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Growing rods in Early Onset Scoliosis: The current scenario

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A B S T R A C T

Background and aims: The treatment of early onset scoliosis is a challenge. Some curves resolve spontaneously, while the more aggressive ones require surgical intervention. Several surgical strategies have been explored in this unique group of patients, though the distraction based growing rods are the mainstay of treatment. The aim of this paper is to consider the current scenario with the surgical treatment for early onset scoliosis with growing rods.
Methods: This is a narrative review that explores the various types of growing rod options that are currently available. The results, as reported in literature, are discussed. The complications and problems with the commonly used growing rods are explored, based on the reported literature and on retrieval analysis that we have published. We discuss some of the newer modifications of growing rods.
Results: There is no real consensus on the ideal timing for the surgery or ways to assess the outcomes of the treatment. The Cobb angle measurement and measures of thoracic growth are surrogate markers. The main indication for surgery is to an increase in the thoracic dimensions and allowing for lung growth. Measures that are linked to lung function are more useful. We report some newer MRI scanning technology. Distraction-based growing rods have been reported to produce consistent and good results. Frequent return to theatre with the Traditional Growing Rods (TGR) and the metallosis related problems with the MCGR are reported.
Conclusions: We have learned a lot from the TGR and MCGR experiences. There is a scope for ongoing research to improve the design of the implant systems and better assess the outcomes on lung function. This review outlines these and helps identify the future trends.

1. Introduction

Early onset scoliosis presents a spectrum of spinal deformities in children in the first decade of life. The underlying diagnosis varies from idiopathic, neuro-muscular, and syndromic scoliosis.[1] Based on the natural history of the underlying condition, the spinal deformities can be either benign, progressive or aggressive. The spinal deformities provide a unique challenge to the development of the chest wall and the lungs. A damage-limitation approach to dealing with the spinal deformity is expected to improve the chest wall compliance, respiratory mechanics, increase the thoracic volume and consequently provide a more favourable milieu for lung development.

Whilst casting or bracing may be an adequate intervention for children with smaller curves, a more robust surgical solution is required for those with progressive curves. Growth friendly procedures involves surgically allowing the spinal column to lengthen during the growth years. The surgical focus is to maintain spinal length, as measured by the T1 – S1 or the T1 – T12, rather than the more surrogate Cobb angle[2]. This allows a more effective increase in the thoracic volume. The usual end point of growth friendly procedures is a final fusion at skeletal maturity.

Growth friendly procedures have been classified by Skaggs et al.[3] as Growth guidance, Compression or Distraction based techniques. The historical growth guidance systems include the Luque trolley and Shilla. They allow spinal growth while controlling the deformity, as the rods slide over the spinal anchors. Compression techniques include staples and tethers and correct the scoliosis by creating a growth inhibiting convex compressive force. The distraction-based techniques include the surgically lengthened growing rods also called Traditional Growing Rods (TGR), Vertical Expanding Prosthetic Titanium Rib (VEPTR) and the Magnetically Controlled Growing Rod (MCGR)[4].

The indications for operating on early onset scoliosis is associated with growth potential and curve magnitude. The real need for the operation is to allow for growth of the thoracic contents especially the lungs. Hence, very young age and large curves are the obvious indications. However, a documented progression of the curve with growth despite casting and bracing are also indications to operate. The discussion with regards the effect of a progressive curve and lung function should be undertaken with the family early on. The surgeon should appreciate the unique differences with scoliosis in older persons and opt

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for a definitive fusion only in selected persons that are older, with a shorter life expectancy or a low functioning and low tone neurogenic scoliosis. In most children with a progressive curve and a young age, growing rods should be offered after failed casting/bracing. Traditional Growing Rods (TGR) and Magnetically Controlled Growing Rods (MCGR) are the current offerings as the distraction based growing rods. Though the TGR have been considered as the gold standard, they involve frequent surgical lengthenings. The issue of multiple anaesthetics has been offset by the development of the magnetically controlled growing rods and the more recent introduction of the One-Way Self Expanding Rods (OWSER) rods and the Spring Distraction Systems (SDC). All the distraction based growing rods are inherently kyphogenic. Clinical experience has taught us to be cognizant of dealing with issues of multiple anaesthesia, radiation exposure, mechanical complications and metallosis leading up to the final fusion at 'graduation'.

2. Distraction based growing rods

Evolution from earlier systems: The advent of pedicle screw-based constructs have paved the way for the growing rods, from the earlier versions of the Harrington rods with sub-laminar wires and the Luque trolley. Small stature iterations were introduced in the market in the 90s. The surgical constructs were modified with dominoes and inline connectors to facilitate regular surgical lengthening through smaller incisions. The 2 rod constructs were clinical and biomechanical superior as compared with the single rod versions, with fewer rod fractures and mechanical complications.[5]

The traditional growing rods (TGR): The typical construct comprised of a fusion block at both ends with spinal anchors. Proximally, a combination of hooks and screws and distally a screw based. Typically, and intentionally, the apical spinal levels are left un-touched and are expected to grow. However, a 3 - 6 monthly re-operation is required for the lengthening. There are anticipated ill effects of multiple anaesthesia and related psychological issues to the young children, due to multiple hospital admissions and planned return to theatres. Despite these shortcomings, this version of the distraction based growing rods has stood the test of time, hence known as 'Traditional Growing Rods' (TGR).

Magnetically controlled Growing rods: The multiple planned returns to theatre were reduced by the introduction of the Magnetically Controlled Growing Rods (MCGR). An external remote-controlled device (ERC) lengthens the rod by the rotation of a magnet housed in the actuator in a section of the rod. It is imperative that this section is not bent or contoured during the surgical placement, to maintain the integrity of the magnet. A systematic review to assess the feasibility and efficacy of MCGR in EOS was performed to include 23 studies of children under 10 years and curves over 40° in 504 patients. The evidence suggested that MCGR is effective in distracting the spine and correcting the scoliosis.[6]

Benefits of MCGR v TGR: Both the types of growing rods will need planned operations to change the rods when they reach the full growth potential. However, there are some benefits of MCGR over TGR. Whilst the standard of care is to perform the TGR lengthening under a full general anaesthesia and with spinal cord monitoring, these are not required for the awake patients in the outpatient setting with the MCGR. The higher index cost of the MCGR rods are offset by the lack of repeated hospitalisations. However, the clinical experience has highlighted problems unique to the MCGR. There can be a failure to lengthen the rods in certain difficult clinical and mechanical situations such as in patients with a high BMI; the presence of a fracture of the actuator pin; 'cross-talk' between magnets if placed in close proximity. This results in clunking or stalling. Clunking or stalling a problem of a mal-functioning rod and requires a rod revision. The potential problem of metallosis and its implications are discussed later in this paper.

Some of these problems have been corrected by design iterations.[7] The addition of rods of different diameters and varying the actuator lengths have improved the usage profile. The usage of this implant has been limited by some significant problems leading to its temporary withdrawal from the market. The first Field Safety Notice (FSN) was issued by the Nuvasive Inc. in March 2020.[8]This was due to cases of O ring dislodgement. This was considered to be a design flaw. Subsequently the use of Magec X rod was discontinued and it was withdrawn from the market while the previous generation rod had been recommended. [9]The strict regulations in the some countries have prevented re-introduction of the MCGR for routine clinical use.[10]

Mechanical problems: The distraction based growing rods have an inherent mechanical disadvantage due to the long un-anchored growing segment of the rods. Early experience with rod breakages with the use of a single growing rod led to the 2 rods construct that mitigates the mechanical complications.[11] In our series with dual rod constructs, we reported a mechanical failure rate of 26%. Most of the mechanical failures were at the end of the lengthening treatment.[12]

The 'law of diminishing returns' represents the clinical experience of a reduction in the ability to lengthen the spine with repetitive lengthening. This lengthening behaviour may be linked to the compliance with the construct, auto-fusion or a reduced compliance of the tissues. It has been reported with the use of the TGR, less so with MCGR.[13]. Some studies show that this behaviour of the rods may be limited to idiopathic and high-tone neuro-muscular curves. In contrast, the more compliant tissues in patients with syndromic scoliosis may provide for more generous lengthening events.[14] However, our series of 53 rods in 28 patients demonstrated that the growth velocity in the MCGR group was maintained relative to the normal spine.[15]All distraction based growing rod systems are inherently kyphogenic and warrant a close observation of the proximal junction during the growth and lengthening periods.

The Growing Rod Graduate: The outcomes of the TGR and MCGR have been reported on a cohort of patients that have completed the growing spine programme and have reached skeletal maturity. These are termed 'growing rod graduates'.[16]

The treatment options at this stage are either to retain the implants or to complete a final fusion. The presence of auto-fusion would favour the former.[17] The long-term effects of leaving the MCGR in situ is of concern and hence explanting them to achieve a final fusion is the recommended option. Whilst removal of the implants is a possible option, a study compared removal of the implant versus retaining them,[18] was abandoned due to the significant inferiority of the results noted during the study. A review of the status of the auto fusion on CT scans would help decide on the final intervention. The final fusion can be performed in situ or with further attempts at correction with additional apical anchors and releases. The incidence of postoperative and longer-term complications and the need for Unplanned Return to OR (UPROR) is higher if the final fusion is performed with attempts at improving the correction with osteotomies, especially if the apex is stiff.

A retrospective review from our unit revealed no major differences in the curve correction, spinal height gain and UPROR following a final fusion, comparing TGR and MCGR.[19] We have recently performed a study on a larger cohort comparing radiological and clinical outcomes between TGR and MCGR, from the Paediatric Spine Study Group (PSSG), at the time of final fusion. This is one of the largest studies comprising of 549 patients (409 TGR and 140 MCGR patients), followed up to 13.8 years following TGR insertion and 5.7 years after the index MCGR insertion. 94% of the MCGR and 67% of the TGR patients underwent a formal final fusion. 29% of the TGR cohort had the implants retained with no further surgery being performed. Implant related complications were lower in the MCGR group, though anchor prominence was a problem in both the groups. UPROR was lower in the MCGR group with the rod breakage being 5 times lower than the TGR. The radiographic measures were similar and good in both the groups. At least 1 complication was noted in 77% TGR and 61% MCGR and at least 1 UPROR in 39% TGR and 28% MCGR patients.[20]

A study comparing the 2 types of growing rods in severe curves (>104°) in 44 patients reported an unplanned revision free survival in 91% MCGR and 77% TGR patients at 2 years, with significantly better major curve corrections in the MCGR groups. Ancillary anterior release and halo-gravity traction can be used in severe early onset curves that are stiff or have a high Cobb angle.[21]

Long term effects of growing rods from retrieval analysis: The analysis of MCGRs retrieved from patients has helped further understanding of their performance in vivo. As is the nature of retrieval analysis, the greatest insights are gained when comparing findings from rods that have been removed earlier than planned (the failed rod) with those removed in line with the original treatment plan (e.g., upsizing of the rod or conversion to final fusion).

Evidence of tissue metallosis has been reported previously in patients that have received surgical treatment with MCGRs[22,23]. This has most commonly been observed at the time of removal as a black staining of soft-tissue within the vicinity of the housing tube. These devices are composed of medical grade titanium alloy (Ti-6Al-4V) which is generally accepted as being highly biocompatible. In some of cases however histology analysis of tissue samples taken from stained regions has indicated inflammatory responses to have occurred following exposure to metal debris. Titanium debris is most commonly released from MCGRs predominantly due to (1) mechanical wear at the junction between the housing tube and extendable rod and (2) a combination of wear and corrosion of components within the housing tube, Fig. 1[7,24,25] (see Fig. 2).

Pin Fractures: Earlier generation MCGRs in particular were found to have failures that were associated with a fracture of the internal locking pin within the lengthening mechanism.[8,24]; the consequence of these fractures was an inability of the rod to distract. Pin fractures have also been discovered in rods that have been removed after successfully achieving their maximum intended length. The manufacturer, NuVasive, issued a Field Safety Notice (FSN) in June 2019 stating that MCGRs manufactured prior to 26th March 2015 had a 5% risk of pin fracture, whilst this issue was not observed in rods manufactured after this date. Analysis of retrieved MCGRs has found that rods manufactured after 26th March 2015 contain locking pins that are thicker in diameter and composed of stronger 465 stainless steel, compared to 440 stainless steel that was used in rods prior to this date[8]. Retrieval analysis has also shown pin fractures to occur in rods manufactured either side of this date in the FSN, demonstrated through a combination of x-ray imaging of the retrieved rods or following sectioning and disassembly of the devices. Data from retrieval studies should not be used to extrapolate to assessments of failure rates in the wider patient population; this level of analysis requires registry level data. However we have seen that whilst pin fractures do continue to occur in rods manufactured after the March 2015 date, their prevalence appears to be lower than in rods made prior to this date[8].

Mechanical Wear: Another commonly reported finding on retrieved rods are wear marks on the telescopic bar, adjacent to the junction between the bar and the housing tube[26,25]. These most often present as regularly spaced lines of surface damage that are circumferentially orientated relative to the bar however have also been observed as longitudinal wear marks, Fig. 3. A commonalty in these damage features has been their occurrence only on one side of the telescopic bar as opposed to extending around their entire circumference. A retrieval study involving 34 MCGRs retrieved from 20 patients showed this wear marks to have resulted in measurable material loss[25]; these had median wear depths of 42 μm and wear areas of 0.577 mm^2. The extent of this material loss has shown to be correlated with the length of time the rods have been in situ (a surrogate for the number of lengthening's); it has also been shown that rods with fractured locking pins have greater amounts of material loss at the extendable junction. It is speculated that these damage marks are due to 'off-axis loading' of the rods which results in greater contact force between the telescopic bar and housing tube on one side. The equally spaced wear marks are thought to occur during each lengthening process. It is speculated that the longitudinal wear marks observed in some rods occur following fracture of the internal locking pin consequently leading to uncontrolled lengthening of the bar driven by the growth and movement of the patient's spine.

Rod Fractures: A recently published retrieval study presented evidence of a fracture of the MCGR construct occurring in a comparatively small number of cases; 7 fractured rods were identified out of a cohort of over 120 retrieved rods, Fig. 4[27]. All fractures occurred in single rod configurations and were found to have ultimately failed due to fatigue fractures (i.e., the progression of a crack from an initiation point during cyclical loading until full fracture occurs). The crack initiation point in these rods appears to align with indentations left behind by the French bender rod contouring tool. Comparison with intact retrieved single rod constructs suggests a greater risk of fracture in rods that have undergone greater amounts of contouring and those with a greater distance between anchoring points. The risk of fracture appears virtually mitigated if dual-rod constructs are used.

End-Cap Loosening: In order to address the concern of fluid ingress to the internal mechanism within the housing tube of MAGEC rods, the manufacturer modified the design of the implant to include a threaded

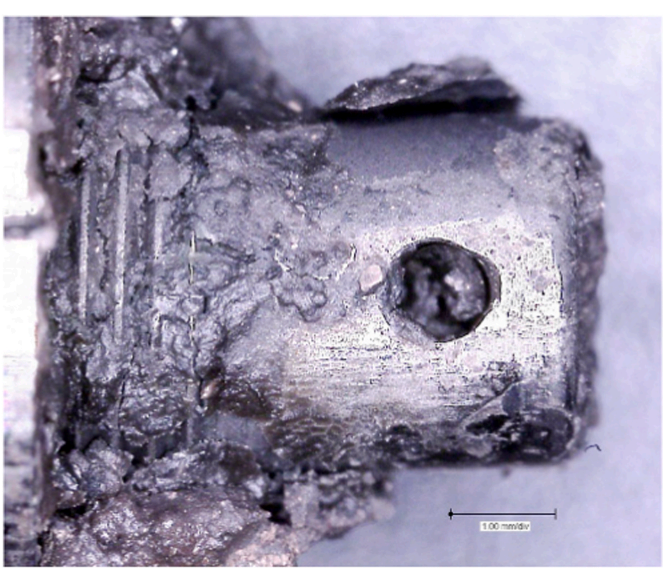

Fig. 1. Titanium debris generated within the internal housing tube of an MCGR (Panagiotopoulou et al., 2017).

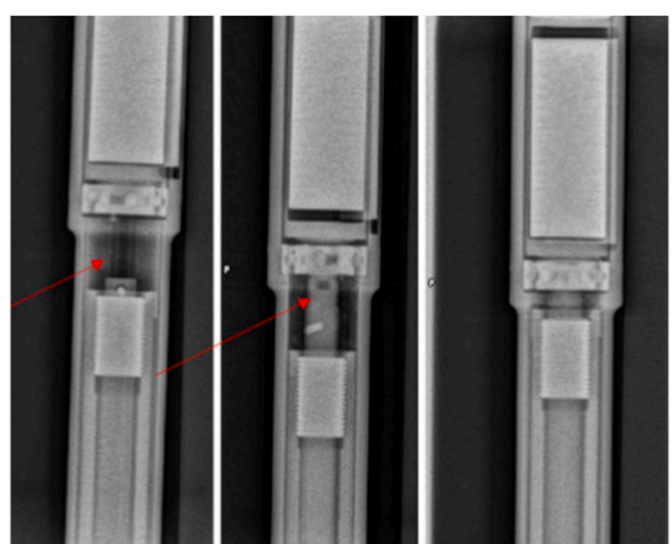

Fig. 2. Examples of x-ray images capture of 3 retrieved rods, in which 2 rods have a fractured locking pin (left and middle) and one rod has an intact pin (right) (Tognini et al., 2021).

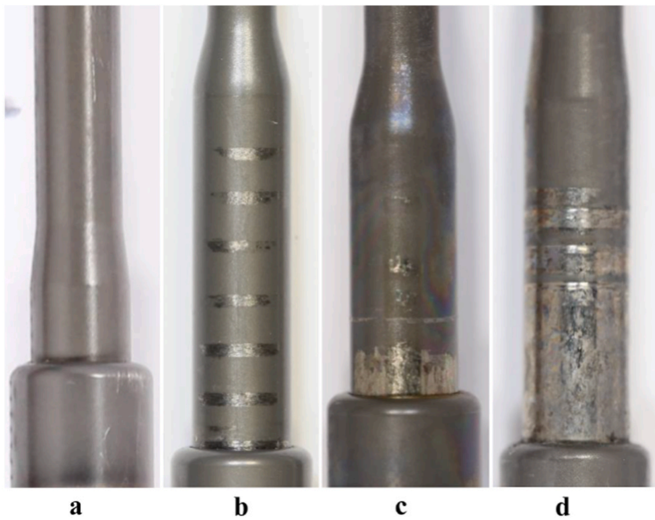

Fig. 3. Macroscopic images of 4 retrieved MCGRs showing (a) no wear marks, (b) circumferential wear marks, (c) longitudinal wear marks and (d) a combination of circumferential and longitudinal wear marks (Wei et al., 2020).

end cap component. This end cap was intended as an additional barrier between the external environment and the internal components. This design, termed the MAGEC X, was however recalled by the manufacturer following reports of a loosening of the end cap whilst in situ, which the manufacturer estimated could occur in 0.5% of rods of this design. The concern with a potentially loose end cap is a greater exposure to the internal housing mechanism that would otherwise occur, leading to greater damage. A recent retrieval study examined 15 MAGEC X rods[9]; one rod was found to have a fully loosened end cap (Fig. 5) whilst a test of the torque necessary to loosen the remaining end caps showed a wide variability. Comparison of the internal damage of the MAGEC X rods showed no difference when compared to the previous generation MAGEC 1.3; there also appeared to be no worsening of internal damage in this single case of in situ end cap loosening (see Fig. 6).

Titanium Debris: Retrieval analysis has shown that considerable titanium debris may be generated in failed rods or failing rods[28]. There is a need now to better understand if blood sampling of patients with these rods can be used to measure metal ion levels as a biomarker for their function[9,28]. That is to say, can a rod that is wearing or corroding excessively be identified through blood metal ion testing and addressed prior to it failing? More broadly, whilst titanium alloy is accepted as being highly biocompatible, there is a natural need to understand the longer-term clinical implications of the exposure to titanium debris in children. Longitudinal blood testing of these patients coupled with clinical and imaging data, and analysis of the eventually removed components will help clarify these questions.

3. Assessing the outcomes of growing rods

The purpose of surgical intervention in children with EOS is to influence the thoracic volume by increasing the thoracic height with growth, thereby facilitating lung development. We achieve this by instrumenting and lengthening the spine.[29]

Intuitively, the assessments of outcome are based on spinal deformity parameters such as the Cobb angle. However, this does not provide any useful prognostic information with regards the pulmonary growth. A more surrogate spinal measure is the T1 T12 length (thoracic height) or the T1 S1 length (spinal height) on the AP radiograph. Measuring these on a lateral radiograph as a sagittal length is more relevant and has been suggested. A statistical correlation of spinal parameters with respiratory parameters has been not met with much success. A more direct measure is to measure the thoracic volume and the mechanics of components of respiration. This has been possible by the development of dynamic MRI scans (dMRI).[30]

Analysis of the diaphragmatic motion is useful in establishing a baseline and assessing the changes with growing rod treatment. When comparing 4D dMRI to computed tomography (CT) and fluoroscopy, a better soft tissue contrast without any exposure to ionising radiation is possible. A greater flexibility in selecting measurements planes with normal free breathing is the game changer. A useful baseline is provided by dMRI with normal breathing in normal children. The assessment of diaphragmatic motion is relevant as it is the main respiratory muscle for inspiration and is reposnsible for 70% of the inspired air volume in normal breathing. Changes in diaphragmatic motion with pathology and with treatment provide relevant respiratory outcome assessment.

Quantitative thoracic dynamic MRI (Q d MRI) is a new technique for evaluating thoracic cage involvement with scoliosis.[31–33] The

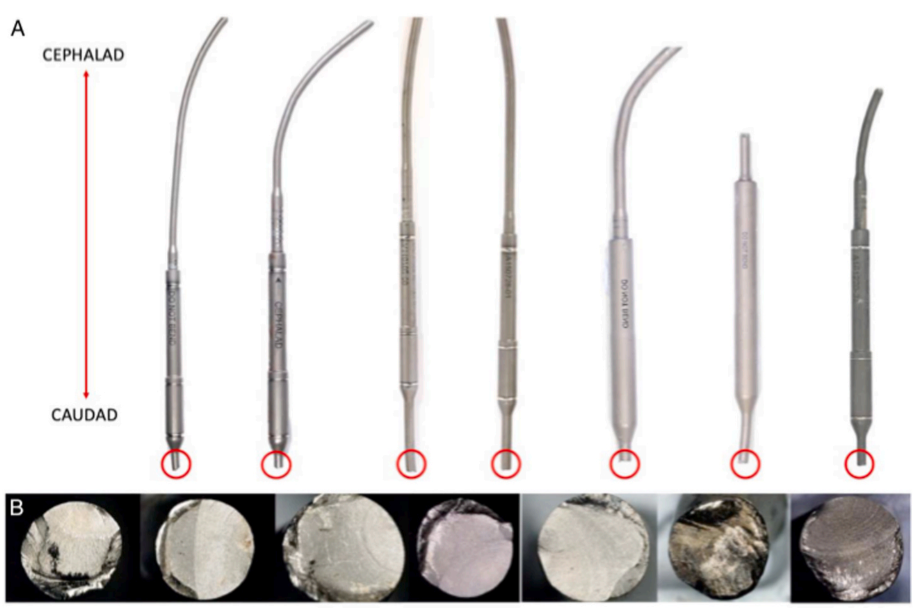

Fig. 4. Showing (a) macroscopic images of 7 single construct MCGRs that fractured in situ and (b) the fracture sites of each rod with features characteristic of fatigue fracture (Tognini et al., 2023).

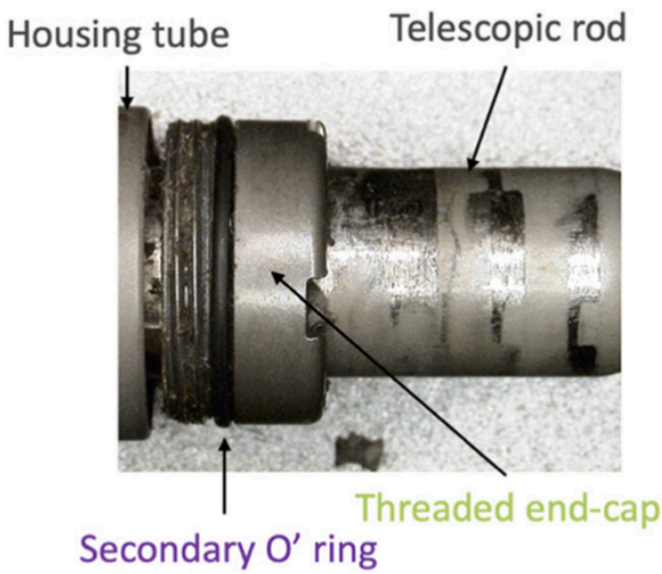

Fig. 5. Macroscopic image of a retrieved MAGEC X component in which the end cap component loosened whilst in situ. The exposed thread of the cap is visible in this image. (Tognini, Hothi, Bergiers et al., 2022).

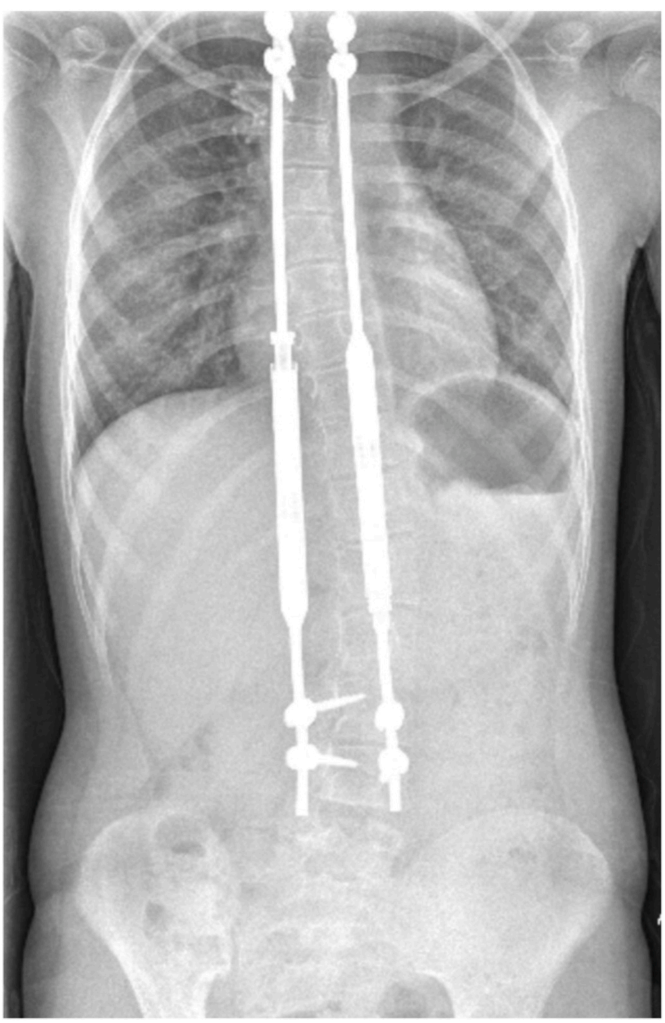

Fig. 6. Radiograph of a patient with O ring dis-engagement.

information is provided by free breathing than by way of a surrogate device for tracing breathing parameters. This technique also permits assessment of the lung parenchyma characteristics. It permits comparison of chest wall mechanics and motion analysis by comparing chest wall motion and volume before and after surgery. This is a more practical approach for assessing physiological changes in lung parenchyma. The diaphragmatic motion analysis confirms that the posterior portion moves more than the anterior part of the diaphragm in normal patients. These findings help us in identifying the effects of the surgery on the deformity, including axial plane deformity on diaphragm function.

4. Newer growing rod systems

Spring Distraction System (SDS): Self distracting, dynamic implant that shows encouraging early results with good curve corrections and continued growth in early studies. The first generation comprised of 4.5 mm CoCr rods with a Titanium alloy spring and buttress and domino connectors with a unilateral hybrid or a bilateral spring construct. Early rod fractures and implant prominence led to design iterations. The next generation included 5.5 mm CoCr rods, modified double dominos with an oversized 6.0 mm hole to allow a distal slide.

The preliminary results are encouraging. 17 patients were idiopathic and non-idiopathic indications were followed up to 1.9 years. The curve correction was 50% and remained stable. The growth rate approached normal values, with T1-T12 being 4 mm/year and T1-S1 being 7 mm/year. The complication profile was favourable. However, this device continues to be closely followed up and is not available for general use as yet.[34–40]

One Way Self Expanding Rod (OWSER): This is a CE marked implant. It comprises of 3 main components. A Titanium alloy rod with a smooth 300 mm section and a notched 6.35 mm section, which comprises of the lengthening reserve and is available in 50- and 80-mm segments. A domino connector is mounted on the notched portion of the rod. An additional smooth rod is available for the proximal fixation into one section of the domino. The distal fixation consists of Ilio-sacral screw and can be placed using minimally invasive techniques. The smooth sections of the rod can be cut and contoured, while the notched portion is not contoured to allow for the 'growth'. Additionally, a split retaining ring system prevents the domino from allowing the rod to slide backwards. A spontaneous and progressive one-way slide in 1 mm per step occurs with normal growth, daily activities, and physiological movements.[41,42]

The bilateral double rod sliding construct relies on a stable distal fixation with a Ilio-sacral screw and proximal 4 hook claws. The initial cohort of 100 neuro-muscular patients have been followed up to a minimum of 5 years.[43,44] The early reports are encouraging with a good correction of the deformity and the pelvic tilt and stable maintenance over time. There was no requirement of a final fusion, and the construct was stable even after skeletal maturity. However, longer term follow-up and more studies are awaited. A Randomised Controlled Trial (BiPOWR) is currently underway to compare these 2 devices.[38]

Active Apex Control (APC): This is a technique that is a modification of the SHILLA growth guidance system. This hybrid system captures the spirit of growth guidance and compression philosophies. A compression force is created at the apex by way of convex pedicle screws. The concave side is not instrumented. The apical fusion of SHILLA is not performed. The proximal and distal contructs comprise of the sliding growth guidance screws with a long rod to allow for the slide with growth. The aim is to control the convex apex while allowing for growth, and a reduction in concave to convex vertebral body heights with a consequent reduction in the apical vertebral wedging. This system has a potential for mitigation against crank-shafting and adding on.

This 'convex tether' model was initially applied to thoraco-lumbar kyphosis and later for early onset scoliosis. It has the advantage of not requiring multiple surgical procedures, as the rods can slide passively with growth in the sliding screws. Early clinical results are encouraging and a apical vertebral remodulation has been noted in the clinical studies.[45–47]

5. Conclusions

Distraction based growing rods continue to be the mainstay of the surgical treatment of early onset scoliosis. The traditional surgical lengthening-based growth rods have led to the use of MCGR with the ability to lengthen in the out-patient setting. The issues around metallosis continue to haunt the clinicians when examining explanted rods. Newer designs are under scrutiny. The assessment of lung function has been improved by newer MRI scanning technology. The future developments would help improve growing rod designs and in identifying the outcomes to the patient, rather than just surrogate spinal measurements.

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