

COMPLEX SPINE OVERVIEW

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Director of Neurosurgery
Mohawk Valley Health System

December 15, 2016



University of Washington



Combined Neurosurgical & Orthopedic Complex Spine Fellowship



GOALS

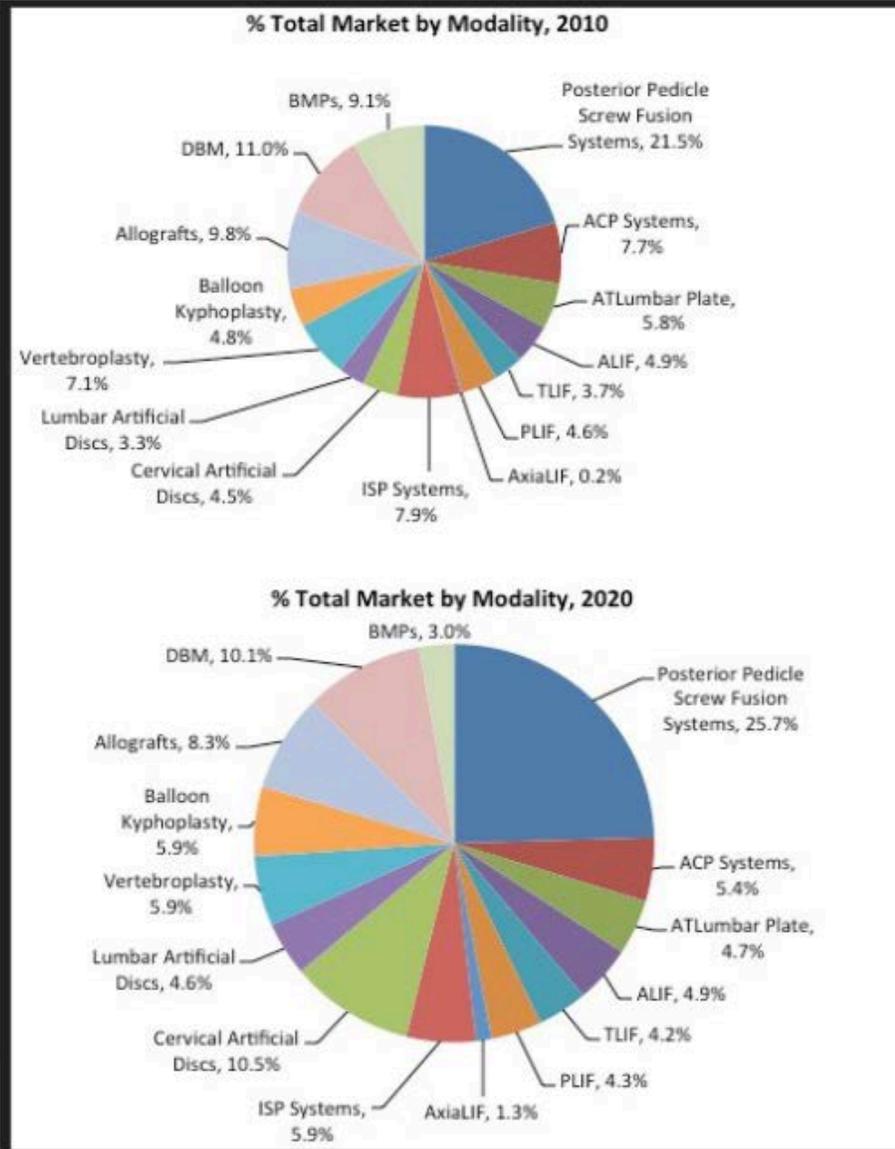
- ① UNDERSTAND WHAT COMPLEX SPINE SURGERY IS
- ② UNDERSTAND CHANGING HEALTHCARE CLIMATE AS IT RELATES TO COMPLEX SPINE
- ③ UNDERSTAND HOW MEDICREA IS UNIQUELY POSITIONED IN THE MARKET WITH THEIR APPLIED TECHNOLOGY

“Life is a Progressive Kyphotic Event”

Dave Polly



COMPLEX SPINE SURGERY

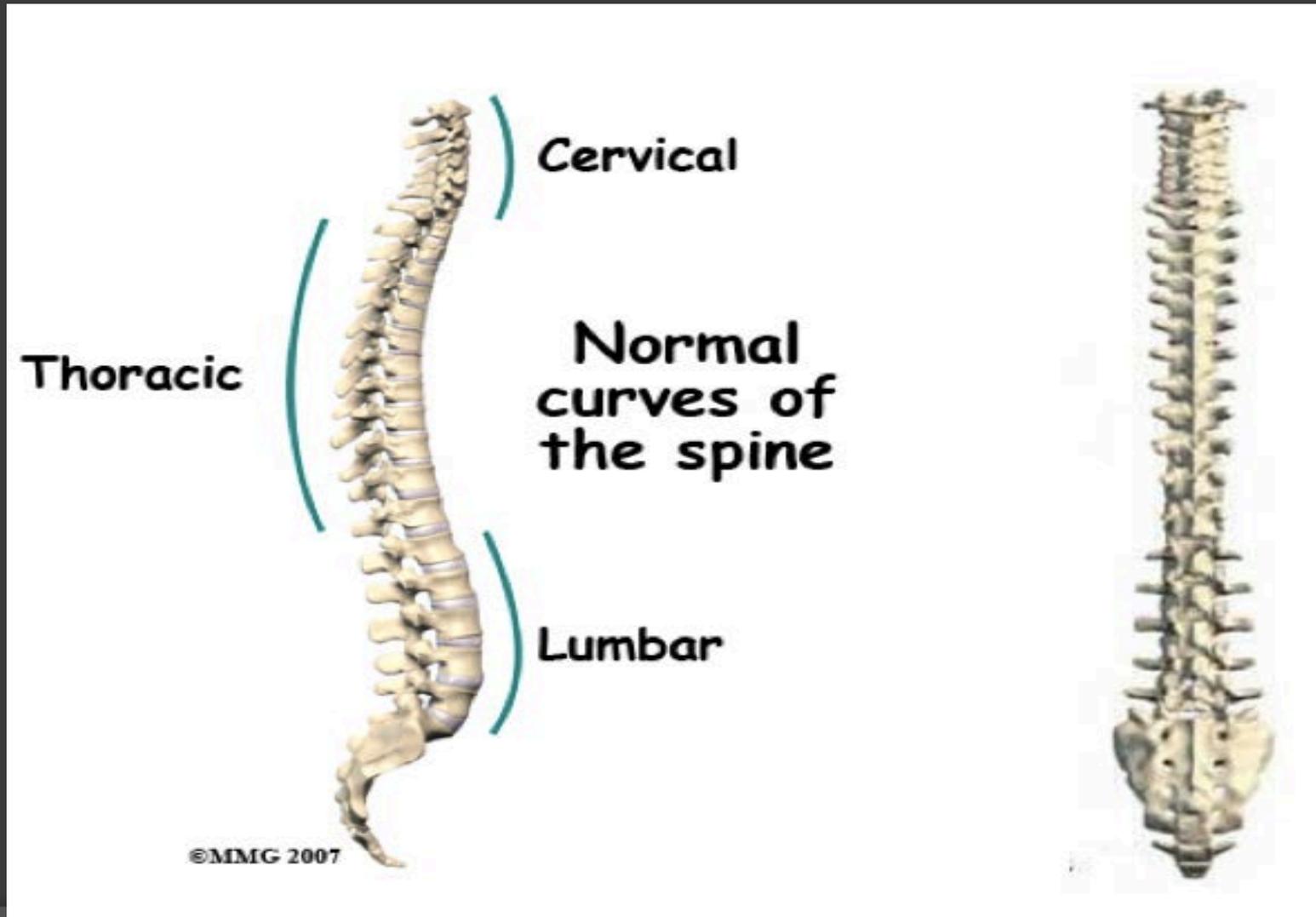


Case

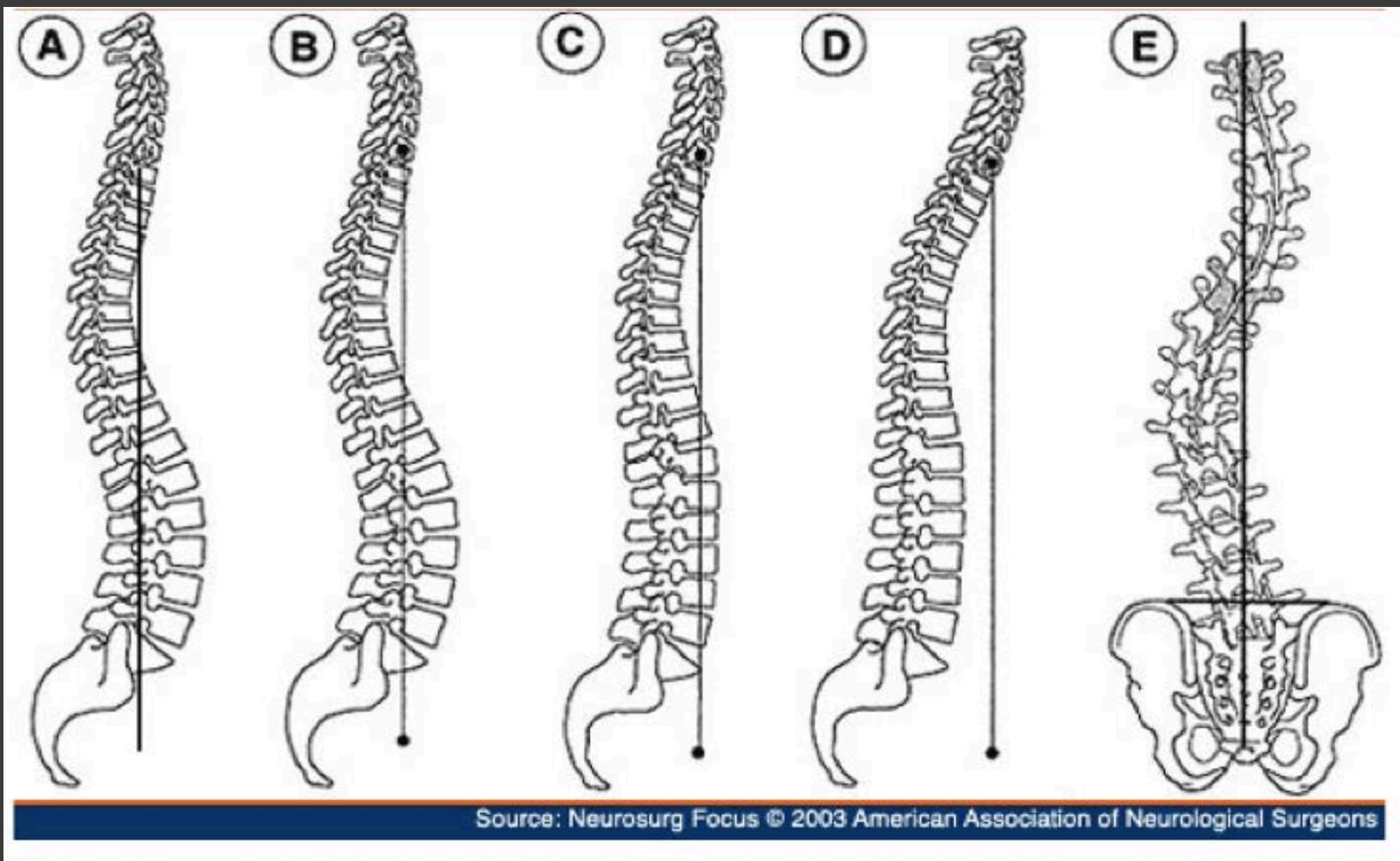




Normal Spinal Anatomy

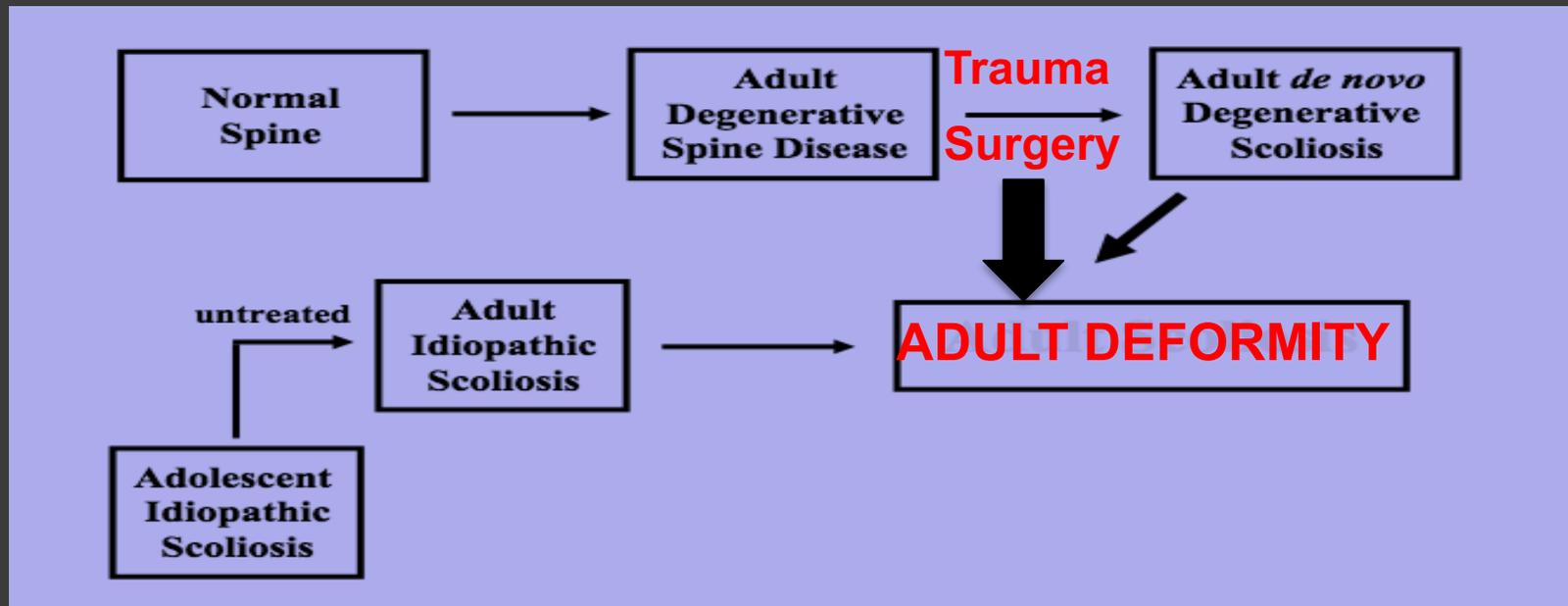


Adult Kypho-Scoliosis



One Common Diagnoses Multiple Presentations

- Degenerative
 - Occurs over a long period time
 - Previous Surgery resulting in flat back
 - Can occur from old treated or untreated trauma



- Idiopathic
 - Once an adolescent becomes skeletally mature, diagnosis changes to adult idiopathic

Presentation



Physical Exam

- ⦿ Forward gaze while ambulating
- ⦿ Standing posture with maximal hip and knee extension
- ⦿ Is lumbar lordosis maintained?
- ⦿ Quantify hip/knee
 - ROM
 - Flexion contractures
 - Thomas test



NON OPERATIVE TREATMENT

SPINE Volume 32, Number 19S, pp S130-S134
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■ A Systematic Literature Review of Nonsurgical Treatment in Adult Scoliosis

Clifford R. Everett, MD, MPH, and Rajeev K. Patel, MD

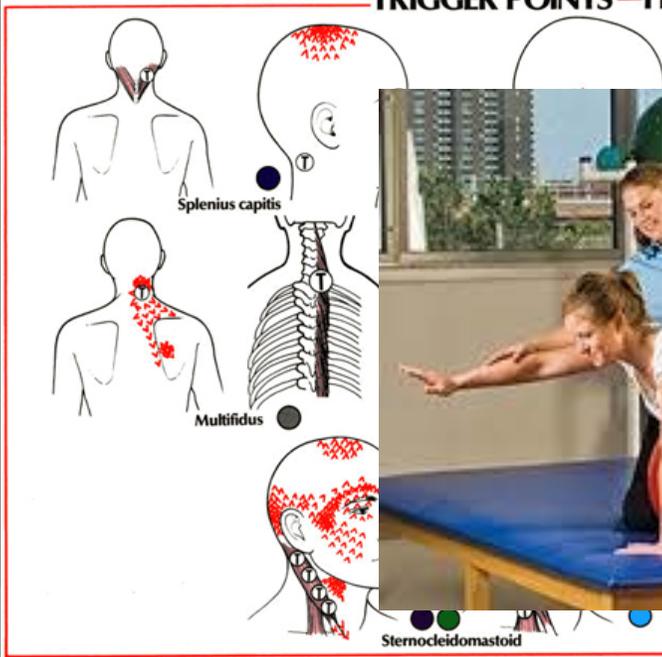
Study Design. A formal systematic review of the literature for conservative treatment of adult deformity was performed.

Objective. To evaluate evidence for the efficacy and

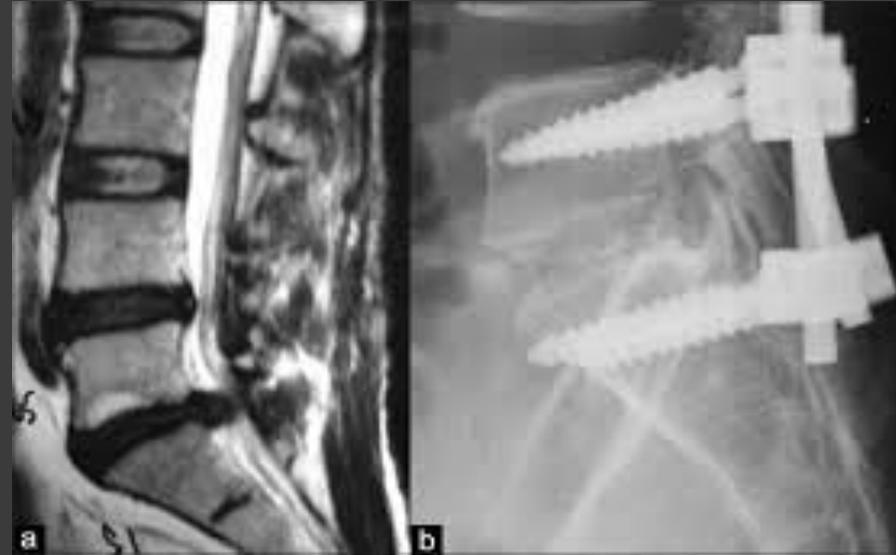
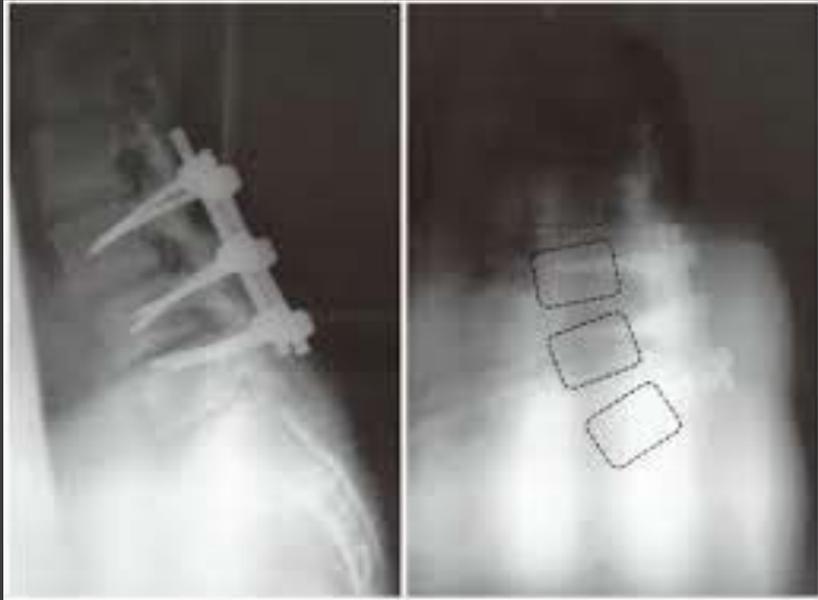
Adult deformity is a significant health issue within the aging population in both the United States and the world communities.¹ This special issue of *Spine* explores the problem and the current evidence for the treatment options. This

➤ **No substantial evidence for any nonsurgical treatment in adult scoliosis.**

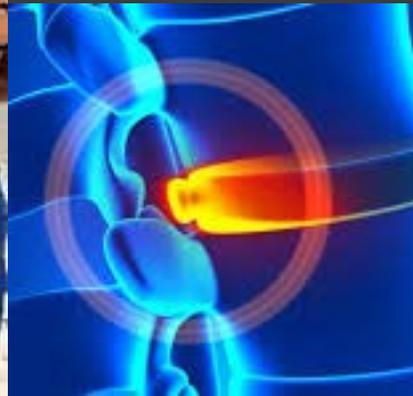
Conservative Tx



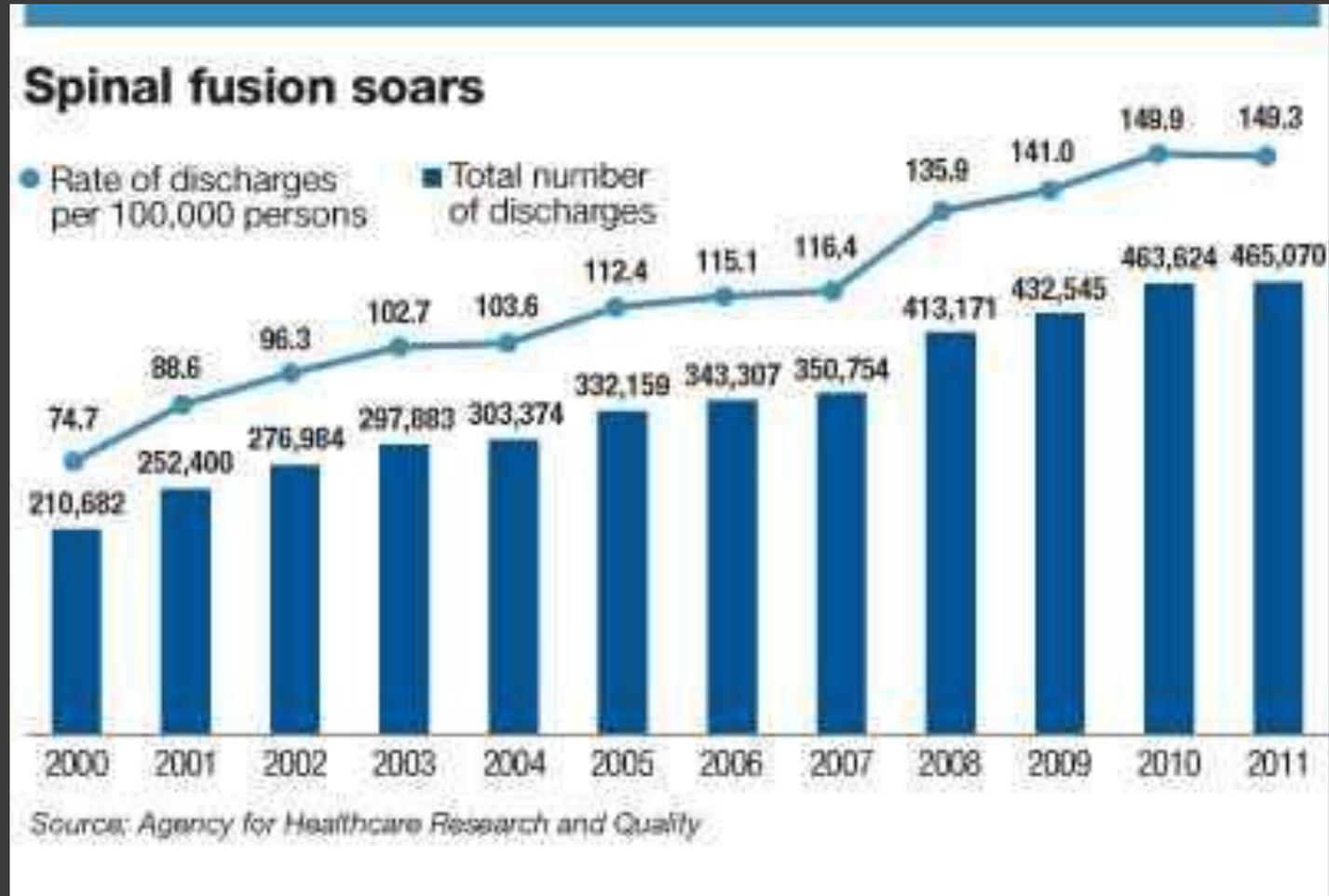
IATROGENIC CAUSE OF DEFORMITY



Hey Doc, can you do Laser surgery on me?

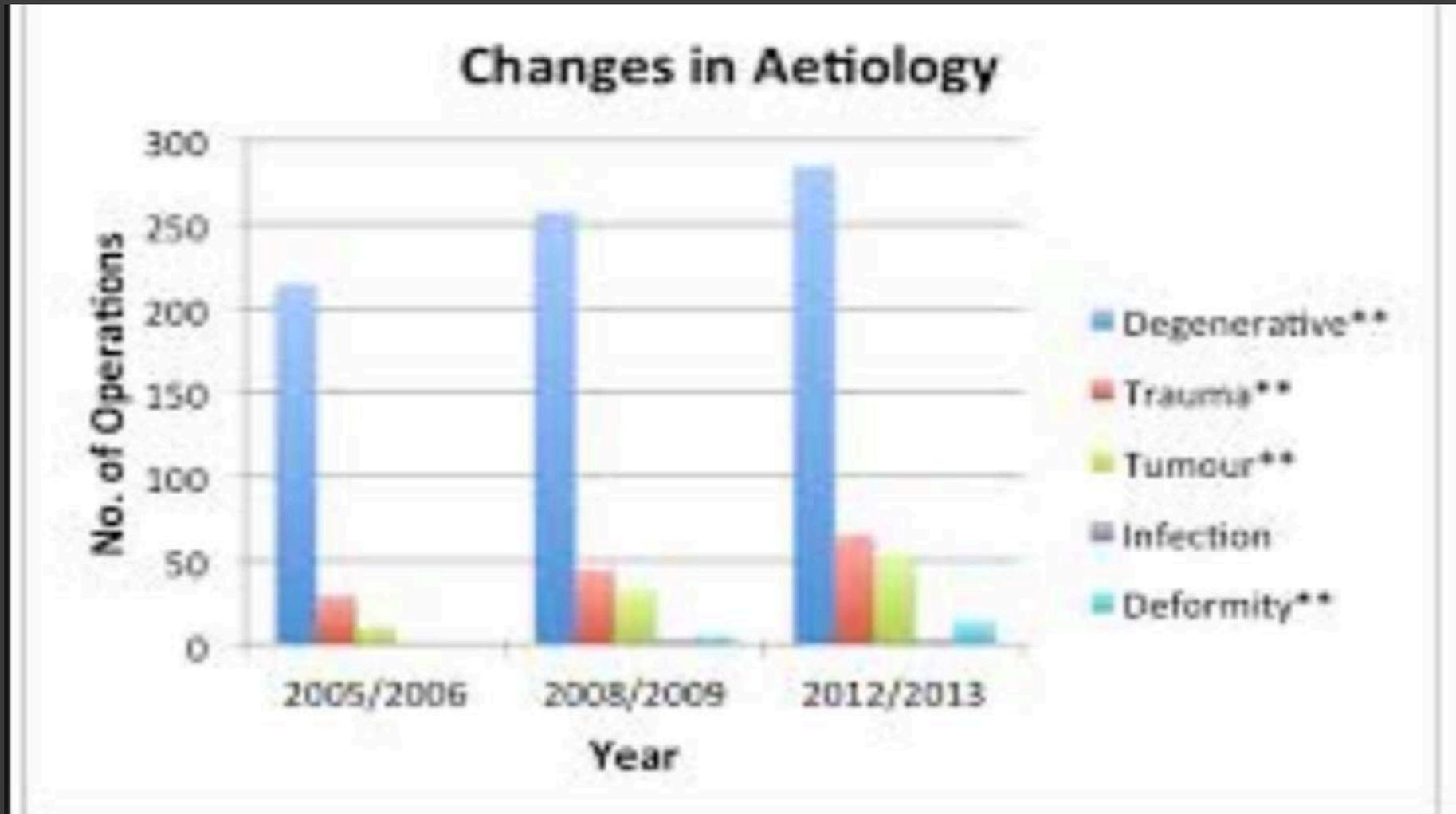


Spine Market



MORE INSURANCE DENIALS
MULTI-DICIPLINARY - EVIDENCE BASED

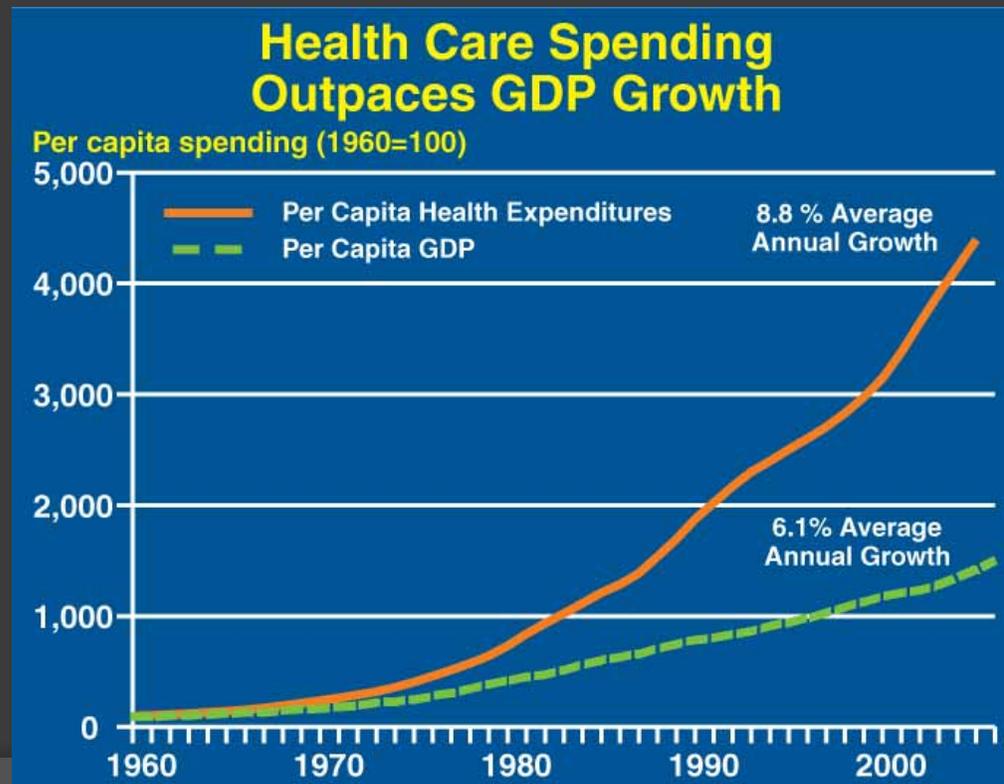
CROSSOVERS



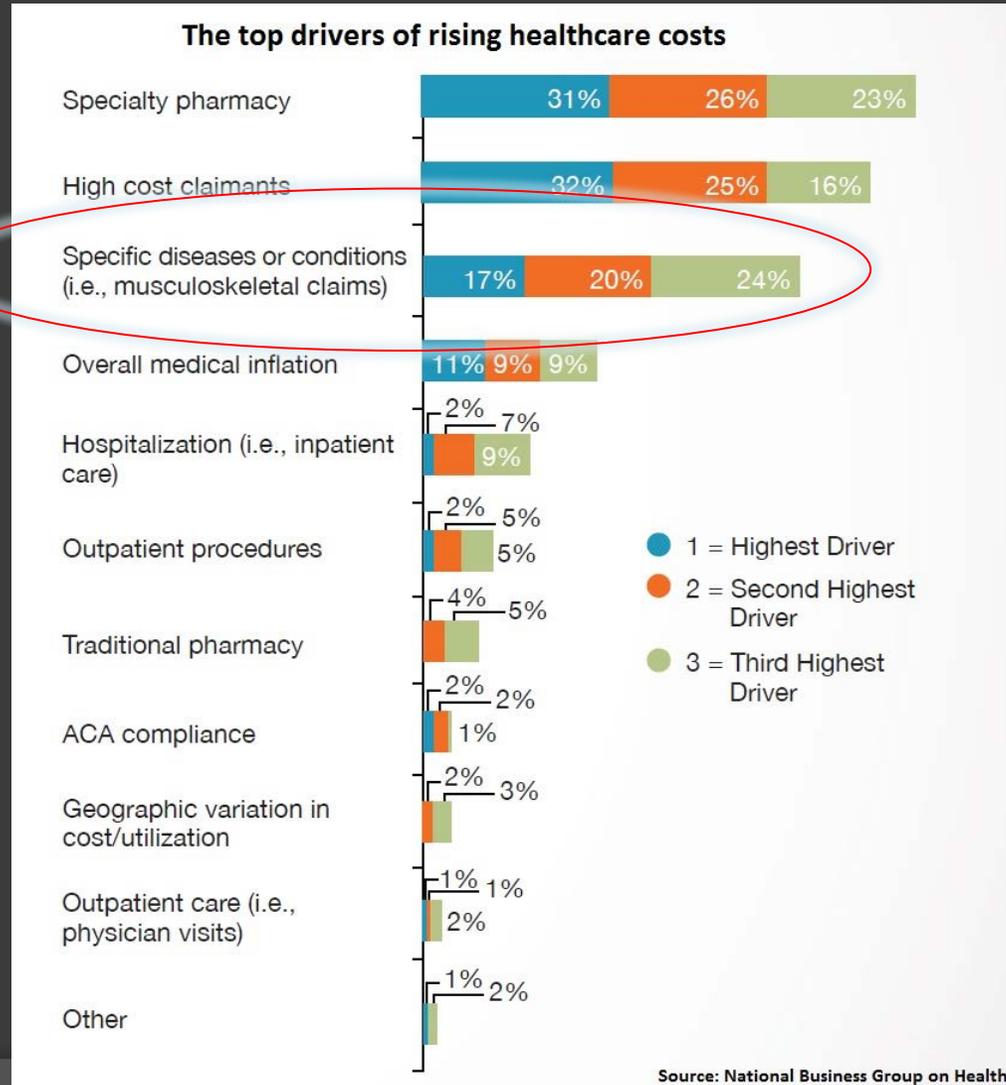


Economic Value

Economic value is an increasingly important component of healthcare policy decision making.



Healthcare Costs



VALUE



METRICS

QALY (Quality Adjusted Life Year)

1 = perfect health while 0 = death

&

DALY (Disability Adjusted Life Year)

1 = death while 0 = perfect health

DALY, in essence, measures health loss in the quality of life. On the other hand, QALY measures the same quality of life in health gain. QALY is usually used in measuring the quality and quantity of care and life when considering options for health treatments for a particular illness.

Measuring and Defining Value

What is an acceptable outcome? SCB

TABLE VII Minimum Clinically Important Difference Values for Current Study Population and Values Previously Reported in the Literature as Compared with Substantial Clinical Benefit Values

| | Substantial Clinical Benefit, Current Study (points) | Minimum Clinically Important Difference (points) | |
|----------------------------------|---|--|--|
| | | Current Study | As Reported in Literature |
| Oswestry Disability Index | 18.8 | 12.8 | 10.0 (Hägg et al. ¹³); 11.0 (Lauridsen et al. ²⁴) |
| SF-36 physical component summary | 6.2 | 4.9 | 5.4 (Ware et al. ¹²) |
| Back pain numeric rating scale | 2.5 | 1.2 | 1.0 (Lauridsen et al. ²⁴) |
| Leg pain numeric rating scale | 2.5 | 1.6 | 2.0 (Lauridsen et al. ²⁴) |

Translating HRQOL to Value

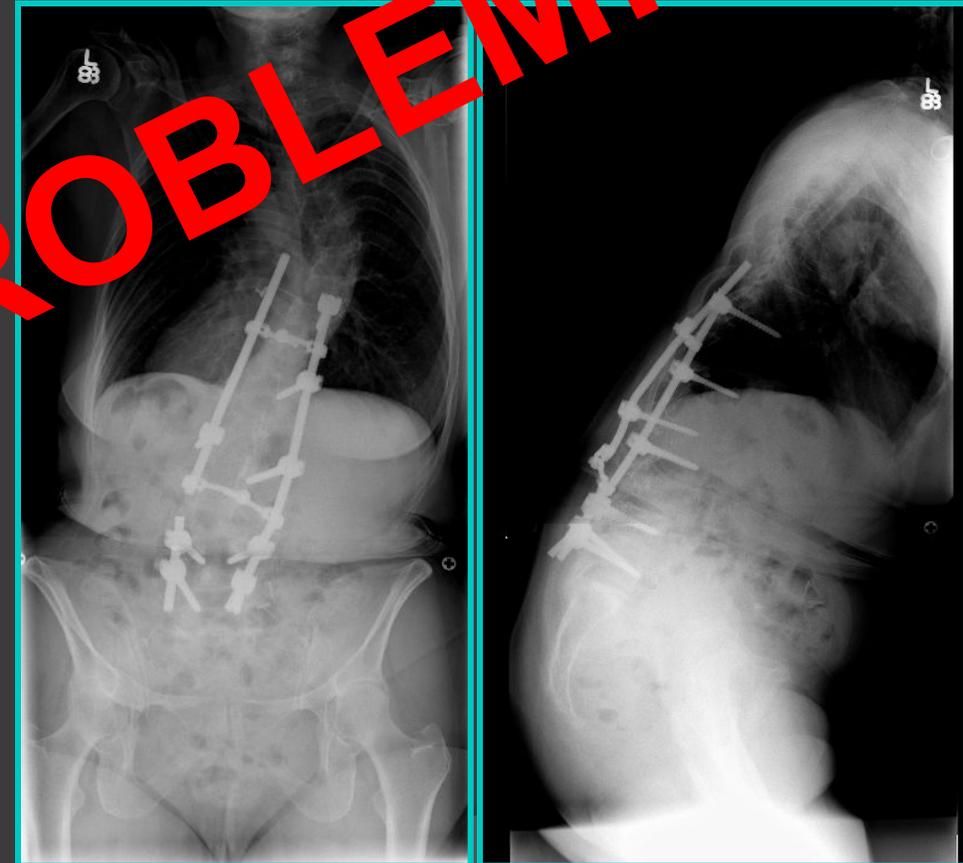
- Cost/QALY has become the primary currency for Healthcare Economics?



- ✓ cost/QALY \$50,000 - \$100,000 is generally considered cost effective.

Revision Spine Surgery

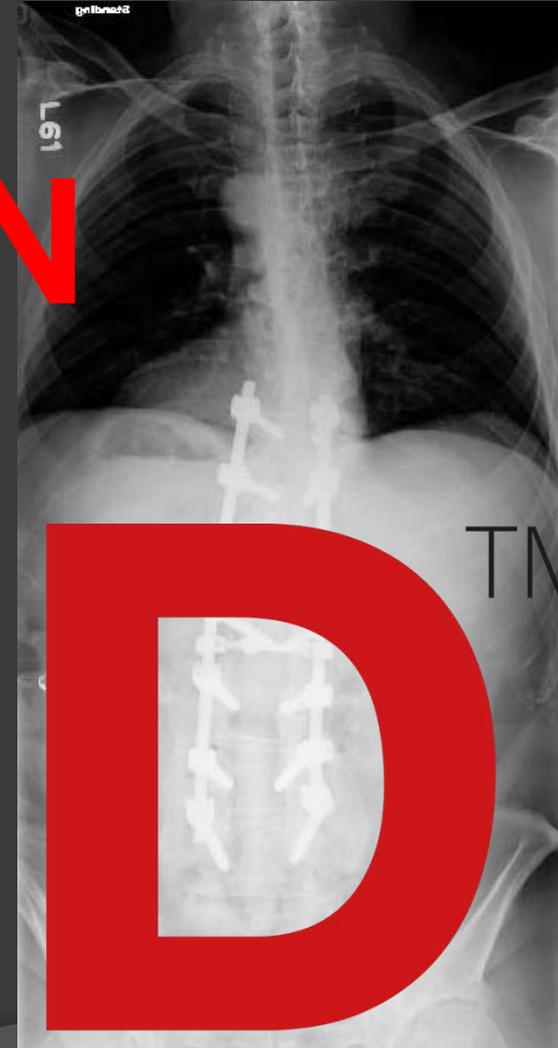
- 7%→50% of spine surgeries eventually require revision
- The more complex the procedure, the more likely something is going to go wrong
- Results of revision spine surgery are usually less satisfactory than primary surgery



Failure to Adequately Correct Deformity



SOLUTION

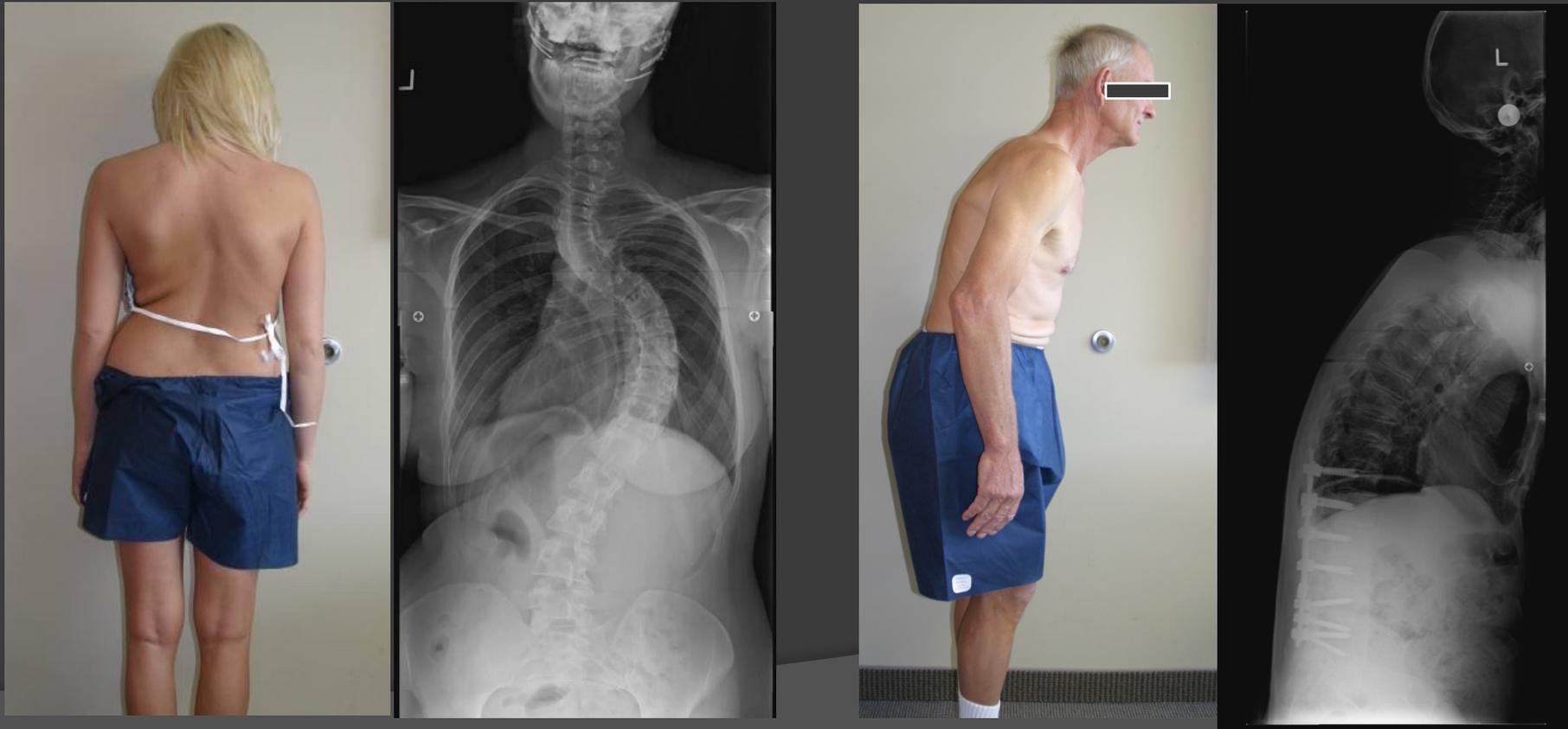


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Assessment of Spinal Alignment

How do we measure spinal balance?



Global Sagittal Alignment

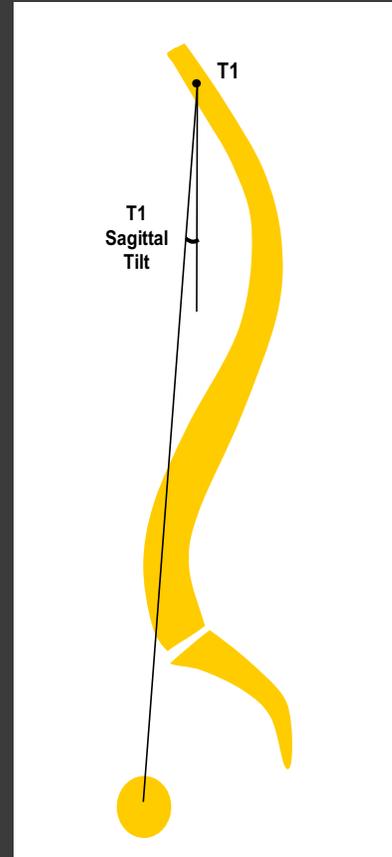
Distance

C7 Plumbline –
Posterior Superior
Corner of Sacrum

SVA
(Jackson)



0 to 5cm



Angle

Vertical vs line
between femoral
heads and T1

T1 angle
(Duval-Beaupere)

-9° to +7°

The Impact of Positive Sagittal Balance in Adult Spinal Deformity

Steven D. Glassman, MD,* Keith Bridwell, MD,† John R. Dimar, MD,* William Horton, MD,§
Sigurd Berven, MD,† and Frank Schwab, MD||

Plumbline Shift Anteriorly

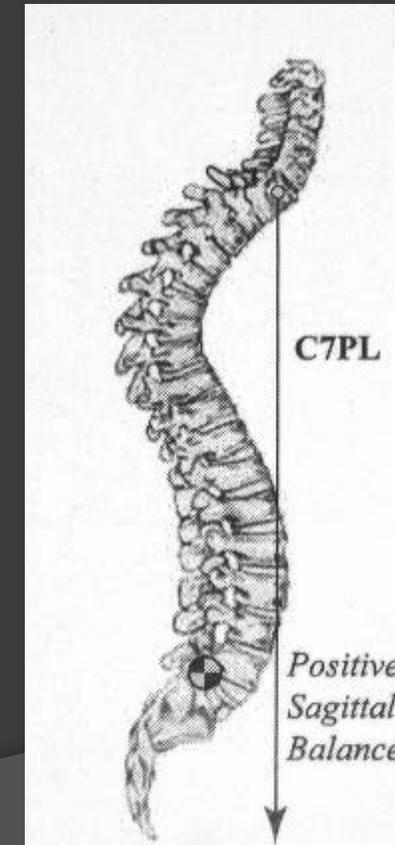


=> **Increasing disability**

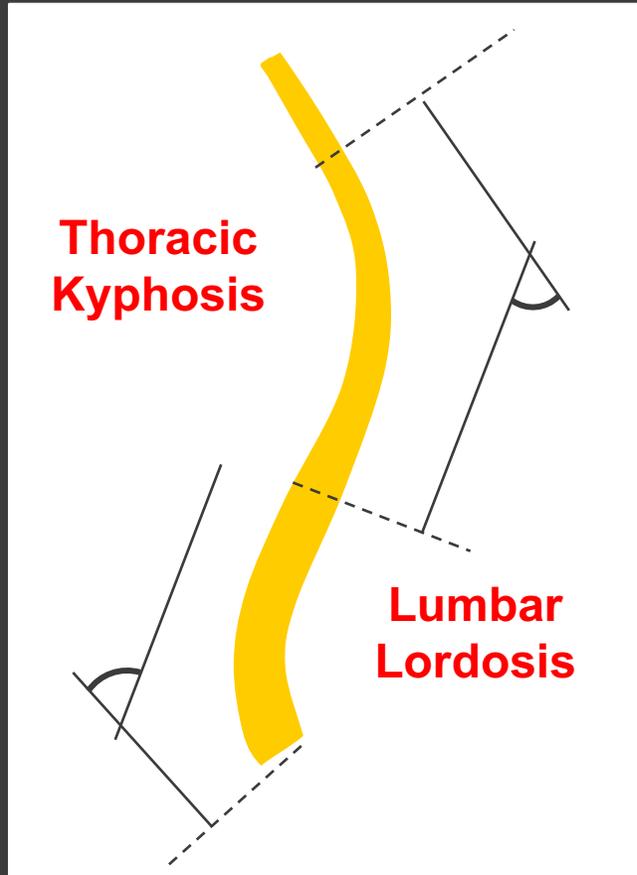
SF-12, SRS-29, ODI ($p < 0.001$)

=> **Lumbar kyphosis marked disability**

SRS-29, ODI ($p < 0.05$)



Regional Sagittal Alignment



| | |
|-------------------|-------|
| Thoracic kyphosis | 20-40 |
| Lumbar Lordosis | 30-80 |



Curves 'Proportional' to One Another

Sagittal Alignment and Symptoms

Conclusion

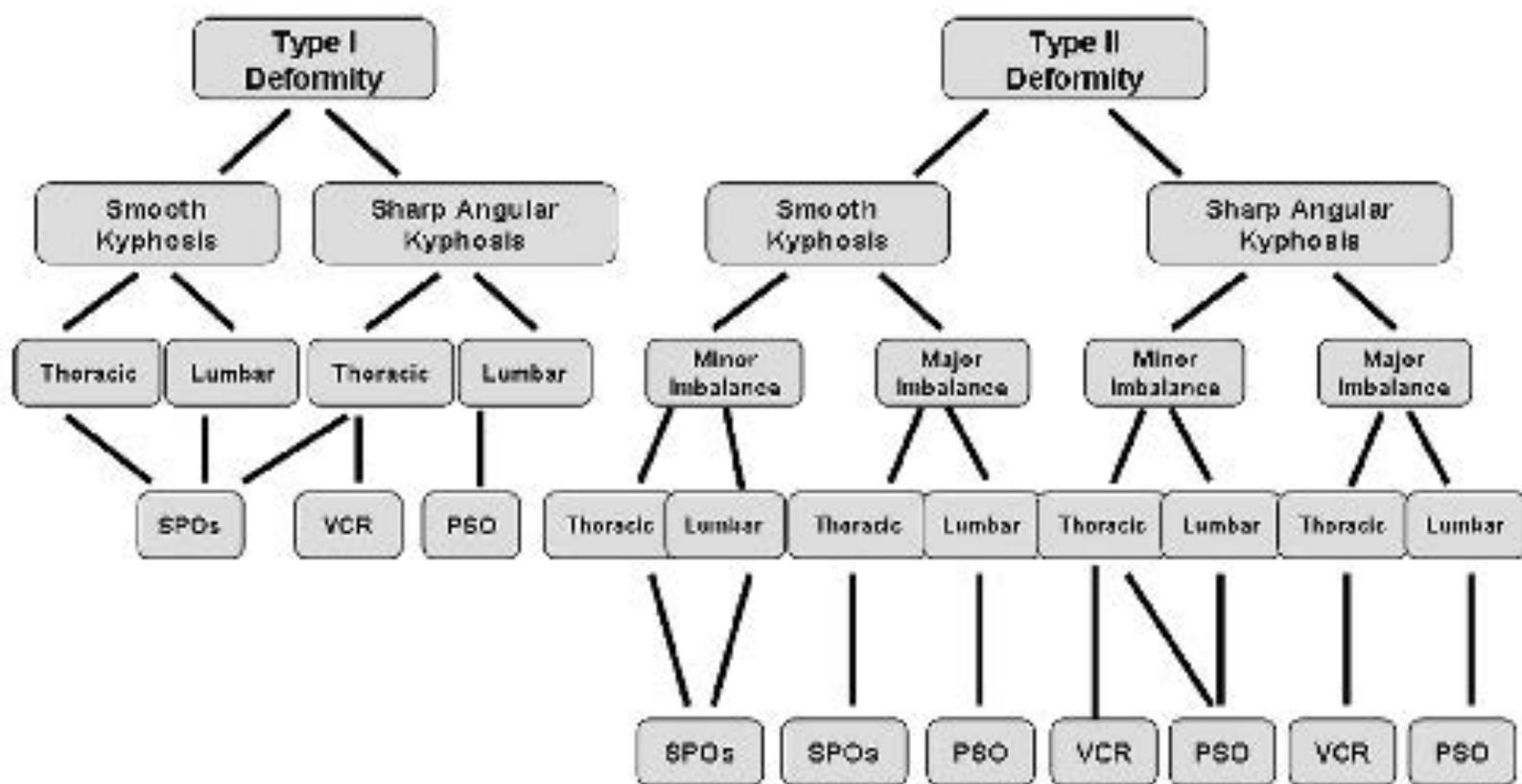


Sagittal Balance is the dominant predictor of HRQOL in Adult Spinal Deformity

Decision Making Regarding Smith-Petersen *vs.* Pedicle Subtraction Osteotomy *vs.* Vertebral Column Resection for Spinal Deformity

Keith H. Bridwell, MD

Decisions on Spinal Deformity • Bridwell S177



Schwab Formula

Utilizing Pelvic Parameters to help Plan Osteotomies

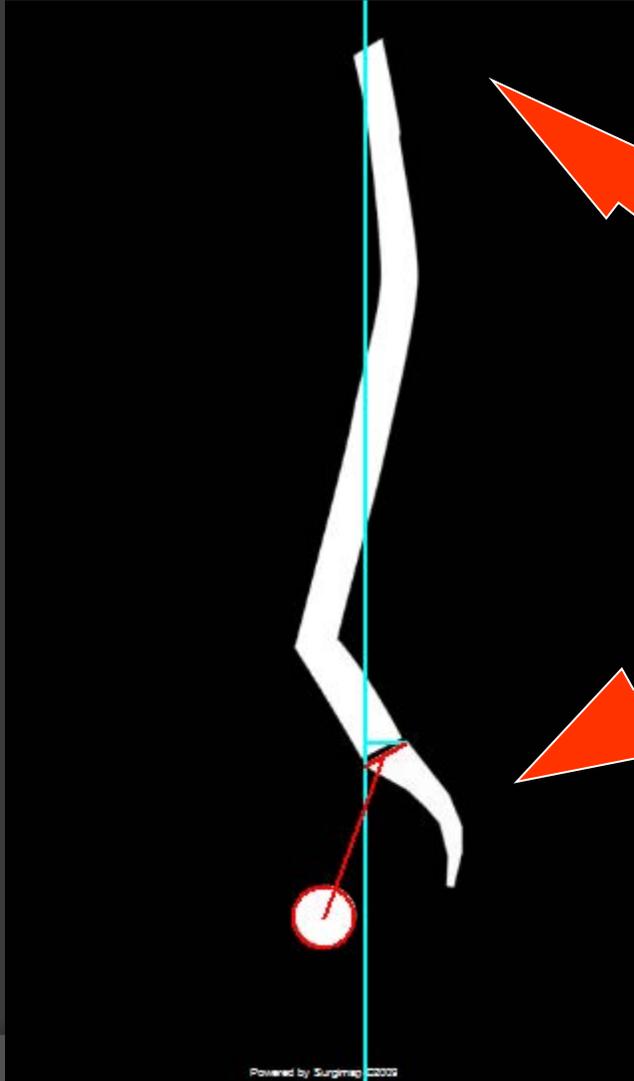


$$PT = 1.14 + 0.71 \times (PI) - 0.52 \times (\text{Maximal Lumbar Lordosis}) - 0.19 \times (\text{Maximal Thoracic Kyphosis})$$

$$SVA = -52.87 + 5.90 \times (PI) - 5.13 \times (\text{Maximum Lumbar Lordosis}) - 4.45 \times (PT) - 2.09 \times (\text{Maximal Thoracic Kyphosis}) + 0.566 \times (\text{Age})$$

Prediction of PT=16.3 Prediction of SVA= -1.8cm

Ex: Reconstruction



Pre-Op Evaluation
Large SVA (>20cm)
Large PT (38 deg)

PSO Planning
SVA + PT correction
PSO 46deg

Post-Op Evaluation
SVA <5cm
PT < 25deg

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Surgeon Name: [Name] Rod: [Type] (L) [Length] (R) [Length]
 Surgery Date (MM/DD/YY): [Date] for 5.5 5.5
 Patient initials: [Initials] Titanium
 Age / Gender: [Age] / female Stand
 Case ID: [ID] Spher
 Levels: [Levels] Calib
 Hospital: [Hospital] Extr

| SPINOPELVIC PAR. | PLAN |
|-----------------------------------|------|
| pelvic Tilt | 12 |
| pelvic Inclination (°) | 49 |
| Sacral Slope (°) | 37 |
| Lumbar Lordosis (LL) (°) | 58 |
| Thoracic Kyphosis (TK) (°) | -9 |
| Pelvic Angle (TPA) (°) | 36 |
| Sagittal Vertical Axis (SVA) (mm) | 3 |
| | -41 |

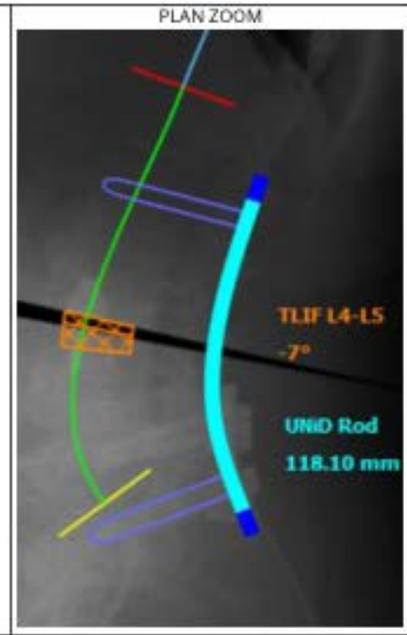
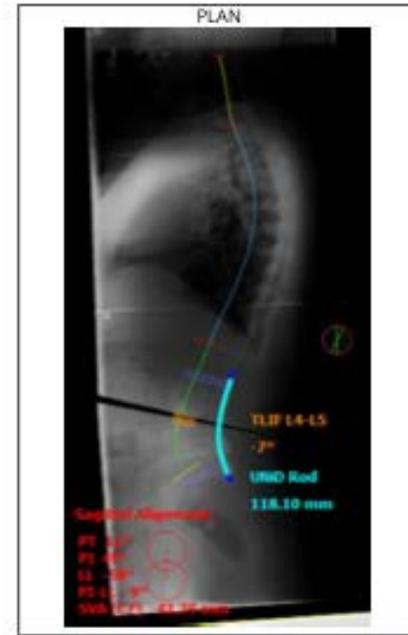
Surgical steps:

Surgical procedure: TLIF
 Vertebrae: L4-L5

1. [Step 1]
2. [Step 2]
3. [Step 3]
4. [Step 4]
5. [Step 5]

Comments:

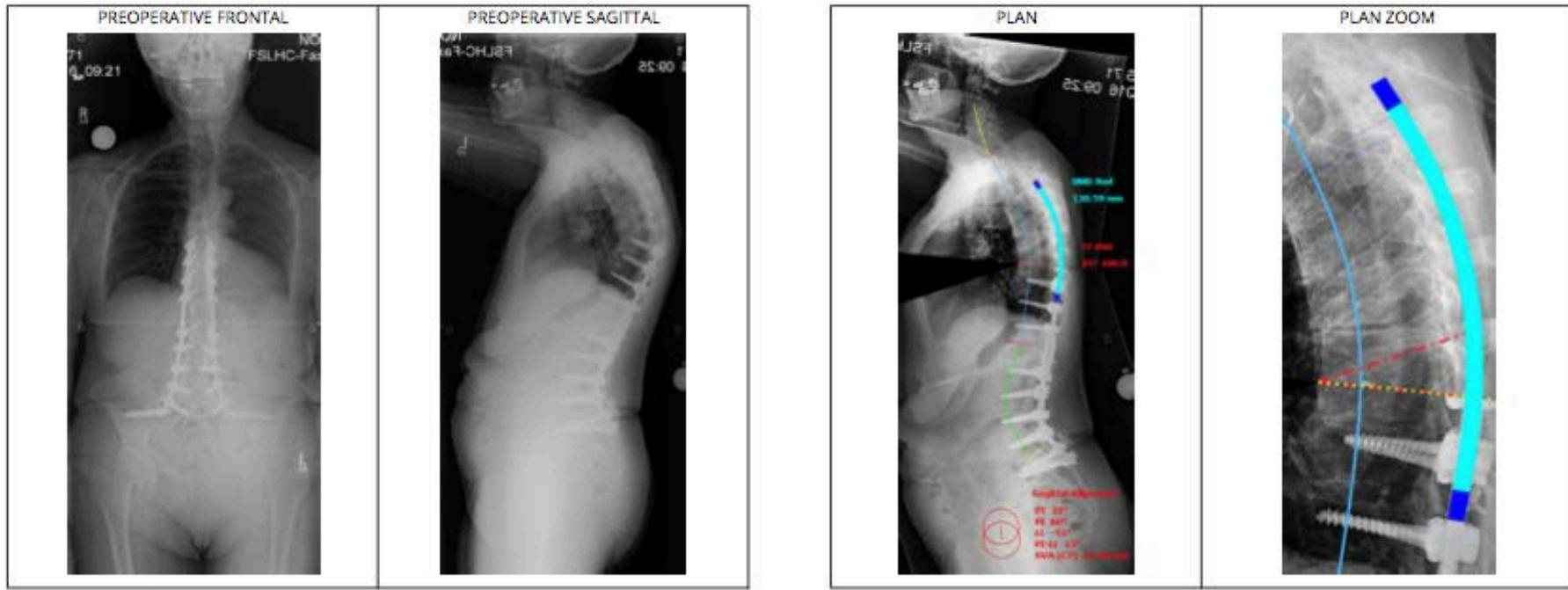
1. Rod to be lengthened according to coronal deformity
2. [Comment 2]
3. [Comment 3]



| | | | | | | | | | |
|-------------------------|---|--------|-------------|-----|----|---------|----|----|------|
| Surgeon Name | h | Rod | (L) | (R) | SF | LVIC PA | OP | TM | PLAN |
| Surgery Date (MM/DD/YY) | | | 5.5 | 5.5 | | | | | |
| Patient Initials | | | Titanu | um | | | | | 22 |
| Age / Gender | male | | Standa | d | | | | | 66 |
| Case ID | | Calibr | Sphere | | | | | | 44 |
| Levels | | Extra | | | | | | | 53 |
| Hospital | c. Luke's | | | | | | | | 13 |
| Surgical steps: | | | | | | | | | |
| 1. | Surgical proced | | vertebra co | d | | | | | |
| 2. | PSO | | T9 | | | | | | |
| 3. | | | | | | | | | |
| 4. | | | | | | | | | |
| 5. | | | | | | | | | |
| Comments: | | | | | | | | | |
| 1. | Rod to be lengthened according to coronal deformity | | | | | | | | |
| 2. | | | | | | | | | |
| 3. | | | | | | | | | |

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(I M) P R O V E

DEPLOYING COMPREHENSIVE
PATIENT SPECIFIC
TECHNOLOGIES TODAY

**ADVANCES IN THE
PERSONALIZED SPINE
MARKET**

medicrea.com | **leading** personalized spine

DECEMBER 15 2016

COMPREHENSIVE PERSONALIZED SPINE

A NEW ERA IN SPINE SURGERY

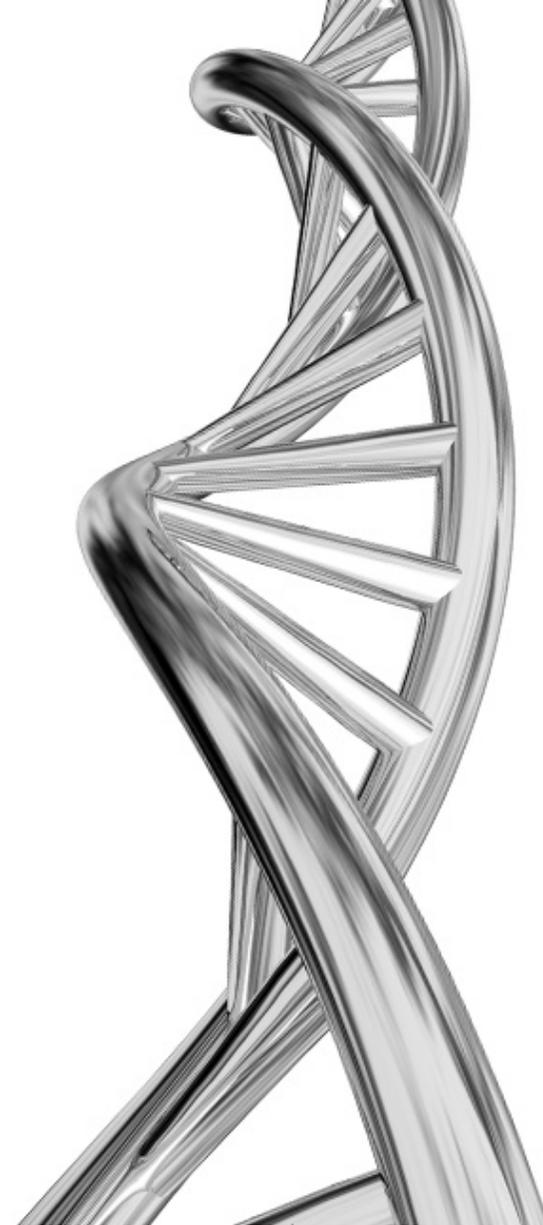
“Personalized Spine” is the ability to create patient-specific implants for complex spine procedures requiring sagittal rebalancing, tailored to achieve the optimal outcome: early and long term structural integrity with global sagittal alignment.

Medicrea offers a unique, service-based approach to complex spine utilizing its UNiD™ IT platform and proprietary manufacturing algorithm.

Medicrea galvanizes surgeons with an iterative system that has both Predictive and Deep Learning capacity, delivering data and information that support surgical case decisions from pre-operative planning to post-operative analysis.

For the first time in this industry, Medicrea is building upon a unique and deep partnership between the surgeon and the UNiD Lab engineers. Medicrea is leading the way in personalized spinal surgery with market-disrupting, proprietary planning, manufacturing and analytical technologies.

THE FUTURE IS NOW



COMPANY OVERVIEW



- HEADQUARTERED IN LYON, FRANCE AND NEW YORK CITY
- COMPREHENSIVE PATIENT-SPECIFIC TECHNOLOGIES FOR COMPLEX SPINE MARKET



- FIRST TO MARKET PATIENT-SPECIFIC IMPLANTS FOR THE SPINE WITH UNID™ RODS
- COMPREHENSIVE 3D-PRINTED PATIENT-SPECIFIC PLATFORM IN-HOUSE
- CENTRALIZED HEADQUARTERS AND MANUFACTURING FACILITIES



- 2015 €27.8M. 2016 SEPTEMBER YTD REVENUE OF €21.6M WITH 81% H1 GROSS MARGIN
- PUBLICLY TRADED ON ALTERNEXT: ALMED TICKER



- RAISED €20 MILLION WITH LEADING U.S. INVESTORS IN AUGUST LED BY ATHYRIUM CAPITAL
- RICK KIENZLE, FOUNDING MEMBER OF GLOBUS MEDICAL, APPOINTED CHIEF COMMERCIAL OFFICER

INVESTMENT HIGHLIGHTS

- INNOVATIVE SERVICE-ORIENTED APPROACH TO COMPLEX SPINE
- PATIENT SPECIFIC IMPLANTS DRIVE OPTIMAL PATIENT OUTCOMES
- DIFFERENTIATED UNiD TECHNOLOGY BENEFITS ALL KEY STAKEHOLDERS
- SIGNIFICANT GLOBAL MARKET OPPORTUNITY WITH LIMITED COMPETITION
- EXPERIENCED MANAGEMENT TEAM FOCUSED ON COMMERCIAL EXECUTION
- ATTRACTIVE FINANCIAL PROFILE



LEADERSHIP



Denys SOURNAC
Founder,
Chairman
& CEO

Successful entrepreneur in the medical supply and orthopaedics industry with over 30 years' experience creating, building and managing companies.



David RYAN
VP Product Dev &
Marketing

Biomechanical Engineer with more than 11 years' experience in orthopedics. Former R&D Director, Scient'x (Alphatec Spine).



Richard KIENZLE
Chief Commercial &
Business
Development Officer

Co-founder of Globus Medical with over 25 years of Executive Sales Management experience in the medical device industry.



Fabrice KILFIGER
Chief Financial Officer

Over 25 years' experience in finance, including over 10 years heading the finance divisions of listed companies.



Pierre OLIVIER
CEO
Medicrea USA

Over 25 years' experience in Marketing and Project Management, mainly in the United States, particularly in sales launches of new innovative products.

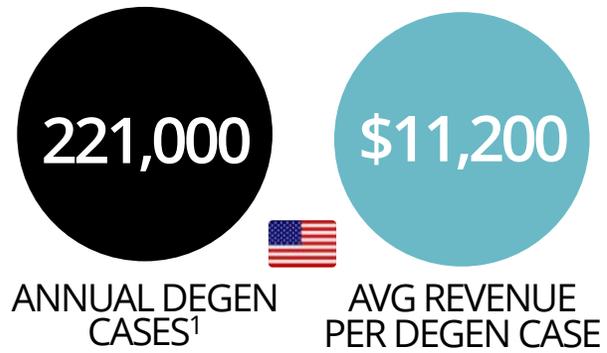
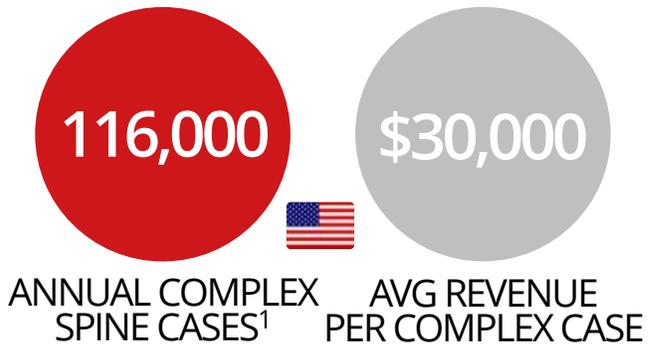


Greg RHINEHART
VP Sales
Medicrea USA

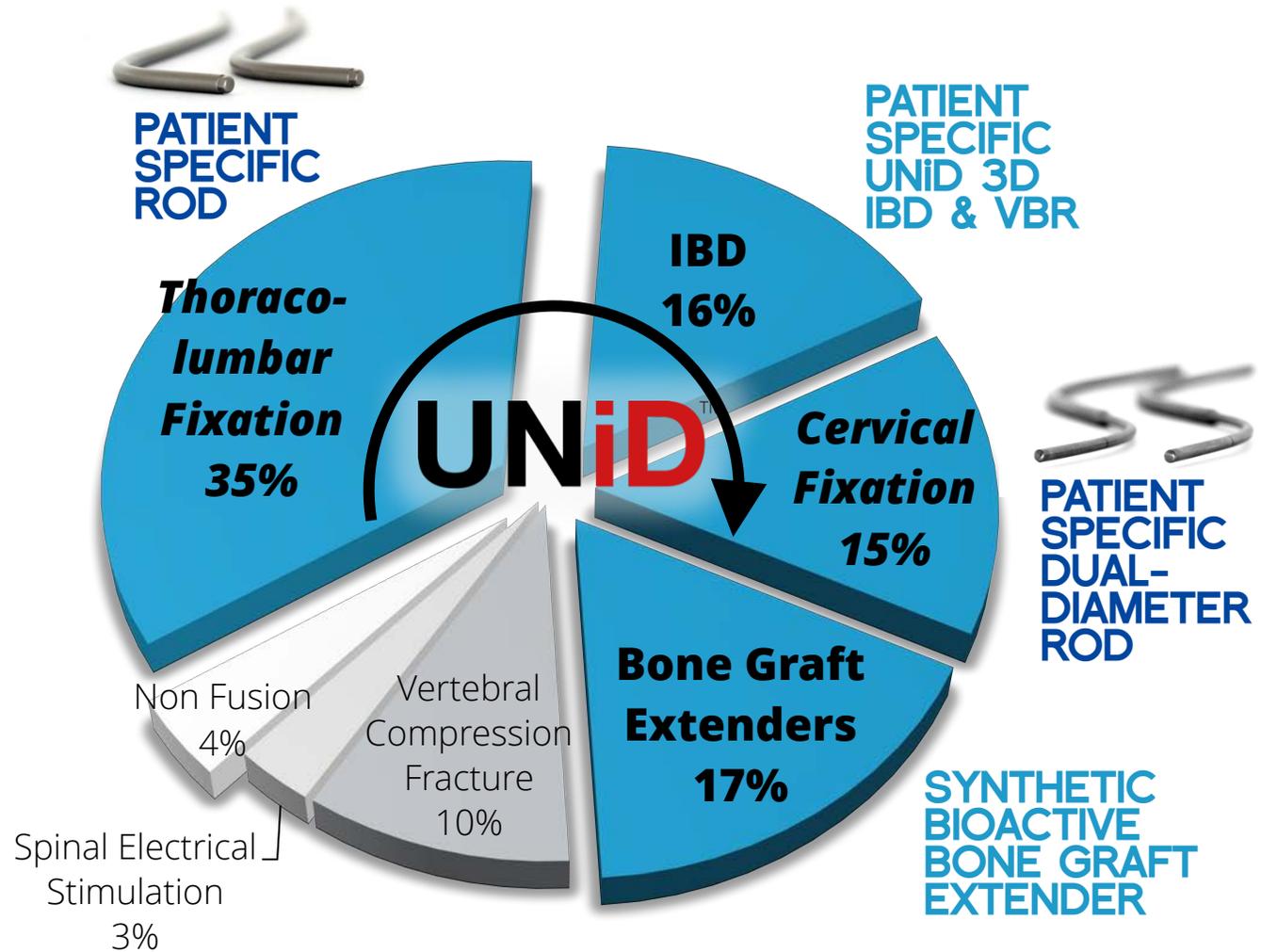
Industry executive with over 20 years of Sales Management experience in the medical device industry.



SPINE MARKET SEGMENTS



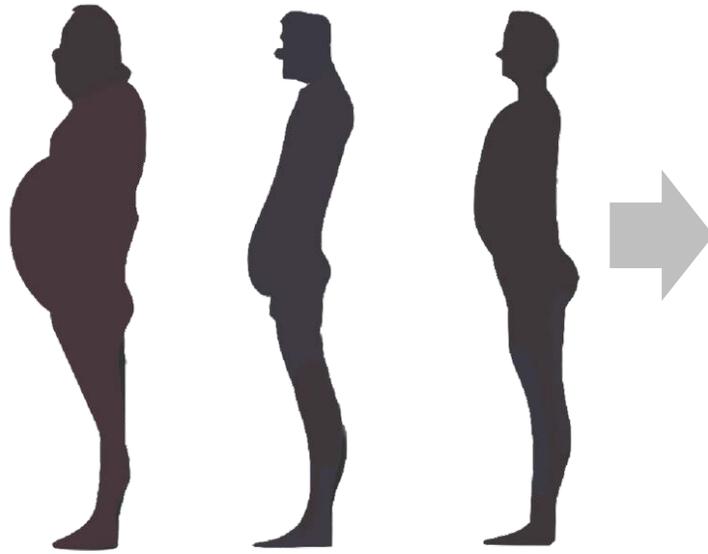
UNID TECHNOLOGIES U.S. MARKET OPPORTUNITY NEARS **\$6B**



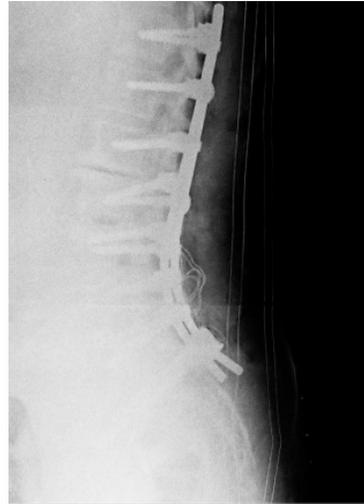
1. 2015 Instrumented Thoracolumbar Procedures annually (409,100). 2013 Millennium Research Group, Inc., Table 87 "Thoracolumbar Fusions, by Indication."

CLINICAL RATIONALE

ONE SIZE DOES NOT FIT ALL...



Post-op X-Ray



HIGH VARIABILITY IN BENDING

Attending Surgeons

Fellows

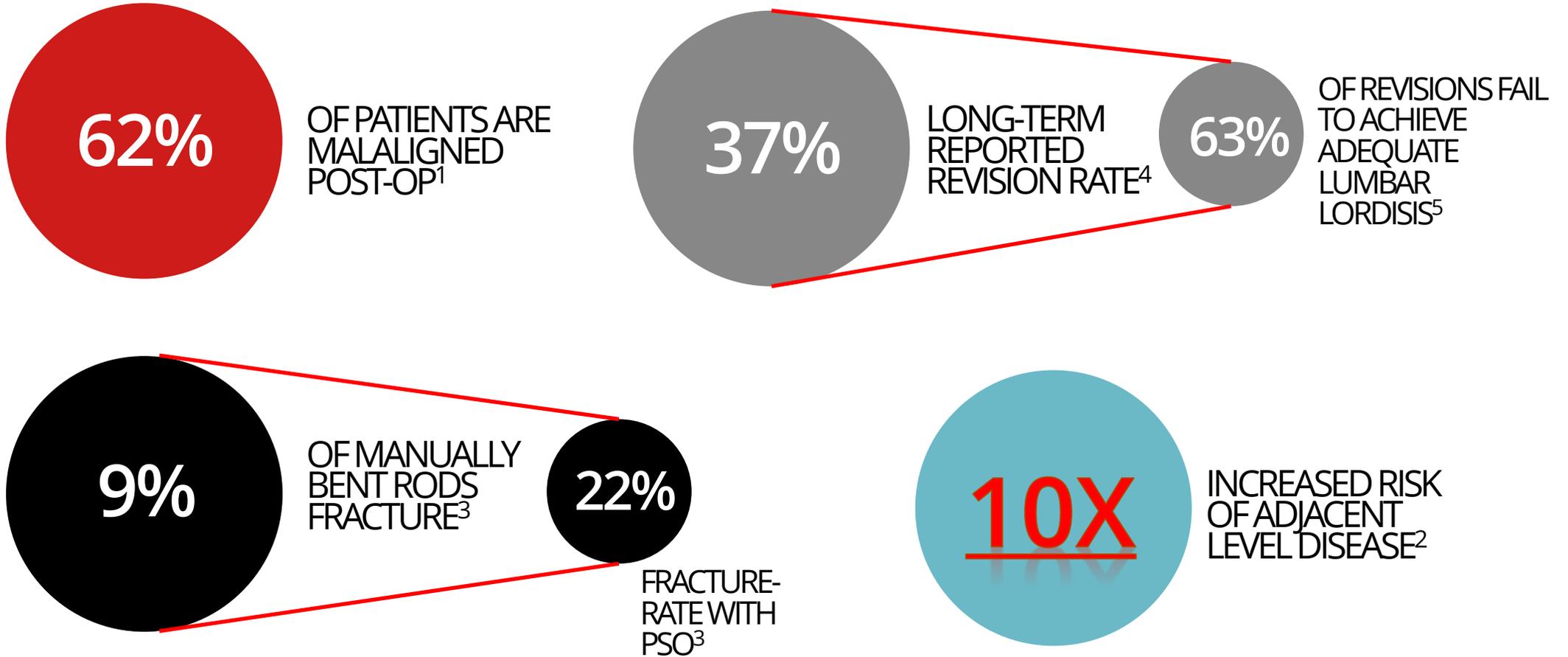


High Variability: Qualitative comparison between the real shape and the bending obtained by the attending and fellow groups.⁷

7. Rod bending lab organized in 2012 included 8 spine surgeons and fellows from major US teaching institution

CURRENT SHORTCOMINGS IN TREATMENT

CLINICAL ISSUES

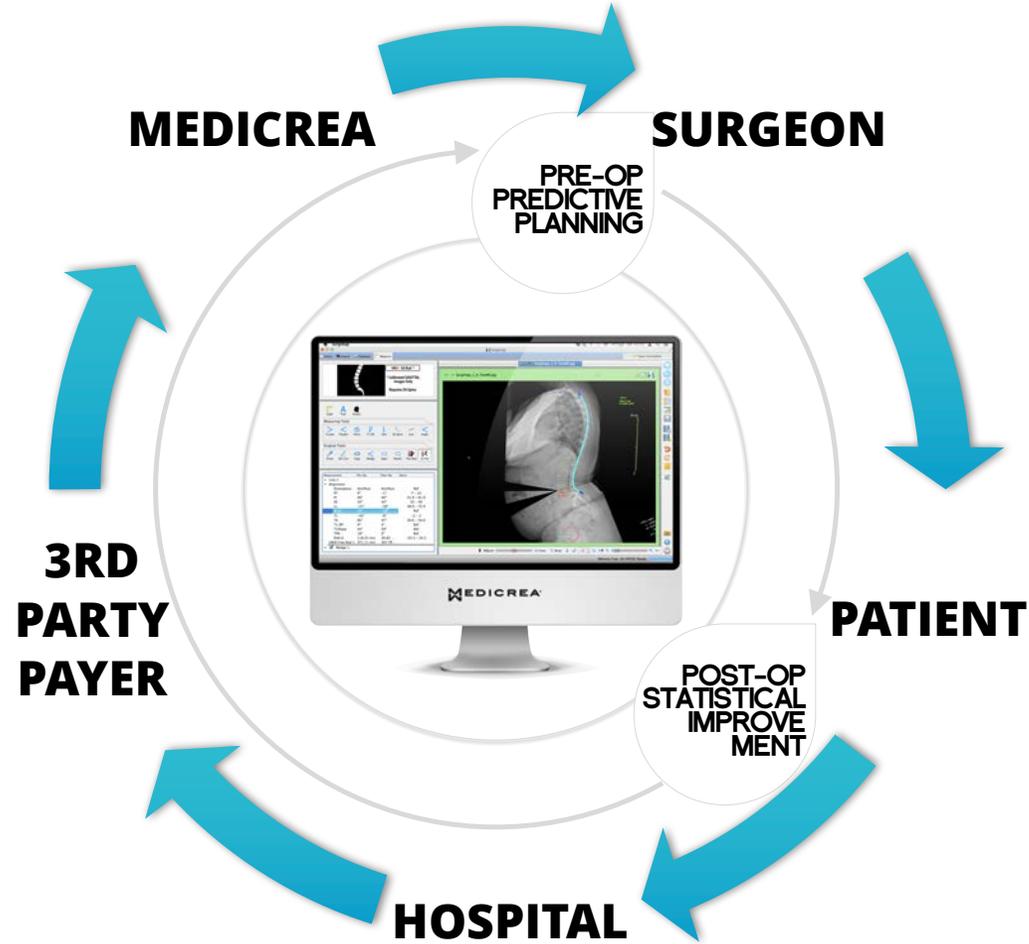


1. Moal B, Schwab F, Ames CP, et al. Radiographic Outcomes of Adult Spinal Deformity Correction: A Critical Analysis of Variability and Failures Across Deformity Patterns. *Spine Deform.* 2014.
2. Rothenfluh DA, Mueller DA, et al. Pelvic incidence-lumbar lordosis mismatch predisposes to adjacent segment disease after lumbar spinal fusion. *Eur Spine J* (2015) 24:1251-1258

3. Smith JS, Shaffrey CI, Klineberg E, et al. Prospective multicenter assessment of risk factors for rod fracture following surgery for adult spinal deformity. *J Neurosurg Spine* 21:994-1003, 2014.
4. Frymoyer JW, Matteri RE, Hanley EN, et al: Failed lumbar disc surgery requiring second operation. A long-term follow-up study. *Spine* 3:7-11, 1978
5. Jang J-S, Lee S-H, Min J-H, Kim SK, Han K-M, Maeng DH. Surgical treatment outcome of lumbar surgery syndrome due to sagittal imbalance. *Spine (Phila. Pa. 1976)*. 2007

COMPREHENSIVE PERSONALIZED SPINE

ITERATIVE DEEP-LEARNING VIRTUOUS CYCLE
BENEFITS ALL STAKEHOLDERS



UNiD™

- DATA-DRIVEN METHODOLOGY
- IMPROVED CLINICAL RESULTS
- REDUCED INCIDENCE OF REVISION
- COST SAVING TO HEALTH SYSTEM
- REDUCED INVENTORY REQUIREMENTS

GLOBAL UNiD ADOPTION

76%



USED WITH
MEDICREA
FIXATION

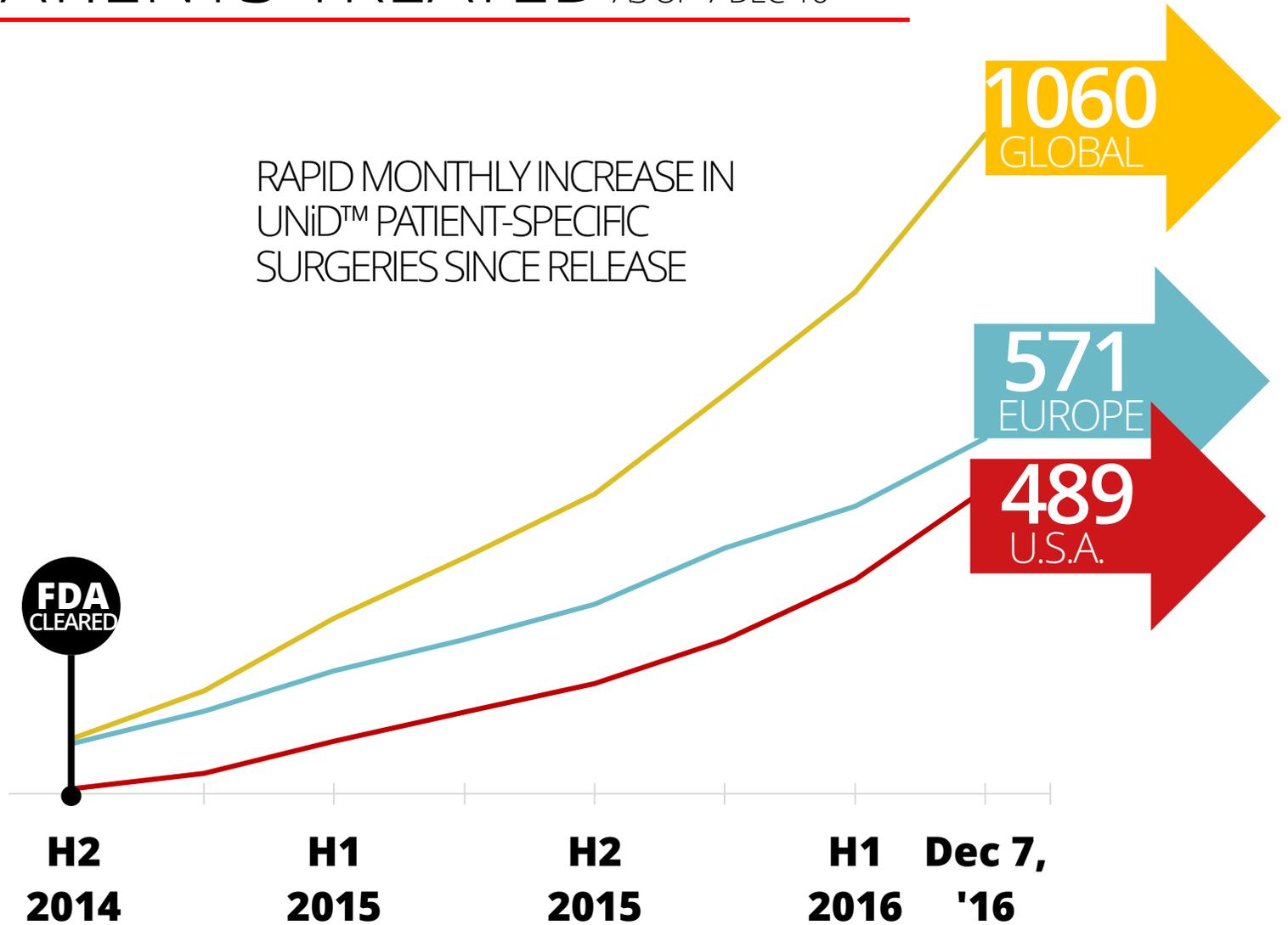
\$9.8M



TOTAL US UNiD
CASE REVENUE
(15% PREMIUM ON
PATIENT-SPECIFIC)

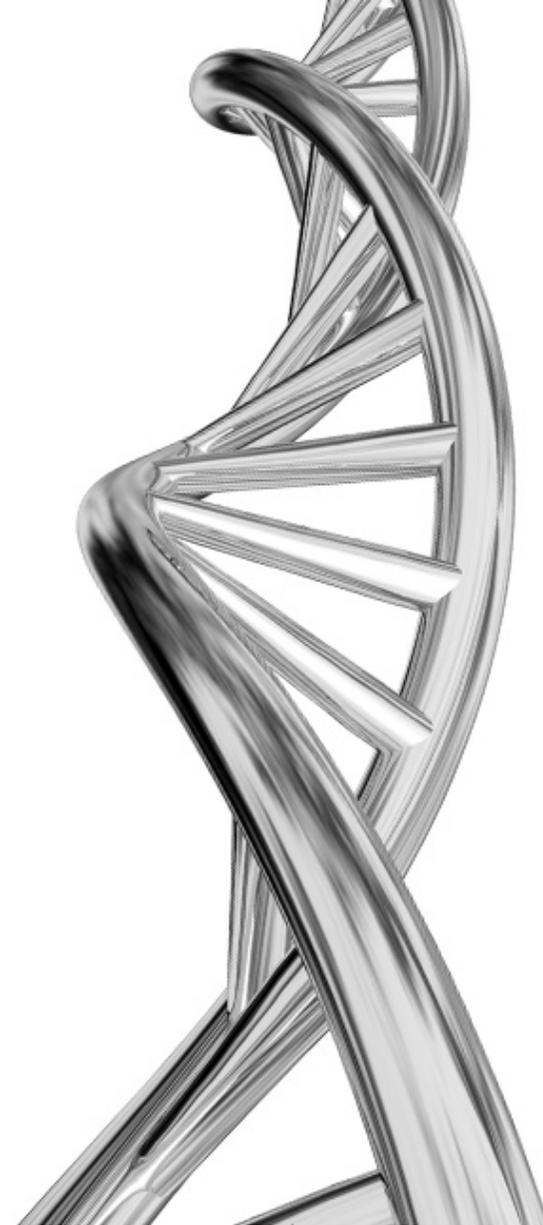
PATIENTS TREATED AS OF 7 DEC '16

RAPID MONTHLY INCREASE IN
UNiD™ PATIENT-SPECIFIC
SURGERIES SINCE RELEASE



AT A GLANCE

- 2016 projected revenue of \$30M
- High gross margin in the 80 % range
- Significant capex spendings in 2016 & 2015 to increase in-source of production and manufacturing efficiency
- EBITDA positive since 2010
- 150+ Headcount
- Transformative € 20M fundraising in August 2016, including € 15M from Athyrium Capital Management in US and € 5M from multiple US investors & Executive team



GROWTH STRATEGY

SALES AND MARKETING

- RICK KIENZLE APPOINTED TO LEAD COMMERCIALIZATION EFFORTS
- DRIVE REVENUE WITH INTEGRATED PRODUCT SOLUTIONS THROUGH UNiD TECHNOLOGY ADOPTION
- BUILD BODY OF EVIDENCE FOR PATIENT-SPECIFIC UNiD ROD
- INCREASE PRESENCE WITH KOLS IN STRATEGIC HOSPITALS AND CENTERS
- INCREASE AWARENESS WITH UNiD WARRANTY PROGRAM
- EXPAND ONLINE MARKETING CAMPAIGN AIMED AT US PATIENTS



MANUFACTURING

- IN-HOUSE TITANIUM 3D PRINTING PATIENT-SPECIFIC IBD & VBR
- U.S. UNiD ROD MANUFACTURING FOR DEGENERATIVE DEFORMITY MARKET
- BRING STERILIZATION CAPABILITIES IN-HOUSE
- SIGNIFICANT COST REDUCTION AND INCREASED EFFICIENCY IN INVENTORY MANAGEMENT VIA UNiD PLATFORM PREDICTIVE TECHNOLOGIES



GROWTH STRATEGY

NEW TECHNOLOGY DEVELOPMENT

Q1
'17

- PREDICTIVE, DEEP LEARNING THRU BIG DATA COMPILATION AND MINING
- COMPLETE UNiD MIS DEVELOPMENT
- FDA FILE SUBMISSION FOR PATIENT-SPECIFIC 3D-PRINTED

Q2
'17

- UNiD LAB ONLINE INTERFACE
- UNiD 3D BIPLANAR ROD DEVELOPMENT, MARKET RELEASE

Q3
'17

- FDA CLEARANCE OF PATIENT-SPECIFIC 3D-PRINTED INTERBODY & VERTEBRAL BODY REPLACEMENT DEVICES



CLINICAL EXPERIENCE WITH UNID TECHNOLOGY

Themistocles S. Protopsaltis, MD

*Director, Adult Spinal Deformity Surgery
Assistant Professor of Orthopaedic Surgery
NYU Langone Medical Center, New York*

- Pre-operative planning using sagittal parameters is becoming more prevalent
- Pelvic Incidence ranges 35-85 degrees
- SRS-Schwab Classification includes sagittal modifiers based on disability measures
- Published alignment targets based on broad age ranges
- Elderly patients have higher rates of PJK and complications
 - Age should be a factor in pre-operative planning

SRS-Schwab Classification 3 Sagittal Modifiers¹

PI minus LL

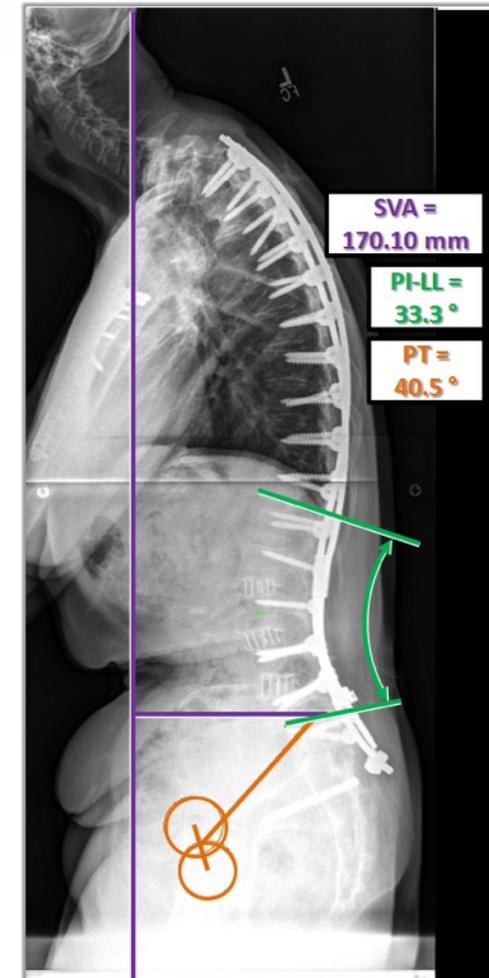
- 0** : within 10°
- +** : moderate 10-20°
- ++** : marked >20°

Global alignment

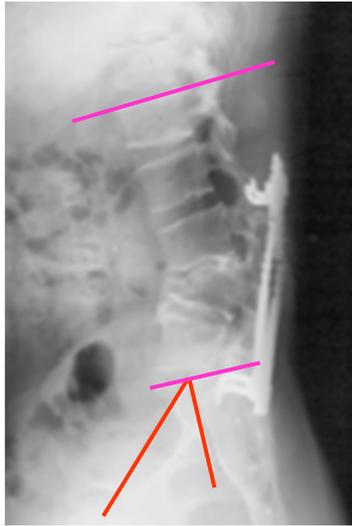
- 0** : SVA < 4cm
- +** : SVA 4 to 9.5cm
- ++** : SVA > 9.5cm

Pelvic Tilt

- 0** : PT < 20°
- +** : PT 20-30°
- ++** : PT > 30°



1. Schwab et al., Spine 2013



Regional
Loss of lordosis
Versus PI

PI-LL < 10°



Global
SVA

SVA < 4.5cm

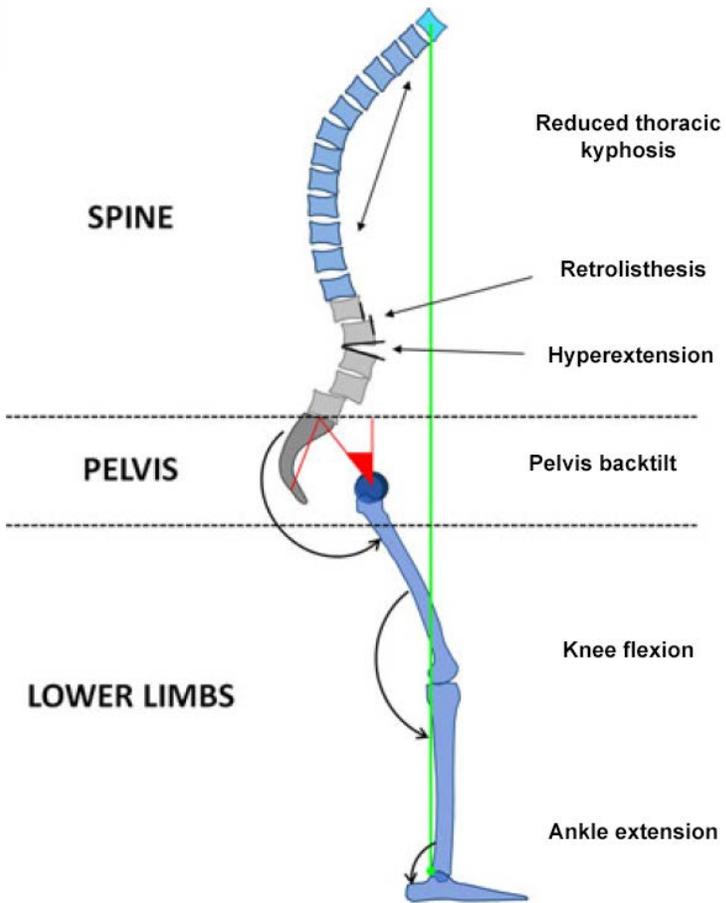


Compensatory
Pelvic tilt

PT < 20°

**Adult deformity databases have been used to propose targets for
deformity correction (Schwab et al Spine 2013)**

Alignment targets are based on baseline analysis of HRQOL and alignment



Alignment targets should not be the same for these patients

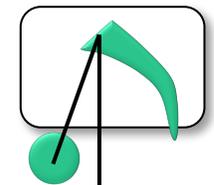
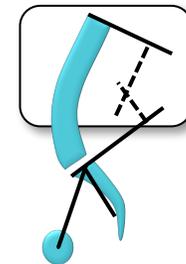
- **Age-adjusted alignments were calculated using simplified formula**
- **Patients were classified as either:**
 - Under corrected (UNDER)
 - Matched (MATCHED)
 - Over corrected (OVER)
- **Threshold for over and under corrected were calculated base on patient age +/- 10 years**
- **Patient reported outcomes were compared between these 3 groups**
 - ANOVA with Tukey's Post-hoc analysis
 - Kruskal-Wallis



$$PT = \frac{(Age - 55)}{3} + 20$$

$$PI - LL = \frac{(Age - 55)}{2} + 3$$

$$SVA = 2 * (Age - 55) + 25$$



SURGICAL LIMITATIONS & REVISION



Preop

| | |
|-------|-------------|
| TPA | 36° |
| SVA | 9 cm |
| PT | 34° |
| PI-LL | 31° |



1st Postop

| | |
|-------|---------------|
| TPA | 21° |
| SVA | 5.2 cm |
| PT | 25° |
| PI-LL | 30° |



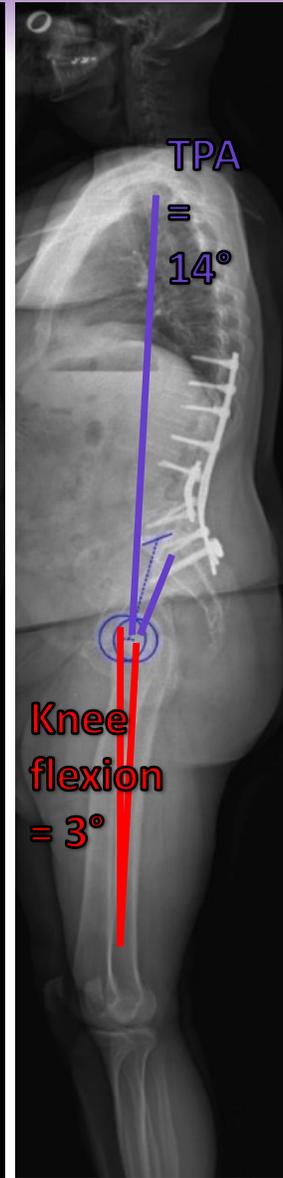
3 year f/u

| | |
|-------|---------------|
| TPA | 37° |
| SVA | 6.8 cm |
| PT | 29° |
| PI-LL | 38° |



TPA =
37°

Knee
flexion
= 15°



TPA =
14°

Knee
flexion
= 3°

45 year old M with post-traumatic lumbar kyphosis

- Undergoes PSO L3 and T10-Plevs **prior to UNiD**
- **2 years F/U: broken rods and loss of sagittal alignment**

Approximation & mechanical weakening in manual bending



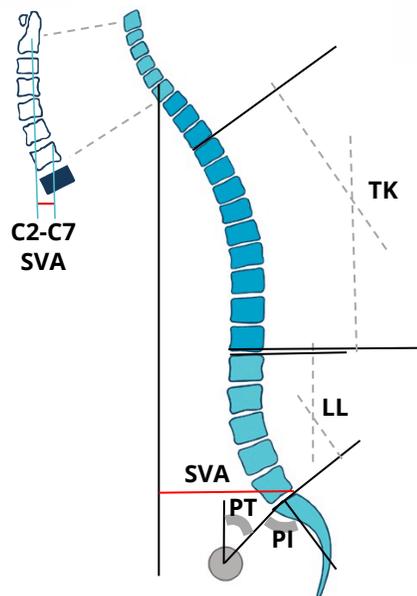
2nd Postop

| | |
|-------|---------------|
| TPA | 14° |
| SVA | 2.3 cm |
| PT | 16° |
| PI-LL | -2° |

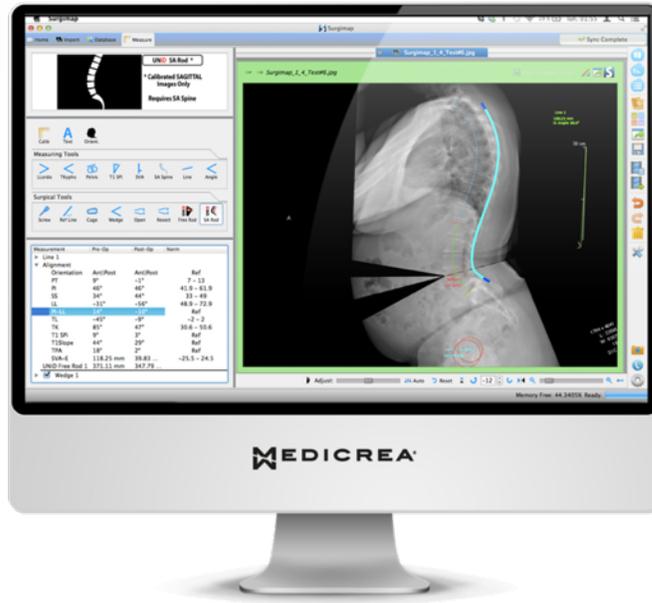
UNiDTM

- OVER 40 UNID ROD CASES PERFORMED SINCE DEC 2014
- ADAPTATION AND IMPROVEMENT OF SURGICAL STRATEGY BASED ON ANALYSIS OF EXPERIENCE
- PRIOR EXPERIENCE PLANNING CASES PERSONALLY
- LIMITED LEARNING CURVE ADOPTING INTO PRACTICE

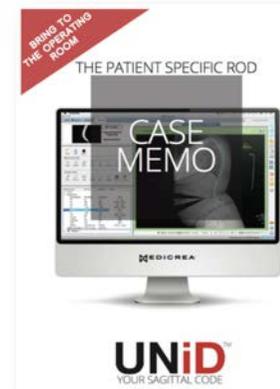
FORMING AN ITERATIVE TECHNIQUE



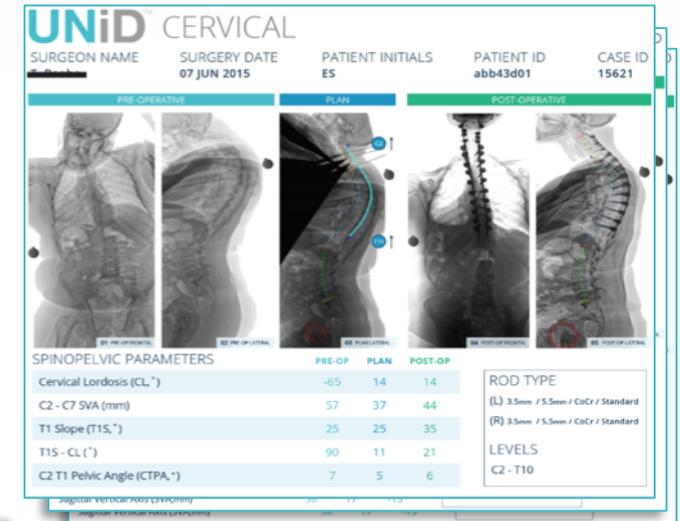
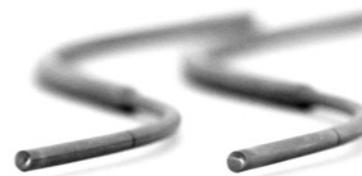
X-RAY MEASUREMENTS



DIGITIZED CASE PLAN SIMULATION



PATIENT-SPECIFIC IMPLANTS



ADVANCED POST-OPERATIVE ANALYSES

SURGICAL STRATEGY

Date: 04/01/15

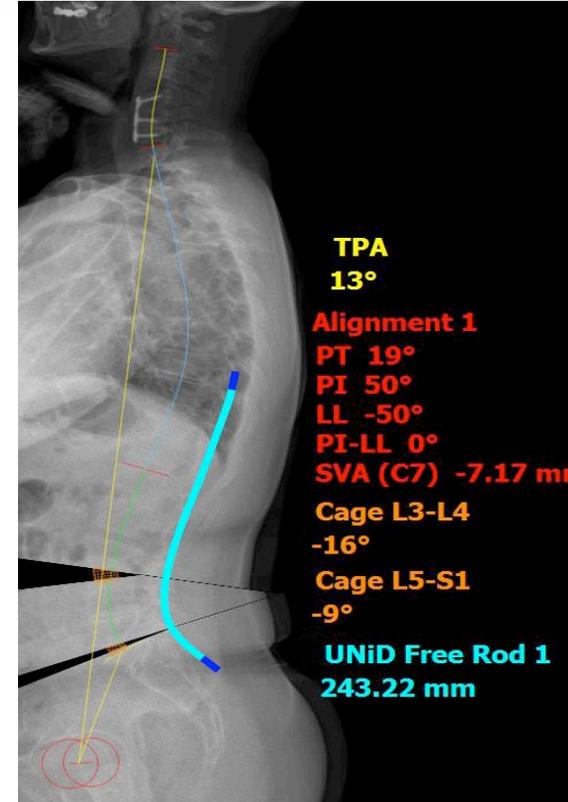
Levels: T10 - Pelvis

Interbody cages: L3-L4, L5-S1

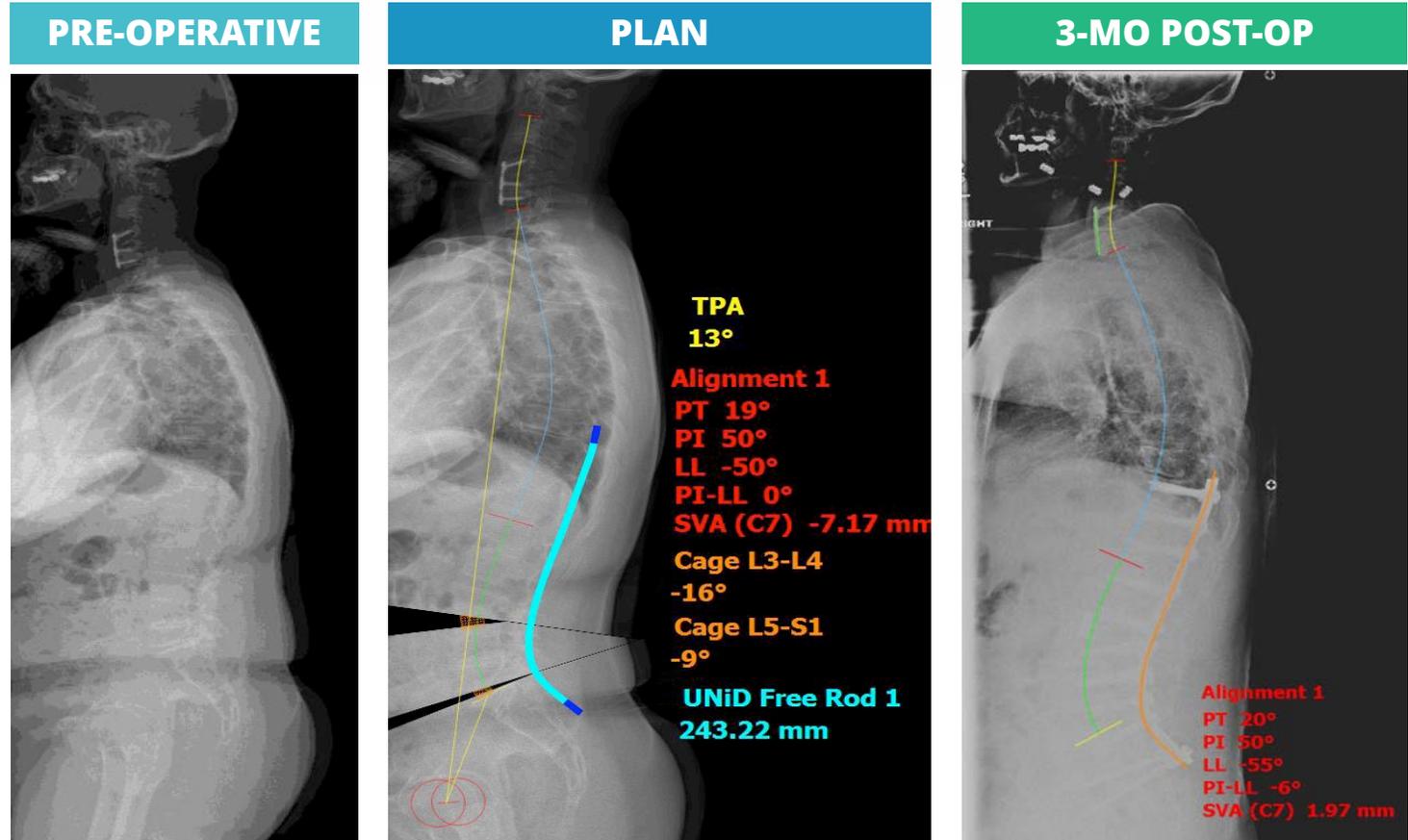
PRE-OPERATIVE



PLAN



| SPINOPELVIC PARAMETERS | PRE-OP | PLAN | 3-MO POST OP |
|--------------------------------------|--------|------|--------------|
| Pelvic Tilt (PT,°) | 29 | 19 | 20 |
| Pelvic Incidence (PI,°) | 50 | 50 | 50 |
| Sacral Slope (SS,°) | 21 | 31 | 30 |
| Lumbar Lordosis (LL,°) | 29 | 50 | 55 |
| PI-LL (°) | 20 | 0 | -6 |
| Thoracic Kyphosis (TK,°) | 32 | 32 | 44 |
| T1 Pelvic Angle (TPA,°) | 27 | 13 | - |
| Sagittal Vertical Alignment (SVA,mm) | 51.9 | -7.2 | 1.95 |



CASE STUDY: PELVIC COMPENSATION

SURGICAL STRATEGY

Date: 08/22/16

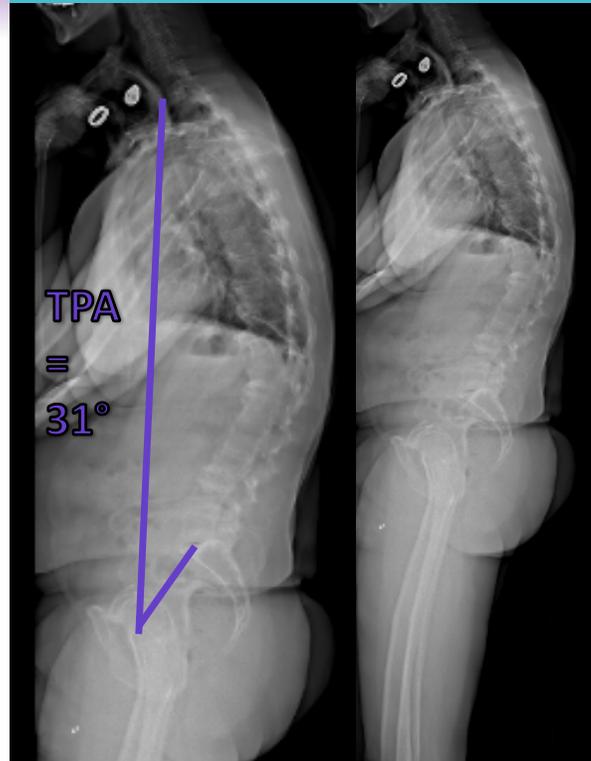
Levels: T10 - Pelvis

Interbody cages: L5/L6, L6/S1

Osteotomy: L5 PSO

Comments: 6 lumbar vertebrae

PRE-OPERATIVE



70 year old M with lumbar flatback and severe spinal stenosis

SPINOPELVIC PARAMETERS

PRE-OP

| | |
|--------------------------------------|------|
| Pelvic Tilt (PT,°) | 34 |
| PI-LL (°) | 28 |
| T1 Pelvic Angle (TPA,°) | 31 |
| Sagittal Vertical Alignment (SVA,mm) | 49.6 |



Rod planned from T2 to Pelvis for intra-op flexibility.

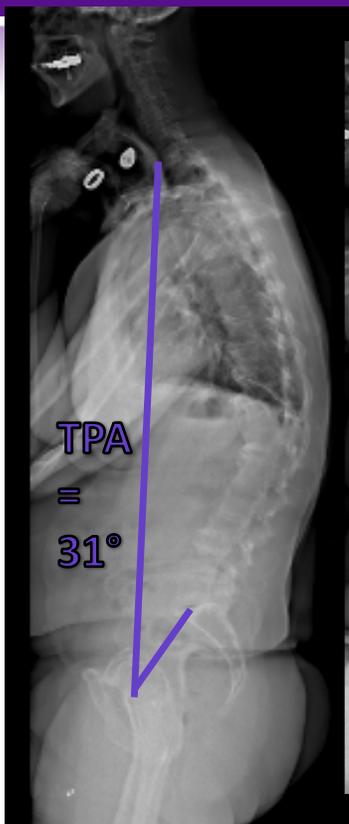
70 year old M with lumbar flatback and severe spinal stenosis

SPINOPELVIC PARAMETERS

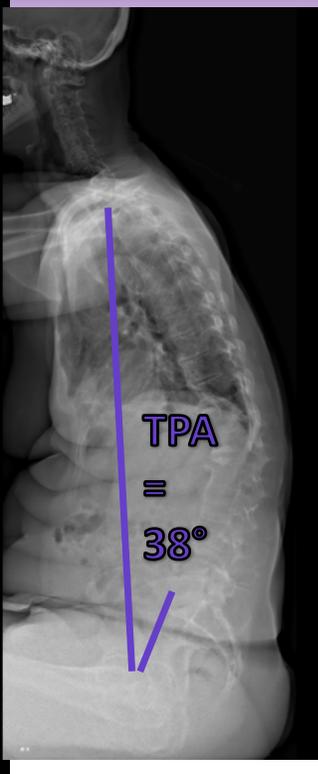
| | PRE-OP | PLAN |
|--------------------------------------|--------|------|
| Pelvic Tilt (PT,°) | 34 | 15 |
| Pelvic Incidence (PI,°) | 46 | 46 |
| Sacral Slope (SS,°) | 12 | 31 |
| Lumbar Lordosis (LL,°) | 17 | 39 |
| PI-LL (°) | 29 | 7 |
| Thoracic Kyphosis (TK,°) | 28 | 28 |
| T1 Pelvic Angle (TPA,°) | 31 | 15 |
| Sagittal Vertical Alignment (SVA,mm) | 52 | 48 |



PREDICTABILITY OF CORRECTION



PRE-OP



SITTING



PLAN



INTRA-OP

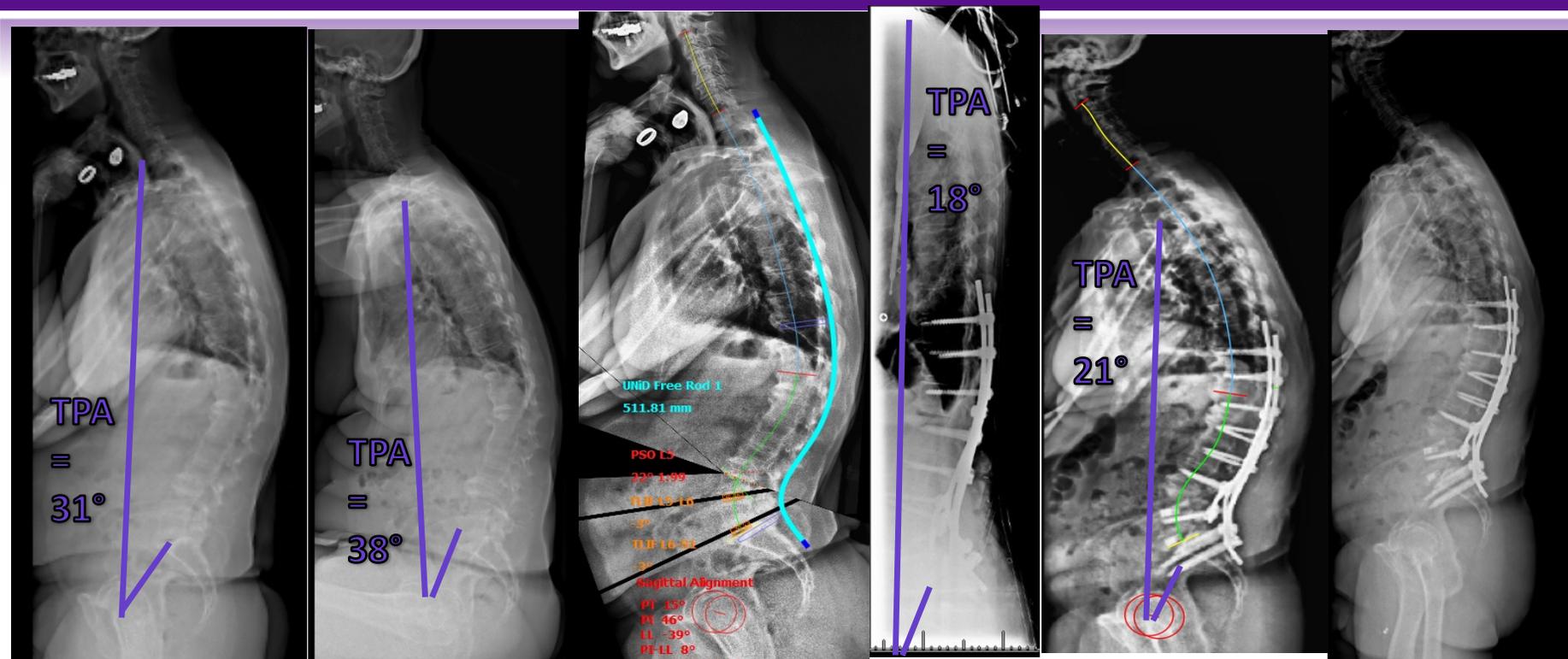
70 year old M with lumbar flatback and severe spinal stenosis

- Undergoes PSO L5 and T10-Pelvis



SPINOPELVIC PARAMETERS

| | | | | |
|--------------------------------------|------|----|----|----|
| Pelvic Tilt (PT,°) | 34 | 37 | 15 | -- |
| PI-LL (°) | 28 | 30 | 7 | 5 |
| T1 Pelvic Angle (TPA,°) | 31 | 38 | 15 | 18 |
| Sagittal Vertical Alignment (SVA,mm) | 49.6 | 80 | 48 | 64 |



70 year old M with lumbar flatback and severe spinal stenosis

SPINOPELVIC
PARAMETERS

PRE-OP SITTING

PLAN

INTRA-OP

INITIAL
POST-OP

| | PRE-OP | SITTING | PLAN | INTRA-OP | INITIAL POST-OP |
|--------------------------------------|--------|---------|------|----------|-----------------|
| Pelvic Tilt (PT,°) | 34 | 37 | 15 | -- | 20 |
| PI-LL (°) | 28 | 30 | 7 | 5 | 5 |
| T1 Pelvic Angle (TPA,°) | 31 | 38 | 15 | 18 | 21 |
| Sagittal Vertical Alignment (SVA,mm) | 49.6 | 80 | 48 | -- | 65 30 |

Pelvic compensation resolved

UNiD™

- Reduction in revision cases
- No rod breakage experienced
- Respects need for comprehensive patient file documentation
- Clear markers for quality of care assessment
- Established working relationship with UNiD Lab
- More consistent start to finish



| UNiD CERVICAL | | | | |
|----------------------------------|--------------|------------------|----------------|---------|
| SURGEON NAME | SURGERY DATE | PATIENT INITIALS | PATIENT ID | CASE ID |
| | 07 JUN 2015 | ES | abb43001 | 15621 |
| PRE-OPERATIVE | | PLAN | POST-OPERATIVE | |
| | | | | |
| SPINOPELVIC PARAMETERS | | | | |
| | PRE-OP | PLAN | POST-OP | |
| Cervical Lordosis (CL,°) | -65 | 14 | 14 | |
| C2 - C7 DVA (mm) | 27 | 27 | 44 | |
| T1 Slope (T1S,°) | 25 | 25 | 35 | |
| T15 - CL (°) | 90 | 11 | 21 | |
| C2 T1 Pelvic Angle (CTPA,°) | 7 | 5 | 6 | |
| ROD TYPE | | | | |
| R2 4.5mm / 5.5mm / C6C7 Standard | | | | |
| R0 4.5mm / 5.5mm / C6C7 Standard | | | | |
| LEVELS | | | | |
| C2 - T10 | | | | |



- 1) PREDICTS PATIENT-SPECIFIC **OPTIMAL SAGITTAL ALIGNMENT**
- 2) PROVIDES ITERATIVE CLINICAL TREATMENT SOLUTION
- 3) SAFEGUARDS AGAINST REVISION
- 4) REMOVES INTRA-OPERATIVE FIDDLE & MATERIAL DAMAGE
- 5) FEEDS BACK STATISTICAL ANALYSIS TO PLANNING SEQUENCE

UNiD TECHNOLOGY MAY BECOME STANDARD OF CARE FOR ALL CERVICAL AND THORACO-LUMBAR COMPLEX SPINE PROCEDURES.

UNiD™

“Understanding and restoring sagittal alignment is key towards providing better patient outcomes and preventing the need for reoperations, a major factor in rising health care costs. By providing rod customization, UNiD™ allows surgeons to precisely execute their preoperative plan and frees them from the antiquated technique of freehand bending, ensuring individual patients receive the most accurate and effective treatment. Having a more precise, personalized rod ready before even stepping foot in the operating room is a game-changer for spine surgery.”

- Dr. Frank Schwab, HSS, New York

“The [UNiD™] patient-specific rod is very much ahead of its time. When we finish the operation, we’ve left them with the best possible appearance for the rest of their lives. The curve is not going to worsen and there is less likelihood of them having pain.”

- Dr. Andrew King, Children’s Hospital New Orleans

“We now realize how important it is to provide a specific alignment of the spine that is unique to each patient. If we do not achieve the optimal alignment during surgery, then we are too-often revising that patient later. UNiD™ is using precision technology and analysis to solve this clinical issue for patients as well as providing an invaluable support service and feedback loop for surgeons.”

- Dr. Evalina Burger, University of Colorado Hospital

“The days of walking into the OR and ‘figuring it out’ are over.”

- Dr. John Steck, LSU, New Orleans