The Learning Curve in Monitoring Magnetically Controlled Growing Rod Distractions with Ultrasound

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ABSTRACT

Study Design: Prospective study

Objective: To determine whether a learning curve exists for ultrasound measurement of magnetically controlled growing rod (MCGR) distractions.

Summary of Background Data: For patients managed by MCGRs, close monitoring of interval distraction length gains is important to determine whether the distractions are translating into actual spine growth. Radiographs are the gold standard for measuring length gains but ultrasound has been shown to be effective in monitoring distraction lengths without radiation exposure. However, it is an operator dependent tool and thus the accuracy of ultrasound measurement of distracted length may improve with experience.

Methods: This is a prospective correlation analysis of patients who underwent MCGR treatment for scoliosis. The study period was inclusive of 19th February 2013 to 31st March 2015. All subjects were consecutively recruited in a prospective manner. Data regarding date of the distraction visit, and the interval radiograph and ultrasound measurements of the distracted lengths were collected. Only those episodes with both radiograph and ultrasound performed were used for analysis. The mean differences in change of radiograph and ultrasound measurements were plotted to determine correlation differences and to observe for a learning curve.

Results: A total of 379 distraction episodes were analyzed. The mean differences between ultrasound and radiograph measurements per distraction episode was -0.3mm for the right rod and -0.1mm for the left rod. For learning curve analysis, there were three distinct timepoints where the difference of correlation became significantly better and were described as clusters. The correlation in the first cluster (19th February 2013 to 15th October 2013) was 0.612 (right rod) and 0.795 (left rod), the second cluster (16th October 2013 to 20th May 2014) was 0.879 (right rod) and 0.918 (left rod), and the third cluster (21st May 2014 to 31st March 2015) was 0.956 (right rod) and 0.932 (left rod). Thus, a plateau was observed at the second cluster which translated to 97-146 rod measurements.

Conclusions: Correlation between radiograph and ultrasound measurements are reasonable to begin with but improves with time. During initial use, successful distractions should correlate between the clinical feel and ultrasound confirmation. Although the absolute value may not be accurate and may require radiographs to confirm, with time and experience, ultrasound measurements can then be more reliable.

Level of Evidence: III

Key Words: Magnetically controlled growing rod; ultrasound; learning curve; measurements; distraction

Key Points:

1. A learning curve exists for ultrasound measurement of MCGR distractions.
2. Excellent correlation between ultrasound and radiographic measurements occurs with 97-146 rod measurements.
3. Determination of a successful distraction depends on the clinician's feel of a "wobble" movement while using the external remote controller.
4. Clunking is manifested by a palpable or audible clunk and indicates a slippage of the rod's internal magnet.

Miniabstract

This prospective correlation study between radiograph and ultrasound measurements proves that a learning curve exists with ultrasound measurement and monitoring of MCGR distraction. Excellent correlation between radiograph and ultrasound measurements occur after 97-146 rod measurements or assessment of 48-73 patients with dual MCGR.

INTRODUCTION

Early onset scoliosis (EOS) are commonly managed with growing rod devices which allow gradual correction of the spinal deformity while maintaining spinal growth.[1-3] The commonly used method for accomplishing this is to implant traditional growth rods (TGRs) that require intraoperative manual distractions every 6 to 12 months which has been shown to be effective in halting curve progression while mimicking spinal growth.[1, 2, 4-8] In view of the increased anesthetic risks and wound complications associated with repeated open distractions[9, 10], the magnetically-controlled growing rod (MCGR) system was developed.[11, 12] The MCGR allows distractions to be performed on an outpatient basis with the patients awake thereby allowing continuous neurological monitoring during the procedures.[13] Preliminary studies have shown its clinical effectiveness[11, 14-16] and safety in gradual correction of severe deformities.[17] Without the need for surgery under general anesthesia, the MCGR has the additional advantage of more frequent and smaller distractions to better mimic physiological spine growth.[11, 13, 15]

Due to more frequent procedures, it is important to have a reliable method to monitor how much length is gained via distractions. For users who perform distractions on a monthly basis, performing radiographs on a monthly basis purely for distraction monitoring in a developing child may lead to increased risks of radiation exposure such as breast cancer and mortality.[18-20] Ultrasonic monitoring for distractions has been developed and has been shown to be feasible and accurate.[21, 22] However, to acquire images and to measure distracted length accurately requires user experience. As shown by other procedures under ultrasound guidance, a learning curve exists to master any technique.[23, 24] Similarly, ultrasound monitoring of MCGR distractions must also have a learning curve. Hence, the following study aimed to identify the learning curve of mastering the ultrasound for monitoring MCGR distractions.

METHODS

Study Design

This was a prospective analysis of patients who underwent MCGR treatment for scoliosis. All subjects were consecutively recruited. Ethics approval was obtained from the local institutional review board. Our center has been using the ultrasound for monitoring MCGR distractions since 19th February 2013. Thus, we included all patients under treatment from the period of 19th February 2013 to 31st March 2015. This period was chosen because we were testing the ultrasound as a monitoring device and thus both ultrasound and x-rays were obtained at every visit for comparison.

MCGR implantation and distraction

All subjects underwent or have had dual MCGR insertion during the period under study by the technique previously described.[11] The rod configuration used for the dual rod system in this study was one standard rod and one offset rod. All subjects began distractions at 2 months postoperatively and then monthly for subsequent visits. A proposed 2mm distraction length was applied for each visit using the external remote controller (ERC).

Imaging Details

All subjects had pre-distraction ultrasound measurements and post-distraction ultrasound, and standing whole spine posteroanterior (PA) radiograph measurements to document the change in length. Ultrasound measurements were performed with the patient lying prone with their arms over a pillow to rest their head for comfort. This was the same position used for MCGR distractions. The methods of calculating length gained have been described.[11, 13, 21] For the ultrasound, the 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 while for the radiographs, the height of the housing unit was measured. For the radiographs, measurements were made on digital images via the Centricity Enterprise Web V3.0 (GE Medical Systems, 2006). X-ray measurements required calibration by correcting for the magnification based on the diameter of the housing unit (9.02mm). All images were enlarged and contrast adjusted to ensure the housing unit was clearly seen and the measurements were recorded to the nearest 0.01mm (**Figure 1**). Data regarding date of the distraction visit, and the interval radiograph and ultrasound measurements of the distracted lengths were collected. Any palpable or audible "clunk", indicating a slippage of the rod's magnetic mechanism during distraction, was also recorded.

Statistical Analysis

The data was described as mean ± standard deviation (SD). Using SPSS version 20 (Chicago, IL, USA), we analysed the point at which measurements of ultrasound and radiographs correlated the best (>0.8) and maintained indicating the plateau region of the learning curve. The change in both radiograph and ultrasound measurements was plotted as such with timepoints indicating significant correlation differences separating time periods called clusters for analysis. Comparisons between the radiograph and ultrasound measurements were made by paired sample t-test. This was also performed for specific time-points. One-way analysis of variance (ANOVA) was used to compare the differences between ultrasound and radiograph measurements over time. Tukey's HSD (Tukey's Honest Significant Difference Test) was used to find the mean of significant differences between the multiple comparison groups of specific time-points. A p-value <0.05 was considered significant and 95% Confidence Intervals (CIs) was reported.

RESULTS

A total of 18 patients (15 females and 3 males) were recruited during the study period. All subjects had dual MCGR inserted. The mean duration of follow-up was 28.6±13.3 months with mean number of 21.1±13.7 distraction episodes per patient. There was a total of 379 distraction episodes (inclusive of both left and right rod measurements) under study. The mean number of clunking episodes per patient was 20.8±25.2. The mean gain of length per radiograph and ultrasound measurement was 2.2±2.7mm and 2.5±2.6mm for the right rod (p=0.053) and 2.7±2.9mm and 2.7±2.8mm for the left rod (p=0.64), respectively. The mean differences between ultrasound and radiograph measurements per distraction episode was -0.3±1.4mm (95% CI: -0.64 to 0.00) for the right rod and -0.1±1.3mm (95% CI: -0.40 to 0.25) for the left rod.

The differences in correlation were able to be divided into three clusters (**Figures 2a and 2b**) from 19th February 2013 to 15th October 2013 corresponding to the first cluster, 16th October 2013 to 20th May 2014 for the second cluster and 21th May 2014 to 31st March 2015 for the third cluster (**Table 1**). The correlation in the first cluster was 0.612 (right rod) and 0.795 (left rod), the second cluster was 0.879 (right rod) and 0.918 (left rod), and the third cluster was 0.956 (right rod) and 0.932 (left rod). The number of ultrasound measurements per rod at these timepoints were added to determine the total number of measurements made to achieve these correlation results. Hence, this corresponded to 1-96 rod measurements for the first cluster, 97-146 rod measurements for the second cluster and 147-379 rod measurements for the third cluster. Therefore, the plateau in correlation occurred during the second cluster, indicating that a learning curve did exist which translated to 97-146 rod measurements by ultrasound or 48-73 patients with dual rods.

DISCUSSION

Monitoring distracted length is important in MCGR management as it helps us determine whether we are achieving adequate interval length gain and whether there is enough rod length remaining to distract. It can also help us to determine if there is loss of distraction or distraction failure. The gold standard for monitoring distractions is reading radiographs as we can directly visualize and measure the gain in height of the housing unit thereby gauge how much actual length gain we have achieved through distraction. However, constant monitoring equates to significant radiation exposure and increases the likelihood of complications like breast cancer and subsequent mortality.[18-20] Although interval radiographs are necessary to assess overall balance and curve correction, utilizing the ultrasound to replace radiographs as the primary distraction monitoring tool can avoid radiation risks associated with x-ray.

The ultrasound has been shown to match radiographs in terms of measurement accuracy.[21, 22] However, unlike radiographs the ultrasound is an operator-dependent tool and is thus reasonable to think that results are more accurate in experienced hands. In view of the MCGR's increasing popularity, there will be increased demand for ultrasound operators. Hence, it is timely for this prospective study to highlight its learning curve. Results show that in general measurements between the ultrasound and radiographs were overall similar. However, the correlation was suboptimal within the first cluster. Nevertheless, the correlation improves with experience and reaches a strong threshold after measuring 97-146 rods or 48-73 patients.

Despite the strong correlations between radiograph and ultrasound measurements, a successful distraction ultimately rests upon the clinician's interpretation. Imaging is only for confirmation purposes and there should not be a reliance on imaging to determine whether the distraction was successful in achieving length gain. When placing the ERC against the internal magnet, a magnetic attraction should be felt. During distraction, a consistent "wobble" should be felt indicating successful rotation of the internal magnet. Any inabilities to distract will be manifested by a palpable or audible clunk and loss of the wobble feeling. Clunking indicates a slippage of the rod's internal magnet and thus prevents it from completing a full rotation.[13] This occurs when the forces exerted by the MCGR are unable to overcome the internal forces of a stiff spine. Hence, there is likely a correlation between the amount of rod distraction and the time to clunking. Although the correlations between measurements observed in our study were strong, the overall results of distraction may be subpar due to the high rate of clunking episodes. The effect of clunking on clinical outcomes however, is beyond the scope of this study and requires specific attention in future work.

One of the main limitations of this study is that it was conducted at the institution where the ultrasound technique was developed and thus the users under study were probably more familiar at baseline regarding the technique than new users. It is possible that new users may require even more experience as analysed here to master the technique. Nevertheless, our aim was to illustrate that a learning curve exists for ultrasound use by which this goal is successful. It is also important to note that the ultrasound can only visualize any changes in surface contour of the rod. Thus, the reference points used in ultrasound measurement are different from radiographs. The distance between the end of the housing unit and the neck of the rod is measured by the ultrasound while radiographs directly measure the length of the expanded housing unit.[21, 22] Nevertheless, the change in length rather than the absolute length was used for analysis and hence, both ultrasound and radiographs datapoints should be identical. Finally, this is only an analysis of distracted measurements without inclusion of time data. Whether ultrasound measurements can be performed quicker with increased experience requires further study.

CONCLUSIONS

This prospective study illustrates a learning curve associated with ultrasound monitoring of distraction episodes by the MCGR. Although overall correlation between radiograph and ultrasound measurements are reasonable, there is an observed improvement with time. It is important for clinicians and new users to correlate between the clinical feel of the distraction with ultrasound confirmation of successful distraction. Although the absolute measurements may not be accurate at the initial stage and may require radiographs to confirm distractions, ultrasound measurements have been shown to be increasingly reliable with experience, specifically after measuring 97-146 rods or 48-73 patients.

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Figure Legend

Figure 1: Technique for measuring the housing unit length (red line) on radiographs. The image should be enlarged and contrast adjusted to visualize the housing unit clearly for the measurement.

Figure 2: The mean change in ultrasound and radiograph measurements through distraction dates for the a) right rod and b) left rod. The values match less for the right rod before 20th May 2014 and for the left rod before 15th October 2013.

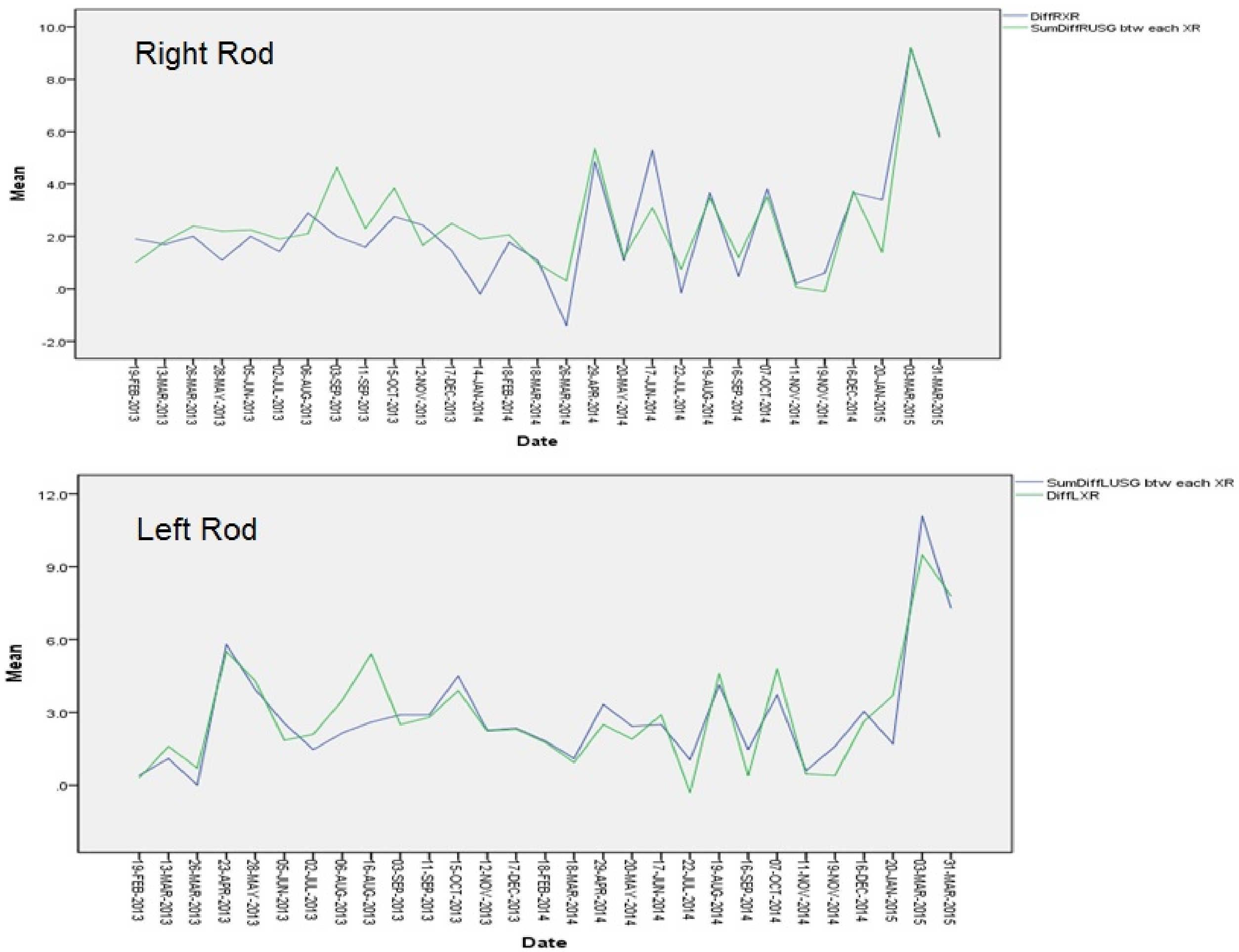

Table 1: Differences between ultrasound and radiograph measurements within each cluster

Cluster	Left rod difference	95% CI	P-value	Right rod difference	95% CI	P-value
1st Cluster	0.08	-0.52 to 0.68	0.79	-0.77	-1.51 to -0.033	0.04
2nd Cluster	-0.28	-0.73 to 0.17	0.21	-0.32	-0.81 to 0.16	0.18
3rd Cluster	-0.07	-0.70 to 0.56	0.83	0.10	-0.36 to 0.56	0.67

CI: confidence interval; 1st Cluster: 19th February 2013 to 15th October 2013; 2nd Cluster: 16th October 2013 to 20th May 2014; 3rd Cluster: 21st May 2014 to 31st March 2015.