

Paper #37

A high degree of variability exists in how “safety and efficacy” is defined and reported in growing rod surgery for early-onset scoliosis: A systematic review



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Summary: Established criteria for reporting safety and efficacy have not yet been defined in growing rod surgery for early-onset scoliosis. A systematic literature review revealed a high degree of variability in how authors stratified complications and patient outcomes as a means to define safety and efficacy for this challenging patient population.

Hypothesis: There is no consensus on the parameters used for reporting safety and efficacy in growing rod treatment for early-onset scoliosis.

Design: Systematic literature review.

Introduction: TGR) and magnetically controlled growing rods (MCGR) using various parameters. Radiographic parameters are most commonly used to measure efficacy, while incidence and type of complications are used to assess safety. A systematic review was performed to identify whether a consensus exists in how safety and efficacy parameters are reported in TGR and MCGR treatment outcomes.

Methods: Four databases were searched to identify qualified peer-reviewed articles using keyword searches (Table 1). All peer-reviewed

Table 1

Searched terms: adverse effects, complications, risk, treatment outcome, safety, efficacy, effectiveness, magnetically controlled growing rod, MCGR, traditional growing rod, conventional growing rod, TGR, CGR, growing spinal implant, growing rod implant, growing rod surgery, magnetic expansion control rod, magnetic driven growing rod, MAGEC, and early onset scoliosis.

Modified Downs and Black Scoring

	TGR	MCGR	P
Reporting Score (%)	86.4 ± 13.5 (50 - 100)	85.1 ± 12.2 (62.5 - 100)	> 0.05
External Validity (%)	75.5 ± 17.9 (33 - 100)	75.4 ± 14.7 (67 - 100)	> 0.05
Internal Validity (%)	39.2 ± 8.0 (22-55)	41.2 ± 4.9 (33-44)	> 0.05
Overall Score (%)	63.9 ± 6.9 (50-75)	64.0 ± 6.3 (50-75)	> 0.05

Demographics

	TGR	MCGR	P
Mean age (years)	6.5 ± 0.8 (5.1-8.7)	8.0 ± 1.7 (4.5-12)	< 0.05
Follow up (years)	4.6 ± 1.3 (2.3-7.2)	1.8 ± 0.6 (0.2-2.5)	< 0.05
Country (most publications)	USA (12/23, 52%)	UK (6/16, 37.5%)	
Control group	4/23 (17.3%)	2/16 (12.5%)	
Study design (Most popular)	Retrospective 21/23 (91%)	Retrospective 8/16(50%)	
Level of evidence (Most popular)	Level III 17/23 (74%)	Level III 9/16 (56%)	

Efficacy measures

	TGR	MCGR	P
T1-T 12 height (Number of papers reported)	3/23 (13%)	9/16 (56%)	> 0.05
T1-S1 height (Number of papers reported)	10/23 (43%)	11/16 (69%)	< 0.05
Coronal Cobb Angle (Number of papers reported)	21/23 (91%)	15/16(94%)	< 0.05
Thoracic kyphosis Angle (Number of papers reported)	10/23 (43%)	8/16(50%)	< 0.05

articles published in English language reporting any data related to safety and efficacy of the TGR and/or MCGR surgical technique were included. Included articles were scored by modified Downs and Black scoring system for non-randomized studies.

Results: Database search found 111 citations including: PubMed (50), Embase (68 with 21 duplicates), Web of Science (29 with 15 duplicates), and CINAHL (15; all duplicates). 56 of 111 citations were excluded during the review of the abstract and 16 were excluded at time of manuscript review. The remaining 39 articles included 23 TGR (2007-2016) and 16 MCGR papers (2012-2016). The overall Downs and Black score was 63.9 for TGR papers vs. 64.0 for MCGR papers (p>0.05). Efficacy measures were not consistently reported among the publications. The only consistently reported efficacy parameter in majority (>90%) of papers was curve size. Complication reporting was highly variable.

Conclusion: Major curve size was the only consistent parameter to report efficacy in peer-reviewed TGR and MCGR publications. Complications were not consistently reported, thus assessing safety of either treatment was infeasible. Establishing standardized safety and efficacy parameters in growing rod surgery for EOS would improve the quality of future studies and makes comparison of different treatment modalities possible.

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Paper #38

Cost analysis of a growth guidance system compared with magnetically controlled and traditional growing rods for early-onset scoliosis in the US: an integrated health care delivery system perspective



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Summary: Traditional growing rods (TGR), magnetically controlled growing rods (MCGR) and growth guidance systems (GGS) have demonstrated comparable radiographic outcomes in the treatment of early-onset scoliosis (EOS). The purpose of this study was to compare direct medical costs of GGS compared to TGR and MCGR using an economic model. Over a 6-year episode of care GGS had lower cumulative costs than MCGR and TGR, saving an estimated \$25,226 vs TGR (16% decrease) and \$29,916 vs MCGR (18% decrease).

Hypothesis: GGS, when compared to TGR and MCGR, will be cost saving over a 6-year episode of care.

Design: Cost analysis using a decision-analytic model.

Introduction: TGR for EOS are effective but require repeated invasive surgical lengthenings that risk complications. Alternatives include MCGR that lengthen noninvasively and the GGS, which obviate the need for active, distractive lengthenings. Previous studies have reported promising clinical effectiveness for GGS similar to TGR.

Methods: An economic model was developed to estimate the cost of GGS compared with MCGR and TGR for EOS from a US integrated health care delivery system perspective. Using dual-rod construct, the model estimated the cumulative costs associated with initial implantation, revisions due to device failure, surgical-site infections, device exchange (at 3.8 years), rod lengthenings (TGR, MCGR), and final spinal fusion over a 6-year episode of care. Model parameters were from peer-reviewed, published literature. Medicare payments were used as a proxy for provider costs. Costs (2016 US dollars) were discounted 3% annually.

Results: Over the 6-year episode of care, GGS was associated with fewer invasive surgeries per patient than TGR (GGS: 3.4; TGR: 14.4). GGS had lower cumulative costs than MCGR and TGR, saving an estimated \$25,226 vs TGR (16% decrease) and \$29,916 vs MCGR (18% decrease). Sensitivity analyses indicated that results were sensitive to changes in construct