Introducing New Technologies to Hospitals

Barriers and Considerations

Sigurd Berven, MD
Professor in Residence
Department of Orthopaedic Surgery
University of California San Francisco

Disclosures

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  - NIH, AO Spine, OREF, NSF
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- Ownership/Stock/Options:
  - Providence Medical, Green Sun Medical
- Royalties:
  - Medtronic, Stryker

Overview

- Innovations in Spine Surgery-
  - Patterns of Adoption …and Abandonment
    - Osteobiologics/Dynamic Stabilization/Interspinous Spacers
- Incremental Value of New Technologies and Techniques
- Levels of Evidence to Compel/Support Change
- Goal of cost-saving innovations in healthcare to bend the cost curve
  - Disruptive Innovations in Spine Surgery
- Role of the Hospital in Adoption System in New Technologies
  - Health Technology Assessment Panels

The Promise of New Technology

- Improve Access to Information
- Increase Productivity
- Reduce Errors
- Save Lives
- Improve Quality of Life

The Promise of New Technology

Computing Capacity

John Bardeen, William Shockley and Walter Brattain at Bell Labs, 1948.

Moore's Law - 2005

Moore's Law Applied to Medicine

- Every 2 years would result in a halving of:
  - Infant mortality
  - Implant failure
  - Readmissions
  - Reoperations
  - Complications

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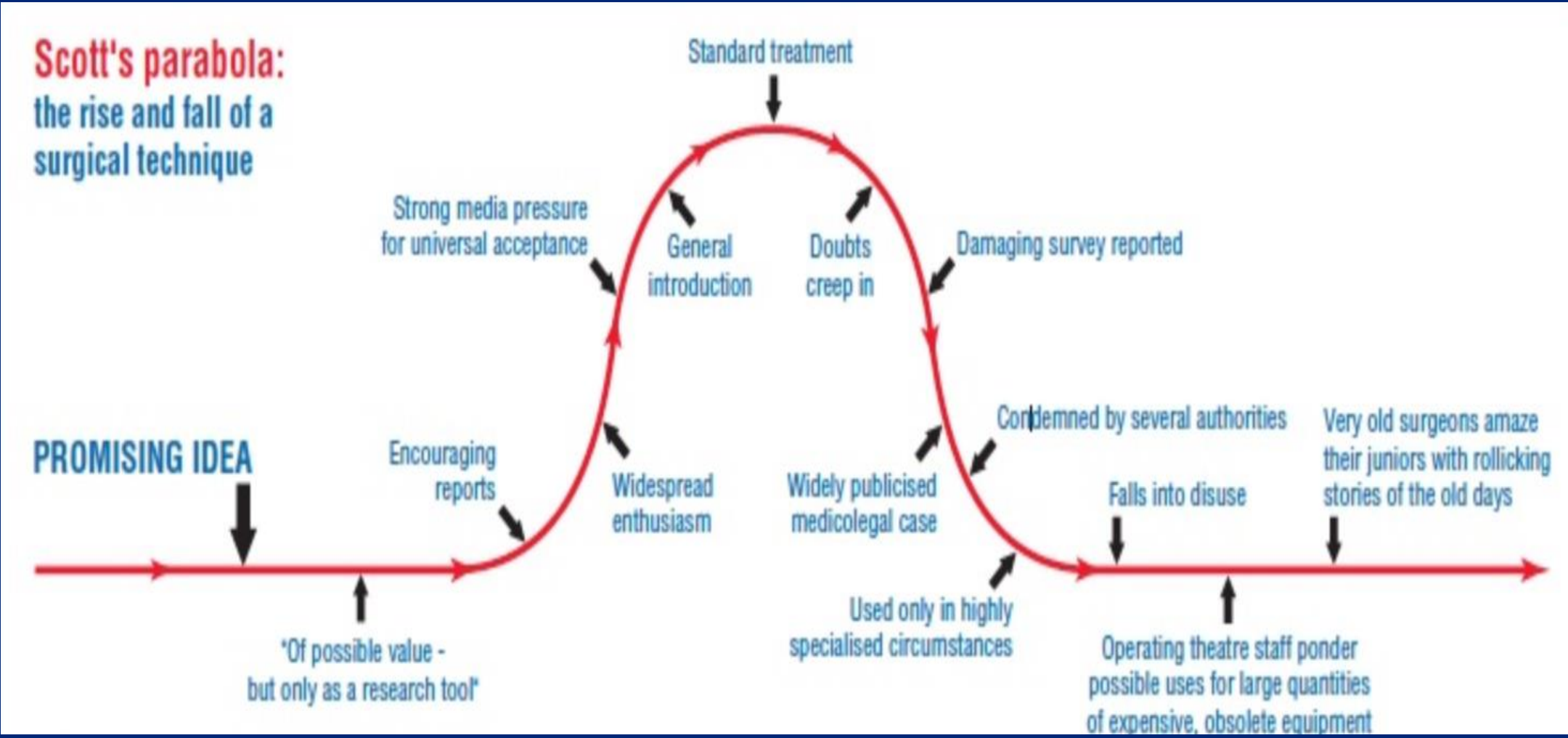
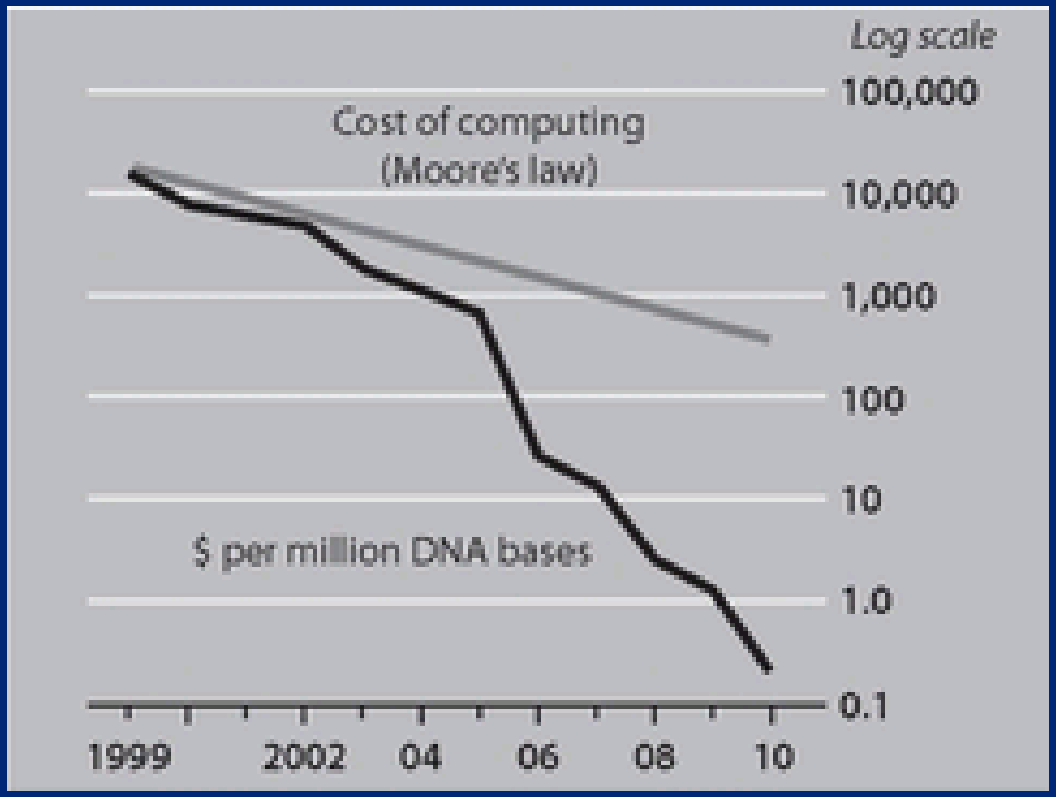
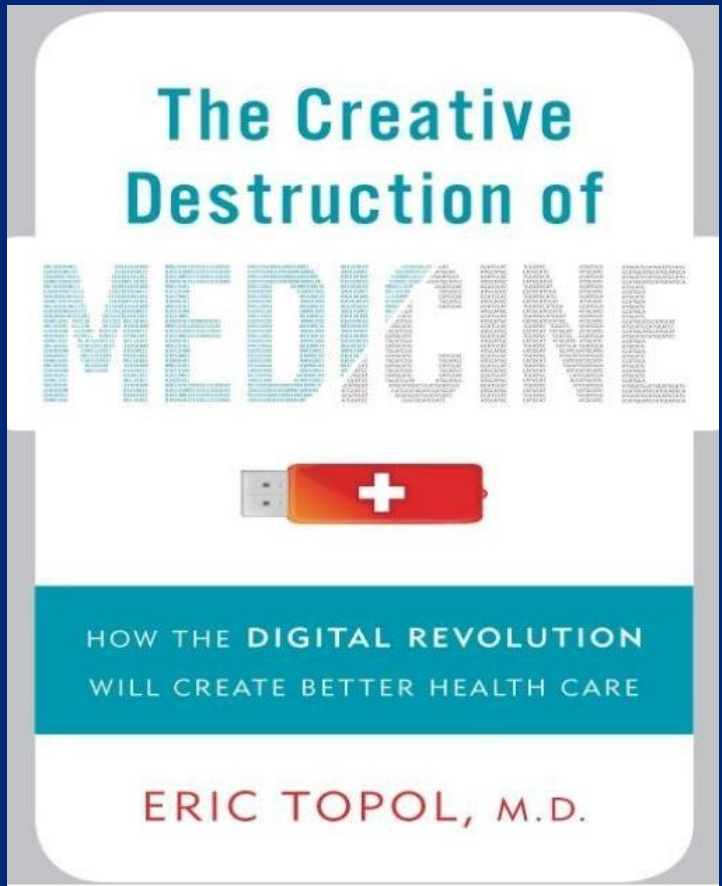
Pathway of Innovative Surgical Techniques in Medicine



Technology in Healthcare





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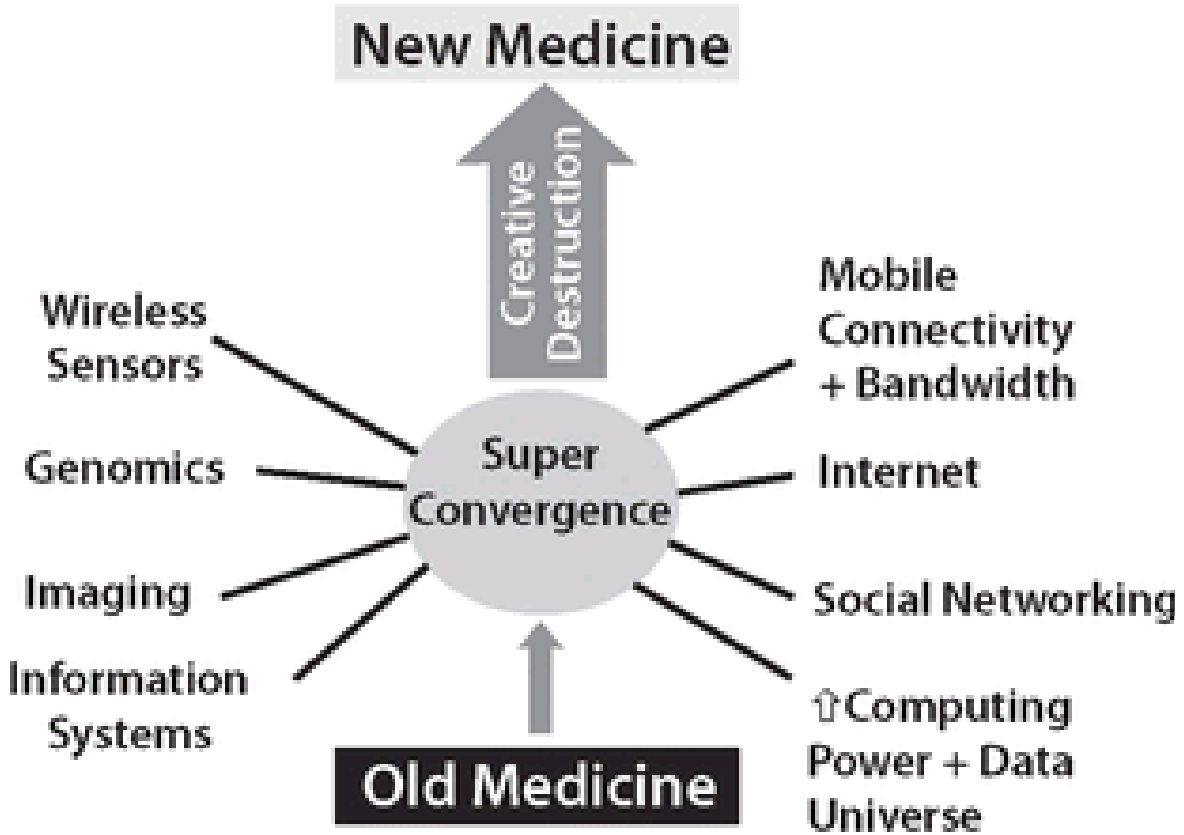
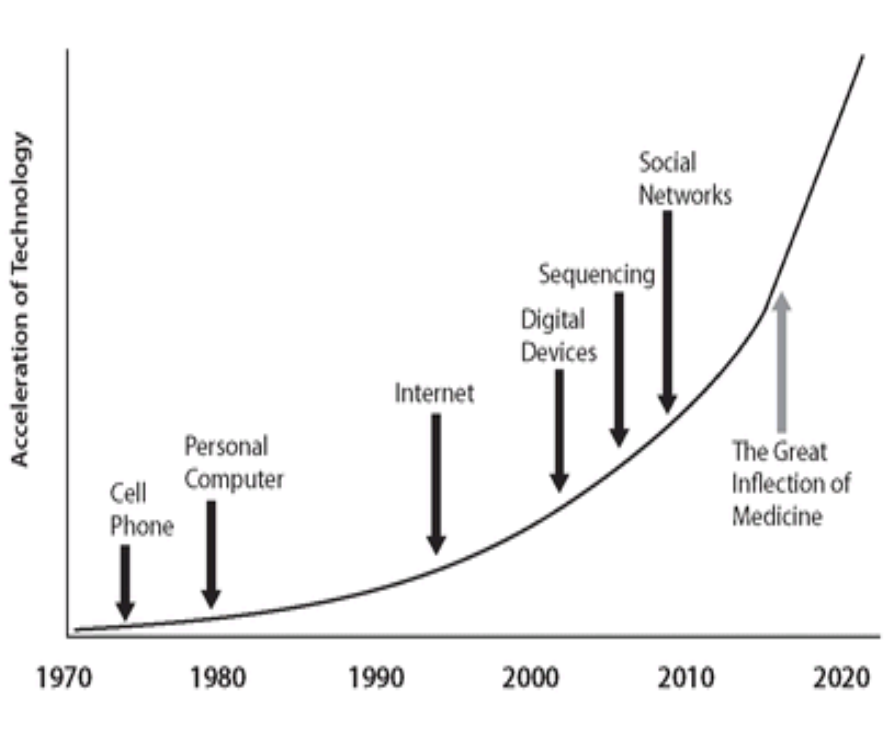
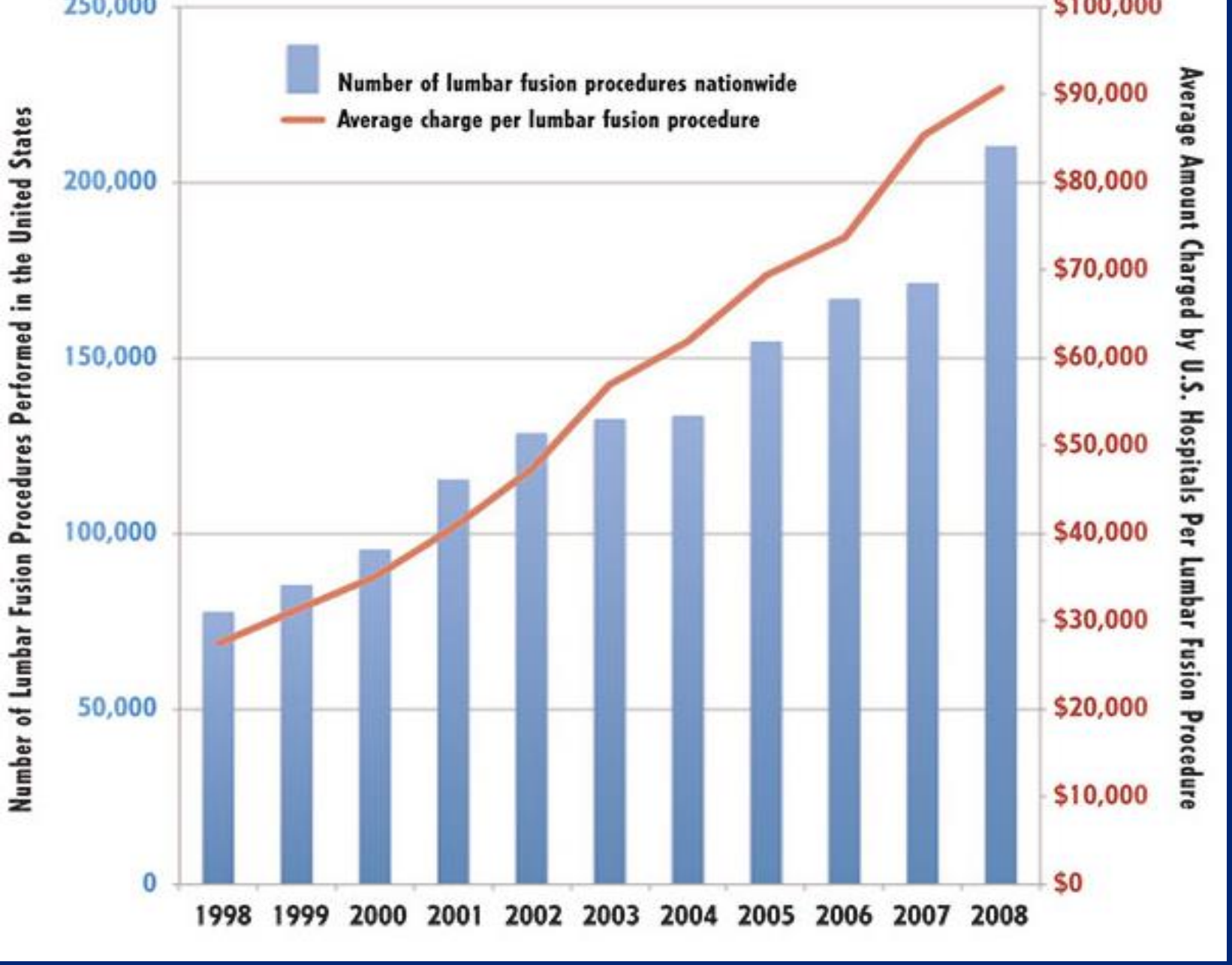




Medical Expenditures in Spine Surgery

- In the first decade of the 21st century:
  - Over 3.6 million fusion-based procedures
  - Over $287 billion= $80,000/case
- Within the Medicare population, the rate of complex spinal surgery has increased nearly 15-fold between 2003-2013
- The cost burden associated with spinal disorders is approaching the cost of common chronic medical conditions including diabetes and cardiovascular disease



Rajaee SS, Bae HW, Kanim LE, Delamarter RB. **Spine** (Phila Pa 1976). 2012 Jan 1;37(1):67-76.

Correlating Spending and Outcomes

- Patients in higher spending regions are:
  - Less likely to receive evidence-based treatments (effective care)
  - No more likely to receive elective major surgical procedures (preference-sensitive care)
    - Wennberg 2004
- Patients with selected serious conditions such as heart attacks over time found that survival was slightly worse in the higher spending regions
    - Fisher, 2003

You Get What you Pay For

In this world, you get what you pay for.

Kurt Vonnegut

"Our financial advice is free
... and it's worth every penny of it."

Drivers of Increased Healthcare Expenditure in the US

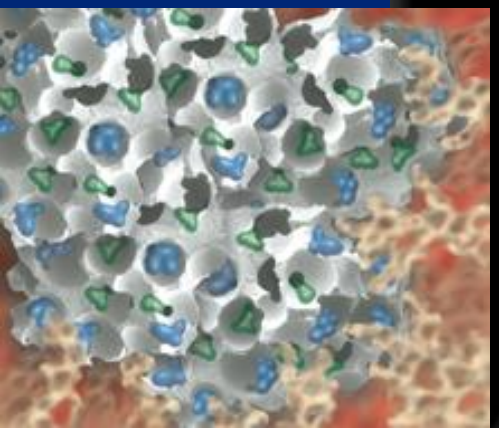
Ginsberg PB. Controlling health care costs. N Engl J Med.

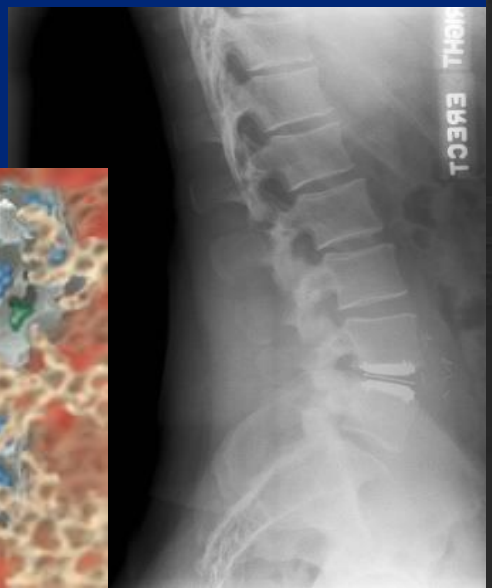
- 2004;351:1591–1593.

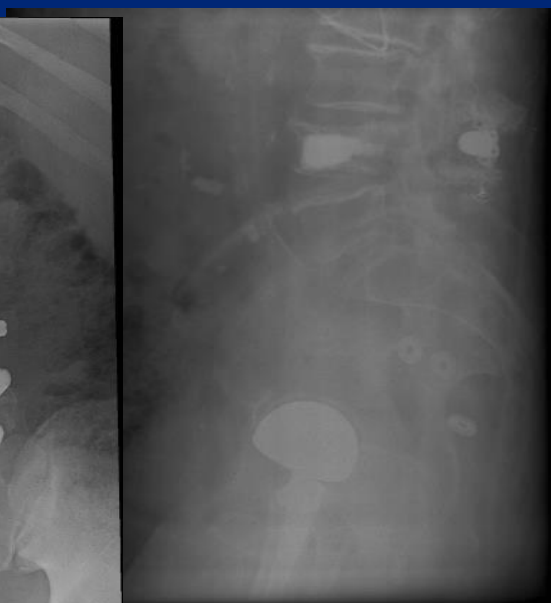
- Development of New Technologies that add cost without clear improvement outcome or performance
- Enthusiastic adoption of New Technologies
  - Pharmaceuticals
  - Surgical Techniques
  - Medical Devices

Value and Innovation

Incremental Cost-effectiveness in the Assessment of New Technologies

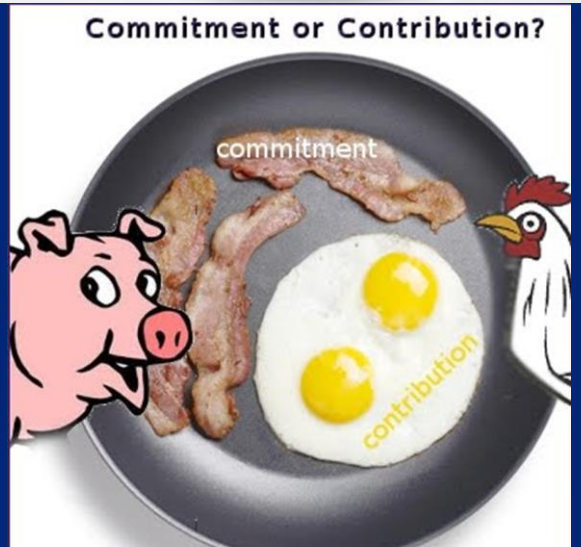






Perspectives on Innovative Technologies

- Perspectives:
  - Payers
  - Hospitals
  - Policymakers
  - Industry
  - Patients/Providers



Physician Perspective

- Safety
- Change in Health Status
  - ODI, NDI, EQ5-D, SF-36, SRS, …
- Patient satisfaction
- Complications
- Cost

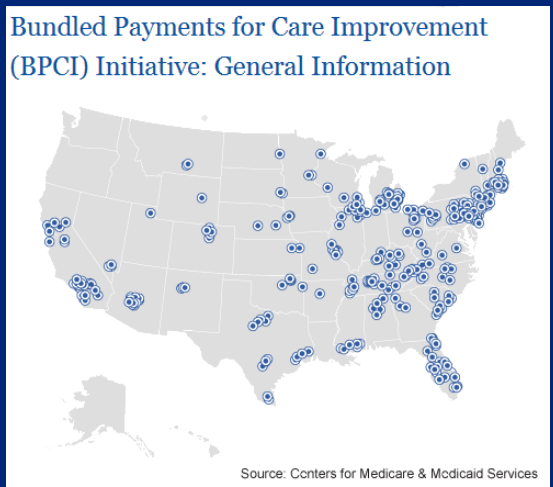
Hospital Perspective

- Cost
- Quality Metrics
  - 30, 90 day readmissions
- Complications
- Improvement of Health Status
- Patient satisfaction
- Long-term outcomes (>2 years)
- Limited Vendor policies

Alternative Payment Models

- Bundled Payments (January, 2013):
  - CMS announced healthcare organizations selected to participate in the Bundled Payments for Care Improvement initiative
- Under the Bundled Payments for Care Improvement initiative, organizations will enter into payment arrangements that include financial and performance accountability for episodes of care.

CMS.gov
Centers for Medicare & Medicaid Services



Bundled Payment Model

- Transition from fee for service to accountable care
- Payment reform-
  - Offloading risk from the payors
  - Shared responsibility and alignment for Hospital and Physicians
  - Patient responsibility for care-
    - confronting patient with financial risk
    - tiered insurance
    - network tiering (incentive to go to less expensive hospital)
  - Data, tracking patients over time
  - Patient-centered care-
    - looking at endpoints that patient's care about- PCORI

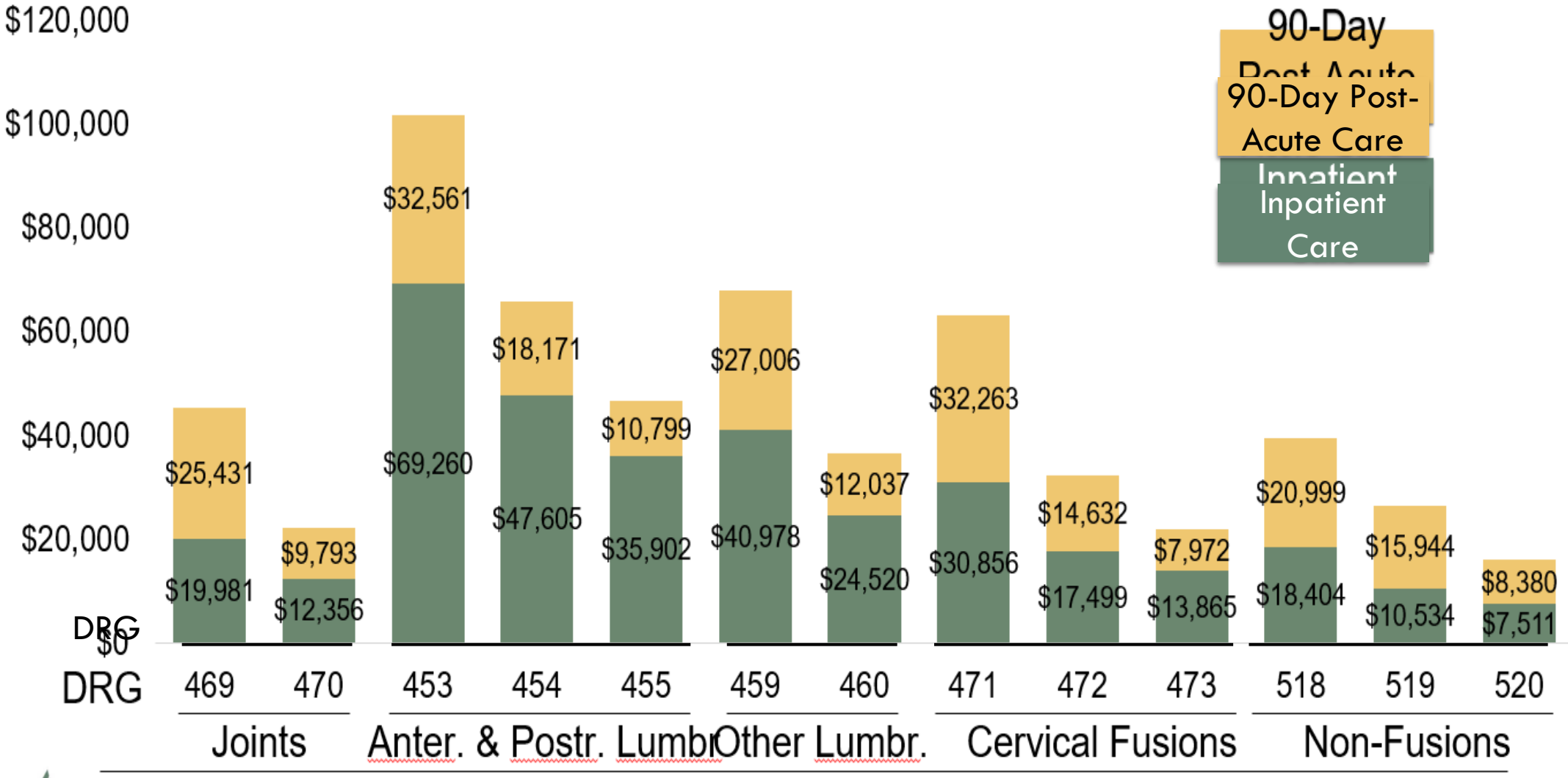
4 Spine Bundled Payment Areas in BPCI Advanced Program

Orthopedics and Spine
- Back and Neck excl. Spinal Fusion
- Back and Neck excl. Spinal Fusion [Outpatient]
- Cervical Spinal Fusion
- Combined Anterior Posterior Spinal Fusion
- Double Joint Replacement of the Lower Extremity
- Fractures of the Femur and Hip or Pelvis
- Hip and Femur Procedures excl. Major Joint
- Lower Extremity / Humerus Procedure excl. Hip, Foot, Femur
- Major Joint Replacement of the Lower Extremity
- Major Joint Replacement of the Upper Extremity
- Spinal Fusion (Non-Cervical)

Cardiovascular
- Acute Myocardial Infarction (AMI)
- Cardiac Arrhythmia
- Cardiac Defibrillator
- Cardiac Defibrillator [Outpatient]
- Cardiac Valve
- Congestive Heart Failure
- Coronary Artery Bypass Graft (CABG)
- Pacemaker
- Percutaneous Coronary Intervention (PCI)
- Percutaneous Coronary Intervention (PCI) [Outpatient]

Other
- Cellulitis
- Chronic Obstructive Pulmonary Disease (COPD), Bronchitis, & Asthma
- Disorders of the Liver excl. Malignancy, Cirrhosis, Alcoholic Hepatitis
- Gastrointestinal Hemorrhage
- Gastrointestinal Obstruction
- Major Bowel Procedure
- Renal Failure
- Sepsis
- Simple Pneumonia and Respiratory Infections
- Stroke
- Urinary Tract Infection (UTI)

2017 National Average Medicare Spend per Patient



Capital Equipment

- OR Table
- Microscope
- Intraoperative Radiology
- Robotic technologies

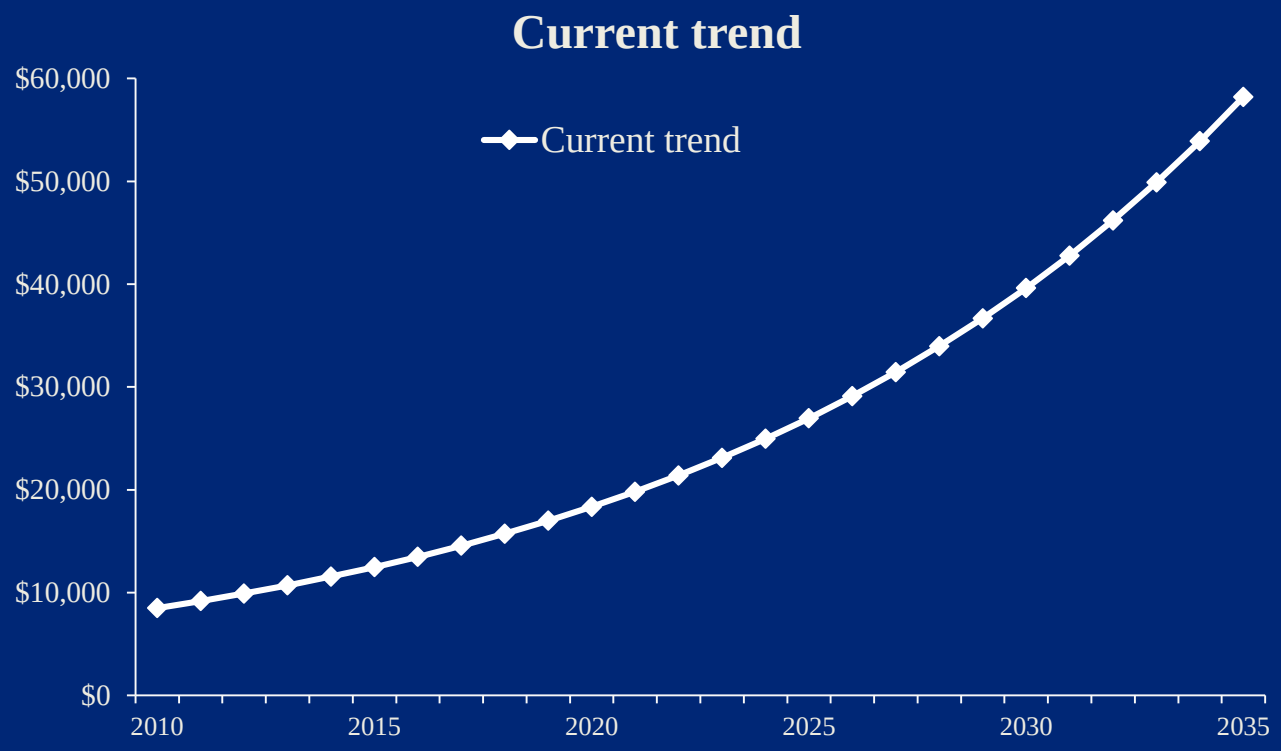
Disruptive Innovations in Spine Surgery

Innovations that add value or are cost-saving.

- Adding Value:
  - Improvement of Benefit/Outcome
  - Increased durability of outcome
- Cost-saving
  - Reduce price
  - Reduce need for readmission/reoperation
  - Improve outcome over time

Bending the cost curve in Musculoskeletal Innovations

- Rapidly increasing spending is **largely accounted for by the widespread adoption of new technologies that do not provide an incremental improvement in clinical outcomes**[1,2]



- Geometric rate of rise in cost without corresponding benefit

Bending the cost curve in Musculoskeletal Care

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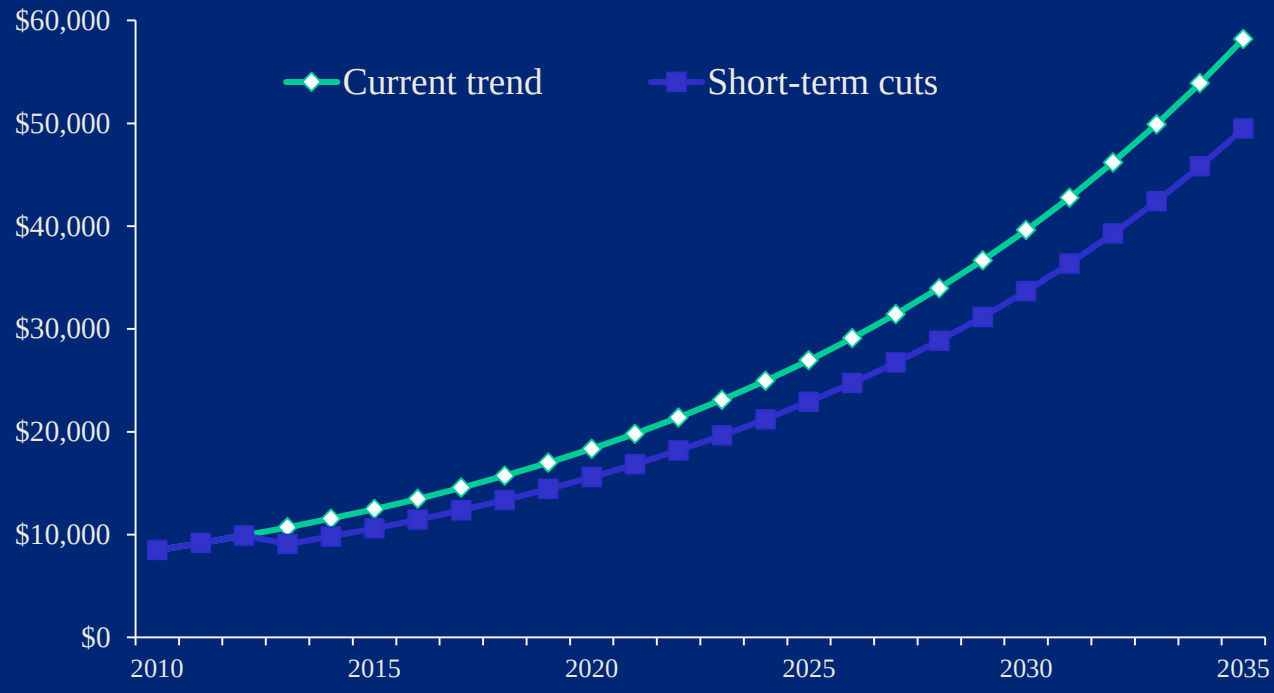
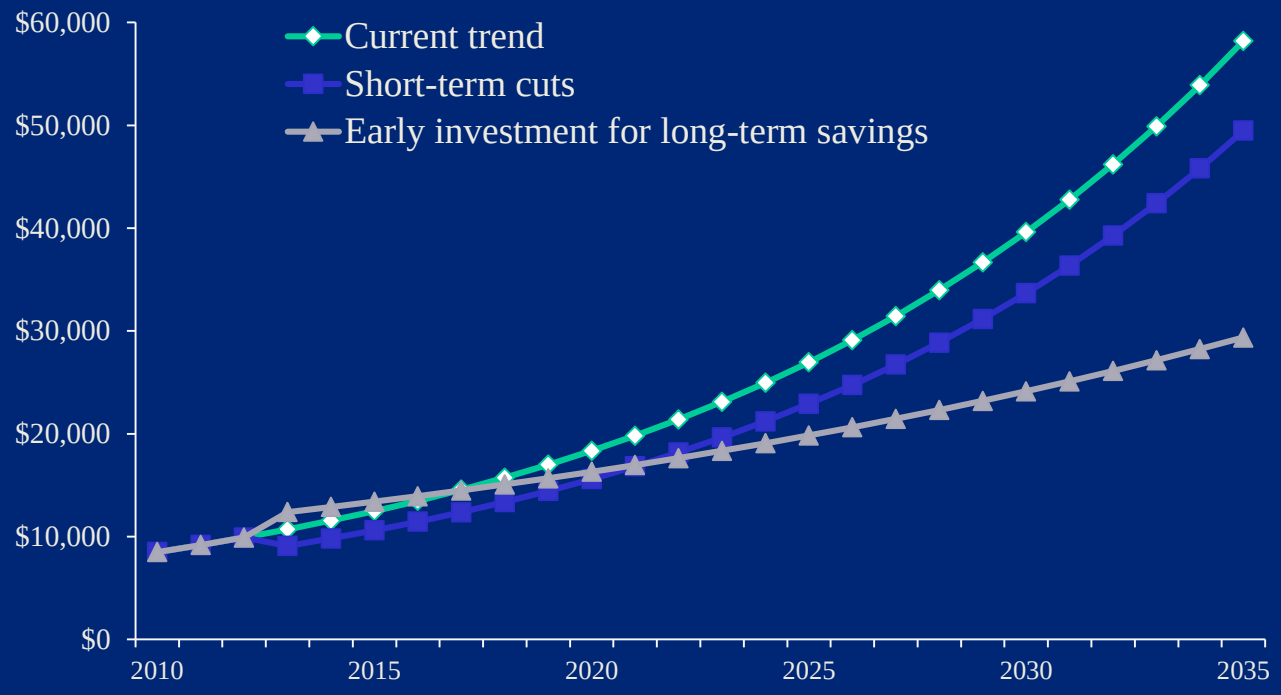


- 5% reduction across the board for reimbursement for healthcare

Bending the cost curve in Musculoskeletal Care

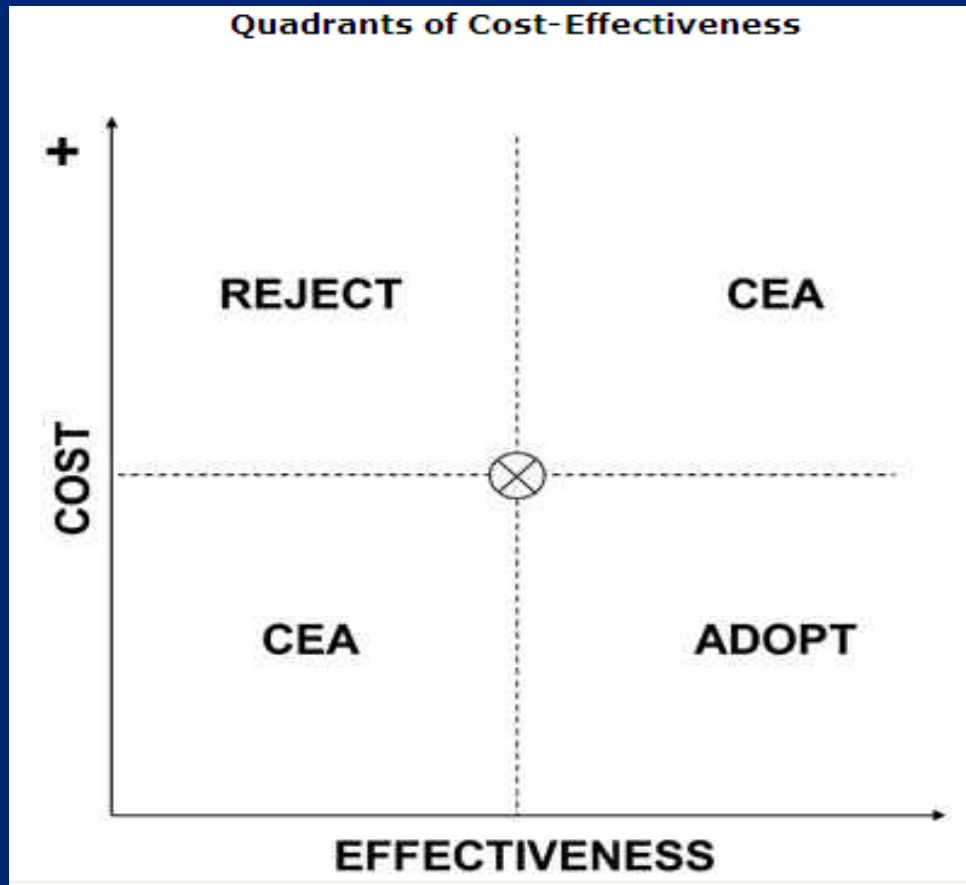
- Rapidly increasing spending is **largely accounted for by the widespread adoption of new technologies that do not provide an incremental improvement in clinical outcomes**[1,2]



- A technology may add value if it improves outcomes or reduces costs
- A short-term investment in value-adding technologies may bend the cost curve and reduce spending over time

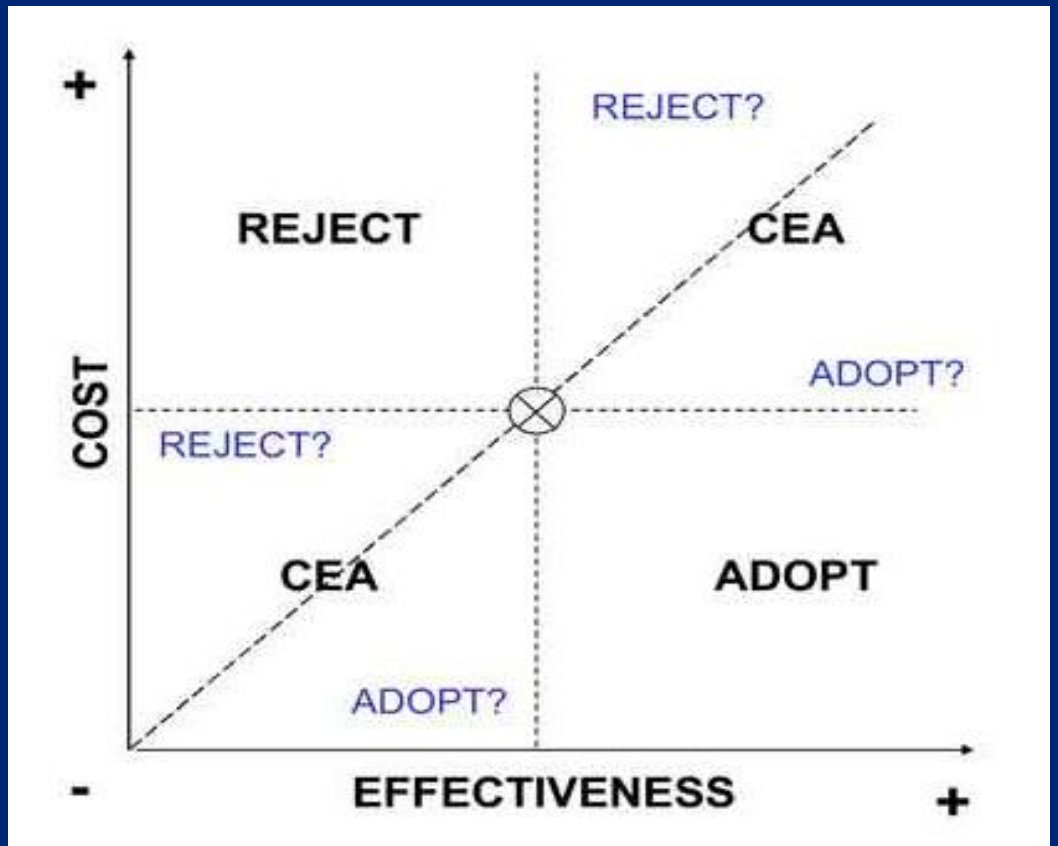
Cost-effectiveness of New Technologies

- Decision analysis in health policy and new technology adoption
- Effectiveness measured in:
  - Implant survival
  - Revision rates
  - Change in Health Status
  - Utility of Intervention

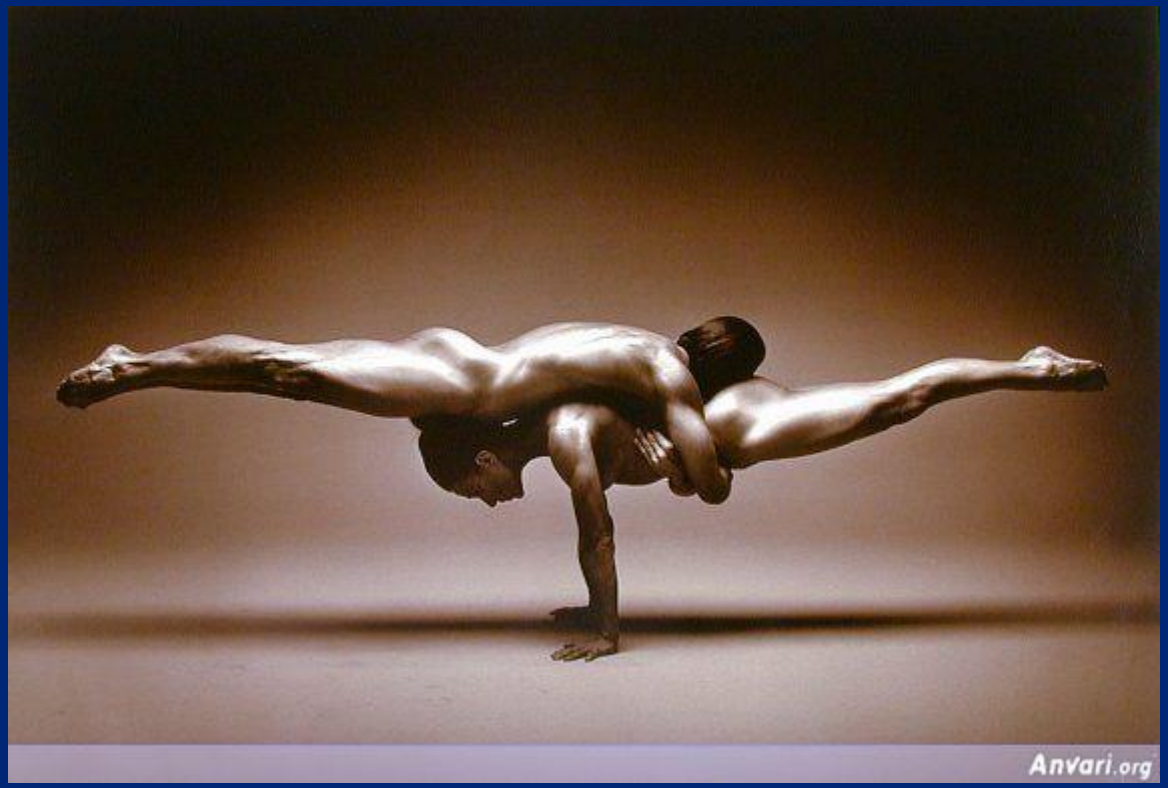


Cost-effectiveness of New Technologies

- Line of Clinical Equipose
- How Much are you willing to pay for an incremental gain?

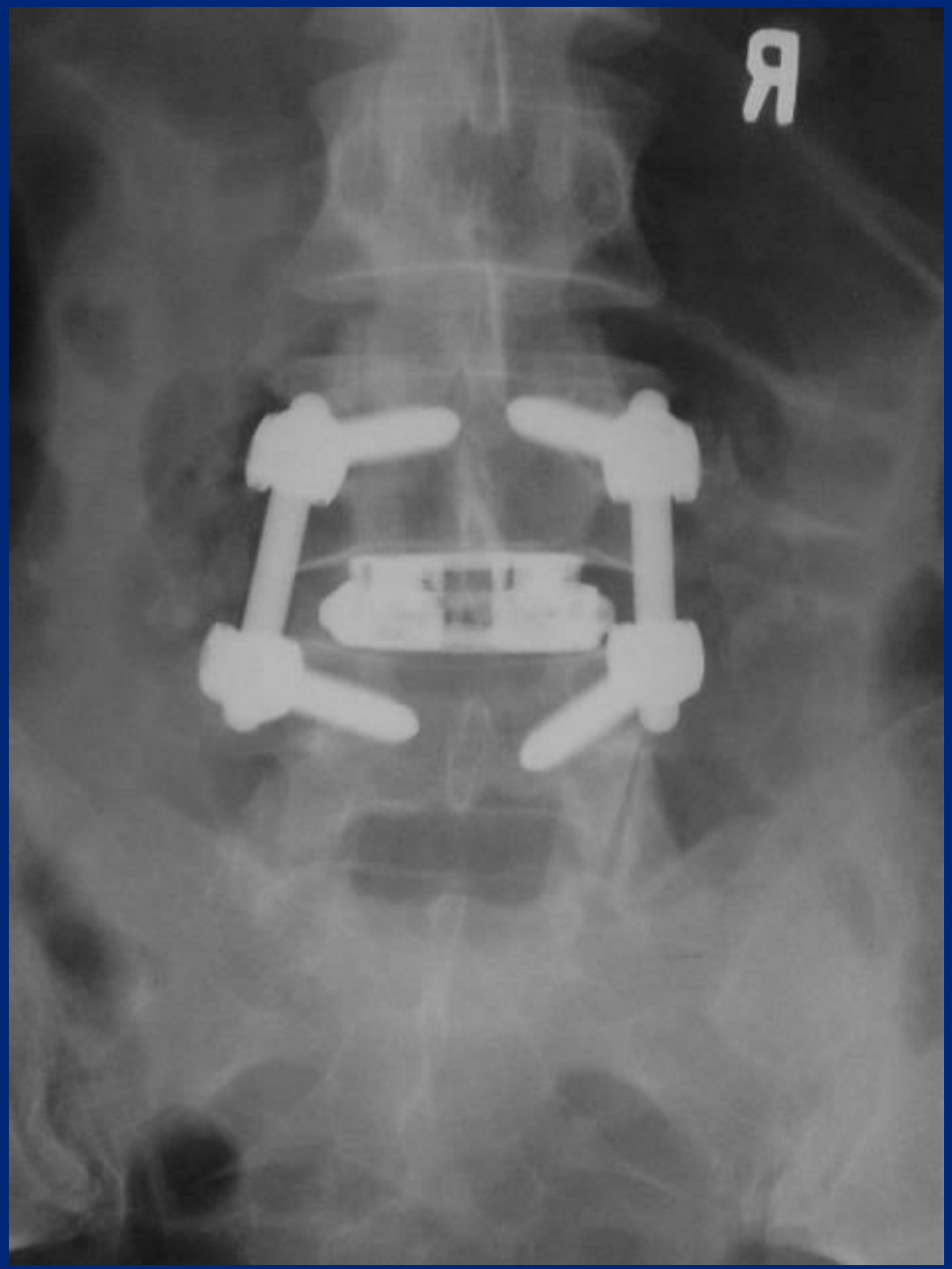


Clinical Equipose



Financial Transparency

Category	MSDRG	Surgeon Name	Avg WRVUs Prime Surgeon	ALOS	UHC Expected	Net Revenue Per Case	Direct Cost Per Case	Cont Margin
Degenerative Spondylolisthesis 1-2 Level Posterior Lumbar Fusion	304		$ 56	3.00	3.31	$ 87,740	$ 27,423	$ 60,316
	454		$ 59	3.00	5.11	$ 60,119	$ 28,690	$ 31,429
	460		$ 52	3.25	3.82	$ 56,580	$ 28,964	$ 27,616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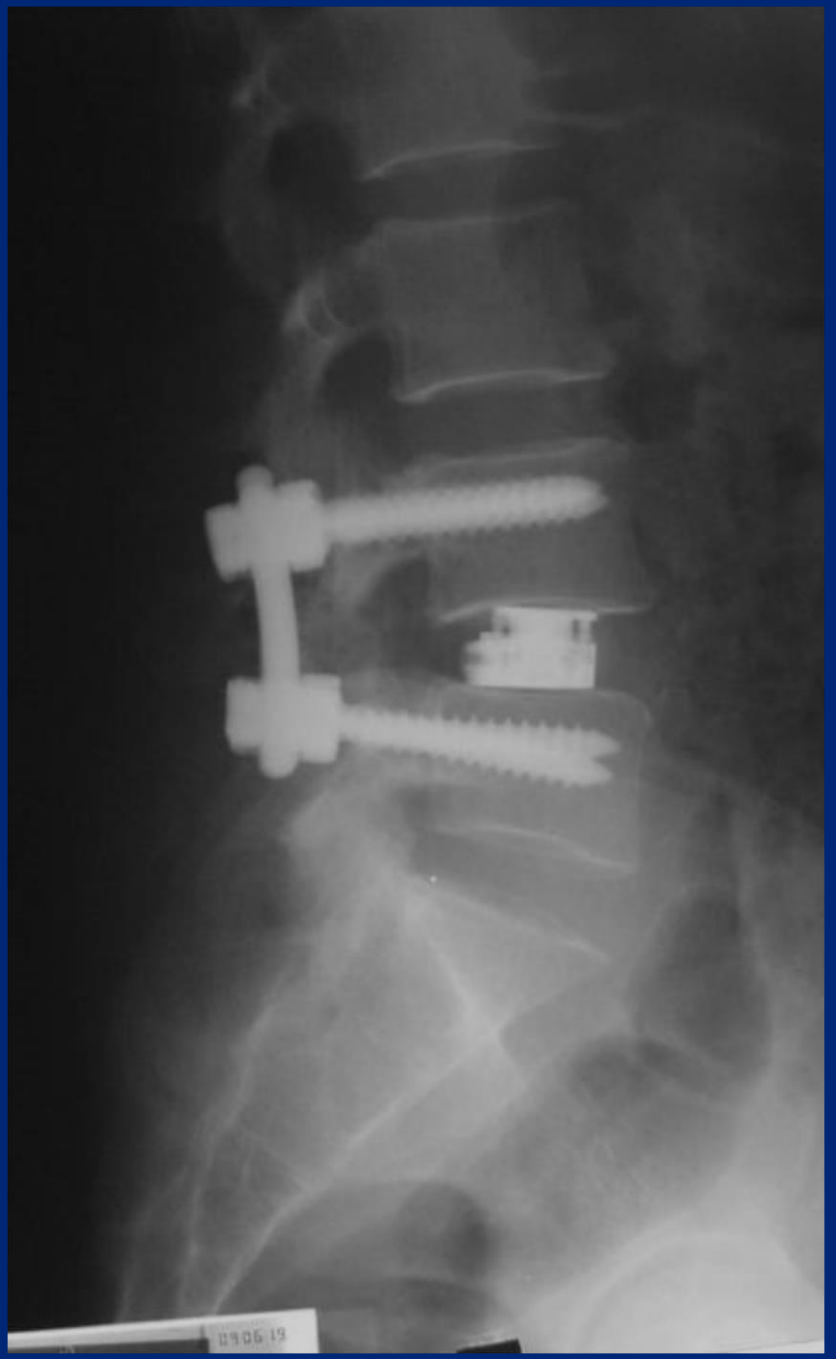

A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis

Peter Försth, M.D., Ph.D., Gylfi Ólafsson, M.Sc., Thomas Carlsson, M.D., Anders Frost, M.D., Ph.D., Fredrik Borgström, Ph.D., Peter Fritzell, M.D., Ph.D., Patrik Öhagen, Karl Michaëlsson, M.D., Ph.D., and Bengt Sandén, M.D., Ph.D.

N ENGL J MED 374;15 NEJM.ORG APRIL 14, 2016

- Prospective randomized study of patients with spinal stenosis with or without olisthesis
- 247 with spinal stenosis
  - 135 with olisthesis >3mm
- Randomized to decompression with fusion vs decompression

Outcomes: ODI

6 min walk, VAS, ZCQ

Table 1. Inclusion and Exclusion Criteria.

Inclusion Criteria

Pseudoclaudication in one or both legs and back pain (score on visual-analogue scale >30)*
1 or 2 adjacent stenotic segments (cross-section area of the dural sac ≤75 mm^2) between L2 and the sacrum on magnetic resonance imaging
Duration of symptoms >6 mo
Written informed consent

Exclusion Criteria

Spondylolysis
Degenerative lumbar scoliosis (Cobb angle >20 degrees)
History of lumbar spinal surgery for spinal stenosis or instability
Stenosis not caused by degenerative changes
Stenosis caused by a herniated disk
Other specific spinal conditions (e.g., ankylosing spondylitis, cancer, or neurologic disorders)
History of vertebral compression fractures in affected segments
Psychological disorders (e.g., dementia or drug abuse) that caused the surgeon to consider participation to be inappropriate

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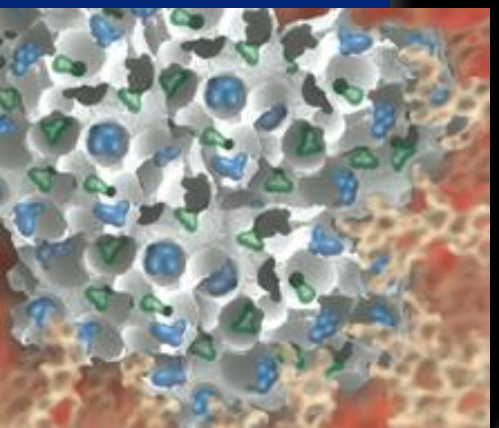
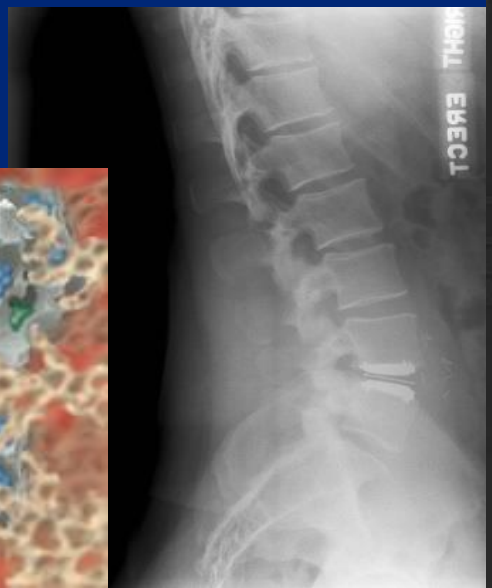
Table 3. Outcomes in the Per-Protocol Population.*

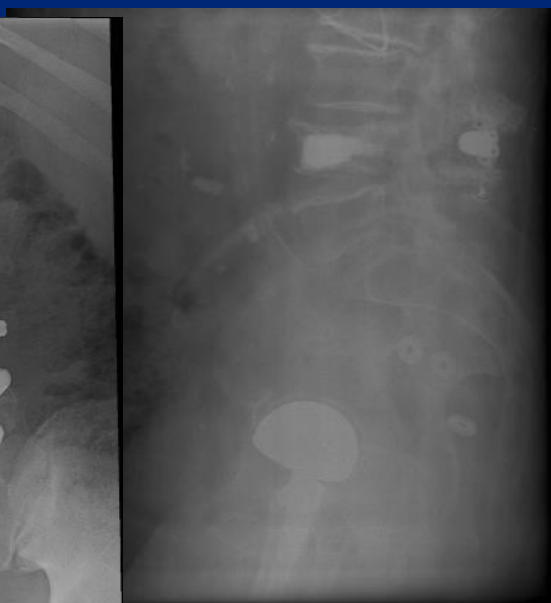
Outcome	Absence of Degenerative Spondylolisthesis				Presence of Degenerative Spondylolisthesis			
	Fusion Group (N=44)	Decompression-Alone Group (N=51)	P Value	Relative Risk (95% CI)	Fusion Group (N=67)	Decompression-Alone Group (N=66)	P Value	Relative Ri (95% CI
During the procedure								
Operating time — min	150±47	80±28	<0.01		149±44	95±40	<0.01	
Amount of bleeding — ml	648±498	288±319	<0.01		686±434	311±314	<0.01	
At 2 yr								
ODI score	29±20	27±18	0.70		25±19	21±18	0.11	
EQ-5D score	0.62±0.31	0.59±0.35	0.85		0.63±0.31	0.69±0.28	0.20	
VAS score for back pain	41±32	45±31	0.66		36±29	26±25	0.15	
VAS score for leg pain	35±31	34±33	0.46		32±30	29±31	0.60	
ZCQ score								
Symptom severity	2.6±1.0	2.5±1.1	0.41		2.4±0.9	2.4±1.0	0.56	
Physical function	1.9±0.7	1.8±0.8	0.20		1.8±0.8	1.7±0.7	0.53	
Patient satisfaction	2.2±0.9	2.1±0.9	0.65		2.1±0.9	1.9±0.8	0.22	
Result of 6-minute walk test — m	417±163	416±130	0.38		382±152	396±144	0.60	
Reporting satisfaction with the surgery — no. (%)†	23 (52)	27 (53)		0.99 (0.67–1.45)	43 (64)	45 (68)		0.94 (0.74–1.2
Reporting decrease in back pain — no. (%)‡	33 (75)	33 (65)		1.16 (0.89–1.51)	53 (79)	54 (82)		0.97 (0.82–1.1
Reporting decrease in leg pain — no. (%)§	36 (82)	35 (69)		1.19 (0.94–1.50)	52 (78)	48 (73)		1.07 (0.88–1.3
Reporting increase in walking distance — no. (%)¶	40 (91)	41 (80)		1.13 (0.96–1.33)	59 (88)	57 (86)		1.02 (0.90–1.1

Value and New Technology

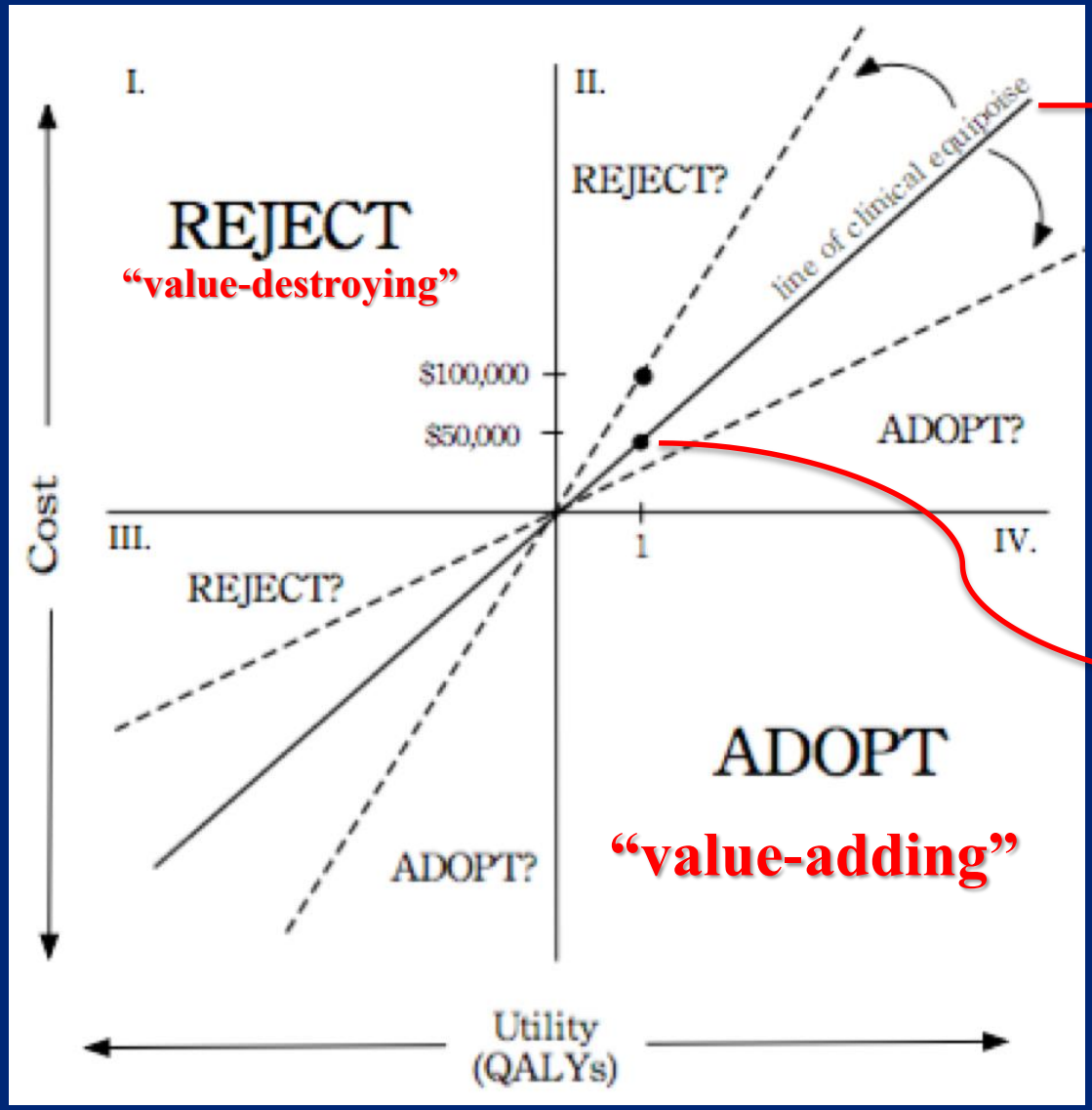
Incremental Cost-effectiveness in the Assessment of New Technologies







Value assessment of new technologies



Line of clinical equipoise: Determines what society is willing to pay for a change in health status

Cost/QALY = Incremental cost of gaining one Quality Adjusted Life Year

Cost-Saving Innovations In Spine Surgery

- Navigation/Robotics
- Novel implant surfaces
- Osteobiologics
- Minimally Invasive Surgery
- Non-operative Techniques
  - Neuromodulation

Cost Effectiveness of CT image guided Navigation

- Observational, Cohort matched
- 2,682 screws placed in 253 patients
- Accuracy:
  - 95.2% navigated
  - 86.9% non-navigated
- Reoperation within one year:
  - 2/253 navigated patients (0.8%)
  - 15/249 non-navigated patients (6%)
- Cost Analysis:
  - $15,961 per reoperation

Economic evaluation comparing intraoperative cone beam CT-based navigation and conventional fluoroscopy for the placement of spinal pedicle screws: a patient-level data cost-effectiveness analysis

Nicolas Dea, MD, MSc, Charles G. Fisher, MD, MHSc, Juliet Batke, BSc, Jason Strelzow, MD, Daniel Mendelsohn, MD, Scott J. Paquette, MD, Brian K. Kwon, MD, PhD, Michael D. Boyd, MD, Marcel F.S. Dvorak, MD, John T. Street, MD, PhD

- **Navigation becomes cost effective if performing over 254 cases per year**
- **LESS EXPENSIVE, EQUALLY ACCURATE NAVIGATION TECHNOLOGY WILL BECOME COST BENEFICIAL AT A MUCH LOWER CASE VOLUME**

Need for Computer Assistance and Robotics is Variable

- Surgeon experience
- Surgical technique
- Case type
  - Deformity
  - MIS
- Operating Room Systems
  - Room size
  - Radiology Technician experience
  - Ratio of Navigation Systems to Cases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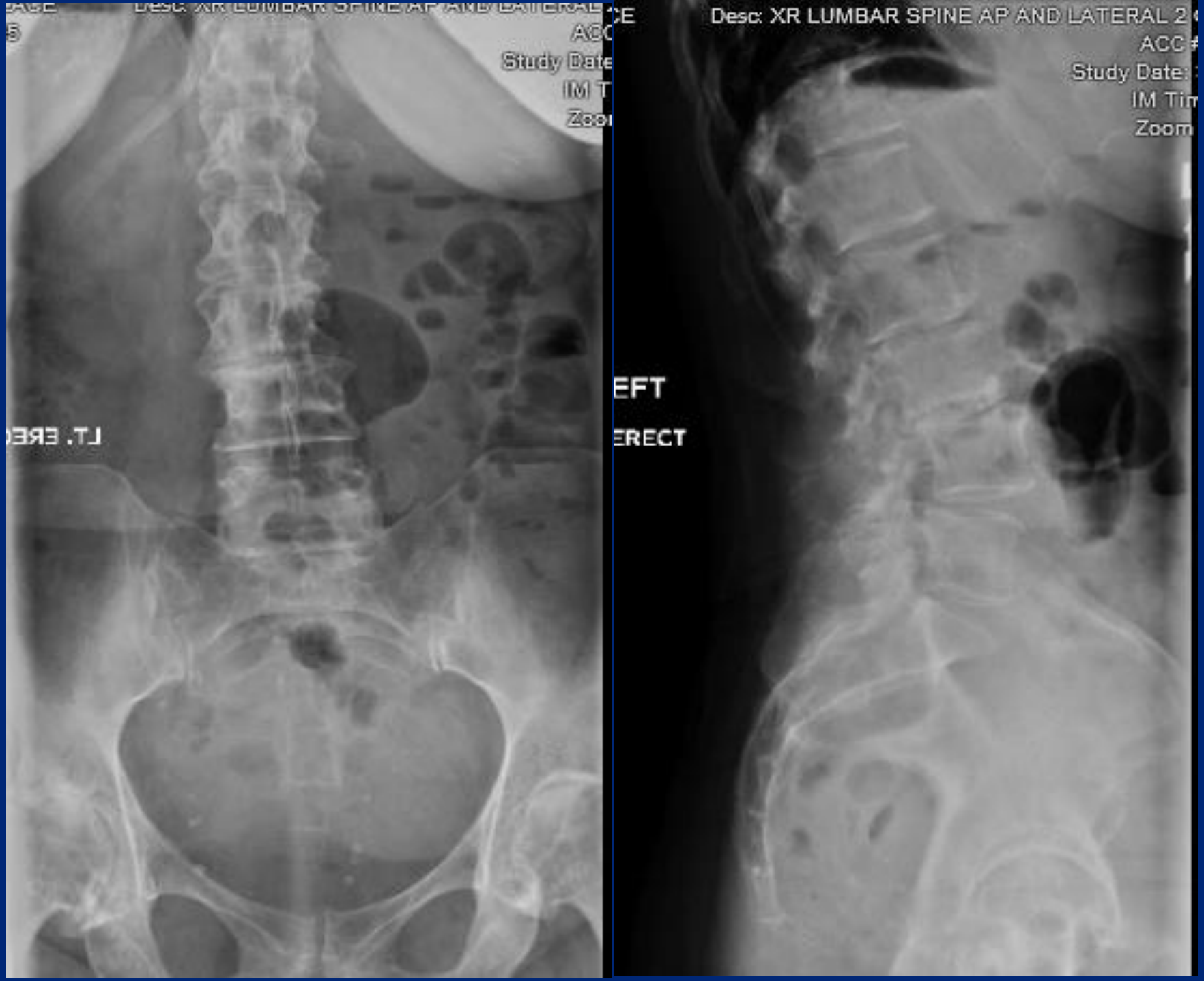
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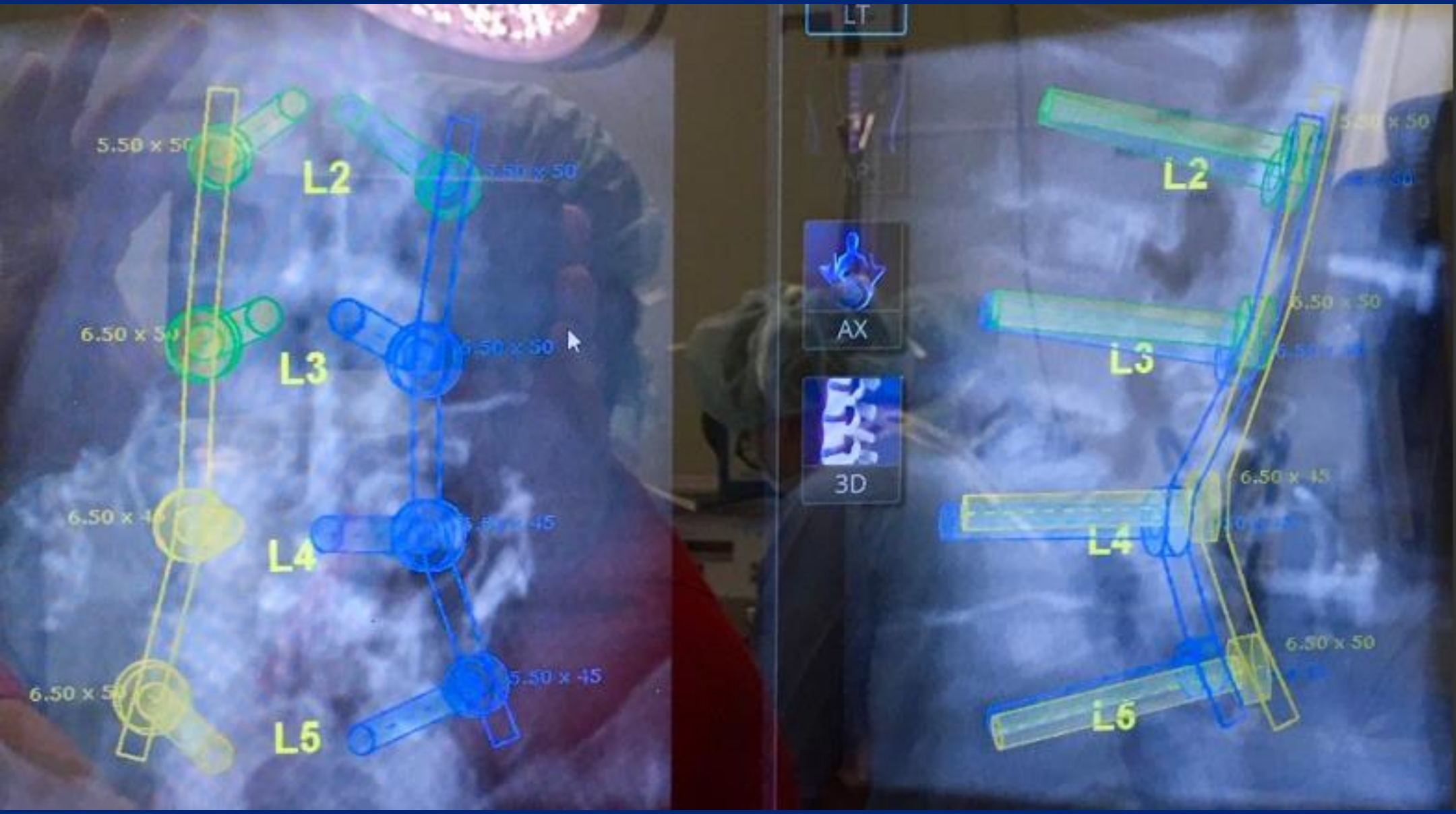
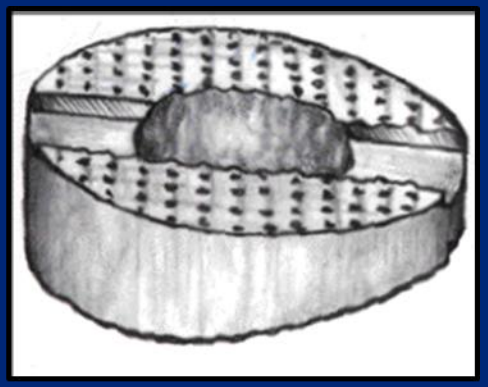

L2
L3
L4
L5
L6
AX
3D
LT


R
STANDING


R

Implant Materials in Spine Surgery

- Interbody Cages
  - Allograft
  - Titanium
    - Porous
    - Acid-Etched
  - PEEK
    - Titanium Coated
    - HA Composites
  - Carbon Fiber
  - HA Coated



Osteobiologics and Spine Fusion

- Factors Impacting the biological activity of bone
  - Cells
  - Proteins
    - Differentiation factors
    - Chemotactic factors
    - Growth factors/mitogens
  - Extracellular Matrix

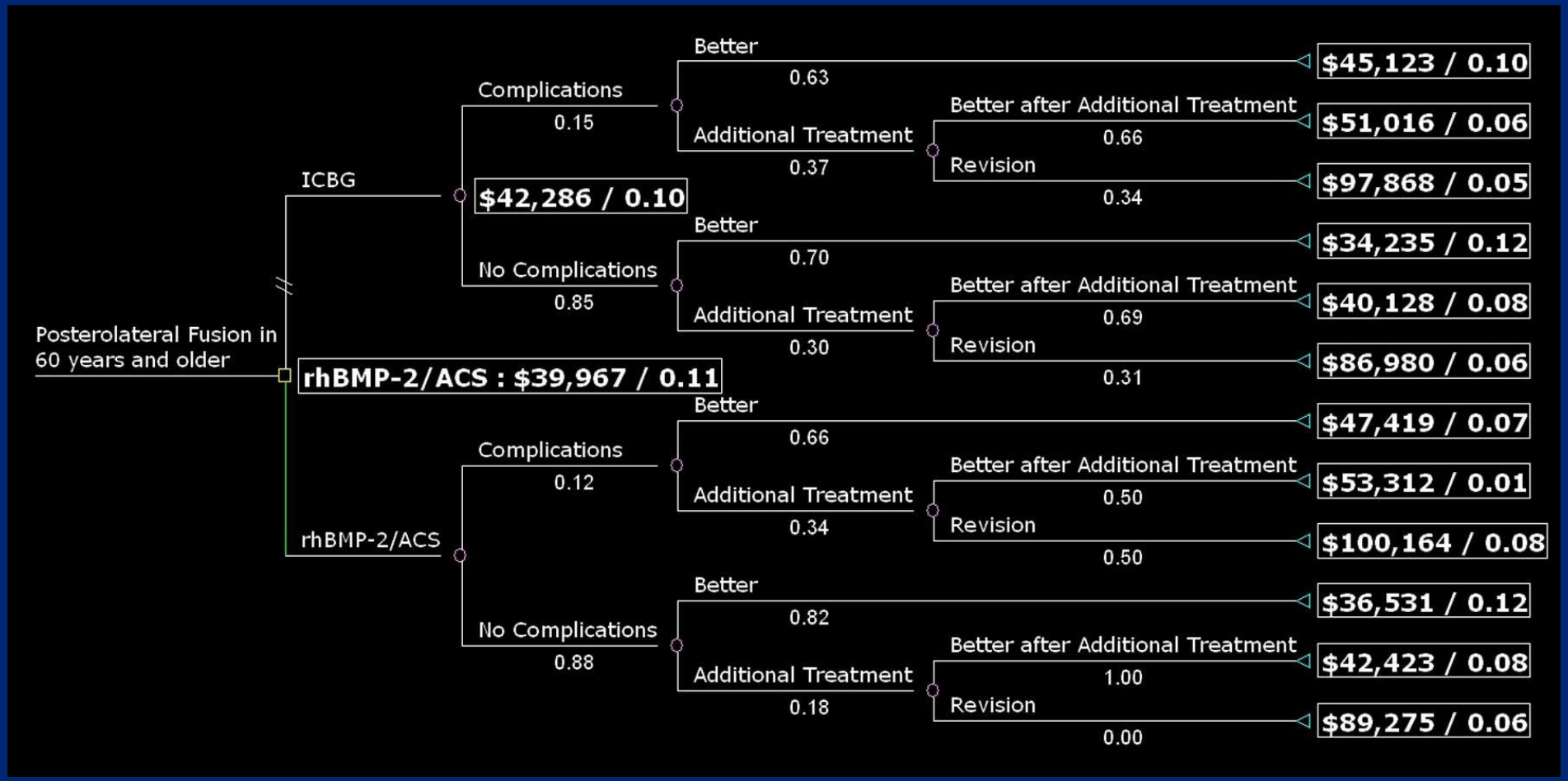
Potential for Cost-Saving Osteobiologics in Spine Surgery

- Avoidance of autograft harvest cost
- Reduction in Reoperations
- Improvement of Health-related Quality of Life
- Avoidance of Anterior Surgery
- Reduction of Complications

RhBMP-2 Versus Iliac Crest Bone Graft for Lumbar Spine Fusion in Patients Over 60 Years of Age: A Cost-Utility Study

Carreon, Leah Y. MD, MSc; Glassman, Steven D. MD; Djurasovic, Mladen MD; Campbell, Mitchell J. MD; Puno, Rolando M. MD; Johnson, John R. MD; Dimar, John R. II MD

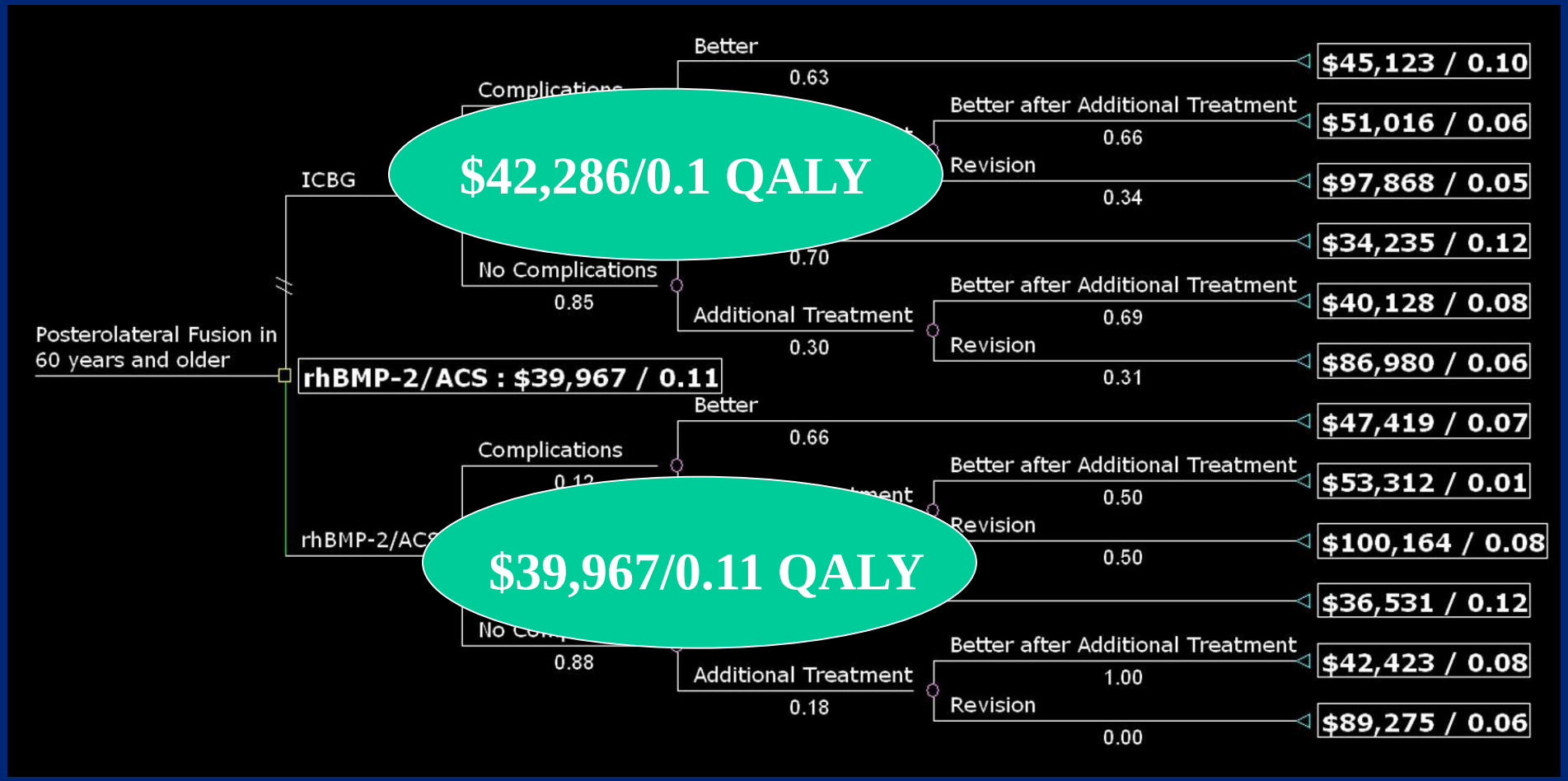
Spine 2009 Feb 1;34(3):238-43



RhBMP-2 Versus Iliac Crest Bone Graft for Lumbar Spine Fusion in Patients Over 60 Years of Age: A Cost-Utility Study

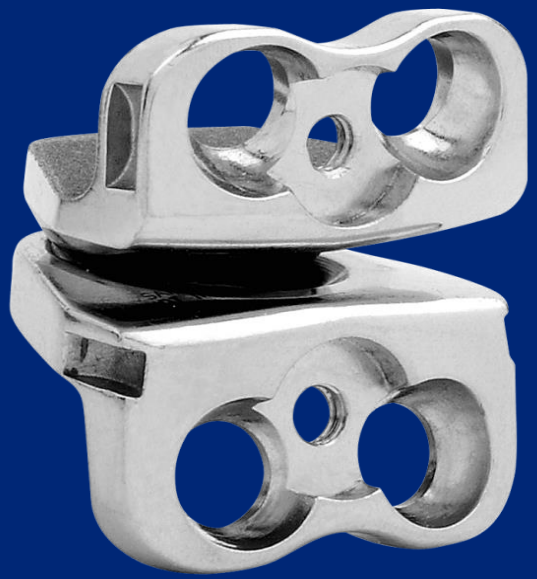
Carreon, Leah Y. MD, MSc; Glassman, Steven D. MD; Djurasovic, Mladen MD; Campbell, Mitchell J. MD; Puno, Rolando M. MD; Johnson, John R. MD; Dimar, John R. II MD

Spine 2009 Feb 1;34(3):238-43

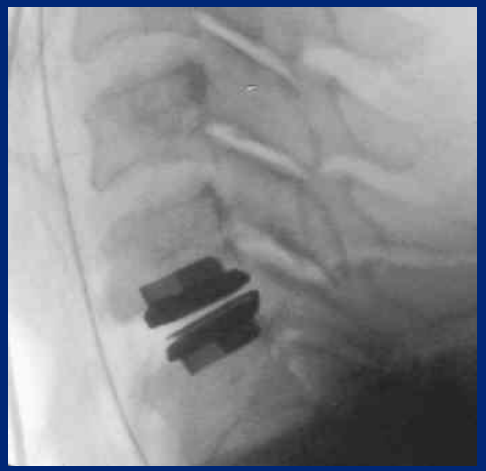


Cervical Disc Replacements

Bryan Disc



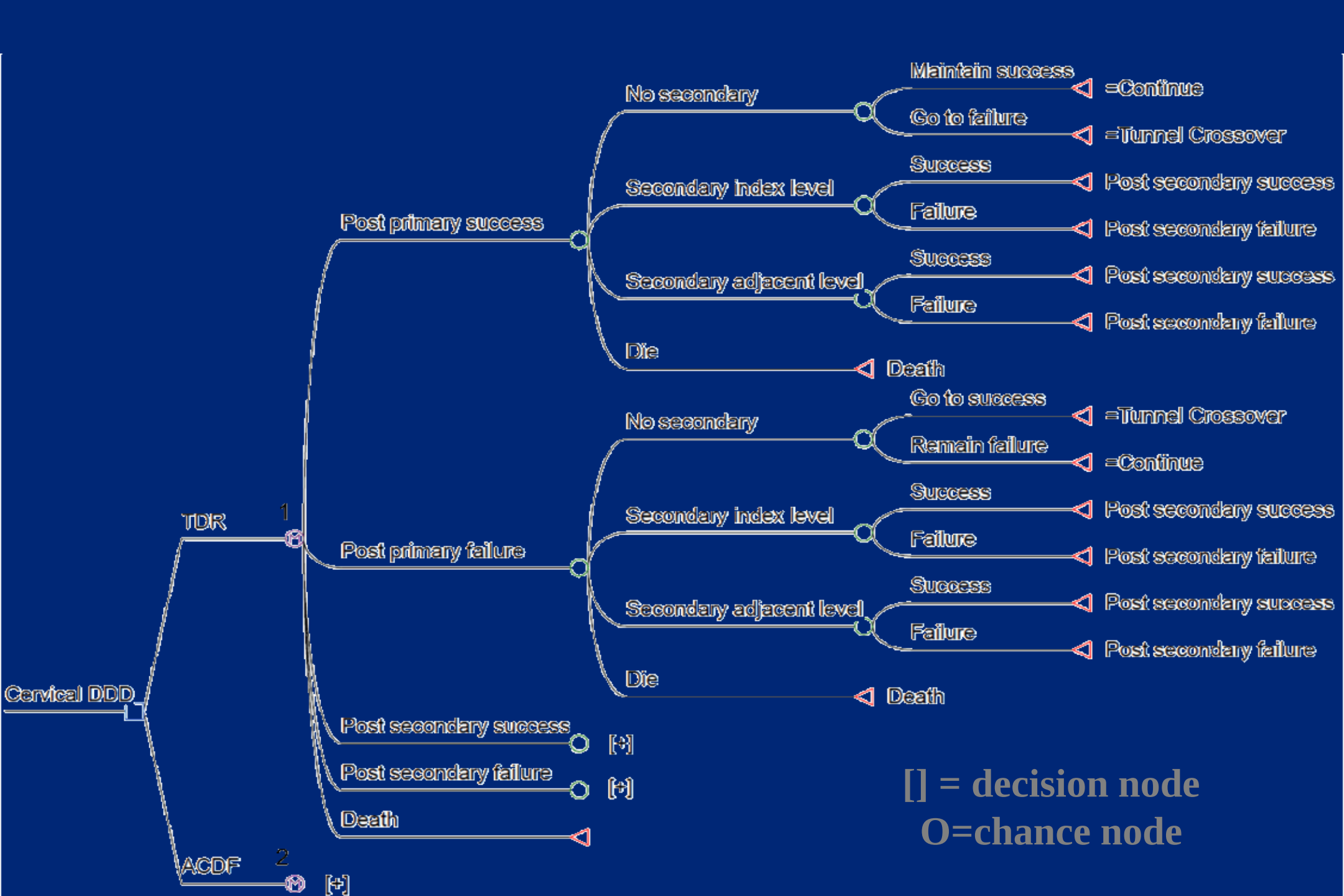
Prestige ST & LP

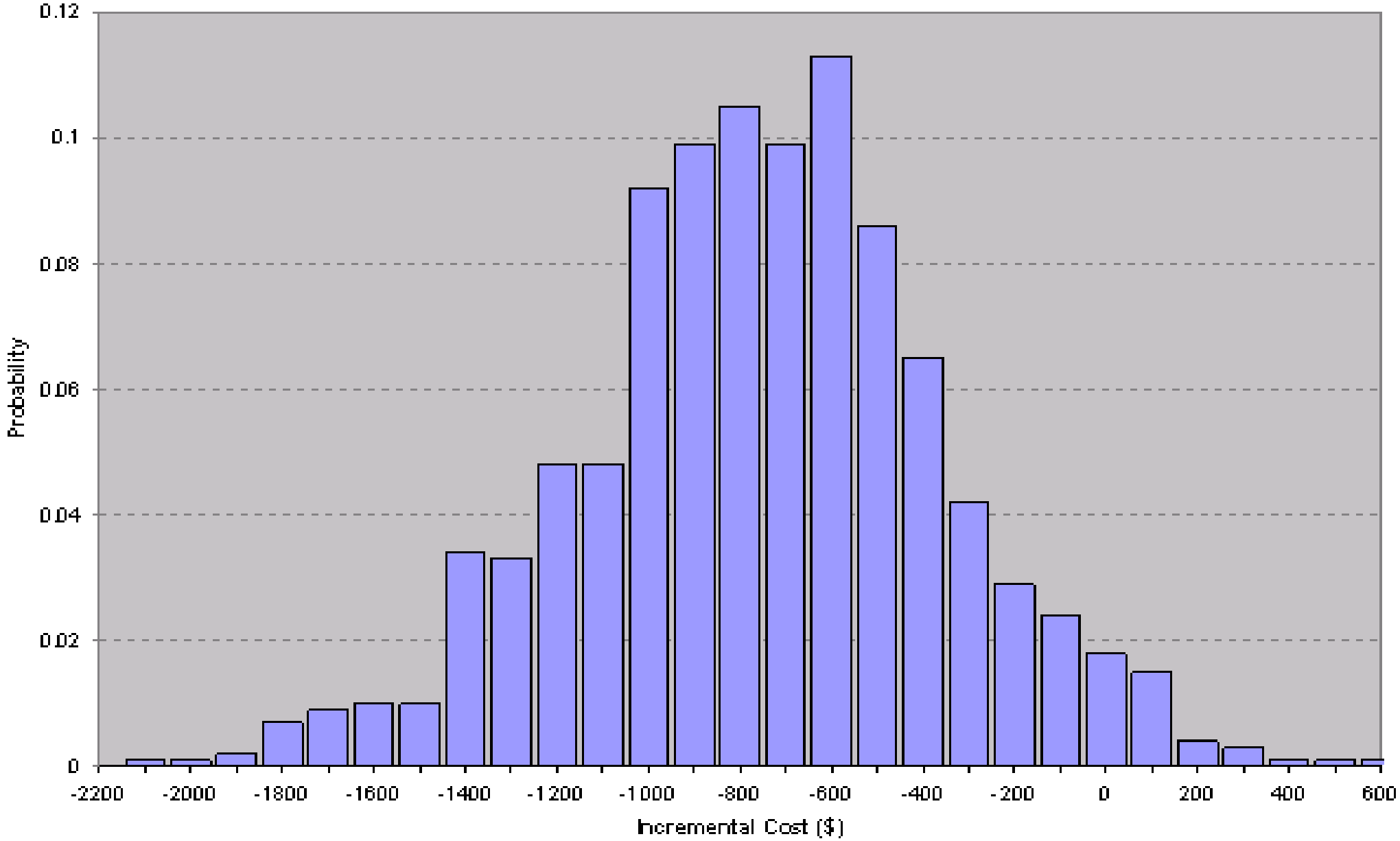


prodisc-c

Incremental Cost Effectiveness of Arthroplasty vs Fusion

- The benefits of cervical arthroplasty compared with arthrodesis may be more apparent with longer term follow-up
- In the absence of long-term data, decision analysis may be useful to model clinical scenarios and to estimate future benefits and costs over time
- Markov modeling permits assessment of future value when risk is ongoing over time.
  - Model defines discrete health states: healthy, sick, dead
  - Estimates probability of each health state with a distribution
  - Assigns a value (utility) to each health state
  - Cycles until all patients meet termination criteria- death


Cervical DDD
TDR
1
Post primary success
No secondary
Maintain success
=Continue
Go to failure
=Tunnel Crossover
Secondary index level
Success
Post secondary success
Failure
Post secondary failure
Secondary adjacent level
Success
Post secondary success
Failure
Post secondary failure
Die
Death
Post primary failure
No secondary
Go to success
=Tunnel Crossover
Remain failure
=Continue
Secondary index level
Success
Post secondary success
Failure
Post secondary failure
Secondary adjacent level
Success
Post secondary success
Failure
Post secondary failure
Die
Death
Post secondary success
[+]
Post secondary failure
[+]
Death
ACDF
2
[+]
[] = decision node
O=chance node


0.12
0.1
0.08
0.06
0.04
0.02
0
Probability
-2200
-2000
-1800
-1600
-1400
-1200
-1000
-800
-600
-400
-200
0
200
400
600
Incremental Cost ($)

Results

- The mean cost of TDR with ProDisc-C was $14,230.28 ± 1,734.51 and the mean cost of ACDF was $15,035.26 ± 2,132.69 ($p < 0.01$). While the primary operation was more expensive for the TDR arm, the reduced rate of secondary procedures led to decreased mean cost over the course of the simulation by over $800 per case
- A 30% reduction in the rate of secondary surgeries would justify a $1000 price differential

Opportunities to Bend the Cost Curve in Musculoskeletal Care

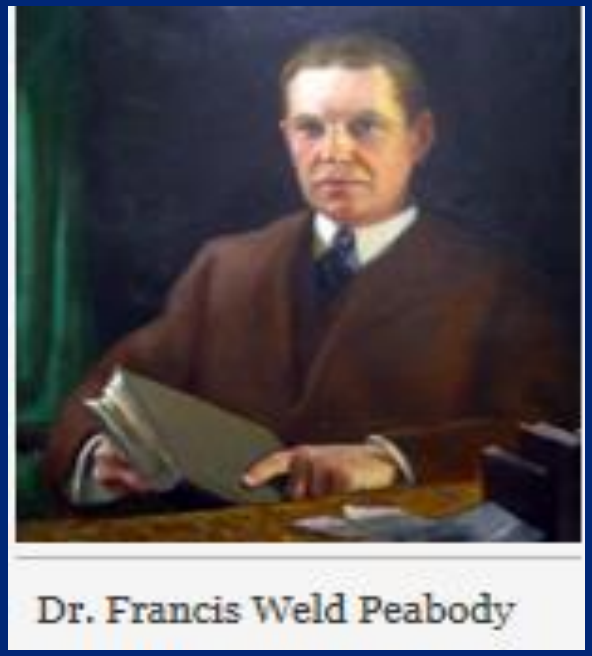
- Improve outcome and durability of outcome
  - $/QALY
- Improving sensitivity of outcome measures to change
- Large data set analyses to evaluate limitations of existing technologies and opportunity for incremental effectiveness of new technologies
- Identifying Cost Drivers
  - Readmission/Reoperation
  - Prolonged ICU and Hospital Stay
  - Pre-operative patient evaluation and diagnostics
- Diagnostic Tools
- Regenerative Technologies
- Surgical Site Infection
- System Reform

Conclusions

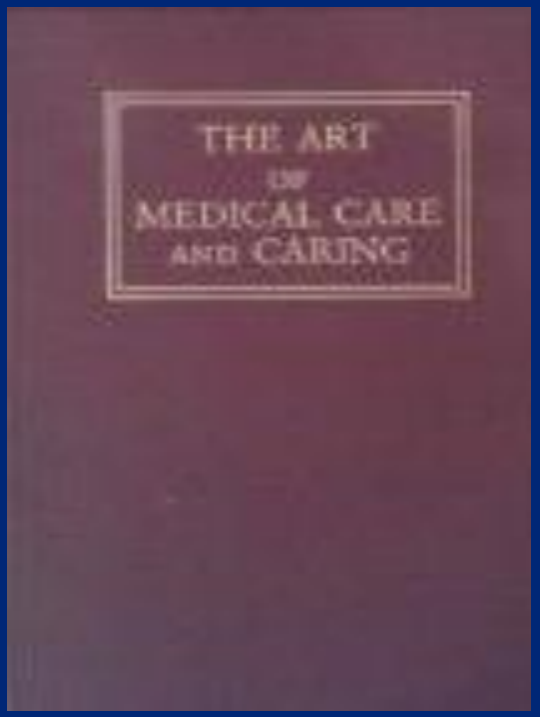
- Enthusiastic adoption of new technologies has been characteristic of spine surgeons in the US
- Many new technologies in spine surgery have been cost generating rather than cost saving, with limited evidence to support measurable improvements in outcomes.
- A responsible adoption of new technologies requires an assessment of the cost and incremental difference in outcome of innovations compared with predicates
- Patient centered focus in evaluating new technologies :
  - “The secret of care for the patient is caring for the patient”

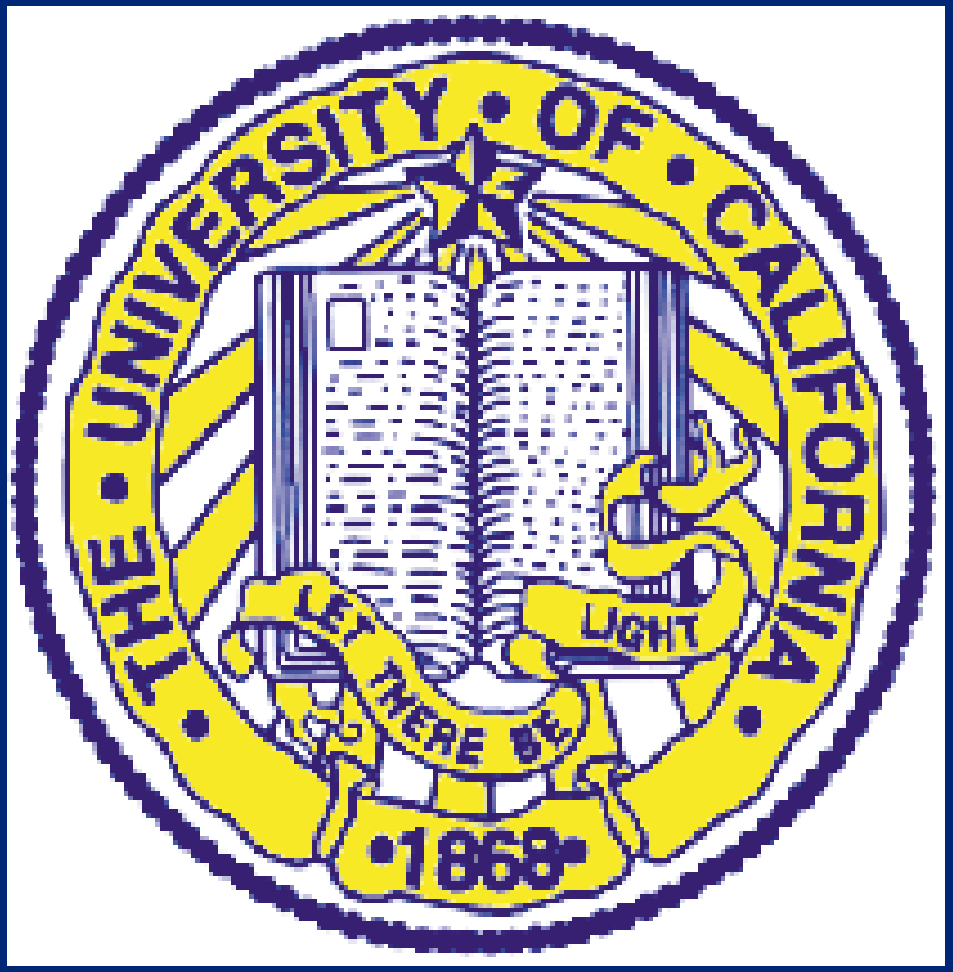
Guidance for Innovation

- *One of the essential qualities of the clinician is interest in humanity, for the secret of the care of the patient is in caring for the patient*



Dr. Francis Weld Peabody





UCSF Center for Outcomes Research