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ABOUT COVER

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WJO covers topics concerning arthroscopy, evidence-based medicine, epidemiology, nursing, sports medicine, therapy of bone and spinal diseases, bone trauma, osteoarthritis, bone tumors and osteoporosis, minimally invasive therapy, diagnostic imaging. Priority publication will be given to articles concerning diagnosis and treatment of orthopedic diseases. The following aspects are covered: Clinical diagnosis, laboratory diagnosis, differential diagnosis, imaging tests, pathological diagnosis, molecular biological diagnosis, immunological diagnosis, genetic diagnosis, functional diagnostics, and physical diagnosis; and comprehensive therapy, drug therapy, surgical therapy, interventional treatment, minimally invasive therapy, and robot-assisted therapy.

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Growing spine deformities: Are magnetic rods the final answer?

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Abstract

Treatment paradigms for Early Onset Scoliosis have changed from fusion to fusionless methods as the harmful effects of early fusion on the growing spine

and thorax were realized. Magnetic rods are a recent addition to fusionless technology for controlling scoliosis in a growing spine. The clinical evidence base on magnet driven growth rods (MDGR) has accumulated over the last 4 years. It has implications for reduction in the number of repeat surgeries required with similar complications as the traditional growth rods (TGR) and at a higher initial cost. However in terms of patient psyche and avoidance of repeat surgeries which are necessary with the TGR, MDGR treatment works out less expensive in the long run with definitely better patient comfort. The authors look at the available literature coupled with their own experience to discuss the current status, limitations and future prospects for this type of technology.

Key words: Growing spine; Magnet driven growth rods; Magnetic growth rods; Growth rods; Early Onset Scoliosis

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Core tip: This editorial focuses on the current status of magnet driven growth rods in the management of Early Onset Scoliosis (EOS). The editorial gives a background of this technology vis a vis the traditional growth rods and looks at the advantages, limitations and complications associated with the magnetic growth rods. Also its effects on lung function and cost comparison with the traditional growth rods is made. The authors attempt to answer the question "Are magnetic growth rods the final answer for EOS?" in the light of the world literature and personal experience on the above subject.

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Progressive Early-Onset Scoliosis (EOS) has remained a management challenge for decades with surgical management themes changing from early operative fusion to the more recent fusionless surgeries. With this there has been an increased interest to find an ideal tool to reach the goal with minimal complications. Desirable characteristics include ease of instrumentation without age restrictions, minimum number of surgeries for curve control or reduction with minimum hardware problems. The advantages and disadvantages of various growth friendly instruments are noted in Table 1.

EVOLUTION OF A NEW IMPLANT

The thought of achieving distraction without repeat surgical interventions started with Takaso *et al.*^[1]. In 1998 they devised a growing rod that could be elongated with a remote controller. The rod contained a motor with remote control receiver (placed in the abdominal cavity). In their experimental study on induced scoliosis in beagle dogs they could achieve correction of curves by 3 weekly distractions using external remote controller non-invasively with the study animal awake. The limitations of the instrument were size of the outer cylinder of the rod (16 mm) and the site for placement of the remote control receiver.

BEGINNING OF MAGNETIC ERA (MAGNET CONTROLLED GROWING RODS, MCGR)

The very first report of a magnetic rod being used for scoliosis dates back to 2004 when Jean Dubousset and Arnaud developed and used the Phenix device. Arnaud Souberian a French aeronautical engineer adopted the idea from expandable rod for bone tumors^[2,3].

The Phenix device consisted of a magnetically controlled extensible rod that was distracted by placing a permanent magnet on the skin over the spine at home. It was first used in 8 paralytic patients. The clinical outcomes of this device were extremely limited. Miladi *et al.*^[4] reported a limited human experience on them.

Akbarnia *et al.*^[5] in 2009 presented the first technical note on Ellipse Technology Inc Device, wherein an implantable magnetic rod was distracted by external adjustment device. It was aimed at providing distraction to the spine by non-surgical means.

The next breakthrough came in 2012 when Akbarnia *et al.*^[5] published their report on MAGEC rod in an experimental study on Yucatan pigs^[6]. In this well-designed study, the authors implanted the MAGEC rods designed by Ellipse technologies and compared the results with a sham group. The rod consisted of an actuator that had a magnet and could not be contoured. The proximal and distal parts could be contoured. Distraction was carried out at 7 mm/wk for 7 wk with the help of an external adjustment device. At the end of 10 wk of the study they found a significant difference in the vertebral unit

height in experimental (MAGEC rod) as compared to sham group. There were no rod related complications. Histological data of the para-aortic lymph nodes revealed inflammatory cells in 2/5 in experimental and 1/3 in sham group. No abnormalities were found in liver, spleen and kidney biopsies.

The post implant removal magnetic resonance imaging (MRI) showed healthy discs and the cord was found to be normal. They could achieve 80% of distraction given by the external adjustment device.

INDICATIONS

Magnetic rods have been designed for EOS of varied etiologies including neuromuscular, idiopathic, congenital, etc. The indications can be extended to a slightly elder age group up to 12 years in selected cases. Because of the limitations of size of the rod most studies have used the rods after 3 to 4 years of age with scoliosis involving the thoracic spine predominantly. It can be used for the more rigid congenital varieties, the results of distraction may not be favorable, but the fact that the rod can act as an internal brace in itself can be of help in maintaining curvature.

MAGNET CONTROLLED GROWING RODS IN THE RECENT ERA

Many studies have been published in last couple of years showing its efficacy in humans covering various aspects of EOS.

In the very first publication on the experience of MAGEC in humans, Cheung *et al.*^[7] described the outcomes in 2 (one of Marfan's and other AIS) of the 5 patients who completed 2 years of follow-up. Length of instrumented segment increased by mean of 1.9 mm with each distraction (1.5-2 mm/mo). There were no implant related complications and no patient complained of pain. All the patients were satisfied with the procedure and had a good functional outcome as per the SRS-30 questionnaire. There was only one instance of loss of distraction that was rectified with the rod design.

Subsequent 3 years have seen a burst of papers on MAGEC exploring its efficacy. The first multicenter study of 33 patients by Akbarnia *et al.*^[8] documented results in 14 cases of EOS (idiopathic, neuromuscular, congenital and neurofibromatosis) treated with MAGEC rod instrumentation. The mean age was 8 year and 10 mo. They compared the results of single vs dual rods. The mean improvement in Cobb angles was 46% and 48% respectively in single and dual rods respectively. There was no significant difference in both groups in the average T1-T12 growth but the difference was significant in T1-S1 growth. Partial loss of distraction was the most common complication after 11 of 68 distractions (2 in dual and 9 in single rods). The loss was regained and maintained in subsequent distractions. No other implant related complications were noted. In none of the cases

Table 1 Advantages and disadvantages of various growth friendly instruments

| Modality | Advantages | Disadvantages |
|---|---|---|
| Traditional growth rods/VEPTR Shilla | Fusionless surgery Fusionless surgery, no repeat surgeries | Repeat surgical distractions, psychological issues Long term results awaited Growth potential dependent |
| Staple/tether | Less invasive, no repeat surgeries | Limited indications, lesser degree of severity |

VEPTR: Vertical Expandable Prosthetic Titanium Rib.

proximal junctional kyphosis was seen^[8].

A second landmark paper came from Dannawi *et al*^[9] in 2013 with 34 children (mean age 8 years) of EOS with mean Cobb's angle of 69 degrees. At a mean follow-up of 15 mo (12 to 18 mo), both groups single and dual rods, had a statistically significant improvement in mean pre-operative, immediate post operative and final Cobb angles and also significant increase in the mean T1-S1 distance. No patient developed a post-operative fusion. The complications met were: Superficial infection and rod breakage in 2 (one in each group), loss of distraction in 2 patients with single rod (rectified subsequently) and hook pull out in one patient with dual rod. Trimming of rod was done in one with hardware prominence. Overall complications were fewer as compared to conventional growth rods.

Hickey in their comparative study of MCGR (magnet controlled growing rods) implantation in primary (mean age 4.5 year, mean Cobb 74 degrees) vs revision cases (mean age 10.9 years, Cobb 45 degrees) of EOS found encouraging results in term of maintenance of Cobb angle with comparable increase in the spinal growth (6 mm/year in primary, 12 mm/year in revision cases)^[10]. Of the two complications in primary procedure one was rod fracture and the other was proximal screw back out. In the revision group there was loss of distraction in one and failure of distraction in another.

La Rosa *et al*^[11], Ridderbusch *et al*^[12] and Yilmaz *et al*^[13] in their case series of EOS with MCGR found it efficacious in allowing non invasive distraction without repeat surgeries. It achieved spinal growth comparable to conventional growth rod techniques.

Teoh *et al*^[14] with the longest follow-up study till date could get a 43% correction of scoliosis in primary cases whereas it was only 2% in the conversion case, but the curves were maintained till the last follow-up.

IMPROVEMENT IN PULMONARY FUNCTION

Yoon *et al*^[15], in a study of the effects of MAGEC rod instrumentation on pulmonary function in cases with neuromuscular scoliosis, compared pre-operative FVC and FEV1 to the post-operative values. They found a significant improvement in the post-operative values; they felt that there may not be longitudinal improvement in the function because of the natural course of the neuromuscular etiology, but the benefits of avoidance of repeat anaesthesia and surgery remain.

Harshavardhana *et al*^[16] in a prospective study of 26 patients of EOS of various etiologies found the Magnet Driven Growth Rods (MdGR) to be effective in reducing the number of complications and distraction surgeries. They quoted a spectacular improvement of PFT in neuromuscular cases with reduced incidence of chest infections and emergency room admissions for pulmonary ailments.

DISTRACTION FREQUENCY

Three monthly vs small more frequent: Akbarnia *et al*^[17] studied the effect of frequency of distraction on the outcomes of MCGR. In the more frequent distraction group (weekly to 2 mo) there were more complications of failure of rod distraction and proximal junctional kyphosis as compared to rod breakage and proximal foundation failure which were seen in other group that underwent distraction every 3 to 6 mo.

CONVERSION FROM TRADITIONAL GROWTH RODS TO MAGEC

Keskinen *et al*^[18] compared the efficacy of using MdGR in primary vs conversion from previously operated traditional growth rods (TGR) and found that scoliosis can be equally controlled after conversion from TGR to MdGR, but the growth from baseline is less in conversion group.

The longest follow-up study (minimum longest follow-up of 44 mo) by Teoh *et al*^[14] quotes that the mid term results of MAGEC are not as promising as the short term results. Single rod construct should be avoided and they indicated a caution in using MAGEC in revision cases.

COMPLICATIONS

Choi *et al*^[19] in a retrospective multi-centric study of MCGR proposed a classification of complications related to the procedure. Of the 115 operated patients 54 had a minimum 1-year follow-up and were analyzed. They classified complications as wound/implant related and early (< 6 mo) or late > 6 mo. Implant related: (1) rod breakage; (2) failure of lengthening requiring revision surgery; and (3) anchor pull outs. Wound related complications: Surgical site infection (deep) requiring additional surgical intervention.

They summarized complications as: (1) 42% had at least 1 complication; (2) 15% revision surgery, at least one; (3) 11% rod breakage (33% early, 66% late); (4) 11% (6)

failure of lengthening, 4 distracted in subsequent visits, 2 rods were exchanged; (5) 13% anchor point problems; and (6) 3.7% (2) deep infection, one each early (drainage and antibiotic)/late (rod penetration, requiring removal of one of the dual rods).

In the longest follow-up study till date Teoh *et al*^[14] reported 75% (6/8) patients required revision surgeries, 4 of which were for rod problems and one for proximal junctional kyphosis. Rod failure occurred mainly after 3 years (average 39 mo). All single rod constructs required revision procedure for failure.

Harshavardhana *et al*^[16] encountered complications that include 3 single and 1 dual rod breakage, one superficial infection, four cases had proximal junctional kyphosis and distal anchor failure in two patients.

HURDLES

With MCGR emerging as the new hope for EOS as seen from the published articles and early results, it brings along with it its own sets of issues to be tackled. Some limitations are as follows: (1) radiation hazard due to frequent X-rays for monitoring the distraction; (2) MRI compatibility: Due to presence of internal magnet in the rod; and (3) cost.

ULTRASOUND FOR MEASURING DISTRACTION

In an effort to reduce radiation exposure due to repeated X-rays for measuring distractions, Stokes *et al*^[20] and Cheung *et al*^[21] found a good inter observer and intra observer variability in using ultrasound vs X-rays for measurement of distraction of the MCGR's, thus reducing the radiation hazard of frequent radiographs for monitoring distractions. This technique requires training, attention to details and rejection of sub-optimal images. Errors can occur during acquisition of images and selection of reference points. The limitations of this technique are the inability to assess the spinal alignment and integrity of construct. Therefore X-rays can be done at 6 monthly interval to assess these parameters.

MRI COMPATIBILITY

Sturm *et al*^[22] in a review article on the management of EOS mention the efficacy of MAGEC and also state that there is no evidence that the electromagnetic field causes any persistent or major side effect with repeated distractions. Although stiffness, spontaneous fusions and diminished returns will also be observed with this technique, avoidance of multiple surgeries is a colossal advantage over TGR.

Budd *et al*^[23] presenting their experimental study stated the safety of MRI with the MAGEC rods *in-situ*, *i.e.*, the lengthening mechanism was not triggered. They found no reduction or enhancement in the ability of the rods to lengthen but the rods did produce an artifact in

imaging the spine.

COST AS COMPARED TO TGR

Charroin *et al*^[24] compared the expenses in TGR vs MCGR over a period of 4 years based on a simulation model using assumptions obtained from literature search or their local experience. They found that MCGR procedure induces a strong expense at start, then costs evolve gradually because of the difference of TGR strategy. Despite its major unit cost, their results show that the use of MCGR could lead to lower direct costs with a time horizon of 4 years. Also improvement of quality of life could be indirectly evaluated considering that about 2 surgeries and hospital stays per patient-year could be avoided using MCGR. The limitations of the study included: (1) the basis of estimation of costs, *i.e.*, a simulation model; (2) not taking into account outpatient direct costs and indirect costs such as parent's time off work; and (3) assumptions of long term results of MCGR based on the short term, few published series. Jenks *et al*^[25] found equal efficacy of both but the added advantage of MAGEC being a robust cost saving at the end of 6 years. Thus NICE issued a positive recommendation for the use of MAGEC for EOS. Similar recommendations were made by Rolton *et al*^[26], Armoiry *et al*^[27], with a significant cost saving at the end of 5 years.

WHAT IS THE EVIDENCE?

Evidence based: TGR vs MAGEC

In the first case matched study between traditional growth rods (TGR) and MCGR in 2014 by Akbarnia *et al*^[28] they compared 12 MCGR patients to 12 case matched TGR patients. The average follow-up for TGR was 1.6 year more as compared to MCGR who had 2.5 year mean follow-up. Major curve correction, annual T1-T12 and T1-S1 growth was similar in both groups. Incidence of unplanned surgical revisions were similar in both groups but the MCGR patients had 57 fewer surgical procedures. Most of the complications were related to implant failure. In the MCGR group loss of distraction was commonest, 63%, and in the TGR it was anchor pull out and rod breakage.

Jenks *et al*^[25] in a meta-analysis of the published literature made provisional recommendations for NICE (National Institute for Health and Care Excellence). These were: (1) MAGEC would avoid repeat surgeries and reduce complications and have benefit for physical and psychological aspects of patient and family; (2) indicated for use in children between ages of 2 to 11; and (3) the system is cost saving as compared to conventional growth rods from about three years after the index procedure.

Figueiredo *et al*^[29] based on a systematic review of 6 papers found MCGR to be a safe and effective technique and an alternative to traditional growth rods. There were limitations due to the limitations of existing literature and

Table 2 Single centre series of 10 patients operated by the senior surgeon

| Parameter | Mean |
|--|-----------------|
| Age | 10.6 yr |
| Pre operative Cobb angle | 83.1° |
| Last follow-up | 65° |
| No. distraction/patients | 3.4 |
| External remote controller distraction | 12.15 mm |
| Actual distraction | 8.9 mm (73.25%) |
| Follow-up | 14.3 mo |
| Correction mean | 18.3° |
| Percentage correction | 21.62% |

potential bias in literature due to this novel technique being in early phases.

The shortcomings of MAGEC

The results of MAGEC are promising but follow-up is short and the device technology does not guard against the risk of gradual stiffening of the spine between lengthening sessions and the limitation of the force of magnetic rod to overcome the scoliosis related stiffness in one or two years of use^[30].

With the newer long-term studies coming up, we are now coming across specific complications of growing rods *viz*: (1) failure of distraction; (2) fatigue failure of implant; (3) proximal junctional kyphosis; (4) loss of sagittal balance due to non-contourable long actuator; (5) less reliable results on conversion from traditional growth rods to MCGR; and (6) more reliability on dual rods.

In a study on sagittal profile following MCGR in EOS, Akbarnia *et al.*^[31] showed that the thoracic kyphosis was reduced in cases with pre-existing thoracic kyphosis more than 40 degrees and had no effect on other regional sagittal parameters.

Inaparthi *et al.*^[32] reported incidence of proximal junctional kyphosis (PJK) in 28% cases of EOS operated with MCGR. It was common in males, all the cases were syndromic in etiology and 50% of them were conversion from traditional growth rods. But the presence of PJK was not an indication for further surgery.

AUTHOR'S EXPERIENCE

We have been using the MAGEC (Ellipse Technologies) since November 2014. In our single centre series of 10 patients operated by the senior surgeon (Dr. Ashok N Johari), 9 cases were of congenital etiology and one neurogenic with associated syringomyelia without neurodeficit. All the patients were females. The data is as shown in Table 2. The mean age at surgery was 10.6 years range (8-13 years). The mean pre operative Cobb's angle was 83.1° and post-operative was 65°, with a mean correction of 21.62%. This correction was maintained till the last follow-up of a mean 14.3 mo (7-21 mo). There were 3.4 distractions per patient with 73.25% (8.9/12.15 mms) distraction achieved *in-situ*.

No patient had any intra-operative complications

or neurodeficit post-operatively but we had difficulties instrumenting the spine due to the complex anatomy of the congenital deformities and severe degrees of curvatures. The rods needed significant contouring and almost always we had to use hybrid constructs (hooks and pedicle screws). We had one rod breakage intra-operatively which was managed by using a rod to rod connector from the routine spine instrumentation inventory.

The patients were advised continuous bracing and distraction started 3 mo later at 3 mo interval. We had problems in distraction in one patient which was recovered in subsequent distraction under a setting of mild sedation in operation theatre as the patient was very apprehensive. Later on she had a smooth course of distraction. All the patients were satisfied with the procedure and none complained of pain during distraction.

SO, ARE MAGNETIC RODS THE FINAL ANSWER?

Problems similar to traditional growth rods like infection, anchors site failure/break outs persist with MCGR, except for elimination of repeat surgeries and its consequences. Although MCGR has reduced the number of planned surgeries for distraction, there are incidences of unplanned visits to operation theatre for its own reasons.

These issues need to be addressed before we give a final verdict on MAGEC. The technology still has scope for improvement. Due to its novel approach this technique kindles many a hopes and with traditional growth rods as the only competitor, MAGEC is here to stay till the next major breakthrough in instrumentation techniques.

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