables are to be passed, the dissection is carried from midline to the medial border of the facet, regularly this only happens at the apex levels of the construction. When inserting the gliding screws, careful attention should be paid in order to leave the periosteum on the bone even with some muscle still attached. Dissection is to be performed with bipolar cautery and forceps at hand to control blood loss and minimize disruption of the periosteum. Avoid removing the spinous processes to prevent stripping the periosteum off the lamina and creating a raw bone surface. Small lateral laminectomies are to be done leaving the periosteum intact, while giving access to the ligamentum flavum. Once the central ligamentum flavum is removed, passage of sublaminar cables can be performed (Fig. 46.4). Once the fixed and gliding anchors are placed, two pairs of 5-mm titanium rods are tunneled in a subfascial/intramuscular fashion (below the fascia, above the periosteum) from the opened proximal and distal incisions. Each rod needs to only have one end rigidly anchored to the spine. In the intermediate segments, a series of gliding spinal anchors maintains the correction by keeping the rods parallel and engaged. As the spine grows, the rigidly proximally fixed rods will move away from the distally fixed rods (Fig. 46.5). One can also only use two rods rather than four and have them fixed distally and have the spine grow off the proximal end (see Fig. 46.5b). Correction of the spinal deformity is achieved with either a classic rod derotation maneuver (Fig. 46.6) or an apical translation reduction maneuver (see Fig. 46.6b) or in combination. As the rods are tunneled and partially engaged in the fixed and gliding anchors, and by rotating or translating the rods, the correction is achieved. The goal is to ensure that the four rods are parallel to each other. The number of gliding anchorage points will influence the ability to correct and maintain the deformity. If the number of the gliding anchors is kept to a minimum, the risk of spontaneous fusion is minimized. However, the risk of residual and recurrence of the spinal deformity is greater (Figs. 46.7 and 46.8). In contrast, if every spinal segment is instrumented, then there is a lower risk of curve progression but a higher risk for growth retardation as spontaneous fusions may occur. The key is to have an adequate number of gliding anchors to translate the apex of the deformity toward midline, ensuring adequate correction and control of the spinal deformity without inducing spontaneous fusion. Different gliding constructs can be tailored to different spinal deformities (Fig. 46.9). This case illustrates the power of cantilevering a rod across the apex of a deformity. The spine was captured with fixed spinal anchors proximally (hooks and screws) and was then cantilevered across the two eggshell resections of the hemivertebra with an apical gliding screw and a set of gliding anchors distally. Follow-up radiographs confirm ongoing growth of the spine. Initially, the left rod extended below the disk of L5/S1 and now is at the level of the L5 pedicle screw. On the right side, a VEPTR 2 implant was used without the locking mechanism that allows for passive-guided growth. The gradual appearance of space within the

Fig. 46.2 (**a**) Midline incisions: either one single skin incision spanning the entire planed instrumented spine. (**b**) Alternatively, two or three separate skin incisions over the proximally, apical and distal segments can be performed

male–female inlay of the VEPTR implants represents the spinal growth across the instrumented spinal growth.

46.3.2 Discussion

The MLT surgical technique is technically demanding and requires strict patient selection to ensure a predictable outcome. The use of sublaminar wiring can be time consuming and has possible risk in the hands of inexperienced surgeons. The risk of neurological complications has been well published in the literature [24–27], but in the hands of experienced surgeon, such complications are rare [28–30]. Passing the rods, engaging the fixed and gliding anchors through the muscle-sparing incision while achieving spinal correction, requires significant experience in deformity surgery. New gliding implants are starting to be available and may help to simplify the surgical technique and hopefully negate the need of sublaminar wires (see Video 46.1).

Patients with comorbid factors carrying additional risks associated with repetitive anesthesia are the ideal candidates for this technique. Patients with SMA and any other flaccid neuromuscular scoliosis are good candidates for this technique. Seeing that any attempt at prophylactic treatment with early bracing in these patients has not prevented curve development nor progression [7], and that early spinal fusion impacts negatively on the development of the lungs and can cause death due to pulmonary failure [31, 32], this technique offers the best option to correct and control long c-shaped paralytic scoliosis during their growth and to an extended period.

Another favorable factor predicting good surgical outcome using this technique is the ability to translate the apex of the spinal deformity back to the midline and reestablishing the normal axis of spinal growth. The risks of add-on below the corrective growth-friendly implant are significant. Hence, having solid proximal and distal fixations is also very important. Even though we tend to try to keep our proximal and distal anchors to a minimum, we often regret not going just a bit longer to ensure no add-on occurs. If patient's morphology allows, the addition of cross-link is suggested across the fixed anchors, particularly if the pelvis is not incorporated into the distal anchor. In all patients with neuromuscular scoliosis, fixation to the pelvis is preferable as this reduces the chances of loss of sagittal and coronal balance in the long term due to the paralytic nature of their deformity. In such distal fixation, cross-links are not needed [33].

In 2020, Mehdian et al. published his latest observations on 16 patients who were treated using a technique similar to the MLT. In such technique, the upper and lower instrumented segments of the construction were anchored using at least 3-3 pedicle screws and then 4 (5 mm) cobalt chrome rods that were guided and directed using sublaminar wires across the not-fused segments over the main curve. The patients were followed for ~6 years, and the authors reported 62% curve correction at the latest FU and expected growth maintained at −1 SD compared to population norm (~1 mm/year/level). On the other hand, the authors experienced 27–54% EBV (estimated blood volume) loss during surgery which maybe because of the extensive surgical exposure and six cases (~38%) fused after hardware failure (rod breakage) [34].

46.4 The One-Way Self-Expanding Rod (OWSER)

46.4.1 Background of the Bipolar Concept

In the beginning, we used a conventional single rod technique, the 3 hooks-2 screws construct (H3S2) which provided satisfactory results despite a high number of rod

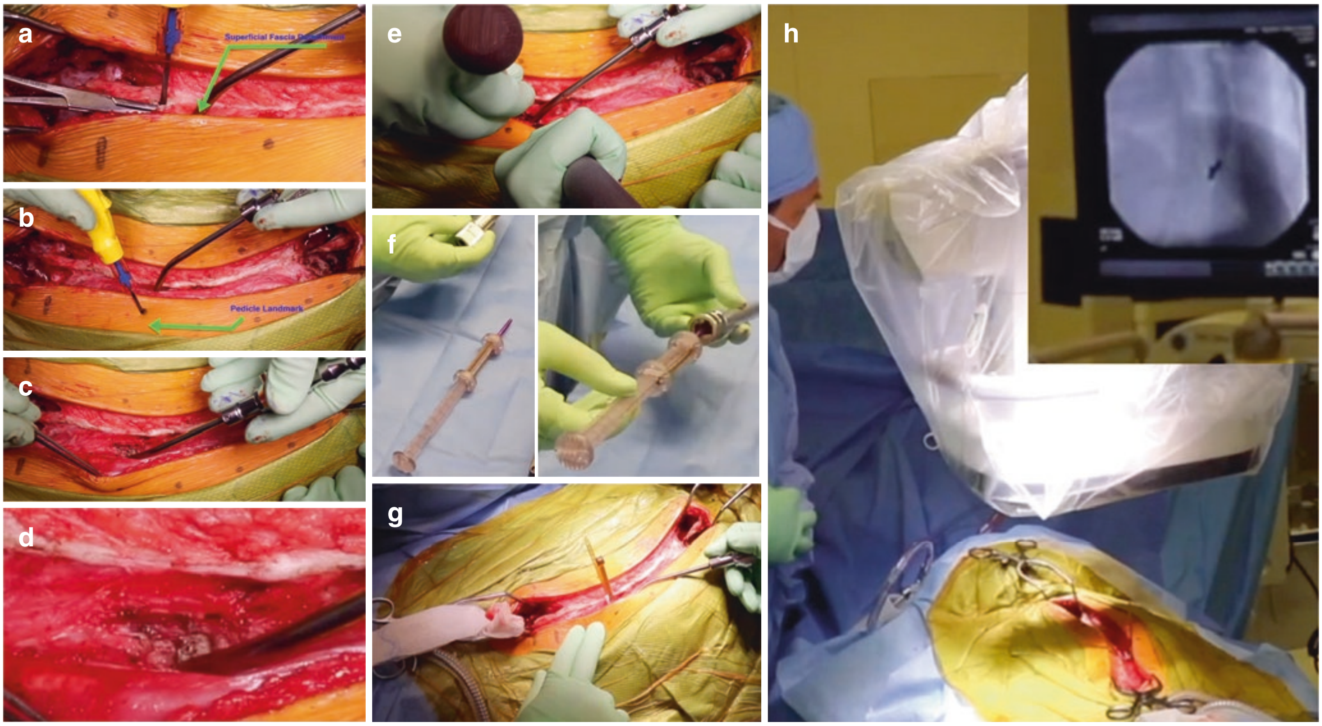


Fig. 46.3 (**a**) The erector spinae are split with the multifidus and spinalis spinous process left medially with the longissimus and iliocostalis reflected lateral. Transverse process is visualized. (**b**) Pedicle is identified using the skin marking obtained using preoperative radiographs. (**c**) The pedicle location is located via a transmuscular approach. (**d**) A close-up of the minimal muscle dissection is shown. (**e**) Freehand or fluoroscopic-assisted gliding pedicle screws are inserted. (**f**) Example of a gliding pedicle screw system while being setup. (**g**) Final example of how the gliding screw belts before the rod is inserted. (**h**) Operating room zoom out while confirmation of the trans-muscular screw

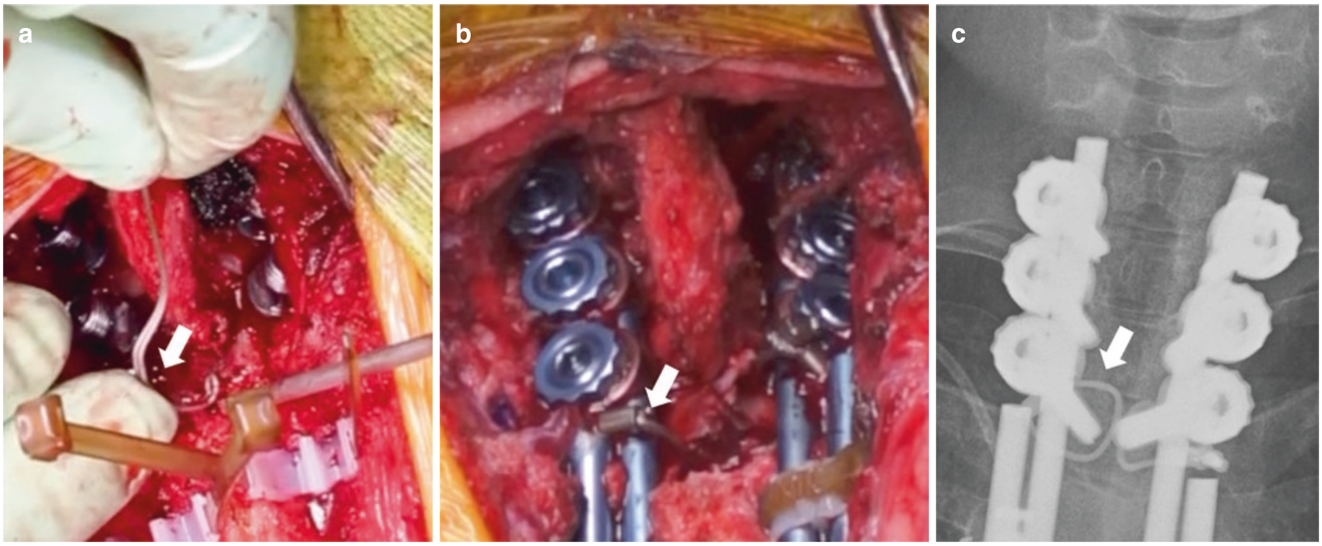


Fig. 46.4 (**a**) Wires are inserted not through the standard midline ligamentum flavum resection but rather by a small lateral laminectomy leaving the periosteum intact (*arrows*). (**b**) Example of apical sublaminar wires capturing the overlapping rods. (**c**) Radiographic image of wires

fractures [5, 6, 8, 17, 35–40]. We then changed to a bilateral bipolar more solid construct, which rapidly became an alternative technique for arthrodesis, especially in neuromuscular and syndromic scoliosis. Its results are now confirmed with a long follow-up of 10 years [40, 41].

Several studies have approached the growing rod principle [12, 13, 18, 21, 22, 42–52] In 2005, we described the first non-surgically expandable rod; the Phenix rod based on a magnetic principle [49–52]. We used it for 5 years in 30 cases with limited satisfactory results, before abandoning it

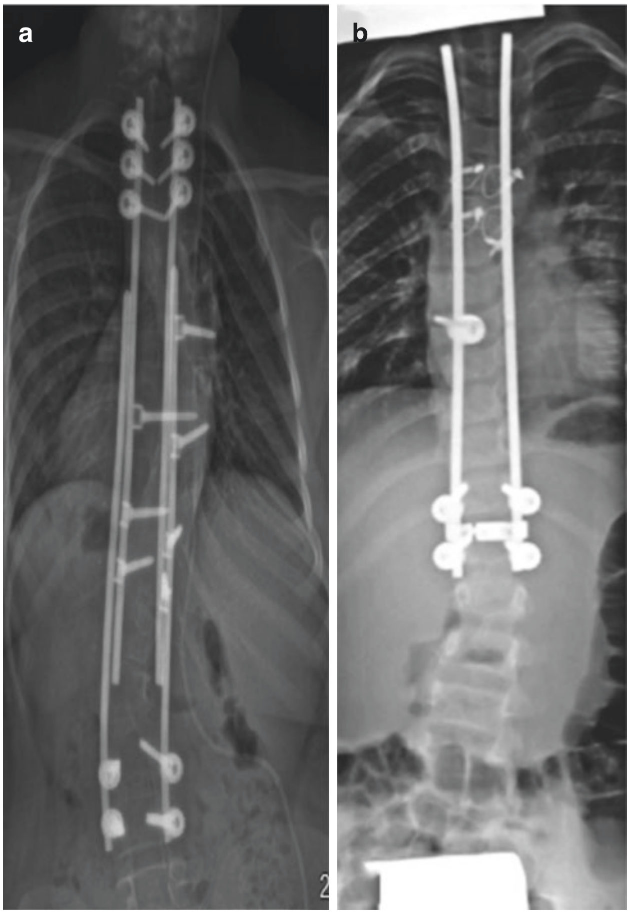


Fig. 46.5 Radiographic differences between two self-growing constructs. For both techniques, a series of gliding spinal anchors maintains the correction by keeping the rods parallel and engaged. As the spine grows, the rigidly proximal-fixed rods will move away from the distally fixed rods. (**a**) The modern Luqué trolley. (**b**) An alternative-guided growth construct

due to technical issues. After stopping the use of Phenix Rod, we worked with a simple lengthening technique based on a mechanical principle allowing a free rod expansion without the need of repeated surgery and in 2013, we developed the One-Way Self-Expanding Rod technique. In this chapter, we report the results of the device in a prospective series of 22 neuromuscular patients with a minimum follow-up of 3 years.

Whatever the etiology of scoliosis, the physiopathology of the deformity is based on a three-dimensional torsion of the spine. This torsional deformity of scoliosis inevitably leads to shortening of the spine. Therefore, avoiding this shortening process prevents the deformity progression. This explains why distraction-based growing rod techniques are the most frequently used techniques for EOS, and why they achieve the best correction of the spinal deformity secondary to prevention of the spinal collapse.

Unfortunately, these distraction techniques need periodic surgeries for rod lengthening that has a high rate of complications and induces an early auto-fusion ultimately compromising the outcomes [5, 17, 37]. In another words, most growing devices or constructs are not resistant enough to hold indefinitely and may require the use of brace [5, 48, 50].

To avoid these drawbacks, we looked for a technique that has the following bases:

- Prevents spinal collapse by maintaining a constant tension
- Preserves the bone growth and avoids repeated surgery
- Be resistant enough to reduce mechanical complications, avoiding the use of postoperative brace and the need for the final fusion, by maintaining a good correction until the skeletal maturity

To achieve these goals, we used a strong bipolar construct with a solid proximal and distal fixation through a minimally invasive approach to avoid early auto-fusion.

We took advantage of our previous experience in single rod technique (H3S2), to develop a solid bilateral construct in order to reduce the risk of the mechanical complications. For our technique, we had learned that a solid proximal fixation has to be vertebral and not on ribs including at least three instrumented adjacent levels preferably fixed by hook claws that offer better resistance against pull-out forces [41, 53]. For distal fixation, we use two or three adjacent levels of pedicle screws in lumbar area for walking patients, and ilio-sacral screws for neuromuscular cases [41, 54].

The bipolar concept is based on a solid telescopic construct including two 5.5 mm diameter rods on each side bridging the curve and linking the two strong proximal and distal anchors. The construct is both flexible and resistant enough to withstand the constraints applied by the patient motion. It is a modular construct following spinal growth and allowing further gradual correction of residual deformities. However, for severe rigid curves, we strongly recommend preparing the patient 3 or 4 weeks prior to surgery with a progressive halo-gravity traction. This preoperative correction is an important step of the treatment as it allows to obtain a better curve correction and decreases the risk of neurological complications in severe spinal deformities.

46.4.2 Design Features of the One-Way Self-Expanding Rod

A new self-expanding device complements the bipolar concept, improving its safety and efficacy while avoiding the need of repeated surgery. The OWSER is a sliding device

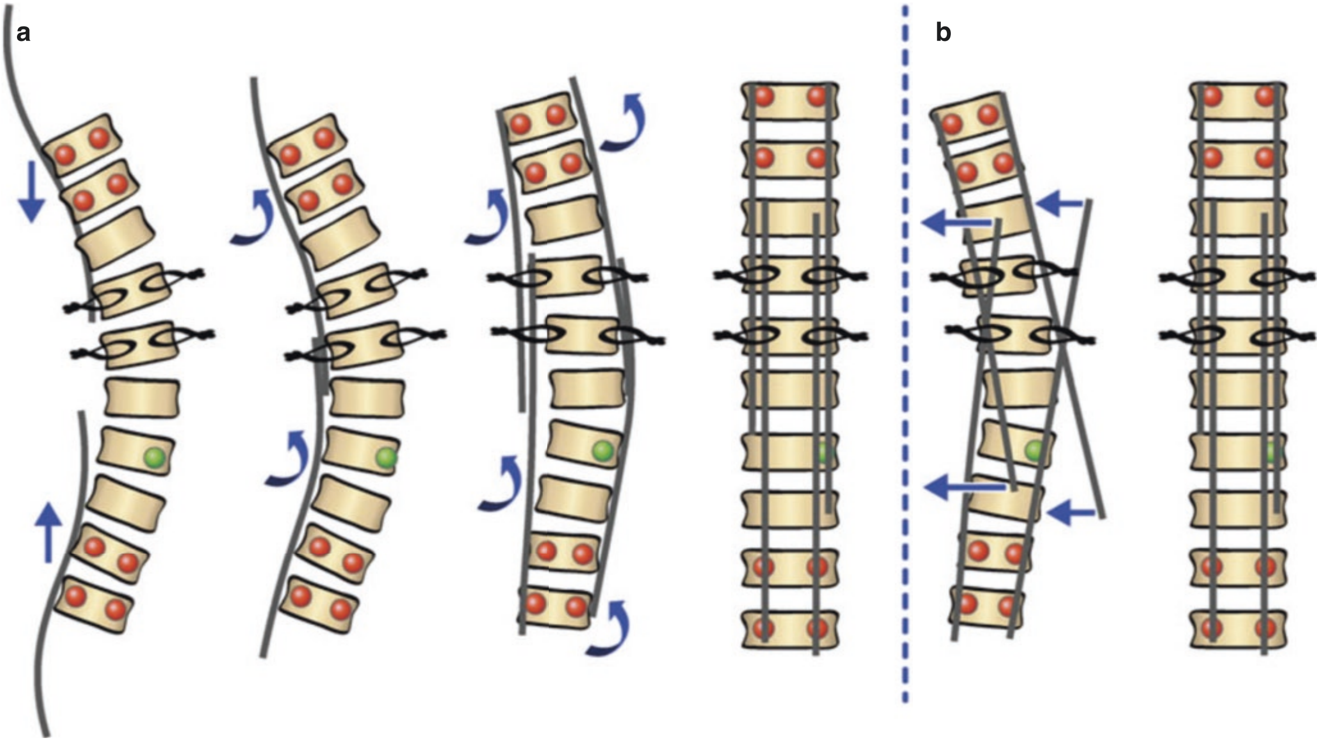


Fig. 46.6 Schemes of the technique of reduction. (**a**) Correction relies on rod rotation and apical translation. Rods are attached to proximal and distal anchors. (**b**) Cantilevered and/or rotated across the midline achieving parallel end vertebra

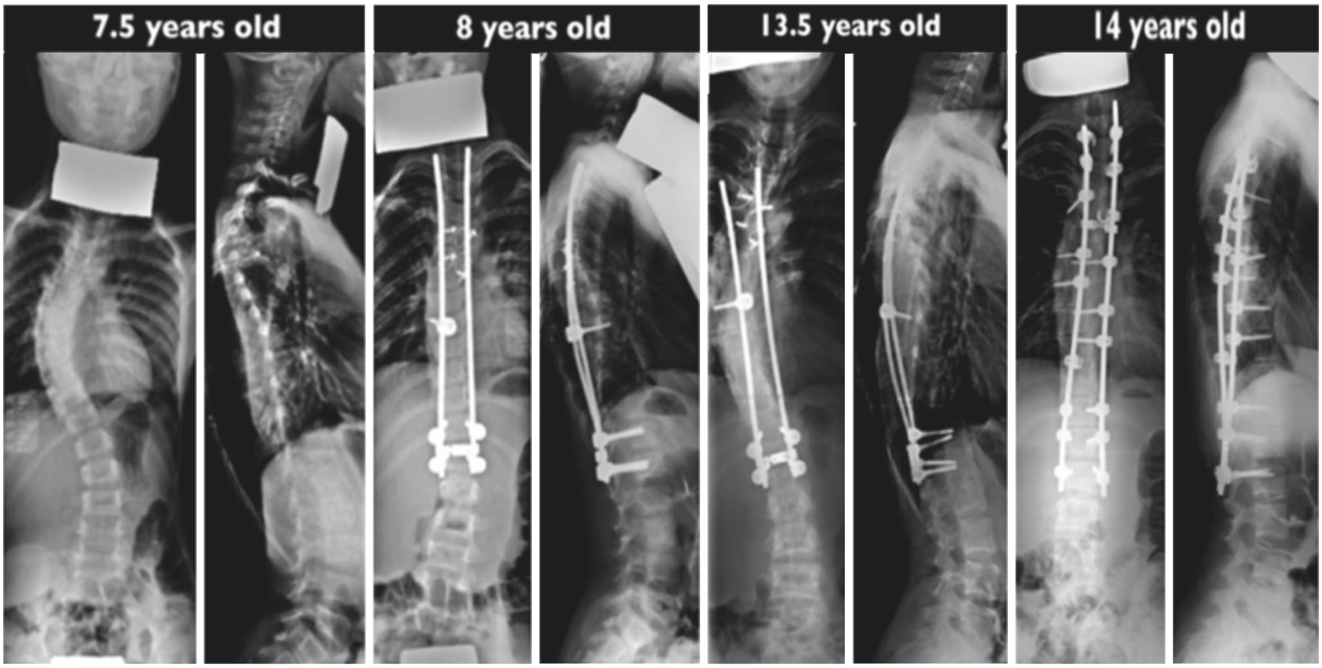


Fig. 46.7 Clinical example of a modern Luqué trolley with inadequate numbers of gliding anchors. Initially, deformity appeared under control. However, over the next 4 years, due to inadequate number of gliding anchors, deformity recurred requiring formal posterior spinal fusion observed 6 months following surgery (8 years old). Five years post-initial trolley (13.5 years old), a loss of proximal fixation, growth across the instrumentation, and a 75% of normal growth without any lengthening surgery could be observed. Final fusion occurred at 14 years of age

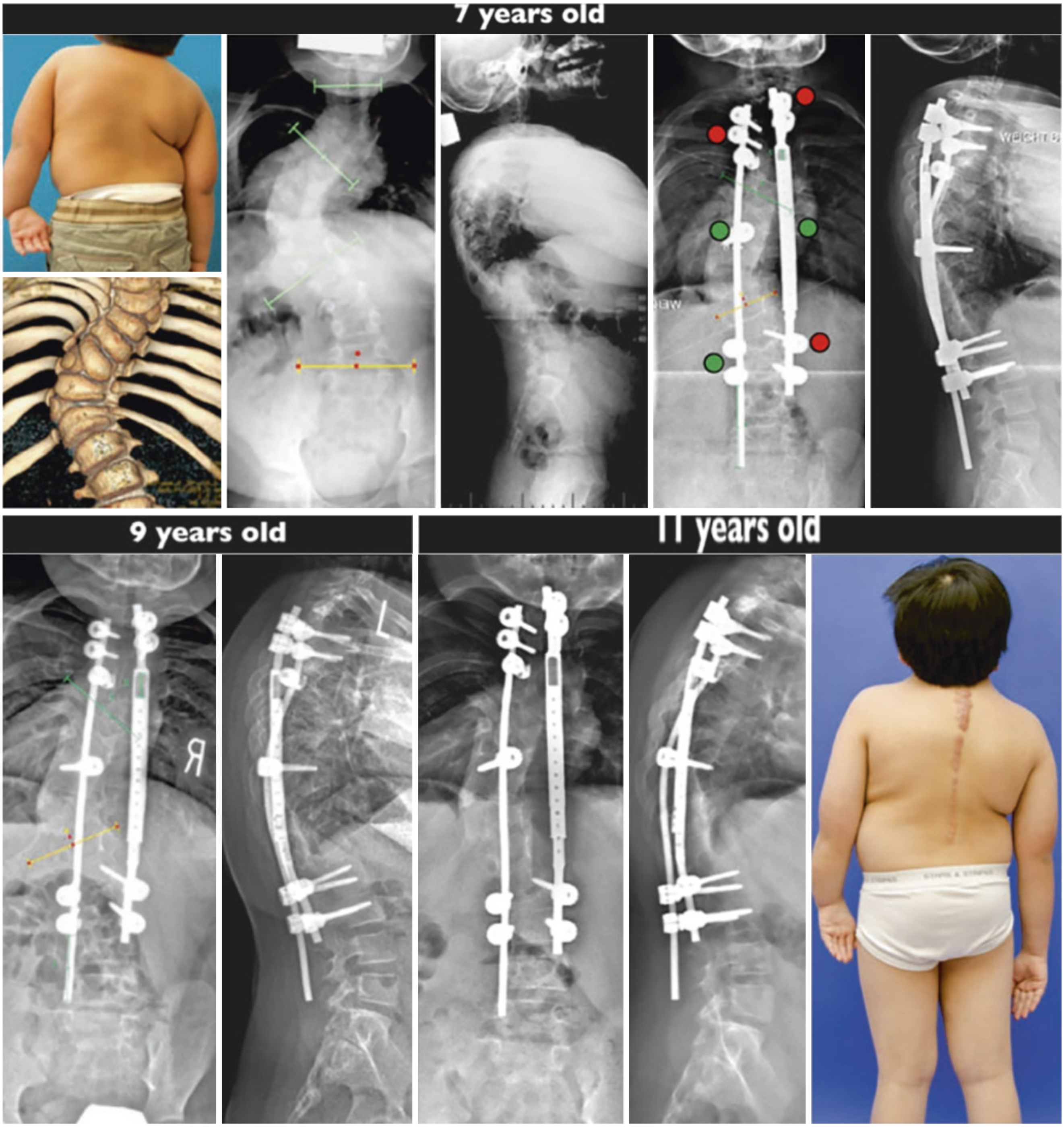


Fig. 46.8 Modified modern Luqué trolley treating early onset scoliosis in a 6-year-old male patient with severely rigid congenital scoliosis with radial hypoplasia. Hybrid construct with a left-sided proximally fixed rod with mid- and distal gliding screws. The right-side construct is a VEPTR used off-label that is not locked, thus allowing for self-growth

made on two titanium alloy components; the first is a 5.5 mm diameter rod with a 300 mm length smooth part and 50 or 80 mm length notched part (6 mm diameter) that represents the lengthening reserve of the device. The second component is a side-to-side domino sliding on the notched part of the rod having a free tunnel where an additional rod is inserted and fixed to the spine (Fig. 46.9). The domino slides gradually on the notched part of the rod in one direction with a mechanical system stopping its recoil. Each excursion of a sliding domino is 1 mm. A flat region on the notched part of the rod prevents the rod rotation and a stop at the end of the notched rod prevents the domino-rod disassembling. The smooth part of the rod can be contoured over its length, especially in the sagittal plane to reduce the constraints on the spinal anchors. The notched part is not bent and not fixed to the spine, allowing it to slide freely between the two ends of the construct. The device expands by two ways:

- A passive way, thanks to spinal growth or the daily activity of the patient
- An active way on-demand by the use of one external method of traction like physiotherapy manual extension, Cotrel auto-elongation method, Stagnara cast, or halo gravity technique (Fig. 46.10)

The external traction method may be chosen on case basis. The power amount and frequency of traction maneuvers are adapted to curve stiffness. The traction forces may be applied symmetrically or asymmetrically depending on the trunk balance or pelvic obliquity.

Fig 46.9 Picture of the one-way self-expanding rod

46.4.3 Surgical Technique

We generally perform the bipolar minimally invasive surgery under intraoperative traction and intraoperative neuromonitoring. Proximal and distal short incisions are performed (Fig. 46.11). The distal fixation is made through a Wiltse transmuscular approach, both at the lumbar incision for idiopathic cases and at the lumbo-sacral incision for neuromuscular cases.

In the proximal approach, a subperiosteal exposure of the lamina of the thoracic instrumented vertebrae is performed. The proximal fixation is with hook claws for all cases. The hooks are inserted without preparation to preserve the entire bone capital of fixed vertebrae. A reduced blade hook is used for supra laminar fixation on each side. Special care should be taken for patients with narrowed spinal canal or cervicothoracic lordosis.

The rods are bent and introduced from one incision to the other in a subfascial plane. They are connected with the dominos and fixed to the implants on each side, first on the concave side.

46.4.3.1 Idiopathic Type Construct

Proximally we perform a bilateral three or four adjacent vertebrae fixation with pedicle-supralaminar hooks claws. If we fix three vertebrae, a hooks claw and a third supra laminar hook one level above is used. Two pedicle screws on each side carry on the distal fixation. Three levels are taken if there is an additional lumbar curve.

The OWSER is placed on the concave side first: the long sliding rod is bent and inserted medially with notched part downwards, secured proximally inside the hooks. It is connected with the domino to a pre-bent short rod fixed laterally to pedicle screws (Fig. 46.12).

An intraoperative curve correction is carried out by mild distraction on the short rod between the domino and the proximal pedicle screw. Then the convex rods are inserted in a symmetrical position, and two cross-links are used at the

Fig 46.10 Patient under traction

Fig 46.11 Preoperative view

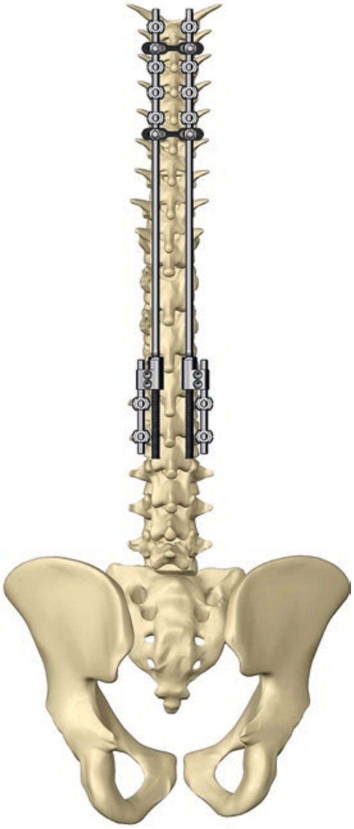


Fig 46.12 Idiopathic version of the construct

proximal part of the long rods, one between the hooks and the other under them. Cross-link is not used in the distal part of the construct in order to avoid the risk of a conflict with a spinous process when the rods migrate proximally. Before closing, the C-shaped locks have to be removed from both OWSER to allow free sliding of the rods.

46.4.3.2 Neuromuscular Type Construct

For neuromuscular patients, the distal fixation is made with iliosacral screws in the pelvis (Fig. 46.13). The proximal fixation is made with double pedicle-supralaminar hook claws on five adjacent vertebrae with a free level between the two claws.

The OWSER is cut, pre-bent, and positioned with notched region upwards and lateral. It is linked through the domino to a long medial pre-bent rod, first secured proximally to the hooks, and distally to the iliosacral connector. Correction maneuvers are performed by concave distraction combined with in situ rod bending. On the convex side, the rods are positioned symmetrically and some compressive maneuvers may be performed if there is a residual pelvic obliquity.

Three cross-links are inserted, two proximal and one distal very close to iliosacral connectors. No decortication or additional bone graft is used. Before closing, the C-shaped locks have to be removed from both OWSER to allow free sliding of the rods.

In the postoperative period, the patients are allowed to sit and stand independently without the support of a cast or brace.

46.4.4 Surgical Indications

The ability to bend the rod over its entire length allows this device to be used regardless the magnitude of scoliosis curve and even in hyperkyphotic cases. This device can also be indicated in all etiologies since it can still expand thanks to the residual bone growth even in the absence of flexibility of the curve such as congenital scoliosis (Fig. 46.14). However, the best indication remains neuromuscular scoliosis in young children less than 10 years of age (9 years of age and younger).

If used in ambulatory neuromuscular patients with sagittal trunk imbalance and fixed to the pelvis, it is necessary to perform a meticulous rod contouring to give a large lumbar lordosis to the patient. This is done to mitigate the risk of a rapid rod expansion that can induce a decrease of lumbosacral lordosis and provoke an anterior imbalance of the trunk.

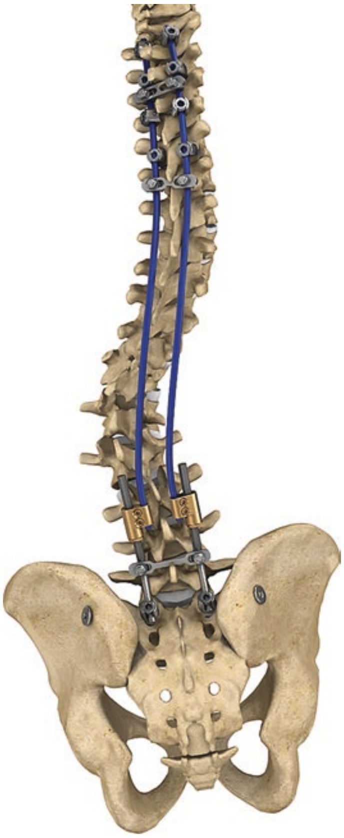


Fig 46.13 Neuromuscular version of the construct

46.4.5 OWSER Outcomes

In 2016 a clinical trial was carried out on the device comprising two groups of 10 cases each, a first group of ambulatory patients with a unilateral construct and lumbar foundation, and a second group of non-ambulatory patients with a bilateral construct extended to the pelvis. The device expanded in 50% of cases in the unilateral group and 100% of cases in the bilateral group. The lack of expansion of the device in the first group was explained by the rotational strains applied on the rod creating resistance to its sliding. These strains were avoided in the bilateral construct group, thanks to the rods fixation by the cross-links which prevented their twisting. The conclusion of this recently published study was to always use this device in bilateral construct regardless the patient's etiology and the level of the distal fixation [55].

From February 2016 to July 2017, we performed a second prospective study in a series of 22 patients with neuromuscular scoliosis, 12 boys and 10 girls who underwent a bilateral bipolar fixation using the OWSER. The minimal follow-up was 2 years and the etiologies were 12 cerebral palsy, 5 spinal muscular atrophy, and 5 other neuromuscular disorders. The Risser Score was 0 in 12 cases, 1 in 7 cases, and 1 case for each of the scores 2, 3, and 4.

All patients were assessed at 3 months and then every 6 months after surgery. The changes in major curve, pelvic obliquity, thoracic kyphosis, lumbar lordosis, and T1-S1 and T1-T12 segments' length were assessed. All types of early and late complications were reported.

The mean age at surgery was 11.4 years and the mean follow-up was 3.4 year. The mean major curve improved from 65° to 38° postoperatively and 32° at last follow-up. Mean preoperative kyphosis was reduced from 41° (range, 11°–98°) to 30° (range, 11°–42°) after surgery ($p = 0.003$) and remained stable at 26° (range, 11°–42°) at last follow-up ($p = 0.137$). Lumbar lordosis increased after surgery with a mean preoperative lordosis of 34° (range, 8°–100°) to 41° (range, 18°–60°) postoperatively ($p = 0.031$) and 38° (range, 21°–54°) at last follow-up ($p = 0.108$). The mean pelvic obliquity improved from 20° (range, 1.3°–55°) to 8° (range, 0.2°–41°) postoperatively, and 6° (range, 1.2°–40°) at last follow-up. The mean growth per month of the T1-T12 segment was 0.8 mm and 1.5 mm for T1-S1 segment. Mean rod expansion in the concavity was 22.1 mm and 18.9 mm in the convexity at 2 years follow-up. The mean rod expansion per month was respectively 1.0 and 0.9 mm.

The mean hospital stay was 8.7 days (range, 5–22 days), and the mean intensive care unit stay was 3.8 days (range, 2–10 days). Four patients required blood transfusion. The mean preoperative body weight was 28.4 kg (range, 15–57 kg) and 34.7 kg (range, 18–61 kg) at latest follow-up.

Five cases (23%) had complications, necessitating an unplanned surgery. That consisted of acute surgical site infection in two cases (9%) treated by surgical debridement and antibiotics without implant removal, and a lack of rod expansion in three cases (14%) due to a conflict between a misplaced cross-link and a lumbar spinous process (Fig. 46.15 a–n). No cases had rod breakage or implant migration. No arthrodesis needed at last follow-up.

This first prospective series of patients showed that the minimally invasive bipolar technique using the OWSER for neuromuscular scoliosis provides good curve correction, while maintaining the spinal growth and reducing the complications rate secondary to avoidance of multiple surgeries.

46.4.6 Discussion

Many early surgical treatment options can be proposed for the treatment of progressive EOS [2]. The advantage of the traditional growing rods techniques is that they achieve effective curve correction and control of spinal deformities, but they require periodic rod lengthening. The guided growth techniques have the advantage of avoiding repeated surgery, but they allow a poor control of the deformity.

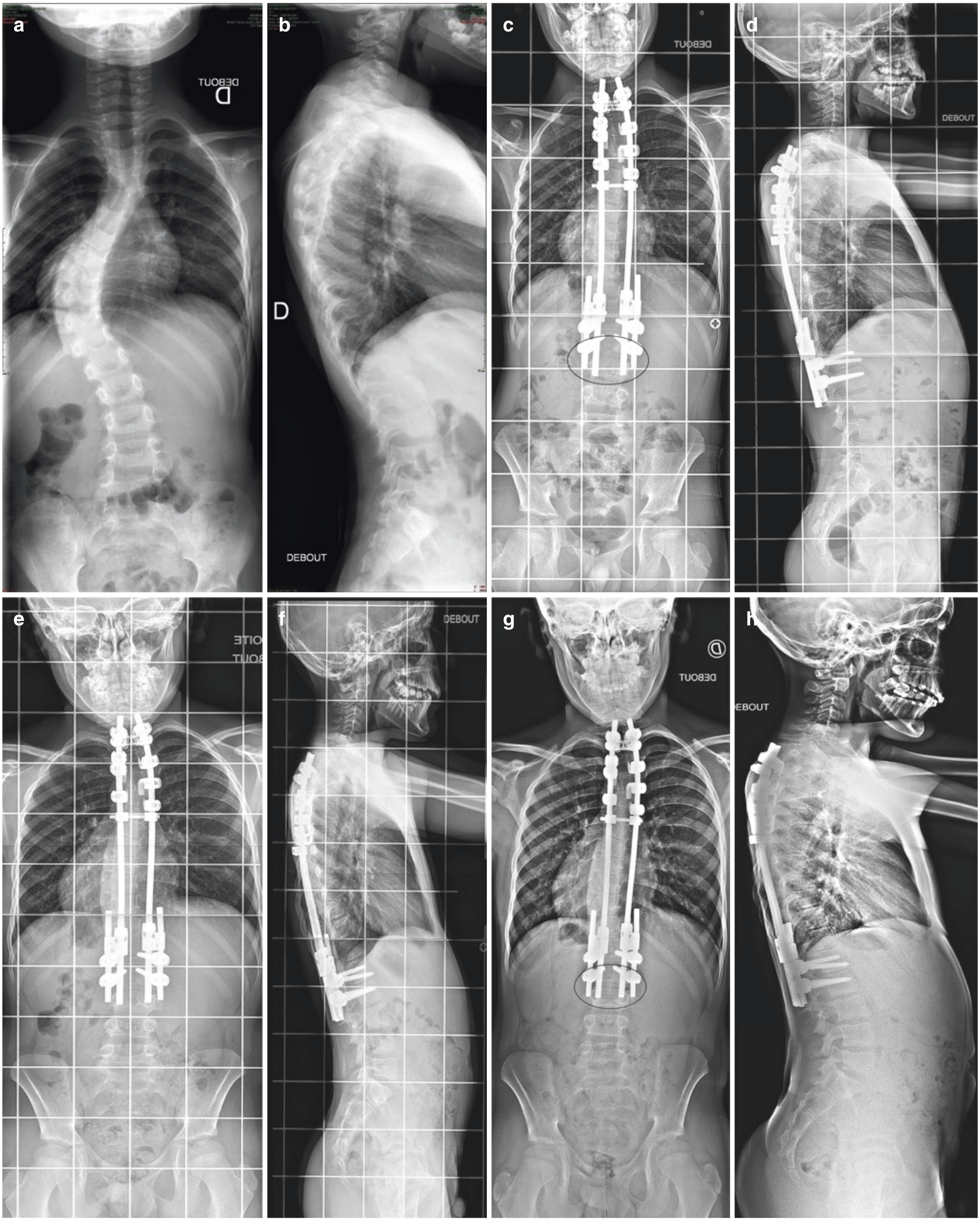


Fig 46.14 Case of an idiopathic EOS 7-year-old patient. Preoperative radiographs (**a**, **b**), postoperative (**c**, **d**), 2 years postoperative (**e**, **f**), 3 years postoperative (**g**, **h**), preoperative picture of the patient (**i**, **j**), and 3 years postoperative (**k**, **l**)

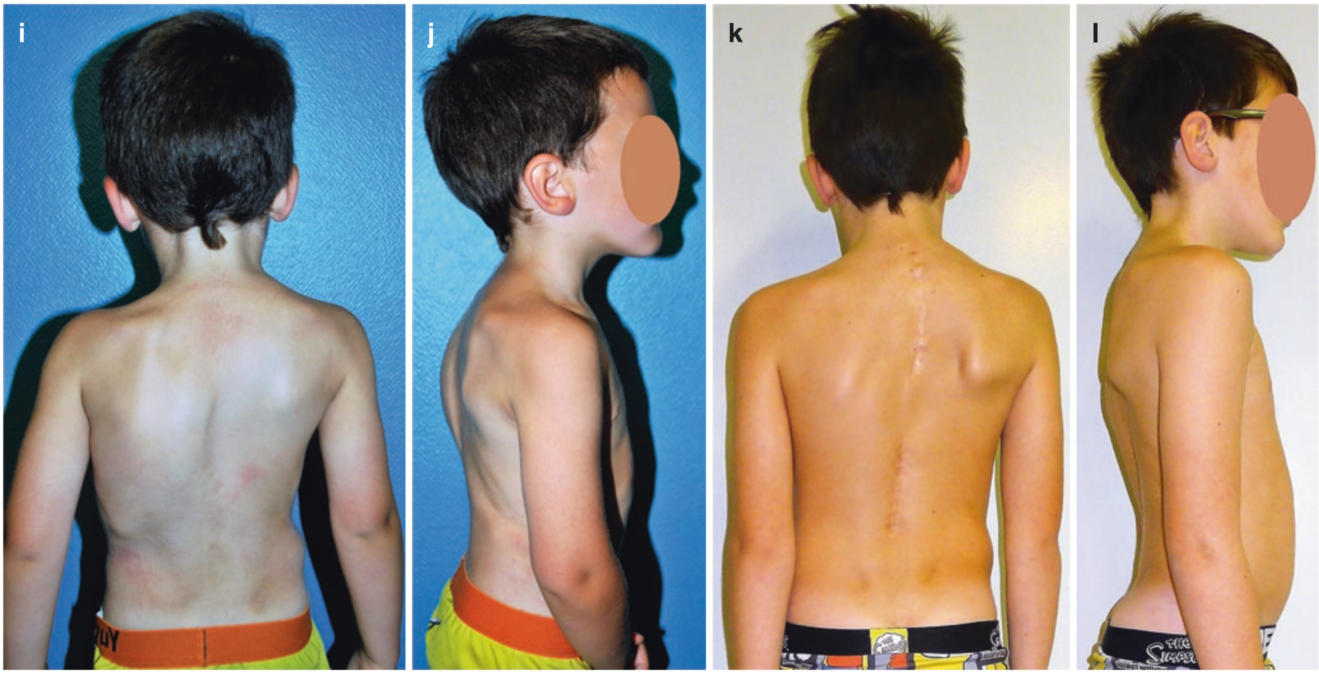


Fig. 46.14 (continued)

The self-expanding bipolar construct combines the advantages of TGR techniques and the guided growth techniques, while avoiding their disadvantages. It may be indicated for all types and etiologies of growing spine deformities even in hyperkyphotic cases.

The bipolar concept is based on an anti-spinal collapse principle that maintains spinal deformity correction and preserves the spinal growth [11]. To be fully effective, this concept mandates a permanent tension between the two ends of the construct. The required tension was initially provided by periodic rod lengthening procedures at the beginning of our experience, which is carried forward with the OWSER technique.

One of the most important advantages of OWSER is that its gradual and continuous elongation that happens when the local conditions are favorable, secondary to the viscoelastic relaxation of the soft tissues of the trunk. This progress comes in opposition to the surgical rod lengthening or other techniques using powered devices that the push is on the bone even though there is no natural extensibility of the local anatomic elements at that timeframe. The OWSER works at a near physiologic condition, preventing the stress on the spinal anchors thereby risk of migration. After surgery, spontaneously or in combination with external traction methods it allows a progressive correction of the residual spinal or pelvic deformities on an awake patient, avoiding the neurologic risks as seen in an immediate surgical correction under general anesthesia.

The combined use of external traction techniques increases the efficiency of the method secondary to the viscoelastic relaxation of the trunk over time, creating a favorable conditioning of the tissues for a gentle and gradual rod expansion. According to the type of spinal deformity, the traction forces may be applied symmetrically or asymmetrically in cases with lateral trunk imbalance or residual pelvic obliquity.

In addition, before its insertion, the OWSER may be contoured over its length to reduce the constraints on the anchors and the risk of rod breakage. It expands progressively in one way when it is possible to maintain a constant tension between the two ends of the construct. It offers the opportunity to improve the deformity correction after surgery, while theoretically mitigating the risk of early auto-fusion and the crankshaft phenomenon. It preserves or even stimulates the spinal growth secondary to the constant elongating forces.

Finally, this device was conceived to be solid enough to avoid the use of a postoperative brace, and to continue holding the spine until it becomes completely stiff over long term. In contrast, most of the other growing devices are fragile and provisory. The OWSER theoretically will avoid the need for final fusion procedure in most cases.

The minimally invasive approach minimizes the risk of early fibrosis and auto-fusion, allowing the sliding method to work until skeletal maturity. Over the long term, permanently leaving the rigid metallic rods in situ may lead to progressive stiffening of the spine, theoretically making it possible to avoid the need of an arthrodesis.

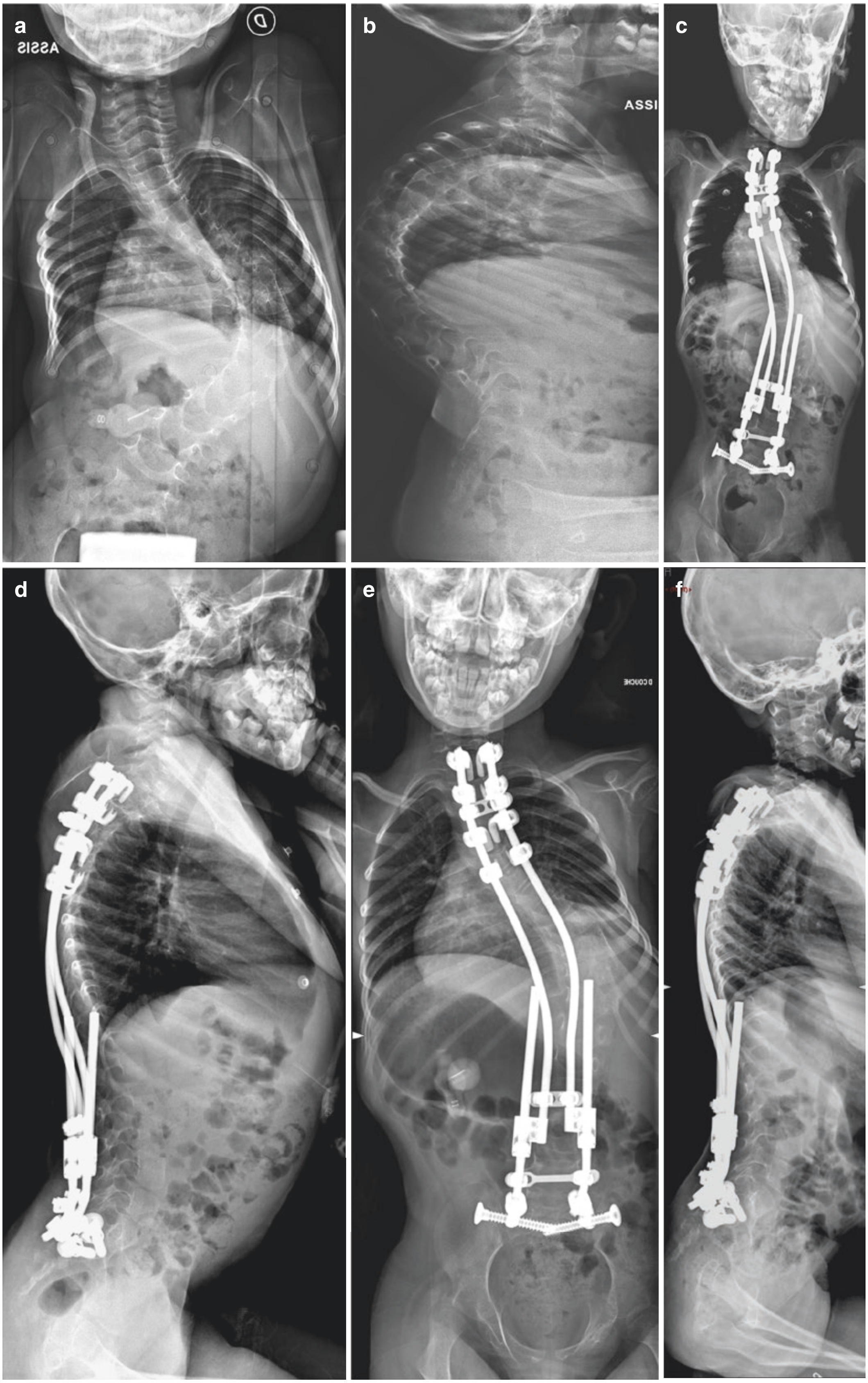


Fig 46.15 Case of spinal muscular atrophy in a 6-year-old patient. Preoperative radiographs (**a**, **b**), postoperative (**c**, **d**), 1 year postoperative (**e**, **f**), after cross-link removal (**g**, **h**), 2 years after cross-link removal (**i**, **j**), preoperative picture of the patient (**k**, **l**), and 3 years postoperative picture (**m**, **n**)

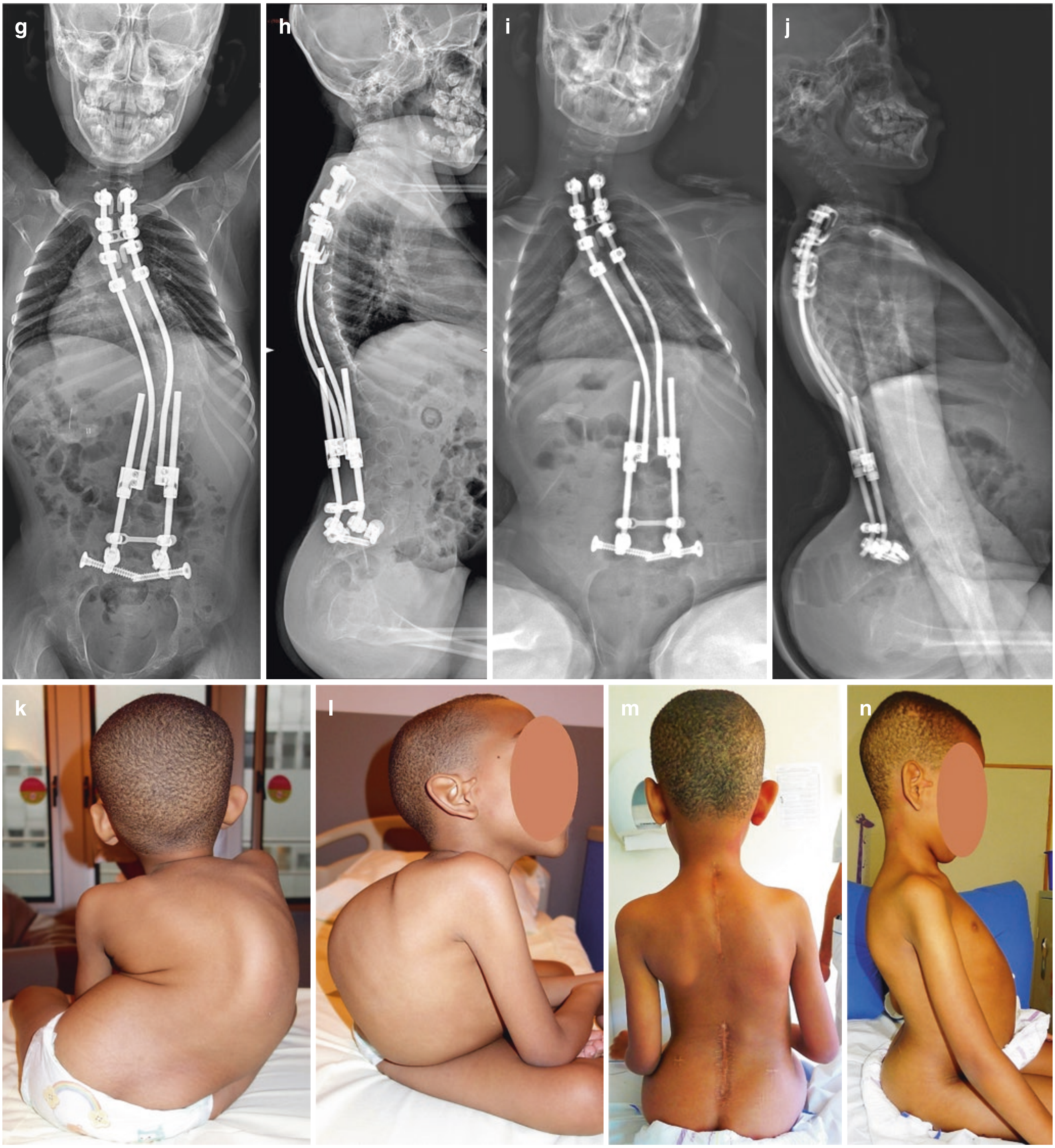


Fig. 46.15 (continued)

46.5 Spring Distraction System (SDS)

Our idea of something close to the ideal system would rely on a permanent internal distraction force. The key component of such a system is a (pre-tensioned) longitudinal helical spring that can deliver such a continuous distraction force. Figure 46.16 shows the basic set up of what we will refer to as the Spring Distraction System (SDS). The coil or helical spring is an ingenious human invention from the fifteenth century that is essential for many technological achievements where mechanics and energy transfer play a role [5, 50, 56–68]. Today, coil springs can be designed and manufactured relatively easily in a wide range of materials, dimensions, and forces. For the purpose of continuous dis-

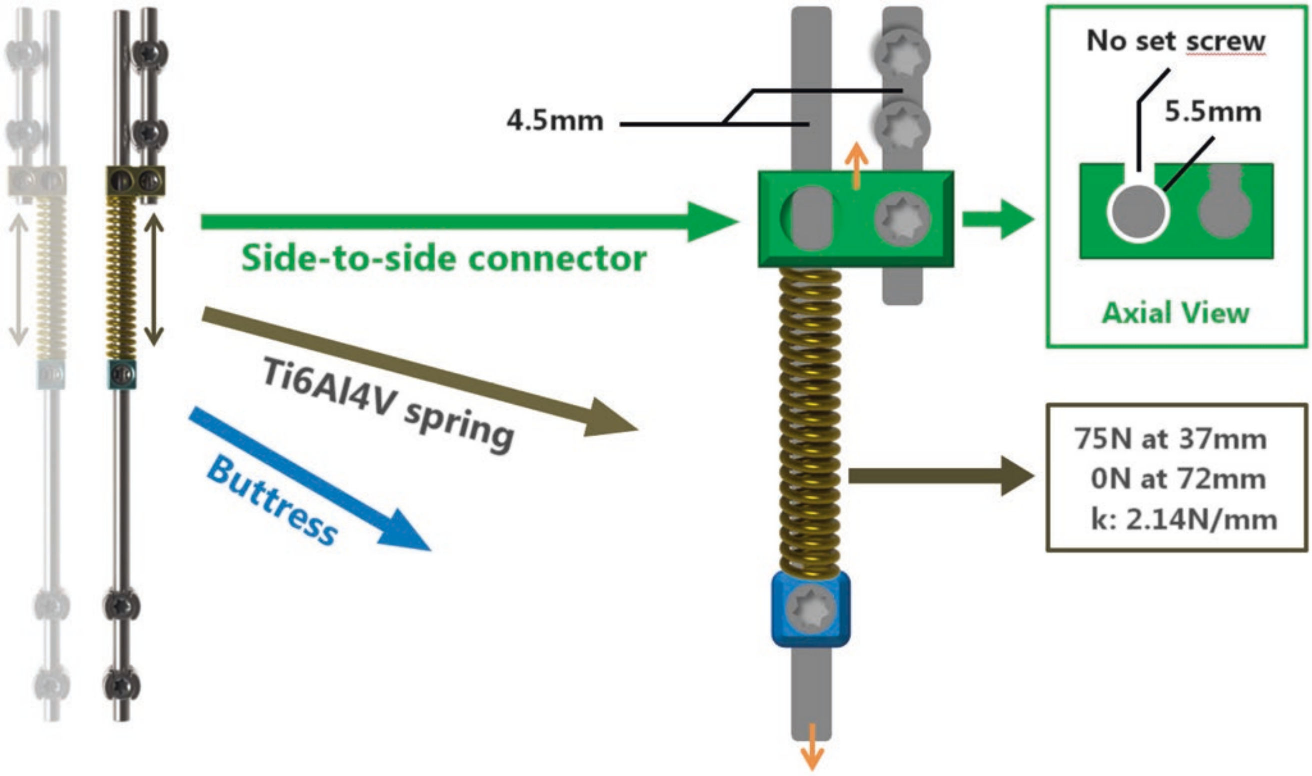


Fig 46.16 Spring distraction system (SDS) concept. Schematic representation of a 4.5 mm, 75 N bilateral version of the SDS. The anchor rod and sliding rod are connected by the side-to-side connector (*green*), which has one oversized hole that is intentionally left open on the side of the sliding rod. The spring is mounted on the sliding rod, compressed, and fixed with the buttress (*blue*). As the spring lengthens, it linearly loses its distraction force

traction of the pediatric spine, the selection of the right materials and dimensions is relatively easy. Obviously, the spring material should be biologically inert, e.g., medical grade titanium (Ti-6Al-4V). The spring should fit around standard rods and should allow for at least 5 cm of distraction (and thus growth). According to Hooke's law there is a linear (inverse) relation between distraction force (F) and length of the spring (L) described as $\Delta F = \Delta L \bullet k$, where k is the spring constant (in N/mm). This means that the longer the working length of the spring, the lower the decrease in force that is lost per unit length of distraction. Selecting the right force is a different matter, because little is known about force-effect relations in the growing spine. A pragmatic strategy is to assume that the maximal force that can be applied safely will be most effective. To determine this safety limit, we performed a literature review that included clinical data on forces applied during growing rod distractions, cadaver experiments, and finite element models [69–72]. Based on these studies, we concluded that a distraction force of 50–100 N on each side of the spine should be safe in children over 5 years of age, without compromised connective tissue conditions. This is well below the force that is generated with MCGR (250 N) or TGR (up to 500 N) [71–73].

46.5.1 Theoretical Advantages

Obviously, as we developed the SDS, uncertainties and concerns arose, like how tissue ingrowth into the spring would affect its function and how the body would react to the metal debris caused by the sliding connections. Nevertheless, if the spring maintains its function, many of the previously described principles for an improved growth-friendly system will be adopted:

- It actively stimulates "growth."
- It can address spinal penetration into the hemi-thorax if needed, due to its versatility.
- Distraction continues gradually over time. Once the spring loses its distractive force (dependent on the spring constant and length), it is very easy to re-tension through a small incision. Typically, this only becomes necessary after a distraction of 3–4 cm over the instrumented vertebrae, which corresponds to approximately 2–3 years of normal growth.
- The spine in between the proximal and distal anchors can remain untouched to minimize spontaneous fusion.

- The connections between the rods allow motion, especially in the axial plane, which may prevent auto-fusion.
- There is load sharing with the spinal segment that is bridged by the system.
- Due to the above load sharing, as well as the mobile connections, the implant is not stiff which mitigates some of the stresses that cause (fatigue) failure. A finite element analysis (FEA) demonstrated a reduction of von Mises stresses up to 20% [74].
- The springs can be mounted around rods that are contoured to any shape, most importantly (but not exclusively) to address the sagittal plane.
- Based on literature and our own observations, continuous, strategic forces allow further reduction of the curve after insertion [75–78].
- Posterior distraction inevitably promotes posterior lengthening which allows the spine to derotate back into the midline [61, 62].
- Any posterior instrumentation rod can be combined with well-designed coil springs.
- The rods including the spring and buttress can be inserted less invasively, like traditional growing rods.

46.5.2 First Application

The SDS was initially developed to treat an exceptional case of progressive congenital lordosis. This 5-year-old girl suffered from the spondylocarpotarsal synostosis syndrome and rapidly developed thoracic insufficiency due to failure of segmentation of the posterior elements. Because passive or static systems would likely fail for this specific condition, due to rapid reoccurrence of fusion, we came up with the idea of a spring-driven dynamic system. She was operated on in 2015 and the results were spectacular in terms of growth maintenance and further correction after implantation, without the need for further surgery (Fig. 46.17).

For this patient we designed a medical grade titanium spring together with engineers from the University of Twente (The Netherlands). It could fit around 4.5 mm rods, generate a maximal distraction force of 75 N, and expanded from 3.7 to 7.2 cm. Because of her small size, a longer spring was not an option. After insertion, she showed an unexpected fast length increase (2.5 cm in 1 year) and correction of the thoracic lordosis into a thoracic kyphosis. Therefore, we decided to exchange the proximal anchor rods after 1.5 years to accommodate another 3.5 cm of spinal growth; at the same time, we re-tensioned the springs. Currently she is growing steadily without sign of recurrence of the deformity.

46.5.3 Prospective Clinical Investigations

After this first patient, we treated several other unique cases which performed very well with the springs both as a hybrid (unilaterally) and bilaterally. Based on that experience and the observation that patients treated with the more traditional systems show disappointing results, we decided to investigate SDS as an alternative for conventional growing rod treatment [56, 63].

A prospective clinical cohort study started in 2016 and included all patients with an indication for growing rod treatment or revisions, except patients with connective tissue disease. We made that exception because in contrast to static distraction systems, SDS will continue to distract in case of ligamentous disruption. Figure 46.18 shows several configurations that are currently being used in the clinical study. We often combine concave distraction with a convex sliding rod (hybrid) that provides apical control [63, 79, 80]. When the dimensions of the patients allow for it, we now use two shorter springs in series or one long spring to allow for prolonged distraction and growth (the generated force on that side of the spine remains the same, but the spring constant k is halved). Currently, over 50 patients have been included with a mean follow-up of more than 1 year. Based on the 2-year results of the first 22 patients, we can make some general conclusions [81]:

- Initial curve correction is around 50%, which is comparable to other distraction systems.
- Curve behavior is very much dependent on the etiology of the scoliosis. Of note, patient with neuromuscular scoliosis, have a further correction on the first day post operatively as the tissue have had a chance to adapt. In contrast, rigid congenital curves tend to have further correction months and years later after implantation illustrating the true growth modulation of the spine [78]. For the idiopathic and revision cases the 75 N distraction force seems to be too low, since a slight increase in the curve over time is seen in many of these patients. Figure 46.19 shows one example of such a case.
- Maintenance of growth after insertion is good and maybe better then generally reported (T1-S1: 1.2 cm/year), and only slightly behind physiological growth (T1-S1: 1.4 cm/year) (Fig. 46.20).
- The failure rate in terms of unplanned reoperations within 2 years [82] is comparable to MCGR (30–50%), although fewer were due to material failure. Most failures could be attributed to inexperience with the system.
- The cases that we revised showed connective tissue in and around the springs that were normally expanded; apparently tissue ingrowth did not prevent distraction consider-

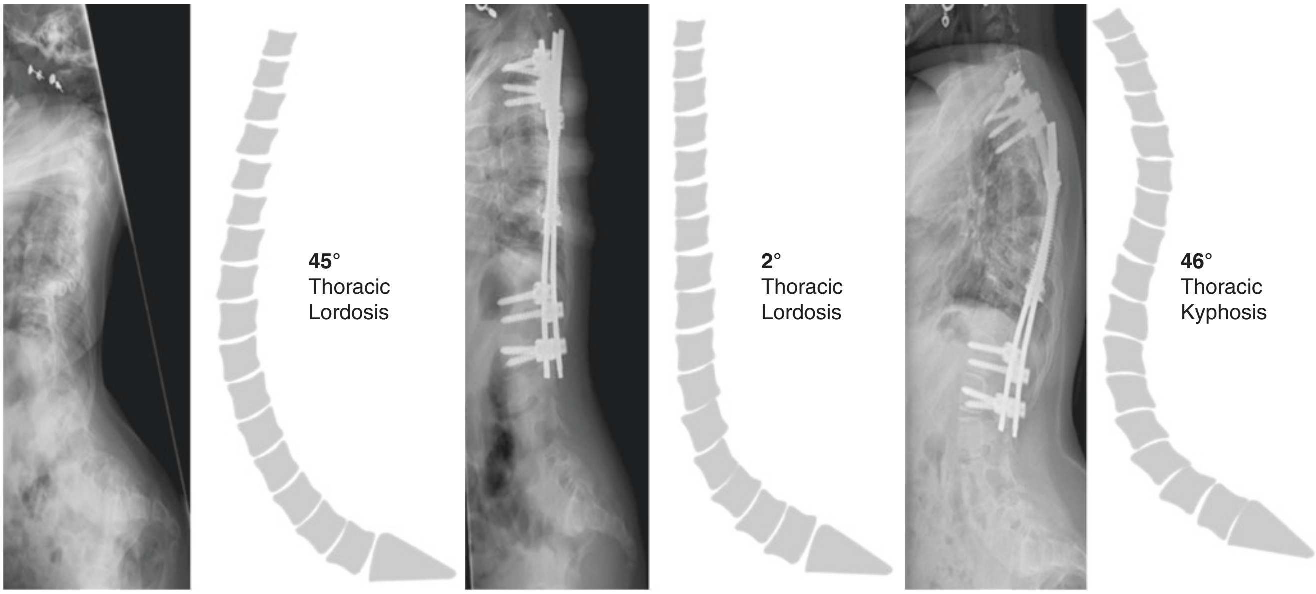
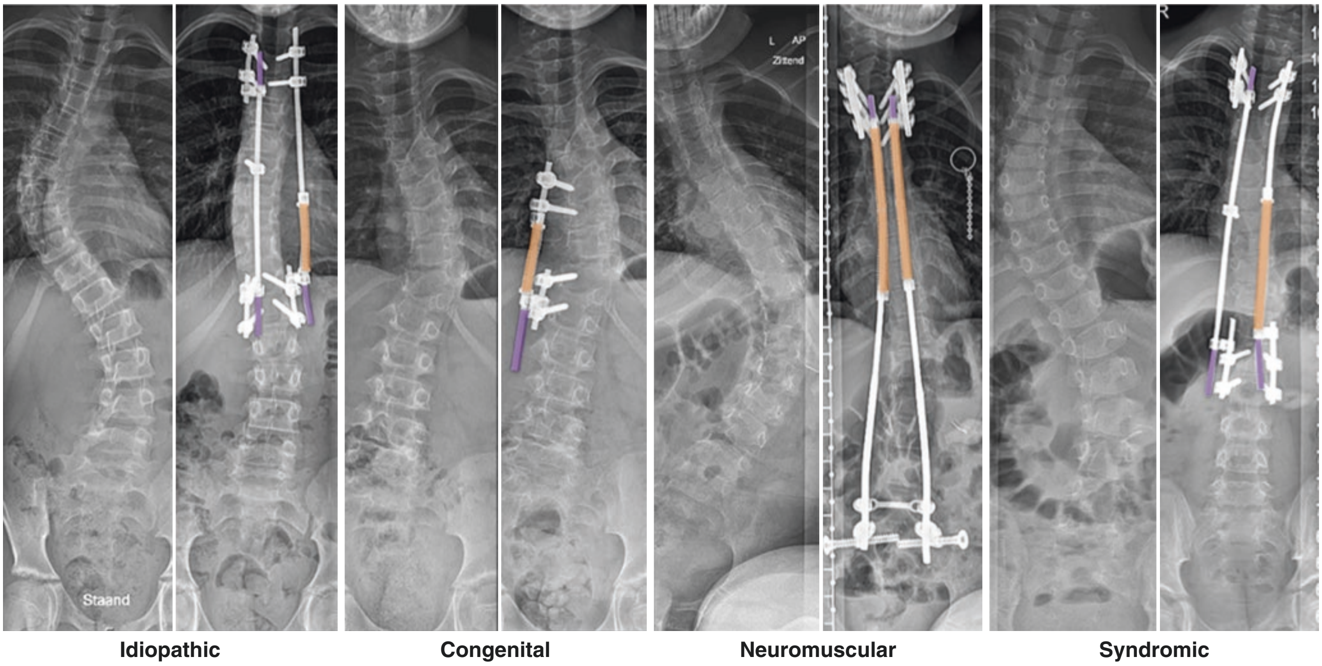


Fig 46.17 Sagittal profile development over 2.5 years in the first SDS patient (treated with bilateral 75 N springs)



Idiopathic Congenital Neuromuscular Syndromic

Fig 46.18 Different SDS configurations. The spring is highlighted in orange; the sliding parts of the rods in purple. For idiopathic cases, we used the hybrid approach with a concave SDS and a convex sliding rod that is fixed to the apex. Congenital deformities are implanted with either a unilateral SDS only or combined with a convex hemi-epiphysiodesis. In neuromuscular cases, two springs are typically implanted in parallel. This doubles the spring strength. As these patients tend to grow and correct further considerably during follow-up, two springs are used in line, which doubles the working length of the springs. Syndromic cases are also often treated with the hybrid configuration

ably. Histology confirmed normal scar tissue formation without adverse inflammatory reaction.

- Patient reported quality of life outcome measures EOSQ-24 [83] indicate the system is well tolerated and does not restrain the patient in functioning.

46.5.4 Surgical Indications

The optimal surgical indication still has to be determined and the technique will vary between different patients with different ages, curve etiologies, curve severities, and ambula-

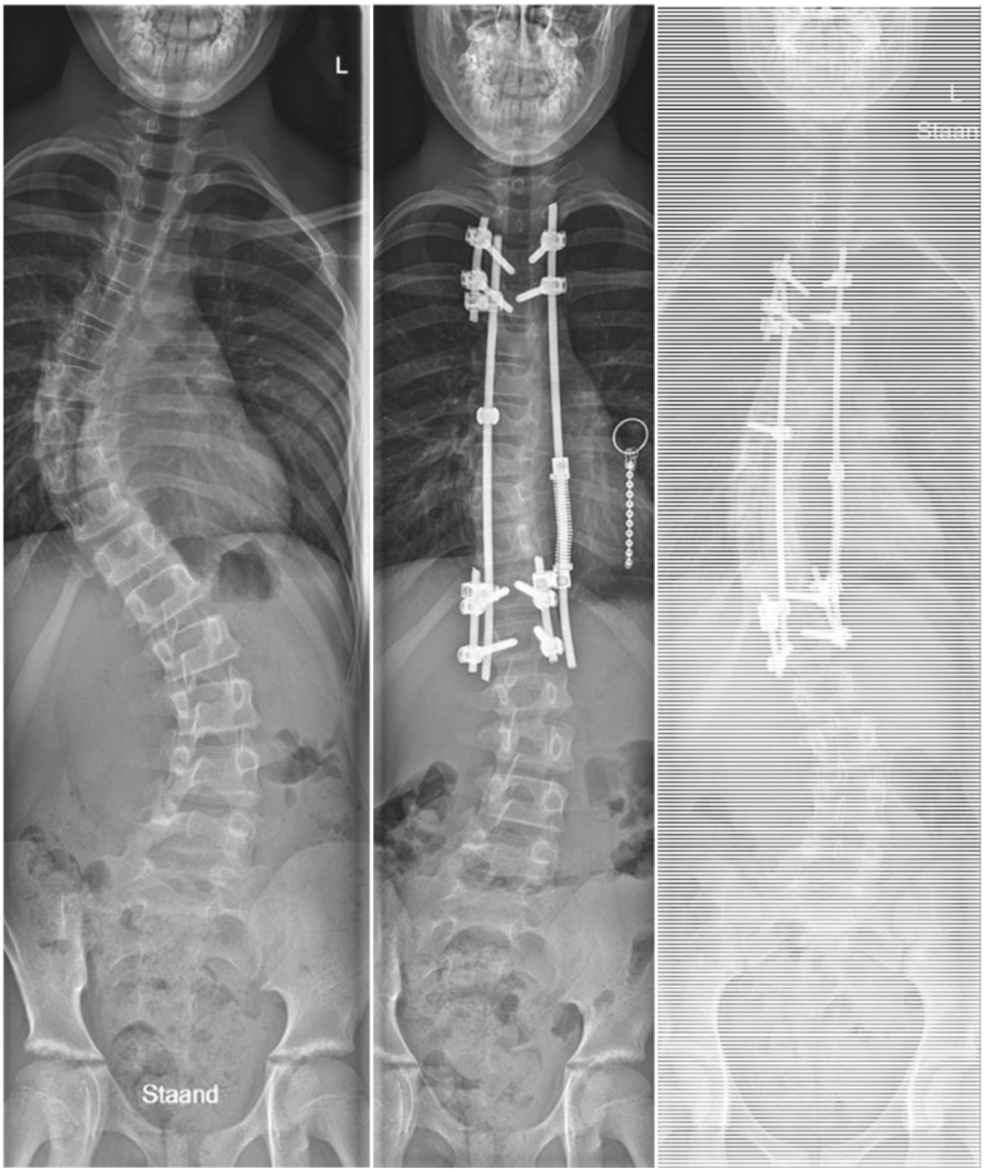


Fig 46.19 Two-year follow-up of idiopathic EOS treated with a single 75 N spring SDS hybrid. Balance and growth are maintained; however, increase in the curve could not be prevented

tory status. In general, we prefer to use the SDS when brace therapy has failed, when patients are over 5 years old, and weigh more than 20 kg. In smaller patients, the possible spring dimensions and therefore the distraction potential will be lower. In addition, in smaller patients there is less room to accommodate residual rod length.

46.5.4.1 Regulations for Use

SDS was initially developed for unique patients and was therefore considered a personalized or custom made implant. According to the European Medical Device Regulations (MDR Annex XIII) it is possible for such implants to deviate from the standard technical file, if this is sufficiently substantiated [84]. This means that the required technical file had to be made according to ISO 13485 standards, but without the regular performance and safety demands and review of a notified body. The department of medical technology and clinical physics of the hospital acted as the manufacturer of the springs and created a file dossier, consisting of: a thorough description of the spring (including specifications, manufacturing process, sample control report, and material inspection certificates); device classification; essential requirement checklist; risk analysis; user manual, processes of quality control; and post market surveillance and vigilance. For the prospective clinical trial, this file was used as the Investigational Medical Device Dossier (IMDD) that was reviewed by the Institutional Review Board (IRB). The clinical data and a far more extensive dossier will be used for further valorization of SDS. This is an exhaustive process which usually takes many years.

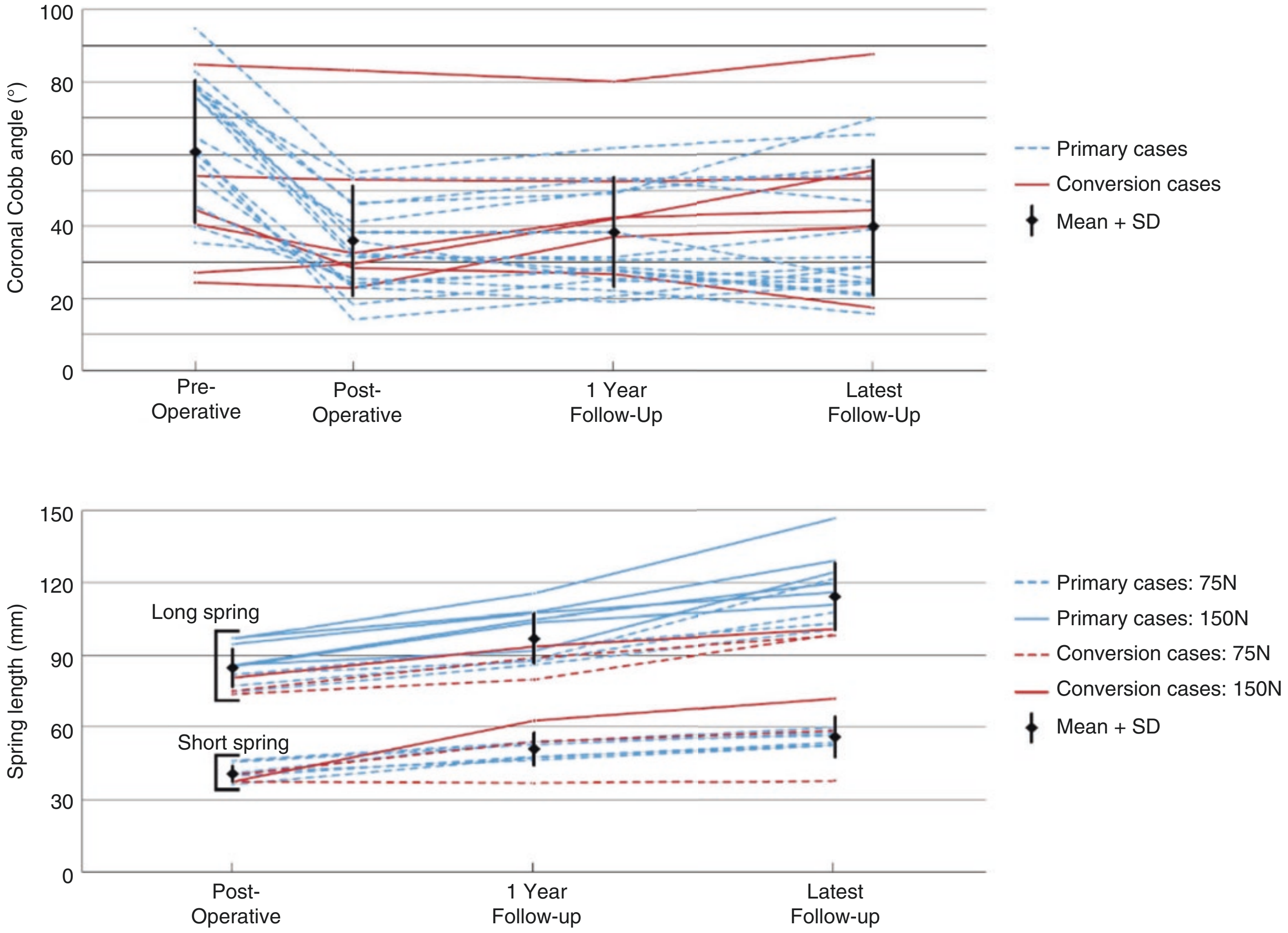


Fig 46.20 Two-year results of 22 SDS patients. *Top*: Coronal curve correction over time in patients treated with SDS as a first treatment (primary cases) and patients that were converted to SDS (conversion cases). *Bottom*: Spring length increases over time. Certain patients received unilateral spring distraction (75 N), while other patients received bilateral spring distraction (150 N). Some patients received a long spring (74 mm) and some patients received a short spring (37 mm). Since we fully compress the spring during surgery, the discrepancy in length at the postoperative radiograph is due to viscoelastic lengthening between surgery and the first standing radiograph

46.5.4.2 Anchor Positions and Configuration

The SDS is extremely versatile and can be used in any conceivable configuration, depending on patient needs and surgeon preference. After the indication for SDS has been made, the position of the proximal and distal anchors is chosen, which is according to the same considerations as in other growth-friendly techniques. If possible, only the primary curve is addressed with unilateral (concave) distraction and an additional convex sliding rod fixed to the apex. In neuromuscular patients, the curve often extends to the sacrum which is a reason to include the lumbosacral joint. As with all systems, great care must be exercised in fusing ambulatory patients to the pelvis.

46.5.4.3 Selection of Spring Size

The spring diameter depends on the posterior instrumentation size. Typically, we now use Ø4.5 mm rods in patients below 30 kg and Ø5.5 in patients above. Based on anticipated growth and available space, we determine the length of the spring and residual rod length. Preferably we use springs with at least 5 cm distraction potential.

46.5.4.4 Spring Force

Based on literature research and our observations, the maximal force that can be applied safely on the vertebral endplates is 0.4 MPa (0.4 N/mm^2) [69, 70]. Based on the upper thoracic vertebral body surface (300–500 mm^2) this corresponds to a distraction force of 120 N in children <5 years and 200 N >10 years. Currently, we have the option to choose between 50 N, 75 N, and 100 N springs. Using two springs in line does not change the distraction force (it doubles the working length and halves the spring constant k), but obviously, spring forces have to be summated when used bilaterally.

46.5.5 Surgical Technique

The anchors are installed via small midline incisions. Then, the distraction rod is carefully contoured and is mounted with a parallel connector fixed at least 5 cm from the end (this is the residual rod length for growth). This fixation is temporary and the parallel connector hole should be oversize (e.g., 5.5 mm for a 4.5 mm rod). The spring is slid over the rod from the other end against the connector and pretensioned between the connector and a buttress (Video 46.2). This "loaded" rod is inserted subfascially from the receiving anchor to the other (push) anchor. Then the parallel connector is mounted on the receiving anchor rod using an appropriate hole size and then fixed permanently. The other end of the rod is mounted to the push anchor and then the temporary fixation of the parallel connector to the sliding rod can be released. Surgery time for this procedure was 2–3 hours. In our cohort, patients are allowed unrestricted activity, but one can choose to limit this in order to allow fusion of the anchor vertebrae which may increase their pullout strength.

46.6 Conclusion

Passive-guided growth using MLT, OWSER, or SDS technique seems to be safe with a low complication rate. However, despite the fewer surgeries using this technique and fewer hardware failures, most patients grow across the instrumented segments. We recommend that patient selection and management of EOS, and particularly neuromuscular scoliosis, should be performed in a specialized center, where a high volume of procedures is carried out, in order to maintain safety and prevent significant complications. Having good medical support staff to deal with these high-risk patients is essential to achieve good results.

References

1. Campbell RM Jr, Smith MD, Mayes TC, Mangos JA, Willey-Courand DB, Kose N, et al. The effect of opening wedge thoracostomy on thoracic insufficiency syndrome associated with fused ribs and congenital scoliosis. J Bone Joint Surg Am. 2004;86-A(8):1659–74.
2. Cunningham ME, Frelinghuysen PH, Roh JS, Boachie-Adjei O, Green DW. Fusionless scoliosis surgery. Curr Opin Pediatr. 2005;17(1):48–53.
3. Yang JS, McElroy MJ, Akbarnia BA, Salari P, Oliveira D, Thompson GH, et al. Growing rods for spinal deformity: characterizing consensus and variation in current use. J Pediatr Orthop. 2010;30(3):264–70.
4. Tis JE, Karlin LI, Akbarnia BA, Blakemore LC, Thompson GH, McCarthy RE, et al. Early onset scoliosis: modern treatment and results. J Pediatr Orthop. 2012;32(7):647–57.
5. Bess S, Akbarnia BA, Thompson GH, Sponseller PD, Shah SA, El Sebaie H, et al. Complications of growing-rod treatment for early-onset scoliosis: analysis of one hundred and forty patients. J Bone Joint Surg Am. 2010;92(15):2533–43.
6. Thompson GH, Akbarnia BA, Kostial P, Poe-Kochert C, Armstrong DG, Roh J, et al. Comparison of single and dual growing rod techniques followed through definitive surgery: a preliminary study. Spine. 2005;30(18):2039–44.
7. Akbarnia BA, Marks DS, Boachie-Adjei O, Thompson AG, Asher MA. Dual growing rod technique for the treatment of progressive early-onset scoliosis: a multicenter study. Spine. 2005;30(17 Suppl):S46–57.
8. Akbarnia BA, Breakwell LM, Marks DS, McCarthy RE, Thompson AG, Canale SK, et al. Dual growing rod technique followed for three to eleven years until final fusion: the effect of frequency of lengthening. Spine. 2008;33(9):984–90.
9. Hell AK, Campbell RM, Hefti F. The vertical expandable prosthetic titanium rib implant for the treatment of thoracic insufficiency syndrome associated with congenital and neuromuscular scoliosis in young children. J Pediatr Orthop B. 2005;14(4):287–93.
10. Motoyama EK, Yang CI, Deeney VF. Thoracic malformation with early-onset scoliosis: effect of serial VEPTR expansion thoracoplasty on lung growth and function in children. Paediatr Respir Rev. 2009;10(1):12–7.
11. Ramirez N, Flynn JM, Serrano JA, Carlo S, Cornier AS. The Vertical Expandable Prosthetic Titanium Rib in the treatment of spinal deformity due to progressive early onset scoliosis. J Pediatr Orthop B. 2009;18(4):197–203.
12. Ouellet J. Surgical technique: modern Luque trolley, a self-growing rod technique. Clin Orthop Relat Res. 2011;469(5):1356–67.
13. McCarthy RE, Luhmann S, Lenke L, McCullough FL. The Shilla growth guidance technique for early-onset spinal deformities at 2-year follow-up: a preliminary report. J Pediatr Orthop. 2014;34(1):1–7.
14. Latalski M, Fatyga M, Koltowski K, Menartowicz P, Repko M, Filipovic M. Guided-growth implants in the treatment of early onset scoliosis. A pilot study. Ortop Traumatol Rehabil. 2013;15(1):23–9.
15. Sanders JO, D'Astous J, Fitzgerald M, Khoury JG, Kishan S, Sturm PF. Derotational casting for progressive infantile scoliosis. J Pediatr Orthop. 2009;29(6):581–7.
16. Fletcher ND, McClung A, Rathjen KE, Denning JR, Browne R, Johnston CE 3rd. Serial casting as a delay tactic in the treatment of moderate-to-severe early-onset scoliosis. J Pediatr Orthop. 2012;32(7):664–71.
17. Sankar WN, Skaggs DL, Yazici M, Johnston CE 2nd, Shah SA, Javidan P, et al. Lengthening of dual growing rods and the law of diminishing returns. Spine. 2011;36(10):806–9.
18. Pratt RK, Webb JK, Burwell RG, Cummings SL. Luque trolley and convex epiphysiodesis in the management of infantile and juvenile idiopathic scoliosis. Spine. 1999;24(15):1538–47.
19. Bono R, Inverno M, Botteon G, Iotti E, Estienne M, Berardinelli A, et al. Prospective study of gross motor development in children with SMA type II. Ital J Neurol Sci. 1995;16(4):223–30.
20. Mullender M, Blom N, De Kleuver M, Fock J, Hitters W, Horemans A, et al. A Dutch guideline for the treatment of scoliosis in neuromuscular disorders. Scoliosis. 2008;3:14.
21. Luqué ER, Cardoso A. Treatment of scoliosis without arthrodesis or external support: preliminary report. Orthop Trans. 1977;1:37–8.
22. Mardjetko SM, Hammerberg KW, Lubicky JP, Fister JS. The Luque trolley revisited. Review of nine cases requiring revision. Spine. 1992;17(5):582–9.
23. Navarro-Ramirez R, Rabau O, Teles A, Ge S, Shebreen AB, Saran N, et al. A novel growing rod technique to treat early-onset scoliosis (EOS): a step-by-step 2D. Neurosurg Focus Video. 2020;2(1):V9.

24. Dayer R, Ouellet JA, Saran N. Pelvic fixation for neuromuscular scoliosis deformity correction. Curr Rev Musculoskelet Med. 2012;5(2):91–101.
25. Akmese R, Kemal Us A. Comparison of subtransverse process wiring and sublaminar wiring in the treatment of idiopathic thoracic scoliosis. J Spinal Disord Tech. 2013;26:79–86.
26. Cervellati S, Bettini N, Bianco T, Parisini P. Neurological complications in segmental spinal instrumentation: analysis of 750 patients. Eur Spine J. 1996;5(3):161–6.
27. Geremia GK, Kim KS, Cerullo L, Calenoff L. Complications of sublaminar wiring. Surg Neurol. 1985;23(6):629–35.
28. Bhojraj SY, Varma RG, Nene AM, Mohite S. Spinal loop rectangle and sub laminar wiring as a technique for scoliosis correction. Indian J Orthop. 2010;44(1):50–6.
29. Benli IT, Buyukgullu O, Altug T, Akalin S, Kurtulus B, Aydin E. Augmentation of third generation instrumentation with sublaminar titanium wiring in late onset idiopathic scoliosis: the surgical results and analysis of trunk balance. Kobe J Med Sci. 2004;50(3–4):83–100.
30. Raney EM. Hooks and wires – tried and true plus how to: POSNA1-DayCourse, April 29, 2009. J Pediatr Orthop. 2011;31(1 Suppl):S81–7.
31. Canavese F, Dimeglio A, Volpatti D, Stebel M, Daures JP, Canavese B, et al. Dorsal arthrodesis of thoracic spine and effects on thorax growth in prepubertal New Zealand white rabbits. Spine. 2007;32(16):E443–50.
32. Wang CH, Finkel RS, Bertini ES, Schroth M, Simonds A, Wong B, et al. Consensus statement for standard of care in spinal muscular atrophy. J Child Neurol. 2007;22(8):1027–49.
33. Kotwicki T, Jozwiak M. Conservative management of neuromuscular scoliosis: personal experience and review of literature. Disabil Rehabil. 2008;30(10):792–8.
34. Mehdian H, Haddad S, Pasku D, Nasto LA. Mid-term results of a modified self-growing rod technique for the treatment of early-onset scoliosis. Bone Joint J. 2020;102-B(11):1560–6.
35. Karol LA, Johnston C, Mladenov K, Schochet P, Walters P, Browne RH. Pulmonary function following early thoracic fusion in non-neuromuscular scoliosis. J Bone Joint Surg Am. 2008;90:1272–81.
36. Skaggs DL, Akbarnia BA, Flynn JM, Myung KS, Sponseller PD, Vitale MG. A classification of growth friendly spine implant. J Pediatr Orthop. 2014;34(3):260–74.
37. Cahill PJ, Marvil S, Cuddihy L, Schutt C, Idema J, Clements DH, et al. Autofusion in the immature spine treated with growing rods. Spine. 2010;35:1199–203.
38. Miladi L, Journe A, Mousny M. H3S2 (3 hooks, 2 screws) construct: a simple growing rod technique for early onset scoliosis. Eur Spine J. 2013;22(Suppl 2):S96–105.
39. Miladi L, Mousny M. A novel technique for treatment of progressive scoliosis in young children using a 3-hook and 2-screw construct (H3S2) on a single sub-muscular growing rod: surgical technique. Eur Spine J. 2014;23(Suppl 4):S432–7.
40. Bouthors C, Gaume M, Glorion C, Miladi L. Outcomes at skeletal maturity of a growing rod technique. About a homogeneous series of 34 early-onset of scoliosis. Spine. 2019;44(23):1630–7.
41. Miladi L, Gaume M, Khouri N, Johnson M, Topouchian V, Glorion C. Minimally invasive surgery for neuromuscular scoliosis. Results and complications in a series of one hundred patients. Spine. 2018;43(16):968–75.
42. Harrington PR. Treatment of scoliosis. Correction and internal fixation by spine instrumentation. J Bone Joint Surg Am. 1962;44:591–610.
43. Moe JH, Kharrat K, Winter RB, Cummine JL. Harrington instrumentation without fusion plus external orthotic support for the treatment of difficult curvature problems in young children. Clin Orthop. 1984;185:35–45.
44. Andras LM, Joiner ERA, McCarthy RE, McCullough L, Luhmann SJ, Sponseller PD, et al. Growing rods versus Shilla growth guidance: better cobb angle correction and T1-S1 length increase but more surgeries. Spine Deform. 2015;3:246–52.
45. Cheung KM, Cheung JPY, Samartzis D, Mak KC, Wong YW, Cheung WY, et al. Magnetically controlled growing rods for severe spinal curvature in young children: a prospective case series. Lancet. 2012;379(9830):1967–74.
46. Teoh KH, Winson DMG, James SH, Jones A, Howes J, Davies PR, et al. Do magnetic growing rods have lower complication rates compared with conventional growing rods? Spine J. 2016;16:S40–4.
47. Teoh KH, von Ruhland C, Evans SL, James SH, Jones A, Howes J, et al. Metallosis following implantation of magnetically controlled growing rods in the treatment of scoliosis: a case series. Bone Joint J. 2016;98-B(12):1662–7.
48. Choi E, Yazsay B, Mundis G, Hosseini P, Pawelek J, Alanay A, et al. Implant complications after magnetically controlled growing rods for early onset scoliosis: a multicenter retrospective review. J Pediatr Orthop. 2017;37:e588–92.
49. Kwan KYH, Alanay A, Yazici M, Demirkian G, Helenius I, Nnadi C, et al. Unplanned reoperations in magnetically controlled growing rod surgery for early onset scoliosis with a minimum of two-year follow-up. Spine. 2017;42:E1410–4.
50. Thakar C, Kieser DC, Mardare M, Haleem S, Fairbank J, Nnadi C. Systematic review of the complications associated with magnetically controlled growing rods for the treatment of early onset scoliosis. Eur Spine J. 2018;27:2061–71.
51. Miladi L, Dubousset J. A new type of growing rod. Preliminary results. J Child Orthop. 2009;3:149–50.
52. Miladi L, Dubousset JF. Magnetic powered extensible rod for thorax or spine: the "Phenix M" rod. In: Akbarnia BA, et al., editors. The growing spine. Berlin/Heidelberg: Springer; 2010. https://doi.org/10.1007/978-3-540-85207-0_39c.
53. Gaume M, Persohn S, Vergari C, Glorion C, Skalli W, Miladi L. Biomechanical cadaver study of proximal fixation in a minimally invasive bipolar construct. Spine Deform. 2020;8:33–8.
54. Miladi LT, Ghanem IB, Draoui MM, Zeller RD, Dubousset JF. Iliosacral screw fixation for pelvic obliquity in neuromuscular scoliosis. A long-term follow-up study. Spine. 1997;22:1722.
55. Miladi L, Khouri N, Pradon J, Elie C, Treluyer JM. One way self expanding rod for early onset scoliosis: early results of a clinical trial of 20 patients. Eur Spine J. 2021;30:749–58.
56. Wijdicks SP, Tromp IN, Yazici M, Kempen DH, Castelein RM, Kruyt MC. A comparison of growth among growth-friendly systems for scoliosis: a systematic review. Spine J. 2019;19(5):789–99.
57. Dimeglio A. Growth in pediatric orthopaedics. J Pediatr Orthop. 2001;21(4):549–55.
58. Dimeglio A, Canavese F. The growing spine: how spinal deformities influence normal spine and thoracic cage growth. Eur Spine J. 2012;21(1):64–70.
59. Heemskerk J, Kempen D, Altena M, Wijdicks S, Castelein R. Spinal growth in patients with juvenile idiopathic scoliosis treated with Boston Brace. Spine Deform. 2016;4(6):454–5.
60. Katz DE, Herring JA, Browne RH, Kelly DM, Birch JG. Brace wear control of curve progression in adolescent idiopathic scoliosis. J Bone Joint Surg Am. 2010;92(6):1343–52.
61. Brink RC, Schlösser TP, Colo D, Vavruch L, van Stralen M, Vincken KL, et al. Anterior spinal overgrowth is the result of the scoliotic mechanism and is located in the disc. Spine. 2017;42(11):818–22.
62. Schlösser TP, van Stralen M, Brink RC, Chu WC, Lam T-P, Vincken KL, et al. Three-dimensional characterization of torsion and asymmetry of the intervertebral discs versus vertebral bodies in adolescent idiopathic scoliosis. Spine. 2014;39(19):E1159–E66.
63. Skov ST, Wijdicks SP, Bünger C, Castelein RM, Li H, Kruyt MC. Treatment of early-onset scoliosis with a hybrid of a concave magnetic driver (magnetic controlled growth rod) and a contralat-

eral passive sliding rod construct with apical control: preliminary report on 17 cases. Spine J. 2018;18(1):122–9.

64. Aslan C, Olgun ZD, Ayik G, Karaokur R, Ozusta S, Demirkiran GH, et al. Does decreased surgical stress really improve the psychosocial health of early-onset scoliosis patients?: a comparison of traditional growing rods and magnetically-controlled growing rods patients reveals disappointing results. Spine. 2019;44(11):E656–E63.
65. Doany ME, Olgun ZD, Kinikli GI, Bekmez S, Kocyigit A, Demirkiran G, et al. Health-related quality of life in early-onset scoliosis patients treated surgically. Spine. 2018;43(2):148–53.
66. Bauer JM, Yorgova P, Neiss G, Rogers K, Sturm PF, Sponseller PD, et al. Early onset scoliosis: is there an improvement in quality of life with conversion from traditional growing rods to magnetically controlled growing rods? J Pediatr Orthop. 2019;39(4):e284–e8.
67. Cain T. Spring design and manufacture. Poole, Dorset, UK: Special Interest Model Books. Trans-Atlantic Publications, Inc. 1988.
68. Spring (device): Wikipedia; 2020 [updated 24-02-2020; cited 13-03-2020]. Available from: https://en.wikipedia.org/wiki/Spring_(device).
69. Luck JF, Nightingale RW, Song Y, Kait JR, Loyd AM, Myers BS, et al. Tensile failure properties of the perinatal, neonatal, and pediatric cadaveric cervical spine. Spine (Phila Pa 1976). 2013;38(1):E1–12. Epub 2012/10/30. https://doi.org/10.1097/BRS.0b013e3182793873.
70. Ouyang J, Zhu Q, Zhao W, Xu Y, Chen W, Zhong S. Biomechanical assessment of the pediatric cervical spine under bending and tensile loading. Spine (Phila Pa 1976). 2005;30(24):E716–23. Epub 2005/12/24. https://doi.org/10.1097/01.brs.0000192280.53831.70.
71. Noordeen HM, Shah SA, Elsebaie HB, Garrido E, Farooq N, Al MM. In vivo distraction force and length measurements of growing rods: which factors influence the ability to lengthen? Spine. 2011;36(26):2299–303.
72. Agarwal A, Agarwal AK, Jayaswal A, Goel V. Smaller interval distractions may reduce chances of growth rod breakage without impeding desired spinal growth: a finite element study. Spine Deform. 2014;2(6):430–6.
73. Poon S, Spencer HT, Fayssoux RS, Sever R, Cho RH. Maximal force generated by magnetically controlled growing rods decreases with rod lengthening. Spine Deform. 2018;6(6):787–90. Epub 2018/10/24. https://doi.org/10.1016/j.jspd.2018.03.009.
74. Lemans J, Kodigudla M, Kelkar A, Kruyt M, Goel V, Agarwal A. Spring distraction system for early onset scoliosis provides continuous distraction without a potential increase in rod fractures, compared to traditional growing rods. Spine Deform. 2018;6(6):819–20.
75. Stokes IA, Mente PL, Iatridis JC, Farnum CE, Aronsson DD. Enlargement of growth plate chondrocytes modulated by sustained mechanical loading. J Bone Joint Surg Am. 2002;84(10):1842–8.
76. Özkaya N, Nordin M. Mechanical properties of biological tissues. In: Fundamentals of biomechanics. New York: Springer; 1999. p. 195–218.
77. Mehta M. Growth as a corrective force in the early treatment of progressive infantile scoliosis. J Bone Joint Surg Brit. 2005;87(9):1237–47.
78. Wijdicks SPJ, Lemans JVC, Verkerke GJ, Noordmans HJ, Castelein RM, Kruyt MC. The potential of spring distraction to dynamically correct complex spinal deformities in the growing child. Eur Spine J. 2021;30(3):714–23.
79. Johnston CE. Apical control in the management of severe early-onset scoliosis. In: The growing spine. Berlin: Springer; 2016. p. 783–91.
80. Dubousset J, Wicart P, Pomero V, Barois A, Estournet B. Spinal penetration index: new three-dimensional quantified reference for lordoscoliosis and other spinal deformities. J Orthop Sci. 2003;8(1):41–9.
81. Lemans JVC, Wijdicks SPJ, Castelein RM, Kruyt MC. Spring distraction system for dynamic growth guidance of early onset scoliosis: two-year prospective follow-up of 24 patients. Spine J. 2021;21(4):671–81.
82. Smith JT, Johnston C, Skaggs D, Flynn J, Vitale M. A new classification system to report complications in growing spine surgery: a multicenter consensus study. J Pediatr Orthop. 2015;35(8):798–803.
83. Wijdicks SP, Dompeling SD, de Reuver S, Kempen DH, Castelein RM, Kruyt MC. Reliability and validity of the adapted Dutch version of the early-onset scoliosis-24-item questionnaire (EOSQ-24). Spine. 2019;44(16):E965–E73.
84. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, (2017).