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Reducing radiation exposure in early-onset scoliosis surgery patients: novel use of ultrasonography to measure lengthening in magnetically-controlled growing rods

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Key Words: ultrasound, radiation, scoliosis, magnetic, growing-rod

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ABSTRACT

Background Context: Magnetically-controlled growing rod (MCGR) technology has been reported for the treatment of early-onset scoliosis (EOS). Such technology allows for regular and frequent outpatient rod distractions without the need for additional surgery. However, pre- and post-distraction spine radiographs are required to verify the amount of lengthening. This increased exposure to ionizing radiation in the developing child significantly increases their risk profile for radiation-induced cancer and non-cancerous morbidity.

Purpose: This study addressed the first and novel application and reliability of the use of ultrasonography, which has no ionizing radiation exposure, as an alternative to plain radiographs in the visualizing and confirming of rod distractions.

Study Design: A prospective study.

Patient Sample: Six EOS patients who underwent surgical treatment with MCGRs were prospectively recruited.

Outcome Measures: Imaging measurements based on ultrasound and plain radiographs.

Methods: All patients were imaged via ultrasound, ease of rod identification was established and the reliability and reproducibility of optimal reference point selection assessed blindly by three individuals. The clinical algorithm, using ultrasound was subsequently implemented. Plain radiographs served as controls.

Results: Assessment of the rod's neck distance on ultrasound demonstrated a high degree of inter-rater reliability (a=0.99; p<0.001). Intra-rater reliability remained high on repeat measurements at different time intervals (a=1.00; p<0.001). Satisfactory inter-rater reliability was noted when measuring the rod's neck (a=0.73; p=0.010) and high reliability was noted in assessing the housing of the rod (a=0.85; p=0.01) on plain radiographs. Under blinded conditions 2mm rod distraction measured on radiographs corresponded to 1.7mm distraction on ultrasound (SD: 0.24mm; p<0.001). Subsequently the clinical algorithm using ultrasound, instead of radiographs, has been successfully implemented.

Conclusions: This is the first study to report the use of a novel technique using non-invasive, non-ionizing ultrasound to reliably document rod distractions in EOS patients. A high-level of inter- and intra-rater reliability was noted. More importantly, the use of ultrasonography may result in fewer whole spine radiographs from being taken in patients who have had MCGRs implanted for EOS; thereby decreasing their exposure to ionizing radiation and the potential risk of future radiation-induced diseases.

Level of Evidence: Level II diagnostic study.

INTRODUCTION

Scoliosis is a three-dimensional deformity [1, 2] of the spine, characterized by lateral deviation in the coronal plane. The majority of patients require no treatment, however, in a small subset, the lack of appropriate treatment can lead to compromise of pulmonary function and unacceptable cosmesis.[3-5] Early-onset scoliosis (EOS) begins before the age of 5 years and is independent of aetiology,[6] which includes both congenital and idiopathic infantile types. Spinal deformity at this young an age presents a particular challenge as the spine, thoracic cage and its contents are all growing rapidly. As such, the thorax cannot support normal lung maturation and respiration.[7] In order to prevent progression of spinal deformity, bracing, casting and spinal fusion have all been employed, [8-10] but conservative measures fail to prevent progression in young patients. [8-10] In addition, spinal fusion in the skeletally immature child will result in loss of normal spinal growth [8-10] with consequent poor respiratory and cosmetic effects. [11]

Growing rods are spinal implants that guide spinal growth. They have been used in order to address the limitations of both bracing and surgery in patients with EOS. [12-16] Traditionally, distraction (i.e. lengthening of the rods) of these systems required invasive, open surgery under general anesthesia every 6 months until skeletal maturity is reached. Such a frequent procedure can lead to potential intraoperative complications, repeat hospitalization, increased health-care costs, and psychological impact for the child and parent. [5, 17] In order to minimize the limitations of this procedure to patients and their families, a magnetically-controlled growing rod (MCGR) system was developed, which had been validated in animals [18] and its safety and efficacy has been noted in humans. [18, 19]

With the use of the MCGR system, distraction can take place regularly and potentially frequently in the outpatient clinic, in order to more closely mimic normal growth of the spine.

At the authors' institution, we have distracted the implant on a monthly basis, with distractions of approximately 2mm at each visit to parallel normal physiologic growth. However, such frequent distractions may inconvenience the parent and child. More importantly, distraction is measured and documented through the use of pre-distraction and post-distraction plain radiographs, which has led to concerns about the amount of ionizing radiation exposure in children. Ionizing radiation is known to cause cell death and genetic mutation, and is associated with cancerous and noncancerous disease. [20, 21] In fact, excess amounts of ionizing radiation exposure in children with scoliosis has led to the development of breast cancer and increased mortality. [22-24]

Ultrasound is a non-invasive, non-ionizing imaging modality with increasing scope of applications, including the measurement of stents implanted in the human body, [25] the relationship of nerves to orthopedic implants [26] and the evaluation of mobile bearings in knee arthroplasty. [27] The use of ultrasound scanning had been reported in the measurement of leg-length discrepancy, [28] assessment of new bone formation during limb lengthening, [29] and measurement of fetal spine length in utero. [30]

As such, in an attempt to reduce the number of plain radiographs required to monitor and chart the distraction of the MCGRs, the following study was undertaken to determine the feasibility and reproducibility of the novel use of ultrasonography to measure rod distractions.

MATERIALS AND METHODS

Six patients who have been treated with the MCGR for scoliosis were volunteered by their parents to participate in the study, and informed consent was taken, when they attended for routine outpatient lengthening at a single institution. They had a mean age of 12.5 years (range: 8 – 16 years). There were 2 males and 4 females. The diagnoses of these cases were idiopathic scoliosis (n=2), neurofibromatosis (n=1), Ehlers-Danlos Syndrome (n=1), Noonan's syndrome (n=1) and Charge syndrome (n=1).

In order to standardize the ultrasound technique, the patients were all positioned on the couch in the same manner **(Figure 1).** The ultrasound images were obtained using either one of 2 machines: the Logiq500 V/R 4.10, GE Medical Systems (Buckinghamshire, U.K.) and the SonoSite TITAN 38 Linear Array probe, Universal Diagnostic Solutions (California, U.S.A.). Between each ultrasound image that was acquired, the investigator removed the ultrasound probe from the patient by a distance of greater than 10cm.

Using the ultrasound probe the investigator located the implant housing and then the extended portion of the rod **(Figure 2).** The ultrasound probe was then gently manipulated until an optimal image was obtained. This image was then measured on the ultrasound machine. An optimal image includes visualization of the housing, the acoustic shadow that it casts, the hyperechoic rod and the terminal reference point and the acoustic shadow cast by it **(Figure 3).**

Study 1. Optimum Reference Point Selection.

When radiographs were used to measure distraction of the MCGRs, the measurements were made directly from the distraction mechanism **(Figure 4).** The distraction mechanism is however housed in titanium and therefore not visible on ultrasound. Consequently, the MCGR had to be measured from the end of the titanium housing to another reference point on the rod. Nine ultrasound images were obtained and measured by a single investigator with the screw as a reference point and 9 further images were obtained and measured with the neck of the rod as a reference point **(Figure 5).**

Study 2. Intra-Rater Reliability

To test the reliability of ultrasound to measure the extended portion of the rod, a single investigator measured the rod on a single patient 5 times. The patient then stood up, before returning to the examination couch and 5 further measurements were obtained. Finally, a set of 5 measurements, were obtained with the patient standing up between each measurement. A total of 15 measurements were made to test the intra-rater reliability of the protocol.

Study 3. Inter-Rater Repeatability

Following the development of the protocol (study 1) and training of 2 other investigators, the reproducibility of ultrasound to measure the extended portion of the rod was tested. Three investigators measured the rod 5 times each, on 3 patients.

Study 4. Demonstration of Lengthening

The use of ultrasound to measure lengthening of MCGRs was demonstrated by a single investigator on 4 patients on 1 occasion and then more than 30 days later a second investigator repeated the demonstration on 3 patients. Both investigators were blinded to whether the rods were distracted and by how much. On both occasions, in all of the cases, the measurements obtained using ultrasound were compared to measurements made from pre and post distraction plain radiographs. The measurements from the radiographs served as controls for this study.

Study 5. Repeatability of Delayed Reference Point Selection

Compounding the potential error in obtaining images of MCGRs using ultrasound, an additional potential error in determination of length is the measurement of the images obtained. In order to address this, a single investigator re-measured 3 of the images from Study 4 using ImageJ 1.46r (National Institutes of Health, USA. http://imagej.nih.gov/ij). Each image was measured 10 times on 3 occasions, separated by 72 hours.

Study 6. Measurement of MCGR on Plain Radiographs

In order to compare the reliability of ultrasound to plain radiograph for measurement of the rods, 2 investigators measured a single radiograph, on maximal magnification, using Centricity PACS (GE Healthcare). Each investigator measured the image in the conventional manner 5 times by measuring the expanded portion in the housing, and then measured 5 times between the 2 reference points being used in the ultrasound protocol **(Figure 4).** These measurements were repeated on 3 occasions, separated by more than 72 hours. This part of the study was undertaken to validate the use of radiographs as controls for the use of ultrasound for the measurement of lengthening of MCGRs and to validate the housing as the most reliable portion of the MCGR to be measured when using plain radiographs.

Statistical Analysis

All statistical analysis was performed by a single investigator. Mean and standard deviations were obtained where appropriate. Alpha values were assessed to determine the strength of reliability. Intra- and inter-rater reliabilities were performed by assessing Cronbach's alpha with the analyses of intraclass correlations to obtain 95% confidence intervals (CI). The threshold of significance was established at $p<0.05$. Cronbach's alpha values less than 0.69 were regarded as poor, values of 0.70 to 0.79 were considered satisfactory, and values equal or greater than 0.80 were considered as exhibiting good to high reliability.[31]

RESULTS

One patient was selected to determine the optimum reference point on ultrasound. Over nine sets of measurement, the mean screw distance was 14.04mm (SD: 0.27mm) and the mean neck of the rod distance was 8.31mm (SD: 0.12mm) on the MCGR **(Figure 5)**. Since the variance was less in the distance of the rod's neck, this reference point was selected as the most optimal.

With respect to inter-rater reliability, assessment of the rod's neck distance on ultrasound was performed in 3 patients, demonstrating a high degree of reliability (a=0.99; 95% CI: 0.99-1.00; $p<0.001$). Intra-rater reliability remained high on repeat measurements at different time intervals (a=1.00; 95% CI: 1.00 - 1.00; $p<0.001$). Satisfactory inter-rater reliability was noted when measuring the rod's neck on plain radiographs (a=0.73; 95% CI: 0.19-0.91; p=0.010) and high reliability was noted in assessing the housing of the rod (a=0.85; 95% CI: 0.49-0.95; p=0.01). In the assessment of distraction on ultrasound compared to actual distraction based on plain radiographs (controls), we noted that when the rod showed distraction on x-rays of 2mm, the mean distraction measured on ultrasound was a mean of 1.7mm (SD: 0.24mm; $p<0.001$). In contrast, in scenarios where no distraction of the rod was noted on plain radiographs, the ultrasound measurements showed no significant difference (mean = 0.52mm, SD: 0.33mm; p=0.20). As such, the findings suggest that distraction of the rods as noted on plain radiographs can be observed on ultrasound **(Figure 6A-D)**.

DISCUSSION

This study is, to our knowledge, the first to explore the use of ultrasonography to measure changes in spinal implant length. In order to demonstrate its feasibility and reliability, we first identified reproducible reference points on the implant that could be used for measurements. We then demonstrated that these measurements had good intra- and inter-observer reliability, and that they were comparable to measurements taken from radiographs.

The reliability of ultrasonography to measure an implant *in vivo* is dependent on minimizing 2 potential sources of error: (1) the acquisition of the image and (2) the selection of the reference points (measurement of the acquired image). Optimal image acquisition requires training, attention to detail and rejection of sub-optimal image quality (i.e. images without clarity of reference points and with any loss of image capture between the reference points). The higher intra-rater agreeability demonstrated by the radiologist compared to the other raters is probably a reflection of her familiarity and training in this imaging modality and her ability to capture an ideal image more easily. The results from Study 1 showed that the optimal terminal reference point was the transition point, or neck in the extended portion of the rod and not the pedicle screw used to fix the MCGR to the spine. We postulate that this is due to the larger and possibly more inconsistent acoustic shadow cast by the larger pedicle screw, compared to the transition portion of the rod. During this study, and subsequently when this technique has been used to document lengthening of MCGRs in the clinic, accurate determination of the terminal reference point (transition point / neck of extended portion of the rod) was difficult in the hands of less experienced investigators when the pedicle screw was sited less than 1cm from the terminal reference point. Therefore, in our institution we now recommend that all pedicle screws are placed more than 1.5cm from the transition point in the extended portion of the rod.

The traditional method of measuring and documenting lengthening of MCGRs is using plain radiographs. [19] Two raters measured the extended portion of the rod (as used in the ultrasonography technique reported in this study) and the housing of the implant (how extension of MCGRs has been measured on plain radiographs previously) on a single radiography, 5 times, repeated on 3 occasions, separated by more than 72 hours. This was done because radiographs are gold standard images used to document lengthening of growing rods, as such, they were used as the controls in this study. Additionally this allowed the housing, as opposed to the neck of the rod, to be validated as the optimal region in which to measure lengthening of MCGRs on plain radiographs. The results show that measuring the MCGR housing is more repeatable and reliable. This is due to the ease of reference point selection in the housing**.** Throughout the study and subsequently when the methodology was demonstrated, radiographs more accurately documented lengthening, but measurements with ultrasound had a narrower distribution of measurements. The higher accuracy of MCGR measurements with plain radiograph compared to ultrasonography was also likely to be in part due to radiographs being measured under 200% magnification and ultrasound being measured without magnification. In our institution, the ultrasound machines were not linked to a viewer with DICOM imaging capabilities and, as such, all measurements were performed in real-time on the ultrasound machines. In institutions with more integrated imaging facilities that are able to measure ultrasonography under magnification, greater accuracy is anticipated. To test whether reference point selection was repeatable, a single investigator measured 3 ultrasounds using ImageJ on 3 separate occasions, separated by more than 72 hours. A high-level of intra-rater agreeability was demonstrated.

The primary purpose of this study was to develop a methodology to reduce the amount of radiation exposure in immature patients undergoing serial out-patient lengthening of MCGRs. Radiation exposure in children is associated with radiation-induced cancer [24, 32-36] and as few as 25 whole spine radiographs have been reported to increase the risk of breast cancer by 70%. [24] MCGRs could be lengthened on a monthly basis, and have been implanted in patients as young as 5 years and 8 months old. [19] Monthly lengthening, accompanied by documentation of lengthening using plain radiographs until skeletal maturity would necessitate considerably more than 25 whole spine radiographs and may therefore result in further excess risk of cancer compared to the general population. If a MCGRs was implanted in a patient of 5-years old, who was subsequently lengthened on a monthly basis for 8-years, with pre and post distraction radiographs then they would receive 192 whole spine radiographs. This study offers an alternative method to measure and document lengthening of MCGRs.

Furthermore, the findings of this study have been reported back to the implant manufacturer (Ellipse Technologies). We have suggested a potential future modification of the implant that may entail a metal ring being affixed or bonded at the transition point on the neck of the rod, which would not affect the torsional or bending rigidity of the implant. Such a modification would allow easier terminal reference point identification using this ultrasound technique and would likely improve the accuracy and ease of measurement of MCGRs.

This study has shown that the technique is easily learned and is acceptable to patients. It took an average of 35 seconds to locate the rod using ultrasound, 9 seconds to capture each image and 10 seconds to measure the rod. At our institution, the ultrasound machine is located in a room adjacent to the room where the patients undergo MCGR lengthening. This setup and novel technique is a further advantage to our patients for their convenience of not having to go to the radiology department and potentially have further waiting time before having plain radiographs taken. Ultrasound scanning is available in most hospitals and is relatively cheap. In our institution, the ultrasound imaging for these patients is being performed by a basic scientist, under the supervision of an orthopedic spinal surgeon; therefore, not placing any additional burden on the radiology department. Furthermore, this technique has the potential for translation to other applications. For example, the measurement of traditional growing rod constructs in spinal surgery and for the measurement of magnetically-controlled endoprostheses for treatment of malignant bone tumors in skeletally immature children.

Limitations for the Use of Ultrasound

Compared to the current standard of radiography, ultrasound scanning, however, does not allow for the assessment of fusion blocks at the proximal and distal fixation points of the MCGRs, nor does it allow the implants themselves to be assessed for other potential complications, such as loosening or implant failure. In addition, correlation of plain radiographs to spinal balance is helpful in the assessment and differential lengthening in some of these patients. Therefore, in our institution, while we no longer use plain radiographs to measure and document lengthening of MCGRs and have adopted the use of ultrasonography to measure rod lengthening, we intend to continue to take a plain radiograph every 6 months post-implantation, with the hope of possibly reducing the frequency of ionizing radiation exposure associated with plain radiographs.

A potential limitation of this technique is the size of the ultrasound probe used to capture the images. We used a 64mm probe in this study. Probes of this size are commercially available. The current design of the MCGRs can only be lengthened to a maximum of 48mm, hence the decision to purchase a probe of this width. Certainly at the initial period after surgery, when the implant has not been distracted so much, smaller US probes can be used. Alternatively if future designs of MCGR allows lengthening beyond

64mm, larger ultrasound probes, or an alternative methodology, such as the use of panoramic ultrasound, [37] will need to be used.

CONCLUSIONS

Our study is the first, to our knowledge, to demonstrate the reliability of using ultrasound technology to assess rod lengthening in patients with EOS undergoing surgical treatment with the MCGR. This practical and easy to administer technique can change clinical practice by decreasing the frequency of plain radiographs and the associated cumulative ionizing radiation exposure in the developing child.

SOURCE OF FUNDING

Ellipse Technologies Incorporated purchased a 64mm ultrasound probe to facilitate image capture for this study. Ellipse Technologies Incorporated was not involved in any of the surgical procedures, distractions, ultrasound assessments, data collection, analysis or interpretation of the results, writing or editing of the manuscript, or the decision to submit the study for publication.

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FIGURE LEGENDS

Figure 1: Photograph of a patient lying prone on the examination table with his arms stretched out in front of him and a pillow under positioned under the upper thorax for comfort.

Figure 2: Photograph of the MCGR. The blue arrow points to the motor (which drives the rod lengthening). The housing is between the 2 yellow arrows, this is the portion of the rod that is first identified by ultrasound. The extended portion of the rod lies to the left of the housing. The neck, or transition point of the rod, is identified by the white arrow. The change in the dimensions of the rod in this region results in a change in the intensity of the hyperechoic ultrasound representation of the rod and an associated acoustic shadow.

Figure 3: Ultrasound image of the MCGR. The yellow arrow points to the terminal portion of the housing and the acoustic shadow that it casts. The white arrow points to the neck of the rod and the acoustic shadow that it casts. The red arrow points to the pedicle screw, used to fix the MCGR to the spine, and the acoustic shadow that it casts.

Figure 4: Plain radiograph showing how distraction of the MCGR has been measured prior to this study (green line and corresponding measurement). The amount of distraction was measured directly from the expansion of the extension mechanism. The yellow line and corresponding measurement indicated the potion of the rod that was measured by ultrasound.

Figure 5: The MCGR implanted in a spinal model. The yellow arrow points to the terminal portion of the housing. The white arrow points to the neck of the rod, this is the point where

the rod diameter changes. The red arrow points to the pedicle screw, used to fix the MCGR to the spine.

Figure 6: (A) Plain radiograph showing 2 MCGRs implanted into a patient. The radiograph was taken prior to distraction. The housing of the left MCGR measured 27.9mm prior to distraction. **(B)** Ultrasound image of the extended portion (measuring 35.1mm between the 2 reference points) of the left MCGR, in the same patient, prior to distraction. **(C)** Plain radiograph showing 2 MCGRs implanted in the same patient following distraction. The housing measured 29.6mm post distraction. Extension of the left MCGRs as measured from distraction from within the housing (grey line) was 1.7mm. **(D)** Ultrasound image of the extended portion (measuring 36.8mm between the 2 reference points) of the left MCGR, in the same patient, following the distraction. The extended potion of the rod was measured to have lengthened by 1.7mm using this imaging modality.


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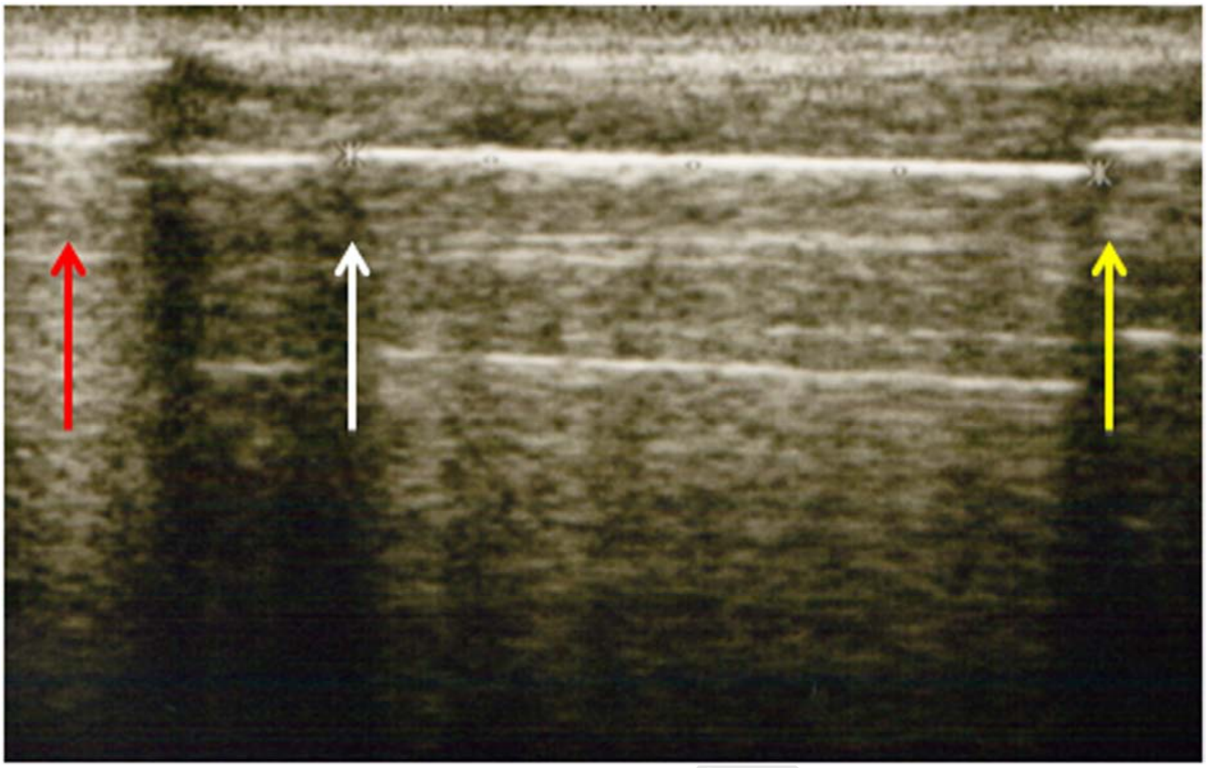
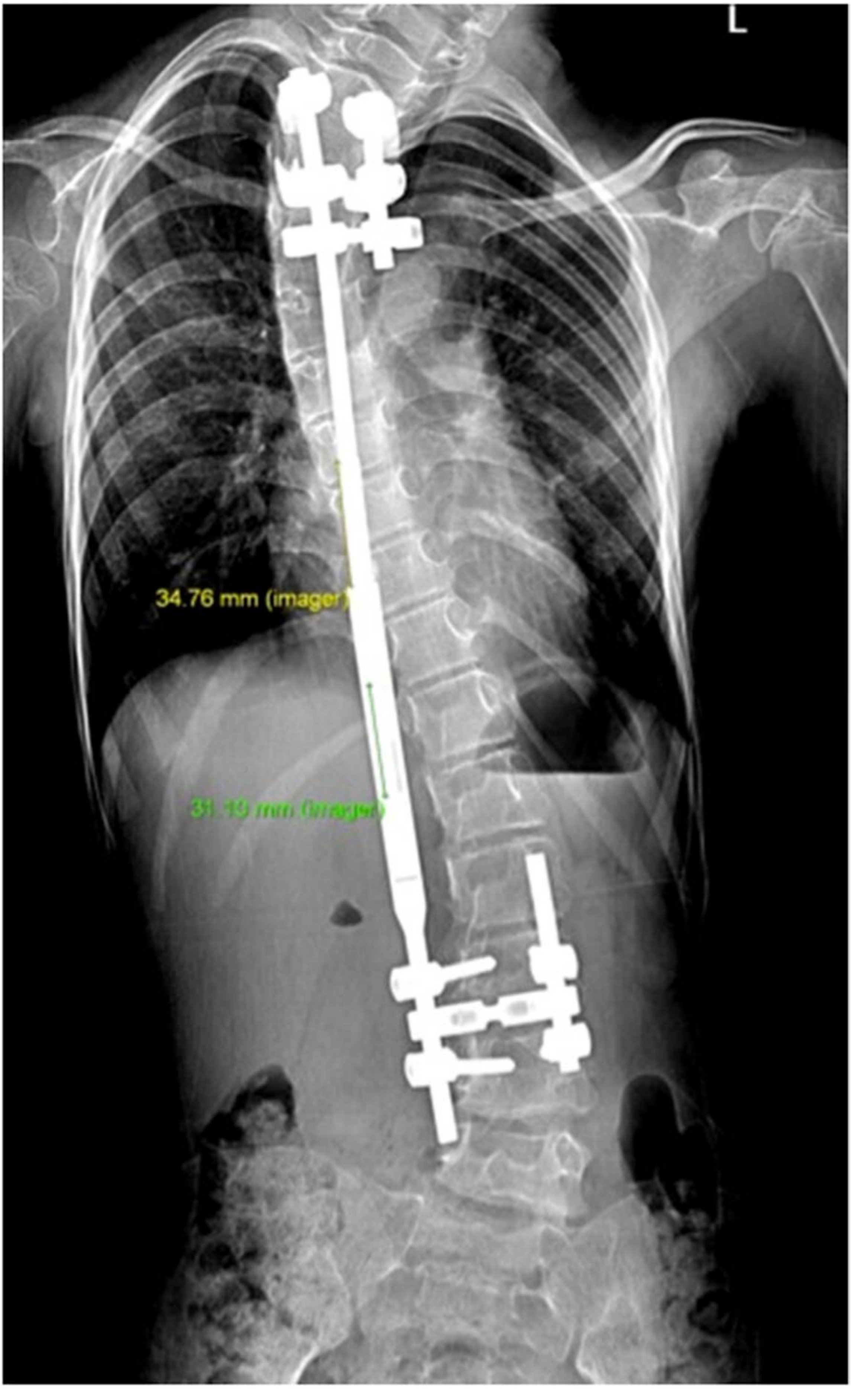
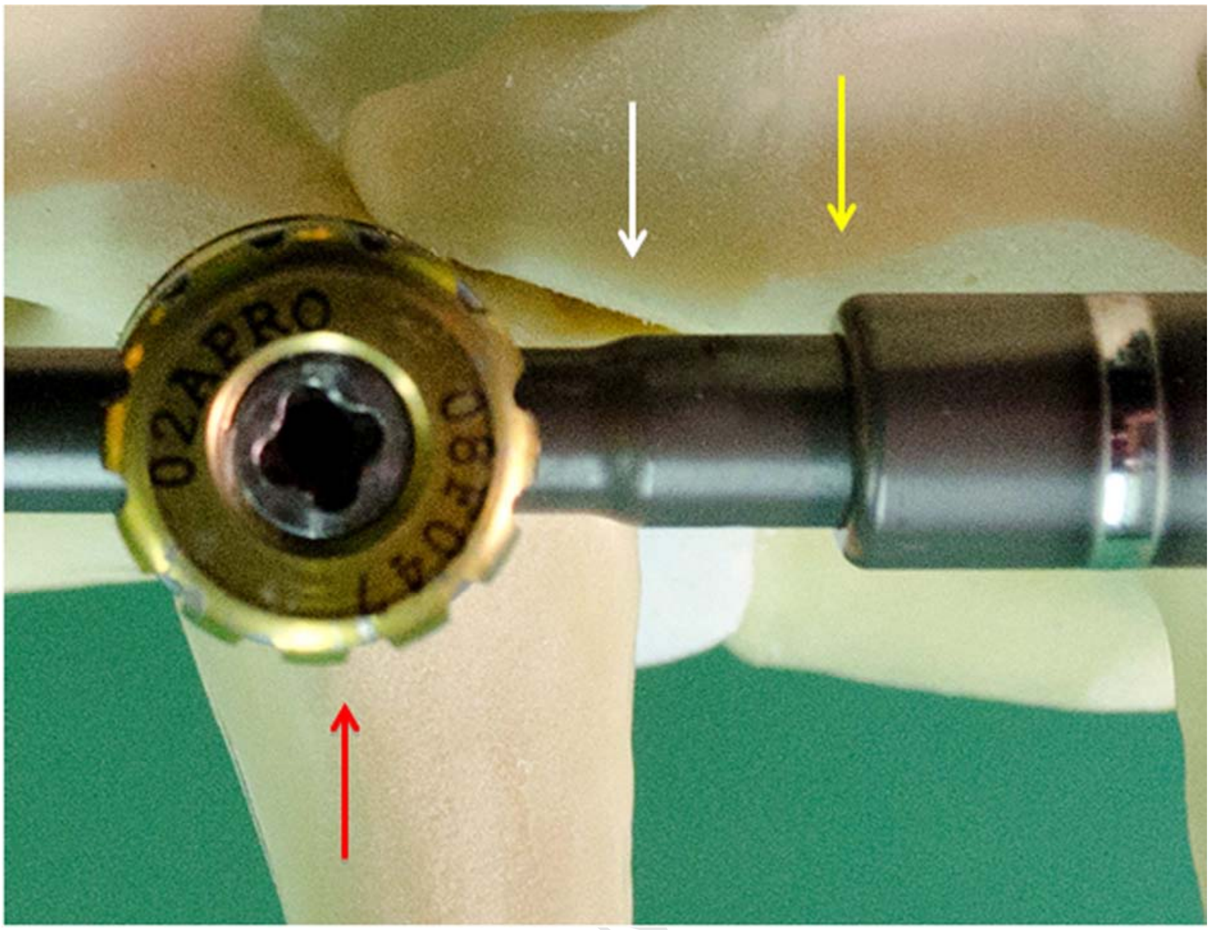
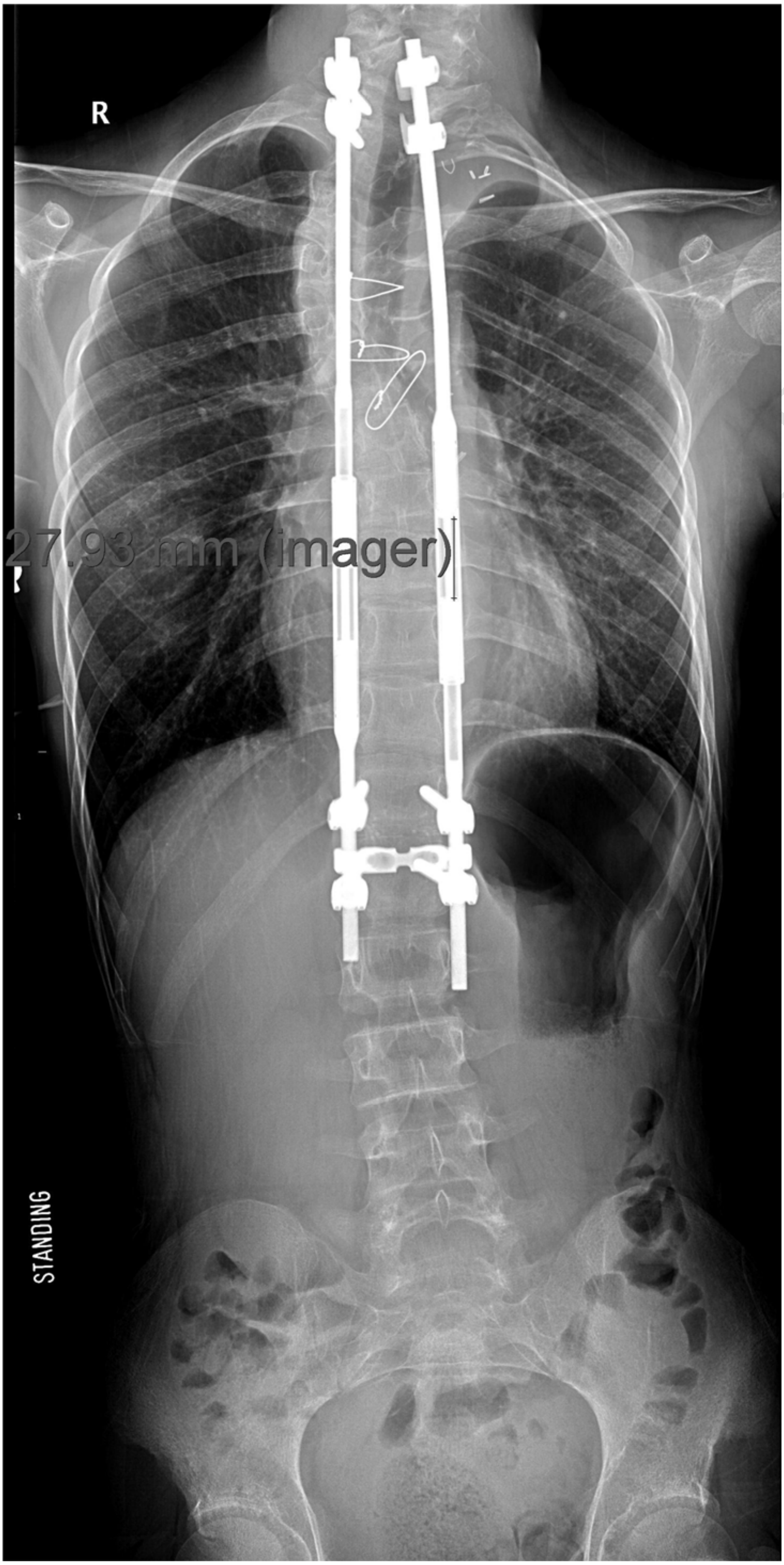
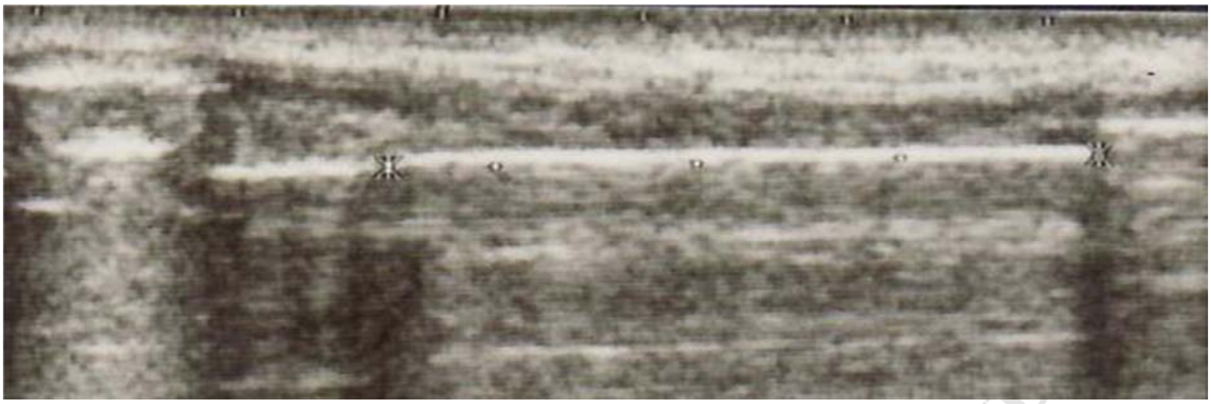
MAGNET

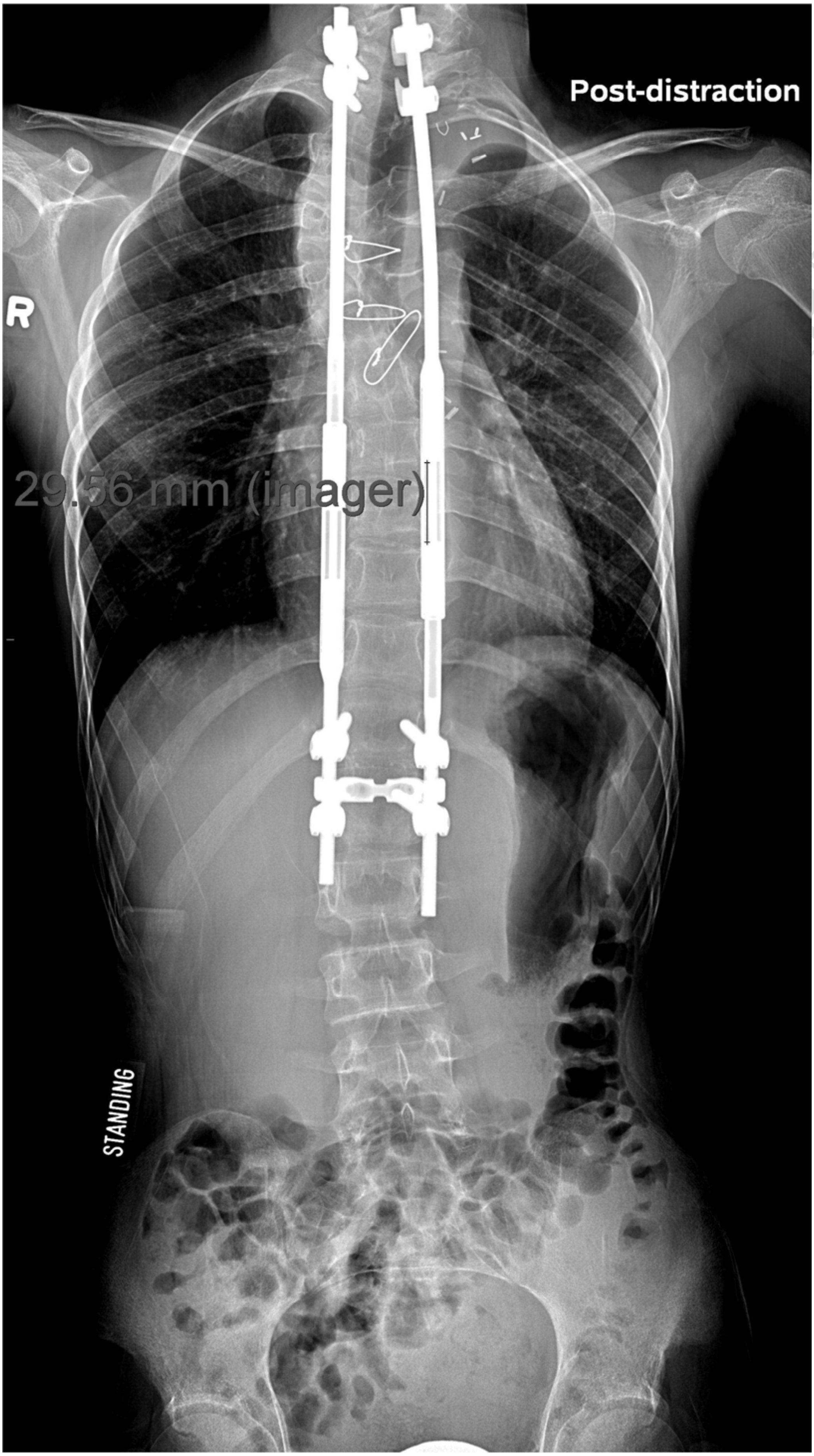



L
34.76 mm (imager)
31.13 mm (imager)


02APRO
06F047


R
27.93 mm (imager)
STANDING




Post-distraction
R
29.56 mm (imager)
STANDING