A biomechanical study on the effect of lengthening magnitude on spine off-loading in magnetically controlled growing rod surgery: Implications on lengthening frequency

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Abstract
Purpose: To assess whether the magnitude of lengthening in magnetically controlled growing rod (MCGR) surgeries has an immediate or delayed effect on spinal off-loading. Methods: 9 whole porcine spines were instrumented using two standard MCGRs from T9 to L5. Static compression testing using a mechanical testing system (MTS) was performed at three MCGR lengthening stages (0 mm, 2 mm, and 6 mm) in each spine. At each stage, five cycles of compression at 175N with 25 min of relaxation was carried out. Off-loading was derived by comparing the load sustained by the spine with force applied by the MTS to the spine. Micro-CT imaging was subsequently performed. Results: The mean load sustained by the vertebral body before lengthening was 39.69N, and immediately after lengthening was 25.12N and 19.91N at 2 mm and 6 mm lengthening, respectively; decreasing to 10.07N, 8.31N, and 8.17N after 25 minutes of relaxation, at 0 mm, 2 mm, and 6 mm lengthening stages, respectively. There was no significant difference in off-loading between 2 mm and 6 mm lengthening stages, either instantaneously ($p = 0.395$) or after viscoelastic relaxation ($p = 0.958$). CT images showed fractures/separations at the level of pedicle screws in six spines and in the vertebral body's growth zone in five spines after 6 mm MCGR lengthening. Conclusion: This study demonstrated MCGRs cause significant off-loading of the spine leading to stress shielding. 6 mm of lengthening caused tissue damage and microfractures in some spines. There was no significant difference in spine off-loading between 2 mm and 6 mm MCGR lengthening, either immediately after lengthening or after viscoelastic relaxation.

Keywords
biomechanical phenomena, stress, mechanical, magnetics, scoliosis, osteoporosis, osteogenesis, distraction, spine, surgery, orthopedic procedure

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Introduction
The traditional growing rod (TGR) has significant limitations, including the risks associated with repeated invasive surgical procedures for distraction and the psychosocial impacts of frequent surgeries disrupting the child’s daily life. The potential of using remote distraction of growing rods to overcome this hurdle was first demonstrated using a magnetically controlled extensible rod.
rod known as the Phenix device. Subsequently, the advent of magnetically controlled growing rods (MCGRs) represented a breakthrough in the treatment of early-onset scoliosis (EOS), allowing for rod lengthening in an outpatient setting without frequent invasive surgeries. Furthermore, MCGRs allow frequent interval distractions at smaller increments to more closely mimic normal physiological growth. The clinical efficacy of MCGR has been demonstrated to be equally effective as TGR with the added benefit of non-invasive distractions. Recent long-term results report consistent spine and rod lengthening throughout growth while providing additional advantages to spine length gain over TGR by avoiding autofusion of the spine associated with forceful surgical distractions at irregular intervals.

Despite these advantages, complications remain common, with up to 46.7% of patients requiring an unplanned operation at 2-year follow-up. While short-term complications are well documented (such as mechanical malfunction, rod slippage, and metallosis), long-term complications require further research. One long-term complication often overlooked is stress shielding due to off-loading of the physiological loads normally imposed on the spine onto rigid spinal instrumentation. Previous studies on vertical expandable prosthetic titanium rib have observed changes in morphology of the vertebral body and pedicles after distraction, stating that stress shielding may be a consequence of distraction forces. If severe, it could affect instrumentation and ability to correct the curvature further during final fusion.

The optimal frequency and magnitude of MCGR distraction are subject to debate, with variations ranging from monthly to 6-monthly distractions. Distraction magnitude is estimated using Dimeglio’s growth chart to mimic physiological growth. MCGRs are lengthened by 2 mm and 6 mm in monthly and 3-monthly distraction frequencies, respectively, and the MCGR is distracted till clunking for 6-monthly distraction frequencies. If severe, it could affect instrumentation and ability to correct the curvature further during final fusion.

This biomechanical study addresses the immediate and delayed consequences of MCGR lengthening by measuring the magnitude of spinal off-loading over time in a porcine model.

**Methodology**

**Specimens preparation**

With local animal research ethics approval (Committee on the Use of Live Animals in Teaching and Research 5397-20(T)), nine healthy, domestic pigs with a median age of 5 months (range, 4–7 months) were used in the study. The animals were sedated and anaesthetized following standard protocol before being killed with the entire spine harvested. Afterward, spinal specimens were prepared using the method previously described by Wilke et al. In short, it involves dissection of the paraspinous musculature, while the posterior bony elements, capsular structures, and ligaments were left intact. Spinal segments were visually inspected for any deformities or pathologies. The porcine spines were then frozen at −30°C in a freezer. In preparation for the compression testing, the spines were left to thaw at ambient temperatures overnight.

Each porcine spine was cut, and 13 vertebral segments from T8 to L6 were obtained. The intervertebral discs from the superior endplate of T8 and the inferior endplate of L6 were removed to facilitate mounting. The T8 and L6 vertebral segments were left intact and mounted in custom-made square aluminum tubs and secured with epoxy resin 24 h before testing. These segments were centered so that the loads pass through their flexion-extension instantaneous center of rotation.

The mounted vertebral segments were instrumented using two standard MCGRs (NuVasive, USA) of 5.5 mm diameter from T9 to L5. The cephalad end of each MCGR was connected to two pedicle screws at the T9 and T10 vertebrae, while the caudal end was connected to two pedicle screws at the L4 and L5 vertebrae. 4.5 mm diameter, 30 mm long titanium poly-axial screws (Medtronic, Ireland) were used as the thoracic and lumbar pedicle screws. Accurate positioning of poly-axial screws was confirmed on post-test X-ray.

A segment, 5 mm in height, of the entire T14 vertebral body was cut out, with the posterior elements remaining intact. A miniature 250-pound load cell (LLB250, FUTEK, USA) attached to acrylic plates on both ends replaced the removed vertebral segment as a means to measure the load sustained by the vertebral body during compression. The local load cell was placed at T14 as it was the midpoint between the proximal and distal anchors of the MCGRs. Different sizes of acrylic plates were used to ensure the load passing through T14 was transferred orthogonally to the load cell button; the plates’ thickness was
chosen to maintain a horizontal positioning of the load cell and secure the load cell in its position by applying a pre-load of 1 kg.

**Biomechanical tests**

On the day of testing, the instrumented specimens were mounted in a universal testing system (MTS 858 mini bionix, MTS Systems Corp., USA) with a 1000N load cell (MTS 661.18 Force Transducer, MTS Systems Corp., USA). The specimens were then wrapped in saline-soaked gauze and regularly sprayed to keep them moist. A static compression test was performed at 0 mm, 2 mm, and 6 mm MCGR lengthening stages to observe the degree of off-loading after distraction. Data from the miniature load cell were collected via a high-resolution USB load cell digital amplifier (USB220, FUTEK, USA) and software (SENSIT, FUTEK, USA).

At each MCGR lengthening stage, the specimens were loaded by an axial cyclic compressive force of 175N using a deformation rate of 1 mm/min. After reaching a compressive load of 175N, displacement was fixed for 25 min to record changes due to the viscoelastic response of the spine during stress relaxation. Five cycles of compression testing were conducted at each MCGR lengthening stage to assure reproducibility. A load of 175N was chosen to replicate the upper body weight of a MCGR EOS patient (mean, 9.5 years) at Queen Mary Hospital, Hong Kong. A pilot trial with two porcine spines was conducted previously to finalize the testing procedures. The pilot trial demonstrated the spine’s condition and strength remained the same after the aforementioned loading protocol, thereby validating the methodology and allowing comparison of data after different distraction magnitudes in the same spine.

After compression at 0 mm, the porcine spine was removed from the MTS and placed in a supine position. An external remote controller distracted the MCGRs bilaterally by 2 mm, and a digital caliper was used to measure the change in MCGR length. The spine was then mounted in the MTS machine and compressed following the loading protocol mentioned above. Following five cycles of compression, MCGRs were further distracted by 4 mm in the same fashion to achieve a total of 6 mm lengthening before being mounted in the MTS following the same loading protocol. After each distraction, the specimen was left to relax for 10 min before being mounted in the MTS machine. Upon completing all cycles of compression at the three lengthening stages, the MCGRs were removed and reset to their pre-distraction length, before being instrumented onto another porcine spine to repeat the experimental procedure.

Percentage of off-loading of the vertebral body was calculated using the following equation

\[
\frac{\text{Load Applied by MTS} - \text{Load Measured by Local Miniature Load Cell}}{\text{Load Applied by MTS}} \times 100\% 
\]

**Figure 1.** The experimental setup with the specimen fixed by epoxy resin in square aluminium tubes. A miniature load cell was embedded in the T14 vertebral body with posterior elements remaining intact (A). Dual magnetically controlled growing rods were implanted in the standard fashion from T9 to L5 (B).
Plain radiography and micro-computed tomography (micro-CT) examinations

After the static compression test, each porcine spine was cut into three segments and examined with plain radiography and micro-CT. The spinal segments were examined using plain radiography (Ultrafocus, Faxitron Bioptics LLC, USA) at 60 kV and 0.10 mA in posteroanterior and lateral views. Micro-CT (Skyscan 1076, Bruker Corp., USA) was performed using a slice thickness of 34.66 μm, speed of 0.800°/rotation at 89 kV, and 110 μA.

Statistical analysis

Statistical inferences on the degree of off-loading at the three different MCGR lengthening stages were performed using analysis of variance (ANOVA). All data presented are the mean with standard deviation. A p-value of <0.05 was considered statistically significant.

Results

At each MCGR lengthening stage, the first two cycles of compression were used to precondition the porcine spine and only the third, fourth, and fifth cycles were used for data analysis.37

The mean load sustained by the vertebral body at T14 immediately after MCGR lengthening was 39.69N (±16.34N), 25.12N (±8.99N), and 19.91N (±13.55N) at 0 mm, 2 mm, and 6 mm lengthening magnitudes, respectively (Figure 2). Percentage of off-loading of the vertebral body was calculated as 77.10% (±9.43%), 85.51% (±5.21%), and 88.53% (±7.79%), at 0 mm, 2 mm, and 6 mm MCGR lengthening magnitudes, respectively. There was no significant difference in percentage of off-loading between 2 mm and 6 mm distraction magnitudes (p = 0.395). However, instantaneous off-loading in 2 mm and 6 mm lengthening stages were significantly different compared to before lengthening (p = 0.015).

After 25 min of viscoelastic stress relaxation, the load sustained by the vertebral body decreased and off-loading further increased. Mean load sustained by T14 after stress relaxation was 10.07N (±3.66N), 8.31N (±4.30N), and 8.17N (±5.67N) at 0 mm, 2 mm, and 6 mm lengthening magnitudes, respectively (Figure 2). There was no significant difference in load sustained by T14 between 2 mm and 6 mm after stress relaxation (p = 0.958).

Plain radiographic, micro-CT examinations

After testing with the mechanical testing system, a fracture or separation was found in the growth zone anteriorly in four

![Figure 2](image-url)
spines using plain radiography (Figure 3). A horizontal fracture across the T13 vertebral body was identified in one spine on X-ray.

On micro-CT examination, a fracture/separation of the growth zone was seen in five porcine spines (Figure 4). Additionally, fractures in the vertebral body at the level of pedicle screws were observed in six spines (Figure 5).

**Discussion**

Mechanical testing of instrumented biological spines is crucial to understand the occurrence of osteoporosis during the treatment and correction of EOS deformity with spinal implants. In this study, porcine spine specimens were instrumented with MCGRs, compressed with 175N, and left to relax for 25 min at 0 mm, 2 mm, and 6 mm distraction stages. In all MCGR lengthening magnitudes, the data observed by the local load cell indicates there was severe off-loading at the vertebral body. Since in a non-instrumented spine the posterior elements only carry 12%–20% of the compressive loads imposed on the spine,41–43 the majority of loads are transmitted through the vertebral body. As a result, they will experience stress shielding due to the severe off-loading by MCGR.21–26 Rigid spinal implants have been reported to cause loss of bone density to instrumented spines,22 and due to the relative rigidity of MCGRs,6 the instrumented spines may experience stress shielding before and after distraction, leading to osteoporosis in patients. As patients graduate with removal of MCGR and final fusion, poor fixation due

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**Figure 3.** Plain lateral radiograph of the L1 vertebrae of a specimen before (A) and after (B) MCGR distraction and non-destructive compression testing. Arrows indicate fractures/separations of the growth zone anteriorly after MCGR distraction. MCGR: magnetically controlled growing rods.

**Figure 4.** Coronal view of micro-CT of the L1 vertebrae of a specimen before (A) and after (B) MCGR distraction and non-destructive compression testing. Arrows indicate fractures/separations of the growth zone extending laterally to medially after MCGR distraction. MCGR: magnetically controlled growing rods.
to osteoporosis inhibits the ability to further correct the scoliotic curvature during final fusion surgery.\textsuperscript{27-29} Even though modern spinal instrumentation provides increased stability and correction in EOS, device-related osteoporosis due to stress shielding remains a challenging clinical complication.

There was no significant difference between off-loading at 2 mm and 6 mm MCGR distraction immediately after lengthening ($p = 0.394$). Furthermore, there was also no significant difference in load measured by the local miniature load cell at T14 after stress relaxation ($p = 0.958$) between 2 mm and 6 mm MCGR distraction, indicating the rods have off-loaded a similar amount of load from the spine given the MTS applied 175N in both cases. As such, similar off-loading of the spine, and thus a comparable degree of stress shielding might arise by MCGR distraction, regardless of the lengthening magnitude. Furthermore, increased instantaneous off-loading of the spine after MCGR distraction, compared to before distraction ($p = 0.015$), was observed. These observations suggest that, in a clinical setting, distraction forces cause an increase in stress shielding, which correlates with clinical observations in previous studies.\textsuperscript{25,26} Additionally, the load sustained by the vertebral body greatly decreased after 25 min of viscoelastic relaxation, indicating an increase in delayed off-loading of the spine compared to the immediate off-loading due to the effects of viscoelastic stress relaxation. Nevertheless, it must be kept in mind that these experimental findings are derived from porcine spines with biological variation in age, weight, and bone mineral density. Consequently, the observed standard deviation of loads measured at the vertebral body are also high.

The optimal distraction frequency and magnitude of MCGR remain subject to debate.\textsuperscript{20} Distraction at monthly intervals was demonstrated in an animal model to lead to a high percentage gain in vertebral body height while simulating vertebral growth.\textsuperscript{44,45} It has also been shown to be clinically effective.\textsuperscript{4,13-15} There have also been suggestions that more frequent lengthening may reduce stresses on implants and reduce rod breakages.\textsuperscript{46} Moreover, frequent monthly 2 mm distractions are more gentle on soft tissues than 3-monthly 6 mm distraction and may avert progressive stiffness and autofusion of the spinal segments.\textsuperscript{14} We observed separations/fractures at the growth zones of vertebral bodies after lengthening the MCGR by 6 mm and subsequent compression testing (Figures 3 and 4). Fractures in the vertebral body at the level of pedicle screws were also seen in six spines (Figure 5). The ultimate strength of the adolescent porcine spine is 4000N–9000N during axial compression,\textsuperscript{47-49} and around 1800N during bending-compression or extension-compression.\textsuperscript{50} Since in this study only a 175N of axial compression was applied, the

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure5.png}
\caption{Axial view of micro-CT of the L4 vertebrae of a specimen after magnetically controlled growing rods distraction and non-destructive compression testing. The arrow indicates a fracture in the vertebral body at the level of the pedicle screws.}
\end{figure}
observed fractures are likely a result of spine tensioning due to MCGR lengthening. Although separation-fracture was only observed on micro-CT in the growth zone of vertebral bodies in five spines, it has been reported to be the weakest zone of the vertebral body, and it is speculated that this portion of the vertebral body is most likely to be damaged due to tensioning by MCGR. Nevertheless, this supports the notion that larger magnitudes of MCGR lengthening may generate tissue and bone damage, which could eventually lead to spontaneous fusion of the spine impeding further distraction of the MCGR to mimic physiological growth.

The “law of diminishing returns” was used to explain the phenomenon of reduction in spinal length gain with each subsequent distraction of the TGR. It was proposed that this phenomenon was due to autofusion of the spine from prolonged instrumentation and distractions with a rigid spinal implant TGR. However, clinical studies have observed no significant reduction in spinal length gain after 2 mm monthly lengthening of MCGRs, suggesting frequent lengthening does not cause autofusion of the spine. Furthermore, Cheung et al. proposed the “law of temporary diminishing distraction gains” for monthly distracted MCGRs, which suggests diminishing distraction length gain is independent of patient factors, and normal distraction length is again achieved after rod exchange. Whether these findings apply to clinicians who distract on a three- or six-monthly basis remains to be seen. Our study demonstrated that neither lengthening regimen increases off-loading from the spine compared to the other; however, damage to the spine’s tissues was observed when larger lengthening regimens were applied. Thus, performing 2 mm lengthening regimens could avoid soft tissue and bone damage associated with larger distraction magnitudes, while avoiding autofusion of the spine causing diminishing returns on MCGR distraction.

A limitation of this study is that it does not consider the remodeling capacity of bone and soft tissues due to the ex-vivo test setting. However, the results are still useful and can be used as a guideline to estimate the off-loading experienced by MCGR-instrumented spines. Future in vivo studies on pigs with repeated MCGR distractions at 1-, 3-, and 6-monthly frequencies should be conducted to better compare the clinical efficacy and complications of different distraction frequencies. Moreover, measurement of bone mineral density using quantitative computed tomography in an in-vivo setting could quantify the bone density loss in instrumented spines due to the effect of different distraction frequencies.

**Conclusion**

Distraction of MCGR caused significant off-loading of the porcine spine, regardless of lengthening magnitude, which may affect instrumentation and inhibit correction of the scoliotic curvature during final fusion as a result of loss of bone density. While there is still no consensus on the optimal distraction frequency, this study suggests that avoiding stress shielding should not be a factor in influencing the clinician’s decision-making in determining their preferred MCGR lengthening frequency.

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