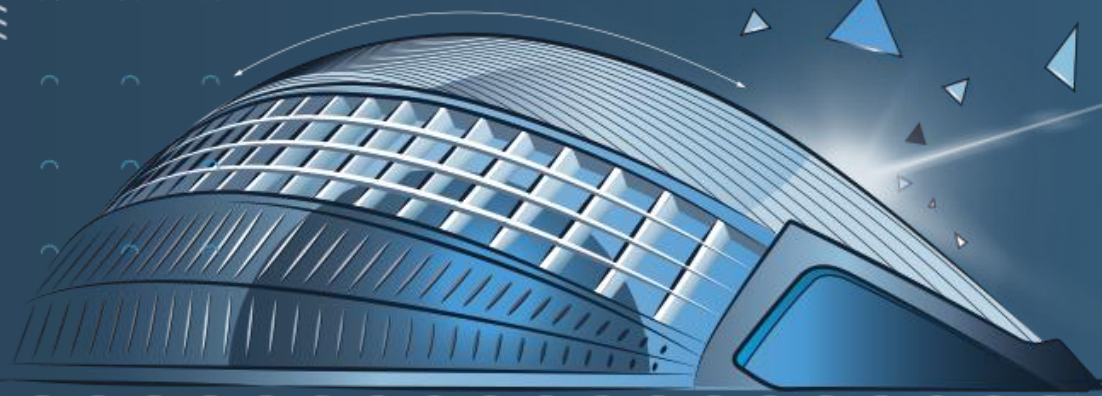


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June 23 – 25, 2022 / Valencia – Spain

Dr. Ali H. Mesiwala, MD, FAANS



Criteria for Choice of Medical Device Manufacturer in Deformity/Degenerative Spinal Surgery

- Personal relationships
- Economic factors
- Ease of use, unique features
- Environmental impact
- Data (improvement in outcome, reduction in complications)

Neo Universal: Cost Improvements



COST ↓ Lowering operational costs by *saving over \$1600/€1415 per case (EU)*

COST ↓ Improved intraoperative efficiency by *cutting time spent in surgery by almost 30%*

COST ↓ Decluttering the O.R. by *reducing instrument & implant requirements by 90%+*

**VALUE
BASED
CARE**



Neo Universal: A Total Technology Ecosystem

Single Use Sterile Platforms
*Pedicle Screws & T/PLIF

Force Control Capabilities
*Implant Failure Reduction

Neo Universal

Accessible AI/AR Technology
*No capital equipment required

Degen. Tumor/Traum a Deformity MIS

Neo Universal: Outcome Improvements

¹Abdalla Y, Hajdari S. New approaches to proven technology: force control posterior thoracolumbar fusion with an innovative pedicle screw system. In review.

²Fusion with the neo pedicle screw and cage systems: a post market clinical follow-up study. Data on file.

RESULT ↑ Improving patient outcomes by **reducing implant loosening & failure by 3x¹⁻²**

RESULT ↑ Improving patient outcomes by **reducing implant deep infection rate to around 1%¹**

QUALITY ↑ Reducing environmental damage through material efficiency by **lowering carbon footprint per case by 75%**



Reoperation Rates

Original Article

Early and Late Reoperation Rates With Various MIS Techniques for Adult Spinal Deformity Correction

Global Spine Journal
2019, Vol. 9(1) 41-47
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Study Design: A multicenter retrospective review of an adult spinal deformity database.

Objective: To characterize reoperation rates and etiologies of adult spinal deformity surgery with circumferential minimally invasive surgery (cMIS) and hybrid (HYB) techniques.

Table 3. Reoperation Timing and Indications for HYB and cMIS Approaches^a.

	HYB	cMIS	P
N	65	68	
Reoperation	22 (33.8%)	19 (27.9%)	.461
Acute	4 (6.1%)	1 (1.5%)	.156
Late	18 (27.7%)	18 (26.5%)	.874
Indications			
Infection	4 (6.1%)	1 (1.5%)	.156
Neurologic	4 (6.1%)	2 (2.9%)	.372
Fixation failure/pseudarthrosis	4 (6.2%)	10 (14.7%)	.169
Fixation failure	4 (6.1%)	6 (8.8%)	.559
Pseudo	1 (1.5%)	4 (5.9%)	.188
Junctional failure	9 (13.8%)	7 (10.3%)	.529
DJF (distal junctional failure)	2 (3.1%)	4 (5.9%)	.436
PJF (proximal junctional failure)	8 (12.3%)	3 (4.4%)	.098
CSF leak	2 (3.1%)	0 (0.0%)	.145
Bowel/bladder	1 (1.5%)	0 (0.0%)	.305

Abbreviations: HYB, hybrid technique; cMIS, circumferential minimally invasive surgery; CSF, cerebrospinal fluid.

Conclusions: Adult spinal deformity correction with cMIS and HYB techniques result in overall reoperation rates **27.9%** and **33.8%**, respectively, at minimum 2-year FU.

The acute reoperations were much less common than later (>30 days) reoperations for both groups.

Complications in Adult Spinal Deformity Surgery

Original Article

Classifying Complications: Assessing Adult Spinal Deformity 2-Year Surgical Outcomes

Global Spine Journal
2020, Vol. 10(7) 896-907
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Data Collection

Retrospective review of prospective database.

Patient data was recorded by surgeons on standardized data collection sheets and collected in a multisurgeon database.

“Complication rates for ASD reported in the literature vary. The recent ASD literature review by Nasser et al. identified a thoracolumbar complication incidence range of <1% -70%. More typical estimates, though, usually range from 8% - 40%”

Table 1. List of Most Commonly Experienced Complication Categories and Specific Complication Subtype Frequencies Per Operative Period (Intraoperative, Perioperative, Postoperative) Broken Down by Severity (Minor-Major).

Operative stage	Type	Complication category, subtype		Frequency
Intraoperative (n = 51: 30.5%)	Major (15.0%)	Cardiopulmonary	Other	2
		Implant	Medial screw breach	1
		Neurological	Motor deficit	3
		Operative	Excessive bleeding	19
		Cardiopulmonary	Arrhythmia	3
		GI	Ileus	1
		Implant	Interbody dislocation	1
	Minor (12.6%)	Neurological	Nerve root injury	2
			Sensory deficit	2
		Operative	Dural tear	11
		Renal	Other	1
		Cardiopulmonary	DVT	4
			Pulmonary embolism	4
		GI	Other	1
Perioperative (n = 81: 48.5%)	Major (12.0%)	Implant	Implant prominence	1
			Screw breakage	1
		Infection	Deep	2
		Neurological	Motor deficit	2
		Operative	Bowel perforation	1
		Radiographic	PJK	1
		Renal	Renal failure	1
		Wound	Dehiscence	1
			Erythema	1
			Pleur effusion	16
		GI	Ileus	18
	Minor (31.7%)	Implant	Screw loose	1
		Infection	UTI	6
		Neurological	Mental state	3
			Other	3
		Operative	Excessive bleeding	1
		Radiographic	PJK	3
		Vascular	Edema	1
			Other	1
			PE	14
			Rod breakage	14
Postoperative (n = 98: 58.7%)	Major (13.2%)	Neurological	Motor deficit	2
			Radiculopathy	2
		Radiographic	Pseudarthrosis	2
		Wound	Incision hernia	1
		Implant	Prominence	1
	Minor (16.2%)	Infection	UTI	1
		Musculoskeletal	Other	2
		Neurological	Radiculopathy	8
		Radiographic	PJK	11
		Vascular	Thrombophlebitis	1

Abbreviations: DVT, deep-vein thrombosis; GI, gastrointestinal; PE, pulmonary embolism; PJK, proximal junctional kyphosis; UTI, urinary tract infection.

Complications in Adult Spinal Deformity Surgery

Original Article

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Global Spine Journal
2020, Vol. 10(7) 896-907
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Classifying Complications: Assessing Adult Spinal Deformity 2-Year Surgical Outcomes

Eric O. Klineberg, MD¹, Peter G. Passias, MD², Gregory W. Poorman, BA³, Cyrus M. Jalal, BA⁴, Abiola Atanda, MD⁵, Nancy Worley, MS⁶, Samantha Horn, BA⁷, Daniel M. Schiubba, MD⁸, D. Kojo Hamilton, MD⁴, Douglas C. Burton, MD⁹, Munish Chandra Gupta, MD⁹, Justin S. Smith, MD⁷, Alexandra Soroceanu, MD⁸, Robert A. Hart, MD⁹, Brian Neuman, MD³, Christopher P. Ames, MD¹⁰, Frank J. Schwab, MD¹¹, Virginie Lafage, PhD¹¹; and the International Spine Study Group (ISSG)

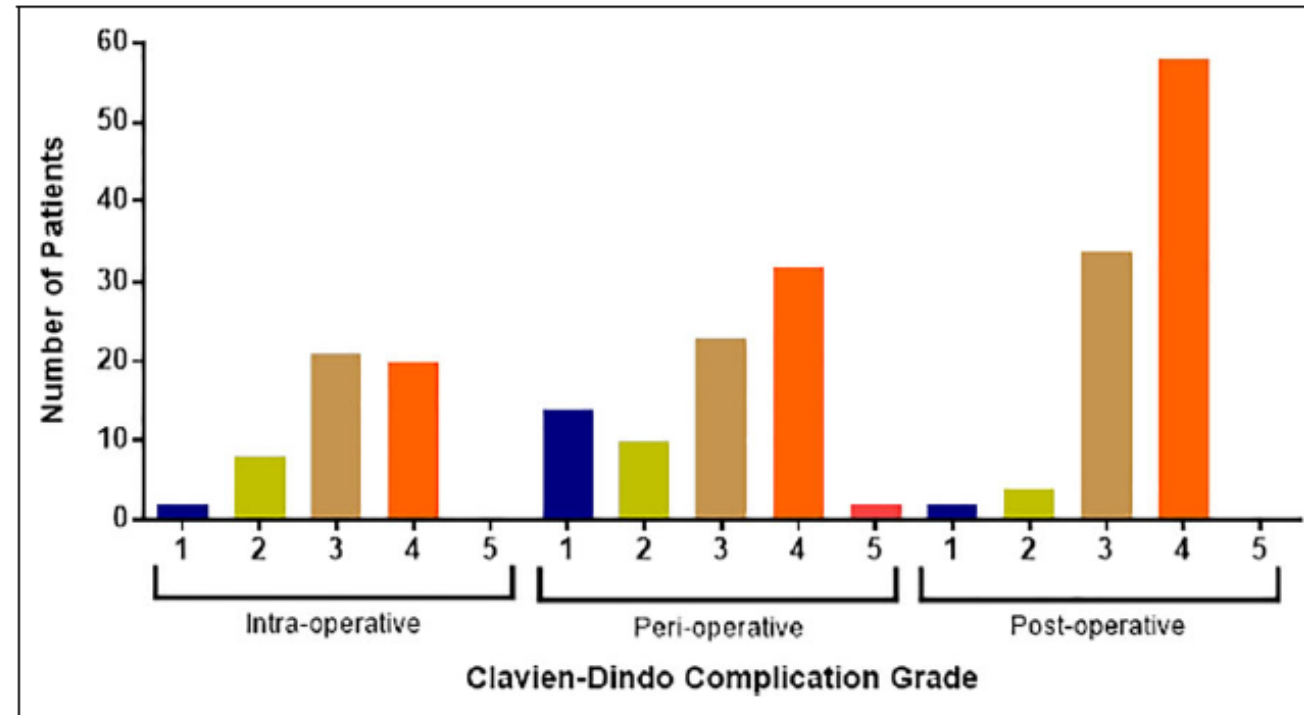


Figure 1. Distribution of intraoperative, perioperative, and postoperative complications experienced based on Clavien-Dindo Classification (Cc) score: (1) minor, (2) potentially life-threatening, (3) potentially life-threatening needing reoperation, (4) associated with residual disability, (5) death as a result.



Complications in Adult Spinal Deformity Surgery

Complications in spine surgery J Neurosurg Spine 13:144-157, 2010

A review

RANI NASSER, B.S.,¹ SANJAY YADLA, M.D.,² MITCHELL G. MALTENFORT, PH.D.,²
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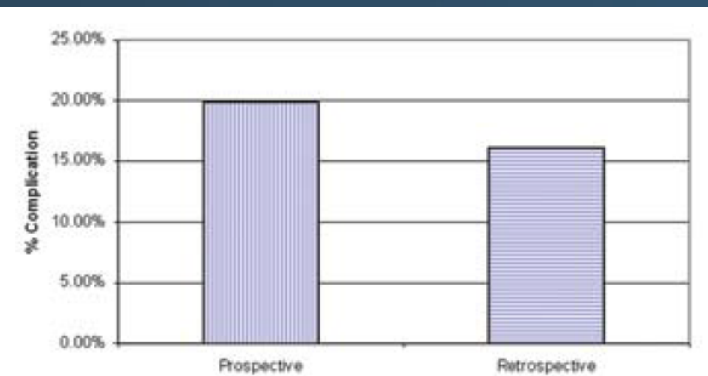


Fig. 2. Bar graph demonstrating a higher incidence of complications with prospectively designed studies (19.94%). Retrospective studies had a complication rate of 16.10%. The prospective complications group had a higher complication incidence, with an OR of 1.30 (95% CI 1.22-1.38, $p < 0.0001$).

Methods

A systematic evidence-based review was completed to identify within the published literature complication rates in spinal surgery (MEDLINE database).

Among the 105 articles were 84 retrospective studies and 21 prospective studies.

Prospective studies yielded a higher incidence of complications (19.9%) than retrospective studies (16.1%; $p < 0.0001$)

The complication incidence for prospective thoracolumbar studies (20.4%) was greater than that for retrospective series (17.5%; $p < 0.0001$)

Conclusions

Retrospective reviews significantly underestimate the overall incidence of complications in spine surgery.

Risk of Revision

Eur Spine J (2015) 24:1251–1258
DOI 10.1007/s00586-014-3454-0



ORIGINAL ARTICLE

Pelvic incidence-lumbar lordosis mismatch predisposes to adjacent segment disease after lumbar spinal fusion

Dominique A. Rothenfluh · Daniel A. Mueller ·
Esin Rothenfluh · Kan Min

Table 2 Levels and number of segments fused

n = 84	ASDis (n = 45)	CTRL (n = 39)
L2–L5 (3)	6	4
L3–L4 (1)	2	2
L3–L5 (2)	9	7
L3–S1 (3)	3	2
L4–L5 (1)	12	10
L4–S1 (2)	8	8
L5–S1 (1)	5	6

- Patients in the ASDis group: significantly higher pelvic incidence than in the CTRL group (60.9 ± 10.0 vs. 51.7 ± 10.4 , $p = 0.001$)
- Large significant difference in spino-pelvic alignment (PI-LL) between the ASDis and CTRL group (12.5 ± 16.7 vs. 3.4 ± 12.1 , $p = 0.001$)

Clinical study

- 45 patients (ASDis) were identified that underwent revision surgery for **symptomatic Adjacent Segment Disease** after on average 49 months (7–125)
- 39 patients were selected as control group (CTRL)

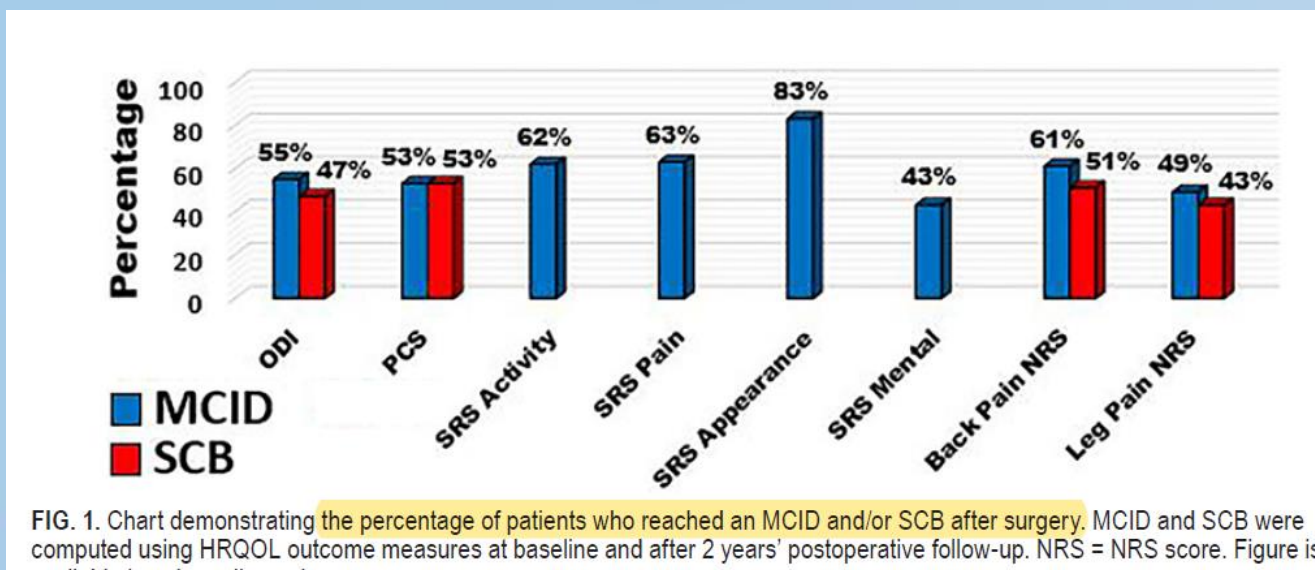
Conclusions

- A high PI with diminished LL seems to predispose to Adjacent Segment Disease.
- Patients with such PI-LL mismatch exhibit a **10-times higher risk for revision** vs. controls if the sagittal malalignment is maintained after lumbar fusion surgery.

The impact of Global Coronal Malalignment (GCM)



- Primary objective was to assess surgical outcomes and complications in patients with severe GCM (GCM; C7 plumb line– midsacral offset)
- Retrospective analysis of a prospective multicenter database.
- 80 patients with severe GCM; 62 patients with a min. 2-year FU
- The mean posterior fusion length was 13.2 levels.



Thresholds for ≥ 1 MCID/SCB improvement were achieved in 43%–83% of patients at the 2-year FU.

MCID = minimal clinically important difference
 SCB = substantial clinical benefit
 HRQOL = Health Related Quality of Life

The impact of Global Coronal Malalignment (GCM)

TABLE 7. Type and rates of complications in 62 adults with severe GCM surgically treated for spinal deformity and a minimum 2-year follow-up

Complication Category	Minor/Major Complication (%), No. of Reops			
	Intraop	Early (≤30 days)	Delayed (>30 days)	Total
Implant	0/0 (0)	0/0 (0)	3/15 (29.0), 8	3/15 (29.0), 8
Rod breakage	0/0 (0)	0/0 (0)	1/11 (19.4), 5	1/11 (19.4), 5
Painful implant	0/0 (0)	0/0 (0)	1/2 (4.8), 2	1/2 (4.8), 2
Screw medial breach	0/0 (0)	0/0 (0)	0/2 (3.2), 1	0/2 (3.2), 1
Implant prominence	0/0 (0)	0/0 (0)	1/0 (1.6)	1/0 (1.6)
Radiographic	0/0 (0)	1/0 (1.6)	4/17 (33.9), 15	5/17 (35.5), 15
PJK	0/0 (0)	1/0 (1.6)	3/7 (16.1), 6	4/7 (17.7), 6
Coronal imbalance	0/0 (0)	0/0 (0)	0/4 (6.5), 4	0/4 (6.5), 4
Pseudarthrosis	0/0 (0)	0/0 (0)	0/4 (6.5), 3	0/4 (6.5), 3
Adjacent-segment disease	0/0 (0)	0/0 (0)	1/1 (3.2), 1	1/1 (3.2), 1
Sagittal imbalance	0/0 (0)	0/0 (0)	0/1 (1.6), 1	0/1 (1.6), 1
Neurological	1/1 (3.2), 1	1/1 (3.2)	2/6 (12.9), 2	4/8 (19.4), 3
Motor deficit	0/1 (1.6), 1	0/0 (0)	0/4 (6.5)	0/5 (8.1), 1
Radiculopathy	0/0 (0)	1/1 (3.2)	2/1 (4.8), 1	3/2 (8.1), 1
Mental status change	1/0 (1.6)	0/0 (0)	0/0 (0)	1/0 (1.6)
Myelopathy	0/0 (0)	0/0 (0)	0/1 (1.6), 1	0/1 (1.6), 1
Op	9/7 (25.8), 2	1/2 (4.8), 1	0/0 (0)	10/9 (30.6), 3
Dural tear	9/0 (14.5)	0/0 (0)	0/0 (0)	9/0 (14.5)
Excessive blood loss	0/3 (4.8)	0/0 (0)	0/0 (0)	0/3 (4.8)
Vascular injury	0/2 (3.2)	0/1 (1.6), 1	0/0 (0)	0/3 (4.8), 1
Positioning	0/1 (1.6), 1	0/0 (0)	0/0 (0)	0/1 (1.6), 1
Pleural injury	0/0 (0)	1/0 (1.6)	0/0 (0)	1/0 (1.6)
Monitoring anomaly	0/1 (1.6), 1	0/0 (0)	0/0 (0)	0/1 (1.6), 1
Lymphocele	0/0 (0)	0/1 (1.6)	0/0 (0)	0/1 (1.6)
Cardiopulmonary	1/1 (3.2), 1	0/3 (4.8)	0/1 (1.6)	1/5 (9.7), 1
Pulmonary embolism	0/0 (0)	0/2 (3.2)	0/0 (0)	0/2 (3.2)
Deep vein thrombosis	0/0 (0)	0/0 (0)	0/1 (1.6)	0/1 (1.6)
Myocardial infarction	0/0 (0)	0/1 (1.6)	0/0 (0)	0/1 (1.6)
Tachyarrhythmia	0/1 (1.6), 1	0/0 (0)	0/0 (0)	0/1 (1.6), 1
Pleural effusion	1/0 (1.6)	0/0 (0)	0/0 (0)	1/0 (1.6)
Infection	0/0 (0)	1/1 (3.2), 1	3/0 (4.8), 3	4/1 (8.1), 4
Deep wound infection	0/0 (0)	0/1 (1.6), 1*	0/0 (0), 3*	0/1 (1.6), 4*
Urinary tract infection	0/0 (0)	1/0 (1.6)	3/0 (4.8)	4/0 (6.5)
GI	1/0 (1.6)	5/0 (8.1)	1/0 (1.6)	7/0 (11.3)
Ileus	1/0 (1.6)	3/0 (4.8)	1/0 (1.6)	5/0 (8.1)
GI bleed	0/0 (0)	1/0 (1.6)	0/0 (0)	1/0 (1.6)
Cholecystitis	0/0 (0)	1/0 (1.6)	0/0 (0)	1/0 (1.6)
Death	0/0 (0)	0/0 (0)	0/0 (0)	0/0 (0)
Total no. of complications (minor/major), no. of reops	21 (12/9), 4	16 (9/7), 2	52 (13/39), 28	89 (34/55), 34
No. of patients affected (%)	15 (24.2)	12 (19.4)	33 (53.2)	45 (72.6)

- A total of 89 complications were reported (34 minor, 55 major)
- 73% (45) patients had ≥ 1 complication.
- The complications with the highest rates were:
 - Rod fracture: **19%** (at T12–L1 to L5–S1)
 - PJK: **18%**
 - Durotomy: 15%

There were 34 reoperations in 22 (**35%**) patients with the most common indications of: PJK (n = 6), Rod fracture (n = 5), Coronal imbalance (n = 4), and Deep wound infection (n = 4).

A residual GCM ≥ 3 cm was associated with a worse outcome, suggesting a potential coronal realignment target threshold to assist surgical planning.

Spinal Alignment

Special Issue Article 2022 **AO SPINE**

Trends in Intraoperative Assessment of Spinal Alignment: A Survey of Spine Surgeons in the United States

Global Spine Journal
2022, Vol. 12(2) 85-86
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Table 2. Utilization of Alignment Assessment Methods.

Method	Affirmative responses, n (%)
Preoperative Assessments	
Quantitative assessment of standing scoliosis radiographs or EOS images	95/108 (88)
Qualitative assessment of standing scoliosis radiographs or EOS images	63/108 (58)
CT imaging	74/108 (69)
MR imaging	74/108 (69)
Surgimap	44/108 (41)
Intraoperative Assessments	
C-arm or spot radiographs	91/108 (84)
Intraoperative full-length radiographs	43/108 (40)
Medtronic O-arm	35/108 (32)
T-Bar	22/108 (20)
Nuvasive Integrated Global Alignment	13/108 (12)
Bendini	6/108 (6)

Abbreviations: CT, computed tomography; MR, magnetic resonance.

Study Design: Survey; 108 experienced US spine surgeons from 77 surgical centers completed the survey.

Objectives: To characterize national practices of and shortcomings surrounding intraoperative assessments of spinal alignment

The factors for which unsatisfactory postoperative alignment results were most often attributed were:

- *general inability to assess alignment intraoperatively (40% of cases)*
- *inability to visualize critical landmarks for measurements intraoperatively (31% of cases).*

Conclusions

- Surveyed surgeons primarily rely on radiographs for intraoperative assessments of alignment.
- The majority of surgeons reporting a need for improvement in technology to assess spinal alignment intraoperatively
- 3 of the top design considerations should include
 - workflow interruption
 - Expense
 - radiation exposure

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

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

TABLE 4.

Rates of implant and radiographic complications in 291 patients surgically treated for ASD who had a minimum 2-year follow-up*

Complication Categories & Subgroups	Minor/Major Complications (%)		
	Periop (≤6 wks)	Delayed (>6 wks)	Total
Implant	3/8 (3.8)	11/59 (24.1)	14/67 (27.8)
Rod breakage	0/1 (1 reop)	0/39 (14 reop)	0/40 (13.7)
Implant prominence	0/1	6/4 (4 reop)	6/5 (3.8)
Painful implant	0/0	2/5 (5 reop)	2/5 (2.4)
Screw breakage	0/1	0/5 (1 reop)	0/6 (2.1)
Screw loosening	1/1 (1 reop)	3/1	4/2 (2.1)
Interbody spacer dislodgment	0/2 (1 reop)	0/1	0/3 (1.0)
Screw medial breach	1/0	0/1 (1 reop)	1/1 (0.7)
Implant failure	0/0	0/1 (1 reop)	0/1 (0.3)
Rod dislodgment	0/0	0/1 (1 reop)	0/1 (0.3)
Screw dislodgment	0/0	0/1 (1 reop)	0/1 (0.3)
Crosslink dislodgment	1/0	0/0	1/0 (0.3)
Fixation failure	0/1 (1 reop)	0/0	0/1 (0.3)
Hook dislodgment	0/1	0/0	0/1 (0.3)
Screw nerve impinge	0/0	0/0	0/0 (0.0)
Screw vascular impingement	0/0	0/0	0/0 (0.0)
Radiographic	4/10 (4.8)	25/42 (23.0)	29/52 (27.8)
PJK	3/8 (6 reop)	15/13 (12 reop)	18/21 (13.4)
Pseudarthrosis	0/0	0/15 (10 reop)	0/15 (5.2)
Adjacent-segment disease	0/0	6/4 (2 reop)	6/4 (3.4)
Coronal imbalance	1/2 (2 reop)	3/2 (2 reop)	4/4 (2.7)
Sagittal imbalance	0/0	1/4 (3 reop)	1/4 (1.7)
Distal junctional kyphosis	0/0	0/4 (2 reop)	0/4 (1.4)

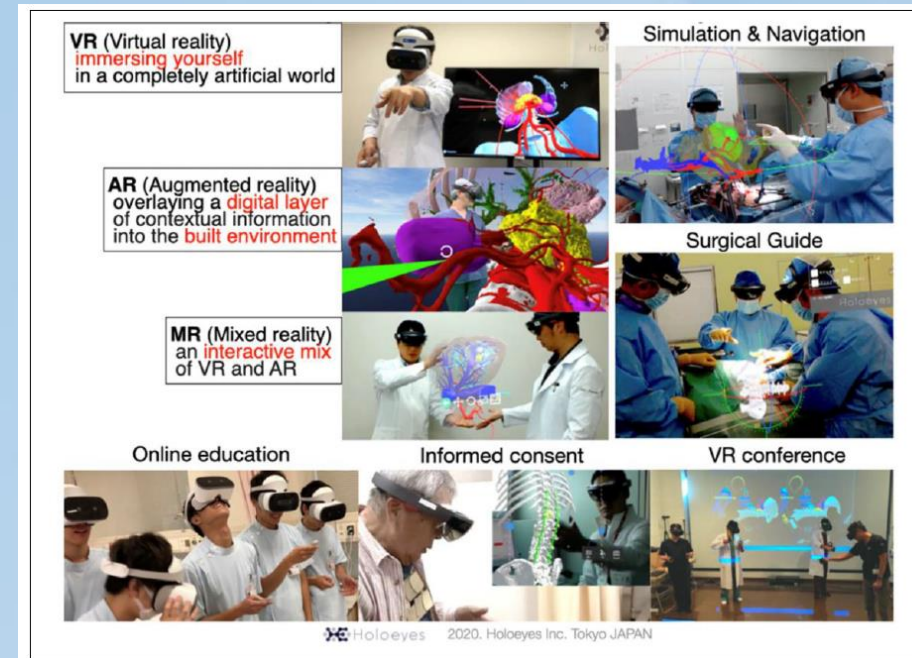
*The number of reoperations indicates the subset of indicated major complications that were associated with the need for reoperation.

Artificial Intelligence in Spine Surgery



KEY MESSAGES

- Current studies focus mainly on the successful placement of pedicle screws via AR-guided instrumentation
- A wider scope of procedures may be assisted using AR, VR or MR technology
- These emerging technologies **offer a significant advantage in the guidance of complex procedures that require high precision and accuracy** using minimally invasive interventions.



Next generation systems must be

- **intuitive**
- **with low learning curve**

to fulfil a role in specialist surgeries where AR is of significant advantage.

Artificial Intelligence in Spine Surgery

Review Article

AO
SPINE

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Artificial Intelligence and Robotics in Spine Surgery

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Wende N. Gibbs, MD³, Ghaith Habboub, MD¹, Michael P. Steinmetz, MD¹,
Edward Benzel, MD¹, and Thomas E. Mroz, MD¹

Review Article

AO
SPINE

Global Spine Journal
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Current Applications of Machine Learning in Spine: From Clinical View

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PeiYang Wang, MD¹, Wei Zhang, MS¹, Yong Huang, MD¹,
YunTao Wang, PhD³, and XiaoTao Wu, MD³

- AI has tremendous potential in revolutionizing spine care
 - Ultimately, in the ever-evolving landscape of spine surgery, one thing is certain:
“AI technologies have arrived—and they are here to stay”

- Machine Learning had achieved excellent performance and hold *immense potential in spine.*

Adjusting Our Technology Adoption Criteria

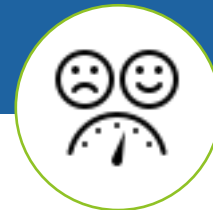
Perioperative Integration

Integrate system design into the perioperative process to help reduce overall operational costs



Support Patient Satisfaction

Improve clinical outcomes, eliminate risk factors and support post-op pain reduction



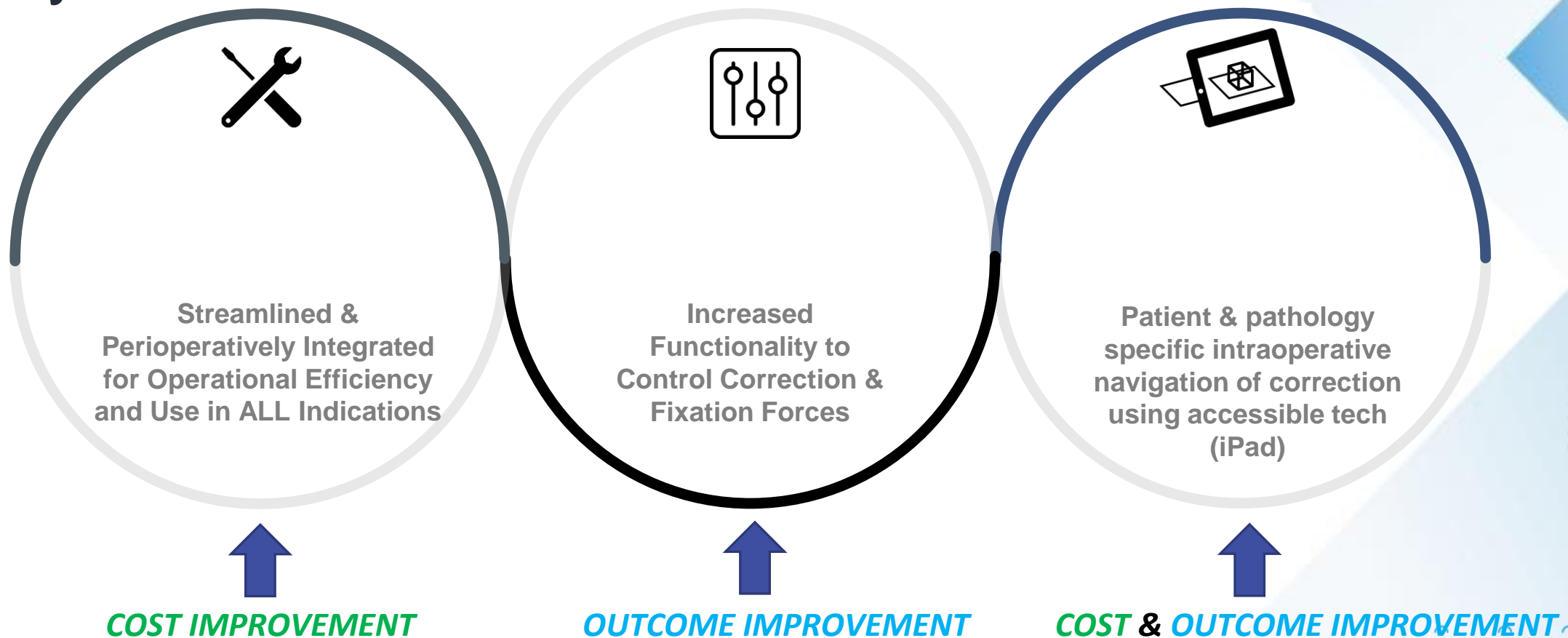
Best-in-Class Technology

Simple and streamlined for staff while still providing high functionality for surgeon at lower overall cost



HAVING BOTH CLINICAL AND ECONOMIC VALUE ARE REQUIRED

Neo Universal: A Total Technology Ecosystem



Fully integrated technology ecosystem bringing new streamlined approaches and smart systems to spinal surgery



Final Thoughts...

Multilevel spinal fusion procedures are expensive, invasive, and complicated, and yet our patients willingly allow us to perform this.

We have an ethical, moral, and global obligation to provide the best care possible, while reducing costs and complications, and improving outcome.

Honest and objective analysis of our collective experience should inform our decision making.

Technology, when used appropriately, will allow us to provide the best possible care and outcomes for our patients.

