

MAGNETICALLY CONTROLLED GROWING RODS In Early Onset Scoliosis Surgery: A Review of English-Language Literature

M.V. Mikhaylovskiy¹, A.A. Alshevskaya²

¹Novosibirsk Research Institute of Traumatology and Orthopaedics n.a. Ya.L. Tsivyan, Novosibirsk, Russia ²Scientific Center for Biostatistics and Clinical Research, Novosibirsk, Russia

The objective of the review is to provide multifaceted information on the treatment of young children with severe onset scoliosis using magnetically-controlled growing rods (MCGR). This promising though controversial method is not yet well known in our country. The review presents the history of the development of the method, surgical technique, the frequency of etiological forms of spinal deformities, and describes in detail the results of scoliosis correction including the most severe cases. Quantitative and qualitative data describe complications that arise during the treatment including those characteristic only for this method (for example, slippage phenomena). The problem of repeated operations is separately discussed, and the capabilities of MCGR and other techniques based on the principle of distraction are compared. The review presents features of the use of MCGR in adult patients, the dynamics of the primary curve in the postoperative period (does the Sankar's law work?), the possibilities of ultrasound when monitoring the effectiveness of magnetic rods, the use of MRI simultaneously with MCGR, and the comparative cost of the method. Particular attention is paid to the problem of a uniform protocol of staged extension of rods. It seems that the initial enthusiasm has somewhat decreased. It is commonly agreed that new research is needed. **Key Words:** early scoliosis, surgical treatment, magnetically controlled growing rods.

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The term "early onset scoliosis" (EOS) was introduced by Dickson in 1994 [1] to refer to spinal deformities diagnosed in patients younger than five years. After SRS Growing Spine Committee publication [2], this definition was used to describe scoliosis identified at the age of under 10 years. These are complex, often very severe progressive deformities of various etiologies significantly affecting anatomy of the spine and the thoracic cage and often leading to complications (for instance, thoracic insufficiency syndrome). The main problem that arises when choosing a method for treating early scoliosis is the need to combine the correction of progressive spinal deformity with preservation of the spinal growth potential. In such situation, achievement of the goal is extremely difficult. Observation without active intervention in the pathological process is justified in case of mild deformities and in the absence of obvious signs of progression. Conservative treatment, which is usually aimed at restraining the progression of deformity with the possibility to

delay surgery to a later date, includes two main options. The first option is a variety of corrective braces (Cheneautype brace or others), while the second option includes multi-staged plaster cast-bracing [3]. Both methods provide a rather limited corrective effect, and their use is accompanied with significant difficulties (for instance, plaster cast should be changed every 3-4 months under general anesthesia). Surgical technologies that allow preserving spinal growth (growth-sparing technique) originate from the 1960s. In his classic work, Harrington [4] presented a method of scoliosis correction in children under the age of 10 using a distraction device with hooks and without bone grafting. Moe et al. [5] developed and popularized the method by incorporating staged distractions until the age when final fusion can be performed. After that, Akbarnia et al. [6] suggested using two rods at the same time, which increased the stability of the system, reduced the number of complications, and made the treatment result more predictable. This technique, regardless of the type of implant, is called "growing rods". Later, the number of techniques aimed at EOS correction has increased. Skaggs et al. [7] classified these techniques based on the type of their therapeutic effect on the growing spine:

- distraction-based: GR, VEPTR, MCGR;
- tension-based: staples, tethering;
- guided-growth: Luque, Shilla.

The most widely used technique is the technique of growing rods (GR). In recent years, it is more usually defined as "traditional growing rods" (TGR) thus emphasizing that the method is quite old and distinguishing it from others based on the principle of distraction. The advantages of TGR are well known: they are relative simplicity and quite satisfactory results. However, there are also a number of serious drawbacks: surgical interventions (staged distraction) every 6–9 months under general anesthesia, frequent hospitalizations, negative effects on the child's mental health [8], difficulties due to the need to break away from work for parents and from school for children. Apparently, the biggest problem is numerous surgical complications. Bess

et al. [9] reported a group of 140 patients, 81 (58 %) of which had at least one complication. The same authors emphasized a growing risk of complications with an increase in the number of interventions: each subsequent distraction increases the risk by 24 %.

This situation requires the search for new methods. The increasing use of magnetically-controlled growing rods (MCGR) was noted at the beginning of the second decade of the 21st century. It is enough to say that, according to the data presented at the conference on the issues related to EOS treatment in 2018 (Lisbon), magnetic rods are used in 85 % of EOS cases in the USA. The literature on MCGR is extensive and multidimensional. However, it contains only one metaanalysis [10], which includes data of six articles. There are no publications in the Russian-language literature, since the method is not used in Russia. The reason for this is the absence of a Russian license from the manufacturer, who is probably not much interested in the development of the Russian market. For this reason, we considered that it would be reasonable and appropriate to present a review of the current literature on the results of the use of MCGR to our colleagues.

History of the method. The first attempt to create an implantable magnetically-controlled correction device was performed by the team of Jean Dubousset in France. At his request, Arnaud Soubeiran, a talented engineer, developed an expandable prosthesis in the early 1990s, which was used after resection of malignant tumors of the limbs. In 1996, Dubousset initiated the development of a device for correcting spinal deformity based on the same principle, i.e. using an external magnetic activator. After a series of experiments on sheep in 1997, the first surgery was performed in the clinic [11, 12]. In 2008, the results of 15 surgeries performed using Phenix M. Rod (the name of the first implant; Fig. 1) were demonstrated at the SRS congress in Hong Kong [13, 14]. The device presents a rod connected to an expandable segment containing a permanent neodymium magnet. Each movement of the outer magnet sets in motion the inner

magnet thus inducing rod lengthening, the maximum length of which can reach 60 mm. The rod can be bent in order to imitate the sagittal contour of the spine. Patients were operated on over the period of three years; the scoliotic curve was reduced on average from 68° to 40° (Fig. 2). There were only two complications during this time: costal hook pullout and development of neurological symptoms, which were stabilized immediately. The authors concluded that the method is highly effective and promising. Distractions were completely painless, they were performed on an outpatient basis or at home and allowed achieving a 1-mm increase in the rod length in less than 2 min. Meanwhile, Dubousset considered it necessary to continue the development of the method in terms of improving the corrective action on the apical region in the horizontal plane for elimination of the torsion component of the deformity. Unfortunately, the death of Soubeiran forced him to abandon this idea. Medtronic Company showed no interest in continuing the studies [15].

An article by Takaso et al. [16], who developed a new type of instrumentation based on the remote-controlled growing rods with an integrated engine, is also worth mentioning. The system consisted of a distraction device, a remote control receiver box (RCRB), and a controller. The distraction device, in its turn, consisted of an outer cylinder, a small gearhead motor, an inner gear, and a growing rod. Hooks are attached to the rod with conical sleeves. When the controller rotates, a torque is generated in the motor, which is converted to distraction force by the inner gear, and the growing-rod stretches without rotation. The authors first tested the system on a scoliosis model and received a smooth correction of deformity, and then conducted animal studies (in dogs). The distraction rod was placed subcutaneously, while RCRB was implanted in the abdominal cavity. After modelling of scoliotic deformity, correction was performed at a rate of 1 cm after week 3, 6, 9, and 12. Thus, stepwise correction of the initial 28° scoliotic curve to 3° was achieved. The authors saw the drawbacks of their system in the size of

the distraction rod (the outer diameter is 16 mm) and the site selected for RCRB implantation. It is unknown whether the device was used in the clinic, as we did not manage to find any other publications of these authors.

Further development of the MCGR method is ascribed to Akbarnia and his colleagues from San Diego. In 2009, they first reported the method of EOS treatment using a new distraction system consisting of two main elements: an implantable distraction device and an external control device, which allows both noninvasive lengthening and shortening of the distraction rod [17]. The latter consists of the two main elements. The main element is the actuator with a diameter of 9 mm. The permanent magnet located in it can be non-invasively activated by the external control device: both for distraction and retraction. A flexible rod with a diameter of 4.50, 5.50 or 6.35 mm is attached to the actuator. The fixation can be rigid or articulated in order to reduce stress on the construct and at the site of contact with the bone. The correction device is attached to the spine with standard screws and hooks. The external control device is a portable tool containing two permanent magnets for automatic regulation of the implant length using a switch (Fig. 3). The distraction rate is displayed on the screen of the device. Lengthening maximum is 48 mm, the average distraction force is 222 N when the outer magnet is 26.5 mm apart from the inner magnet. Lengthening by 1 mm is achieved within 7 s.



Fig. 1 Appearance of the Phenix M. Rod (courtesy of Dubousset)

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Fig. 2

One of the first patients treated with Phenix M. Rod: an 8-year-old girl with neuromuscular scoliosis progression despite brace treatment: \mathbf{a} – axial traction radiography; \mathbf{b} – radiography immediately after growing rod implantation; \mathbf{c} – radiography after 4 years and 6 sessions of outpatient rod distraction demonstrates stability of the curve, a 25-mm increase in the rod length (courtesy of Dubousset)

Akbarnia et al. [18] presented the results of an experimental study conducted on nine Yucatan mini-pigs. Magnetic distraction rods were placed and fixed with pedicle screws. Distractions were performed on a weekly basis at a rate of 7 mm per week, the implant was removed after 7 weeks, and animals were killed after additional 3 weeks. As a result, 39-mm distraction was achieved, which constituted 80 % of the intended distraction. A 10 % loss, according to the authors, could be due to a change in the rod contour and its rotation during lengthening, while another reason is a thick layer of subcutaneous fat. An accelerated increase in vertebral unit height was noted in the distraction area after implant removal. The authors suggested that pulsed stimulation activated the growth plates after removal of the distraction rod. No complications were noted. The obtained results encouraged optimism for the prospects of using the method.

In 2013, Akbarnia et al. [19] published the first results of the clinical use of MCGR in 14 patients with spinal deformities of various etiologies. The authors found the results to be quite encouraging, since the method seemed to be safe and effective. As compared to TGR, the number of surgical interventions was sharply reduced, and the level of complications was shown to be low. The follow-up period for this group of patients was only 10 months. The most common complication was a partial loss of the achieved correction: 11 cases out of 68 lengthenings. This loss was regained in subsequent distractions. There were no other complications except for one case of superficial wound infection.

Next, the authors [20] performed a comparative study of the effectiveness of TGR and MCGR. The study of two groups of patients (12 people each) sharing similar basic parameters showed the following results: major curve correction was equal for both systems; spinal growth (T1–S1) was 8.1 mm/year in the MCGR group and 9.7 mm/year in the TGR group; lengthening of the thoracic spine (T1-T12) was 1.5 and 2.3 mm/ year, respectively; TGR patients underwent 73 surgeries, 56 of which were distractions, while MCGR patients underwent 16 surgeries and 137 noninvasive lengthenings; there were five and four unplanned surgeries in the TGR and

MCGR groups, respectively. After a twoyear follow-up period, a conclusion was made that both methods have similar effectiveness, despite the fact that the number of planned surgeries was expected to be higher for the TGR group, while the number of unplanned interventions turned out to be surprisingly equal in both groups.

Two years later, Akbarnia et al. [21] presented results comparing the effectiveness of MCGR placed primarily and as a conversion from TGR. There were a total of 40 patients. It was shown that spinal deformity is equally controlled by both types of rods. However, the spinal growth is less pronounced in the TGR group than after MCGR implantation.

Intervention technique [22]. The study is performed under general anesthesia. The patient is placed in prone position; two linear cuts are made at the level of the planned fixation. In case of a revision surgery, it is reasonable to perform access along the entire length of the postoperative scar in order to remove TGR and place a magnetic rod. Posterior vertebral regions are exposed subperiosteally at the site of fixation. Fixations are formed using various combinations of pedicle screws and hooks. The magnetic rod is placed through an axillary access and then fixed. If one rod is used, it is placed on the concave side of the curve. The length of the vertebral fixation area does not depend on the construction type (single- or dual-rod systems). If two rods are used, they can be attached to each other via a connector in order to increase the construct strength. At sites of subperiosteal exposure of the posterior vertebrae, bone grafting with local tissues is performed. For dual-rod system, many surgeons use the offset technique, which implies standard placement of one rod (caudally placed actuator), while the second rod is installed in the opposite position (cranially placed actuator). This allows preventing the mutual influence of the two magnets during rod lengthening. The level of fixation placement depends on the type of curve, but typically, cranial fixation is formed at T2-T4, while caudal fixation is formed at the neutral vertebra (which is bisected by the central sacral line; Fig. 4).

According to Hosseini et al., the use of lateral rods [23] does not provide more effectiveness. Lengthening procedures are carried out by using a remote controller containing two permanent magnets that can be rotated by a gear mechanism. The controller is placed over the patient's back at the level of the actuator of the corresponding rod. The magnetic field of the latter is identified by using an external magnet which is attracted to the rod. Once activated, the external controller activates rotation of the magnet in the rod actuator. This procedure is performed at the outpatient clinic in the absence of anesthesia. The estimated lengthening value (mm) is displayed on the external remote controller, which can be used not only for distraction but also for retraction of the rod in case a patient experiences pain or discomfort.

Capabilities of the method. The results of using MCGR are presented in a large number of publications, which allows one to perform an objective assessment of the observed effect. We have summarized all the information at our disposal in a series of tables to make it easier for readers and to compare the results obtained by different authors. Table 1 presents data on the etiology of spinal deformities treated with MCGR [20, 23-45]. It is noteworthy that the number of cases of idiopathic scoliosis does not prevail over other etiologies at all. Even if not taking into consideration the works by Harshavadhan et al. [33] and Samdani et al. [44], which are devoted to neuromuscular deformities only, idiopathic scoliosis does not take the first place in the number of cases. This is not something fundamentally new, we just note this fact in order to emphasize once again the diversity of the early-onset spinal deformities.

Analysis of Table 2 which contains information from 34 publications, allows one to draw some preliminary conclusions. Number of patients in the considered groups varies widely: from 5 to 67 (mean, 25.3) patients, which is quite significant, considering that the pathol-



Appearance of the magnetically-controlled growing rod and the external remote controller, the screen displays 5-mm distraction [38]

ogy is relatively rare. The average age of MCGR implantation and the first distraction is below 7 years only for the three groups, while in some cases it reaches 9-10 years, which is the upper age limit of EOS. It is unlikely to be the result of late diagnosis but rather a desire to postpone the start of treatment to a later date when the progressive nature of the pathology becomes evident. The average follow-up period in the vast majority of cases does not exceed three years. It is enough to say that, of the 800 patients presented in these works, final fusion is mentioned in only four (!) cases [35, 52]. As for the remaining cases, the treatment continues, and it is too early to draw conclusions about the final result of applying the method. Data on the outpatient MCGR lengthening protocol present a rather contradictory picture. The intervals between the rod lengthening procedures vary in a very wide range: from one week to six months. There are no compelling reasons for preferring one protocol to another in these works. Only a few authors [31, 35, 38] noted that the protocol they chose (1-1.5 mm growth)per month with mean interval between lengthening procedures of 78 days) was based on a study by Canavese and DiMeglio [62], which presents data on normal growth of vertebral bodies at different periods of the child's life. This technique, which was named "tail gaiting", provides spinal growth of 2.2 cm/year in children under the age of five years, 1.1 cm/year at the age of 5-10 years, and 1.8 cm/ year in children older than 10 years of age. Cheung et al. [34] believe that infrequent small distractions allow more consistent length gain although not presenting any convincing evidence. Bow et al. [63] suggest that the effect of one distraction per month is similar to that of one distraction procedure per three months. The authors emphasize that the maximum correction is achieved during the first surgery and then maintained in the future.

The mean Cobb angle of the major curve is in the range of 50–75° in 25 studies and exceeds this value in only two publications [43, 48]. As it can be seen from the works, the correction achieved

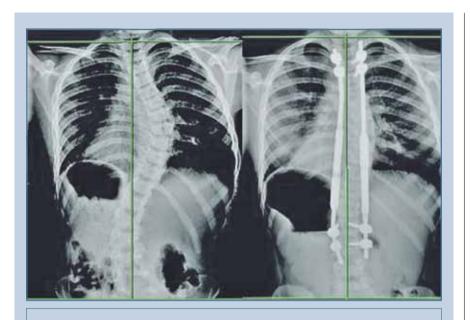


Fig. 4 Pre- and postoperative radiographs of the spine in an 8-year-old patient with idiopathic scoliosis, the follow-up period is 23 months [38]

after the first surgery (MCGR implantation and distraction) rarely exceeds 40 % of the initial value. According to a series of publications [19, 26, 35, 36, 38, 44, 60], the Cobb angle is reduced by a few more degrees at the end of the follow-up period as compared to the first distraction, while a certain (up to 10°) loss of the achieved correction is reported in 14 works [20, 23, 24, 31, 32, 39, 41, 43, 45, 48, 51, 52, 55, 57]. Thoracic kyphosis is mentioned in 16 works [19, 23, 24, 26, 32, 35, 36, 38, 41, 43–45, 48, 50, 55, 57]. This information does not contain any new insights: first, curve flattening due to implantation of a straight rod, then return of the sagittal contour (full or partial) to the baseline are reported. Data on lumbar lordosis before and at the time of treatment are presented only in two studies [45, 50], which probably indicates a lack of great interest in them.

In six works [21, 23, 38, 53, 57, 60], the authors included in the study groups of patients who started treatment with the so-called traditional growing rods (TGR) and later, due to objective or subjective reasons, underwent conversion to MCGR. A change in the Cobb angle in this group of patients (convention-

al group) sharply differed from that in patients treated with magnetic rods only (primary group). The angle was initially reduced (less than 50° in five papers [21, 23, 53, 57, 60] out of six), the first effect of the magnetic rod was only 3–10° and then remained almost unchanged. Technically, the only result was maintenance of the effect achieved using TGR.

The distance between T1 and T12 determined on the spondylogram and its change in the postoperative period were noted in 13 studies [19, 20, 23, 24, 32, 35, 36, 39, 43, 45, 55, 57, 59]. The average initial distance was 180 mm, it reached 200 mm immediately after the first surgery and 211 mm at the end of the follow-up period. Thus, multi-stage outpatient distractions with magnetic growing rods allowed lengthening of the thoracic spine by only 11 mm, while the first distraction allowed 20-mm growth. The distance between T1 and S1 was studied by the authors of 16 publications [19, 20, 23, 24, 26, 32, 35, 36, 38, 43, 45, 52, 53, 55, 57, 59]; it was initially equal to 287 mm. As a result of the first surgery, it was increased to 318 mm and then reached 338 mm by the end of the follow-up period. Thus, the length of the thoracic

and lumbar spine increased by 31 mm immediately after MCGR implantation and demonstrated a steady increase by another 20 mm during the entire followup period.

When discussing the capabilities of MCGR, their use in special cases should be also mentioned. One of them is the so-called neglected deformity. There are two approaches to treat it. Welborn et al. [64, 65] claim (without providing any reference) that the incidence of complications after MCGR implantation reaches 100 % (!), with the mean incidence of 44 %. Further, they note that, in severe deformities, IRC (implant-related complications) is the result of the rigidity of scoliosis. Decreased rigidity caused by halo traction results in reduced stress on the implant and potentially reduces the risk of complications. The authors presented results of the treatment of 30 patients with more than 80° deformities or less than 10 % mobility. Halo traction was used as a preoperative preparation prior to MCGR implantation, which allowed decreasing the frequency of complications to 8 %. Another application of MCGR in the most severe deformities is daily lengthening of the rods. To treat severe kyphoscoliosis (102° scoliosis, 72° kyphosis) in a 12-year-old child, Cheung et al. [66] placed pedicle screws at the level of T2-L3 (for future spinal fusion) and magnetic rods at the first stage. Distraction was first carried out at a rate of 2 mm per day and then at 1 mm/day due to the pain and in order to prevent increasing stiffness or autofusion. A total of 43 mm of distraction length was obtained after 7 weeks. At postoperative 10 weeks, 47 mm total distraction length was obtained, the Cobb angle of the major curve and kyphosis were 66° and 62°, respectively. Scoliosis was reduced to 28°, and thoracic kyphosis reached 54° after final surgery (MCGR removal, implantation of conventional growing rods, posterior spinal fusion). Koller et al. [67] and Di Silvestre et al. [48] used the same approach in 16 patients with an average Cobb angle of 99°. The correction was 68°, while twoyear postoperative progression rate was only 1.9°.

Table 1

Etiological forms of spinal deformities in patients operated on using MCGR, n

Authors	Patients	Idiopathic	Congenital spine	Neurofibromatosis	Neuromuscular	Syndromic
		scoliosis	deformities		scoliosis	scoliosis
Cheung et al. [24]	5	1	1	1	_	2
Akbarnia et al. [25]	14	5	2	1	4	2
Dannavi et al. [26]	34	14	2	3	11	4
Akbarnia et al. [20]	12	3	1	-	4	4
Stokes et al. [27]	6	2	-	1	-	3
Yoon et al. [28]	6	-	1	2	2	1
Ridderbusch et al. [29]	24	2	4	4	7	7
Nordeen et al. [30]	6	-	-	-	1	5
Rolton et al. [31]	21	3	1	-	3	14
La Rosa et al. [32]	10	5	-	-	1	4
Harshavadhana et al. [33]	23	-	-	-	23	_
Cheung et al. [34]	8	2	-	2	-	4
Heydar et al. [35]	18	8	4	1	4	1
Ridderbusch et al. [36]	24	3	1	4	5	11
Teoh et al. [37]	10	7	2	-	-	1
Thompson et al. [38]	19	5	-	-	5	9
Hosseini et al. [23]	23	5	6	-	8	4
Ahmad et al. [39]	35	9	4	-	3	19
Cobanoglu et al. [40]	19	4	-	-	1	14
Kwan et al. [41]	30	8	6	-	8	8
Gilday et al. [42]	31	6	1	-	11	13
Dahl et al. [43]	19	8	3	-	5	3
Samdani et al. [44]	37	-	-	-	37	-
Lebon et al. [45]	30	7	3	-	11	9
Total:	464	107	42	19	154	142

Another special case is the use of MCGR in adult patients. Birkenmaier et al. [68] were probably the first to report such a case. A 19-year-old patient had paralytic right-sided scoliosis of the lumbar spine (118°) and spastic paraparesis of the lower limbs. The main complaints were pain and inability to sit without additional support. A baclofen pump was implanted at the first stage of treatment followed by placement of two magnetic rods on the concave side of the curve with inferior support on the iliac crest. The overall distraction period was 4 months. When the curve was reduced to 55°, posterior fusion was performed. No pain complains were obtained after two years, and the patient regained the ability to sit.

In 2011, Sankar et al. [69] conducted a study of the effectiveness of TGR and came to the conclusion that the main

curve correction is achieved during the very first distraction, while each subsequent stage provides a gradually decreasing corrective effect. This phenomenon is called "the law of diminishing returns" (Sankar's law). According to the authors of the study, this is the result of the formation of spontaneously fused vertebral segments (autofusion) due to prolonged immobilization by the implanted rods. In 2015, Cheung et al. [70] were the first to make an attempt to understand whether the Snakar's law is applicable to magnetic rods. The working hypothesis was that frequent small distractions would help avoiding the Sankar's effect. A total of 31 MCGR distractions with a 2 mm lengthening per month were performed in 7 patients in the period of 3.8 years. The authors observed no gradual loss of correction every 6 months. The T1-S1 distance was changing but not

in accordance with the Sankar's law. In 2017, Ahmad et al. [39] presented a different result. In 35 patients treated using MCGR for the period 30 months, T/I (true distraction/intended distraction) ratio, which is a ratio of the achieved to the planned distraction values, was calculated for each lengthening. After the first distraction, the T/I ratio was 0.93 on the concave side and 0.81 on the convex side of the curve; the values were 0.40 and 0.43, respectively, after 24 months and 0.17 and 0.18, respectively, after 51 months; thus, the correction gain gradually decreased. The authors concluded that the effect of MCGR complies with the Sankar's law. This has been confirmed by Ihnow et al. [71], who presented the results of scoliosis correction in 34 patients for the overall period of 31.8 months. A total of 302 distractions were performed (8.9 on average per patient),

Authors	Patients, n (n = 800)	Mean age, years	Follow-up period, years	Distraction protocol	Major curve before/ immediately after surgery/at the end of the follow-up, deg.	Thoracic kyphosis before/immediately after surgery/at the end of the follow- up, deg	Lumbar lordosis before/immediately after surgery/at the end of the follow- up, deg	TGR to MCGR conversion before/ immediately after surgery/at the end of the follow-up, deg.	T1-T12 distance before/immediately after surgery/at the end of the follow-up, mm	T1–S1 distance before/immediately after surgery/at the end of the follow- up, mm
		t			021 01 10					
Akbarnia et al. [21]	1	6.1	I	1	64/ U/ 39	1	1	41/0/39	1 000	1
Ahmad et al. [39]	35	I	1	1	52/37/39	I	1	1	222/228/243	1
Akbarnia et al. [19]	14	8.9	1	43 days	60/34/31	39/31/48	1	1	178/198/208	292/322/338
Akbarnia et al. [20]	1	6.8	2.5	I	59/32/38	1	I	1	166/186/189	279/295/307
Bow et al. [46]	13	I	I	1 month	1	1	1	1	1	1
Choi et al. [47]	54	7.3	1.6	Surgeon's decision	1	1	1	1	1	1
Dahl et al. [43]	21	9.7	1.0	73 days	76/42/52	42/32/37	1	1	186/0/207	301/0/339
Dannawi et al. [26]	34	8.0	1.3	87 days	69/47/41	33/29/32	I	I	I	304/336/348
Di Silvestre et al. [48]	15	I	1	18 days	99/32/34	99/32/34	I	I	I	I
Doani et al. [49]	44	6.7	2.8	6–12 weeks	58/0/32	1	I	I	I	I
Fahmy et al. [50]	11	8.8	I	1	1	69/39/41	39/22/41	1	1	+17,2
Gupta et al. [51]	67	2 - 13	2.0	1	71/39/44	1	1	1	1	1
Harshavardhana et al. [52]	23	9.0	5.2	I	69/45/65	1	1	1	I	316/339/369
Heydar et al. [35]	18	7.3	1.5	78 days	68/35/34	43/29/33	1	1	171/197/215	289/330/357
Hickey et al. [53]	8	1	2.4	6—8 weeks	74/42/42	1	1	45/42/44	I	215/273/286
Hosseini et al. [23]	23	6.6	2.0	I	61/34/39	45/29/58	I	49/43/44	156/177/181	252/288/292
Ihnow et al. [54]	34	7.8	2.8	3 or 6 months	1	1	I	I	I	I
Cheung et al. [55]	22	10.2	4.1	45 days	56/23/28	27/17/24	I	I	203/211/235	333/335/380
Cheung et al. [24]	5	I	2.0	45 days	67/25/29	43/16/34	I	I	199/203/229	314/331/360
Cheung et al. [56]	30	7.3	2.9	1 week to 6 months	I	I	I	I	I	I
Cobanoglu et al. [40]	16	I	I	3 months	1	1	I	I	I	I
Keskinen et al. [57]	50	7.3	1.0	1 week to 3 months	64/35/40	53/0/50	I	47/36/40	165/192/196	265/308/311
Kwan et al. [41]	30	7.3	3.1	1 week to 6 months	55/31/33	36/22/22	I	1	I	l
La Rosa et al. [32]	10	7.2	2.3	3 months	64/26/28	42/28/29	I	1	162/189/206	271/311/338
Lebel et al. [58]	32	7.7	2.0	2 months	64/0/32	1	I	1	I	l
Lebon et al. [45]	30	9.1	1.5	3 months	66/40/44	39/35/42	48/41/48	1	184/218/220	290/349/355
Ridderbusch et al. [36]	33	8.9	1.9	4 months	63/29/26	43/27/32	I	1	182/203/217	295/333/349
Rolton et al. [31]	21	7.8	2.0	3 months	54/34/35	1	I	1	I	I
Samdani et al. [44]	37	7.1	2.4	l	73/37/31	66/0/42	l	l	l	1
Subramanian et al. [59]	31	7.7	3.9	I	54/0/37	I	I	I	168/0/198	287/0/338
Teoh et al. [60]	10	8.2	4.0	I	74/42/38	1	1	45/42/43	I	I
Thompson et al. [38]	19	9.1	1.9	I	59/37/32	46/37/45	I	66/56/57	I	296/309/348
Yilgor et al. [61]	4	1	I	2–3 months	69/0/39	1	l	1	1	I
Voon et al [91]	9	75	2.5	³ —6 months						

with the first distraction providing 88.5 % of the planned increase in the rod length, while the 13th distraction provided only a 31 % increase. Based on their experience of treating 42 patients, Welborn et al. [64, 65] concluded that the Sankar's law starts working 2 years after the implantation procedure.

Complications and repeated interventions. Complications arising during treatment with MCGR and reoperations that surgeons had to perform are mentioned in 28 publications summarized in Table 3. These works describe the results of treatment of 706 patients with 325 (46 %) complications detected in total. Five papers [23, 51, 54, 59, 73] mention only the number of complications without specifying the latter: a total of 167 patients and 144 complications. Thus, in the remaining 539 patients, there are 181 complications: 53 rod breakages, 33 screw and hook pullouts, 4 subcutaneous implant protrusions, 39 cases of slippage phenomena, 22 cases of junctional kyphosis, 21 cases of superficial wound infection, 1 adding-on phenomenon, and 4 others. In addition, one patient died two years after the start of treatment. Table 3 should be supplemented with a description of MCGR-specific complications: slippage-phenomena and metallosis. In 2015, Cheung et al. [77] for the first time described the so-called clunking effect which is defined as an audible and palpable phenomenon that occurs during magnetically-controlled distraction of the rod. It occurs due to slippage of the rod in the actuator when the rod fails to complete its full internal rotation and thus returns to its original position. The authors noted that this phenomenon is a result of the inability of the magnetic rod to lengthen the spine because of the latter's stiffness. Another possible reason is the cross-talk between the two magnets located too close to the apex of the major curve. This usually occurs in the offset position of the rods (when one magnet is located caudally and the second one is located cranially) and within the first year of rod implantation [78].

Jones et al. [79] described two cases when patient experienced a popping sensation in his back during distraction. In both cases, examination revealed a pin fracture, and metallosis was observed during revision surgery. The authors believe that clunking occurs when the magnet's strength is not enough to overcome the resistance of the tissue around the distractor and suggest that pin fractures are a result of metal fatigue.

Cheung et al. [55, 80] distinguished two forms of slippage phenomena: early (occurring during the first six distractions) and late (corroding after the first six distractions) rod slippage. Factors determining the onset of complication are the following: the stage of body maturation, age of MCGR implantation, BMI, number of distractions, time after implantation, curve angle and spine mobility in this region, length of the fixation area, as well as position of rods relative to each other and to the apex of the scoliotic curve. Of 22 patients, early rod slippage was detected in 14 cases (mean age 8.6 years), while late slippage was diagnosed in 8 patients (mean age 4.8 years). The authors could not establish reliable risk factors responsible for the phenomenon. Boom-Beng Tan et al. [78] observed 25 % slippage cases out of 168 distractions, with most of them attributed to the offset rod placement. The average period between implantation and the first slippage was 11 months. Despite this, lengthening of the rod and the spine was noted; there were no pain complaints, patients and their parents did not express any dissatisfaction.

Severe metallosis was observed by Teoh et al. [60] in four patients treated with MCGR, which the authors define as aseptic fibrosis, local necrosis or implant destabilization due to metal corrosion.

A total of seven rods were implanted in these patients; the mean period before implant removal was 35 months, the mean age of the revision surgery was 11 years. The surgery revealed fractures of the two rods and pseudocapsule formation around the actuator. Abrasive changes were noted for all growing rods. After removal of the device, a large amount of metal debris was found. According to the electron microscopy data, the debris consisted of metal titanium fragments with an average size of 3.36 microns. Histological examination revealed granulation tissue, fibrosis, and chronic inflammatory response.

Fracture of the locking pin was detected in four magnetic rods, which resulted in the formation of a piston mechanism between the actuator elements. The locking pin connects magnet to a lead screw. When the magnet is rotated by an external remote controller, the lead screw moves the rod in the actuator and ensures its lengthening. When the pin is broken, the mechanism fails, and the pistoning effect occurs resulting in the deposition of metal debris inside and outside the actuator. Soft tissue metallosis manifests itself in the formation of a pseudocapsule.

As it can be seen from the Table 3, a total of 200 reoperations were performed in a group of 706 patients. Cheung et al. [75, 81, 82] published the first studies on revision surgeries after MCGR implantation. They reported that repeated interventions were performed on average 17 months after rod placement. Their frequency accounted for 42.3 % of the number of operated patients. The authors did not find any connection between the Cobb angle of the major curve, age, fixation length, number of distractions and TGR to MCGR conversion surgeries.

Teoh et al. [37, 60] stated that reoperation was required in all cases involving MCGR implantation. Seven patients treated only with MCGR underwent eight revision surgeries, and 21 patients had 14 revisions after TGR to MCGR conversion procedures. The authors state that the results are somewhat worse than expected. Kwan et al. [41] reported 14 unplanned surgeries in 30 patients (46.7 %) conducted on average 22 months after the start of treatment. The only reliable risk factor, in their opinion, was the distraction protocol: a total of 71 % of reoperations were performed in the period of up to two months, and 25 % of revision surgeries were required in the period of 3-6months after treatment. The reasons for reoperation are bending of the rod too close to the magnet and thickness

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Table 3

Complications and reoperations after MCGR, n

Authors	Patients, n	Complications	Unplanned
(n = 706)			reoperations
			10
Ahmad et al. [39]	35	10 (4 broken actuator pins, 2 broken rods, 3 loosening of the cranial	10
111		fixation, and 1 deep infection)	
Akbarnia et al. [19]	14	13 (1 superficial infection, 1 subcutaneous implant protrusion,	_
111	10	and 11 loss-of-correction cases)	
Akbarnia et al. [20]	12	12 (4 general surgical complications, 8 IRCs)	-
Choi et al. [47]	54	21 (6 broken rods, 6 cases of lack or loss of distraction, 7 PJK cases, and 2 cases of infection)	15
Chun Wai Hung et al. [73]	12	14	15
Dahl et al. [43]	21	6 (3 pedicle screw loosening, 1 broken rod, 1 hook fixation failure,	4
		and 1 adding-on case)	
Dannawi et al. [26]	34	7 (1 hook pullout, 2 broken rods, 1 subcutaneous implant protrusion,	-
		2 loss-of-correction cases, and 1 superficial wound infection)	
Fahmy et al. [50]	11	8 (3 broken rods, 4 PJK cases, and 1 DJK case)	_
Gupta et al. [51]	67	61	45
Harshavardhana et al. [52]	23	10 (3 broken rods, 5 PJK cases, 1 case of DJK,	-
		and 2 surgical site infections)	
Hickey et al. [53]	8	5 (1 rod fracture, 1 screw pullout, 1 loss of distraction, 1 lack of distraction,	-
		and 1 PJK)	
Hosseini et al. [23]	23	41 (14 IRCs)	_
Ihnow et al. [54]	34	5	4
Cheung et al. [24]	5	No complications	-
Cheung et al. [56]	30	11 (5 impaired distractions, 3 proximal fixation failure, 2 broken rods,	11
		and 1 superficial wound infection)	
Keskinen et al. [57]	50	10 (6 broken rods, 3 impaired distractions, and 1 surgical site infection)	15
Kwan et al. [41]	30	No data available	14
La Rosa et al. [32]	10	3 (2 rod fractures, and 1 hook pullout)	-
Lebel et al. [58]	32	7 (3 proximal fixation loosening, 3 infection cases, and 1 broken rod),	7
		1 death 2 years after the start of treatment	
Lebon et al. [45]	30	24 (7 hook pullouts, 3 rod breakages, 6 distractions failures, 1 PJK,	13
		3 deep infections, and 4 others)	
Ridderbusch et al. [36]	33	6 (1 loss of distraction, 2 screw pullouts, and 3 PJK cases)	-
Rolton et al. [31]	21	6 (3 hook pullouts, 2 broken rods, and 1 subcutaneous implant protrusion)	6
Samdani et al. [44]	37	4 superficial wound infections; no other information was presented	10
Subramanian et al. [59]	31		22
Teoh et al. [60]	10	9 (2 broken rods, 3 screw pullouts, 3 impaired distractions,	8
Thompson at al. [70]	10	and 1 surgical site infection) 2 (1 fixation pullouts and 1 superficial wound infection)	1
Thompson et al. [38]	19		1
Yilgor et al. [61] Yoon et al. [91]	14 6	5 (4 rod breakages and 1 hook dislodgment) 2 (1 broken rod and 1 subcutaneous implant protrusion)	-

of the soft tissues, which can reduce the corrective effect. Gilday et al. [42] managed to demonstrate that the distraction achieved is inversely proportional to the depth of rod placement. Risk factors do not include etiology of the deformity, Cobb angles of the major curve and thoracic kyphosis, type of fixation, number of distractions, and previous history of TGR placement at the site of MCGR insertion.

Roye et al. [83] examined the issue of unplanned surgeries by comparing MCGR and VEPTR. A preliminary analysis taking into consideration different follow-up duration and deformity severity showed that the rate of unplanned revision after 2 years is maintained at the same level (plateau) when using VEPTR and increases after MCGR implantation. In general, the risk of unplanned surgery is approximately the same for the both instrumentation techniques. The authors note that the initial enthusiasm associated with introduction of MCGR in practice was high.

MCGR versus TGR and VEPTR. Comparison of the effectiveness of the existing and new methods is quite logical and reasonable. The first attempt of this kind was made by Akbarnia et al. [20]. The authors compared the results of surgical treatment of two groups of patients of 12 people each with deformities of various etiologies and comparable in age, follow-up period (at least 2 years), and the number of implanted rods. The authors reported the absence of differences in the rate of major curve correction and changes in the distance between T1–T12 and T1–S1.

TGR patients underwent a total of 73 surgeries: 12 rod implantations, 56 staged distractions, and 5 unplanned revisions. Complications were noted in 11 patients: 13 IRCs and 8 cases not associated with correction, including 4 cases of superficial wound infection. On average, there were 1.5 complications per each patient per year.

In the MCGR group, 16 surgeries were performed, including 4 unplanned revisions and 137 rod lengthening sessions. Four patients had at least one complication (8 IRCs and 4 complications unrelated to the correction method).

Doani et al. [49] reported the results of treatment of 44 patients (19 MCGR cases and 25 TGR cases) with a slightly greater deformity correction level and the rate of satisfaction of the patients and their parents with MCGR.

Bekmez et al. [84] compared the treatment results of two groups consisting of 10 patients each. The corrective effect of the multi-stage treatment and the level of complications differed slightly between the groups. The average number of surgeries was significantly lower in the MCGR group (1.3 versus 8.8); however, the authors did not notice any significant improvement in the quality of life of these children.

Comparison of the effectiveness of MCGR and TGR in patients with neuromuscular scoliosis was carried out by Samdani et al. [44]. A total of 37 patients underwent treatment with MCGR, while 155 patients had TGR implantation.

The analysis showed that magnetic rods provide better correction and more reliable preservation. Moreover, MCGR has an advantage over TGR in the rate of wound purulent complications (10.8 % versus 25.2 %) and the number of unplanned interventions (29.4 % versus 51.6 %). It is still unclear whether the etiology of the deformity plays a crucial role in such outcomes.

Varley et al. [85] analyzed the data of 19 USA clinics (25 TGR and 125 MCGR cases) and concluded that conventional growing rods are used as often as magnetically-controlled ones. The main choice in favor of TGR is dictated by considerations to preserve the sagittal profile of the spine and the patient's dimensions, which is impossible in case of MCGR implantation. All researchers agree that more studies are required in order to make a final conclusion.

Hung et al. [73] compared MCGR and VEPTR in terms of complications and unplanned surgeries. In 22 patients operated on using MCGR, 14 implantrelated complications were found, and 15 unplanned surgeries were performed. As for the VEPTR patients (52 in total), there were 31 complications and 44 unplanned surgeries.

Thus, the use of MCGR increases the risk of IRC and the risk of unplanned surgeries by 5.6 and 4.6 times, respectively. The authors note that the early enthusiasm caused by the development and the first experience of using MCGR should be replaced with a serious attitude to patient selection. Li et al. [86] found that patients treated with VEPTR have a higher serum titanium levels than MCGR patients. The titanium content may be due to prolonged treatment and also depend on the number of rods used for implantation. The significance of this is yet unclear.

Aslan et al. [87] investigated the psychological state of two groups of patients of 10 people each operated on using MCGR and TGR. Age, etiology of deformities, and the Cobb angle value were the same among the groups. Psychological health was shown to be decreased in the MCGR group. The authors explain it by the availability of more time for the TGR patients to accommodate to a new style of living.

Safe control: ultrasound instead of radiographic examination. In case of using TGR, as well as in spinal surgery in general, postoperative monitoring is performed by conducting panoramic spondylography of the thoracic and lumbar spine in two standard projections before and after each intervention. Since staged distractions are performed every 6–9 months, each patient undergoes up to 8 radiograph imaging procedures annually. Such a dose of ionizing radiation is dangerous and can result in very undesirable consequences [88]. Staged MCGR distractions are performed more frequently: typically with an interval of 2-4 months thus rapidly increasing the number of required examinations. This was realized very soon, and the search for a safe substitute for X-ray examination began.

As early as 2014, Stokes et al. [27] reported the use of the ultrasound machine to assess the MCGR distraction rate in 6 patients. Their study showed that 2 mm distraction in the X-ray image corresponds to 1.7 mm gain in the ultrasound scan. The overall duration of examination was less than 1 min.

In 2015, Perez Cervera et al. [89] described the use of ultrasound control for estimating magnetic rod distraction on an outpatient basis. They published a case of ultrasound use in a 3-year-old child with 60° scoliosis and multiple concomitant pathologies. Distraction was achieved on both sides: 2 and 4 mm (due to twisted pelvis). No radiographic examination was used in the study. In 2015, Bow et al. [46] reported the use of ultrasound before and after monthly 2-mm distractions according to their own protocol. Control X-ray examination is performed every 6 months, and comparison of the results obtained by the two different methods showed almost complete identity: 4.8 mm according to ultrasound and 5.0 mm according to radiographic data. In the same year, Morris et al. [90] reported that the use of ultrasound allows them to perform only one X-ray examination per year. They also noted that the actual lengthening of the rod is

1.7 mm less than that displayed on the external magnetic controller.

In their works, Yoon et al. [91] and Cheung et al. [92] once again confirmed the high reliability of the data obtained using ultrasound: the average discrepancy with the X-ray data did not exceed 0.3 mm. Yoon et al. also mentioned additional advantages of ultrasound examination: the possibility to assess the surrounding soft tissues (fluid collections, soft tissue masses, vascular disorders, and inflammatory processes). At the same time, ultrasound has some drawbacks as well: the need for an operator, limited study area and depth, which makes obtaining information on the spinal shape and balance impossible. Cobanoglu et al. [40] presented the results of the use of ultrasound in 16 patients with primary and conversion MCGR surgeries (distraction protocol: 4 mm once in 3 months). A total of 100 measurements were conducted. The authors assume that, although ultrasound allows estimating rod lengthening, this estimation is not accurate enough as compared to X-ray examination in primary cases. After TGR to MCGR conversion, the results become more accurate. Karlen and Riemann [93], in turn, confirmed the rationale to replace X-ray with ultrasound examination and announced the establishment of a special unit at their clinic, which allowed a 83 % reduction in radiation exposure for patients and 64 % reduction in time interval between examinations. The latest report is attributed to Srinivas et al. [94], who examined 19 patients and confirmed the identity of ultrasound and X-ray data.

MCGR and MRI. The compatibility of magnetic rods and MRI imaging was studied by Budd et al. [95] and Woon et al. [96]. These studies demonstrated that MRI does not affect functioning of the magnetic rods, while the magnetic field does not interfere with scanning of craniocervical sections. The conclusion was made that magnetic rods are not activated and not damaged during MRI. Cervical spine and head are clearly resolved in contrast to the two upper thoracic rods. The magnetic lengthening effect is also not affected by catastrophic changes. On the contrary, MRI scanning of the thoracic and thoracolumbar spine may be limited due to artifacts. Woon et al. conducted a survey among 118 surgeons who confirmed that no loss of fixation, implant mobility, impaired distraction, and magnet overheating were noted. Thus, the magnet function is not affected.

Relative cost as an important factor. Taking into account the technological complexity of MCGR, the question of the price of the multi-stage treatment should have been raised inevitably, considering the fact that there was something to compare it with (TGR). Cheung et al. [24] presented the first (very encouraging) results of the use of MCGR in five patients and noted a higher cost of one magnetically-controlled growing rod compared to a conventional growing rod: 50,000 Hong Kong dollars versus 25,000 (6,541 and 3,225 US dollars, respectively).

The first focused study was conducted in France [97]. Literature data, patient survey results and expert opinion were taken into account. The model included a four-year-time horizon. The use of TGR turned out to be more expensive than MCGR: 49,067 euros versus 42,752 euros, respectively. The length of hospital stay, magnet price, and the number of surgeries played the main role in determining the cost.

British researchers Rolton et al. [31] presented the following indisputable fact to sustain their research: "in an increasingly fragile financial climate, health economics has become the barometer for efficiency, effectiveness and value in healthcare delivery." They took into account such parameters as postoperative examination, postoperative hospital stay, outpatient follow-up, duration of surgical treatment, staff salaries, and the cost of implants and diagnosis. The total cost of multi-stage treatment adjusted for inflation over the period of 5 years was £52,923 for TGR and £43,405 for MCGR.

In the comparative study by Polly et al. [98], the following aspects were considered: the cost of initial implantation, distraction (MCGR after 3 months and TGR after 6 months), revision, rod exchange after reaching the maximal length of 4.8 cm after 3.8 years, and final spinal fusion 6 years after the start of treatment. Based on the literature data, the frequency of surgical site infection (2.34 % for invasive surgery) and implant failure (0.37 % for MCGR and 0.59 % for TGR per month) were taken into account. The results are as follows: of 1,000 simulated patients, MCGR provided 270 fewer deep surgical site infections and 195 fewer revisions due to implant failure than TGR. The cost of treatment becomes approximately equal for the both methods after the period of 3 years. The cumulative cost (MCGR minus TGR) over the 6-year period of care was \$2,218 per patient. The high cost of magnetic rods is balanced by the cost of frequent surgeries.

Su et al. [99, 100] created a model for comparing the cost of the two correction systems in the USA over the 5-year period after implantation. The following price sources were used: literature data, expert consultation, and official data from healthcare databases. Travel expenses and salary loss of the patient's parents were not taken into consideration. As a result, the use of MCGR was shown to require a higher cumulative price only in the first 2 years of treatment, while TGR becomes more expensive in the period of 3-5years of care: \$166,098 versus \$126,467, respectively.

Harshavardana et al. [101] came to the same conclusion: a 5-year MCGR treatment is £20,552 cheaper. According to Wong et al. [102], the use of two MCGRs (with rod exchange every 2 or 3 years) becomes cheaper than the use of two TGRs starting from the fourth year of treatment. Oetgen et al. [103] believe that MCGR implantation is more expensive because of the implant price; as for all other categories, the cost of the two systems is considered approximately equal.

As early as 2012, Torode [104] formulated the philosophy of the new method. The philosophy, in his opinion, rests on three pillars:

1) only the major curve requires correction, while blocking as less vertebrae as possible helps preventing spontaneous autofusion; 2) constant corrective effect is needed; in fact, it assumes daily minimal distractions, while infrequent large changes can result in implant displacement or bone fracture;

3) constant feedback is required: in order to modulate the frequency of actions depending on the resistance to the corrective action.

Judging by the data presented in the current review, these three principles have not been fully implemented. At the same time, significant experience in the use of MCGR for the period of over 10 years has been accumulated in the World's literature. This experience and its interpretation are reflected in numerous publications, analysis of which is presented in the current review. It seems that interpretation of the method is ambiguous. On the one hand, there are high hopes and an increasing number of patients operated on with the use of this technique, while on the other hand, we see a high level of complications and a complete lack of consensus on the treatment protocol.

The new instrumentation system was approved for practical use by very authoritative organizations: it was recommended for use by the National Institute for Health and Care Excellence (NICE) from the United Kingdom (June 18, 2014) based on its potential advantages and previous study results [105]. At the time of the study of the effectiveness of MCGR in NICE, only three clinical series were available, and only two cases with a more than two-year follow-up period were reported.

A slightly late approval for the use of the technique was obtained from the Food and Drug Administration in the United States. However, the first two implantation surgeries had been performed earlier in the USA with the special permission of the FDA [106].

In order to overcome this barrier, the device must have the same intended use and be at least as safe and effective as a device that is already available on the market. Technological characteristics should be similar or not raise new safety and efficacy issues. Magnetic rods were regarded as an equivalent to the Harrington system, which was introduced in practice in the 1950s. The magnetic actuator had been approved by the FDA earlier for the use in intramedullary rods, thus meaning that the Harrington rod and intramedullary rods were regarded as predicate devices. This characterization is quite surprising because it is known that even small changes can lead to complications and unforeseen consequences. These data are presented in the article by Rushton et al. [107], the subtitle of which sounds like a warning ("note of caution"). The authors note that inconsistency and limited availability of the data create an urgent need to conduct more research. Since the authors are English natives, they provide examples of the issues occurring in English practice in their article. In 2016, the British Scoliosis Society collected data on 195 patients (369 growing rods implanted in total) from 11 hospitals, among which there were 43 (22 %) unplanned revisions, 11 (6 %) rod breakages, 14 (7 %) drive pin fractures, and 10 cases of metallosis (23 % of them revealed upon revision surgeries). Another problem was that only 28 % of the patients operated on using MCGR were incorporated into the British Spine Registry, which is by no means acceptable. Such situation is not typical for England only.

Meanwhile, there have been methods developed that allow preventing many problems upon introduction of medical equipment in practice. Malchau [108] proposed a stepwise approach to solving the problem.

The first step is to identify the frequency and severity of the pathology. Early onset scoliosis is rare; however, the negative impact it has on the patient's health is high. The second step involves proposing a solution (in this case, MCGR). The third stage is determining the degree of the universal dilemma, which presents a gap between preclinical results (animal experiments, biomechanics) and actual clinical outcomes. This gap is yet to be found for MCGR. The fourth step is finding a compromise solution this dilemma entails. At this stage, reports on the failures of the method may come in handy. The fifth and the final stage is to determine the economic efficiency of the method.

Another way to determine the treatment effectiveness is the so-called IDEAL Framework algorithm (Idea, Development, Exploration, Assessment, Longterm study), which was proposed as a rational strategy to reduce the rate of failures when introducing new devices in practice [109]. In general, both systems require small prospective studies at the beginning, then large multicenter and ideally randomized prospective studies, and only then the widespread use of the new implant is allowed. An integral part of such studies is the long-term monitoring and analysis of the results.

In conclusion, Rushton et al. [107] rightfully state that the method can potentially provide great advantages in the treatment of EOS patients, although the long-term results are still unknown. Surgeons must perform careful selection of the patients for these surgeries, report the necessary data into national registries, conduct thorough follow-up examination, and subject all of the removed rods to independent analysis.

The current review of English-language literature is not systematic; it is devoted to a wide range of issues related to the use of MCGR. The strategy of searching databases and data reviewing were arbitrary; the authors did not find it necessary to evaluate the quality of the studies included in the review and draw far-reaching conclusions.

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Address correspondence to:

Mikhaylovskiy Mikhail Vitalyevich Novosibirsk Research Institute of Traumatology and Orthopaeducs n.a. Ya.L. Tsivyan, 17, Frunze str., Novosibirsk, 630091, Russia MMihailovsky@niito.ru

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Mikhail Vitalyevich Mikhaylovskiy, DMSc, Prof., chief researcher of Department of Children and Adolescent Spine Surgery, Novosibirsk Research Institute of Traumatology and Orthopaeducs n.a. Ya.L. Tsivyan, 17, Frunze str., Novosibirsk, 630091, Russia, ORCID: 0000-0002-4847-100X, MMihailovsky@niito.ru; Alina Anatolievna Alsbevskaya, MD, PbD, Head of the Department of Biomedical Research, Scientific Center for Biostatistics and Clinical Research, 6/1, Acad. Lavrentieva Pr., Novosibirsk, 630090, Russia, ORCID: 0000-0002-7307-4524, Alina.a.alsbevskaya@eol-labs.com. HIRURGIA POZVONOCHNIKA 2020;17(1):25-41

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