

Failing to Appreciate that an Excessive Soft Tissue Envelope May Lead to Spinal MCGR Dysfunction

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Abstract: Surgical management of Early Onset Spinal Deformity with magnetically controlled growing rods (MCGR) is a common intervention. Multiple complications of the use of these devices have been reported in the literature. To date, failure of the device to lengthen due to the physical distance of the rods from the external controller due to patient body habitus has not been reported. Consideration of the resultant distance from the external remote controller to the rods should be part of preoperative planning and intraoperative decision-making.

Key Concepts:

- Patient body habitus should be a consideration at the time of MCGR implantation.
- If in doubt, test the functionality of actuator location at time of MCGR implantation.
- Small changes in actuator position prevent problems with lengthening.

Introduction

Growth-friendly strategies are used routinely in skeletally immature patients with Early Onset Spinal Deformity (EOSD). Traditional distraction-based growing constructs using spine, rib, or pelvic anchors require multiple surgical interventions and anesthesia exposures to lengthen the implants. An externally controllable magnetically controlled growing rod (MCGR) (MAGEC, NuVasive, Inc., San Diego, CA) has been approved for use in the United States since 2014. This system allows lengthening in the clinic or office setting utilizing an external remote control (ERC) coupled with a magnetic actuator on the rod to generate length, thereby avoiding exposure to anesthesia and minimizing the risk of multiple surgeries.¹⁻⁴

The frequency of lengthening using an MCGR system varies in the literature but is performed most commonly every 3-6 months.^{1,2} Outpatient lengthenings generally proceed with few complications, particularly early on after implantation. However, like all distraction-based growing devices, the ability to lengthen appears to decrease over time and complications increase. Published complications of the MCGR system include rod fracture, loss of proximal and/or distal fixation, metallosis, fracture of the actuator pin within the lengthening mechanism, and failure of the device to lengthen.⁵⁻¹⁰ To date, there are no reports of inadequate coupling of the ERC to the internal magnet of the device due to excessive physical distance in an obese patient.

We believe that the distance between the external control unit and actuator, due primarily to the intervening soft tissue envelope and the patient's overall body mass, limited the ability of the ERC to effectively activate the actuator and lengthen the rods.

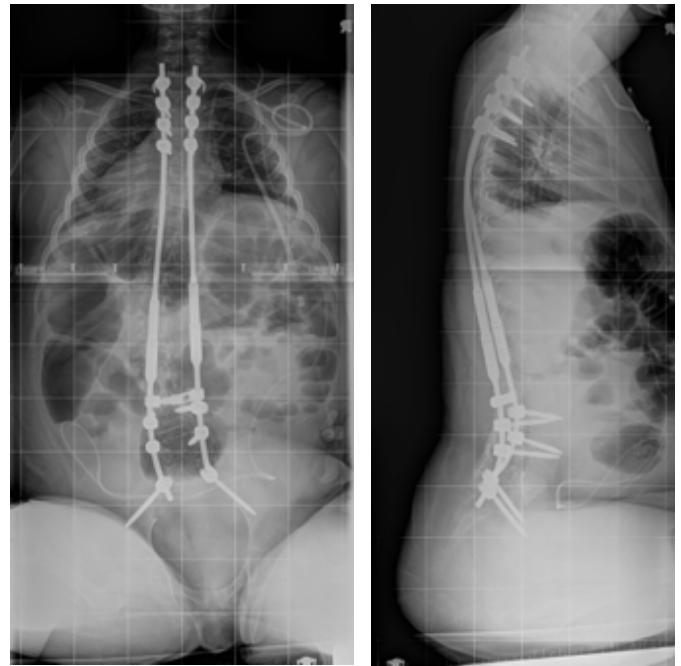
Case Report

A 4-year-old male was diagnosed with neuromuscular scoliosis when he presented for evaluation of orthopaedic aspects of spastic quadriplegic cerebral palsy. His neurologic involvement was the result of an anoxic brain injury secondary to a near drowning incident. He was non-ambulatory, non-verbal, and had significant extensor tone. The original recommendations for his spinal deformity were a soft spinal orthosis and wheelchair modifications. Despite these interventions, over the ensuing 3 years his deformity increased significantly, and was causing difficulties with positioning and seating. After discussion with his family, surgical intervention was recommended (Figure 1).

Figure 1. Upright PA image at the time of surgical recommendation



Due to his age and skeletal immaturity (7 years of age), a growth-friendly, posterior distraction-based, non-fusion procedure was recommended. Use of an MCGR (MAGEC, NuVasive, Inc., San Diego, CA) was planned



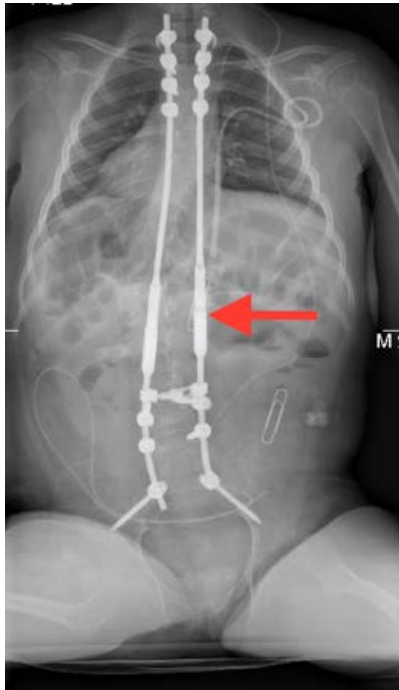
Figures 2A and 2B. Immediate post-index procedure upright PA and lateral images

to minimize the risks of repeated operative lengthening procedures and multiple anesthesia exposures.

At the time of original implantation, the patient weighed 38.5 kg, and had a BMI of 26.6 (99th percentile). Surgery was uneventful, with use of hybrid segmental thoracic spine fixation proximally and lumbo-pelvic pedicle screws distally. The rods were placed in a subfascial position. Local fusions were performed at the proximal and distal fixation points to ensure stable foundations. Postoperative images are seen in Figures 2A and 2B.

The initial attempt at lengthening was performed in the clinic 3 months postoperatively. Localization of the actuators was difficult, even with multiple locator magnets provided by the manufacturer. An attempt with the patient in the lateral position failed to generate any change in the length of the implants. Significant changes in patient positioning were limited by the patient's spasticity, body habitus, and recent surgery. A second attempt at lengthening with the patient prone after radiographic localization with metallic skin markers

Figure 3. PA image with skin marker (arrow)



(paper clips taped to the skin) was more successful, and approximately 4 mm of lengthening of one rod was obtained.

An attempt was made again to lengthen the construct at the patient's 6-month postoperative visit. His BMI at this time had decreased slightly (22.18) from the value calculated preoperatively. Despite localization radiographs with surface markers (Figure 3), multiple attempts in multiple positions were unsuccessful.

Unfortunately, access to diagnostic ultrasound, either for device localization or determination of depth of the actuator assembly, was not available.

At this point, discussions were had with the family regarding possible causes for the failure, as well as potential options. It seemed unlikely that the spine had become sufficiently stiff this early in the postoperative period to resist lengthening. We hypothesized that the physical distance of the internal device from the ERC, secondary to the thickness and density of the intervening soft tissue envelope, appeared to render the external controller unable to couple to the internal magnetic actuator enough to generate lengthening. Lateral

radiographs at that visit revealed 3.6 cm and 4.2 cm from the posterior edges of the actuators to the edge of the soft tissue shadow, which was presumed to approximate the skin surface (Figure 4).

After lengthy discussion with the family, plans were made for revision of the lengthening system after examination and attempted lengthening under general anesthesia with radiographic control.

The patient returned to the operating room and was placed prone on a spine table after intubation. With significant manual counter pressure on his abdomen, and under fluoroscopic guidance, several unsuccessful attempts were made at lengthening. At that point it was felt that revision and realignment of the implants were indicated. The MCGR was found just deep to the spinal fascia. Following the plan for revision, the rods were cut proximally and distally with a metal cutting burr in a sequential fashion such that one rod remained in continuity at all times to maintain distraction. The actuators each lengthened normally with the intraoperative testing device. Continuity was



Figure 4. Lateral radiograph demonstrating pre-revision actuator depth



Figure 5A and 5B. Lateral and PA radiographs post-revision demonstrating improved actuator depth.

reestablished utilizing side-to-side connectors to rotate the sections of the rods with the actuator approximately 90 degrees dorsally, which effectively brought the rods more proximal and superficial than their original positions.

To ensure that the rods could couple sufficiently with the external device in the new positions, the soft tissues were closed provisionally, and the ERC was covered and brought sterilely into the operative field. Once the rods were noted to lengthen appropriately with the ERC, both radiographically and by direct inspection, the wound was irrigated and closed in standard fashion. The paraspinal fascia was closed around, but not over, the realigned components.

Lateral post revision images demonstrated <3 cm measured from the actuator to skin surface (Figure 5). The patient did well postoperatively and was lengthened without incident at 3- to 6-month intervals for approximately 3 years, despite persistently high BMI (> 75th percentile at the last successful lengthening). Adequate alignment and spinal balance were maintained,

although diminishing amounts of lengthening were obtained over time. At 3 years post-revision, his sitting balance was acceptable, and the implants appeared to be stable. Further lengthenings were discontinued at that time (Figure 6A and 6B). Due to his underlying medical fragility, an extensive final fusion procedure was not recommended. Plans are to follow him clinically and radiographically for development of any further deformity or implant-related complications.

Discussion

Lengthening of a MCGR requires interaction between the magnets of the external control unit and those of the actuator portions of the rods. Centering of the external unit on the lengthening portion of the rods, either simultaneously (standard) or in an individual (offset) fashion, maximizes the ability of the magnets to couple and generate lengthening. It seems inherent that increased distance from the source of the external



Figure 6A (left). Most recent upright PA radiograph
Figure 6B (right). Most recent lateral image with measurements from actuator to skin

stimulus (ERC) may limit the ability to activate the lengthening portions (actuators) of the rods.

Regarding the relationship between the ERC and the actuators; there appears to be a consensus (supporting product development and engineering data) that the baseline ideal coupling distance of the ERC and actuator is 1 centimeter, and that at 3 centimeters the coupling efficiency is diminished by greater than 50% of that expected at 1 centimeter. Thus, at distances beyond 3 centimeters, it is much more likely that the stimulus from the ERC would be insufficient to generate the activity within the actuator that is necessary to lead to lengthening of the rod (multiple sources, personal communication). Unfortunately, to our knowledge, there is no published literature that addresses these specific numerical values.

In our experience, very few patients with EOSD have a similar body habitus to the patient in this report. Many are small for age, often have multiple associated medical issues, and may be relatively thin compared to others in their age cohort.^{11,12} Generally, concerns over the prominence of growth implants, even those placed sub-fascially, are more common.¹¹ In this patient, the opposite was the problem. The combination of his elevated BMI, large soft tissue envelope, and the resultant distance from the ERC to the rods, precluded normal functioning of the MCGR system in its original position. After the implants were revised and the actuators were placed more superficially and dorsal to the paraspinal fascia, the ERC and the actuators coupled and functioned adequately, even with the patient's persistently high BMI and overall body habitus.

The authors recognize that there may be some concern that this patient was not an appropriate MCGR candidate due to his BMI of greater than 25 kg/m² at the time of initial implantation. However, accurate measurement of height and weight, and thus determination of BMI, in a nonambulatory patient can be difficult to obtain and reproduce, thus limiting the usefulness and reliability of

the value.¹³ In addition, attempts at lengthening failed at the 6-month post-index visit with a BMI of less than 25 kg/m², and successful lengthenings occurred post-revision despite an elevated BMI. We suggest that the distance to the ERC to the actuator is a more significant consideration than BMI.

For the sake of completeness, it seems necessary to address the possible role of spinal stiffness in the difficulty in achieving lengthening in our patient at 3-months post-index procedure, and then the complete failure at 6 months. Sankar, et al.⁹ have described the well-known "Law of Diminishing Returns" regarding progressive difficulty obtaining length with traditional growing rods. Noordeen, et al.¹⁴ similarly demonstrated decreasing lengthening with each distraction, along with a doubling of the initial force required by the 5th lengthening. It is difficult to imagine that a significant increase in spinal stiffness developed in the first 6 months postoperatively in this patient, particularly in light of the lengthenings that were achieved post-revision.

We strongly recommend that surgeons managing EOSD with an MCGR device consider the issue described in this report, particularly in those EOSD patients with a high and/or increasing BMI. In retrospect, this should have been recognized and factored into the initial rod placement based on the depth of the soft tissue envelope on the preoperative lateral image.

If there is any question about the resultant depth of the implants at the time of placement, then provisional closure and a trial of the external device in a protected manner on the surgical field might be considered. Utilization of supra-fascial positioning of the implants in larger patients may be indicated in some situations as well. Forethought and knowledge of the specific biomechanical attributes and limitations of the MCGR system used may minimize the occurrence of this previously unreported complication, and thereby avoid the potential risks inherent in future revision surgery.

Additional Links

1. www.posnacademy.org/Media/Mehta+Casting+Technique/1_145fa2mx

2. www.posnacademy.org/MAGEC+Insertion+vs+Serial+lengthenings/0_nuo9j8hj

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