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Original article

Direct costs associated with the management of progressive early onset scoliosis: Estimations based on gold standard technique or with magnetically controlled growing rods

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ABSTRACT

Background: The main disadvantage of the surgical management of early onset scoliosis (EOS) using conventional growing rods is the need for iterative surgical procedures during childhood. The emergence of an innovative device using distraction-based magnetically controlled growing rods (MCGR) provides the opportunity to avoid such surgeries and therefore to improve the patient's quality of life.
Hypothesis: Despite the high cost of MCGR and considering its potential impact in reducing hospital stays, the use of MCGR could reduce medical resource consumption in a long-term view in comparison to traditional growing rod (TGR).
Materials and methods: A cost-simulation model was constructed to assess the incremental cost between the two strategies. The cost for each strategy was estimated based on probability of medical resource consumption determined from literature search as well as data from EOS patients treated in our centre. Some medical expenses were also estimated from expert interviews. The time horizon chosen was 4 years as from first surgical implantation. Costs were calculated in the perspective of the French sickness fund (using rates from year 2013) and were discounted by an annual rate of 4%. Sensitivity analyses were conducted to test model strength to various parameters.
Results: With a time horizon of 4 years, the estimated direct costs of TGR and MCGR strategies were 49,067 € and 42,752 €, respectively leading to an incremental costs of 6135 € in favour of MCGR strategy. In the first case, costs were mainly represented by hospital stays expenses (83.9%) whereas in the other the cost of MCGR contributed to 59.5% of the total amount. In the univariate sensitivity analysis, the tariffs of hospital stays, the tariffs of the MCG, and the frequency of distraction surgeries were the parameters with the most important impact on incremental cost.
Discussion: MCGR is a recent and promising innovation in the management of severe EOS. Besides improving the quality of life, its use in the treatment of severe EOS is likely to be offset by lower costs of hospital stays.
Level of evidence (with study design): Level IV, economic and decision analyses, retrospective study.

1. Background

Early onset scoliosis (EOS) has the potential to induce major spinal deformity, which can lead to cardio-thoracic insufficiency syndrome and result in poor prognosis if untreated [1,2]. Its management remains challenging since therapeutic approach aims at

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reducing and controlling the spinal curvature while maintaining growth of spine and thorax [3]. Until spinal fusion is indicated, the current gold standard for severe EOS management when orthopaedic management has failed is the surgical implantation of spinal growing rods. Non-fusion instrumented surgery reduces the curvature and maintains the correction by iterative distraction surgeries [4]. Although effective, EOS surgeries using traditional growing rods (TGR) can lead to several complications and affect the quality of life due to the number of surgical procedures and hospitalizations [5–7].

Some new systems have been developed to obtain a stable correction of spinal curvature while avoiding repetitive surgeries using distraction-based magnetically controlled growing rods (MCGR) [8,9].

An MCGR system was recently CE marked and is available in European countries but its use is limited as the substantial cost of this innovative device is not currently supported by Healthcare systems [10].

Despite the cost and considering the potential impact of MCGR in reducing hospital stays, we hypothesized that the use of MCGR could reduce medical resource consumption in a long-term view in comparison to TGR. Since no study reporting current costs of EOS management using TGR is available, a cost analysis was performed based on French healthcare perspective in order to evaluate whether MCGR could be cost saving compared to TGR.

2. Methods

The case of a young patient, presenting severe early onset scoliosis (Cobb angle superior to 45°), progressing despite optimal conservative treatment (progression of the curvature of > 5° over a twelve-month period), for whom a fusionless surgery strategy, either with TGR or MCGR, is decided, was considered regardless of EOS etiology.

A cost-simulation model was constructed to compare the estimated long-term cost between TGR and MCGR with limitation to direct costs.

Cost analysis was performed in the perspective of the French National Sickness Fund. Indeed, the French health care system is characterized by its social insurance system with full support in management of severe disabling conditions such as spinal deformities. The time horizon chosen was 4 years as from the first surgical procedure. All costs were expressed in euros (€), were calculated using rates from year 2013, and were discounted by an annual rate of 4% as recommended by the French National Authority for Health's guidelines [11].

2.1. Medical resource expenses for TGR strategy

Medical resource expenses were estimated on the basis of data from a cohort of EOS patients treated in our centre (Hôpital Femme-Mère–Enfant, Lyon, France) with TGR between 2003 and 2010 and follow-up after index surgery – TGR implantation – for at least 12 months. Clinical data and medical expenses were retrospectively collected from those patient medical records and from the hospital information system. The mean number and duration of hospital stays, the type of instrumentation implanted, as well as the mean number of medical consultations and radiographs were considered. Eight patients (6 boys, 2 girls) with a mean age at first surgery of 5.9 ± 2.6 years were selected. All EOS were non-idiopathic with various etiologies: neurologic (38%), syndromic (38%) or congenital (25%). The mean follow-up duration from TGR implantation surgery (75% single rod/25% dual rod) to last follow-up date was 4.4 ± 2.9 years.

The expense of medical resources due to unplanned events was considered with limitation to growing rod fractures [12]. As this event did not occur in our local cohort, the associated probability was estimated based on Pubmed literature search. In case of a rod breakage, an emergency surgery was considered to repair the rod with a connector but assuming this would not modify the frequency of distraction surgeries (i.e. if a rod fracture is observed 3 months after the latest distraction surgery, a surgery would be performed but the next distraction surgery would then occur 6 months later).

At last, other medical resource consumption were estimated based on the interview of two senior paediatric orthopaedic surgeons experienced in EOS management and included:

- spinal bracing: each patient was considered to have one custom-molded orthosis every 18 months;
- physiotherapy visits: each patient was considered to have one session per week;
- medicalized transport: we considered that 50% of patients would require medical transportation after index surgery, and that 25% of patients would require transportation after distraction for an average distance of 60 km.

All the assumptions concerning medical resource expenses are reported in Table 1.

2.2. Medical resource expenses for MCGR strategy

The use of the MCGR system called MAGEC[1] was considered for this strategy. It consists of a growing rod that is magnetically drivable once implanted using a hand-held magnetic external remote controller placed on the patient's back [4] allowing non-invasive distractions. This medical device was CE marked in September 2010. We assumed its support by the French national health insurance system in addition to hospital stays. The medical resource expenses with the MAGEC system were estimated on the basis of data from the UK experience [9] which is the largest cohort reported so far (34 patients; 13 boys/21 girls; mean age at first surgery: 8 years; mean follow-up: 15 months) as well as data from our local experience on the use of this device (5 patients, 4 boys/1 girl, mean age at first surgery: 9.7 years; mean follow-up: 8 months). As for TGR, we considered an initial implantation surgery using single MCGR in 75% of cases and dual MCGR in 25% of cases plus conventional instrumentation (including screws, hooks, and connectors). After index surgery, medical expenses were medical outpatient distraction visits and full spine radiographs using EOS low dose imaging system. The capacity of MCGR to maintain spinal curvature over time after outpatient distraction visits has been described in published data up to 2 years. We considered this efficacy maintained between years of follow-up three and four on the basis of clinical experience from UK specialists.

As for TGR, the expense of medical resources due to unplanned events was considered with limitation to growing rod fractures and was estimated based on the data from the UK experience. In case of a rod breakage, an emergency surgery was considered to repair the rod with a connector adding one surgery to the management of patients.

At last, the same assumptions as the one of TGR strategy were considered for spinal bracing, physiotherapy visits, and medical transportation.

All the assumptions concerning medical resource expenses are reported in Table 1.

[1] Ellipse MAGEC™ Spinal System, Ellipse Technologies, DB2C France.

Table 1
Base case values of medical resource parameters and ranges for sensitivity analysis.

Medical resource consumption	Base case	Source	Range for sensitivity analysis			
			Minimum	Source	Maximum	Source
TGR strategy						
Surgeries (including initial implantation) (per patient-year)	2.3	LC	1.9	LC	2.6	LC
Medical visits (per patient-year)	2.5	LC	1.9	LC	3.4	LC
Vertebral radiographs (per patient-year)	2.8	LC	1.9	LC	3.9	LC
Rod fracture (%/year)	3.6	[12]	2.7	EI	4.5	EI
MCGR strategy						
Outpatient distraction visit *(per patient-year)*	6	LC	3.8	[9]	8	EI
Vertebral radiographs (frequency per year)	6	LC	None applied		12	EI
Rod fracture (%/year)	4.7	[9]	3.5	EI	5.8	EI
TGR and MCGR surgery						
Single rod/dual rod at index surgery (mean proportion)	0.75/0.25	LC	0.5/0.5	EI	1/0	EI
Screws/hooks (mean number at index surgery)	2.5/3.75	LC	None applied		None applied	
Spinal bracing (frequency of replacement)	1 per 18 month	EI	None applied		None applied	
Physiotherapy visits (frequency)	1 per week	EI	None applied		None applied	
Medical transportation						
After index surgery (% of benefiting patient)	50	EI	None applied		None applied	
After distraction (% of benefiting patient)	25	EI	None applied		None applied	

MCGR: magnetically controlled growing rods; TGR: traditional growing rod; LC: data based from our centre; EI: value based from expert interview.

2.3. Economic valorisation of medical resource

The costs of medical resources consumed were calculated on the following basis:

- hospital stays: official Diagnosis-Related Groups (DGRs)'s tariffs for scoliosis surgery (cost of standard hospital stay with low-grade of severity: 4313 €, cost of standard hospital stay with mid-grade of severity: 5763 €) were considered;
- implantable medical devices: costs were estimated based on official fares knowing that conventional devices are reimbursed in addition to hospital stay tariffs, depending on the type of construct (rod: 78 € per unit, screw: 185 € per unit, hook: 154 € per unit, connector: 73 € per unit); for MCGR, we considered the current French tariffs for the MAGEC system: 22,772 € for a single MCGR, and 33,404 € for dual MGCGs; those tariffs include the provision of the external remote controller by the French distributor;
- spinal bracing: official fares were taken into account (1018 € for orthosis and the molding);
- medical and physiotherapy visits: costs were valued according to the French nomenclature rate (23 € for medical visits and 27 € for physiotherapy visits);
- full spine radiographs: costs were valued according to the French nomenclature rate (57 €);
- medical transportation: cost was estimated taking into account the most frequently observed proportion of transportation modes [ambulance (42%) – sanitary vehicle (23%) – taxi (31%) – or other (4%)]. The average distance limit between the institution and the patient's home was set at 30 km, corresponding to a mean transportation cost of 66 €.

All the values for costs are reported in Table 2.

2.4. Statistical analysis and sensitivity analysis

The incremental cost was calculated as the difference between the cost of MCGR and the cost of TGR. The effect of time horizon variation on cumulated costs was examined.

Table 2
Base case values of costs.

Medical resource consumption	Base case (€)	Range for sensitivity analysis	
		Minimum (€)	Maximum (€)
Hospital stays			
Standard hospital stay with mid-grade of severity	5763	4322	7203
Standard hospital stay with low-grade of severity	4315	3237	5394
Medical devices			
Single traditional rod (TGR)	78	*None applied*	
Single MCGR[a]	22, 772	17,079	28,465
Dual MCGR[a]	33, 404	25,053	41,755
Screw	185	*None applied*	
Hook	154	*None applied*	
Connector	73	*None applied*	
Spinal bracing (orthosis and moulding)	1018	*None applied*	
Other			
Medical visits	23	*None applied*	
Physiotherapy visits	27	*None applied*	
Full spine radiographs	57	*None applied*	
Medicalized transportation	66	*None applied*	

MCGR: magnetically controlled growing rods; TGR: traditional growing rod.
[a] Including the provision of the external remote controller by the French distributor for each distraction.

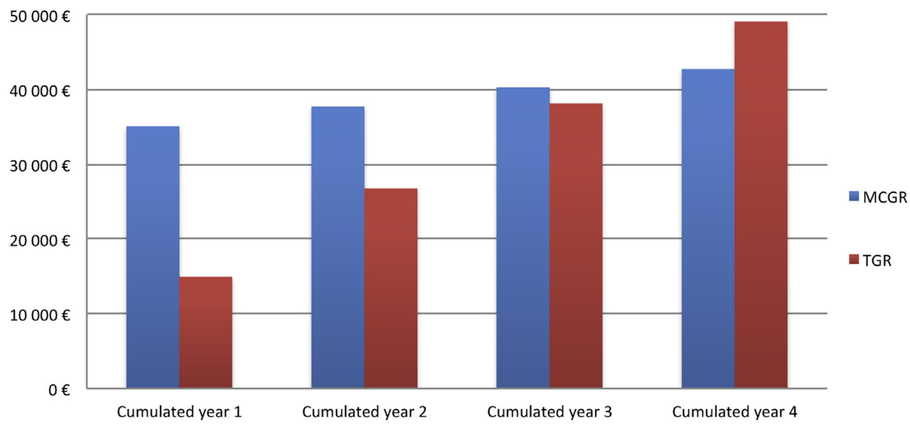

Fig. 1. Cumulated costs over time horizon for traditional growing rod and magnetically controlled growing rod strategies.

A one-way sensitivity analysis was conducted to assess the impact that a fixed change in each parameter has on cost differential and was represented using a tornado diagram.

The ranges for sensivity analysis were based on documented data from the different cohorts whenever possible, or were chosen in accordance to expert interviews. In such cases, a variation of plus or minus 25% was mostly applied to parameters. Ranges for sensitivity analysis are listed in Table 1 for medical resource consumption. A sensitivity analysis was also performed for MCGR's tariffs (plus or minus 25%), annual discount rate (0% to 5%), and standard hospital stay's tariffs (plus or minus 25%). At last, a three-way sensitivity analysis was performed taking into account the three parameters having individually the most important impact on incremental cost. Analyses were performed with Microsoft Excel® 2010.

3. Results

3.1. Estimated costs for both strategies and incremental cost

On the basis of assumptions from Tables 1 and 2, the direct costs of the standard management of patients with EOS was estimated at 49,067 € with a time horizon at 4 years and was mainly represented by hospital stays expenses (41,148 € per patient, 83.9%). In contrast, reported costs of medical devices, medical visits or vertebral radiographs were minor and reached respectively 1148 € (2.3%), 230 € (0.5%), and 638 € (1.3%) of the total amount.

For MCGR strategy, given a time horizon of 4 years, mean direct cost could be estimated at 42,752 € and is mainly represented by the cost of the device (59.5%).

Based on those results, incremental cost at 4 years was estimated at −6135 €.

The diagram of Fig. 1 illustrates the cumulative costs of both strategies over time horizon: incremental cost decreases over time (from 20,146 € at year 1 to −6135 € at year 4). At 3 years, cumulative costs between the two strategies have almost equal values and then the trend is reversed in favour of MCGR group.

3.2. Sensitivity analysis

One-way sensitivity analysis on incremental cost between TGR and MCGR strategies were represented in a Tornado diagram based on assumptions previously described (Fig. 2). The vertical axis represents the incremental cost between both strategies when all parameters are fixed to the value used in the baseline analysis. From top to bottom, parameters are ranked according to their degree of sensitivity: the horizontal bar on top is the one with the largest uncertainty. Parameters having the most influence on incremental cost include: tariffs of hospital stays, tariffs of the MCGR, frequency of distraction surgeries, and use of single or dual vertebral installation. For those four variables, the amplitudes of incremental cost variation were 16,577 €, 12,715 €, 11,491 €, and 5277 €, respectively. At exception of the tariffs of hospital stays, the diagram shows that the variation of parameters one by one does not reverse the trend. When considering the most pessimistic scenario (−25% for the tariffs of hospital stays, +25% for the tariffs of MCGR, and a frequency of distraction surgeries of 1.9 per patient-year), the three-way sensitivity analysis estimated the incremental cost between MCGR and TGR strategies at 13,268 €. In contrast, when considering the most-optimistic scenario (+25% for the tariffs of hospital stays, −25% for the tariffs of MCGR, and a frequency of distraction surgeries of 2.6 per patient-year), the incremental cost was estimated at −27,108 €.

4. Discussion

MCGR system is a promising technique in the management of EOS with severe curvature. Its capacity to enable non-invasive distraction was first demonstrated in a porcine model [8].

In the first clinical case study, Cheung et al. reported encouraging results on the use of MCGR showing good efficacy and tolerance in two patients followed up to 2 years [4]. More recently, Dannawi et al. reported technical and clinical outcomes of MCGR in 34 EOS children in a prospective study, which was able to confirm the device efficacy in stabilizing the curvature scoliosis after a mean follow-up duration of 15 months. Furthermore, the rate of severe complications was very low [9].

Within the scope of the recent commercialization of a MCGR system in Europe and the growing interest of this technique in France (more than 20 national cases performed as of September 2013), our objective was to assess and compare the direct costs associated with the management of EOS using TGR or MCGR.

One of the main reasons to conduct this cost study was to convince our health authorities to consider reimbursement of this technique. Indeed, the current unit cost of MCGR in France (from 23,000 to 33,000 € depending on the type of spinal construct) is much higher than the one mentioned in the literature (about 5200 € in the Chinese report) [4,13]. Furthermore, as MCGR are not yet reimbursed by insurance plans, their use is currently supported by hospital budgets. At last, this evaluation was justified by the absence of any published data reporting the cost of the current gold standard approach of severe EOS using TGR.

Our study emphasizes that conventional strategy using TGR leads to substantial costs for the French sickness fund even though the overall economic burden is rather limited considering the rarity of EOS cases treated surgically.

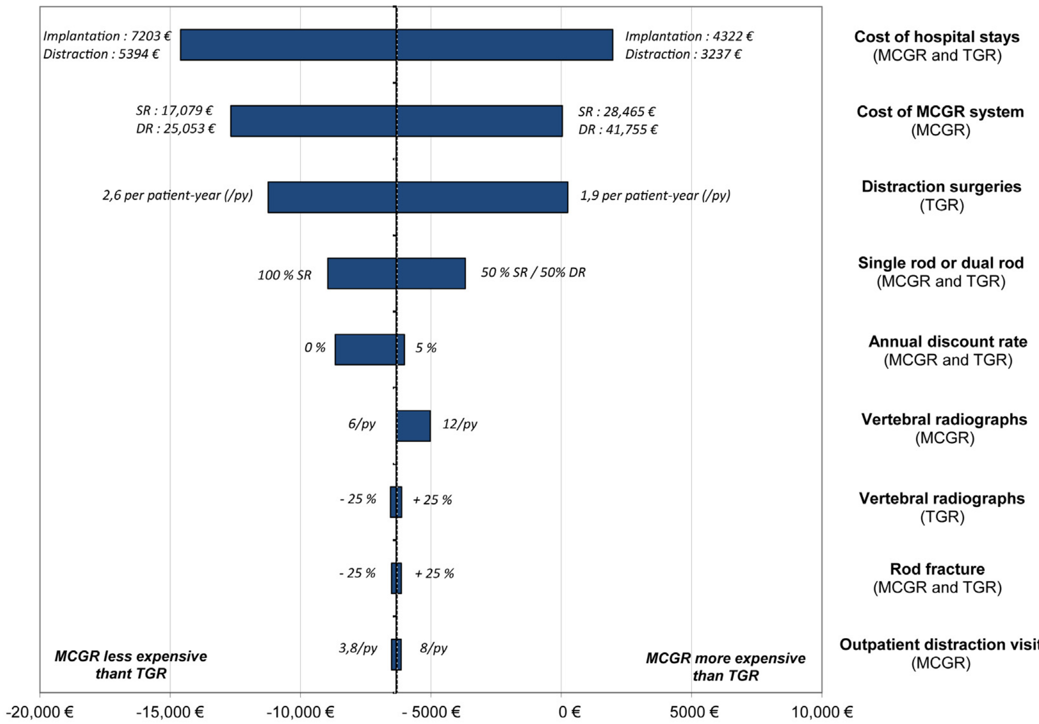

Fig. 2. Tornado diagram assessing sensitivity on cost differential.

Despite its major unit cost, our results show that the use of MCGR could lead to lower direct costs with a time horizon of 4 years.

The typology of medical resource consumption should be greatly modified when using MCGR since it should avoid the need for surgical distractions with TGR. Interestingly, as illustrated on Fig. 1, MCGR procedure induces a strong expense at starting, then costs evolve gradually at the difference of TGR strategy.

We believe that the choice of a four-year-time horizon for cost estimation is consistent with child growth as well as the lengthening capacity of MCGR. Indeed, the moment of rod's implantation usually corresponds to the phase of slow growth, which occurs before the pubertal growth spurt. Over this period, the average growth of thoracic and lumbar spine from T1 to L5 is 14 mm per year (0.82 mm per year for one vertebra) [14]. When using MCGR system, a reasonable strategy would be to perform non-invasive distractions as regularly as possible in order to reduce the risk of stiffness of elongated area which is commonly described with TGR and responsible for the law of diminishing returns [15]. In our practice on 5 patients that have been implanted with MCGR, non-invasive distractions are planned every 2 months in outpatient visit. The amplitude of distractions varies depending on the number of vertebrae included in the spinal construct. For one vertebra, an extension of 0.205 mm is performed every 2 months corresponding to an annual lengthening of 1.23 mm: 0.82 mm of which corresponds to the theoretical growth of a vertebra, and 50% of it are accounted to reduce progressively the spinal curvature. In our TGR cohort, the mean number of vertebrae concerned with TGR was 9.5 (range 4–14). This latest value was then taken into account so as that simulate how MCGR could have been used in the same cohort. Based on that, an annual lengthening of 1.23 mm per vertebra would result in a total lengthening of 11.685 mm per year. Considering that MCGR has a maximum lengthening capacity of 48 mm, we assume that this potential would almost be reached within a four-year period.

This study has several limitations. The major one is that our cost-comparison is not based on data obtained from a prospective, randomized, head-to-head comparison study between TGR and MCGR. This approach could bring the highest level of evidence to support the cost-effectiveness of MCGR. However, we believe this type of design is very unlikely to be set up due to acceptability and feasibility issues. Indeed, EOS is a severe affection with important associated disabilities. We assume that a study design comprising for an EOS patient, after failure of an orthopaedic treatment, two surgical strategies, one with initial surgery and a distraction surgery every 6 months, and this other with initial surgery and outpatient distraction visits every 2 to 3 months, would lead to a high proportion of refusal by the patient and/or his/her family. Furthermore, EOS being a rare syndrome, this low acceptability could not guaranty the feasibility of such a study. We also believe that a prospective here/elsewhere study design would not be feasible considering that many patients in centres solely proposing TGR strategy would not give their consent to participate. Furthermore, taking the example of French expert EOS centres, the use of MCGR strategy has become widely predominant in the last 18 months and so surgeon would refuse not to propose the best treatment to their patient. To date, no prospective comparative study has been initiated based on the current ClinicalTrials.gov list. As a consequence, we performed a cost-comparison based on a simulation model using assumptions obtained from literature search or our local experience. Even though the costs that we describe may sound theoretical or virtual, modelling is a commonly used method in health economic evaluation as indicated in the methodological guide from the French National Authority for Health [11].

Other limitations may be emphasized. First, we did not take into account outpatient direct costs such as drugs or medical visits. Secondly, indirect costs, such as parents' time off work are worth considering but are complicated to estimate. Furthermore, a longer time horizon evaluation could be interesting until spinal fusion is achieved. The lack of published data on long-term evaluation of patients treated with MCGR leads us to assume that the capacity of MCGR to maintain spinal curvature during years 3 and 4 would be maintained. This has to be confirmed by further investigations. At last, the costs associated with skin infections were not considered for both strategies. The reason is that we considered that this event could not be correctly estimated in the MCGR because the largest report from the UK experience solely mentioned 2 cases of superficial wound infection out of 34 patients and no deep wound infection. However, this event being mainly a complication of surgery, it is expected that the rate of wound infections, as well as its associated costs, should be highly decreased by the use of MCGR.

Very little is known about mechanical possibilities of the device, and its ability to extend reliably and regularly. Some differences between the theoretical lengthening indicated on the external remote controller and lengthening really obtained measured on radiographs have already been identified in our center, which varies greatly depending on corpulence of the patient and stiffness of spinal deformity. Our protocol is therefore a theoretical basis landmark that will evolve gradually with the use of MCGR in our centre.

MCGR technique is expected to reduce the spinal curvature and to maintain it during growth thanks to frequent growth related distraction, while avoiding iterative surgeries. Considering the patient's quality of life, this new approach could overpass the gold standard treatment using TGR. Therefore, cost-utility studies including quality of life measurement using the EOS questionnaire [16] should be of great interest but such an approach would necessitate a prospective head-to-head comparison, which seems to be unlikely as previously discussed. However, 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.

Although the expected medical benefit of this novel technology is tremendous, long-term perspective on MCGR efficacy is currently lacking which is of particularly importance knowing that EOS patients are usually treated for a long period before spinal fusion is indicated. Our study provides original data on a rare pathology and provides economic support on an expansive management. If the effectiveness of MCGR is further confirmed, this could be one of those preferable situations in which a breakthrough technology proves cost saving.

5. Conclusion

The management of severe EOS using conventional growth rods is characterized by a substantial cost per patient due to the iterative distraction surgeries and associated hospital stays. Moreover, despite its efficacy to control the deformity, high complication rates are reported proportionally to the number of distraction surgeries. This specific morbidity advocates for non-invasive distraction techniques. In this indication, the use of magnetically controlled growing rods is promising and despite its high unit cost, further clinical studies should be encouraged to confirm the potential cost-effectiveness of this innovative technique.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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