Cost Analysis of Magnetically-Controlled Growing Rods Compared with Traditional Growing Rods for Early Onset Scoliosis in the United States

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Disclosures

- **David Polly:** Scoliosis Research Society President
- **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:** Depuy-Synthes, Nuvasive, K2M, Ellipse, K Spine, Nocimed.

Introduction

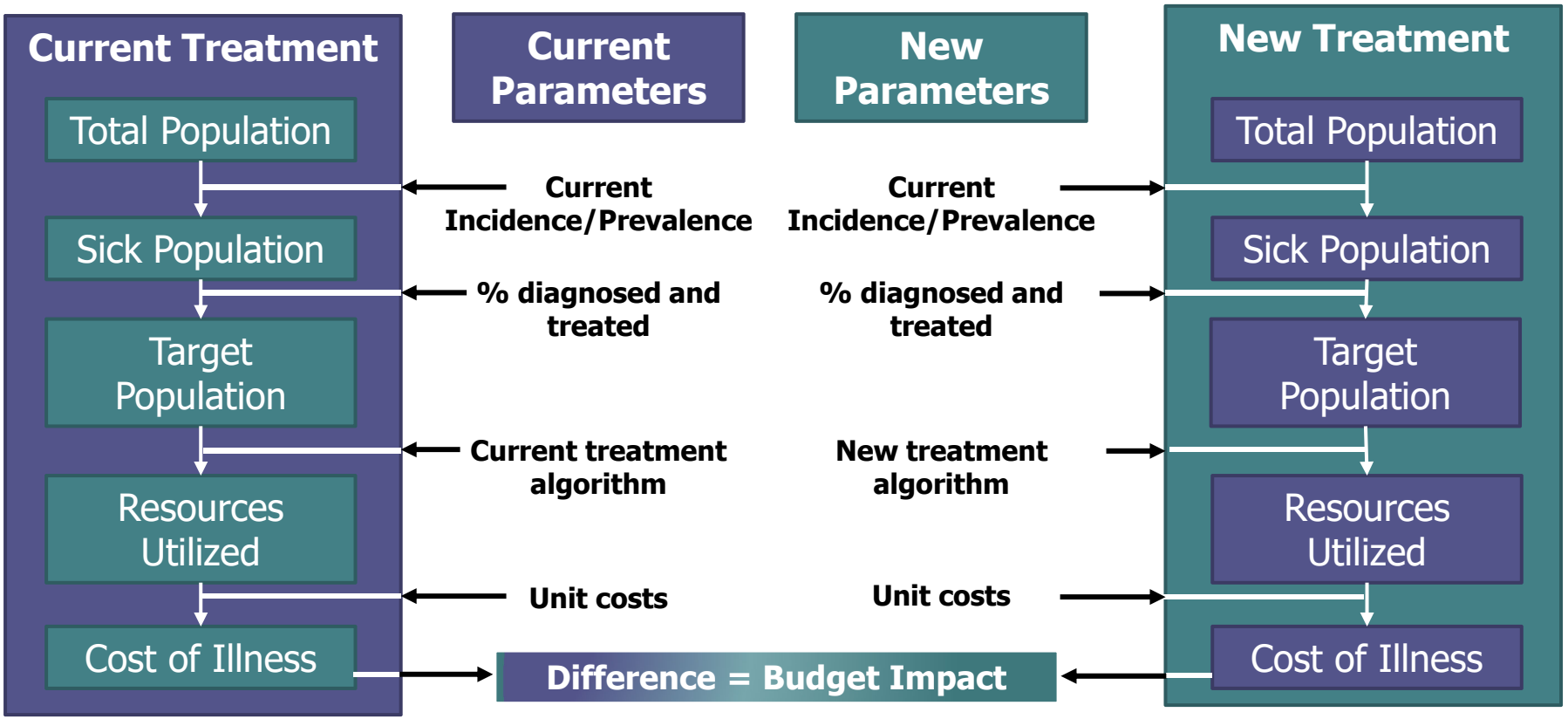
- Treatment of early onset scoliosis (EOS) with traditional growing rods (TGR) requires repeated surgical lengthenings.
- Magnetically-controlled growing rods (MCGR) can be lengthened non-invasively in a physician office setting using an externally applied remote control device.
- The objective of this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

Objective and Framework

- **Aim:** BIM of MCGR compared with TGR for EOS in the United States
- **Perspective: Integrated healthcare delivery system**
- **Settings of care:**
  - TGR distraction: hospital inpatient or hospital outpatient
  - MCGR distraction: physician office
- **Timeframe:** 6-year episode of care (ages 6-12 years)
- **Payer mix:** 51.5% Private payer/ 48.5% Medicaid
- **Discount Rate:** 3.0% per annum
- **Model Design:** Budget Impact Model
- **Unit of Analysis:** Episode of illness
- **Clinical effectiveness:** The model assumes equivalent clinical effectiveness between MCGR and TGR (curve correction and increase in thoracic height).

What is a Budget Impact Model?

- Measures the net cumulative cost of treatment with a particular therapy for a given number of patients in a specific population and health-care setting, typically with resource constraints.



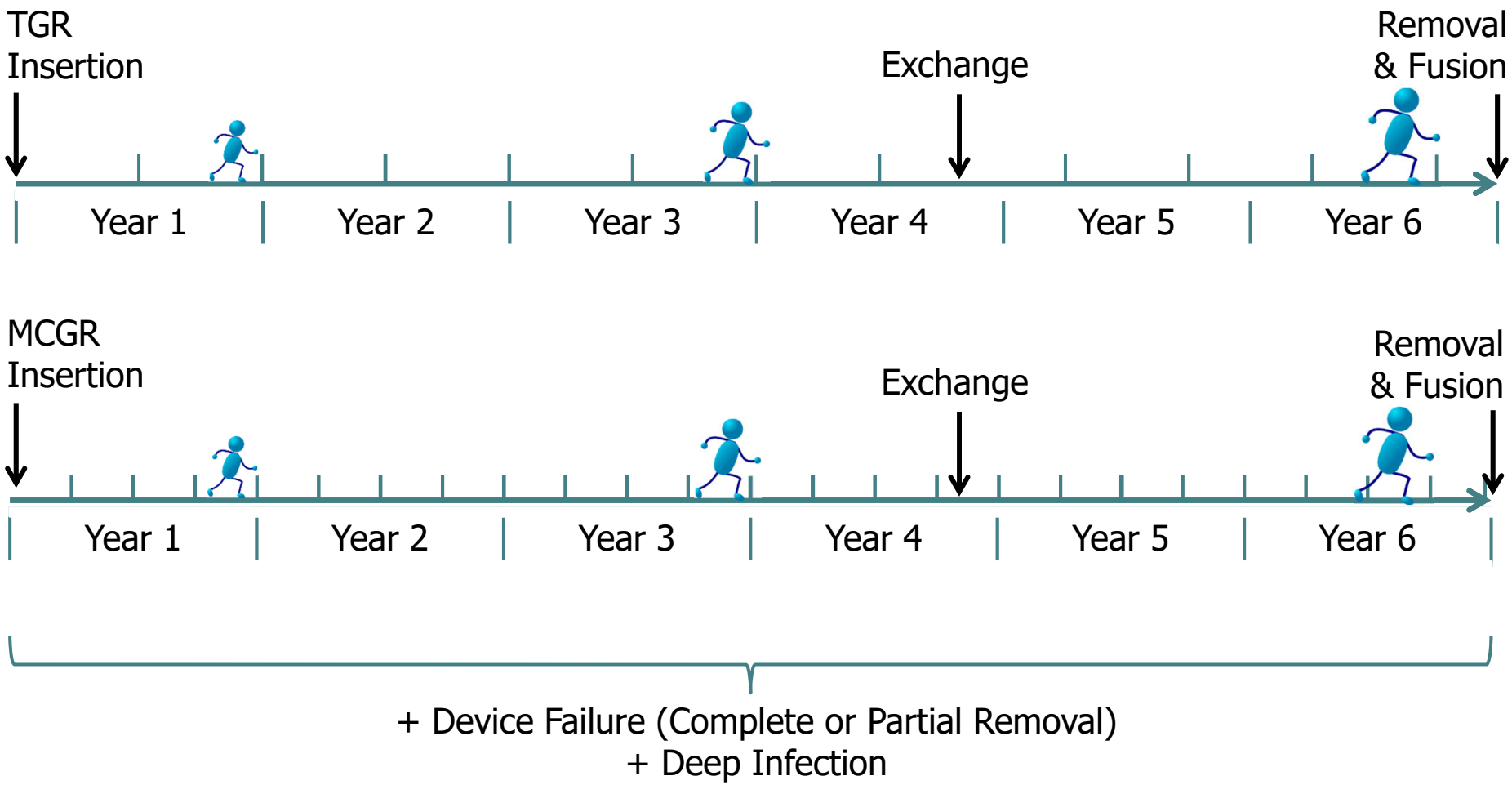
Methodology: Data Sources

- 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 private payers
  - 2 hospital purchasers

- Analysis of Growing Spine Study Group (GSSG) database

Methodology: Model Framework



The model tracks any given number of children, over a 6-year episode of care.

Methodology: Key Model Parameters

Framework	Base case (sensitivity analysis)
Frequency of MCGR distractions	Every 3 (1–6) months
Frequency of TGR distractions	Every 6 (6–12) months
% of dual rods	85% (0–100%)
Years to implant exchange	3.8 (3–5) years
TGR distraction setting of care	
- Hospital Outpatient	46% (0-100%)
- Hospital Inpatient 1-Day Short Stay	30%
- Hospital Inpatient Standard Ward	19%
- Hospital Inpatient ICU	5%
MCGR distraction setting of care	
- Physician office	100%

Methodology: Key Model Parameters

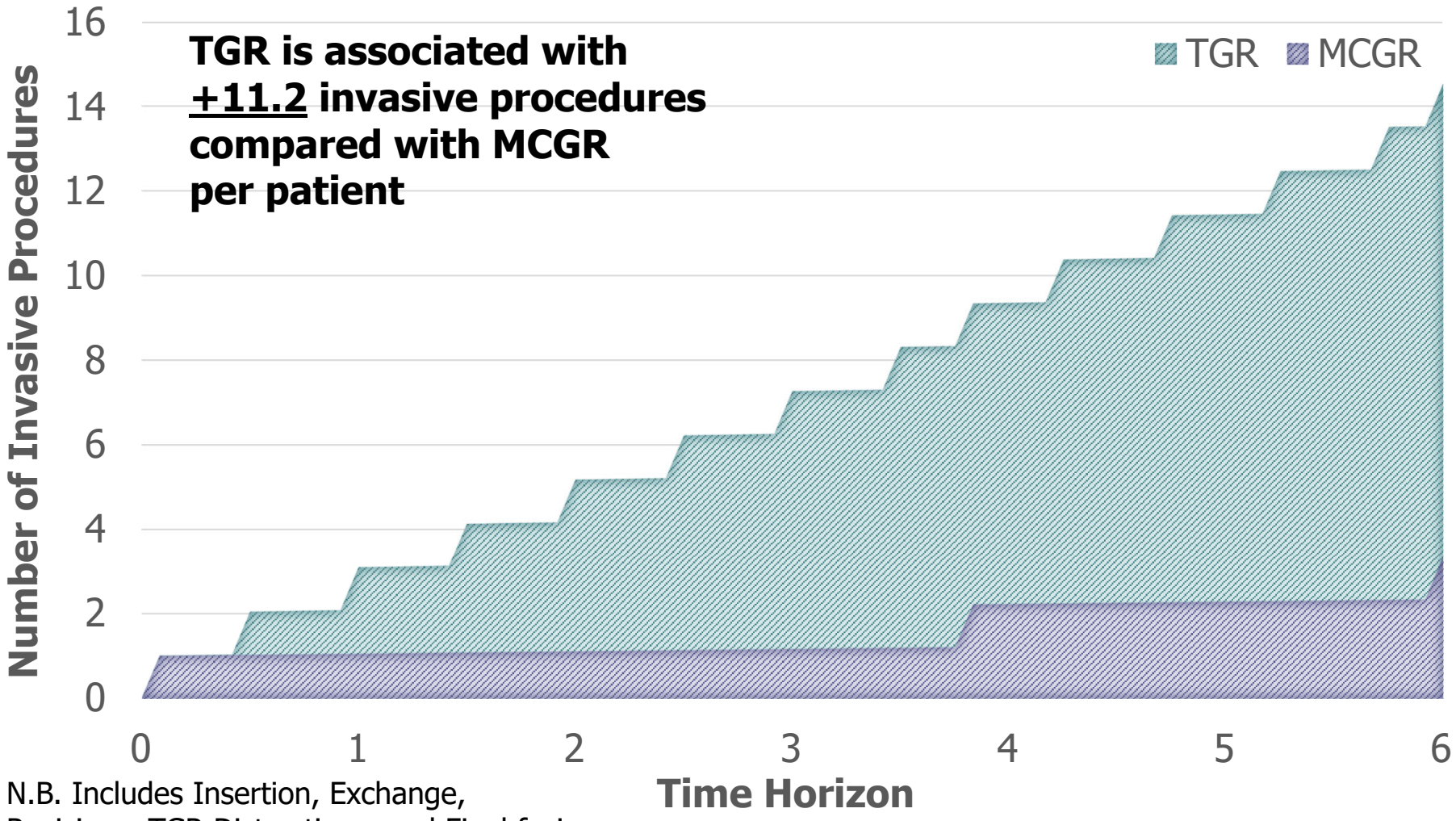
Device Failure and SSIs	Base case (sensitivity analysis)
TGR Device Failure	0.59 (0.3–1.18) % per month
MCGR Device Failure	0.37 (0.19–0.74) % per month
% of device failures requiring complete removal (vs. partial)	5.8 (2.9–11.6) %
Surgical site infection	2.34 (1.17–4.68) % per invasive surgery
% of deep surgical site infections (vs. superficial)	68 (34–100) %

Other risk factors	RR (sensitivity analysis)
Device failure: Single rods (vs. dual rods)	2.64 (1.32–5.28)
Surgical site infection: Medicaid patients (vs. all other patients)	2.06 (1.19–3.58)

Methodology: Key Model Parameters

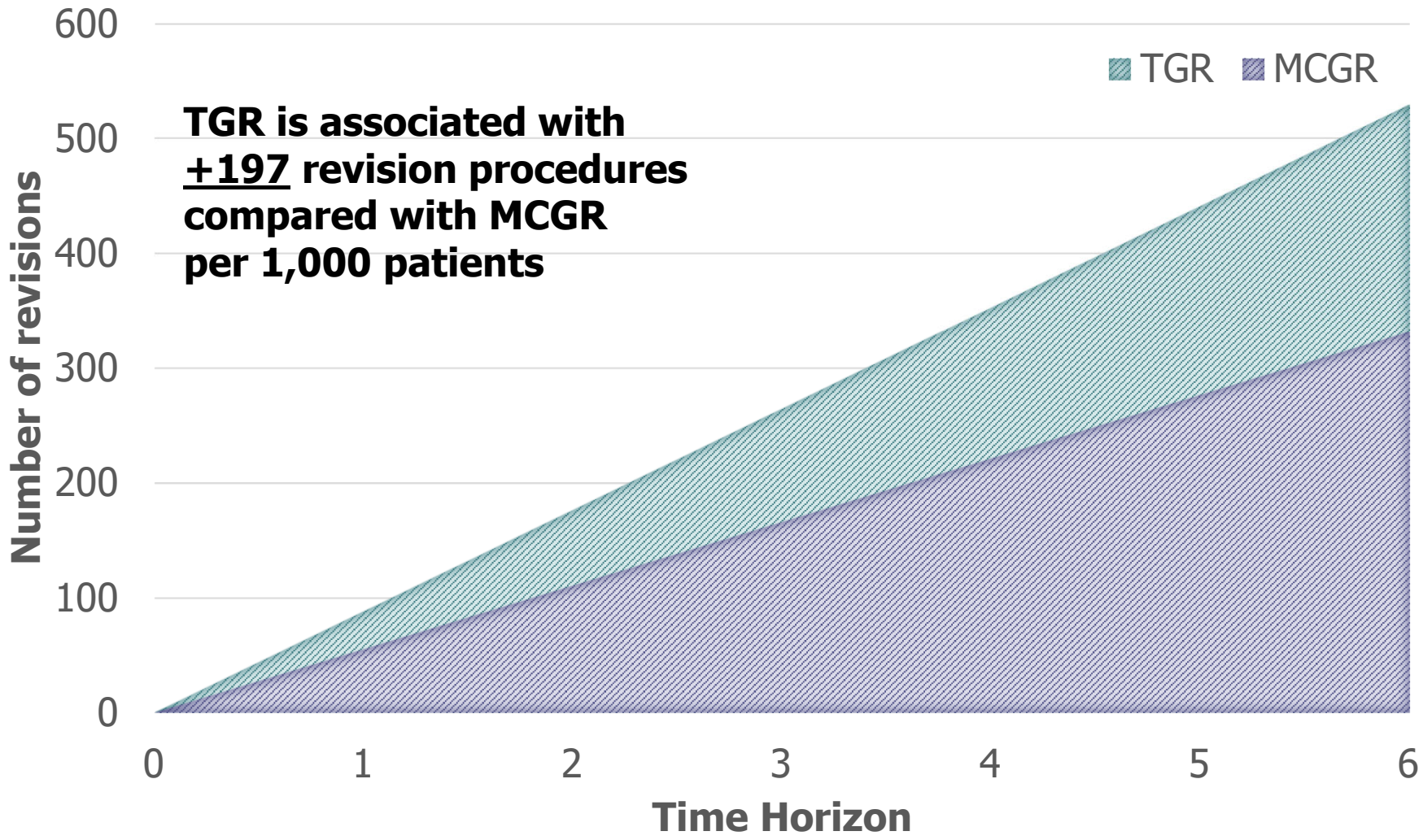
Cost to hospital	TGR	MCGR
Insertion	$34,555	$64,744
Distraction (outpatient)	$4,378	-
Distraction (weighted inpatient)	$6,314	-
- Inpatient 1-day short stay	$4,378	-
- Inpatient standard ward	$12,003	-
- Inpatient ICU	$14,177	-
Distraction (physician office)	-	$176
Exchange	$12,672	$42,861
Complete Revision	$12,672	$42,861
Partial Revision	$11,475	$41,664
Deep Infection	$12,672	$43,589
Removal and Fusion	$35,967	$35,967

Results: Number of invasive procedures, per patient

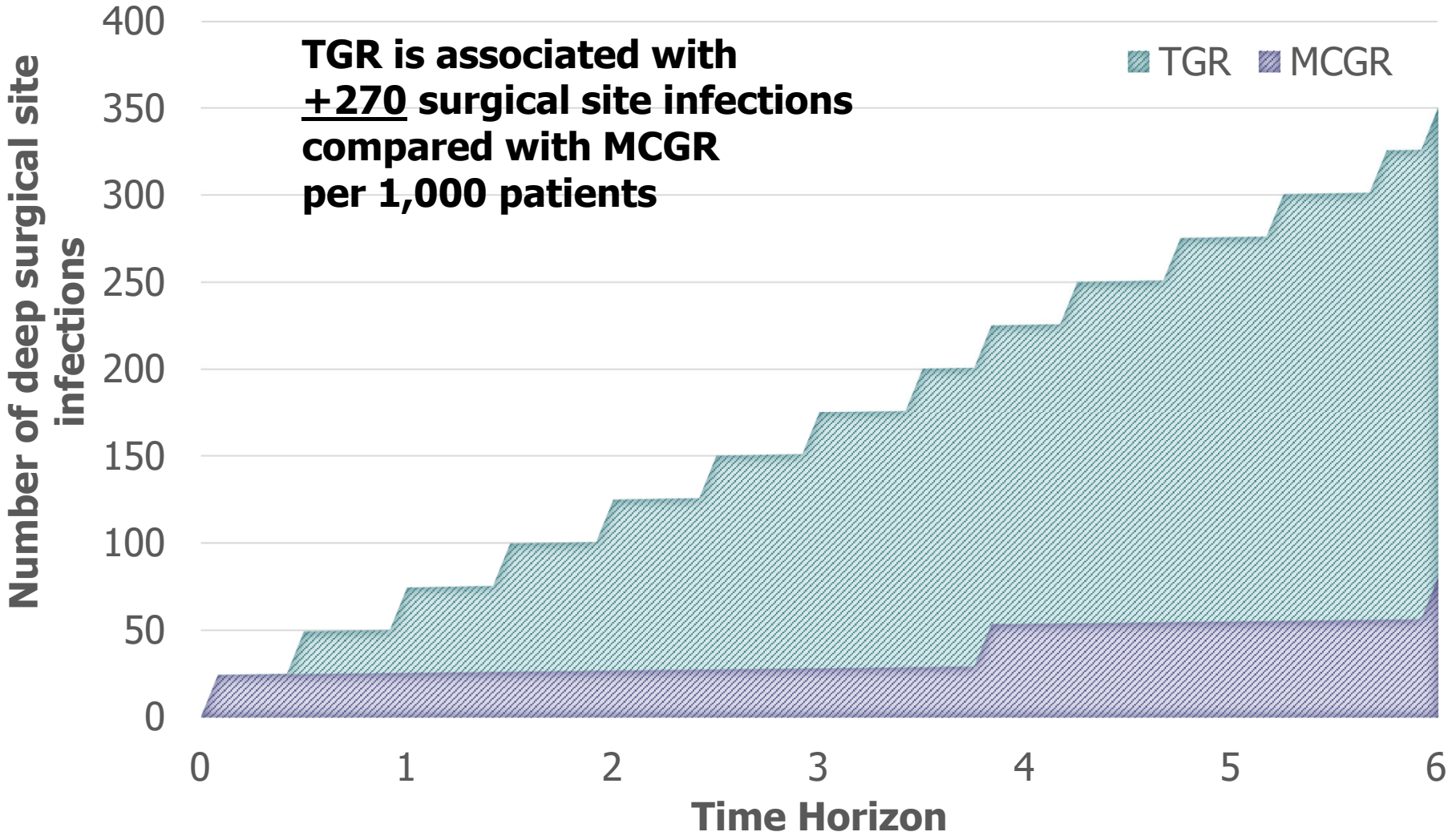


N.B. Includes Insertion, Exchange, Revisions, TGR Distractions, and Final fusion.

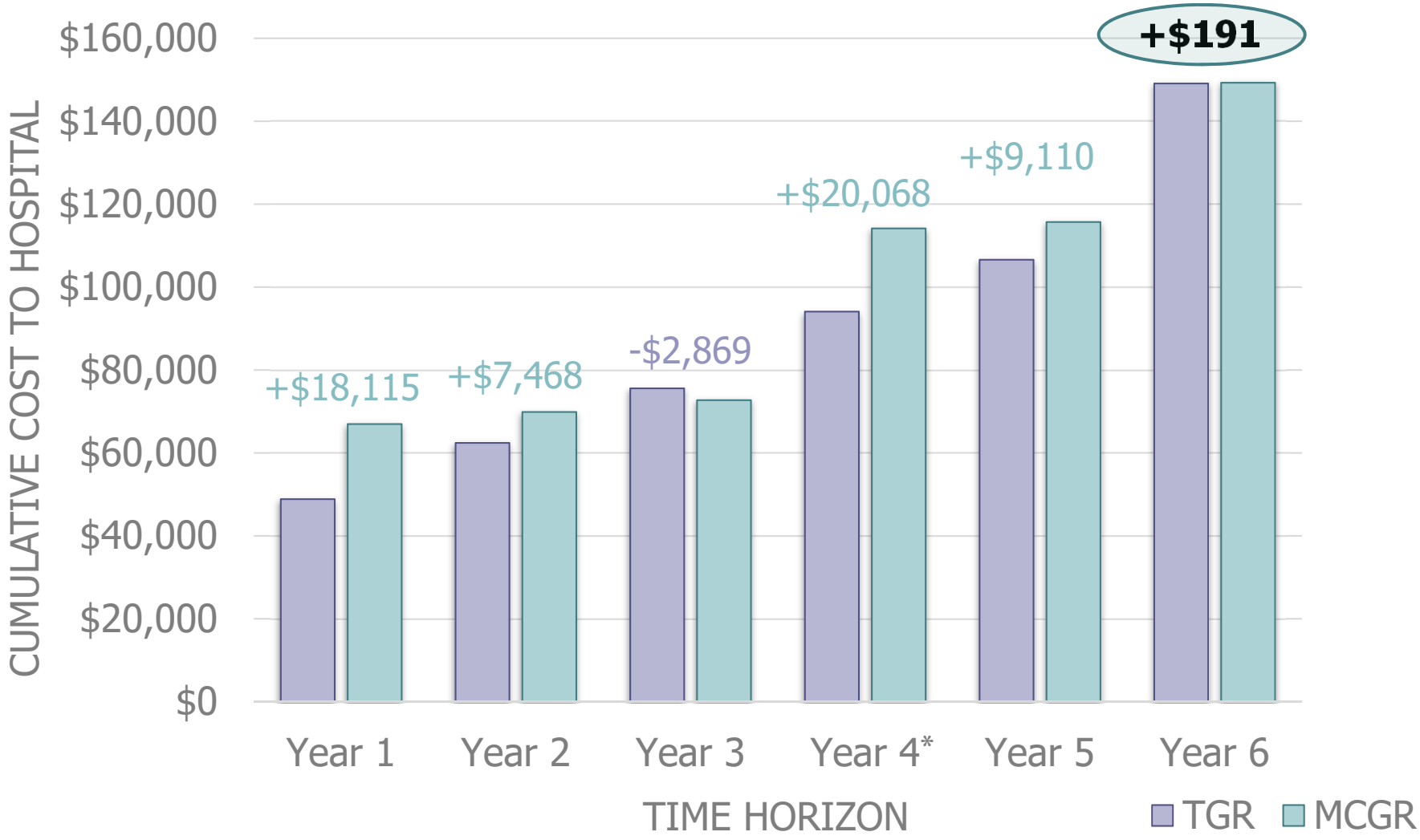
Results: Number of revisions, per cohort of 1,000 patients



Results: Number of deep infections, per cohort of 1,000 patients

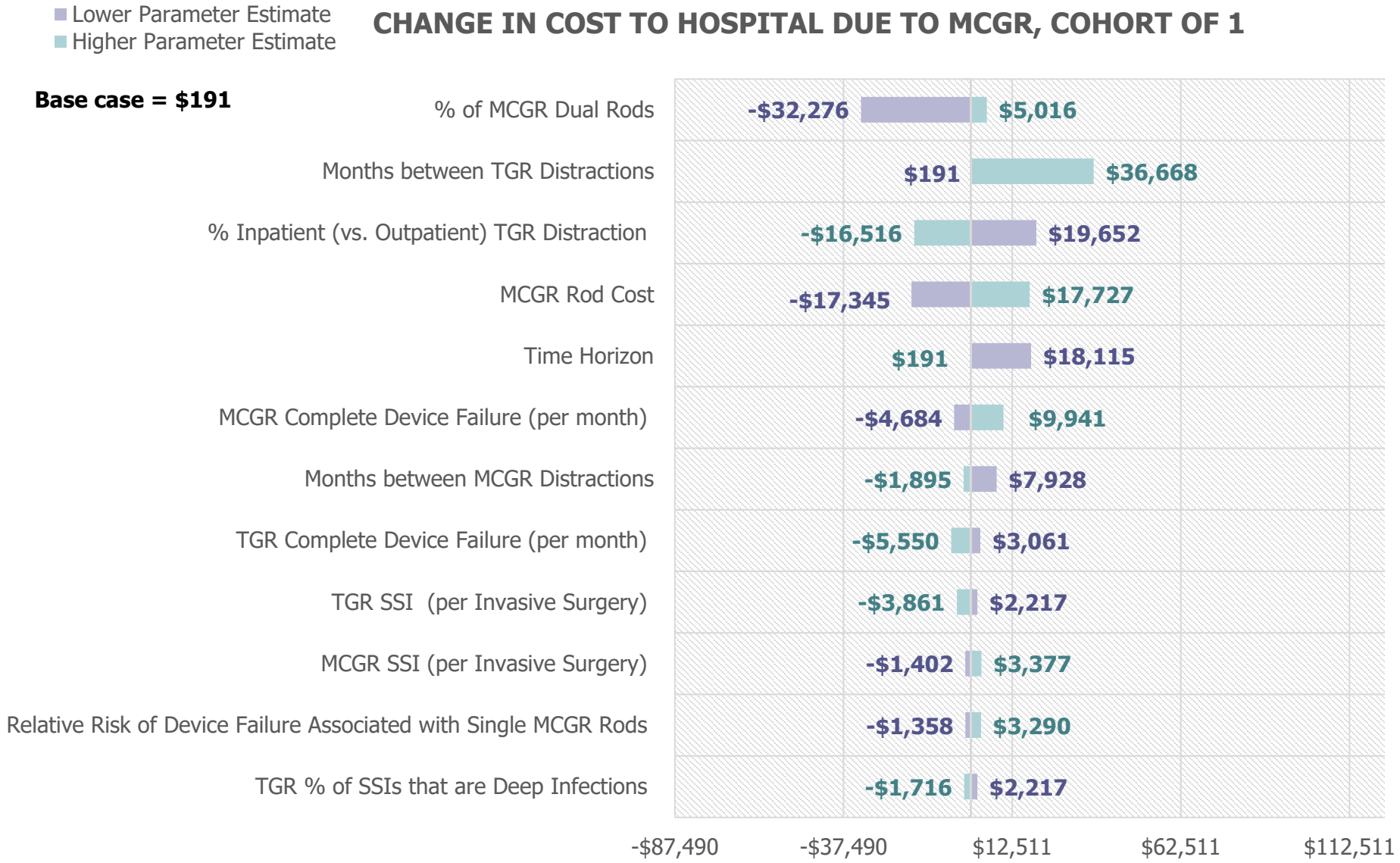


Results: Cumulative Cost, per patient



*Includes exchange surgery

Sensitivity Analysis



Key Cost Drivers

	Reduces MCGR Budget Impact	Base case	Increases MCGR Budget Impact
% of MCGR Dual Rods	**0%**	**85%**	**100%**
	-$32,276	$191	$5,016
Months between TGR Distractions	**6 months**	**6 months**	**12 months**
	$191	$191	$36,668
% Inpatient (vs. Outpatient) TGR Distraction	**0%**	**53.81%**	**100%**
	$19,652	$191	-$16,516
MCGR Rod Cost	**$13,125**	**$17,500**	**$21,875**
	-$17,345	$191	$17,727
Time Horizon	**1 year**	**6 years**	**6 years**
	$18,115	$191	$191
MCGR Complete Device Failure (per month)	**0.19%**	**0.37%**	**0.74%**
	-$4,684	$191	$9,941
Months between MCGR Distractions	**1 month**	**3 months**	**6 months**
	$7,928	$191	-$1,895
TGR Complete Device Failure (per month)	**0.30%**	**0.59%**	**1.18%**
	$3,061	$191	-$5,550

Cost offsets

Cost offsets for MCGR driven by:

- Non-invasive MCGR distractions
- Fewer infections
- 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

European Perspective I: France
Charroin et al. (2014)

Charroin C, Abelin-Genevois K, Cunin V, et al. Direct costs associated with the management of progressive early onset scoliosis: estimations based on gold standard technique or with magnetically controlled growing rods. Orthop Traumatol Surg Res **2014**; 100(5): 469-74. doi: 10.1016/j.otsr.2014.05.006. Epub Aug 13.

- Model: Cost minimization model
- Outcome: Incremental cost of MCGR compared to TGR
- Perspective: French Sickness Fund
- Time Horizon: 4 years
- TGR surgeries: 2.3 per patient year
- Rod fracture: 3.6% per TGR year; 4.7% per MCGR year
- Infection, exchange, and final fusion not included
- Discounting: 4% per annum
- Results (cumulative cost per patient)
  - Direct cost of TGR: **49,067 €**
  - Direct cost of MCGR: **42,752 €**

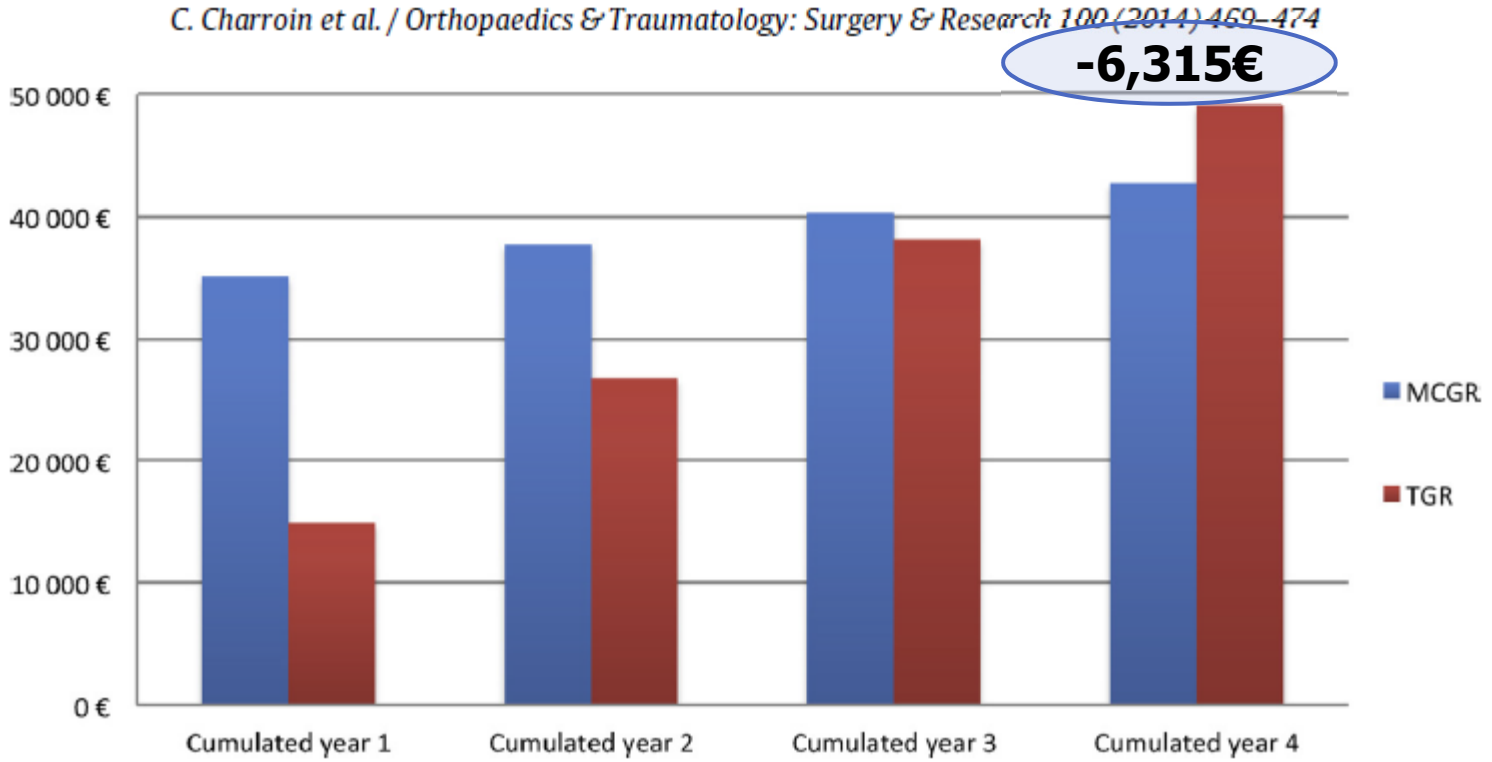


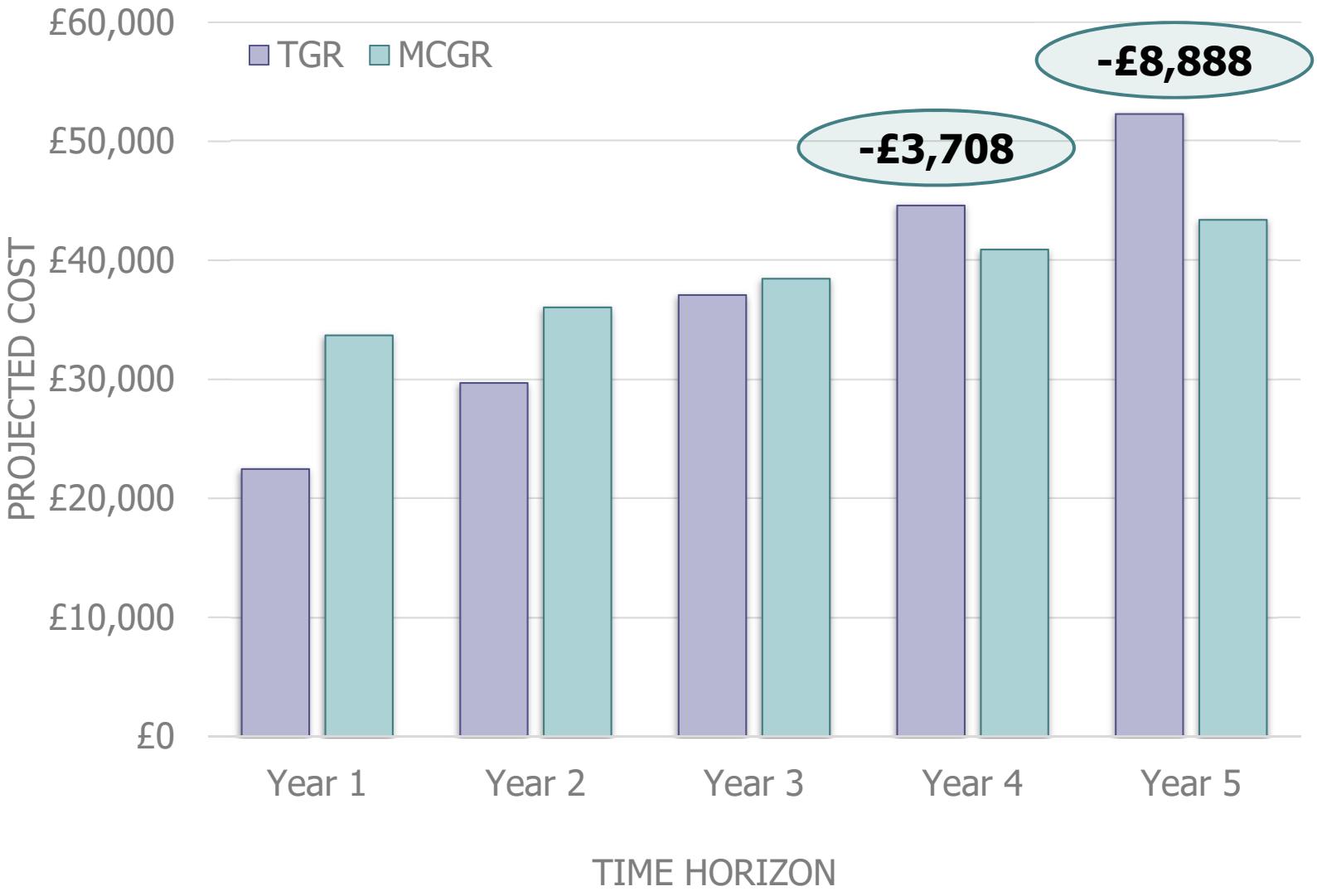
Fig. 1. Cumulated costs over time horizon for traditional growing rod and magnetically controlled growing rod strategies.

European Perspective II: United Kingdom
Rolton et al. (2014)

Rolton D, Richards J, Nnadi C. Magnetic controlled growth rods versus conventional growing rod systems in the treatment of early onset scoliosis: a cost comparison. Eur Spine J **2014**; 30: 30.

- Model: Budget impact model
- Outcome: Incremental cost of MCGR compared to TGR
- Perspective: Hospital
- Exchange and fusion surgeries do not appear to be considered
- Time Horizon: 5 years
- Discounting: Not stated, assume none
- Inflationary pressures of 2% per annum
- Results (cumulative cost per patient)
  - Direct cost of TGR: **£52,293**
  - Direct cost of MCGR: **£43,405**

Cumulative Cost Per Patient (Rolton et al.).



This analysis perspective does not account for:

- Pain, psychological distress, and compromised health-related quality-of-life associated with invasive TGR distraction surgeries.

- Shorter recovery time with MCGR distractions, which results in less time away from usual activities for young patients and their families.

Conclusion

- The cost impact of MCGR is offset by eliminating repeated TGR surgical lengthenings.

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