Magnetic growth modulation in orthopaedic and spine surgery

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ABSTRACT

Purpose: To examine distraction-based methods for treatment of early onset scoliosis (EOS), focusing on the magnetically controlled growing rod system (MCGR) relative to traditional growing rod system (TGR). To briefly discuss internal magnetically controlled nails for bone lengthening as another application of magnetic growth modulation.

Results: Relative to TGR, MCGR involves fewer complications related to infection and general anesthesia because of fewer successive surgeries required. Further, MCGR accounts for better psychosocial patient outcome and potentially a lower long-term cost, mainly because of shortened periods of hospitalization. Intramedullary lengthening nails involve fewer complications compared to internal limb lengthening devices related to infections, nerve damage, shortening, improper healing, stiffness, and scarring. Intramedullary lengthening nails appear to alleviate psychosocial burden of patients especially when compared to external fixators.

Conclusions: Although the current gold standard for treating some types of early onset scoliosis (EOS) is the traditional growing rod system, the magnetically controlled growing rod (MCGR) system is an alternative method for treating EOS. MCGR is promising in that it involves less surgical procedures, shorter hospital stays, and lower long-term cost relative to TGR. Similarly, the use of magnetically controlled intramedullary lengthening nails is a promising alternative to the Ilizarov method for limb lengthening.

1. Introduction

Novel magnetically controlled devices, such as magnetically controlled growth growing rod system and intramedullary lengthening nails, have emerged as alternatives to treat spine curvature and limb length deformities.

The diagnosis of early onset scoliosis (EOS) in children entails a spinal curvature greater than or equal to 10° .¹⁹ EOS begins before 10 years of age¹⁷ and is particularly problematic because of interference with normal pulmonary development and function. Treatment protocol first and foremost includes evaluation, and bracing and serial casting when appropriate for curvature severity and patient age.¹⁶ However, for progressive congenital cases or for cases when less invasive treatments fail, surgical intervention is favored. Early fusion as a potential treatment for EOS does not allow full growth of the spine and thorax.¹⁹ The current surgical “gold standard” for treatment of early onset scoliosis (EOS) with severe curvature of the spine is the traditional growing rod system (TGR)² (Fig. 1). The idea behind growth rods in treating EOS is to fix the spine deformity and still permit skeletal growth.¹⁶ Early spine fusion, on the other hand, would not be appropriate for a patient who has not achieved optimal spinal or thoracic growth. Still, TGR is not an appropriate treatment for all cases of EOS.¹

2. Early onset scoliosis severity, pulmonary function and surgery

EOS is a rare condition.¹⁸ Spinal curvature is measured using the Cobb angle, which is the angle of intersection between perpendicular lines at the top and bottom of the curvature.¹ Cobb angle can be used to define scoliosis and its severity. Progression of scoliosis is associated with negative pulmonary function and cosmetic appearance.

Once scoliosis is diagnosed, the severity of the curvature and age of the patient must factor into the course of treatment. Bracing as non-invasive treatment is not effective in young patients, nor is it effective for treating neuromuscular or congenital scoliosis.⁴ The main problem with early spinal fusion as a surgically invasive treatment, on the other hand, is its interruption of normal lung development. Patients with neuromuscular scoliosis are the most prone to pulmonary infection and restrictive lung disease.¹⁰ For this reason, pulmonary function tests are useful for assessing respiratory impairment caused by the scoliosis. In fact, anesthesia involved for growth rod systems may not be advised for patients who present FVCs less than 30%. Yoon et al. found positive correlation between extent of distraction and positive change from preoperative to postoperative FVC and FEV1.

Surgery is recommended when curvature is severe and progressive. The goal is not only to address the deformity, but also to encourage

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Fig. 1. Preoperative postero-anterior radiograph of 7-year old with infantile idiopathic scoliosis showing 62° curve (first). Postoperative radiograph of single TGR system showing 30° major curve (second). Postoperative radiograph showing 40-fold improvement of curve (third). Postoperative postero-anterior radiograph following fusion procedure (fourth).¹⁶

Fig. 2. Preoperative photograph of patient with kyphoscoliosis (left). Preoperative standing plain radiograph (top). Immediate postoperative standing anteroposterior radiograph (bottom left). Postoperative anteroposterior standing plain radiograph (bottom right). Postoperative photo of treatment results (right).⁸

normal growth and development of the spine and lungs.⁵

3. “Growth-sparing methods” for treating EOS: TGR and MCGR

Severe EOS is defined by a Cobb angle greater than 45°. “Growth-sparing methods” are favored for treating EOS.⁴ These methods are favorable before a child reaches skeletal maturity.⁶ The three types of growth-sparing techniques are distraction-based, tension-based, and guided-growth.⁵ Distraction-based methods include TGR, vertical expandable prosthetic titanium rib (VEPTR) devices for thoracic expansion, hybrid methods, and magnetically controlled growing rod (MCGR) systems.¹⁹ Distraction based-methods are the most popular types of implants used to treat EOS. TGR is the most widely used of the various distraction-based methods.⁵

TGR implants include fused anchors on proximal and distal areas of the spine to which distractible rods are attached.¹⁹ Growth remains uninterrupted throughout the distraction process because fusion is not performed in the space between hook and screw anchors. TGR involves a number of rod distraction surgeries for a young patient, usually one every 6 months.¹ A child may undergo about 15 procedures as part of the TGR system.⁶ It has been found that more frequent distraction for TGR patients correlates with increased gain and deformity correction relative to patients who underwent lengthening during intervals greater than 6 months. Akbarnia et al. reported T1 to S1 growth of 1.8 cm per year for the former relative to 1.0 cm per year for the latter.¹⁹

There are disadvantages to TGR, including risk of wound infection, general anesthesia complications, implant failure, auto-fusion, and rod prominence.⁴ In fact, Bess et al. noted that a greater number of surgical procedures increases the risk of complications.³ Specifically, a 24% increase was found with each successive procedure, reaching 80% by 11th procedure. Further, Sankar et al. described a limitation of TGR known as “the law of diminishing returns,” by which lengthening potential can diminish with successive distraction procedures and may lead to implant rod failure.¹ Rod fracture is another risk of TGR that occurs in 15% of patients.⁶

There are psychosocial disadvantages involved with TGR that interfere with a child’s daily function, including school absences and limitation of normal physical and social activity. Iterative invasive procedures can have an effect on psychological health, as they can make the child more prone to PTSD and depression compared to patients who undergo a single procedure.⁴ There is an added burden regarding the level of care and attention that caregivers must provide to children undergoing many procedures, as well as the cumulative costs.¹

An alternative strategy for management of EOS is the magnetically controlled growing rod system (MCGR), which consists of implantation of a non-invasively distractible rod system¹ (Fig. 2). Because distraction

is not invasive, MCGR does not preclude general anesthesia for iterative distractions.⁵ MCGR implants include distal and proximal anchors to which magnetically distractible rods are attached.¹⁹ MCGR was developed as a way to treat EOS in young patients for whom TGR, bracing, and fusion would not be appropriate due to the severity of curvature or implications in skeletal growth.¹ Indications for the MAGEC system allow implantation in children as young as 2 years of age.¹⁴ Early clinical results of MCGR appear to be up to par with those that can be achieved by TGR.¹⁹ It is important to reiterate, however, that only early MCGR data is available.

MCGR accounts for a less negative effect to quality of life and psychosocial measures for the child because it does not involve iterative procedures as in TGR, so it leads to shorter hospital stays.¹⁴ MCGR could imply a reduction of surgical procedures for rod lengthening and consequently fewer days of hospitalization compared to TGR. Akbarnia et al. reported that there was a difference of 57 total procedures between 12 TGR and MCGR patient subsets, where the MCGR subset underwent fewer procedures, despite no statistically significant difference in spinal growth achieved.^{12,19} Charroin et al. made theoretical projections that MCGR may account for approximately 2 fewer surgical procedures and hospital stays per year for a patient compared to TGR.²

Shortened hospitalizations are especially significant for measures of cost-effectiveness because hospital stay represents the bulk of the expense for either MCGR or TGR system within a 4-year period.² MCGR cost is estimated at 42,752€ corresponding to a 4 year course of treatment.² Though MCGR has a high initial cost due to the expense of the device, on average the expenses for the two systems should be equal by the third year. After the third year, the cumulated cost over time theoretically becomes higher for TGR relative to MCGR because of greater expense of hospital stays in the case of TGR (Fig. 3). In fact, TGR cost is estimated at 49,067€ for a 4-year course of treatment. TGR also entails a greater long-term cost when personnel service and post operative-care periods are considered.¹³ MCGR short-term cost is comprised of the implant device, potential revision surgery, and a single post-operative care period. When costs are projected over a 5-year period, MCGR is a more cost-effective option relative to TGR.¹³

Akbarnia et al. found percent of curve correction to be comparable between MCGR and TGR.¹² The gain in spinal height and thoracic height per year within the distraction period were also comparable between the MCGR and TGR groups. Cobb angle change with MCGR appears to be maintained at post-operative follow-up period, both for MCGR as a primary procedure and as a revision procedure.⁶ Hickey et al. reported 43% correction for the MCGR primary procedure group and 44% correction for the MCGR revision group that had previously been subjected to TGR. Correction in MCGR is not only comparable to that in TGR, but also might resemble normal growth more closely

relative to TGR, which prevents neurologic risks that can arise from acute correction of severe deformities.¹

A disadvantage of TGR relative to MCGR is the frequent exposure of the young patient to ionizing radiation as a way to assess iterative distractions.⁷ Images must be taken before and after every distraction, thus the amount of radiation received over the period of the intervention is significant.⁹ As a nonionizing alternative to radiation, ultrasound has proven to be an effective and reliable way to observe and measure distraction compared to plain radiographs. An alternative is to combine ultrasound with less frequent radiographs to assess lengthening. Average MCGR rod lengths appear to be consistent between ultrasound and radiographs. Ultrasound also provides the added benefit of observing soft tissue in the vicinity of the rod system. Further, ultrasonography is considered accessible in the health care setting and has a relatively low cost.⁷ However, though ultrasound images can reduce the frequency with which plain radiographs are taken, they do not completely replace the need for radiography in assessing distractions. Ultrasound alone cannot be used to evaluate the bony components, anchoring blocks, or the implants themselves for problems such as loosening or breakage.

There are risks associated with MCGR. In fact, patients who undergo distraction-based methods to treat EOS are at a high risk of experiencing complications.¹⁹ As with any non-fusion method, including TGR, there is the risk of rod fracture.⁴ Anchor malfunction is common.¹⁹ MCGR is not exempt from the risk of implant prominence.¹² Loss of distraction is a complication unique to MCGR, but revision patients may be more prone to it due to increased rigidity of spine post-surgery.⁶ Loss of distraction can be rectified with manufacturer revision of the design and further lengthening.⁴ Some common complications for MCGR include superficial infections, which can be treated with antibiotics. No negative effects have been found related to the magnetic field in the MCGR system.

4. MCGR core technology

MCGR consists of surgical implantation of a titanium rod with a magnetically distractible middle segment¹ (Fig. 4). The spine surgeon can select a between a single construct and a dual construct titanium rod to be implanted for MCGR.¹ A selection will be made according to the patient's size and further adjustments can be made to the rod as necessary. Single constructs may be used for smaller and slimmer patients.⁴ Selection also depends on which method the surgeon personally favors.

The perioperative procedure for implantation is almost identical for MCGR and TGR.¹ The surgery involves two incisions, one distal and one proximal for the respective cephalad and caudad foundations, and placement of anchoring blocks on the spine before rod insertion. Proximal instrumentation is usually around T2-T4 and distal instrumentation is at the CSVL.⁴ Both hooks and pedicle screws can be used in the anchor sites. A connector between rods is added in the dual rod system, where one rod has an offset position to avoid interference between the magnets during distraction procedures. Finally, bone grafts are made in the anchoring block sites.

After surgery, post-operative distractions may take place once every 3 months. The magnet that makes distraction possible is contained within an actuator in the middle of the rod. Distraction procedures in the outpatient setting involved an external remote control (ERC) consisting of two magnets that causes internal rotation of the rod's gear mechanism to lengthen or retract the rod.^{4,5} The patient is conscious during the procedure, which can last as little as 30 s.¹ An advantage of MCGR is the ability to monitor the patient during the distraction for any neurological complications or deficits. The lengthening can average 1.5 and 2.0 mm each month. Patients who undergo distraction at shorter intervals have exhibited greater annual growth.⁴ Radiographs are used throughout the follow-up period.

5. Example cases

Cheung et al. reported the first two cases of scoliosis interventions with MCGR from a 24-month follow-up period. Patient 1 was a 5 year-old with Ehlers-Danlos syndrome scoliosis¹ (Fig. 5). Patient 2 was a 12-year old with idiopathic early onset scoliosis. Patient 1 received a single rod construct and Patient 2 received a dual rod construct. Patient 1's T9-L5 Cobb angle changed from 74° in preoperative period to 19° postoperatively, and then to 26° by the 24-month period. Patient 2's T5-T11 Cobb angle changed from 60° in preoperative period to 31° postoperatively, and then remained at 31° by the 24-month period. Patient reports were favorable towards MCGR regarding pain, function, and satisfaction. MCGR proved successful in correcting the distal curvature and promoting normal growth of the spine with no significant complications related to the MCGR itself. The results of the lengthening met the predicted results.

Dannawi et al. found that the more stable dual rod system resulted in more effective curvature correction⁴ (Fig. 6). Supporters of this system claim that it achieves expected growth more effectively compared to the single rod system. For Dannawi et al., there was a

Fig. 4. MCGR core technology. Illustration of MCGR system (top).⁹ Single rod MCGR system on spine model (left).¹ External remote control for MCGR distraction (middle).³ Intraoperative image of MCGR insertion in porcine model (right).³

Fig. 5. Example cases of MCGR system for patient 1 (top A–F) and patient 2 (bottom A–F). Patient 1's radiographs showing preoperative curvature (A, B); postoperative curvature (C,D); and curvature at 24 month follow-up (E,F).¹

Fig. 6. Radiographs of single rod system postoperatively with a Cobb angle of 47° degrees (left) and at 12 month follow-up with Cobb angle of 36° (right).⁴ Radiograph of preoperative Cobb angle of 62° not shown.

significant difference in Cobb angle correction between the single rod system group and the dual rod system group between pre-operative and post-operative period.

Similarly, Akbarnia et al. found more effective correction of the deformity with dual rod (DR) system relative to single rod (SR) system.⁵ The difference in mean improvement of Cobb angle was statistically significant between single and dual rod systems.

6. More applications of magnetic growth modulation: limb lengthening

Limb length deformities can be present at birth or develop later on due to premature growth plate arrest, malunion, nonunion, bone loss related to open fractures, osteomyelitis, or tumors.¹⁵ Traditionally, the Ilizarov technique is followed for limb lengthening at a rate of 1 mm per day with a system of external fixators. However, it precludes a sensitive time course for treatment. If distraction is too fast, there is a risk of nonunion, nerve injury, and joint shortening. If distraction is too slow, there is a risk of premature healing of the bone.

Although external fixator devices are effective, there are some drawbacks. It is a process that lasts for months.¹⁵ Daily strut/nut accommodations can be a burden for patients, especially for young patients. Possible complications include infections, hardware malfunction, transfixation of the soft tissue, scarring, muscle shortening, impaired movement of the joints,¹⁵ residual discrepancies, delayed healing, early consolidation, unsuccessful regenerate formation, refractures, and dislocations.¹¹ These complications also apply to methods combining both internal and external fixators.¹⁵

Internal bone lengthening devices involving intramedullary lengthening nails have emerged as an alternative to external fixator devices.¹⁵ These nails better address complications such as infection, stiffness, improper regenerate formation, scarring, fractures and implant rejection.¹¹ The nails are used to correct limb length difference of at least 2 cm. They are implanted into the intramedullary canal of long bones via an osteotomy procedure.¹⁵ A nail is distally and proximally fixed to the bone such that distraction causes lengthening. However, the technique for monitoring and controlling distraction has been deficient. Irregularity of distraction rate can cause nonunions, nerve injuries, and nail fractures.

A new magnetically controlled internal lengthening device tries to address limitations of previous bone lengthening nails¹⁵ (Fig. 7). The PRECICE nail's core technology consists of a magnet attached to a gear box and screw shaft. When the implanted magnet comes into contact with 2 "revolving" magnets in the ERC, the nail elongates and causes lengthening of the bone in a mechanism that mimics MCGR.

The PRECICE nail is inserted via an osteotomy.¹⁵ As a rule of thumb for choosing nail length, 2–3 cm of the thicker nail segment should fall within the segment of the distracted bone by the time lengthening is

finalized. Rod size is typically 12.5 mm in diameter and 230 mm in length.¹¹

The timing of the first distraction depends on the distracting bone of interest. For example, the first distraction for a femur is on the fifth postoperative day and on the seventh postoperative day for a tibia.¹⁵ The rate of distraction can be divided into three daily distractions of 0.33 mm each or four daily sessions of 0.25 mm each. Additionally, clinic-based follow-up involving radiographic imaging happens at 2-weekly intervals during the lengthening period and at 1-monthly intervals during the consolidation period up until the healing of the distracting bone. Daily physiotherapy was part of the follow-up period as well.¹¹

The PRECICE nail appears to be a better alternative to other intramedullary lengthening devices, as it carefully manages the rate of distraction to prevent complications in bone consolidation.¹¹ Further, the PRECICE nail yields better results for range of motion (ROM), which is perhaps one of its greatest benefits to patient's quality of life.

Shabtai et al. address limb lengthening devices specifically for treatment of congenital femoral deficiency and congenital fibular hemimelia, in which at least part of the fibular bone is absent.¹¹ One case is of a 9-year old male with coincident congenital femoral deficiency and fibular hemimelia (Fig. 8). The patient presented a leg length discrepancy of 5.5 cm. After treatment, the final length was of 6.1 cm. Though the patient met the lengthening goal at present, he will probably need continued intervention. The average lengthening of their patient subset was 4.4 cm.

7. Summary

Magnetic growth modulation methods, such as MCGR and intramedullary lengthening nails, appear to be effective alternatives to traditional methods in treating scoliosis and limb length discrepancy, respectively.

The fewer number of surgeries and hospitalizations of MCGR relative to TGR are mainly what make it a favorable method for better patient outcomes and quality of life. MCGR as a less invasive procedure may eventually be used as a safe alternative for younger children at an age where growth gain could be highest and whose curvature is too severe to be treated via other methods such as bracing.

Intramedullary lengthening devices as another application of magnetic growth modulation entail fewer complications relative to previous internal lengthening devices in treating limb length discrepancy, mainly because of better control of the rate of distraction.

8. Future directions

Future application of magnetic growth modulation systems is not limited to scoliosis or limb lengthening and could involve other

Fig. 7. Outpatient distraction of intramedullary lengthening nails.¹⁵ (leftmost). Anteroposterior (left) and lateral (right) postoperative radiographs show limb lengthening. 14-year old male after anterograde lengthening to address 3.8 cm femoral length deformity (A). 30-year old male after retrograde lengthening to address 3.6 cm femoral length deformity (B). Postoperative radiograph of a 41-year-old male after limb lengthening for 4.0-cm tibial discrepancy due to bone loss and arthrodesis (C).¹⁵

Fig. 8. Preoperative radiograph depicts LLD of 5.5 cm (left). 3-month postoperative radiograph (middle). 6-month postoperative radiograph depicts consolidation at 6.1 cm length (right).¹¹

disorders.¹

The optimal intervals for rod distractions, extent of rod distraction, and frequency of post-lengthening radiographs are not yet determined.⁶ MRI compatibility has not yet been tested and is unknown, but the magnetic actuator should appear as artifact.⁵

Some limitations of the available studies for MCGR are short follow-up periods demonstrating only early clinical results, and variability in type of diagnosis, curvature severity, and amount of distractions.⁴ Overall, MCGR appears to be promising for replacing TGR as the gold standard for treatment of some types of EOS.

Some limitations of available studies for intramedullary lengthening devices are small sample size and lack of long-term data. Further comparative analyses should be conducted.¹⁵

Variability in distraction intervals and surgeons for the same patient may not lead to the best possible outcomes.¹² Guidelines should be established to increase the consistency of case results.

Conflicts of interest

Adam E. M. Eltorai discloses a relationship with Springer and Lippincott. The other author does not have any relevant conflicts of interest.

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