

# Metallosis: A Complication in the Guided Growing Rod System Used in Treatment of Scoliosis

## Abstract

Soft tissue reaction following metallic debris formation with the use of guided growing rod system has not been previously reported in human. The purpose of this study is to report complications caused by metallosis in a guided growing rod system. A 9-year-old female patient, who underwent treatment for the progressive idiopathic scoliosis (with Cobb's angle of 71°) with the guided growing rod system. Her Cobb's angle was corrected to 13° with the index surgery. During the 5 years postoperative period, she manifested recurrent episodes of skin irritation and progressive worsening of lateral curvature of the spine to an angle of 57°. Furthermore, at her final followup, Risser stage 4 with a gain in height of 26.4 cm was achieved. Considering adequate growth attainment and deterioration in the curvature, revision surgery with fusion was performed. Postoperative Cobb's angle of 23° was achieved with the final correction. During the revisional surgery, signs of implant wear and metallosis were observed at the location of the unconstrained screws. On histological evaluation, chronic inflammation with foreign body granules was seen. However, titanium level in the body was within normal range. She was discharged without any complications. More research on implant wear as a complication in the guided growing rod system is necessary before its widespread use. The occurrence of metallosis with the use of guided growing rod system in growing young children should be considered, when designing the implants.

**Keywords:** *Scoliosis, guided growing rod system, implant wear, metallosis, spine*

**MeSH terms:** *Scoliosis, bone lengthening, growth and development, spinal curvatures*

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## Introduction

The “growing rod” system is one of the most remarkable recent additions to the armamentarium of spine surgeons for the management of scoliosis. This technique attains the correction of scoliosis by applying distractive forces over the proximal and distal end of the scoliotic curvature through rods, screws, or hooks, without hindering the growth of the thoracic cavity and vertebral bodies simultaneously.<sup>1</sup> It effectively combines the principles of minimal fusion with optimum correction of curvature in the background of continued spine growth. Most of the corrections happen at the index surgery followed by incremental correction and lengthening of the spine through rods at regular intervals. Several authors have observed significant obstacles in achieving an effective application of the technique to manage scoliosis, due to the high incidence of complications.<sup>2-4</sup> The key complication factor stems from the need for frequent rod-lengthening procedures (usually every 6 months).<sup>2-4</sup>

The Shilla growth guidance technique was envisioned by McCarthy *et al.*<sup>5,6</sup> with the goal of overcoming the hindrance caused by repeated surgeries required for achieving and maintaining alignment and continued vertebral growth in scoliosis. The technique employs instrumentation and fusion of the apex of the curvature with rods attached at the upper and lower ends of the curve on gliding pedicle screws, which allow the rods to glide through the unlocked screw heads as the spine grows.<sup>5,6</sup> However, the risk of implant wear associated with metallosis has been demonstrated in animal and *in vitro* studies.<sup>5-7</sup> The clinical significance of metal-wear at the screw rod interface in guided growth system has not yet been explored, raising safety concerns in its application in growing children.

In our clinical practice, we have come across implant wear and metallosis in one of our patients, who underwent a corrective surgery using the guided growing rod system (modified Shilla technique) for early onset scoliosis. We report our experience with this yet unreported, to the best of

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our knowledge, complication of the guided growing rod system.

### Case Report

A 9-year-old female patient with progressive spinal deformity and shoulder imbalance visited our scoliosis research institute. At the index surgery, her Cobb's angle was 71° with Risser stage 0 and an open triradiate cartilage [Figure 1]. She was skeletally immature with height and weight of 134.7 cm and 25 kg, respectively. Considering the risk of progression, corrective surgery was done using the modified guided growing rod system as described by McCarthy *et al.*<sup>5,6</sup> Through a posterior approach, mono-directional screws (maintain alignment) and rods were placed from T3 to L2, with tightening of the inner cap done only over the T8 and T9 (the apex of the spinal curvature). Rest of the screws were not tightened so that the rod could slide through the unlocked gaps. Posterior fusion was not done. The postoperative Cobb's angle was 13°.

After the index surgery, the 5 years followup was uneventful, except for persistent complains of recurrent irritation by the rod and gradual loss of correction after the 1<sup>st</sup> year [Figure 1]. Her Cobb's angle was 30° by 2 years, 40° by 4 years with a final Cobb's angle of 57°. During the 5-year followup period, the truncal height (from T1 to T12) increased from 146 to 203 mm with an increase in lung volume from 658,540 to 994,533 mm<sup>3</sup> and 502,246–886,303 mm<sup>3</sup> on the concave and convex side, respectively [Figure 2]. Considering unsuccessful spinal

correction and symptoms of recurrent skin irritation, she was readmitted for a revision surgery for posterior instrumentation and fusion. At this juncture, her Cobb's angle was 57° with a height of 161.1 cm (an increase of 26.4 cm from index surgery) and Risser stage 4.

At the revision surgery, the rod and pedicle screws were exposed by an incision through previous healed surgical scar. Preoperatively, the proximal and distal pedicle screws, which had space for sliding of the rod, showed significant changes of implant wear and metallosis [Figure 3]. Whereas, no such changes were observed in the T8 and T9 segment screw-rod construct (apex), which were previously fixed and tightened with the inner cap. The effects of implant wear and metallosis at proximal and distal pedicle screws were more apparent after the removal of the rod. Considering the significant findings, the tissue sample was sent for a culture and biopsy, and loose pedicle screws were removed, followed by thorough irrigation and debridement. New pedicle screws replaced the loosened ones, and additional fixations at L3 to L5 level were implemented to correct the deteriorated scoliotic deformity. Finally, contoured rods were inserted with inner caps and tightened with deformity correction through derotation maneuver, followed by the tightening of the inner caps was done. In addition, thoracoplasty was done to correct the thoracic rib hump. The postoperative Cobb's angle was 23°. The histological examination of the tissue sample sent was reported as chronic inflammation, fibrosis with foreign body granules [Figure 4]. Postoperatively, the

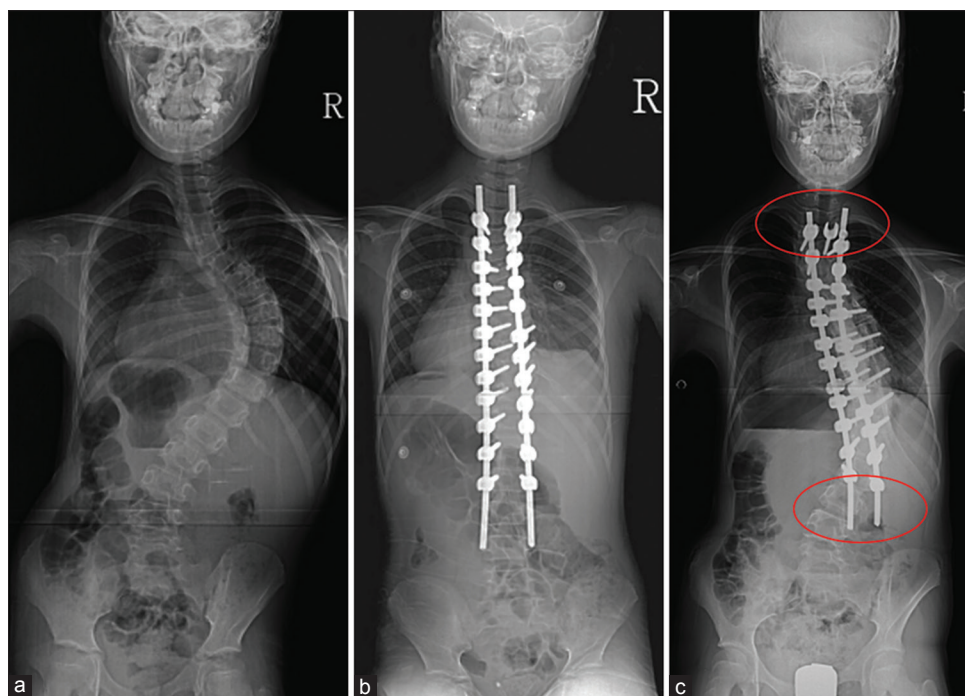


Figure 1: (a) X-ray of whole spine anteroposterior view showing Risser stage was 0 and the Cobb's angle 71°. (b) After operation, Cobb's angle was corrected from 71° to 12°. Considering the vertebral growth, the longer rod than exact vertebral length was used. (c) At 3 years followup, patient's Cobb's angle had progressively worsened from 12° to 46°. However, shortening of the spare length of the rod (which was inserted at initial surgery for guided spine growth) was observed (red circle)

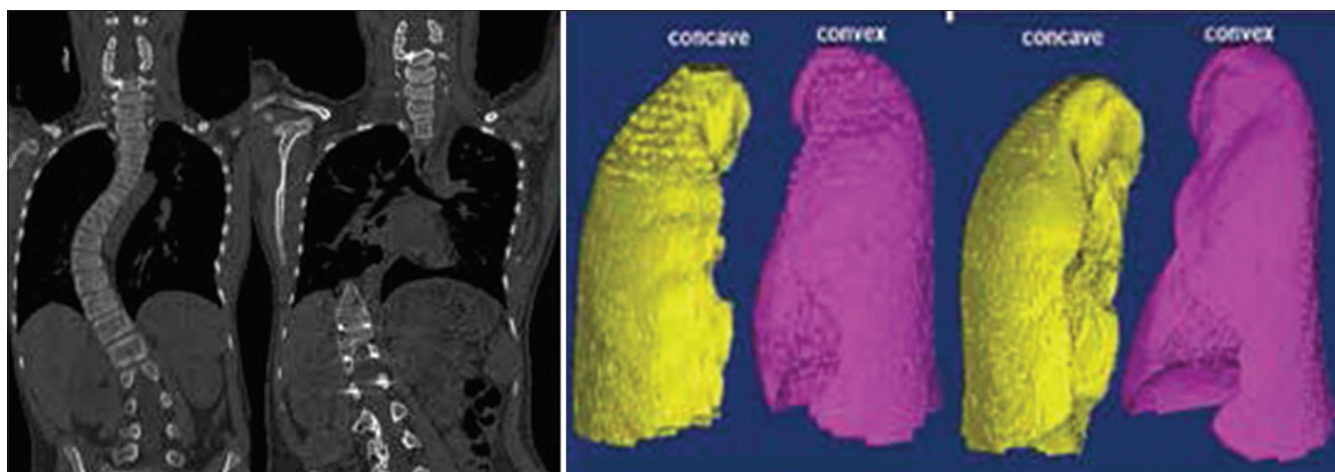


Figure 2: Five years postoperative truncal change (2009–2014). Computed tomography taken in 2009 and 2014 for the measurement of change in truncal height and lung volume. Truncal height measured from the center of T1 to T12 improved from 146 mm to 203 mm, showing 28% improvement. The lung volume increased by 33% at concave side and by 34% at convex side

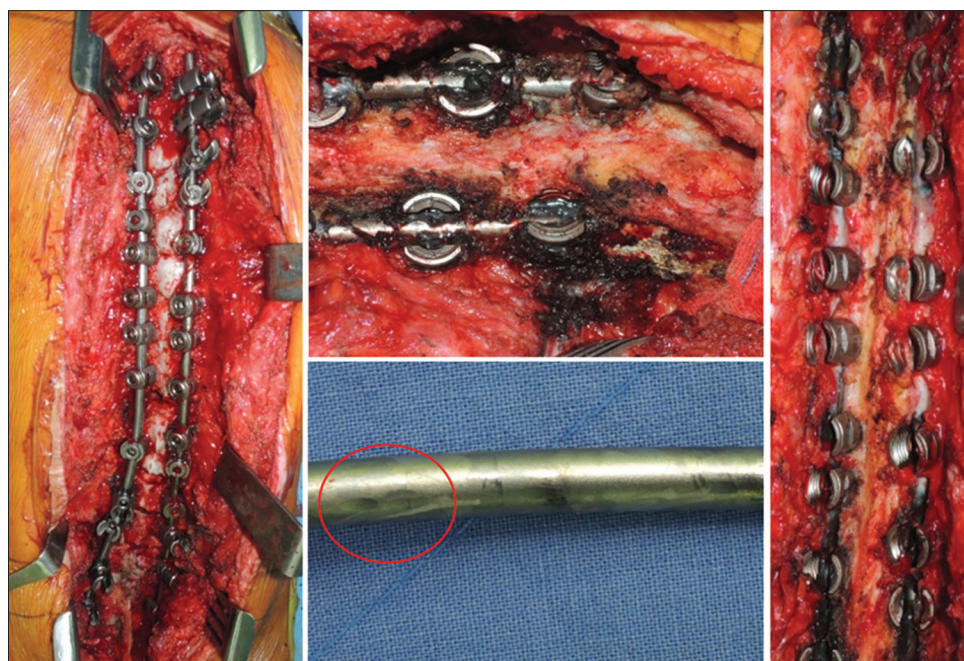


Figure 3: Perioperative clinical photographs at revision surgery, (5 years postoperative) showing that at the upper part of the rod, metal implant wear is visible, at the proximal and distal part of the screws. Metal debris disseminating throughout the surroundings was visually confirmed

patient's hair was examined for the titanium concentration in order to rule out the systemic spread of metallosis. The hair examination manifested a normal range of titanium concentrations. The patient was discharged without any complications. A radiograph of 2 years followup shows corrected vertebral bodies, maintaining Cobb's angle of 23°, without an observable sign of skin irritations [Figure 5].

## Discussion

Metallosis is a rare condition, subsequent to corrosion of metal implants, in which metallic debris buildup in the soft tissues of the body. It has been more commonly reported in hip replacement patients, where metal debris

are known to cause gray discoloration of the tissue around the implant.<sup>8</sup> Though the clinical impact of metallosis has not yet been fully elucidated, it has been linked to several side effects such as implant failure, loosening, and local tissue necrosis.<sup>9</sup> In contrast, there have been only sporadic reports of metallosis with spinal instrumentation with various clinical effects ranging from paraparesis to tissue discoloration.<sup>10-12</sup> Vieweg *et al.*<sup>12</sup> observed that corrosion and metallosis in spinal implants can be attributed to either the metallurgical composition (common with stainless steel) or to the geometric configuration and the construction design. Owing to its construction, the telescopic rod was found to have a stronger tendency to corrode. Because two components are in contact with each other, surface

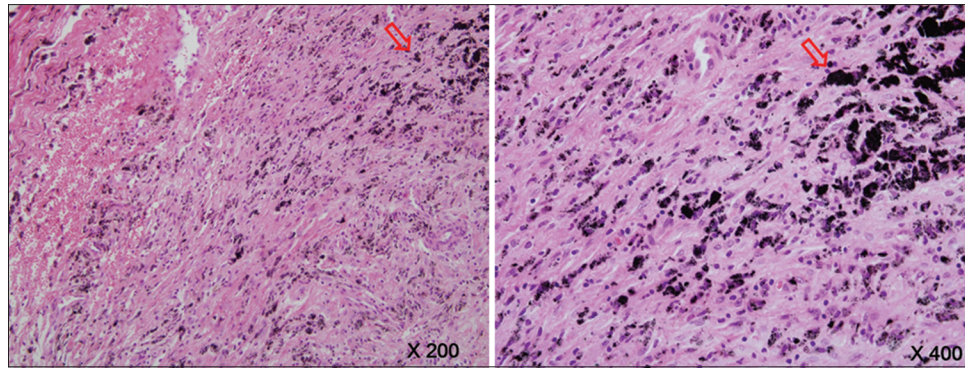


Figure 4: Histopathology (magnification  $\times 200$  and  $\times 400$  respectively) showing metal debris (red arrows) and surrounding inflammatory reactions



Figure 5: Clinical photograph showing hypertrophied scar (red circle with dotted line) caused by skin irritation. However, except for the existing hypertrophied scar (red circle with linear line), no other signs of skin irritation was observed at the final followup

damage occurs, by which mechanical fretting may cause local breakdown of the oxide film. The recently introduced guided growing rod system is one such telescoping rod system, allowing motion within the system with growth. Only animal studies and *in vitro* test have explored the metal-wear properties of the growing rod system. Recently, McCarthy *et al.*<sup>5</sup> reported promising preliminary results of a 2 years followup study with the Shilla technique. The study revealed the optimal correction of spinal deformity with an acceptable complication rate and ability to grow brace free without repeated trips to the operating room for lengthening.<sup>5</sup> The study did not find any metal related complication with the technique. The systemic or localized tissue toxicity due to metal fretting at the unconstrained part of guided growing rod system is yet to be reported in human subjects. With this background, we have tried to elucidate the unexplored entity of metal-wear of the system components and its adverse effect of metal debris on tissues.

In our experience, the possible complications of the guided growing rod system were as follows. First, wear of the system components (i.e., rod and screw) and metallic wear debris is observed on unconstrained implants in the proximal thorax and distal lumbar regions. The wear of implants and metallic wear debris was more prominent in the distal lumbar area, possibly attributing to the increase in the momentum at the rod and pedicle screw interface that usually occur during normal daily activities. The findings are similar to the results reported in animal and *in vitro* studies. In an animal study using goat, McCarthy *et al.*<sup>6</sup> reported implant wear and metallic wear debris in the guided growing rod system at the rod screw interface. However, they suggested that the wear of implants such as a rod, pedicle screw, and set screws did not cause failure of the construct. Singh *et al.*<sup>7</sup> also performed an *in vitro* test for possible wear in guided growing rod system and suggested that the wear rate and wear particle size is proportional to the articulating spinal implants. However, due to the discrepancies between animals and humans in walking posture and the rod breakage frequencies, the applied load and stress caused by the guided growing rod system in human can differ from that of animals. Some data support this discrepancy: The preliminary results of the guided growing rod system used in human showed a high breakage rate of 10% (1/10 patients).<sup>5</sup> In addition, the degree of rod-bending during correction differs in correlation with different scoliotic curves and demands of daily activities. Therefore, *in vitro* test results may not be directly applicable in human cases. They can only be used as reference data.

Second, the local effects or systemic toxicity of the metallic debris due to metal irritation was observed. In our case, the patient was constantly complaining of recurrent irritation by the rod underneath her skin over the back, which may have been due to inflammatory reaction attributable to local infection. However, the onset of this irritation occurred only after 1 year of surgery. Although during the surgery, there was some evidence of infection, the sample sent along with the tissue for biopsy and culture could not identify any pathogen. During

the revision surgery, there was local evidence of severe invasion of the soft tissue adjacent to the growth guidance screws by the metallic debris with granulation tissues. The tissue sample sent for the histological examination revealed moderate to severe inflammatory reaction with metallic debris. In previous animal studies, the authors have reported similar findings of moderate to extensive inflammatory reaction in local tissue by metallic debris.<sup>6,7</sup> The authors of *in vitro* test on the guided growing rod system suggested that the metallic debris caused by wear was not harmful to patients due to its small amounts, since similar small size particles did not have any clinical effects in total disc arthroplasty.<sup>13,14</sup>

The limitations of study were surgical technique used for the correction of scoliosis differed from the original technique; pedicle screws were inserted at level of completely mobile segment of the spine, followed by the placement of the guided growing rod. This technical difference could have increased friction between the rod and the screw and increased the chance of wear. However, our surgical technique has applied McCarthy's surgical concept properly and similar surgical devices which were used in the original technique. As metallosis has been reported already in original technique, raising its importance, our case report could be educationally important to spine surgeons in terms of the complication of guided rod system.

In summary, surgeons should be aware of such implant properties, before using the guided growing rod system to treat early onset scoliosis patients.

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#### Conflicts of interest

There are no conflicts of interest.

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