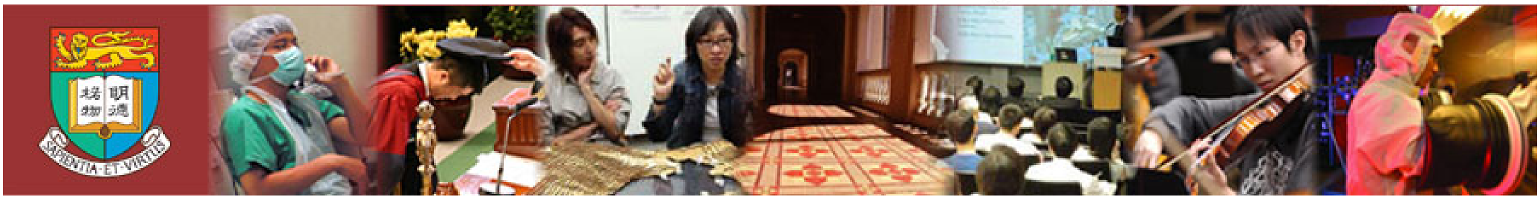

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Special article: Update on the magnetically controlled growing rod: tips and pitfalls

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ABSTRACT

Magnetically controlled growing rods (MCGR) have become an important treatment option in young patients with spinal deformities. This device allows for gradual lengthening on an outpatient setting with continuous neurological monitoring in an awake patient. With its growing popularity and interest, this study reports the tips, pitfalls, and complications of the MCGR for management of scoliosis. On 3 June 2015 at the University of Hong Kong, 32 participants from 16 regions shared their experience with MCGR. Current indications for surgery include early-onset scoliosis patients. Adolescent idiopathic scoliosis and congenital scoliosis patients have less favourable outcomes. The number of instrumented levels should be minimised, as all instrumented levels must be included in the definitive fusion surgery. Rod contouring is important and owing to the straight portion of the rod housing the magnet, there is limited proximal rod portion for proper contouring, which may predispose to proximal junctional kyphosis. There is currently no consensus on the rod configuration, timing, frequency, technique, and amount of distraction. Risk factors for distraction failure include larger patients, internal magnets too close to each other, and magnets too close to the apex of the major curve. Future studies should resolve the issues regarding the technique of distraction, optimal frequency and amount of distraction per session. More comprehensive cost analyses should be performed.

Key words: *complications; scoliosis; spine; ultrasonography*

INTRODUCTION

Early-onset scoliosis may occur in young children and if left untreated, the curvature may rapidly deteriorate and lead to disfigurement and poor pulmonary development.[1–8] Growing rods are the gold standard for management of early-onset scoliosis because they can prevent curve deterioration while allowing physiological spinal growth.[9–11]

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Traditionally, growing rods require open manual distractions approximately every 6 months[9,10,12–16] and are associated with increased risk of anaesthetic and wound complications.[1] To overcome the limitations of traditional growing rods, a remotely distractible, magnetically controlled growing rod (MCGR) system has been developed to allow for gradual, non-invasive spinal lengthening under continuous neurological monitoring in an awake patient on an outpatient setting.[17,18]

The MCGR has undergone multiple design changes in the past 3 years including insertion of a stainless steel 'keeper plate' next to the internal magnet to prevent loss of distraction, change of the welding method for the actuator from the use of a pulsed laser to a continuous laser to avoid rod fractures at weak points, the use of smaller actuators (70 mm as compared to 90 mm) to accommodate smaller patients, and changing the loading mechanism of the rod to prevent housing pin dislodgement (Fig. 1). On 3 June 2015 at the University of Hong Kong, 32 participants from 16 regions including Australia (n=3), Canada (n=1), China (n=1), Denmark (n=2), Hong Kong (n=9), India (n=2), Ireland (n=1), Korea (n=2), Myanmar (n=1), Netherlands (n=1), New Zealand (n=1), Pakistan (n=1), Singapore (n=1), Taiwan (n=1), Turkey (n=1), and USA (n=4) shared their experiences and discussed tips and tricks, pitfalls and complications with MCGR use (Table).

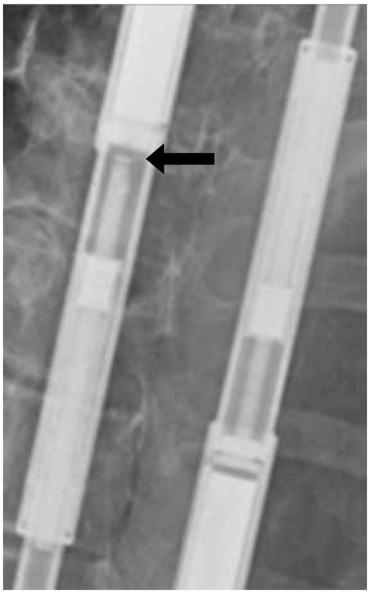

Figure 1 A dislodged housing pin (arrow) on the left rod leading to an inability to distract the rod.

CASE SELECTION

The current indication for MCGR is patients with early-onset scoliosis who have a sizeable Cobb angle, high potential for further spine growth and curve progression, and are at risk of pulmonary complications. Most participants agreed that results of MCGR for early-onset scoliosis are generally good especially if dual rods are inserted.[17,19–21] Similar length gains are questionable in late juvenile or young adolescent idiopathic scoliosis patients owing to their inherent stiffness. Hence, congenital scoliosis patients with unsegmented bars and adolescent idiopathic scoliosis patients who are older and larger also have increased incidence of distraction failure, as the MCGR may not be able to impart enough force to allow for lengthening. Distraction failure is manifested during the distraction procedure by a palpable and audible 'clunk'. This 'clunking' or 'stalling' indicates slippage of the rod's magnetic mechanism where the internal magnet fails to complete a full revolution and flips back to its original position. Clunking may occur as a result of the internal magnet's inability to lengthen the spine because the stiffness of the spine resists the distraction force. This is in contrast to the normal 'wobble' feeling during distraction characterised by smooth continuous turning of the magnet.

The role of MCGR in thoracic insufficiency syndrome remains unknown. Vertical expandable prosthetic titanium rods and MCGR hybrids can allow for differential thoracic cage volume and spinal length increases, but this still depends on the growth potential of patients, which is usually limited. MCGR can also be used as a temporary internal device for safe, gradual correction of severe deformities.[22] This is similar to halo-gravity traction for spinal correction in awake patients to reduce the risk of neurological complications and technical difficulties during the definitive corrective surgery. This technique is also helpful for evaluating the overall balance of the spine in standing radiographs and thus aids in level selection for instrumentation.

Previously, MCGR was not advisable in patients that may require magnetic resonance imaging (MRI) follow-up such as those with syringomyelia. There was suggestion that the MRI might affect the efficacy of the distraction mechanism with regards to the magnet function. However, no problems in rod lengthening have been reported after MRI. MRI only produces a half turn of the internal magnet and thus distraction loss is unlikely. Nonetheless, safety remains a concern as the effect of magnet heating in MRI remains unknown. In addition, image artefacts

Table
Issues discussed by participating surgeons

Parameter	Consensus	Lack of consensus
Case selection	Good indication: (1) thin patients, (2) early onset scoliosis, (3) ligamental laxity Less favourable cases: (1) obese patients, (2) congenital scoliosis, (3) late juvenile and young adolescent idiopathic scoliosis	(1) Syringomyelia (necessitating magnetic resonance imaging for follow-up), (2) for kyphosis owing to difficulties in proximal rod bending
Implant decision/rod construct	(1) Dual rods preferred, (2) pedicle screws preferred over claw constructs to prevent proximal junctional kyphosis	(1) One standard and one offset rod versus 2 standard rod configuration for better distraction force, (2) pedicle versus rib-based anchors, (3) use of cross-links
Instrumented levels	End-to-end vertebrae	T1 or T2 as the upper instrumented vertebrae (problem when addressing proximal junctional kyphosis)
Intra-operative technique	(1) Subfascial rod insertion, (2) concave rod insertion first, (3) avoid bending near rigid portion of rod	Whether to distract intra-operatively (may cause immediate clunking)
When to start distraction	-	3 weeks to 3 months
Distraction frequency	-	Monthly to 6-monthly
Distraction amount	-	2 mm per month to distraction until clunking
Dealing with clunking	-	To stop when clunking occurs or to continue until the intended distraction length on the external remote controller
Distraction technique	-	(1) Concave vs. convex rod first, (2) one vs. single magnet, (3) when to use alternating technique
Monitoring distraction		Radiography versus ultrasonography
Magnetic resonance imaging	(1) No problem with distraction of the rod, (2) difficult to visualise owing to artefacts and image distortion	Unknown heating effect
Complications	-	Whether to reuse rods in infection cases

up to 30 cm of image distortion have been observed.[23] It is advised that if MRI is anticipated, the internal magnet should be placed away from the imaging area of interest or a shorter (70-mm) actuator unit be used.

INSTRUMENTED LEVELS

Instrumented levels usually incorporate the end-to-end vertebrae. In general, surgeons try to minimise the number of instrumented levels, because in the final fusion surgery, no fewer than the original instrumented levels can be accepted. Longer fusion may even be required depending on the position of the neutral or stable vertebrae to include added-on levels.

Decision making for instrumented levels is especially difficult in smaller children. The shortest available actuator (70 mm) may still be too long for smaller children, and a long segment of the spine may be instrumented and result in a longer final fusion. Surgeons may consider delaying the surgery in these small children and use casting or bracing instead until the rods can be inserted without sacrificing unnecessary levels.

Distraction with the MCGR generally causes flattening of the spine especially with the long straight portion of the rod (magnet and housing unit) and increases the risk for proximal junctional kyphosis. Contouring of the rod to accommodate for sagittal alignment is suboptimal as compared to the traditional growing rods owing to the rigid portion of the rod. Over-contouring of the proximal portion of the rod may be helpful to preserve the sagittal alignment. T1 and potentially T2 should generally be avoided in instrumentation in case proximal junctional kyphosis occurs and these levels need to be included in the final fusion surgery.

For neuromuscular scoliosis, surgeons tend to instrument longer. Offset dual rods (one rod in standard and the other in inverse orientation) are suggested to allow for preferential lengthening of one side, which is particularly useful in correcting pelvic obliquity or coronal imbalance.

IMPLANT DECISION

The use of dual rods is generally preferred owing to the advantage of increased distraction forces and to enable differential correction.[16,17] Surgeons only resort to the use of a single rod when the soft tissue coverage is inadequate in smaller and thinner patients. Also, severe rotatory deformity with an apparent gibbus may be an indication for the use of a unilateral rod on the concavity. Nevertheless, further study is required to determine the optimal rod configuration.

Despite the lack of consensus, most surgeons recommended one standard and one offset rod configuration for differential correction (Fig. 2a). Although some considered that 2 standard rod configuration (Fig. 2b) might increase the distraction force applied to the spine, internal mechanical testing by Ellipse Technologies showed that similar distraction forces are generated by both configurations. In addition, differential lengthening is more difficult with the 2 magnets so close together in 2 standard rod configuration. Technical difficulties such as 'cross-talk' may occur when magnets are placed <4 mm apart. In these cases, a larger external distraction force is required to overcome the internal forces. One standard and one offset rod configuration increases the distance between the magnets and thus avoids 'cross-talk'. The rate of clunking may also be affected, as each rod can be distracted separately by smaller amounts. Good evidence to support either configuration is lacking.

Some surgeons preferred pedicle screws for the anchor sites as they have a stronger pull-out strength than hooks. Hooks, however, are less stiff and may allow more vertebral rotation for differential lengthening. Some surgeons preferred rib-based hooks to avoid disruption of peri-spinous musculature, which may lead to autofusion of the spine.[24,25] The use of cross-links is controversial and some challenged whether cross-links are even necessary in cases with pedicle screws used as foundation anchors. When using hooks as anchors, most surgeons would use a cross-link to avoid foundation failure.[26] The anchor foundations should move as a single block and thus are adequate for stability. Using 4 anchor points at the foundations provides more stability than using cross-links.

INTRAOPERATIVE TECHNIQUE

All surgeons agreed that rod insertion subfascially is preferred, as there is less skin impingement. Most surgeons usually insert the concave rod first because it is easier to deal with. The rod should not be bent too close to the rigid portion of the rod to avoid problems

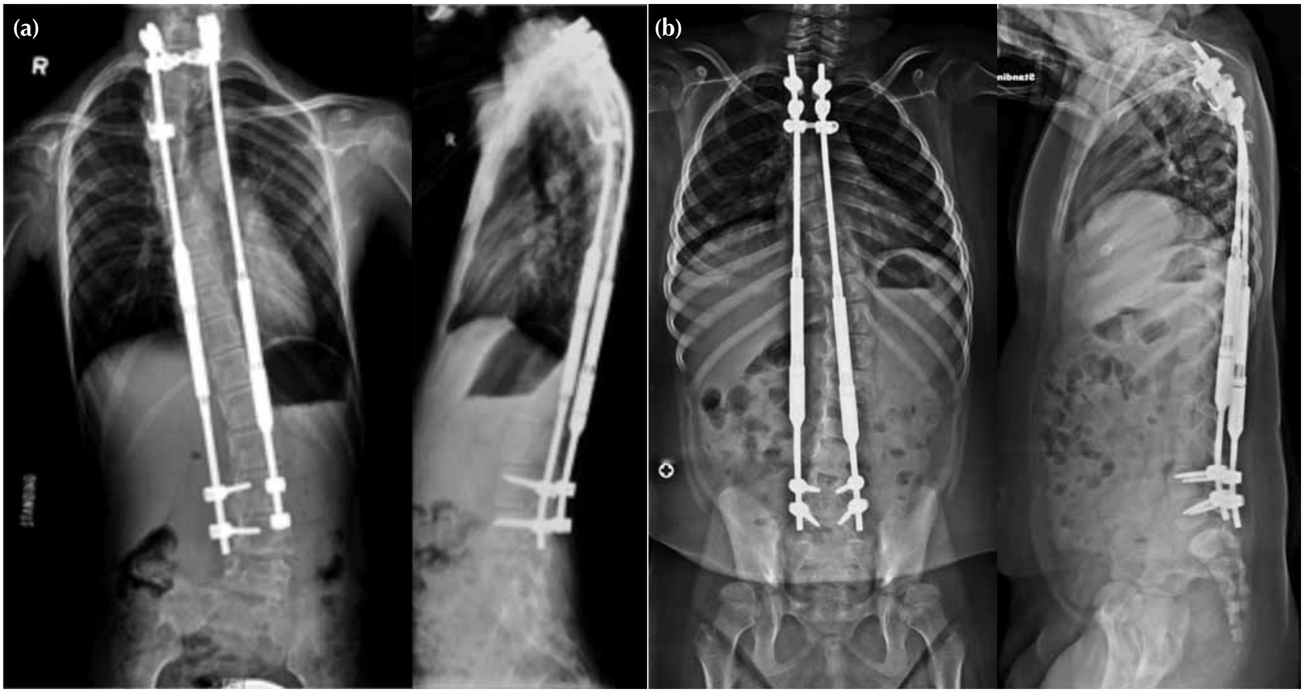

Figure 2 Radiographs showing dual magnetically controlled growing rods in **(a)** one standard and one offset rod configuration and **(b)** 2 standard rod configuration.

with the motor and subsequent distraction difficulties. When using standard or offset rods, attention should be directed to the arrow indicated on the rod. This indicates the cephalad and caudal direction of the rod. If the directionality of the rods is incorrect, distraction will fail. Intra-operative distraction can be carried out in a similar manner to the traditional growing rod by using a distractor between the rod holder and screw. However, some surgeons avoided loading the implants intra-operatively because of a higher risk of implant failure, ploughing, and clunking in the first few distractions. If clunking occurs early, it is difficult to discern whether there is a genuine rod problem or whether it is a result of rod loading. There was no consensus on the extent of intra-operative distraction and correction. In-situ rod insertion or maximal correction has been practiced by some participants.

DISTRACTION

There was no consensus on when to begin distraction or the frequency of distractions, which depends on availability of distraction services in each centre and geographical convenience. The time to begin distraction has reported to vary from 3 weeks to 3 months, whereas distraction frequencies varied from monthly (to distract 2 mm) to 6-monthly (to distract maximally until clunking or patient discomfort). One study suggested that more complications of proximal junctional kyphosis and distraction failure occurs with shorter distraction intervals (1 week to 2 months vs. 3 to 6 months).[27] However, the sample size was only 30 patients and foundation failure occurred more often in the 3-to-6-month-distraction group.[27]

Distraction failure can be either technical or mechanical in origin. Technical causes include bending the rod too close to the expanded portion of the rod or inserting the rod in the wrong direction. Mechanical causes include spontaneous bone formation near the housing unit limiting further distractions, a dislodged housing pin (inside the actuator, Fig. 1), and clunking. Clunking may be related to 'cross-talk' or magnets too close to the apex of the major curve. It occurs more often in the offset rod and within the first year of rod implantation.[28] As the external magnet can generate on average 44 lbs of force in a single rod and 80 lbs in dual rods,[29] clunking may occur if the internal forces exceed this, or in larger patients in whom tissue stiffness increases internal forces that resist the external forces generated by the magnet. Increased body mass index may result in an increased distance between the external and internal magnets hence reducing the amount of distraction forces transferred internally and increased requirements of external distraction forces. The optimum distance between the external and internal magnets is <1 cm; thus obese patients may have unsatisfactory results. Some surgeons stop distractions once clunking occurs, whereas others continue until the planned distraction amount. Whether further length is gained with continuing distractions post-clunking is unknown.

In addition to the standard distraction technique of centering the 2 external magnets of the external remote controller (ERC) over the internal magnet, additional techniques have been described to improve the success rate of distraction and avoid clunking. Firstly in patients with a big rib hump, a single magnet technique may be useful to approximate the ERC magnet to the internal magnet (Fig. 3). An alternating technique can also be used where the ERC is alternatively applied to the rods with a distraction amount of only 0.2 to 0.5 mm at a time. This reduces the stress placed on the adjacent rod when distraction is completed on one side before moving to the other rod. A third technique is to insert 2 standard rods side by side and place the ERC between the 2 rods to distract both rods simultaneously.

Radiography is used for monitoring spinal distractions, but there is concern for radiation exposure. Ultrasonography is as accurate as radiography in measuring changes of rod length.[30] Although the number of radiographs can be reduced, radiography is still necessary every 6 or 12 months to assess the overall balance, curve magnitude, and any complications that may arise from distraction such as proximal junctional kyphosis, distraction

Figure 3 Single magnet distraction is used in patients in whom the hump precludes placement of 2 magnets close to the internal magnet.

failure, and rod fracture. EOS imaging may reduce the amount of radiation exposure,[31,32] but the image may become distorted if the patient is unable to keep still during the scanning. Ultrasonography is hence a better alternative, and studies have verified its use for monitoring distractions, thereby decreasing exposed ionised radiation to children.[30,33]

COMPLICATIONS

Prior to continuous laser welding, breakage may occur at the interval between the housing unit and the rest of the rod. Replacement of the broken rod is advised as one broken rod, if left alone, increases the risk of breakage of the second rod.[34] Due to the cost concerns, replacing the unbroken rod in addition to the broken rod at the same setting is not advised.

The use of pedicle screws may be superior to hooks for preventing proximal junctional kyphosis as screws provide a stiffer construct. However in young patients, small pedicles may preclude the insertion of pedicle screws, and thus claw constructs may be implemented instead. Further proximal instrumentation is likely required during the final fusion in these patients, as claw constructs cannot correct the overall balance as reliably as pedicle screw constructs owing to less tolerance for intra-operative distraction. More kyphosis should be built into the proximal segment of the rod with preservation of the posterior ligamentous complex to avoid proximal junctional kyphosis.[35] Owing to flattening of the thoracic spine, instrumentation up to T1 or T2 may be required. Overcorrection of thoracic kyphosis should be avoided, but the definition of 'normal alignment' is debatable and varies among ethnicities and age groups.

Infection does not necessitate removal of implants.[36] Rods are commonly replaced in the revision surgery. It is debatable whether the removed rods can be reused to reduce costs. Autoclaving of the rods may damage the magnet and should be avoided; other forms of sterilization may be acceptable.

Accumulation of calcified deposits between the actuator and rod junction may cause distraction failure. The reason for this remains unknown as this portion of the implant is subfascial and far from the bone surface.

FUTURE DIRECTIONS

There is still no consensus on the optimal technique, frequency, or amount of distraction. Applying a device that gauges the forces going through the rod during distraction may allow matching of the external distraction force and the resisting internal forces. The relationship of growth rate and distraction length is of interest. The extent of growth contributed by normal spine growth or distractions is unknown, as is whether remodelling of the vertebra occurs with distraction. Experience shows that ploughing of screws occur instead of actual vertebral remodelling. The relationship between distraction force/length and the improvement of apical rotation or curve correction should also be assessed.

Several cost model analyses in Europe and the US have shown that inclusion of revision surgeries and complications, the overall cost of the MCGR is similar to that of traditional growing rods.[37–39] Nonetheless, further regional studies should be performed. There are also other social and psychological factors to consider including patient satisfaction and complications. Repeated general anaesthesia and aesthetic issues associated with open surgeries also need to be addressed.[40]

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