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One-Way Self-Expanding Rod in Neuromuscular Scoliosis

Preliminary Results of a Prospective Series of 21 Patients

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Background: Fusionless techniques for the treatment of neuromuscular early-onset scoliosis (EOS) are increasingly used to preserve spinal and thoracic growth and to postpone posterior spinal fusion (PSF). These techniques have greatly improved thanks to magnetically controlled growing rods, which allow the avoidance of repeated surgery. However, the surgery-related complication rate remains high. The objective of the current study was to report the preliminary outcomes of 21 patients with neuromuscular EOS who were treated with a 1-way self-expanding rod (OWSER). This device was designed to avoid repeated surgery and preserve spinal and thoracic growth thanks to its free rod sliding.

Methods: Patients with neuromuscular EOS who underwent OWSER fixation were prospectively reviewed; follow-up was a minimum of 3 years. The instrumentation relies on a bipolar construct from T1 to the sacrum, with proximal fixation by double thoracic hook-claws and distal fixation by iliosacral screws. The device comprises a rod with a notched part sliding in 1 direction inside a domino. Changes in Cobb angle, pelvic obliquity, thoracic kyphosis, lumbar lordosis, T1-S1 and T1-T12 length, space available for the lung, and chest width were assessed. Complications were reviewed.

Results: The mean age at surgery was 10.5 years. The mean follow-up was 3.9 years. The mean pelvic obliquity improved from 20° preoperatively to 8° postoperatively and to 6° at the latest follow-up. The mean Cobb angle improved from 66° preoperatively to 38° postoperatively and to 32° at the latest follow-up. The mean preoperative kyphosis was reduced from 41° to 26° at the latest follow-up (p = 0.14). The mean lordosis was 34° preoperatively and 38° at the latest follow-up. The mean growth per month was 0.8 mm for the T1-T12 segment and 1.5 mm for T1-S1. The global complication rate was 38% (2 surgical site infections, 3 cases of lack of rod expansion, 1 case of pyelonephritis, and 2 central venous catheter-related infections). No PSF had been performed at the latest follow-up.

Conclusions: Use of the OWSER with a minimally invasive bipolar technique for neuromuscular EOS provided satisfactory correction of spinal and pelvic deformities at 3 years of follow-up. A longer follow-up is required.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Early-onset scoliosis (EOS) is defined by the Scoliosis Research Society as a deformity of the spine that occurs in individuals ≤9 years of age[1]. In neuromuscular cases, the deformity usually worsens over time despite nonoperative treatment, as a result of muscle weakness, dystonia, and a lack of trunk balance. Early spinal fusion is not a strategy to control severe neuromuscular EOS because of its adverse effects on spinal growth, with concomitant consequences on lung development, and a high complication rate. In particular, surgical site infection, severe blood loss, transfusion, and admission to an intensive care unit are common[2,3].

Fusionless techniques for the surgical treatment of progressive EOS are increasingly used to preserve spinal and thoracic growth and to postpone posterior spinal fusion (PSF). In treating neuromuscular scoliosis, the use of traditional growing rods (TGRs), a vertical expandable prosthetic titanium rib (VEPTR), and modified Luque trolley techniques are common[4]. Fusionless techniques have improved further with the use of magnetically controlled growing rods (MCGRs), offering the avoidance of repeated surgery. However, the perfect way of treating EOS has yet to be achieved, and MCGRs still have a high rate of complications. Thakar et al.[5] reported an average 44% surgery-related complication rate and a 33% rate of revisions. Complications commonly are related to anchor migration due to the inability to contour the MCGR through its central actuator, its

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJSOA/A351).

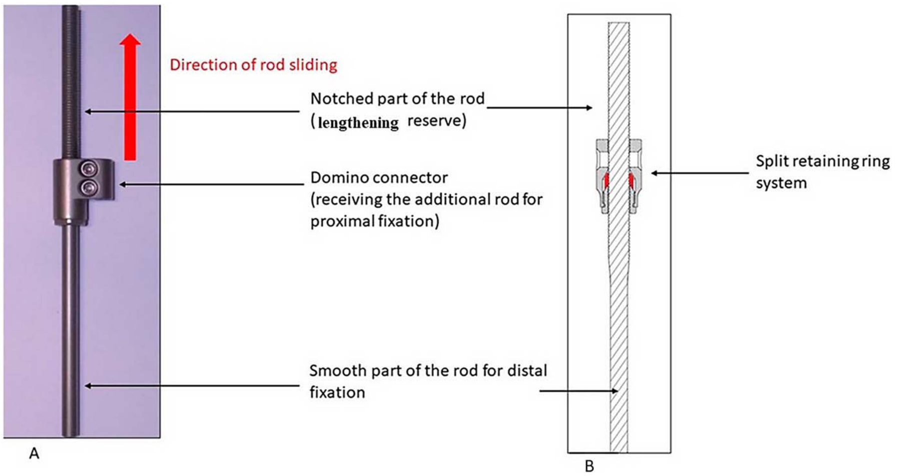

Fig. 1

Fig. 1-A The 1-way self-expanding rod. **Fig. 1-B** Cross-sectional view of the domino showing the split retaining ring system (in red).

failure to lengthen, and rod breakage. More recently, Rushton et al.[6] reported on a multicenter study involving the largest cohort managed: 55 MCGR constructs (99 rods) in a series of 53 patients. Rods were rarely fully lengthened because of mechanism failure after around 3 years of follow-up.

In the current study, we present a review of our experience with an alternative growing-rod construct in the management of neuromuscular EOS. The purpose of this prospective study was to report the preliminary clinical and radiographic outcomes as well as complications of 21 patients with neuromuscular EOS treated with a new 1-way self-expanding rod (OWSER).

Materials and Methods

Study Design

Twenty-one consecutive patients with neuromuscular EOS were prospectively reviewed. They underwent surgery between January 2016 and October 2017 in our orthopaedic department, which is the national reference center for neuromuscular scoliosis. The study was approved by the appropriate ethics committee (CPP, ID-EUDRACT #2014 A010043 44). Informed consent was obtained from the parents/guardians of all participants.

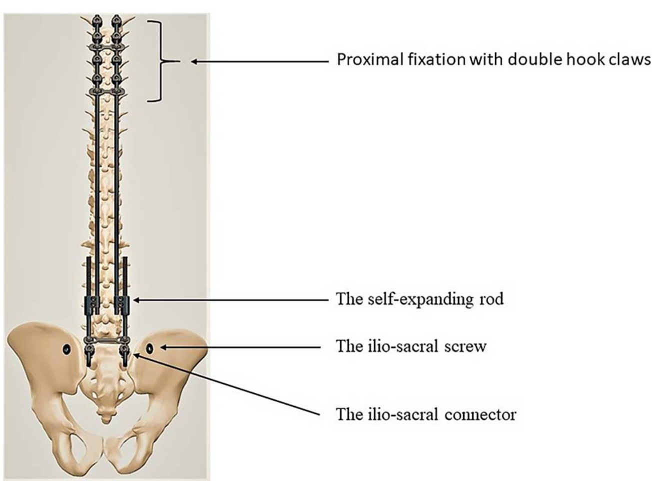

Fig. 2

The bipolar construct anchored proximally by double hook-claws and distally by iliosacral screws.

All patients were assessed with full-spine anteroposterior and lateral radiographs in a sitting position every 6 months.

For each patient, the following radiographic parameters were recorded before surgery, immediately after surgery, and at 2 and 3 years of follow-up using previously described methods[7-10]: the Cobb angle of the major curve, pelvic obliquity, T1-T12 and T1-S1 spinal length, T1-T12 thoracic kyphosis, L1-S1 lumbar lordosis, space available for the lung, and maximum inner chest-width parameters.

Infections and mechanical, neurological, and medical complications were reported. Complications that occurred intraoperatively, during the hospital stay, or within 3 months after the index surgery were considered perioperative complications. Complications that occurred at 3 months or later were considered postoperative complications.

Description of the New OWSER

The new OWSER is CE (conformité Européenne)-marked, is registered as a NEMOST rod, and is manufactured by EUROS. It has 3 components: (1) a titanium alloy rod with a 300-mm-long smooth section measuring 5.5 mm in diameter and a notched section 6.35 mm in diameter corresponding to the lengthening reserve, available in 2 sizes (50 or 80 mm); (2) a domino connector mounted on the notched part of the rod; and (3) an additional standard smooth rod introduced in a channel of the domino connector for proximal fixation to the spine (Fig. 1-A).

For constructs extended to the pelvis, the smooth rod is cut, contoured, and fixed to the iliosacral connector. The notched rod is positioned upward and laterally (Fig. 2). This portion must remain straight to allow proper rod sliding. However, it does not prevent the bending of the smooth part of the rod or additional rods as expected, especially in the sagittal plane.

Fig. 3
Active axial traction performed on a patient who is awake.

The domino connector slides gradually and passively (1-mm steps) along the notched part of the rod in a 1-way direction allowed by a split retaining ring system that prevents the domino from moving back in the other direction (Fig. 1-B).

The device expands spontaneously and progressively (1 mm per step), following the natural spinal growth and daily activity according to the physiological movements of the patient. In a case of severe deformity, the expansion of the rod can be helped by axial traction of the trunk (Fig. 3), allowing for the avoidance of repetitive surgical rod-lengthening[11]. The frequency of the sessions is decided by the surgeon, from daily to once a month, depending on the patient's condition.

Operative Technique

The original bipolar technique with minimally invasive fusionless instrumentation for neuromuscular scoliosis was described in 2018[12]. All patients are operated on under somatosensory and motor potential monitoring on a spinal surgery table. The head is fixed with a Mayfield skull clamp, and distal traction (10% to 15% of body weight) is applied with boots on the legs. In case of pelvic obliquity, the traction is asymmetric.

The construct extends from T1 to the sacrum and is proximally anchored to the 5 first thoracic vertebrae by double hook-claws on each side[13] and distally, by iliosacral screws[14,15].

The iliosacral screws are inserted percutaneously from the posterior part of the iliac bone to the S1 body, in an oblique posterior-to-anterior direction, avoiding the spinal canal. A short midline lumbopelvic incision is performed, followed by a paramedian transmuscular approach to gain access to the lumbosacral joint (Wiltse approach). The posterior sacral cortex is exposed from the L5-S1 joint medially to the sacral ala laterally and the first posterior sacral foramina distally. A small trough is created laterally to the L5-S1 joint and proximal to the first posterior sacral foramina using a dedicated osteotome. The iliosacral connector is fixed by a connector holder and introduced inside the trough. A specific guide is then attached to the connector holder to allow an automatically guided screw insertion. The guide determines the entry point, the trajectory, and the screw length. After guide removal, a 7-mm cannulated screw is inserted percutaneously through the iliosacral connector, from the posterior part of the iliac wing to the sacrum, in an oblique posterior-to-anterior direction to pass in front of the spinal canal and to reach the S1 body. Next, the screw is locked inside the iliosacral connector by a locking screw.

The rods are inserted in the subfascial plane between the 2 incisions. After rod insertion, a moderate concave distraction is performed before implant locking. The correction is mainly obtained as a result of intraoperative traction on a relaxed patient. The sagittal-plane correction is obtained as a result of meticulous 3-dimensional rod-contouring before rod insertion and an additional in situ rod-bending if necessary. The long proximal rods are connected to the OWSER fixed to the pelvis to build a free-sliding frame construct. Two proximal crosslinks and 1 distal crosslink are added to increase the stability of the construct (Fig. 2).

The average operative time was 2 hours and 46 minutes (range, 2 hours and 33 minutes to 3 hours and 39 minutes).

Statistical Analysis

Two-tailed paired Student t tests were used to evaluate the significance of changes in variables from preoperatively to immediately postoperatively and to the final follow-up. Significance was defined as $p \leq 0.05$. Data were analyzed using SPSS Statistics software (version 23.0; IBM).

Source of Funding

No funding was received for this study.

TABLE I Baseline Data of All Patients

No. of patients	21
Sex *(no.)*	11 M/10 F
Age at surgery * *(yr)*	10.5 (6-13)
Follow-up* *(yr)*	3.9 (3.3-4.0)
Body weight* *(kg)*	
Preoperative	28.4 (15-57)
Last follow-up	34.7 (18-61)
Diagnosis *(no.)*	
Cerebral palsy	11
Spinal muscular atrophy	5
Muscular dystrophy	3
Other neuromuscular disorders	2
Motor function status *(no.)*	
GMFCS 4†	3
GMFCS 5†	18
Curve pattern *(no.)*	
Right thoracolumbar	8
Left thoracolumbar	8
Right thoracic	3
Left thoracic	1
Left lumbar	1
Preoperative Risser score *(no.)*	
0	14
1	7
Hospital stay* *(days)*	8.7 (5-22)
Intensive care unit stay* *(days)*	3.8 (2-10)
Blood transfusion *(no.)*	3

*The values are given as the mean, with the range in parentheses.
†GMFCS = Gross Motor Function Classification System.

Results

Clinical Outcomes

Baseline data of all patients are reported in Table I. Axial traction was performed for 3 patients because of stiffness related to spinal deformity.

Radiographic Outcomes

Changes in radiographic parameters are reported in Tables II and III. There were no significant pre- or postoperative differences in any radiographic parameter between the group with cerebral palsy and those with muscle diseases (spinal muscular atrophy [SMA] and muscular dystrophy).

The mean postoperative Cobb angle correction was 43%, with an additional gain of correction of 9% at the latest follow-up. The total correction was 52%.

The mean postoperative pelvic-obliquity correction was 65% and reached 70% of correction at 3 years of follow-up. Spontaneous continuous correction of the residual pelvic obliquity was observed in 7 patients (Figs. 4 and 5).

Mean rod expansion was 22 mm in the concavity and 19 mm in the convexity at 2 years postoperatively. The mean rod expansion per month was 1 mm in the concavity and 0.9 mm in the convexity at the latest follow-up.

The mean preoperative thoracic kyphosis was 41° (range, 11° to 98°) and was reduced to 31° (range, 11° to 43°) after surgery ($p = 0.01$) and remained stable at 26° (range, 11° to 42°) at 3 years of follow-up ($p = 0.14$).

Ten patients with hyperkyphosis (excessive kyphosis of >50°) demonstrated improvement from a mean preoperative kyphosis of 68° to 33° at 3 years of follow-up. In 9 patients, the physiological kyphosis was preserved. In 2 patients, kyphosis was reduced to less than physiological, with a mean kyphosis of 21° preoperatively and 3° at 3 years of follow-up.

Complications

The overall complication rate was 38%, including 3 mechanical complications (14%) and 5 infections (24%).

Perioperative Complications

Two acute surgical site infections were treated with debridement and intravenous antibiotics without implant removal. No intraoperative neuromonitoring alert or perioperative neurological complications were observed.

Postoperative Complications

In 3 of the first cases, there was a lack of rod expansion due to a misplaced crosslink that prevented rod expansion because of a conflict with a lumbar spinous process. This complication was managed by crosslink removal after 1 to 2 years, and the expansion was effective for all 3 of these patients after revision.

No other implant-related failure or rod breakage was reported.

Non-Surgery-Related Complications

One case of pyelonephritis and 2 central venous catheter-related infections were reported.

Discussion

In neuromuscular diseases, spinal deformities and progressive pelvic obliquity result from abnormalities in muscle tone leading to poor trunk control. These deformities often start in the first years of life and require early treatment[1,16] starting with nonoperative methods (bracing, physical therapy) followed by PSF at the end of growth. However, nonoperative treatment is not efficient for preventing curve progression in most cases[17], necessitating early surgical treatment. Early spinal fusion used to be the common solution to limit severe deformity progression[18,19], but the respiratory consequences on lung development due to the limitation of spinal and chest growth indicated the need for better solutions. Karol[20] reported that PSF for thoracic deformities at an early age was no longer supported worldwide. Spinal deformity is not controlled by early fusion, and patients underwent surgical revision in 24% to 39% of cases. Restrictive pulmonary disease was reported for

TABLE II Overall Radiographic Results*

	Preoperative	Immediate Postoperative	2-Yr Follow-up	3-Yr Follow-up
Cobb angle of major curve *(deg)*	66 (34-110)	38 (6-94)	31 (4-90)	32 (5-86)
Pelvic obliquity *(deg)*	20 (1-55)	8 (0-41)	6 (0-40)	6 (1-39)
Thoracic kyphosis *(deg)*	41 (11-98)	31 (11-43)	28 (12-43)	26 (11-42)
Lumbar lordosis *(deg)*	34 (9-100)	41(18-61)	40 (15-96)	38 (21-54)
T1-T12 length *(cm)*	20 (14-30)	22 (15-30)	24 (17-31)	26 (19-32)
T1-S1 length *(cm)*	32 (22-43)	34 (23-45)	37 (27-51)	40 (35-54)
Space available for lung *(%)*	84 (64-96)	92 (84-99)	—	92 (85-99)
Maximum inner chest width *(cm)*	19 (14-28)	20 (15-29)	—	22 (16-31)

*The values are given as the mean, with the range in parentheses.

43% to 64% of patients, and thoracic growth was limited by 50%, leading to major respiratory dysfunction. Rumalla et al.[21] analyzed 2,154 cases of neuromuscular scoliosis treated with PSF and found a 40.1% rate of complications. Weiss and Goodall[22] reported a pooled average complication rate of 35% (range, 0% to 89%) and major complication rate of 17.4% (range, 0% to 39%), which exceeded the rates for idiopathic and congenital scoliosis.

TABLE III Detailed Results by Patient*

			Age at Initial Surgery	Major Curve *(deg)*			Pelvic Obliquity *(deg)*			T1-S1 Length *(cm)*				
Patient	Etiology	Sex	*(yr)*	Preop.	Immediate Postop.	3-Yr Follow-up	Preop.	Immediate Postop.	3-Yr Follow-up	Preop.	Immediate Postop.	2-Yr Follow-up	3-Yr Follow-up	Complications
1	CP	F	10	40	20	11	15	4	3	26	**32**	**32**	35	**Lack of rod expansion**
2	Other	F	13	34	6	5	1	1	1	43	43	45	46	0
3	CP	M	12	90	94	86	55	41	39	22	23	27	29	Central venous catheter infection
4	SMA	M	6	84	59	52	29	11	11	24	27	32	36	0
5	CP	F	11	69	49	50	12	8	8	29	31	33	35	Pyelonephritis
6	SMA	M	12	70	55	55	23	15	14	33	34	36	37	0
7	CP	M	12	88	52	40	30	10	2	38	**40**	**40**	42	**Lack of rod expansion**
8	CP	F	8	46	10	10	19	6	4	30	33	35	38	0
9	CP	M	6	79	41	41	34	12	12	25	28	31	37	0
10	SMA	M	12	65	30	15	10	6	7	34	36	43	45	0
11	MD	M	13	79	36	19	25	0	1	39	42	45	46	0
12	CP	F	11	73	35	30	13	1	1	29	33	36	38	0
13	MD	F	9	81	45	38	34	17	16	31	35	38	41	0
14	CP	M	9	110	47	34	53	11	1	24	27	35	37	Central venous catheter infection
15	CP	F	12	40	11	11	10	2	2	31	33	36	37	Surgical site infection
16	Other	M	10	50	25	25	5	5	5	32	**34**	**34**	37	**Lack of rod expansion**
17	MD	M	12	35	31	11	10	3	3	38	41	44	46	0
18	CP	M	13	79	40	22	12	6	1	41	45	51	54	0
19	SMA	F	11	80	40	37	27	12	1	36	40	42	44	0
20	CP	F	7	45	25	26	10	1	1	30	33	37	39	Surgical site infection
21	SMA	F	12	50	50	50	4	4	2	31	33	35	37	0

*CP = cerebral palsy, SMA = spinal muscular atrophy, Other = other neuromuscular disorder, and MD = muscular dystrophy.

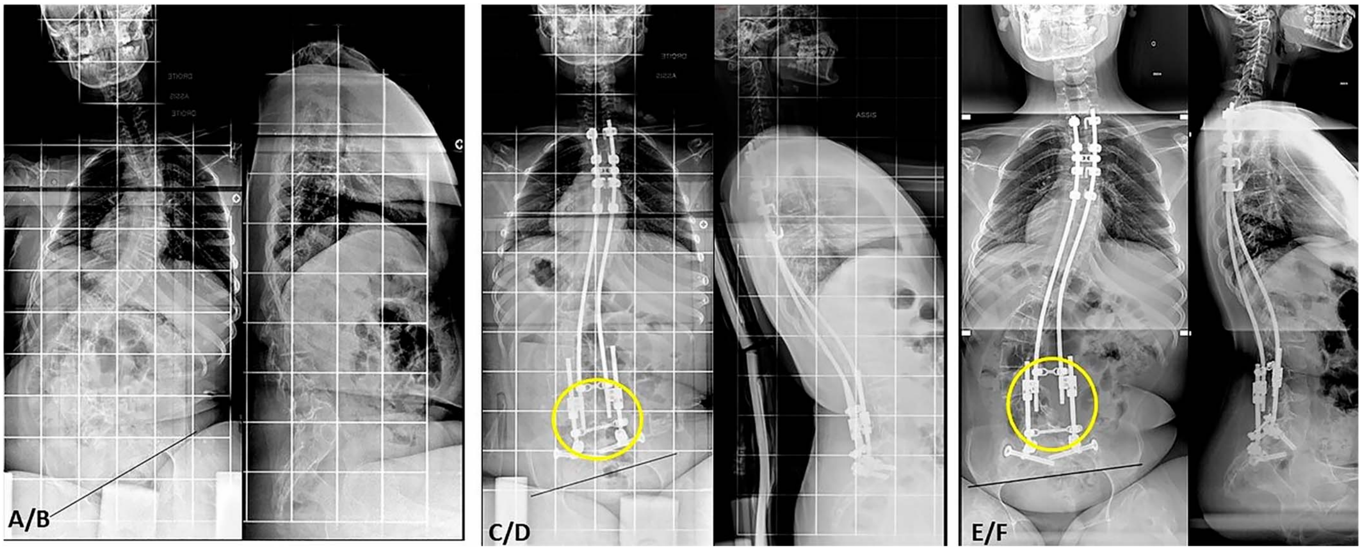

Fig. 4

Figs. 4-A through 4-F Radiographs of a 9-year-old girl with spinal muscular atrophy. **Figs. 4-A and 4-B** Preoperative radiographs. **Figs. 4-C and 4-D** Radiographs after the initial surgery. **Figs. 4-E and 4-F** Radiographs at 2 years of follow-up, with improvement of pelvic obliquity.

Different fusionless techniques in the surgical treatment of EOS, to preserve spinal and thoracic growth and to postpone PSF, have evolved in recent years[23]. Fusionless TGR techniques are widely used for neuromuscular scoliosis but have high rates of complications (40% to 73%) in this high-risk population[24-26].

Our group[12] previously described the use of a bipolar construct for neuromuscular scoliosis with a minimally invasive, fusionless technique, which demonstrated a lower rate of complications compared with other TGR series[27,28]. The bipolar, telescopic construct is strong and stable thanks to its proximal fixation with hook-claws[13] and distal fixation using iliosacral screws[14,15]. However, this technique needs repetitive surgery for rod lengthening. The OWSER used in the original study was designed to avoid repetitive surgery[11].

In contrast to the episodic surgical lengthening of TGRs or remote-controlled expansion of MCGRs, the concept of this new device is based on a progressive expansion of the rod (1 mm per step) that is allowed by physiological growth and the viscoelastic relaxation of soft tissues over time. The device is not motorized, and the risk of overlengthening is limited by the stiffness of the curve. In our experience, traction maneuvers resulted in a maximum of 2 or 3 mm of rod

Fig. 5

Photographs of the same patient as in Figure 4, made preoperatively (**Figs. 5-A and 5-B**) and at the latest follow-up (**Figs. 5-C and 5-D**).

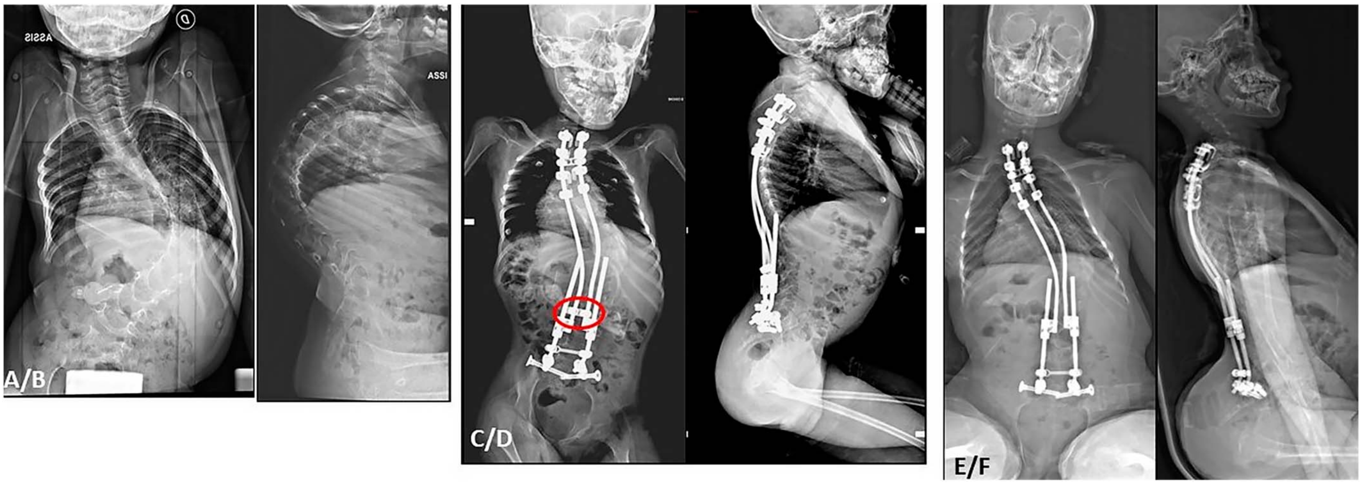

Fig. 6
Figs. 6-A through 6-F Radiographs of a 7-year-old boy with cerebral palsy. **Figs. 6-A and 6-B** Preoperative radiographs. **Figs. 6-C and 6-D** The intermediate crosslink (red circle) prevented rod expansion because of a conflict with the spinous process. **Figs. 6-E and 6-F** The rod expanded after removal of the misplaced crosslink.

lengthening per session. That is why repetitive traction sessions according to the patient's condition are recommended to improve the correction.

The self-expanding rods can expand differently on the concave and convex sides. An end stop block avoids disconnection of the domino from the rod at the end of the lengthening reserve. The gradual asymmetric and continuous lengthening of the rod explains the postoperative improvement of the residual spinal deformity and/or pelvic obliquity observed in 7 cases in the series.

The absence of neurological complications is ascribed to the progressive correction of the deformity.

The OWSER used in this series allowed for satisfactory spinal growth, with an estimated mean growth per month of 0.8 mm for the T1-T12 segment and 1.45 mm for T1-S1, matching normal spinal growth of 0.7 cm and 1 cm per year for T1-T12 and T1-S1, respectively[29]. The lack of rod expansion in 3 cases in this series was due to a conflict between a misplaced crosslink and a lumbar spinous process. A small amount of titanium debris was found at the revision surgery. This complication was managed by crosslink removal after 1 to 2 years, and the expansion happened afterward for all 3 of these patients. Since then, the construct was modified by changing the position of the intermediate crosslink, which is now placed more

Fig. 7
Photographs of the same patient as in Figure 6 made preoperatively (**Figs. 7-A and 7-B**) and at 2 years of follow-up (**Figs. 7-C and 7-D**).

proximally, immediately under the distal hooks to allow free rod sliding (Figs. 6 and 7). This complication was part of our learning curve at the beginning of use of the technique. No more similar complications were observed after this modification.

In the literature, the mechanical complication rate remains high. Teoh et al.[30] reported that 75% of patients had at least 1 complication requiring revision surgery in a series treated with MCGRs. Lebon et al.[31] reported 34 mechanical complications in a 30-patient study. Ridderbusch et al.[32] reported a 21% mechanical-complication rate, with 5 revision surgeries. Thakar et al.[5] noted a 22% rate of MCGR device-related complications. In the present series, the preliminary results suggest a reduced rate of mechanical complications (14%, with 3 revision surgeries) at 3 years of follow-up.

Pelvic fixation is a major challenge in children with neuromuscular scoliosis because of the poor quality of bone. Various techniques have been used, with a high mechanical-complication rate[33]. The solidity of pelvic fixation with iliosacral screws used for the bipolar construct permitted us to overcome this difficulty, and the strength and stability avoided the need for additional lumbar fixation. Pelvic fixation with iliosacral screws has been used for >40 years in long PSF[14] and, more recently, with fusionless constructs, with a reduced mechanical complication rate[15]. Moreover, the OWSER allows contouring in the sagittal plane that is not possible with an MCGR and contributes to a better correction of both the deformity and pelvic obliquity.

A lower surgical site infection rate (9%) was observed compared with that in a previous series using surgical rod lengthening (16%) with a similar bipolar construct for neuromuscular scoliosis[7]. This rate is comparable with those of MCGR-related surgical site infections, ranging from 0% to 10%[34-36]. However, the etiologies of EOS in these series were various and not only neuromuscular. The infection rate should be compared with caution to that of patients with neuromuscular scoliosis, who are known to have a poor general status[37-39].

The avoidance of repeated surgeries and the absence of outpatient clinic visits for rod lengthening[40] could improve patients' quality of life and reduce the psychological impact.

At the latest follow-up, there was no need for device removal and replacement, or conversion of the fusionless bipolar construct to PSF, for any patient[41]. Some of the patients were as young as 6 years of age, and more time would be needed to determine whether a patient this young will require PSF. However, in a recent article using a similar bipolar construct requiring rod lengthening[42], the stable clinical and radiographic evolution allowed the avoidance of performing PSF as initially planned. Long-term follow-up is required to confirm the effectiveness of this device and its results.

Conclusions

Use of the self-expanding device with a minimally invasive bipolar technique for neuromuscular scoliosis provided encouraging preliminary results in controlling spinal and pelvic deformities, with an acceptable rate of complications. Thanks to the spontaneous expansion of the device, repetitive surgical procedures were avoided in most of the patients. Longer follow-up is required to confirm these results. ■

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