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Clinical Study

Do magnetic growing rods have lower complication rates compared with conventional growing rods?

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Abstract

BACKGROUND CONTEXT: The main advantage cited for the use of the magnetic controlled growing rod (MCGR) system over the conventional growing rod (CGR) in early-onset scoliosis is avoiding repeated invasive surgical procedures for lengthening, thus reducing, complications.
PURPOSE: The study aimed to evaluate the complications of the MCGR system against the CGR system in our center.
STUDY DESIGN/SETTING: This is a retrospective case control series.
PATIENT SAMPLE: The sample includes patients with early-onset scoliosis treated with MCGR or CGR.
OUTCOME MEASURES: Complications and unplanned return to theater were the outcome measures.
RESULTS: Of the 37 patients (MCGR, N=10; CGR, N=27) in our cohort, 28 patients (76%) had at least one complication. Taking into account the follow-up period, MCGR had a higher complication rate than CGR group (0.32 complication per patient per year vs. 0.15 complication per patient per year). The use of MCGR was associated with a lower risk of deep infection (odds ratio [OR]: 0.22; p=.22) and superficial infection (OR: 0.07, p=.017) but increased risk of metalwork problems (OR: 4.67; p=.045) and unplanned return to theater (OR: 2.92; p=.05) compared with CGR.
CONCLUSIONS: Although MCGR has a lower rate of both deep and superficial infections when compared with CGR, it does not completely avoid repeated invasive surgical procedures as previously suggested. It does have a significant increased risk of metalwork problems and unplanned return to theater.

Keywords: Complications; Deformity; Early-onset scoliosis; Growing rods; Magnet; Remote control; Scoliosis

FDA device/drug status: Approved (MAGEC System, Ellipse Technologies Inc; Paediatric ISOLA or Paediatric Expedium, DePuy Synthes, Johnson & Johnson).

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Introduction

Early-onset scoliosis (EOS) is a lateral curve of the spine that is diagnosed before the age of 10. Following failure of conservative treatment, such as bracing or casting, surgical treatment is usually the only option as these curves are typically progressive. Untreated progressive spinal deformity in early life can cause significant health problems, such as pulmonary compromise, for this group of young children [1]. Complications are common with surgical treatment of EOS [2–6]. This is particularly so in patients who might also have associated medical problems or syndromes. The main aim of the surgery is to correct the severe spinal deformity while maintaining spinal growth until the child is close to skeletal maturity

so he or she can have definitive spinal fusion. This is also known as growth-sparing spinal surgery.

Growth-sparing spinal surgery in EOS can usually be achieved by growing rods. Before magnetic controlled growing rods (MCGR), conventional growing rods (CGR) were the gold standard. However, CGRs require repeated invasive surgical lengthening under general anesthesia every 6 months throughout childhood. The treatment period is often long and protracted in EOS and may take many years to complete. They are known to be associated with high complication rates as frequent surgeries increase the risk of general complications, such as wound infections, anesthetic risk, and delayed recovery for the child [2,4]. This also has direct and indirect financial implications for the family—more surgeries and increased cost to treat the complications and more time off work for parents.

Because of the high complication rate associated with CGR, MCGR in EOS has become a popular treatment option [7–10]. In the United Kingdom, the National Institute for Health and Care Excellence and the National Health Service England have approved this system for use in EOS [11,12]. Although MCGRs are implanted in a similar way as CGRs, the main difference lies in the magnet within the actuator of MCGRs. This is connected to a lead screw and can be rotated non-invasively by a magnetic field with a device known as external remote controller, which also contains a permanent magnet. This causes lengthening of the rod, thus distracting the spine in an outpatient setting without the need for anesthesia or sedation. Therefore, the main benefit of MCGR is the avoidance of repeated surgical lengthening procedures, which should lead to a reduction in surgical complications. The purpose of this study was to evaluate the complications of the MCGR against the CGR system in our center.

Materials and methods

We conducted a retrospective case control study comparing children with EOS treated with growing rods in our center by either the conventional system or magnetic system. In our center, we started using MCGR in 2011 (MAGEC System, Ellipse Technologies Inc, Irvine, California, USA). The conventional growth rods used in our center were either Paediatric ISOLA or Paediatric Expedium (DePuy Synthes, Johnson & Johnson, Raynham, MA, USA). Four of the CGRs (N=4, 15%) were converted to MCGR, ie, two following rod breakage and two following deep infection with removal of metalwork.

Inpatient and outpatient medical case notes and operative notes were reviewed for diagnosis, demographic data, and complications. Complications noted included superficial infection, deep infection, metalwork problems or implant failure, and reoperation or unplanned return to theater. Superficial infection was defined as a wound infection that resolved with antibiotics, whereas deep infection was defined as an infection that required a reoperation or revision procedure. If there were multiple reasons for an unplanned procedure (eg, rod breakage and screw pullout), the primary reason for the surgery was considered as a single complication. For reoperation, we felt that using unplanned return to theater would make the comparison fairer between both groups as complications such as metalwork problems or implant failure can be potentially dealt with at the next scheduled surgery (in our center usually 6 months from previous extensions) in the CGR group. We defined unplanned return to theater as at least 2 months before the scheduled surgical extension (ie, if a reoperation happened between 0 and 4 months after extension, we would consider this unplanned). Serial radiographs were also evaluated to determine the Cobb angle and to confirm the presence of certain complications (eg, rod breakage, screw pullout).

Both types of growing rod system were inserted using standard operative techniques. Under general anesthesia, patients were positioned prone, with intravenous antibiotics given on induction. All procedures were performed through a standard open posterior midline approach, with insertion of pedicle screws or lamina hooks proximally and distally of the curve. The growing rods were cut to fit the patient and contoured before implantation. The growing rod was then connected to the proximal and distal anchorages. In the MCGR group, non-invasive distraction of the MAGEC rods was started between 3 and 6 months from initial implantation. In our center, distractions are carried out at eight weekly intervals under ultrasound guidance. In the CGR group, the patients returned to theater every 6 months for surgical distraction of the growing rods.

Statistical analysis

Two-tailed Student *t* tests were used to evaluate differences in continuous variables between the MCGR and CGR groups. Using Fisher exact test and chi-square test, statistical analysis was used to evaluate differences in categorical data between both groups. Fisher exact test was used in proportion comparisons where values in any cells fell below 5. Chi-square test was used in proportion comparisons where values in all cells were above 5. Cross-tabulation tables were used to calculate odds ratios (OR) for the categorical variables. Significance was defined as $p \leq .05$. Data were analyzed using SPSS Statistics Software 20.0 (IBM, Armonk, NY, USA).

Results

Demographics

There were 10 patients in the MCGR group, whereas there were 27 patients in the CGR group. Table 1 shows the basic demographics for each group. The groups were similar in terms of diagnosis of the EOS. However, we had a significant proportion of males in the MCGR compared with the CGR group (80% vs. 41%). The average age at implantation of growing rod was not statistically different. The average follow-up was significantly longer in the CGR group, but this is expected as we only started using MCGR from 2011. The average number of extensions were 11 in the MCGR group and 9.2 in the CGR