Safety and Quality in Early Onset Scoliosis – International Perspective

Ilkka J. Helenius, MD, PhD

Professor and Chairman

Department of Paediatric Orthopaedic Surgery, University of Turku and Turku University Hospital, Turku, Finland;



Turun yliopisto University of Turku

Disclosures

Ilkka Helenius: consultant for Medtronic; grants and research funding from Medtronic, Baxter International, K2M via Innosurge As.

Aims of Safety and Quality in EOS



Risk of complications high in growth-friendly management

58% Traditional growing rods during 5-yr
FU (Bess et al. JBJS 2010)
88% until graduation in severe EOS (Helenius et al. Spine 2019)

How can we improve safety? Is this improving our quality of care at the same time

Preoperative assessment Perioperative care Follow-up

Ideal Outcomes (Quality) Minimum # of surgical procedures & complications Best available correction and growth of spine

Preoperative assessment in EOS



Pehrsson et al. Spine 1992

Recognition of high risk patient groups Severe deformity Skeletal dysplasia Syndromic patients

Identification of associated medical conditions

Heart (pulmonary hypertension, cardiomyopathy) Pulmonary (restrictive lung disease) Great vessels (Loews-Dietz, Marfan) Epilepsy

The value of multiciplinary preoperative conference Orthopaedics, pediatrician, neurologist etc. Orthopaedic surgeon has to have the final responsibility

Standardization of Perioperative Care



"When a particular work flow is variable, unpredictable, and ambiguous, it is impossible to differentiate practices which yield value from those that produce waste" Founder of Lean Methodology, Taiichi Ohno

How much we can standardize perioperative care of early onset scoliosis as compared with adolescent idiopathic scoliosis?

Much more surgical options: Growth guidance, distraction based, compression based techniques available

1st task would be to describe our thinking process



The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

Alex B. Haynes, M.D., M.P.H., Thomas G. Weiser, M.D., M.P.H., William R. Berry, M.D., M.P.H., Stuart R. Lipsitz, Sc.D., Abdel-Hadi S. Breizat, M.D., Ph.D., E. Patchen Dellinger, M.D., Teodoro Herbosa, M.D., Sudhir Joseph, M.S., Pascience L. Kibatala, M.D., Marie Carmela M. Lapitan, M.D., Alan F. Merry, M.B., Ch.B., F.A.N.Z.C.A., F.R.C.A., Krishna Moorthy, M.D., F.R.C.S., Richard K. Reznick, M.D., M.Ed., Bryce Taylor, M.D., and Atul A. Gawande, M.D., M.P.H., for the Safe Surgery Saves Lives Study Group*

3733 vs. 3955 consecutive non-cardiac patients >16 years before and after implementation of surgical check list

Risk of death: $1.5\% \rightarrow 0.8\%$ (p=0.003)

Risk of Inpatient complication: $11.0\% \rightarrow 7.0\%$ (p<0.001)

VURNAL SOURNAL SOURNAL	 SPINE Improving quality spinal surgery THE TEAM APPROACH 	and safety in pa	ediatric	
F. Miyanji, B. Greer, S. Desai, J. Choi, J. Mok, M. Nitikman, A. Morrison From British Columbia Children's Hospital, Vancouver, Canada	Aims The aim of this study was to evaluate spinal surgery following the implemen (PSST) in the operating theatre. Patients and Methods A retrospective consecutive case stud January 2008 and December 2009), an the implementation of PSST, was per including surgical site infection (SSI), (LOS), unplanned staged procedures (was performed between the two grou postoperative years was also compare	improvements in the quality an itation of a specialist Paediatric of paediatric spinal operations d after (between January 2012 ormed. A comparative analysis operating time (ORT), blood los USP) and transfusion rates (allo ps. The rate of complications di between the groups.	rd safety of paediatric Spinal Surgical Team s before (between and December 2013) t of outcome variables ts (BL), length of stay ogenic and cell-saver) uring the first two	
urgical outcomes				
variables of interest		Pre-PSST (n = 130)	Post-PSST (n = 277)	p-value
ite infections, SSI, %		6.9	0.4	< 0.001
rating time (ORT), mir	(SD) (SD)	404.5 (14.4)	351.6 (6.7)	0.013
Ith of stay (LOS), days	; (SD)	14.3 (2.5)	8.9 (0.7)	0.019
mated blood loss (BL)	, ml (SD)	909.1 (93.5)	580.2 (30.1)	0.135
ime of allogeneic bloc	od transfused volume, ml (SD)	268.7 (42.4)	86.9 (14.0)	< 0.001

Table III. Su

Outcome variables of interest	Pre-PSST (n = 130)	Post-PSST (n = 277)	p-value [*]
Surgical site infections, SSI, %	6.9	0.4	< 0.001 [†]
Mean operating time (ORT), mins (SD)	404.5 (14.4)	351.6 (6.7)	0.013^{\dagger}
Mean length of stay (LOS), days (SD)	14.3 (2.5)	8.9 (0.7)	0.019^{\dagger}
Mean estimated blood loss (BL), mI (SD)	909.1 (93.5)	580.2 (30.1)	0.135
Mean volume of allogeneic blood transfused volume, ml (SD)	268.7 (42.4)	86.9 (14.0)	< 0.001 [†]
Mean volume of cell-saver blood transfused volume, ml (SD)	201.5 (40.9)	87.3 (7.8)	0.401
Unplanned staged procedures (%)	6.2	2.9	0.001 [†]



5-yr-old boy with Marfan



Preop

Index

2-yr FU

Conversion to MCGR – Is it safe?



2,3 yrs postop/9th lengthening

Eur Spine J (2016) 25:3294–3300 DOI 10.1007/s00586-016-4597-y

ORIGINAL ARTICLE

Preliminary comparison of primary and conversion surgery with magnetically controlled growing rods in children with early onset scoliosis

 $\begin{array}{l} \mbox{Heli Keskinen}^{1} \cdot \mbox{Ilkka Helenius}^{1} \cdot \mbox{Colin Nnadi}^{2} \cdot \mbox{Kenneth Cheung}^{3} \cdot \mbox{J. Ferguson}^{4} \cdot \mbox{Gregory Mundis}^{5} \cdot \mbox{Jeff Pawelek}^{5} \cdot \mbox{Behrooz A. Akbarnia}^{5} \end{array}$





Neuromonitoring change



Standard rod exchange and difficult revision of fixation points results into left-sided loss of motor evoked signals

Bone loss around left-sided pedicle screws

Checklist Neuromonitoring change

GAR CONTRA OF BOIRS	ANTERNOCOM	NO-ROL MUSICHING. OSC	BARK M
 Intrasponder packs step case and anotherapy to the room 	Contention content actions processing (MAP)	Checuse status, of presidente agents	Distance events and enforce sel prior to signal loss and consider reventing actions:
Eliminate extraneous strinut (e.g. maraic, porsenations, etc.)	Q Optimize Temploart	Check address of resentenceder bincheder and degrees of panelysis	D Remove Franken (F spokcatiko
C Summon AFTERDANG accelhesiologist, SCHOR	Contensions between performance process	Clock approves and convertings	Decressionnove distriction or other corrective forces
soundaged or soundcoatel, and EXPERENCED name	© Seali acontrotherania	Determine pattern and Brong of signal scheroper	C Remove rods
C Anterpatie road for intrasponitive and/or pertepantive imaging if nit readly desitible	Discuss POTENTIAL and Screeks-up Mit will. ATTENDERS areothesiologist	Check rook and link producing, shock link product of table impacially if unlateral fore	and proto for breach C Evaluate for spinal corel compression, examine oracionity and
and the state of the state of the	Whitebordy allow Chitrarportative anothr performative imaging (e.g. O-see, Americanopy, x-ray) to evaluate replace photometric		
 REVEXT exectled by the bit considerations and confirm that they are optimized Webship test Executed on with a colleager Continue surgical procedure versus staging procedure N starsic process: Mathybrid isolates to taging in first to, then 5.4 mg/hg/tr for east. 23 forst 			

Vitale et al. Spine Def 2015

Protocol: Neuromonitoring change



Checklist started

Turns out that pedicle probe has been too medial when preparing the revision screws

Surgery paused

MAP elevated >90mmHg

Hb, Arterial gas optimized

Left-sided MEPs return within 20 minutes

O-arm and navigation brought into the room

Navigated pedicle screws inserted without complications

No postoperative deficit

Screw Pull-Out with Neuro Deficit



Conversion to MCGR 2.5 years after index surgery (four Th PS & no cross-link) 1.5 years later screw pull-out and canal encroachment producing progressive paraplegia After revision surgery complete recovery



SPINE
Outcomes of growing rod surgery for severe compared with moderate early-onset scoliosis

A MATCHED COMPARATIVE STUDY

I. J. Helenius, H. M. Oksanen, A. McClung, J. B. Pawelek, M. Yazici, P. D. Sponseller, J. B. Emans, F. J. Sánchez Pérez-Grueso, G. H. Thompson, C. Johnston, S. A. Shah, B. A. Akbarnia

107 severe EOS vs. 107 Matched moderate EOS

More complications in the severe group. Surgery can not be delayed beyond $MC > 90^{\circ}$

Risk of neurologic deficits in severe EOS: 4.7% (5/107)

Mechanisms of neurologic deficits

- 1. Difficulties in placing upper thoracic pedicle screws revision (5 pts)
- 2. Pedicle screw pull-out (2 pts)
- 3. Correction of severe deformity (2 pts)

Other methods than pedicle screws should be considered at upper thoracic spine to improve safety at least in difficult revisions.

Neuromonitoring mandatory not only in index but also during revisions

How should we end GR treatment?



After repeated lengthenings spine becomes stiff (autofusion) and no formal final fusion may be necessary allowing observation only (Jain et al. JBJS 2016)

Removal of GR instrumentation results into recurring deformity (Kocyigit et al. JBJS 2017)

Growing Rod Graduate



4-year-old girl with 94° idiopathic early onset scoliosis. 10-yr FU. Two rod fractures. No final fusion. 3 years follow-up after last lengthening / Courtesy of Professor Paul Sponseller, MD

Sagittal balance



Same patient as in the previous slide. Note elongation of vertebral bodies.

Mean 6-Year Follow-up of Magnetically Controlled Growing Rod Patients With Early Onset Scoliosis: A Glimpse of What Happens to Graduates

Jason Pui Yin Cheung, MBBS,
MMedSc, MS, FHKCOS,
FHKAM(Orth), FRCS(Edin)
Karen Yiu, MSc
Kenny Kwan, FHKCOS,
FHKAM, FRCSEd
Kenneth MC Cheung, MBBS,
MD, FRCS, FHKCOS, FHKAM

BACKGROUND: There is no agreement on frequency of distractions of magnetically controlled growing rods (MCGRs) but more frequent and smaller amounts of distractions mimic physiological spine growth. The mid- to long-term follow-up and management at skeletal maturity is unknown.

OBJECTIVE: To analyze patients with mean 6 yr of follow-up and describe the fate of MCGR graduates.

METHODS: Early onset scoliosis (EOS) patients treated with MCGRs with minimum 4 yr of follow-up and/or at graduation were studied. Parameters under study included Cobb angle, spine and instrumented lengths, and rod distraction gains. Relationship between timing of rod exchanges with changes in rate of lengthening was studied.

Neurosurgery 0:1–12, 2018

DOI:10.1093/neuros/nyy270

www.neurosurgery-online.com

- 10 children (mean age 10.1 years)
- Min 4-yr FU (mean 6.1 years), mean 40.1 distractions
- Mean T1-S1 growth (post-index 4yr FU): 35 mm = 8.8 mm / year
- 40% risk for rod distraction failure
- 4 underwent posterior spinal fusion
 - Limited major curve correction (stiff spine)
 - Additional T1-S1 length gain 20 mm
 - Metallosis around the rod-anchor junction and extendable portion of MCGR
- "Surgeons should consider removal of the rods as soon as the patient is in the graduation stage"

Final Fusion after MCGR





Final fusion



Outcomes

Perioperative Outcome in Posterior Spinal Fusion for Adolescent Idiopathic Scoliosis

A Prospective Study Comparing Single Versus Two Attending Surgeons Strategy

Chris Yin Wei Chan, MS, Orth, and Mun Keong Kwan, MS, Orth

In AIS two attending surgeons shorten operative time (-30%, p<0.001) and reduce blood loss (-26%, p<0.05)

Postoperative morphine use reduced by 50%, p<0.001

Copyright © 2018 by The Journal of Bone and Joint Surgery, Incorporated

Tranexamic Acid Is Efficacious at Decreasing the Rate of Blood Loss in Adolescent Scoliosis Surgery

A Randomized Placebo-Controlled Trial

Susan M. Goobie, MD, FRCPC, David Zurakowski, PhD, Michael P. Glotzbecker, MD, Mary E. McCann, MD, MPH, Daniel Hedequist, MD, Robert M. Brustowicz, MD, Navil F. Sethna, MD, Lawerence I. Karlin, MD, John B. Emans, MD, and M. Timothy Hresko, MD





I. Helenius, H. Keskinen, J. Syvänen, H. Lukkarinen, M. Mattila, J. Välipakka, O. Pajulo

From Turku University Hospital, Turku, Finland

SPINE

Gelatine matrix with human thrombin decreases blood loss in adolescents undergoing posterior spinal fusion for idiopathic scoliosis

A MULTICENTRE, RANDOMISED CLINICAL TRIAL

VOL. 98-B, No. 3, MARCH 2016

- Gelatin matrix with human thrombin
 - Decreased blood loss by 171 mL (-31%), p = 0.027
 - Hb decreased less (-6g/l), p = 0.013
 - Level I evidence

Preemptive Pregabalin: No Reduction in Pain or Opioid Use

Total oxycodone consumption, mg/kg/h



• Double-blind, randomized clinical trial on 63 children undergoing posterior spinal fusion (Level I evidence) JBJS 2020, in press.

Our intraoperative protocol

- Dedicated Spine Team (Surgical & Anesthesiology)
- Tranexamic acid 30mg/kg iv + bolus 10mg/kg/h
- Cefuroxime 30mg/kg iv 15 min before incision
- Two attending surgeons
- Use of gelatin matrix with human thrombin for bleeding pedicles & tunneling if bleeds
- O-arm & navigation in every revision of fixation points

Postoperative care

- At our institution at postoperative intensive care unit
 - MAP aim for 24 hours postop
 - Mobilization more than difficult than on ward
- Do we need brace?
- Standardization of lengthening intervals and final fusion

Conclusions

Description of protocols is important to reduce variablity Anaesthetic and surgical protocols How to select method: MCGR, TGR, VEPTR etc

Checklist to increase awareness WHO surgical checklist (preop & postop) Checklist for neuromonitoring change

Difficult to provide Level I evidence on early onset scoliosis RCT on MCGR vs. TGR ongoing (PSSG) Extrapolation from AIS studies typically employed