

# Cost Analysis of Magnetically-controlled Growing Rods Compared to Traditional Growing Rods for Early Onset Scoliosis in the United States

David W. Polly, Jr, MD  
Stacey J. Ackerman, PhD  
Karen Schneider, PhD  
Jeff B. Pawelek, BS  
Behrooz A. Akbarnia, MD

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UNIVERSITY of CALIFORNIA  
SAN DIEGO

# DISCLOSURES

- **David Polly:** *None.*
- **Stacey Ackerman:** *Consultant to the medical device industry, including Ellipse Technologies, through employment at Covance. No direct compensation received for consulting engagements.*
- **Karen Schneider:** *Consultant to the medical device industry, including Ellipse Technologies, through employment at Covance. No direct compensation received for consulting engagements.*
- **Jeff Pawelek:** *None.*
- **Behooz Akbarnia:** *A: Depuy-Synthes, Nuvasive; B: Nuvasive, K2M, Ellipse, K Spine; D: Nuvasive, Ellipse, K Spine, Nocimed; F: Depuy-Synthes, Nuvasive.*

# INTRODUCTION

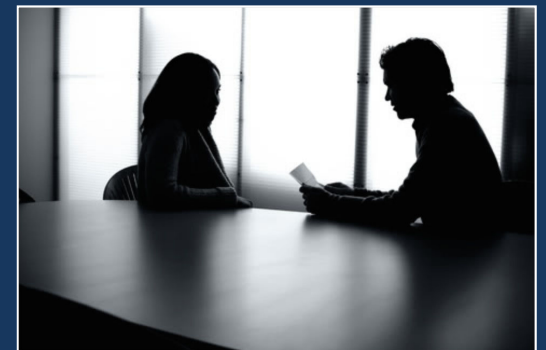
- Treatment of early onset scoliosis (EOS) with traditional growing rods (TGR) requires repeated surgical lengthenings.
- Magnetically-controlled growing rods (MCGR) can be lengthened non-invasively in a physician office setting using an externally applied remote control device.
- The objective of this research was to present an economic analysis (budget impact model or BIM) of MCGR compared to TGR in the United States (U.S.).



# METHODS

## To obtain parameter estimates for the BIM:

- A targeted literature search was conducted in May 2014 using PubMed, and was limited to publications from the previous 5 years
- A series of one-on-one interviews were conducted with:
  - *6 pediatric orthopedic surgeons*
  - *2 commercial payers*
  - *2 hospital purchasers*



# RESULTS

The following data tables detail the components used to develop the BIM including:

- Model framework parameters
- Medical resource use parameters
- Clinical efficacy
- Associated costs



# RESULTS

## Model framework parameters:

<b>Perspective</b>	Hospital purchaser	<b>At-risk stakeholder in U.S.</b> Confirmed through interviews with private payers, hospital purchasers, and ped ortho surgeons. Assumes integrated health care delivery system (where faculty practice plan is integrated with the hospital institution and physicians are employees of the system).
<b>Comparator</b>	Traditional growing rods (TGR)	Jenks M, Craig J, Higgins J, et al. The MAGEC system for spinal lengthening in children with scoliosis: A NICE medical technology guidance. Appl Health Econ Health Policy. 2014 Aug 30. Confirmed for U.S. through interviews with payers, hospital decision makers, and ped ortho surgeons.
<b>Setting of care</b>	TGR: Same-day surgery MGR: Physician office or hospital outpatient clinic	Interviews with ped ortho surgeons in U.S.
<b>Timeframe</b>	6 years (1-5 years)	Jenks M, Craig J, Higgins J, et al. The MAGEC system for spinal lengthening in children with scoliosis: A NICE medical technology guidance. Appl Health Econ Health Policy. 2014 Aug 30.
<b>% of Private Payer Patients</b>	51.50%	ICD-9-CM, NHAMCS, NHDS (45% commercial, 42% Medicaid – grossed up to 100%).
<b>% of Medicaid Patients</b>	48.50%	
<b>Discount rate</b>	3.00%	Congressional Budget Office (2011). CBO's 2011 long-term projections for social security. Accessed: September 30, 2014.

# RESULTS

## Medical Resource Use Parameters:

<b>Frequency of MCGR distractions</b>	Every 3 months (range, 1-6 months)	<p>Craig J, Jenks M, Willits I et al. MAGEC system for spinal lengthening in children with early onset scoliosis. Nov 2013.</p> <p>Jenks M, Craig J, Higgins J, et al. The MAGEC system for spinal lengthening in children with scoliosis: A NICE medical technology guidance. Appl Health Econ Health Policy. 2014 Aug 30.</p>
<b>Frequency of TGR distractions</b>	Every 6 months (range, 6-12 months)	<p>Akbarnia B, Marks D, Boachie-Adjei O, et al. Dual growing rod technique for the treatment of progressive early-onset scoliosis: a multicenter study. Spine. 2005 Sep 1;30(17 Suppl):S46-57.</p>
<b>% of dual rods</b>	85% (range, 75-85%)	<p>Thompson G, Akbarnia B, Kostial P, et al. Comparison of single and dual growing rod techniques followed through definitive surgery: a preliminary study. Spine. 2005 Sep 15;30(18):2039-44. Clinical judgment.</p>
<b>Years to implant exchange</b>	3.8 years	<p>Moe JH, Winter RB, Bradford DS, Lonstein JE. The normal spine: anatomy, embryology, and growth. In: Scoliosis and Other Spinal Deformities. Philadelphia: W.B. Saunders Company; 1978:78-79.</p>

# RESULTS

## Clinical Efficacy:

<b>TGR Complete Device Failure</b>	0.59% (per month)	<p>Craig J, Jenks M, Willits I et al. MAGEC system for spinal lengthening in children with early onset scoliosis. Nov 2013.</p> <p>Jenks M, Craig J, Higgins J, et al. The MAGEC system for spinal lengthening in children with scoliosis: A NICE medical technology guidance. Appl Health Econ Health Policy. 2014 Aug 30.</p> <p><i>For complete device failure, a period of 38 months was selected by NICE for TGR to allow a more direct comparison with the shorter MCGR follow-up.</i></p>
<b>MCGR Complete Device Failure</b>	0.37% (per month)	
<b>TGR <u>Overall Surgical Site Infection</u></b>	0.21% (per month) <i>Reflects initial implantation, exchanges, revisions, and repeated invasive lengthening procedures</i>	
<b>MCGR <u>Overall Surgical Site Infection</u></b>	0.21% (per month) <i>Reflects initial implantation, exchanges, and revisions</i>	



# RESULTS

## Clinical Efficacy:

<p><b>TGR and MCGR</b>  <b>% of <u>deep</u> surgical site infections vs. superficial</b>  <i>(among all surgical site infections)</i></p>	<p>68.00%</p>	<p>Combination of clinical papers. Lack of published data to inform this parameter for MCGR. Assumed to be the same as TGR.</p>
<p><b>TGR and MCGR</b>  <b>% device failures requiring complete removal of instrumentation (vs. partial)</b></p>	<p>5.8%</p>	<p>Bess S, Akbarnia B, Thompson G, et al. Complications of growing rod treatment for early-onset scoliosis: Analysis of one hundred and forty patients. J Bone Joint Surg Am., 92(15), 2533-2543. Epub 2010 Oct 1. Clinical advisors.</p>
<p><b>TGR and MCGR relative risk of device failure associated with single rods (vs. dual rods)</b></p>	<p>2.64</p>	<p>Based on the unplanned surgery due to implant problems the relative risk (self calculated) = (19 patients/71 single growing rod patients)/(7/69 dual growing rod patients) = 2.637827. Bess S, Akbarnia B, Thompson G, et al. Complications of growing rod treatment for early-onset scoliosis: Analysis of one hundred and forty patients. J Bone Joint Surg Am., 92(15), 2533-2543. Epub 2010 Oct 1. Clinical advisors. Lack of published data to inform this parameter for MCGR. Assumed to be the same as TGR.</p>
<p><b>TGR and MCGR relative risk of surgical site infection in Medicaid patients (vs. all other patients)</b></p>	<p>2.06            (range, 1.19-3.58)</p>	<p>Manoso MS, Cizik AM, Bransford RJ, Bellabarba C, Chapman J, Lee MJ. (June 30 2014). Medicaid Status Is Associated With Higher Surgical Site Infection Rates After Spine Surgery. Spine. <a href="http://www.ncbi.nlm.nih.gov/pubmed/24983931">http://www.ncbi.nlm.nih.gov/pubmed/24983931</a>. Accessed 9 September 2014.</p>

# RESULTS

## Cumulative costs associated with:

- Initial implantation
- Surgical site infection
- Device failure
- Revision/exchange surgeries
- Rod lengthening
- Rod removal and definitive fusion



## Distraction Costs:

Cost	TGR Distractions	MCGR Distractions
Physician fee	X	X
Hospital facility fee	X	X
Anesthesia	X	
X-ray	X	X
Intra-op neuro monitoring	X	

# RESULTS

	<b>Assumption</b>	<b>Reference</b>
<b>Clinical effectiveness</b>	Equivalent clinical effectiveness (curve correction, sagittal alignment, and increase in thoracic volume) between MCGR and TGR.	Clinical advisors
<b>Resource use and risk</b>	Resource use and risk are similar between TGR and MCGR with respect to first implantation, revision, exchange, rod removal and final fusion <i>(with the exception of the growing rod costs)</i> .	Clinical advisors
<b>Timing of exchange surgery</b>	All patients (boys and girls) for MCGR and TGR require one exchange surgery across the 6 year episode of care.	Moe JH, Winter RB, Bradford DS, Lonstein JE. The normal spine: anatomy, embryology, and growth In: Scoliosis and Other Spinal Deformities. Philadelphia: W.B. Saunders Company; 1978:78-79.
<b>Treatment for complications</b>	Deep infection and prominent implants leads to complete removal of implants. All other complications lead to only partial removal. Superficial infection requires antibiotics only.	Clinical advisors
<b>Antibiotics</b>	Infection requires 6 weeks of intravenous antibiotics and 12 months of oral antibiotics (clindamycin).	Clinical advisors
<b>X-ray usage</b>	One x-ray per MCGR and TGR lengthening procedure.	Clinical advisors

# SUMMARY OF RESULTS

- Sensitivity analyses evaluate model robustness.
- A threshold analysis assesses the break-even point (months after initial implantation) when MCGR becomes cost saving.
- Cost offsets for MCGR driven by:
  - *Non-invasive MCGR distractions*
  - *Lower device failure rate resulting in fewer revisions*
  - *No hospital facility costs for distractions in the physician office*
  - *No anesthesia or intra-op neuro monitoring during distractions*

# CONCLUSIONS

- The BIM model provides a rigorous framework for assessing cost impact of both TGR and MCGR surgeries.
- This model is intended to help inform treating physicians and hospital purchasers.



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