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Clinical Study

Clinical utility of ultrasound to prospectively monitor distraction of magnetically controlled growing rods

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Abstract

BACKGROUND CONTEXT: Growing rods are commonly used for surgical treatment of skeletally immature patients with scoliosis, but require repeated surgeries for distractions and are fraught with complications. As an alternative, the use of magnetically controlled growing rods (MCGR) allows for more frequent non-invasive distractions to mimic normal growth. However, more plain radiographs are needed to monitor increased distraction frequency, thereby increasing ionizing radiation exposure to the developing child. The use of ultrasound, which emits no radiation, has been found in a cross-sectional study to be reliable in measuring MCGR distractions.

PURPOSE: The study aims to address the prospective clinical utility of ultrasound compared with plain radiographs for assessing MCGR distractions.

STUDY DESIGN: This is a prospective study.

PATIENT SAMPLE: The study includes patients with early-onset scoliosis undergoing distractions after MCGR implant.

OUTCOME MEASURES: The distraction length on plain radiographs and ultrasound was measured.

METHODS: This is a prospective study of patients treated with MCGR. Patients with both single- and dual-rod systems were included. Outpatient distractions were performed at monthly intervals, targeting 2 mm of distraction on each occasion. Assessment of distraction length was monitored by ultrasound at each visit; plain radiographs were taken every 6 months and were compared with ultrasound measurements.

RESULTS: Nine patients (5 female, 4 male), with a mean of 29 distractions (standard deviation [SD] ±14.3), were recruited. The mean distracted length per 6 months was 5.7 mm (SD ±3.6 mm) on plain radiographs and 5.2 mm (SD ±3.9 mm) on ultrasound for the concave rod, and 6.1 mm (SD ±3.6 mm) on plain radiographs and 5.9 mm (SD ±3.8 mm) on ultrasound for the convex rod. Excellent inter- and intra-rater reliabilities were observed for radiographic and ultrasound measurements. An excellent correlation was noted between the two imaging modalities (r=0.93; p<.0001).

FDA device/drug status: Approved (Magnetically controlled Growing Rod).

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CONCLUSIONS: This is the first prospective study to validate that ultrasound assessment of MCGR distraction lengths was highly comparable with that of plain radiographs. The present study has verified that ultrasound can be used to document length changes by distraction over time and that it had high clinical utility. Ultrasound can be a reliable alternative to plain radiographs, thereby avoiding radiation exposure and its potential detrimental sequelae in the developing child.

Keywords: Controlled; Correlation; Distraction; Growing; Magnetically; Rod; Ultrasound

Introduction

Scoliosis deformity in young children is particularly difficult to manage. If left untreated, these deformities are at risk of rapid progression, cosmetic disfigurement, and pulmonary insufficiency [1–8]. By addressing the need to control these deformities while allowing for physiological spine growth, distractible spinal implants or growing rods were developed [9–11]. Patients are recommended to receive open distraction surgeries using these traditional growing rods (TGRs) every 6 months to effectively control progression of spinal deformity, gradually straighten the spine, and mimic spinal growth [9,10,12–16]. However, this method of treatment has significant limitations, including the need for repeated surgeries, and increased risk for anesthetic and wound complications [1,2]. Repeated admissions for surgery also add further psychological distress to both the child and the family. Furthermore, TGR surgery has increased cost implications [17], and hence creates a substantial burden on health care.

In response to the limitations of TGR, a remotely distractible, magnetically controlled growing rod (MCGR) system has been developed to allow for gradual lengthening on an outpatient basis [18,19]. This allows for safe spinal lengthening with continuous neurologic monitoring and real-time feedback by the patient. Moreover, the rods can be retracted if any pain is experienced during the distraction. Preliminary studies have shown its clinical [18,20–22] and cost [17] effectiveness, as well as its safety in the gradual correction of severe deformities [23]. The MCGR may also potentially mimic normal physiological growth more closely as smaller and more frequent distractions can be performed without invasive surgery [18,21].

However, with increased distraction intervals, the requirement for plain radiographs to confirm and monitor distractions is increased. Unfortunately, the health risks of ionizing radiation exposure increase with each x-ray exposure in the developing child. This is a valid concern as ionizing radiation exposure to children has been linked to breast cancer and subsequent mortality [24–26]. Other effects of ionizing radiation exposure also include the development of sarcomas and heart disease, among other conditions [27–30]. "Ultrasonography" is a non-invasive, non-ionizing imaging modality that has been shown to be feasible in the assessment of distractions [31]. In the authors' practice, ultrasound has been incorporated into a routine measurement tool for distraction lengths since 2013. As such, the present study aimed to address the prospective clinical utility of ultrasound compared with plain radiographs for assessing MCGR distractions.

Materials and methods

This was a prospective study of patients treated with MCGR for early-onset scoliosis at a single institute. All patients had preoperative Cobb angle of >30° and were skeletally immature (premenarche status for female patients, open phalangeal physis, Risser 0). Ethics approval was obtained from the local institutional review board. The Scoliosis Research Society definition of early-onset scoliosis (spine deformity diagnosed before the ages of 8–10) was adopted. Patients with early-onset scoliosis were included only if they were skeletally immature (ie, premenarche status for female patients, open phalangeal physis, Risser 0) at the time of surgery. All patients were consecutively recruited from April 2013 to March 2015.

All patients had MCGR inserted as previously described [18]. Either hooks or screws were used as fixation anchors at the upper and lower instrumented vertebra. Only one set of cross-links was used for dual-rod systems, which was placed near the lower instrumented vertebra. Outpatient distractions were performed at monthly intervals with expected 2-mm distraction on each occasion. Ultrasound assessment (Fig. 1) was performed at each follow-up pre- and post-distraction to confirm the distraction length according to previously described methods [31]. Distraction length was measured at the extended portion of the rod between the end of the housing unit and the reference point at the neck of the rod. Anteroposterior standing plain radiographs were obtained at each six monthly follow-up to measure the radiographic parameters. Distraction length was directly measured on plain radiographs (Fig. 2) from the housing unit. Measurements were made on the digital image using the Centricity Enterprise Web V3.0 (GE Medical Systems, St. Louis, MO, USA, 2006). All radiographic measurements were calibrated and corrected for magnification using the diameter of the housing unit (9.02 mm) Both measurements on ultrasound and plain radiograph were measured to the nearest 0.01 mm. Independent observers measured the ultrasound (CB) and the plain radiographs (JPYC). Both observers were blinded to the other observer's measurements, and statistical analysis was performed blindly to