

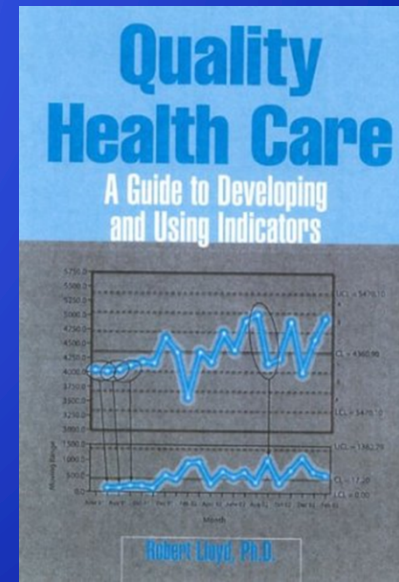


Complications in Spine Surgery

Classification and Impact



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Disclosures

- Research/Institutional Support:
NIH, NSF, AO Spine, OREF
- Honoraria:
Medtronic, DePuy, Stryker, Globus, Innovasis
- Ownership/Stock/Options:
Providence Medical, Simpirica
- Royalties:
Medtronic, Stryker

Overview

- Variability in description of complications
 - Severity
 - Rates
- Utility of a systematic categorization
 - Define the risk/appropriateness of treatment options
 - Quality of care metric
 - Outcome variable in predictive modelling
- Review of complication classifications
- Development of a universal system for classifying complications

Describing Complications

MAJOR

Minor

SERIOUS

Expensive

Impactful

Permanent

Transient

Devastating

Defining the Complication Problem

- Complications are an important metric for quality of care
- Complications are critical for defining the risks of care and appropriateness of interventions
- Understanding complications is fundamental to empower informed choice
- The rate and impact of complications are highly variable

Goals of a Classification System

- Systematic categorization for comparison of alternative treatment options
- Correlate severity with impact
 - Duration
 - Treatment required
 - Health-related quality of life
 - Cost of Care
- Outcome variable in predictive modelling
- Guide Evidence-based Decision-making

Importance of Studying Complications

- Knowledge of these complications is important and valuable for both the patient and the surgeon.
 - Empowering patient informed choice
 - Informing the choice of surgical strategies that optimize the ability to effectively minimize the risks of complications.
- Recognition of potential complications may lead to prevention of adverse outcomes in practice
- Complications are the most commonly used proxy for quality of care

Spectrum of Perioperative Complications

- Neural
- Cardiac
- Pulmonary
- Gastrointestinal
- Renal/Genitourinary
- Hematologic
- Infectious
- Endocrine
- Integumentary
- Musculoskeletal
- Implant related
- Anesthetic Complications
- Death



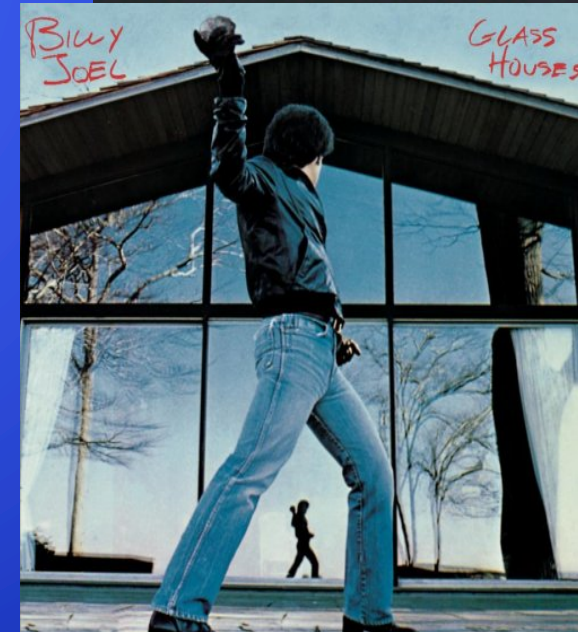
What is an acceptable Rate?

- Observed Rate of Complications
- Expected Rate of Complications
- O:E ratio provides a meaningful metric of quality of care
- Requires accurate risk stratification and global standardization/benchmarking



What is an acceptable Rate?

- Institutional Database
- Society/Academy Database
- Case Reports/Series
- Prospective IDE trials



Detecting Perioperative Complications

Broad Spectrum of Reported Rates

- Database limitations
 - Institutional databases
 - Voluntary society databases
 - Insurance databases
- Need to return to OR for resolution
- Perioperative vs Late complications



Scoliosis Research Society Morbidity and Mortality of Adult Scoliosis Surgery

Charles A. Sansur, MD, MHSc,* Justin S. Smith, MD, PhD,† Jeff D. Coe, MD,‡ Steven D. Glassman, MD,||
Sigurd H. Berven, MD,§ David W. Polly Jr., MD,¶ Joseph H. Perra, MD,# Oheneba Boachie-Adjei, MD,**
Christopher I. Shaffrey, MD†

SPINE Volume 36, Number 9, pp E593–E597

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- 108,480 cases submitted between 2004 and 2007
 - 4980 cases of adult scoliosis (AS)
- 521 patients with complications (10.5%)
 - total of 669 complications (13.4%)
- Predictors of complications:
 - Osteotomies
 - Revision Surgery
 - Combined Anterior/Posterior Approaches

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TABLE 1. Complications in 4980 Cases of Adult Scoliosis Patients from the Years 2004–2007 Stratified by Patient Age

Complication, N (%)	Patient Age* (yrs)		
	All (n = 4980)	≤60 (n = 2920)	>60 (n = 2060)
Dural tear	142 (2.9%)	77	65
Wound infection			
Superficial	46 (0.9%)	28	37
Deep	73 (1.5%)	43	46
Implant complication	80 (1.6%)	50	30
Acute neurological	49 (1.0%)	31	18
Delayed neurological	41 (0.5%)	22	19
Epidural hematoma	12 (0.2%)	8	4
Wound hematoma	22 (0.4%)	12	10
Cardiac	7 (0.1%)	1	6
Pulmonary embolus	12 (0.2%)	7	5
Pulmonary (not PE)	31 (0.5%)	21	10
DVT	9 (0.2%)	4	5
Death	17 (0.3%)	9	8
Sepsis	6 (0.1%)	3	3
Visual acuity change	3 (0.06%)	2	1
Other complication	119 (2.4%)	65	54
Total number patients with complications	521 (10.5%)	295 (10.1%)	226 (11.0%)
Total complication†	669 (13.4%)	384 (13.2%)	321 (15.6%)

DEFORMITY

The Morbidity and Mortality of Fusions from the Thoracic Spine to the Pelvis in the Adult Population

Christopher R. Howe, MD, Julie Agel, MA,* Michael J. Lee, MD,† Richard J. Bransford, MD,* Theodore A. Wagner, MD,† Carlo Bellabarba, MD,* and Jens R. Chapman, MD*

TABLE 1. Return to the Operation Theatre

Infection	18 (17%)
Adjacent segment disease	12 (12%)
Nonunion	4 (4%)
Lumbosacral hardware failure	3 (3%)
Epidural hematoma	2 (2%)
Hardware removal	1 (1%)
Retained drain removal	1 (1%)
Removal of symptomatic hardware	1 (1%)
Displaced interbody allograft	1 (1%)
Total	43 (35%)

TABLE 2. Medical Complications in the 103 Patients

Major Complication	Number
Myocardial infarction	4 (4%)
Pulmonary embolism	4 (4%)
Adult respiratory distress syndrome	4 (4%)
Pneumonia	4 (4%)
Acute renal failure	3 (3%)
Cerebrovascular accident	3 (3%)
Blindness	1 (1%)
Total	23 (12%)

Scoli-RISK-1: Neural Change

	Total
Discharge (N = 266)	
Decline	59 (23%)
Six Weeks (N = 268)	
Decline	48 (18%)
Six Months (N = 268)	
Decline	30 (11%)



Prospective multicenter assessment of perioperative and minimum 2-year postoperative complication rates associated with adult spinal deformity surgery

J Neurosurg Spine February 26, 2016

Justin S. Smith, MD, PhD,¹ Eric Klineberg, MD,² Virginie Lafage, PhD,³ Christopher I. Shaffrey, MD,¹ Frank Schwab, MD,³ Renaud Lafage, MS,³ Richard Hostin, MD,⁴ Gregory M. Mundis Jr., MD,⁵ Thomas J. Errico, MD,³ Han Jo Kim, MD,⁵ Themistocles S. Protopsaltis, MD,³ D. Kojo Hamilton, MD,⁶ Justin K. Scheer, BS,⁷ Alex Soroceanu, MD,⁸ Michael P. Kelly, MD,⁹ Breton Line, BSME,¹⁰ Munish Gupta, MD,² Vedat Deviren, MD,¹¹ Robert Hart, MD,¹² Douglas C. Burton, MD,¹³ Shay Bess, MD,¹⁰ Christopher P. Ames, MD,¹⁴ and the International Spine Study Group

- Prospective study of 346 patients, 291 with 2 year f/u their mean age was 56.2 years.
- Overall, 203/291 patients (69.8%) had at least one complication
 - 52.2% of patients with perioperative complication
 - 42.6% of patients had a delayed complication
 - 28.2% required at least one revision

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TABLE 2. Rates of complications in 291 patients surgically treated for ASD who had a minimum 2-year follow-up

Complication Category	Minor/Major Complications (%)		
	Periop (<6 wks)	Delayed (>6 wks)	Total
Implant	3/8 (3.8)	11/59 (24.1)	14/67 (27.8)
Radiographic	4/10 (4.8)	25/42 (23.0)	29/52 (27.8)
Neurological	21/24 (15.5)	16/20 (12.4)	37/44 (27.8)
Operative	41/32 (25.1)	0/1 (0.3)	41/33 (25.4)
Cardiopulmonary	31/20 (17.5)	1/3 (1.4)	32/23 (18.9)
Infection	11/20 (10.7)	5/7 (4.1)	16/27 (14.8)
Gastrointestinal	24/1 (8.6)	0/0 (0)	24/1 (8.6)
Wound (excluding infection)	3/7 (3.4)	0/5 (1.7)	3/12 (5.2)
Vascular	4/0 (1.4)	1/0 (0.3)	5/0 (1.7)
Musculoskeletal	0/0 (0)	3/0 (1.0)	3/0 (1.0)
Renal	1/2 (1.0)	0/0 (0)	1/2 (1.0)
Other	2/1 (1.0)	0/0 (0)	2/1 (1.0)
Total (minor/major)	270 (145/125)	199 (62/137)	469 (207/262)
Mean no. of complications/patient (minor/major)	0.93 (0.50/0.43)	0.68 (0.21/0.47)	1.61 (0.71/0.90)
Number of patients affected (%)	152 (52.2)	124 (42.6)	203 (69.8)

Impact of Complications

- Quantifying Severity
 - Treatment-based measures
- Clinical Outcome
- Economic Outcome



Limitations of Major/Minor Classification

- Subjective assessment with poor reliability
- Poor correlation with:
 - Impact of Complication
 - Cost of Complication
 - Patient-assessment of complication severity



The Impact of Perioperative Complications on Clinical Outcome in Adult Deformity Surgery

SPINE Volume 32, Number 24, pp 2764–2770

Steven D. Glassman, MD,*† Christopher L. Hamill, MD,‡ Keith H. Bridwell, MD,§
Frank J. Schwab, MD,¶ John R. Dimar, MD,*† and **Thomas G. Lowe, MD||

- Matched cohort study comparing patients with major, minor and no complications after surgery for ASD
- Minor Complications had little impact on health status at 1 year after surgery
- Major Complications were associated with worsening of general health status at 1 year follow-up compared to patients with no or minor complications

The Impact of Perioperative Complications on Clinical Outcome in Adult Deformity Surgery

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Table 1. List of the Complications Noted as Part of the Adult Deformity Outcomes Study

	Intraoperative Complications	Postoperative Complications Noted Before Hospital Discharge	Complications Noted at Follow-up
Major	Bowel/bladder deficit Cardiac arrest Cauda equina deficit Cauda equina injury Cord deficit Death Inadvertent extubation Malignant hyperthermia Nerve root injury Optic deficit Vascular injury Visceral injury	Bowel or bladder deficit Death Deep vein thrombosis Infection—deep Motor deficit Myocardial infarction Neurological complications Optic deficit Pneumonia Pulmonary embolism Reintubation Sepsis Stroke Other cardiopulmonary	Instrumentation or junctional failure Cerebrovascular accident Infection—deep wound Myocardial infarction Major neurological deficit Pneumonia Pulmonary emboli Deep vein thrombosis Wound dehiscence Vascular injury
Minor	CSF Excessive bleeding Ineffective fixation Intraoperative coagulopathy Pedicle infraction Posterior element fracture Vertebral body fracture	Infection—superficial Postoperative radiculopathy Sensory deficit Skin complications Excessive postoperative bleeding Thrombophlebitis-superficial	Infection—superficial Minor neurological deficit Postoperative CSF leak Seroma Thrombophlebitis-superficial

Spine Adverse Events Severity System SAVES



**Spine Study Group
Adverse Event Form**

Version 1.0 (2015)

To be completed by the treating physician

Read the instructions carefully before completing this form. It is intended to be used as a standard form for reporting adverse events in spine surgery. It is not intended to be used for non-surgical spine procedures. It is not intended to be used for non-surgical spine procedures. It is not intended to be used for non-surgical spine procedures.

1. Patient Information

2. Procedure Information

3. Adverse Event Information

4. Management and Outcome

5. Comments

6. Signature and Date

NORTH AMERICAN SPINE SOCIETY
and
THE SPINE JOURNAL

2015 OUTSTANDING PAPER AWARD
Surgical Science

is presented to
Sven Karstensen, BSc; Tamir Bari, BSc; Martin Gehrhan, MD, PhD;
John Street, MD, PhD; Benny Dahl, MD, PhD, DMSc

Morbidity and Mortality of Complex Spine Surgery:
A Prospective Cohort Study in 679 Patients Validating the
Spine Adverse Event Severity (SAVES) System in a European Population

Impact-based Classification of Complications

- Grading adverse events by clinical impact:

I: No or Minimal Treatment Required

II: Treatment required with no expected sequelae at > 6mos

III: Treatment required with expected sequelae at >6 mos

IV: Death

An economic evaluation of perioperative adverse events associated with spinal surgery

Erik K. Hellsten, BA^{a,b}, Michelle A. Hanbidge, BESC^c, Aspasia N. Manos, BSc^a,
Stephen J. Lewis, MD, FRCSC^{d,e}, Eric M. Massicotte, MD, FRCSC^{e,f},
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The Spine Journal 13 (2013) 44–53

■ Clinical impact and Cost:

I:	\$4224	3.6 days
II:	\$23,500	14 days
III:	\$147,285	74.5 days
IV:	\$121,366	46.4 days

Reoperation rates and impact on outcome in a large, prospective, multicenter, adult spinal deformity database

Clinical article

J Neurosurg Spine 19:464-470, 2013

JUSTIN K. SCHEER, B.S.,¹ JESSICA A. TANG, B.S.,¹ JUSTIN S. SMITH, M.D., PH.D.,² ERIC KLINEBERG, M.D.,³ ROBERT A. HART, M.D.,⁴ GREGORY M. MUNDIS JR., M.D.,⁵ DOUGLAS C. BURTON, M.D.,⁶ RICHARD HOSTIN, M.D.,⁷ MICHAEL F. O'BRIEN, M.D.,⁷ SHAY BESS, M.D.,⁸ KHALED M. KEBASHI, M.D.,⁹ VEDAT DEVIREN, M.D.,¹⁰ VIRGINIE LAFAGE, PH.D.,¹¹ FRANK SCHWAB, M.D.,¹¹ CHRISTOPHER I. SHAFFREY, M.D.,² CHRISTOPHER P. AMES, M.D.,¹² AND THE INTERNATIONAL SPINE STUDY GROUP

■ Impact of Reoperation

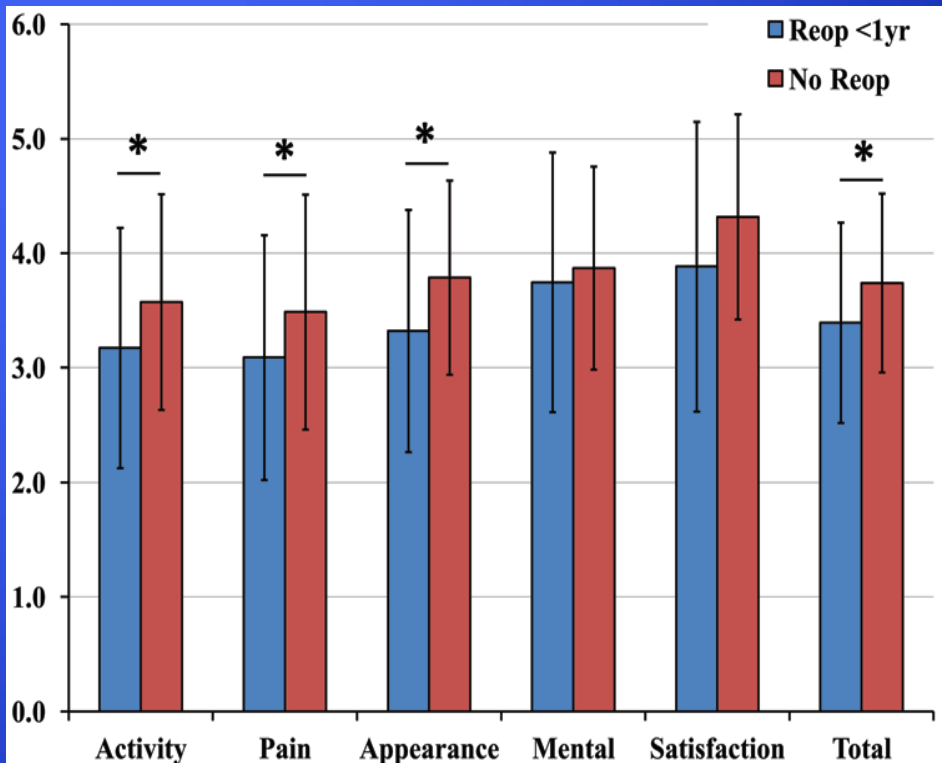
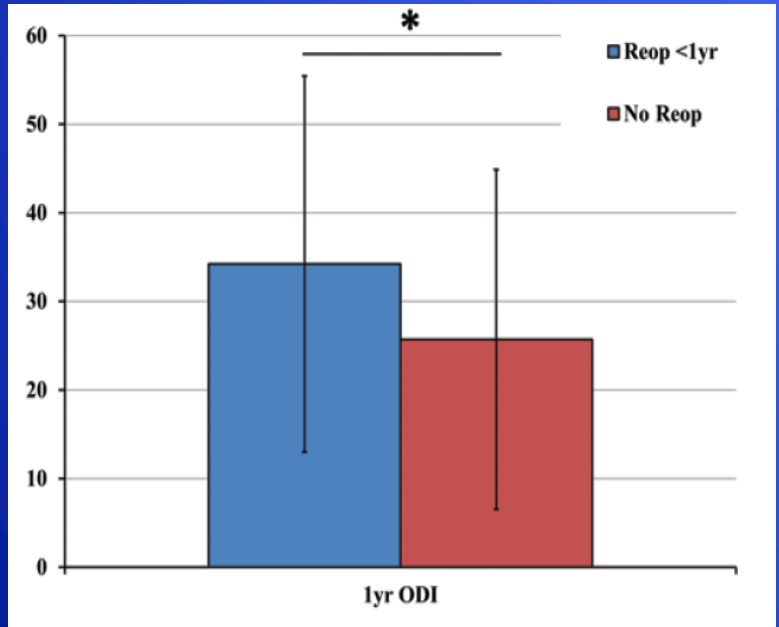


FIG. 1. Mean total ODI score for patients who underwent reoperation within 1 year compared with score for those who did not.

Complication Classification- Short

- 1) Complication: System and Description
- 2) Severity- Non-neural:
 - 1) No intervention
 - 2) Testing/Diagnostic
(Monitoring alone, blood work, imaging, consultation);
Minimal Interventions (Medicine changes, transfusion, intra-operative)
 - 3) Invasive Non-surgical interventions
(Injections, IVC, cardioversion, Hemo-dialysis, angio, chest tube)
 - 4) Surgical Intervention (or aborted surgery)
- 3) Severity- Neural:
 - 1) Radicular injury with LEMS change <5
 - 2) Radicular injury with LEMS change ≥ 5
 - 3) Spinal cord injury- incomplete, ambulatory with assistance
 - 4) Spinal cord injury- complete and/or bowel/bladder deficit
- 4) Resolution:
 - 1) Completely resolved
 - 2) Residual impairment- unresolved
 - 3) Chronic impairment
 - 4) Death

Conclusions

- Complications in deformity surgery are significant and classifying complications is a priority for future research
- Classification system should have high correlation with:
 - Clinical Impact of Complications
 - Duration of impact/Recovery Rate
 - Cost of Complication
- Limited burden of data capture
 - Periop
 - Follow-up
- Utility in Establishing Quality Benchmarks and in quantifying risks and appropriateness of treatment options



UCSF Center for Outcomes
Research