Risk Factors for Multiple Implant-Related Complications (MIRC) with Growing-Rod for Early-Onset Scoliosis

Haijun Jiang
Liangxiang Teaching Hospital, Capital Medical University
Junrui Jonathan Hai
High School Affiliated to Renmin University of China
Yong Hai (prof.haiyong@yahoo.com)
Beijing Chao-Yang Hospital
Peng Yin
Beijing Chao-Yang Hospital
Qingjun Su
Beijing Chao-Yang Hospital
Lijin Zhou
Beijing Chao-Yang Hospital
Shiqi Zhu
Beijing Chao-Yang Hospital
Aixing Pan
Beijing Chao-Yang Hospital
Yunsheng Wang
Beijing Chao-Yang Hospital
Ziyang Liu
Beijing Chao-Yang Hospital

Research Article

Keywords: early-onset scoliosis, traditional growing rod, implant-related complications

Posted Date: November 16th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-1078273/v1

Abstract

Study design: A retrospective single center study.

Objective：To identify risk factors for multiple implant-related complications with growing-rod for early-onset scoliosis.

Background: High incidence of implant-related complications in the treatment of early-onset scoliosis with traditional growing rod. The risk factors for multiple implant-related complications **(MIRC)** have not been adequately studied.

Methods: Data of 59 early-onset scoliosis patients who had been underwent growing rod surgery at Beijing Chao-yang Hospital from September 2007 to December 2017 were reviewed. All patients had complete clinical and radiographic data. Patients were divided into groups with or without MIRC. The univariate and multivariate logistic regression analysis were performed to identify the risk factors associated MIRC**.**

Results: The average age of insertion was 8.9 years and mean follow-up was 51.91 months. 234 implantation or expansion surgeries were performed and the average operation interval was 11.4 months. A total of 60 implant-related complications occurred. Ultimately, MIRC developed in 20 (33.9%) of 59 patients. Number of surgery procedure > 3 times , follow-up time ^{3}50 months , preoperative thoracic kyphosis > 50°, postoperative thoracic kyphosis >50°, postoperative lumbar lordosis >50°, postoperative sagittal vertical axial >40mm are potential risk factors for MIRC (P<0.1). Multivariate logistic regression analysis showed that Number of surgery procedure > 3 times, postoperative thoracic kyphosis >50°, postoperative lumbar lordosis >50°are independent risk factors for MIFRC (P<0.05), Among them, patients with postoperative thoracic kyphosis >50°had an 18.647 times higher risk of MIFRC than postoperative thoracic kyphosis angle <50°.

Conclusions: Traditional growing rod in the setting of EOS has excellent clinical and radiographic outcomes but a high multiple implant-related complications. Number of surgery procedure > 3 times, postoperative thoracic kyphosis >50°, postoperative lumbar lordosis >50° are independent risk factors for MIRC.

Introduction

Early-onset scoliosis (EOS) refers to spinal deformities that occur before the age of 10 and are caused by a variety of pathological factors [1]. Because EOS patients are in the rapid growth period of the spine and the critical development period of cardiopulmonary function, early detection and timely treatment are essential [2]. EOS patients develop rapidly, and spinal deformity maybe worsens rapidly in a short period of time, and the initial treatment may not be effective all the time, therefore, close observation is also a very important measure. Surgical intervention is mainly used to treat scoliosis that cannot be controlled by bracing or plaster treatment, or the child is too young to insist on wearing it [3].

The traditional growing rod (TGR) is the most widely used technology in the treatment of EOS, not only preserves the growth ability of the spine, but also maintains the development of lungs and thorax [4]. To our knowledge, some authors have described outcomes of EOS patients treated with growing rods, which achieving satisfactory results in correcting deformity, spinal height, and thoracic volume [5–10]. The dual growing rod technique can obtain better correction of coronal deformities and provide sufficient support for spine growth, and the incidence of complications is lower than the single growing rod, but the incidence of implant-related complications is higher than the single growing rod. Previous studies have shown total complication rates for TGR procedures to be as high as 48%-79%[5, 11–12]. Thus the incidence of implant-related complications were 21.7%-59.3%[5, 9, 11–12]. Implant-related complications include implant dislodgement, implant loose, rod fracture, proximal junctional kyphosis and so on. Thoracic kyphosis (TK) is an important parameter for assessing the severity of scoliosis, increased kyphosis may cause high loading in the middle of the growing rod and increase the risk of local fatigue fracture of the implant, the proximal and distal foundation sites may bear more stress, which leads to implant-related complications [13]. In a multicenter retrospective study, thoracic scoliosis >50 degrees and Cobb angle >50 degrees are risk factors for unplanned reoperations after growing-rod surgery [14]. In addition, some researchers have observed that EOS patients with hyperkyphosis tend to suffer more complications [13]. The risk factors for treating EOS with implant-related complications were well evaluated in previous studies, however the risk factors for multiple implant-related complications have not been adequately studied. The study was conducted to identify the rate and risk factors of more than once implant-related complications with growing rod surgery for EOS.

Materials And Methods

Patient Selection

We reviewed the records of patients with EOS who received traditional growing rod surgical for scoliosis. Inclusion criteria were: 1) unsuccessful conservative management; 2) Cobb angle ≥50 degrees or curve progression; 3) a minimum of 2-years follow-up; 4) lengthening surgery more than once. Patients with insufficient follow-up time, incomplete data and revision surgeries were excluded. We evaluated patients who were suffered from more than once implant-related complications (MIRC) due to EOS with TGR or less than once implanted-related complications (N-MIRC). All the radiographs were calibrated to achieve accurate distance measurements. Clinical records were reviewed for data including age at the initial surgery, gender, height, weight, etiology, body mass index (BMI), living altitude. The clinical data and the surgical data were all collected and shown in Table I. Complications were also recorded, details were noted.

Radiographic Evaluation

Radiographic measurements were performed independently by two of the authors using a picture archiving and communication system (PACS). All upright standing or sitting posteroanterior and lateral images preoperatively, after surgery, at the last follow-up with growing rods were measured. The radiological measurements included Cobb angle, thoracic kyphosis(TK), lumbar lordosis(LL), T1–S1 range(mm), T1–T12 range(mm), sagittal balance, coronal balance, distance between the C7PL and sagittal vertical axis, pelvic incidence(PI), sacral slope(SS), and pelvic tilt(PT).

Risk factors for MIRC were analysed of the following factors: initial age at surgery (≥8, <8, yrs), follow up time (≥50, <50, month), living altitude, number of operations (>3, ≤3, times), preoperative Cobb angle (>90, ≤90, degree), postoperative Cobb angle (>60, ≤60, degree), preoperative thoracic kyphosis (>50, ≤50, degree), postoperative thoracic kyphosis (>50, ≤50, degree), preoperative lumbar lordosis (>60, ≤60, degree), postoperative lumbar lordosis (>50, ≤50, degree), preoperative sagittal vertical axis (>40, ≤40, mm), postoperative sagittal vertical axis (>40, ≤40, mm), preoperative pelvic incidence (>50, ≤50, degree), postoperative pelvic incidence (>50, ≤50, degree), preoperative sacral slope (≥35, <35, degree), postoperative sacral slope (≥35, <35, degree).

Institutional review board approval was obtained from our institution before initiation of the study. All methods were performed in accordance with the relevant guidelines and regulations, and a consent form was signed by parents of each child.

Surgical Technique

Both the initial surgery and lengthening surgery were all performed under general anesthesia. Neurophysiological monitoring was essential. Single growing rods were used for well-balanced trucks or thin patients, while dual growing rods were mainly used for patients with unbalanced trucks.. The skull to the upper thoracic curve and the stable vertebrae and were selected as the lower instrumental vertebra (LIV) and the upper instrumental vertebra (UIV), respectively. When stripped under the periosteum in the upper and lower fixation areas, the integrity of the joint capsule should be protected. Pedicle screws, hook or hybrid fixations were used. The selection of the anchor sites were depending on severity of the curve, etiology. The proximal and distal anchor points can be limited fusion locally. The connecting rod should be bent for adapting with the curvature of scoliosis. Proper lengthening procedure should be carried out initially. Lengthening surgery was performed for generally 6-12 months. When lesser distraction can be obtained, a risser sign >1°, or menstruation in female patients, final fusion should be adopted.

Statistical Analysis

SPSS Statistics for windows (version 24.0; IBM, Armonk, NY, USA) was used for statistical analysis. Chi-square test or Fisher exact test was utilized for evaluate differences in categorical data. Student-t test was used to examine continuous variables. The risk factors with a p-value <0.1 on univariate analysis were identified as potential of multiple implant-related complications. Multivariate logistic regression was performed to determine the independent risk factors for MIRC.

Results

Fifty-five patients (24 males, 35 females) with EOS from our department treated with TGR between September 2007 and December 2017 met the inclusion criteria. The average age was 8.9±2.4 years at the time of initial surgery. Median follow-up was 51.91±25.23 months (range 24–132). In terms of etiology, 31 patients were idiopathic, 1 patient was syndromic, 18 patients were congenital, 10 patients were neuromuscular. The average number of lengthening was 3.97±1.72 (range, 2–10). An average interval of 11.4±3.0 months (rage from 4 to 24) was performed. Thirty-one of the 59 EOS patients had underwent definitive fusion.

Basic information of MIRC group and N-MIRC group are shown in Table 1. The MIRC group consisted of 10 males and 10 females, with the average initial surgery age of 8.6±2.46 years(range,5-14), The N-MIRC group consisted of 14 males and 25 females, with the average initial surgery age of 9.05±2.40 years（range,5-14）. Etiologies included 11 idiopathic, 6 congenital, 2 neuromuscular, 1 syndromic in MIRC group, and 19 idiopathic, 12 congenital, 8 neuromuscular in N-MIRC group. In MIRC group, 6 underwent dual growing rod surgery and 14 received single growing rod treatment, thus 22 underwent dual growing rod surgery and 17 received single growing rod treatment in N-MIRC group. There was no significant difference between groups for age at initial surgery, curve etiology, sex, height, weight, BMI, single or dual rods, subcutaneous or submuscular, average interval of operations, patients with final fusion. In MIRC group, the mean follow-up time was 65.2±27.98 months (range,24-132）and the mean follow-up time was 44±20.59 months (range, 24-107）in group N-MIRC, which showed a statistically significant difference(P<0.05). Distribution of UIV and LIV were showed in Table 2 and 3.

Table 1
Baseline data

index	MIRC	N-MIRC	P-value
No. of patients	20	39	
Sex (male/female)(no.)	10/10	14/25	0.297
Age at initial surgery (year)	8.6±2.46(5-14)	9.05±2.40(5-14)	0.5
Height (cm)	114.38±11.67(94-140)	119.39±13.67(95-141)	0.168
Weight (kg)	22.3±6.79(11-40)	24.458.26(12-45)	0.317
BMI	16.31±2.22(12.44-20.78)	16.71±3.22(11.45-23.92)	0.621
Diagnosis			0.405
Idiopathic	11	19	
Congenital	6	12	
Neuromuscular	2	8	
Syndromic	1	0	
Duration of follow-up (mo)	65.2±27.98(24-132)	44±20.59(24-107)	0.002
Surgical procedures per patient (no.)	101/5.05	133/3.41	
Patients with final fusion (no.)	13	18	0.17
Single/dual rods (no.)	14/6	22/17	0.311
Subcutaneous/submuscular(no.)	11/9	19/20	0.648
Number of surgical procedures	11.31±3.33(5-24)	11.48±2.71(5-24)	0.71

Table 2
Distribution of UIV and LIV

	MIRC	N-MIRC	total
UIV			
C6	0	1	1
C7	0	1	1
T1	3	4	7
T2	10	21	32
T3	4	8	12
T4	1	4	5
T5	1	0	1
T8	1	0	1
LIV			
T12	0	1	1
L1	1	2	3
L2	0	4	4
L3	8	14	22
L4	5	13	18
L5	6	5	11

The average Cobb angles were similar in MIRC and N-MIRC groups preoperatively, postoperatively and at the last follow-up (P=0.158, 0.213, 0.13). The corrections of Cobb angle were 41.54%±16.58% (10%-66%)in the MIRC group and 41.38%±12.91%（17%-69%） in the N-MIRC group (P=0.941). TK was different postoperatively (P=0.018) between two groups. While they were not different preoperatively and at the last follow-up (P=0.378, 0.063). LL was different at the last follow-up (P=0.047) between two groups, while they were not different preoperatively and postoperatively (P=0.328, 0.478). T1-S1 height was similar in MIRC and N-MINC groups preoperatively, postoperatively and at the last follow-up (P=0.088, 0.984, 0.548). T1-12 height was different in MIRC and N-MINC groups preoperatively and postoperatively (P=0.039, 0.045), while it was similar at the last follow-up (P=0.465). The corrections of T1-S1 height were 26.15%±12.8%（6%-55%）in the MIRC group and 28.8%±17.28（8%-79%）in the N-MIRC group (P=0.548). The corrections of T1-12 height were 38%±34.47%（7%-159%）in the MIRC group and 30.8%±18.71%（3%-80%）in the N-MIRC group (P=0.301). The average PI were similar in MIRC and N-MIRC groups preoperatively, postoperatively and at the last follow-up (P=0.801, 0.648, 0.43). The average PT was different preoperatively (P=0.042) between two groups. While they were not different preoperatively and at the last follow-up (P=0.891, 0.525). The average SS was different at the last follow-up (P=0.048) between two groups, while they were not different preoperatively and postoperatively (P=0.105, 0.409). The average SVA was different postoperatively (P=0.033) between two groups, while they were not different preoperatively and at the last follow-up (P=0.08, 0.279). The average C7PL−CSVL was not different preoperatively, postoperatively and at the last follow-up (P=0.703, 0.448, 0.064). (Table 4, 5)

Table 3
Distal and proximal fixation in the two groups

	MIRC	N-MIRC
UIV		
Screw	5	15
Hook	1	4
Hybrid	14	20
LIV		
Screw	58	133
Hook	0	0
Hybrid	1	0

Table 4
Pelvic parameters in all patients and between the two groups

Index	MIRC	N-MIRC	P value
Pelvic incidence			
Preoperation(°)	39.95°±11.89°(121°-64°)	39.16°±11.04°(16°-58.8°)	0.801
Postoperation (°)	39.37°±11.29°(16.3°-59.4°)	40.77°±10.98°(20°-62°)	0.648
Last follow-up (°)	38.4°±10.25°(16.7°-51.4°)	40.74°±10.98°(15.2°-64.3°)	0.43
Pelvic tilt			
Preoperation(°)	11.90°±13.5°(-7.1°-46.4°)	5.52°±9.76°(-18°-20°)	0.042
Postoperation(°)	8.23°±11.85°(-22.6°-28.3°)	7.78°±11.72°(-14.5°-28°)	0.891
Last follow-up (°)	6.80°±12.86°(-13.5°-37°)	5.01°±8.49°(-15°-27.9°)	0.525
Sacral slope			
Preoperation(°)	30.42°±7.59°(12.7°-40.7°)	33.63°±6.83°(15.5°-46.1°)	0.105
Postoperation(°)	31.14°±8.15°(12.9°-42.3°)	32.97°±7.94°(10°-48°)	0.409
Last follow-up (°)	31.6°±9.29°(12.4°-47.2°)	35.73°±6.29°(18.8°-50°)	0.048
Sagittal balance			
Preopreation (mm)	38.12±26.66(5.85-103.26.22)	26.37±22.51(0-89.22)	0.08
Postoperation(mm)	23.19±14.51(4.67-51.91)	37.49±27.34(4.15-107.91)	0.033
Last follow-up (mm)	30.42±24.33(0-91.09)	38.41±27.64(3.97-109.21)	0.279
Coronal balance			
Preoperation(mm)	26.96±24.55(4.09-97.97)	29.67±26.67(0-102.76)	0.703
Postoperation(mm)	22.79±16.92(2.43-58.72)	27.34±23.68(2.05-111.87)	0.448
Last follow-up(mm)	27.39±19.15(5.48-72.76)	19.05±14.19(0-59.85)	0.064

Finally, sixty of IRC occurred in 35 patients (59.32% of all patients). While MIRC occurred in 20 patients (33.90% of all patients). There were 6 cases of implant dislodgement, 10 cases of implant loosen, 15 cases of rod fracture and 14 cases of PJK in MIRC group. There were 4 cases of implant dislodgement, 4 cases of implant loosen, 2 cases of rod fracture and 5 cases of PJK in N-MIRC group. No patient had spinal cord or nerve injury caused by dislocation of internal fixation. Unplanned reoperation was not performed when the displacement of internal fixation was not obvious or did not cause discomfort to the patient. Unplanned reoperation will increase the incidence of complications. (Table 6, 7)

Table 5
Rdiological results in all patients and between groups

	MIRC	N-MIRC	P value
Cobb angle			
Preoperation(°)	97.42°±16.14°(70°-124.2°)	89.1°±23.2°(47.1°-130.5°)	0.158
Postoperation (°)	57.5°±20.82°(27.4°-103°)	51.42°±15.58°(16.2°-77.7°)	0.213
Last follow-up (°)	52.55°±14.89°(23.6°-74.1°)	45.5°±17.61°(5.1°-81.3°)	0.13
Cobb initial correction rate(%)	41.54%±16.58%(10%-66%)	41.38%±12.91%(17%-69%)	0.941
Thoracic kyphosis			
Preoperation(°)	69.74° ±26.64°(17.1°-109.9°)	62.2°±31.76°(4.4°-145.4°)	0.378
Postoperation (°)	44.42°±23.3°(5.8°-83.3°)	32.02°±15.68°(5°-75.3°)	0.018
Last follow-up (°)	49.26°±21.8°(13.6°-82.5°)	39.37°±17.35°(9.7°-79.4°)	0.063
Lumbar lordosis			
Preoperation (°)	57.13°±18.34°(25.1°-91.1°)	62.09°±18.25°(30°-107°)	0.328
Postoperation (°)	48.9°±13.26°(23.1°-72.2°)	46.03°±15.23°(10°-73.1°)	0.478
Last follow-up (°)	47.1°±12.3°(23.1°-69.5°)	53.80°±11.91°(31.4°-79.4°)	0.047
T1−S1 Height			
Preoperation(mm)	238.35±41.98(160.5-312.7)	253.71±52.26(154.68-359.75)	0.249
postoperation(mm)	298.25±48.13(198.96-363.78)	320.19±44.82(203.24-425.52)	0.088
Last follow-up(mm)	356.82±58.24(254.93-465.51)	357.11±48.36(258.73-464.87)	0.984
T1−S1 initial increasing rate(%)	26.15%±12.8%(6%-55%)	28.8%±17.28(8%-79%)	0.548
T1−T12 height			
Preoperation(mm)	130.08±38.6(68.1-210.1)	150.48±33.31(95.45-224.6)	0.039
Postoperation (mm)	173.07±41.9(87.88-253.27)	192.46±29.76(139.04-261.91)	0.045
Last follow-up(mm)	207.13±44.5(123.35-292.06)	214.73±33.1(132.44-266.88)	0.465

	MIRC	N-MIRC	P value
T1−12 initial increasing rate(%)	38%±34.47%(7%-159%)	30.8%±18.71%(3%-80%)	0.301

Table 6
Complications in all patients and between groups

	MIRC	N-MIRC	Total
Implant dislodgement	6	4	10
Implant loosen	10	4	14
Rod fracture	15	2	17
Proximal junctional kyphosis	14	5	19
	45	15	60

To avoid missing potential risk factors, P-values <0.1 were considered statistically significant in the univariate analysis. Significant risk factors for MIRC, identified by univariate analysis were as follows: follow up time ≥50 month (P=0.008), number of operations >3 times (P=0.00), preoperative thoracic kyphosis >50 degrees (P=0.043), postoperative thoracic kyphosis >50 degrees (P= 0.001), postoperative lumbar lordosis >50 degrees (P=0.092), postoperative sagittal vertical axis >40 mm (P=0.004). All of the potential predictors were then entered into the binomial logistic regression model with the presence of MIRC as the response variable. The following significant independent risk factors for MIRC were number of operations >3 times (OR,0.052), postoperative thoracic kyphosis >50 degrees (OR,18.647), postoperative lumbar lordosis >50 degrees (OR 0.173). (Table 8, 9)

Table 7
Details of Implant-Related Complications

patients	Implant dislodgement	Implant loosen	Rod fracture	Proximal junctional kyphosis	Complications / number of operations
1			1	1	2/4
2	1	1	1		3/7
3	1	1		1	3/5
4	1			1	2/5
5		1	1		2/5
6				2	2/3
7			2		2/4
8	1		1		2/7
9			1	1	2/4
10		1	1		2/5
11		1	1		2/4
12	1	3			4/10
13	1		2		3/6
14				2	2/6
15		1		1	2/6
16				2	2/6
17		1		1	2/3
18			2		2/4
19			2		2/5
20				2	2/2
21				1	1/5
22	1				1/2
23				1	1/4
24	1				1/4
25				1	1/7
26				1	1/2

patients	Implant dislodgement	Implant loosen	Rod fracture	Proximal junctional kyphosis	Complications / number of operations
27			1		1/2
28	1				1/7
29		1			1/2
30			1		1/4
31		1			1/5
32		1			1/2
33		1			1/2
34				1	1/5
35	1				1/4

Table 8. Univariate Analysis of MIRC Risk Factors

Index	MIRC	N-MIRC	total	P value
Initial age at surgery(years)				0.885
≥8	14	28	42	
<8	6	11	17	
Follow up time(month)				0.008
≥50	13	11		
<50	7	27		
Living high altitude or not				0.311
Yes	6	17	23	
No	14	22	36	
Number of operations				0.00
>3	17	14	31	
≤3	3	25	38	
Preoperative Cobb angle(degree)				0.17
>90	13	18	31	
≤90°	7	21	28	
Preoperative Cobb angle(degree)				0.885
>60°	6	11	17	
≤60°	14	28	42	
Preoperative thoracic kyphosis (degree)				0.043
>50°	17	23	40	
≤50°	3	16	19	
Postoperative thoracic kyphosis(degree)				0.001
>50°	10	4	14	
≤50°	10	35	45	
Preoperative lumbar lordosis (degree)				0.848
>60°	4	7	11	
≤60°	16	32	48	
Postoperative lumbar lordosis (degree)				0.092

Index	MIRC	N-MIRC	total	P value
>50°	8	24	32	
≤50°	12	14	26	
Preoperative sagittal vertical axis(degree)				0.257
>40cm	8	10	18	
≤40cm	12	29	41	
Psotoperative sagittal vertical axis(degree)				0.004
>40cm	1	16		
≤40cm	19	23		
Preoperative pelvic incidence (degree)				0.787
>50°	4	9	13	
≤50°	16	30	46	
Preoperative pelvic incidence (degree)				0.308
>50°	2	8	10	
≤50°	18	31	49	
Preoperative sacral slope (degree)				0.909
<35°	12	24	36	
≥35°	8	15	23	
Preoperative sacral slope (degree)				0.939
<35°	12	23	35	
≥35°	8	16	24	

□ 9.Multivariate Analysis of MIRC Risk Factors

Parameters	B	S.E.	Wald	df	P	Exp（B）	95% CL
Number of operations >3times	-2.951	0.907	10.583	1	0.001	0.052	0.009-0.309
Postoperative thoracic kyphosis >50°	2.926	1.026	8.128	1	0.004	18.647	2.495-139.357
Postoperative lumbar lordosis >50°	-1.757	0.813	4.674	1	0.031	0.173	0.035-0.849

Discussion

Implant-related complication included implant dislodgement, implant loosen, rod fracture, proximal junctional kyphosis. The database from The Scoliosis Research Society (SRS) showed the overall IRC rate of deformity surgery was 0.19% [15]. The continuous development of growing rod technology and treatment concepts, the principal purpose of which is to give full play to the role of traditional growing rods in the treatment of early-onset scoliosis, reduce the occurrence of complications during the treatment process and maximize the benefits of patients, thus the occurrence of implant-related complications is one of the main factors affecting the treatment effect [16]. Nikouei [10] reported 22 patients with early-onset scoliosis treatment with dual growing rods and demonstrated curve correction, but the incidence of implant-related complications was 54.5%, which were the main reasons for unplanned reoperation[9]. A retrospective study indicated 110 patients with growing rod for early-onset scoliosis, a total of 87 patients (79%) had 263 complications and 84 unplanned reoperations, of which implant-related complications were 49%, surgical site infections were 23%, the primary operation age less than 7.6 years, the thoracic kyphosis angle greater than 38° and the main curve Cobb angle greater than 84° were risk factors for complications [11]. Zhang et al [17] identified growing rod treatment of 55 early-onset scoliosis patients with a total of 272 operations were performed, and 37 (14%) complications occurred in 23 cases (42%), of which implant-related complications occurred 25 times, multivariate regression analysis showed patients with a larger Cobb angle of the main curve during follow-up are more likely to have postoperative complications, the younger age at the initial operation will increase the number of operations and increase with duration, which will increase the incidence of complications. Raymond et al. [18] analyzed 48 cases of growing rod treatment for EOS, of which 26 patients had 52 cases of implant-related complications, and the average number of complications per capita was 2.0 to 1.5 times (1-8 times), 14 patients have two or more internal fixation-related complications, the risk factors for IRCs include: female patients, younger age and smaller pelvic incidence angle, for patients with low pelvic incidence angle, more attention should be paid to the sagittal balance. In a multi-center study by Akbarnia [19], 138 growing rods were used to treat patients with EOS and 56 patients (40.6%) had at least one growing rod fracture, the study found that growing rod fracture was associated with pathology, BMI, and mean interval lengthening are irrelevant. Stainless steel growing rods are more prone to fracture than titanium alloy growth rods, and growing rod fracture often occurs in a diameter of less than 4mm. A study on IRCs in scoliosis patients with neurofibromatosis type, including 59 patients, 17 cases (28.8%) of IRCs occurred, of which scoliosis aggravated (7 cases), screws Loosening (3 cases), adding-on (3 cases), rod fracture (2 cases), PJK (2 cases), nail cap loosening (1 case), pedicle screw extraction (1 case), univariate logistic regression analysis showed that age <9 years, thoracic kyphosis angle < 50° and growing rod application are risk factors for IRCs, multivariate logistic regression analysis showed that thoracic kyphosis angle >50° and the application of growth rods are independent risk factors for IRCs, the author believes that the kyphosis angle is too large, and there may be malnutrition for the kyphotic vertebral body, the apical vertebral area around the internal fixation bears more pressure, which will cause the connecting rod to break or the screw to pull out, younger patients need more growth of the spine, and the diameter of the internal fixation implanted for the first time is smaller, so IRCs are more likely to occur, the authors suggest that the pathological classification of dural expansion and EOS should be considered when selecting distal and proximal fixation segments [20].

In our study, there was no statistical difference in gender, height, weight, and BMI between the MIRC group and the N-MIRC group (P=0.297, 0.168, 0.317, 0.621), and there was no statistical difference in the diagnostic classification of the other two groups (P=0.405). The MIRC group was younger than the N-MIRC group preopreatively, but the difference was not statistically significant (P=0.5). In previous study, younger patients before the initial surgery was prone to occur IRCs [21], but in our study, although patients in the MIRC group were younger, it was not statistically different.

The number of single and dual growing rods in the MIRC group and N-MIRC group were 14/6 and 22/17 respectively. There was no significant difference in statistical analysis (P=0.311). previous studies have shown that single growing rod is more prone to occur IRCs complications, thus our study is different from previous [10, 13, 17, 22]. The interval lenthening in the MIRC group and N-MIRC group was 11.31 to 3.33 months and 11.48 to 2.71 months, respectively. There was no significant difference in statistical analysis (P=0.71). This conclusion is consistent with the results of Akbarnia [19]. The rod interval had no effect on the occurrence of multiple implant-related complications.

The pelvic incidence of patients in the MIRC group changed from 39.95°∼11.89° preopreatively to 38.4°∼10.25° at the last follow-up, there was no significant difference in statistical analysis (P>0.05). The pelvic incidence angle of the N-MIRC group was changed from preoperatively 39.16°∼11.04° became 40.74°∼10.98° at the last follow-up. There was no significant difference in statistical analysis (P>0.05). In the past, it was reported that with age increasing, the PI angle continued to increase until maturity, thus the increase of PI was limited due to the curvature of the spine or application of implant in EOS patients [21, 23–24], which was confirmed in our literature. There was no significant difference of PT between the MIRC and N-MIRC group preoperatively, postoperatively and at the last follow-up (P=0.801, 0.648, 0.43). The preoperative PT of the two groups were 11.90°∼13.5° and 5.52°∼9.76°, respectively (P=0.042). There was no significant difference in the PT between postoperative and the last follow-up (P=0.891, 0.525). There was no significant difference between the two groups of SS preoperatively and postoperatively (P=0.105, 0.409). There was significantly difference of SS at the last follow-up between two groups (P=0.048), due to the PT and SS are two variety parameters as age increasing, body position changes or other pathological factors exist [18].

Here major Cobb angle in the MIRC group was 97.42°∼16.14° preoperatively, while 89.1°∼23.2° in N-MIRC group (P=0.158), Previous studies [20] indicated that the Cobb angle of the major curve greater than 84° was a risk factor for complications. The complications involved in implant-related complications, surgery site infection and other complications, our study mainly research implant-related complications. The correction of major Cobb angle in two groups were all satisfactory, but MIRC group was better than N-MIRC group (P<0.05). There was no significant difference in TK between the two groups preoperatively and at the last follow-up (P=0.378, 0063), while the postoperative TK of the two groups were 44.42°∼23.3° and 32.02°∼15.68°, respectively (P=0.018). There was no significant difference in T1-S1 comparison between the two groups preoperatively, postoperatively, and the last follow-up (P=0.249, 0.088, 0.984). The results of the study showed that the occurrence of multiple implant-related complications did not affect T1- S1 growth. There was statistically significant difference in the length of T1-12 between the MIRC group and the N-MIRC group preoperatively and postoperatively (P=0.039, 0.045) but there was no significant difference in the T1-12 between the two groups at the last follow-up (P=0.465), and the correction rate of T1-12 in the two groups was also not statistically significant (P=0.301). The results show that despite multiple implant-related complications, the growth of T1-12 was not affected.

Univariate analysis of the following factors showed: number of operations >3 times, follow up time ≥50 months, preoperative thoracic kyphosis >50°, postoperative thoracic kyphosis >50°, postoperative lumbar lordosis >50°, postoperative sagittal vertical axis >40mm are statistically different) (P<0.1); age at initial operation <8 years, live at high altitude, preoperative Cobb angle >90°, postoperative Cobb >60°, preoperative lumbar lordosis >60°, preoperative sagittal vertical axis >40mm, preoperative pelvic incidence >50°, postoperative pelvic incidence >50°, preoperative sacral slope ≥35°, postoperative sacral slope ≥35° were not statistically different (P>0.1). Multivariate logistic regression analysis showed that number of operations >3 times, postoperative thoracic kyphosis >50° and postoperative lumbar lordosis >50° are independent risk factors for multiple implant-related complications. Among them, patients with a postoperative thoracic kyphosis >50° postoperatively had an 18.647 times higher risk of MIRC than those with postoperative thoracic kyphosis <50° (OR=18.647, P=0.004). Previous studies had shown that abnormal TK, especially increased TK was the reason for complications, Our research was consistent with previous studies[11, 13–14, 20, 25].

This purpose of our study mainly explored the occurrence the risk factors for more than twice implant-related complications. Postoperatively TK>50° should be pay more attention, the main considerations as follow: firstly, the abnormal postoperatively TK lead to more stress on proximal and distal anchors, EOS patients were young and had poor bone mineral density, pedicle screw pullout, loosen and kyphosis were Easier to occur. Secondly, Abnormal TK required larger curvature of the growing rod to match it and the initial implantation would bring more growth, thus the shape of the growing rod might decrease stiffness of the growing rod. Thirdly, patients with abnormal TK might strip more in the distal and proximal anchor points during the initial operation, the articular capsule of adjacent segments was damaged, which might cause the stability of the anchor points to decrease. Fourthly, EOS patients with postoperatively TK>50°, the balance of spinal sequence and growing rod might be changed after the initial surgery, which resulted in abnormal stress between spinal sequence and implant, that might increase the incidence rate of MIRC. In the previous study of our team [26], the results showed that postoperative upper thoracic scoliosis >50° was a risk factor for PJK. This study also emphasizes the importance of keeping the proximal posterior joint capsule and posterior ligament intact.

Multivariate logistic regression analysis showed that the number of operations >3 times was the risk factor for MIRC. Previous studies reported that longer follow-up time and more operations were the risk factors of postoperative complications [17]. Multiple operations include multiple rod adjustment operations and unplanned reoperations, which caused by complications. Multiple lengthening of growing rods would lead to changes of spinal curvature, which might lead to mismatching of growing rods with spinal curvature, long-term accumulation of abnormal stress might lead to IRCs. In our group, one patient in MIRC group had 10 times operations and 4 times of IRCs occurred (1 implant dislodgement and 3 screw loosening). Another one patient had 7 times of operations and 2 times of IRCs occurred (1 implant dislodgement and 1 rod breaking). 3 patients in the N-MIRC group completed 7 times of operations, 2 patients had one IRC (1 PJK and 1 implant dislodgement), and one patient had no IRC. Although the above patients had more operations, there were no more IRCs. Despite this, we should still pay more attention to patients with more than 3 times of operations.

The loss of LL was the cause of back pain and dysfunction after adult scoliosis surgery, LL could be used to evaluate the adverse effect of treatment methods on adult scoliosis, and guide surgeons to select spinal osteotomy to correct sagittal balance [27]. Previous studies had shown that excessive LL after surgery could lead to PJK in adult patients with scoliosis and require revision surgery [28]. At present, there were few studies on the efficacy and complications of LL and EOS. The results of our study showed that the immediate postoperative LL>50 ° was an independent risk factor for MIRC in patients with EOS treated with growing rod. LL, TK and PI worked together to maintain sagittal balance, abnormal LL might increase the stress at the distal and proximal anchor points or increase the abnormal stress to the growing rod, which resulting in the occurrence of MIRC.

At present, there were few studies on IRCs of EOS and pelvis parameter. Foreign studies have reported that small pelvic incidence angle is a risk factor for PJK and IRCs [18]. In our study, preoperative PI >50 °, postoperative PI >50 °, preoperative SS ≥35 ° and postoperative SS ≥35 ° were not risk factors for MIRC, and the preoperative PI of patients in MIRC group and N-MIRC group were 39.95°±11.89° and 39.16°± 11.04° respectively. Qiu Yong et al. [13] reported that patients with single growing rod were more prone to growing rod fracture and repeated rod fracture than patients with dual growing rod. In this paper, the proportion of patients with single growing rod in the MIRC group was 60.9% and 56.4% in the N-MIRC group ($P = 0.311$). The purpose of this paper was to study the causes of MIRC rather than rod fracture or multiple rod fracture. Previous study indicated that the follow-up time is a risk factor for complications with growing rod for EOS, the longer follow-up time, the greater possibility of complications [17]. In our study, one-way ANOVA showed that the follow-up time of MIRC group and N-MIRC group were 65.2 ± 27.98 months and 44 ± 20.59 months respectively ($P = 0.002$), which was similar to that reported in the literature, but multivariate logistic regression analysis showed that the follow-up time ≥50 months was not a risk factor for MIRC.

In this study, 1 patient had 4 times of IRCs (1 implant dislodgement and 3 screw loosening), 3 patients had 3 times of IRCs (1 screw loosening and 1 rod fracture and 1 proximal dislodgement, 1 PJK and 1 dislodgement and 1 screw loosening, 1 PJK and 2 rod fracture), 16 patients had more than once implant-related complications. 15 patients with 1 IRC during treatment were divided into N-MIRC group. When EOS patients had one of the three factors during operation as follow: number of operations >3 times or postoperative TK >50° or postoperative LL >50°, the patient should be treated individually and followed up closely in combination with the patient's initial operation age, severity of scoliosis, etiological classification, radiographic parameters, reduce the incidence of IRCs. Patients have MIRC during the treatment process, which increases difficulties in the treatment process, brings more pain to patients, and even serious complications may occur, resulting in the impact of the final treatment effect. Therefore, more research are needed for MIRC.

Our study has several limitations. Firstly, this was a retrospective study, and no randomization was performed between the MIRC and N-MIRC group. Secondly, the sample size was not big enough, and all cases were from a single institution, which can cause selection bias, thirdly, the incidence of MIRC with growing rods might be underestimated since not all of the patients were followed until final fusion, finally.

Conclusions

Traditional growing rod in the setting of EOS has excellent clinical and radiographic outcomes but a high multiple implant-related complications. Number of surgery procedure > 3 times, postoperative thoracic kyphosis >50°, postoperative lumbar lordosis >50° are independent risk factors for MIRC.

Abbreviations

IRCs
Implant-Related Complications
MIRC
Multiple Implant-Related Complication
TGR
Traditional Growing Rod;
TK
Thoracic Kyphosis;
LL
Lumbar Lordosis;
PI
Pelvic Incidence;
SS
Sacral Slope;
PT
Pelvic Tilt;
EOS
Early-Onset Scoliosis;
MCGRs

Magnetically Controlled Growing Rods;
PACS
Picture Archiving and Communication System;
LIV
Lower Instrumental Vertebra;
UIV
Upper Instrumental Vertebra;
BMI
Body Mass Index.
SVA
Sagittal Vertical Axis
PJK
Proximal Junctional Kyphosis

Declarations

Acknowledgments

We would like to acknowledge the significant contribution of the patients, families, researchers, clinical staff, and sponsors included in this study.

Authors' contributions

JHJ carried out the study and design of this manuscript, the acquisition of the data, the analysis and the interpretation of the data and the drafting of the manuscript. JJH, AXP and YSW followed up, collected the data and responsible for the data collection and radiographic measurements.QJS, ZXS and PY interpretation of data and revision. YH conceived of the study and participated in its design and coordination, revised the manuscript critically for important intellectual content, and gave final approval of the version to be published. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study protocol was reviewed and approved by the Committee on Ethics and the institutional review board of Beijing Chao-Yang Hospital, Capital Medical University. It was confirming that all methods were performed in accordance with the relevant guidelines and regulations in the methods section, and a consent form was signed by parents of each child.

Funding

This study was supported partially by research fund provided by National Natural Science Foundation of China (NSFC) No. 81372008.

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Consent for publication

No applicable

Competing interests

These authors declare that they have no competing interests.

Author details

[1] Department of Orthopedic Surgery, Beijing Chao-yang Hospital, Capital Medical University, Beijing 100020,China.

[2] Department of Orthopedic Surgery, Liangxiang Teaching Hospital, Capital Medical University, Beijing 102401,China.

[3] High School Affiliated to Ren min University of China

References

1. Williams BA, Matsumoto H, McCalla DJ, Akbarnia BA, Blakemore LC, Betz RR, Flynn JM, Johnston CE, McCarthy RE, Roye DP Jr, Skaggs DL, Smith JT, Snyder BD, Sponseller PD, Sturm PF, Thompson GH, Yazici M, Vitale MG. Development and initial validation of the Classification of Early-Onset Scoliosis (C-EOS). J Bone Joint Surg Am. 2014,20;96(16):1359–67.
2. Hasler CC. Early-onset Scoliosis: Contemporary Decision-making and Treatment Options. J Pediatr Orthop. 2018,38 Suppl 1:S13-S20.
3. Redding G, Song K, Inscore S, Effmann E, Campbell R. Lung function asymmetry in children with congenital and infantile scoliosis. Spine J. 2008 ,8(4):639–44.
4. Tis JE;Karlin LI;Akbarnia BA.Early onset scoliosis: modern treatment and results. Journal of Pediatric Orthopaedics,2012,Vol.32(No.7):647–65.
5. Akbarnia BA, Marks DS, Boachie-Adjei O. Dual growing rod technique for the treatment of progressive early-onset scoliosis: a multicenter study. Spine,2005, 30:S46–57.
6. Tello CA.Harrington instrumentation without arthrodesis and consecutive distraction program for young children with severe spinal deformities.Experience and technical details.Orthopedic Clinics of North America,1994,Vol.25(No.2):333–384.
7. Thompson, George H.Comparison of Single and Dual Growing Rod Techniques Followed Through Definitive Surgery: A Preliminary Study.[Miscellaneous].The Spine Journal,2005,Vol.30(No.18):2039–2044.
8. Xu GJ, Fu X, Tian P.Comparison of single and dual growing rods in the treatment of early onset scoliosis: a meta-analysis.J Orthop Surg Res,2016 Jul 12,11(1):80.

9. Nikouei F,Ghandhari H.Complications of fusionless correction of early onset scoliosis using dual growing rods. Arch Iran Med,2018,21:595–599.
10. Bouthors C, Gaume M.Outcomes at skeletal maturity of 34 children with scoliosis treated with a traditional single growing rod.Spine,2019,44:1630–1637.
11. Upasani VV,Parvaresh KC.Age at initiation and deformity magnitude influence complication rates of surgical treatment with traditional growing rods in early-onset scoliosis.Spine Deform,2016;4:344–50.
12. Jiang H, Hai JJ, Yin P, Su Q, Zhu S, Pan A, Wang Y, Hai Y. Traditional growing rod for early-onset scoliosis in high-altitude regions: a retrospective study. J Orthop Surg Res. 2021 Aug 10;16(1):483.
13. Chen Z, Qiu Y.How Does Hyperkyphotic Early-Onset Scoliosis Respond to Growing Rod Treatment? J Pediatr Orthop,2017 Dec,37(8):e593-e598.
14. Anari JB,Flynn JM,Cahill PJ,Vitale MG,Smith JT.Children's Spine Study Group. Unplanned return to OR (UPROR) for children with early onset scoliosis (EOS):a comprehensive evaluation of all diagnoses and instrumentation strategies.Spine Deform,2020,(2):295–302.
15. Chen Z, Qiu Y. How Does Hyperkyphotic Early-Onset Scoliosis Respond to Growing Rod Treatment? J Pediatr Orthop,2017 Dec,37(8):e593-e598.
16. Shillingford JN, Laratta JL, Sarpong NO. Instrumentation complication rates following spine surgery: a report from the Scoliosis Research Society (SRS) morbidity and mortality database. J Spine Surg. 2019 Mar;5(1):110–115.
17. Jeans K A,Johnston C E.Exercise Tolerance in Children With Early Onset Scoliosis: Growing Rod Treatment "Graduates".Spine Deformity,2016,4(6):413–419.
18. Liang J, Li S, Xu D, Zhuang Q. Risk factors for predicting complications associated with growing rod surgery for early-onset scoliosis.Clin Neurol Neurosurg,2015,136:15–9.
19. Carender CN,Morris WZ.Low Pelvic Incidence Is Associated With Proximal Junctional Kyphosis in Patients Treated With Growing Rods.Spine,2016,May;41(9):792–7.
20. Hosseini P, Pawelek JB, Nguyen S.Rod fracture and lengthening intervals in traditional growing rods:is there a relationship?Eur Spine J,2017,26(6):1690-1695. [20]Yao Z, Li H, Zhang X.Incidence and Risk Factors for Instrumentation-related Complications After Scoliosis Surgery in Pediatric Patients With NF-1.Spine (Phila Pa 1976), 2018,4 3(24):1719-1724.
21. Shah SA,Karatas AF,Dhawale AAGrowing.The effect of serial growing rod lengthening on the sagittal profile and pelvic parameters in early-onset scoliosis. Spine,2014,39(22):E1311-7.
22. Xu GJ, Fu X, Tian P.Comparison of single and dual growing rods in the treatment of early onset scoliosis: a meta-analysis.J Orthop Surg Res,2016 Jul 12,11(1):80.
23. Bekmez S, Demirkiran HG, Dede O.Spinal Instrumentation in Growing Children Retards the Natural Development of Pelvic Incidence.J Pediatr Orthop,2019, 39(3):141–145.
24. Bess S,Akbarnia BA,Thompson GH.Complications of growing-rod treatment for early-onset scoliosis: analysis of one hundred and forty patients. J Bone Joint Surg Am, 2010,92:2533–43.

25. Schroerlucke S R.How does thoracic kyphosis affect patient outcomes in growing rod surgery? Spine,2012,37(15):1303–1309.
26. Pan A, Hai Y, Yang J.Upper instrumented vertebrae distal to T2 leads to a higher incidence of proximal junctional kyphosis during growing-rod treatment for early onset scoliosis. Clin Spine Surg,2018,31:337–41.
27. Boissière L, Bourghli A, Vital JM, Gille O, Obeid I.The lumbar lordosis index: a new ratio to detect spinal malalignment with a therapeutic impact for sagittal balance correction decisions in adult scoliosis surgery.Eur Spine J,2013 Jun,22(6):1339–45.
28. Kim HJ,Bridwell KH,Lenke LG,Park MS,Song KS.Patients with proximal junctional kyphosis requiring revision surgery have higher postoperative lumbar lordosis and larger sagittal balance corrections.Spine,2014,9(9):E576-80.