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Clinical Study

Spring distraction system for dynamic growth guidance of early onset scoliosis: two-year prospective follow-up of 24 patients

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Abstract

BACKGROUND: Current surgical treatment options for early onset scoliosis (EOS), with distraction- or growth-guidance implants, show limited growth and high complication rates during follow-up. We developed a novel implant concept, which uses compressed helical springs positioned around the rods of a growth-guidance construct. This spring distraction system (SDS) provides continuous corrective force to stimulate spinal growth, can be easily contoured, and can be used with all standard spinal instrumentation systems.

PURPOSE: To assess curve correction and -maintenance, spinal growth, complication rate, and health-related quality of life following SDS treatment.

STUDY DESIGN: Prospective cohort study.

PATIENT SAMPLE: All skeletally immature EOS patients with an indication for growth-friendly surgery and without bone- or soft tissue weakness were eligible to receive SDS. For this study, all included patients with at least 2-year follow-up were analyzed.

OUTCOME MEASURES: Coronal Cobb angle, sagittal parameters, T1-T12, T1-S1, and instrumented (ie, bridged segment) spinal height and freehand length, complications and re-operations, and the 24-Item Early Onset Scoliosis Questionnaires (EOSQ-24) score.

METHODS: All primary- and conversion patients (conversion from failed other systems) with SDS and ≥2 years follow-up were included. Radiographic parameters were compared preoperatively, postoperatively and at latest follow-up. Spinal length increase was expressed as mm/year.

RESULTS: Twenty-four skeletally immature EOS patients (18 primary and 6 conversion cases) were included. There were five idiopathic, seven congenital, three syndromic, and nine neuromuscular EOS patients. Mean age at implantation was 9.1 years (primary: 8.4; conversion: 11.2). Major curve improved from 60.3˚ to 35.3˚, and was maintained at 40.6˚ at latest follow-up. Mean spring length increase during follow-up was 10.4 mm/year. T1-S1 height increased 9.9mm/year and the instrumented segment height showed a mean increase of 0.7 mm/segment/year. EOSQ-24 scores dropped after surgery from 75.6 to 67.4 but recovered to 75.0 at latest follow-up. In total, 17 reoperations were performed. Ten reoperations were performed to treat 9 implant-related complications. In addition, 7 patients showed spinal growth that exceeded expected growth velocity; their springs were retensioned during a small reoperation.

CONCLUSION: The 2-year follow-up results from this prospective cohort study indicate that the concept of spring distraction may be feasible as an alternative to current growing spine solutions. Curve correction and growth could be maintained satisfactory without the need for repetitive lengthening procedures. However, as in all growth-friendly implants, complications

FDA device/drug status: Investigational.

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and reoperations could not be prevented, which emphasizes the need for further improvement.

Keywords: Distraction; Early onset scoliosis; Growing rod; Growth-friendly; Growth guidance; Spring

Introduction

Early onset scoliosis (EOS), if left untreated, can cause severe cardiopulmonary dysfunction [1–3]. Different "growth-friendly" implants have been developed that aim to control the scoliotic curve whilst allowing for continuous spinal growth, thereby supporting truncal development. Current distraction-based implants are lengthened intermittently, either with repeated surgical procedures (traditional growing rod; TGR) or with a magnetic actuator (magnetically controlled growing rod; MCGR) [4,5]. While these systems are widely used for the surgical treatment of EOS, they are not without disadvantages. First, as these systems are distracted at intervals, they do not mimic continuous physiological spinal growth [6]. Second, these implants are stiff which may contribute to autofusion of the spine, leading to the "law of diminishing returns" seen in both TGR and MCGR [7–10]. Third, the rigid nature of these implants leads to increased implant stresses and subsequent implant failures [11–14]. The MCGR in particular is complex, is difficult to contour, and has many components that can fail. Recent studies have shown that less than one in five retrieved MCGRs still function as intended [15–17]. It is also an expensive device, precluding its use in large parts of the world. To address these drawbacks, we developed the Spring Distraction System (SDS), which employs the continuous distraction force of a compressed helical coil spring that is positioned around a standard rod that is allowed to slide at the proximal- or distal foundation (Fig. 1) [36]. The system does not require periodic lengthenings (unlike TGR and MCGR), and can be built into any given configuration, utilizing the advantages of both guided-growth and distraction-based systems.

We aimed to assess curve correction, growth and complication rate following SDS treatment during a minimum of 2-year follow-up. Secondary aims were to assess health-related quality of life (HRQoL) and to compare outcomes between patients undergoing SDS as their first growth-friendly implant (primary cases) and patients that were revised to SDS after another (failed) system (conversion cases).

Materials and methods

Ethical review and eligibility criteria

The current single-center prospective cohort study was approved by the Institutional Review Board of the UMC Utrecht (METC 16/276). All skeletally immature (ie, open triradiate cartilage on radiography) EOS patients from 2016 onward with a progressive curve >45° with an indication for growing-rod surgery were eligible and included after informed consent. Patients whose current "growth-friendly" system had to be revised (eg, because of implant failure) were also eligible for inclusion. Exclusion criteria were the presence of connective tissue diseases (eg, Marfan- and Ehlers-Danlos syndrome, neurofibromatosis) or severe bone pathology like osteogenesis imperfecta. For the current analyses, only patients with at least 2 years of follow-up were included. This study followed the STROBE guideline for reporting observational studies [18].

Investigational medical device

The key component of the experimental device (SDS) consists of a custom-made helical coil spring that was designed after extensive literature reviews to determine force safety limits and spinal growth [6,19–23]. We chose a maximum spring force of 75 N, which is much lower than the distraction force of a single MCGR rod (around 200 N), and forces applied in TGR lengthenings (which may easily exceed 500 N) [15,19,23]. The medical grade titanium (Ti-6Al-4V) spring was manufactured by Lesjöfors AB (Karlstad, Sweden) to fit around a 4.5 mm rod, with an uncompressed length of 72.0 mm, compressed length of 38.0 mm, spring constant of 2.15 N/mm and maximum compressed force of 75 N [36]. Since Lesjöfors AB does not have a quality management system for producing medical devices, the ISO 13485 certified department of Medical Technology and Clinical Physics of the the UMC Utrecht acted as the manufacturer of the spring, took lead in the design and manufacturing process and created an Investigational Medical Device Dossier, including quality control, risk analysis and postmarket surveillance and vigilance.

Spring distraction system

The SDS consists of three components (Fig. 1): (1) A side-to-side connector with one oversized hole, (2) The spring that can be compressed, and which provides a distraction force, and (3) A locking buttress that is used to compress the spring over the rod during surgery. The spring and locking buttress are placed over the 4.5 mm sliding rod that has 4-6 cm of residual length. This rod bridges the scoliotic curve on its concavity and joins the short anchor rod in the parallel connector with an oversized hole to allow for sliding. By moving the buttress across the rod toward the parallel connector, the spring can be compressed. Implanting bilateral springs doubles the distraction force to 150 N, while implanting two springs in series doubles the working

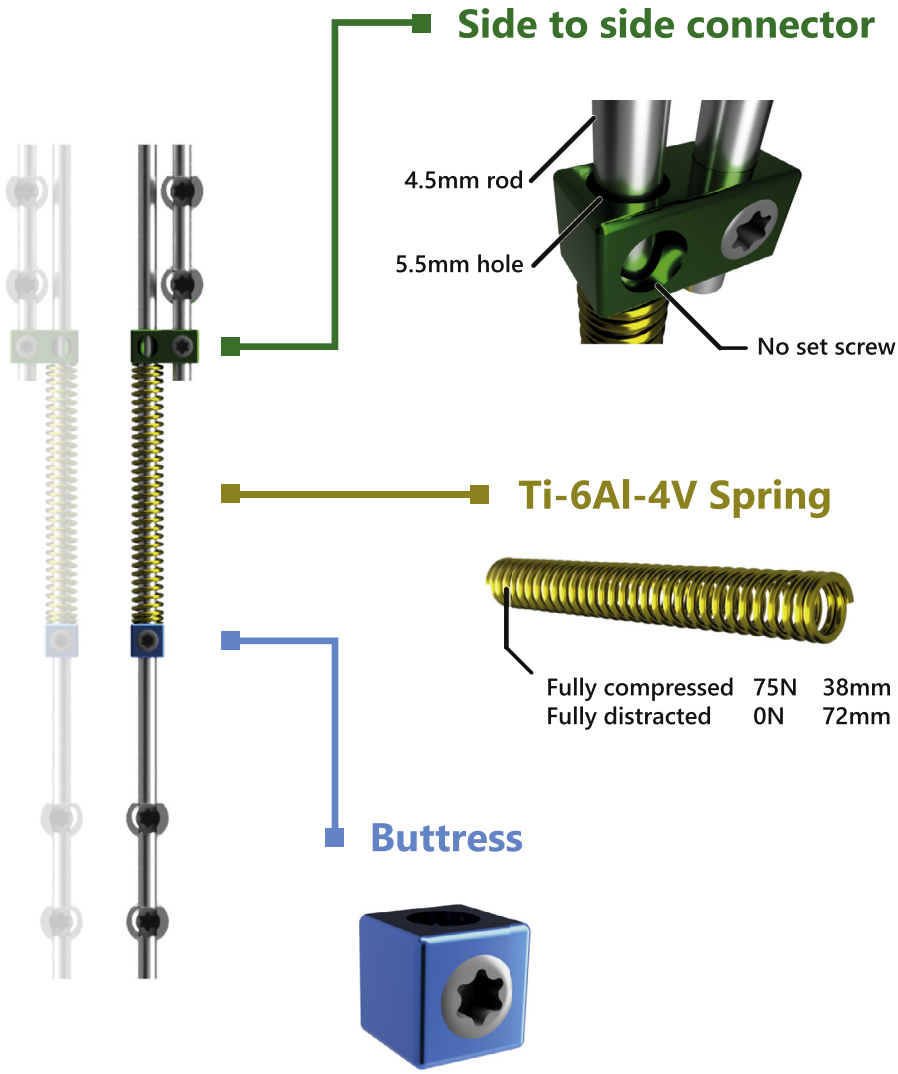

Fig. 1. Spring distraction system concept.

length to 68 mm while the force remains unaltered. The convexity of the curve can either receive a similar distraction construct, or, when apical control is preferred, a passive sliding rod, fixed to the apex as described previously for MCGRs [37,38]. To maintain distraction when full expansion has taken place, the spring can be retensioned by repositioning the buttress in a small surgical procedure. Fig. 2 shows multiple SDS configurations that can be used depending on EOS type and surgeon preference.

Surgical technique

Surgery was performed through a posterior midline skin incision, using separate small transmuscular exposures for the foundations. Pedicle screws (Legacy, Medtronic, Dublin, Ireland) were placed with the freehand technique, the rods were passed subfascially. The sliding rods were cobalt-chromium (CoCr) to prevent titanium-on-titanium friction with the side-to-side connectors (K2M, Leesburg, VI, USA) and were contoured into the desired shape in both the coronal and sagittal plane. After surgery, patients were allowed normal activities without restrictions or braces.

Outcome parameters

The radiological outcomes were coronal Cobb angles, T5-T12 kyphosis, L1-S1 lordosis, height and freehand length of T1-T12, T1-S1 and the Instrumented segment (ie, all vertebrae bridged by the instrumentation) as well as length of the springs. Segment heights were measured as the perpendicular distance between horizontal lines going through the midpoints of the vertebral endplates (Fig. 3). To determine spinal length gain in these segments, the freehand method was used by drawing a curved line through the midpoint of the upper and lower endplate of all involved vertebrae [6,24]. All measurements were performed on the pre- and postoperative radiographs, and on the radiographs at latest follow-up. Growth rates (mm/year) were calculated based on the difference between the postoperative and latest follow-up radiograph, thus

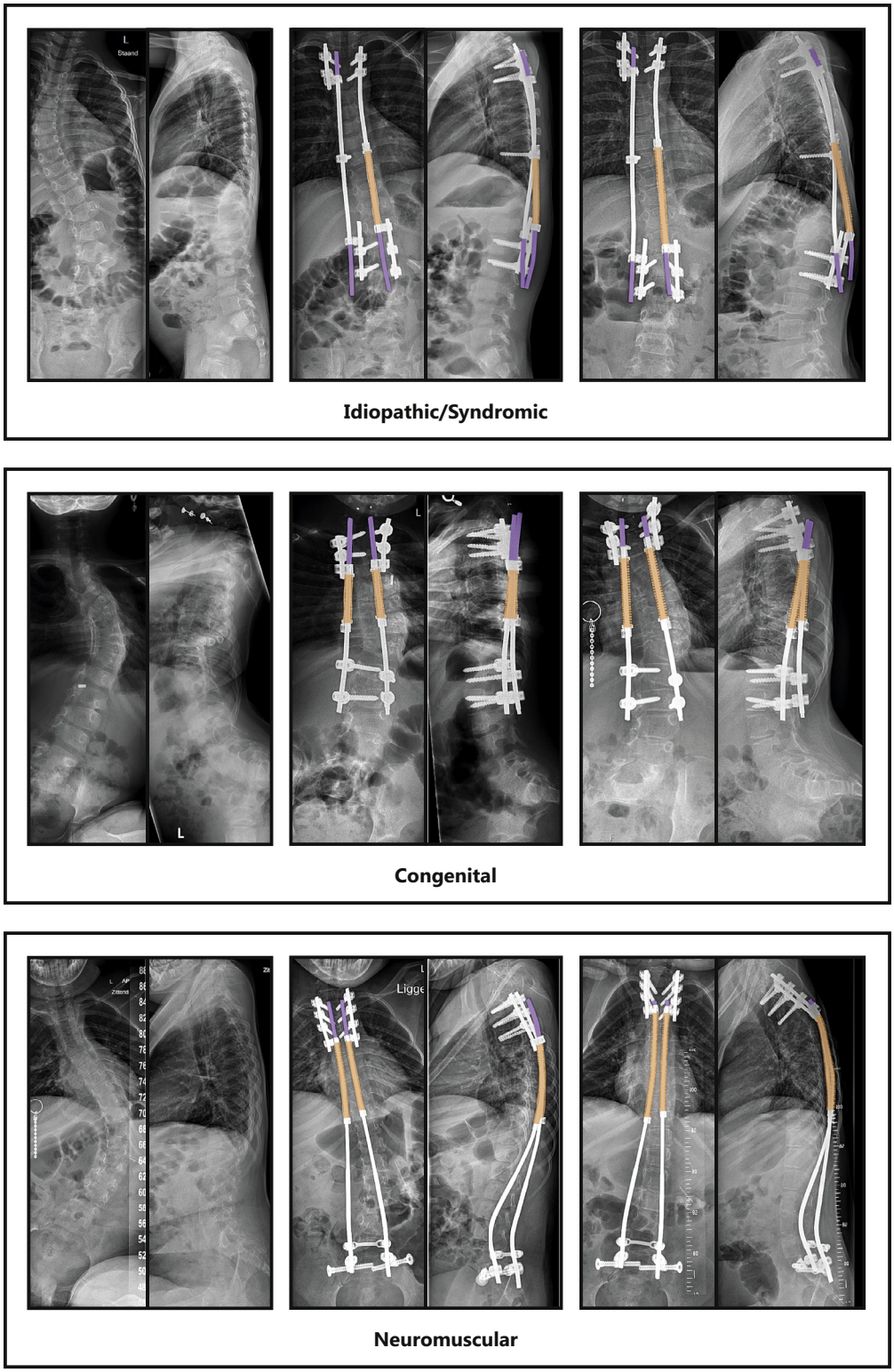

Fig. 2. Spring distraction system configurations. Left: Preoperative, Middle: Immediately postoperative, Right: Latest follow-up. Spring is colored orange, sliding rods are colored purple. For idiopathic and syndromic cases, a hybrid of the SDS on the curve concavity was often combined with a sliding rod with apical control on the convexity. For congenital cases, a concave SDS was implanted and combined with a sliding rod, hemi-epiphysiodesis or no instrumentation on the curve convexity. Neuromuscular cases were instrumented with bilateral springs that were fixated distally with iliosacral screws and proximally with pedicle screws.

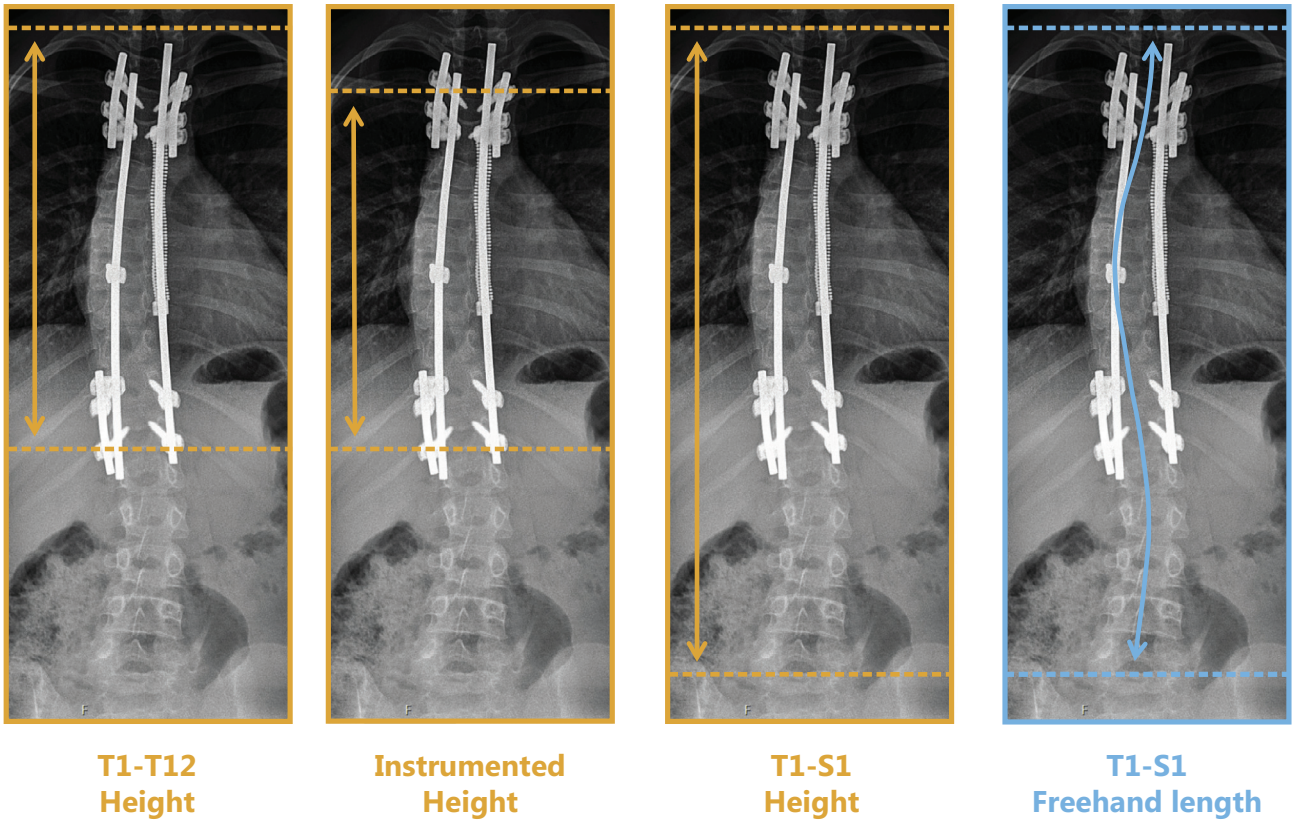

Fig. 3. Spinal growth measurements. The first three panels show the different segment heights (T1-T12, Instrumented, T1-S1). The fourth panel show the T1-S1 segment measured with the freehand method. Note the difference in length compared to the third panel.

excluding the length gain from initial surgery and definitive spinal fusion [6]. All measurements were performed on calibrated radiographs using Surgimap v.2.3.1.1 (Nemaris Inc, New York, NY, USA).

Surgical outcomes such as skin-to-skin surgery time, estimated blood loss and occurrence of complications and reoperations were prospectively recorded. Patient-reported outcomes were measured using the validated Dutch EOSQ-24 questionnaire filled out preoperatively, 6 weeks postoperatively and at 1- and 2-year follow-up [39].

Statistics

Descriptive statistics was performed on baseline characteristics and outcome parameters were reported as means with standard deviation. Differences in characteristics between primary- and conversion cases were compared with independent *t* tests for continuous variables, and with Pearson Chi-squared tests for categorical variables. Intrapatient differences in outcomes were analyzed with paired sample comparisons, either paired *t* tests (parametric) with 95% confidence interval (CI), or Wilcoxon Signed-Rank tests (nonparametric) with Hodges-Lehmann estimator and 95% CI, depending on whether the paired differences were normally distributed. Significance for all tests was set at $p<.05$. Statistical analysis was performed with IBM SPSS Statistics 25.0.0.2 (IBM Corp. Armonk, New York, NY, USA).

Results

Patient demographics

From 58 SDS patients, all patients who had at least 2 years of follow-up (N=24) were included and analyzed; 18 primary SDS patients and 6 conversion patients (3 TGR; 3 MCGR). Patient characteristics and comparison between primary- and conversion cases are shown in Table 1. All EOS etiologies were represented with 5 (21%) idiopathic cases, 7 (29%) congenital cases, 3 (13%) syndromic cases and 9 (38%) neuromuscular cases. The mean number of instrumented segments was 12.8±3.3. Mean follow-up was 2.4±0.3 years.

No significant differences were seen between primary and conversion cases with respect to sex, EOS etiology, sagittal profile, and follow-up length. As expected, primary patients were significantly younger (8.4 vs. 11.2 years). They also had larger primary curves at time of SDS surgery (65.0° vs. 45.9°) and had a higher number of instrumented segments (13.7 vs. 10.3). Surgery was also significantly longer (230 vs. 123 minutes), with higher blood loss (372 vs. 167 mL) and they were discharged later (6.9 vs. 4.0 days).

Table 1.
Baseline characteristics

	Primary SDS (N=18)	Conversion SDS (N=6)	p Value	All patients (N=24)
Age at surgery (years)	8.4±2.0	11.2±2.0	0.006	9.1±2.3
Male	9 (50%)	2 (33%)	0.478	11 (46%)
EOS etiology			0.179	
Idiopathic	3 (17%)	2 (33%)		5 (21%)
Congenital	4 (22%)	3 (50%)		7 (29%)
Syndromic	2 (11%)	1 (17%)		3 (13%)
Neuromuscular	9 (50%)	0		9 (38%)
Previous growing system			NA	
TGR	NA	3 (50%)		3 (13%)
MCGR	NA	3 (50%)		3 (13%)
Preoperative primary curve (˚)	65.0±16.2	45.9±21.9	0.032	60.3±19.3
Preoperative T5-T12 kyphosis (˚)	18.6±21.0	33.4±26.2	0.173	22.3±22.7
Preoperative L1-S1 lordosis (˚)	47.8±13.4	52.5±15.2	0.473	48.9±13.7
Surgery skin to skin time (minutes)	230±62.6	123±34.3	0.001	203±73.5
Estimated blood loss (mL)	372±148 (N=17)*	167±60.6	<0.001	318±159 (N=23)*
Instrumented levels	13.7±3.1	10.3±2.7	0.027	12.8±3.3
Time to discharge (days)	6.9±2.1	4.0±1.3	0.004	6.2±2.3
Follow-up length (years)	2.4±0.3	2.3±0.3	0.511	2.4±0.3

SDS, spring distraction system.
Mean and standard deviation are provided and differences were analyzed with the independent samples *t* test.
* For one patient, estimated blood loss data was unavailable.

Radiographic outcomes

For primary SDS patients, the main curve corrected from a mean of 65.0˚ to 33.2˚ (49% reduction), which was maintained at 35.6˚ at latest follow-up (Table 2). Conversion cases started with a mean primary curve of 45.9˚, which was reduced to 41.6˚ (9% reduction), and increased again to 55.8˚ at latest follow-up. Primary curve development for each patient is shown in Fig. 4. Nine patients showed additional curve correction during follow-up, seven patients showed a progression of the curve >10˚ compared to postoperatively. For secondary curves, similar trends were seen.

In primary cases, thoracic kyphosis decreased from a mean of 18.6˚ to 16.7˚ postoperatively. During follow up, a significant increase was seen to 27.0˚ (p=.001). Two patients with a congenital thoracic lordosis of >20˚ due to posteriorly fused segments improved to a modest (5˚−10˚) thoracic kyphosis during follow-up. Conversion cases increased from a mean kyphosis of 33.4˚ to 36.3˚ postoperatively which increased significantly to 46.0˚ at latest follow-up (p=.028). Lumbar lordosis showed a similar pattern as thoracic kyphosis.

Spinal height and length values are reported in Table 3 and spring length values are shown in Table 3 and Fig. 5. Mean T1-T12 height gain during follow-up was

Table 2.
Curve correction and sagittal profile

		Preoperative	Postoperative	Latest follow-up	Change during follow-up†
Primary curve (˚)	Primary	65.0±16.2	33.2±11.8	35.6±15.6	+2.4 (−3.4 to +8.1); p=.401‡
	Conversion	45.9±21.9	41.6±22.8	55.8±22.8	+14.2 (−0.1 to +28.5); p=.051‡
	All patients	60.3±19.3	35.3±15.1	40.6±18.1	+5.3 (−0.14 to 10.8); p=.056‡
Secondary curve (˚)	Primary (N=16)*	34.3±15.2	21.6±14.3	23.1±13.5	+1.5 (−1.9 to +4.9); p=.363‡
	Conversion	24.4±7.86	21.0±9.66	23.9±6.80	+3.7 (−2.2 to +7.3); p=.173¶
	All patients (N=22)*	31.6±14.1	21.4±13.0	23.3±11.9	+1.9 (−0.8 to +4.5); p=.152‡
T5-T12 Kyphosis (˚)	Primary	18.6±21.0	16.7±13.2	27.0±15.1	+9.7 (+4.0 to +16.3); p=.001¶
	Conversion	33.4±26.2	36.3±26.2	46.0±27.7	+9.8 (+4.5 to +12.7); p=.028¶
	All patients	22.3±22.7	21.6±18.8	31.7±20.2	+9.6 (+5.8 to +13.0); p<.001¶
L1-S1 Lordosis (˚)	Primary	47.8±13.4	41.2±10.4	49.6±19.4	+8.5 (+0.4 to +16.5); p=.041‡
	Conversion	52.5±15.2	51.2±14.2	58.5±13.8	+7.0 (−3.7 to + 18.8); p=.043¶
	All patients	48.9±13.7	43.7±12.0	51.8±18.3	+8.2 (+1.9 to +14.4); p=.013‡

* Two patients did not have a secondary curve and were not evaluated.
† A positive number indicates an increase during follow-up.
‡ Parametric distribution of differences. Paired *t* test was performed and mean and 95% CI are provided.
¶ Nonparametric distribution of differences. Wilcoxon-Signed Rank test was performed and Hodges-Lehmann estimator and 95% CI are provided.

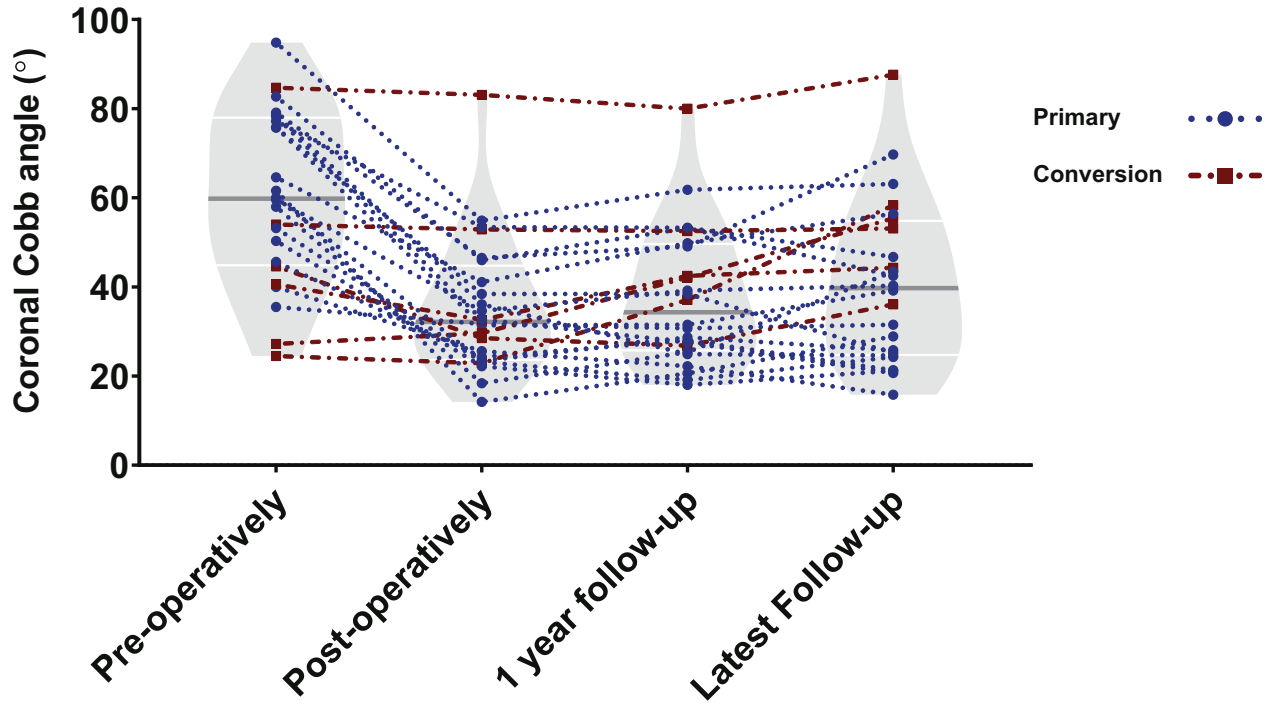

Fig. 4. Coronal Cobb angle over time. Cobb angle change over time is plotted for each patient and distribution of data is shown as a violin plot (showing the probability density of the data at different Cobb angles).

Table 3.
Spinal growth

		Preoperative	Postoperative	Latest follow-up	Postoperative growth (mm/year)*
T1-T12 height (mm)	Primary	172±29.4	191±26.8	212±28.3	+8.7 (+6.5 to +10.8); p<.001†
	Conversion	200±33.9	205±35.0	218±41.7	+5.7 (+1.3 to +10.1); p=.046†
	All patients	179±32.2	194±28.9	213±31.2	+7.9 (+6.0 to +9.8); p<.001†
T1-T12 freehand length (mm)	Primary	192±26.7	199±24.9	222±28.4	+9.8 (+7.6 to +12.0); p<.001†
	Conversion	209±28.6	214±30.6	235±35.9	+9.3 (+4.8 to +13.9); p=.011†
	All patients	196±27.6	202±26.6	225±30.1	+9.7 (+7.8 to +11.5); p<.001†
T1-S1 height (mm)	Primary	288±43.1	319±40.5	346±42.5	+11.6 (+7.9 to +15.3); p<.001†
	Conversion	329±33.3	341±36.3	354±39.7	+4.8 (−2.1 to +11.8); p=.137†
	All patients	298±44.0	324±39.9	348±41.1	+9.9 (+6.7 to +13.1); p<.001†
T1-S1 freehand length (mm)	Primary	319±41.4	330±37.8	362±44.4	+13.4 (+9.6 to +17.2); p<.001†
	Conversion	344±34.1	356±34.6	390±46.5	+14.2 (+3.7 to +24.7); p=.029†
	All patients	325±40.6	336±38.1	369±45.7	+13.6 (+10.2 to +17.0); p<.001†
Instrumented height (mm)¶	Primary	NA	250±65.3	272±72.0	+0.8/segment (+0.5 to +1.1); p<.001†
	Conversion		207±33.3	220±37.7	+0.4/segment (−0.1 to +0.9); p=.069†
	All patients		239±61.3	259±68.3	+0.7/segment (+0.5 to +0.9); p<.001†
Instrumented freehand length (mm)¶	Primary	NA	259±65.0	286±75.1	+0.9/segment (+0.6 to +1.2); p<.001†
	Conversion		220±39.0	241±41.0	+0.6/segment (+0.3 to +1.0); p=.018†
	All patients		249±61.3	274±70.2	+0.8/segment (+0.6 to +1.1); p<.001†
Spring length (mm)	Single spring (N=9)	NA	40.9±3.7	56.3±9.3	+6.5 (+3.6 to +9.4); p=.001†
	Double spring (N=15)		83.7±7.6	113±15.3	+12.7 (+9.8 to +15.6); p<.001†
	All patients		67.7±22.1	91.6±30.9	+10.4 (+8.0 to +12.7); <.001†

* A positive number indicates an increase during follow-up.
† Parametric distribution of differences. Paired *t* test was performed and mean and 95% CI are provided.
¶ For instrumented postoperative growth rates, the growth per segment spanned by the instrumentation is reported.

7.9 mm/year (primary: 8.7, conversion: 5.7). For T1-S1 height, the mean gain was 9.9 mm/year (primary: 11.6, conversion: 4.8) and for the instrumented segment, the mean gain was 0.7 mm/segment/year (primary: 0.8, conversion: 0.4). The mean freehand length gain was 9.7 mm/year for T1-T12, 13.6 for T1-S1 and 0.8 mm/segment/year for the instrumented segment, with only small differences between primary and conversion cases.

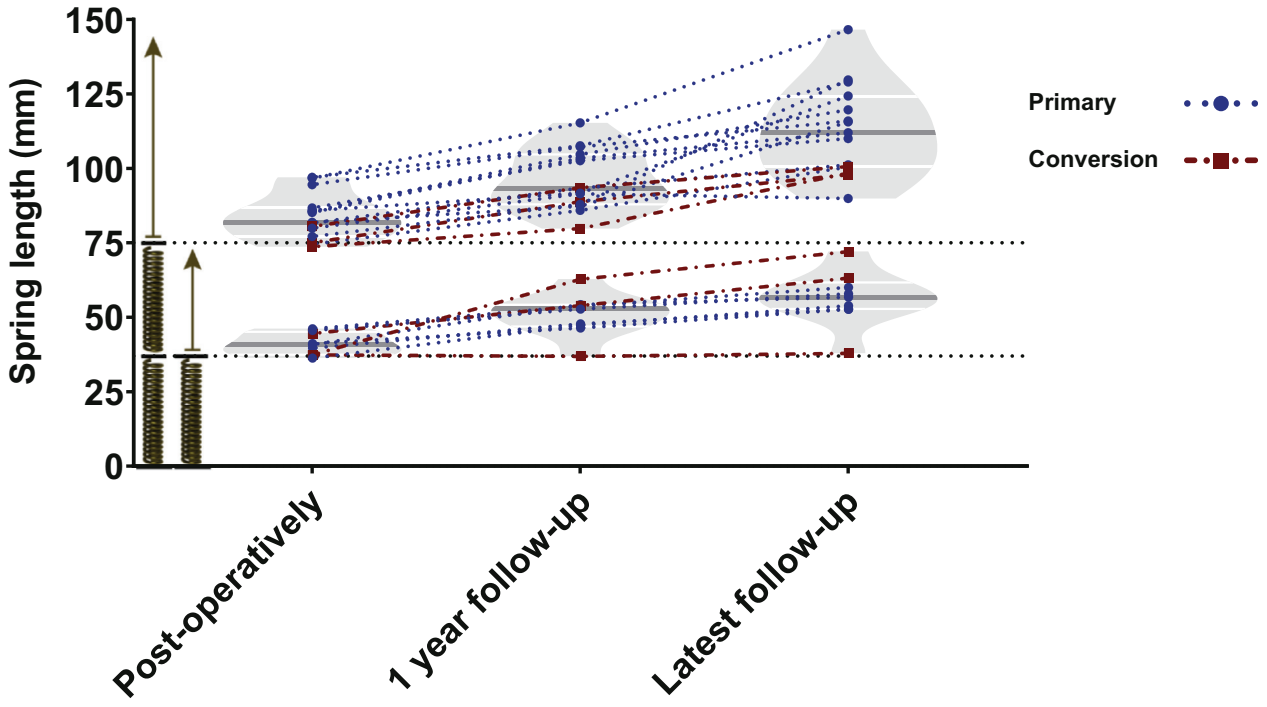

Fig. 5. Spring lengthening over time. Spring length increase over time is plotted for each patient and distribution of data is shown as violin plots (showing the probability density of the data at different spring lengths). The dotted lines denote the length of one (bottom) or two (top) fully compressed spring(s) and the tip of the right and left arrow denote the fully distracted length of one and two springs respectively. Note that some springs had already distracted somewhat at the time of first erect radiograph.

Complications and reoperations

There were no intraoperative complications, patients recovered well and could be discharged after a mean of 6.2±2.3 days. The springs did not show any failures in terms of fracture or dysfunction due to tissue encapsulation. During ≥2 years of follow-up, 17 reoperations were performed in 13 patients. Ten reoperations were performed for 9 implant-related complications in 8/24 patients (33%). Implant prominence was the most common complication, and occurred in 3 patients. One patient needed two re-operations for a deep surgical site infection. The other complications are listed in Table 5. In addition to the complications, 7/24 patients (29%) needed a (small) reoperation for retensioning of the spring, after a mean of 1.9±0.6 years. This was due to unexpected high length gain immediately after insertion of the system (tissue relaxation/creep), and/or a spinal growth rate that exceeded expectations.

Health-related quality of life

Twenty patients filled out the EOSQ-24 questionnaire during all follow-up moments and were analyzed (Table 4). Mean preoperative EOSQ-24 score patients changed from 75.6±7.6 (out of 100) preoperatively, to 67.4±10.6 postoperatively (with decreases in pain/discomfort, physical function, fatigue/energy, and emotion domains) and increased again to 75.0±7.7 after 2 years.

Discussion

The current study investigated the feasibility and safety of the SDS for surgical treatment of many types of EOS. The concept of distraction itself is not new and dates back to the early use of Harrington rods [25–27]. Springs were even used at that time to treat adolescent idiopathic scoliosis, but that technique never fully matured, probably due to the emergence of pedicle screw fixation and its potential for powerful correction [28]. In the current study, postoperative Cobb angle correction with the SDS was 50% for primary patients, and this correction was maintained during ≥2 year follow-up. This is similar to contemporary systems that rely on repetitive distractions [29]. In the primary patient group, T1-S1 height increase was 11.6 mm/year; which seems to be higher than reported for other growth-friendly systems [6,29]. In general, patients tolerated the SDS well and although HRQoL decreased initially after surgery, patients recovered fully and experienced little to no discomfort of the SDS.

The complication rate necessitating reoperation was relatively low (9/24; 0.38 complications/patient) when compared to other systems (TGR: 1.48–2.30, MCGR: 0.43–0.90) [30–32], although the number of reoperations was still relatively high, owing to the considerable number of retensioning surgeries (7/24, 29%). These were caused by unexpectedly fast length gain in the

Table 4.
Health-related quality of life

	All patients (N=20)*			
	Pre-op	Post-op	1 year follow-up	2 year follow-up
General health	72.5±18.3	70.0±21.0	74.0±20.1	72.5±20.3
Pain/discomfort	71.3±23.8	57.0±19.8	72.6±17.7	77.0±19.3
Pulmonary function	85.6±19.7	83.2±21.3	79.5±24.2	84.5±20.2
Transfer	75.5±23.8	61.1±29.4	70.5±27.8	68.0±27.1
Physical function	72.7±30.6	58.5±30.7	66.4±34.0	69.7±32.6
Daily living	61.1±31.1	59.2±30.6	64.9±31.7	64.0±35.3
Fatigue/energy level	71.0±24.5	56.5±18.9	71.5±23.2	71.0±21.9
Emotion	82.5±18.5	65.8±24.3	75.0±24.8	76.5±22.8
Parental burden	76.3±23.3	70.0±26.8	73.5±23.1	76.6±23.3
Financial burden	90.0±14.8	91.0±17.3	87.0±21.2	93.0±13.1
Overall satisfaction	73.2±20.7	69.4±17.3	71.0±16.7	72.0±21.8
Mean domain score	75.6±7.6	67.4±10.6	73.3±5.8	75.0±7.7

Five-point Likert scale scores were converted to a score ranging from 20 (minimum) to 100 (maximum). Higher scores denote better patient outcomes.
* Only patients with filled out questionnaires at all 4 timepoints were included.

Table 5.
Reoperations and complications

Patient	Number of reoperations	Reason for reoperation	Treatment
P-01	0		
P-02	0		
P-03	0		
P-04	0		
P-05	0		
P-06	2	High growth rate; rod grew out of connector	Implantation of longer rod and re-tensioning of spring
		Distal iliosacral screw failure	Implantation of new iliosacral screw
P-07	0		
P-08	1	High growth rate; spring fully distracted	Re-tensioning of spring
P-09	3	Deep Surgical Site Infection	Irrigation and debridement (2x)
		Distal iliosacral screw failure	Implantation of new iliosacral screw
P-10	1	Rod fracture	Implantation of new rod
P-11	0		
P-12	1	High growth rate; spring fully distracted	Retensioning of spring
P-13	1	High growth rate; spring fully distracted	Retensioning of spring
P-14	0		
P-15	1	Protrusion of instrumentation	Additional bending of rod
P-16	1	High growth rate; spring fully distracted	Retensioning of spring
P-17	0		
P-18	1	Protrusion of instrumentation	Additional bending of rod
C-01	1	Connector failure	Definitive fusion
C-02	2	Protrusion of instrumentation	Additional bending of rod
		High growth rate; spring fully distracted	Re-tensioning of spring
C-03	1	Rod-connector slippage	Implantation of new set screw in connector
C-04	1	High growth rate; spring fully distracted	Retensioning of spring
C-05	0		
C-06	0		

P-XX denote primary patients, C-XX denote conversion patients.

system and subsequent loss of distraction force. Although ideally, only a single SDS surgery is performed without reoperations, the rapid spinal growth can be considered a sign of treatment efficacy. By using two springs in series, spring forces can be spread out over a longer distance, and the risk of rapid force loss (and thus the need for retensioning) is reduced, although the cranial or caudal rod extensions must be left longer. When regarding only complications, implant prominence was the most frequent reason for reoperation, which can be related to the increase in thoracic kyphosis that is enforced by the posterior distraction. Currently, we use

two stacked side-to-side connectors instead of just one to prevent this excessive kyphosis in the implant.

We observed several differences between primary cases and conversion cases; a main difference was the amount of postoperative curve correction which was substantially lower in the conversion group (49% vs. 8%). In addition, conversion cases had a tendency to exhibit somewhat lower segment height growth, although these differences disappeared when comparing freehand length instead. Since the freehand measurements are much less influenced by coronal curve changes (evidenced by the fact that pre- and postoperative freehand length values are similar), this provides a more accurate measure of true spinal growth. Freehand length parameters showed that both groups exhibit similar spinal growth, close to or exceeding normative values found in literature [33,34].

Technical advantages of the SDS include the fact that it is easy to contour and that the system is relatively mobile due to the sliding connections. Theoretically, a dynamic system is less vulnerable to fatigue failures as compared to static rods which has also been demonstrated in recent finite element models [40]. The simplicity of the technique is also advantageous, we observed excellent distraction in all springs despite considerable tissue ingrowth. This is in contrast to MCGR, where failure to distract is common due to component failure of the driving mechanism [15–17,30,35].

Strengths of the current study include the relatively large patient cohort that was prospectively followed for at least 2 years. In addition, the diverse patient group represents a varied EOS population, as observed by the considerable variation in baseline EOSQ-24 domain scores. Limitations of this study include the absence of a control group. Although we always offer MCGR as a standard treatment to our patients (SDS is only implanted as part of a clinical trial), only one patient opted for this. With the increasingly disappointing results of MCGR (in our own experience and also observed in the literature), we foresee difficulties including and randomizing patients to that treatment arm when performing a randomized controlled trial, but obviously, such studies should be performed when SDS is registered for medical use [30,35,37,38]. Another limitation is that the majority of patients have only short- to medium-term follow-up. It is possible that as follow-up increases, additional complications will manifest. Also, while we did include HRQoL results with the EOSQ-24, we did not specifically investigate pulmonary function in the SDS patients. Future studies should correlate the radiographical and HRQoL outcomes of SDS patients to changes in pulmonary function. Finally, the SDS is not yet fully optimized. It is composed of a custom-made spring and uses several components in an off-label manner. Especially the CoCr on titanium sliding through the side-to-side connector is a concern, because of metal debris and lack of kyphosis control. We are currently optimizing the SDS design, while simultaneously pursuing medical registration, although the latter will be a laborious process, especially with the impending new European Medical Device Regulations.

Conclusion

The SDS appears to be a promising technique for surgical treatment of EOS. Curve correction in primary pateints was 50% and could be maintained for at least 2 years. Mean T1-S1 height gain during follow-up was 11.6 mm/year, which compares favorably to contemporary systems that need intermittent distractions. Complications and reoperations could not be prevented, but the complication rate seems modest compared to contemporary systems, and there are opportunities to decrease this further. Improvement of this in-house developed implant and medical registration are our next steps.

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