



Outpatient Spine Surgery: **The Next Five Years**

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Disclosures

- Aqueduct Neurosciences, Board of Directors
- angelMD, Chief Medical Officer
- Nuvasive, Inc., Health Policy Consultant
- Consultant
 - Medtronic, Streamlined Design Systems (SDS)
 - Synthes, Outpatient Cervical Surgery
 - Surgery Partners, Outpatient Spine Surgery
 - Spineology, Wenzel, Stryker

Trend Analysis

1.

Clinical
Trends

2.

Cost Reduction
Trends

3.

Healthcare
Trends



1. Clinical Trends

Trend Analysis

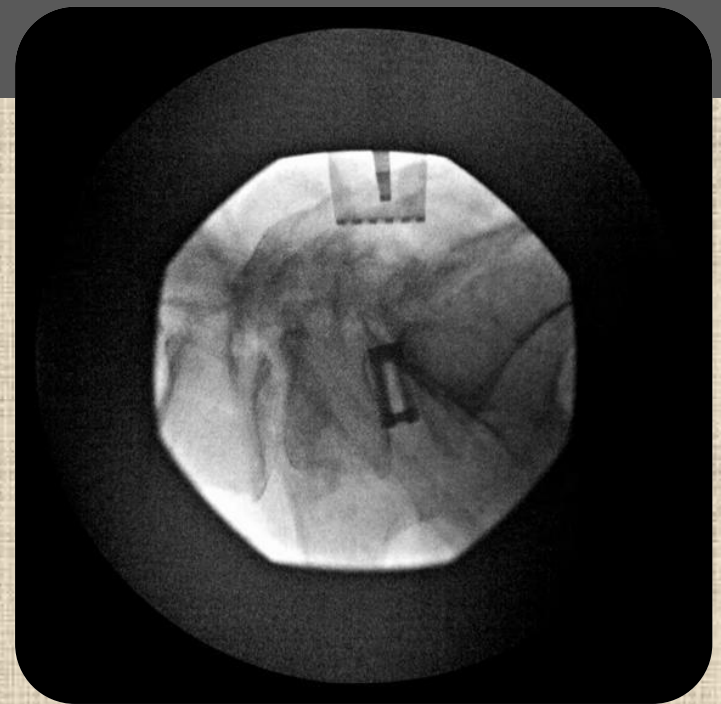
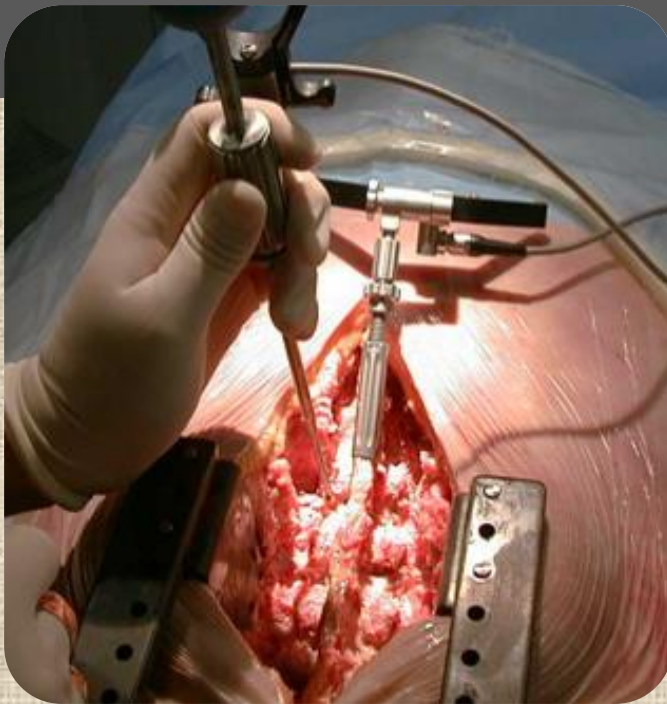
- Inpatient to outpatient
- Open to minimally invasive
- Fusion to arthroplasty
- Intraop fluoro to image guidance
- Image guidance to robotics
- Surgery to regenerative biology
- Evidence based medicine (DATA!)

INPATIENT TO OUTPATIENT

- Increasing numbers of outpatient non-instrumented spine surgeries
- Increasing numbers of outpatient instrumented fusions
 - ACDFs
 - Posterior cervical fusions
 - Lateral lumbar interbody fusions
 - L5-S1 anterior lumbar interbody fusions
 - TLIFs
 - SI joint fusions
- Increasing lumbar MIS internal fixation instead of pedicle screws
- Increasing use of post-op rehab facilities and hotels

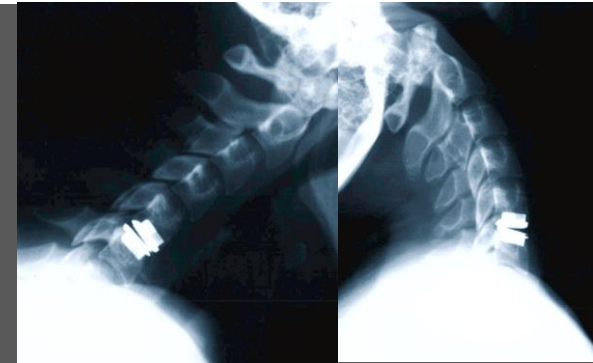
OPEN TO MINIMALLY INVASIVE

- Transition from open to MIS TLIFs



FUSION TO ARTHROPLASTY

- The Spine Journal, 2014: ProDisc II, followed 181 patients for five to 10 years.
 - Improved baseline VAS and ODI scores
 - 86% satisfactory to high patient satisfaction
 - 14.4% complication rate
 - 7.2% revision rate for general or device related complications
- Spine, 2013: ProDisc-C compared to fusions
 - 2.9% of TDR patients had re-operations within 5 yrs of initial surgery, compared with 14.5% of ACDF patients
 - No re-operations in TDR patients due to device failure
 - Pseudarthrosis was most common reason for re-operation at the index level among ACDF patients



CERVICAL DISC ARTHROPLASTY

Disc replacements are designed to maintain physiologic motion and minimize the downsides of fusion.

IDE Clinical Studies have shown for disc replacement vs fusion:

**Less
radiographic
adjacent level
degeneration**

*Up to
3.5x less*

**Fewer
reoperations**

*Almost 4x
fewer*

**Better
disability
improvement**

*Up to 16.5%
better*

**Maintenance
of motion**

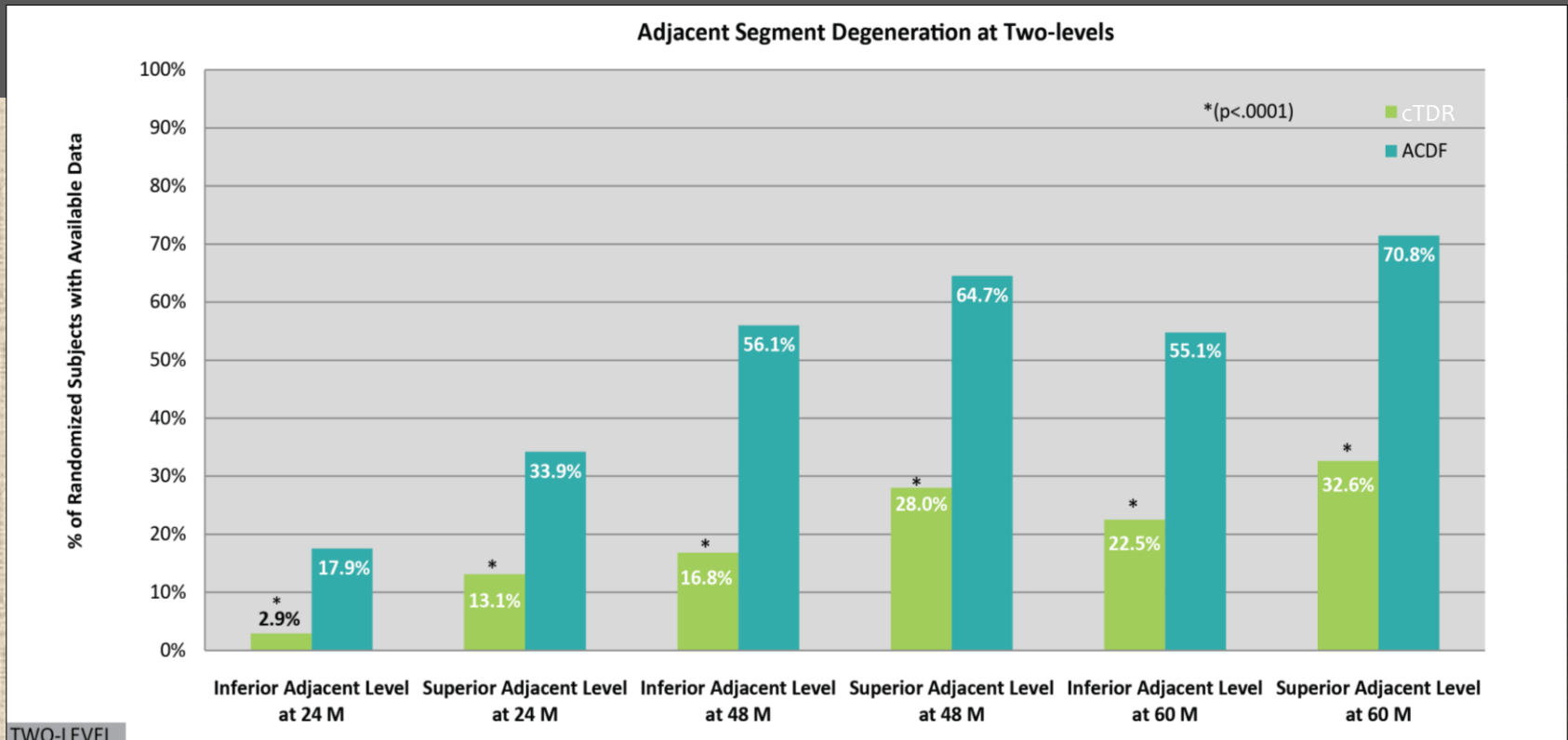
*Up to
7 years out*

**Faster
return to
work**

*Up to 3
weeks faster*

CERVICAL DISC ARTHROPLASTY

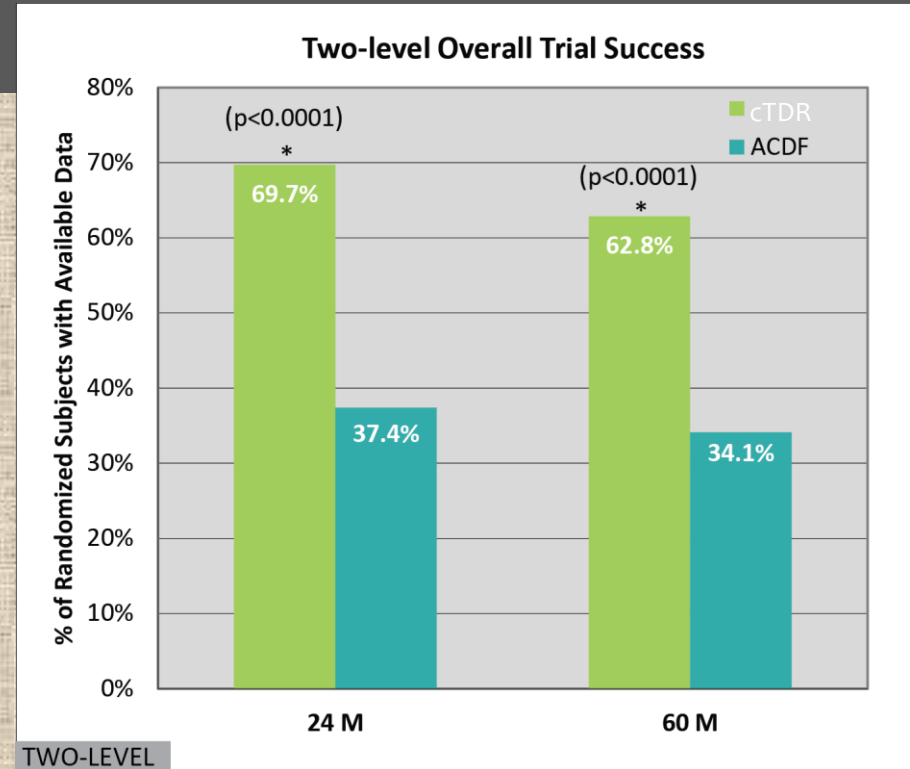
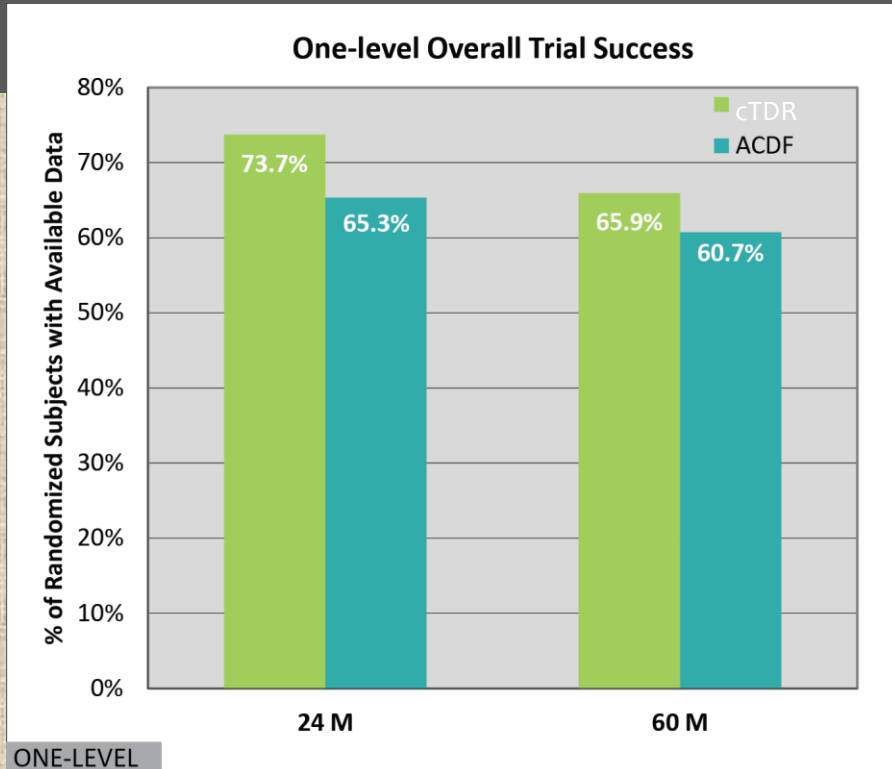
Two-level cTDR patients consistently demonstrated less adjacent segment degeneration than fusion patients through 5 years¹⁵



Radiographic ASD defined by the Kellgren-Lawrence scale¹⁵
 Independent radiographic analysis by MMI, Houston, Texas

TWO LEVEL ARTHROPLASTY

Non-inferiority to fusion at one-level
 Statistical Superiority to fusion at two-levels



MEDICAL COVERAGE FOR CERVICAL DISC ARTHROPLASTY

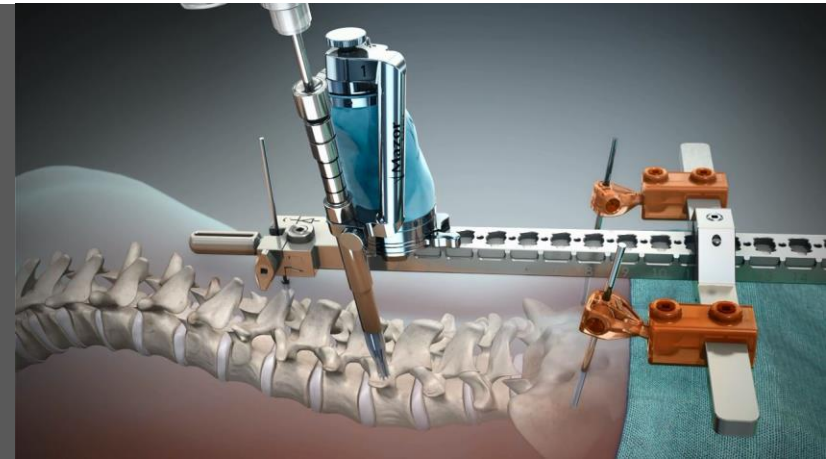
- **Noridian has removed the Total Cervical Disc Replacement procedure codes 22856, 22858, and 22861 from the Non Covered Services policy, effective January 11, 2016.**
- Beginning January 11, 2016, surgeons may perform cervical disc replacement procedures (1- or 2-level) on patient candidates who meet the indications for use granted by the FDA for cervical arthroplasty (see LDR's Mobi-C indications for use). Because Medicare does NOT have a prior authorization process, surgeons can perform the procedure and bill Medicare for the applicable CPT codes. However, this is NOT a guarantee that Noridian will actually cover the procedure - it will be reviewed on a case by case basis. It is recommended that the surgeon have the patient sign an Advanced Beneficiary Notice (ABN), which is a common practice with Medicare, should the procedure not be covered. If it is not, there is a process for Medicare appeals.

INTRAOP FLOURO TO IMAGE GUIDANCE

- **Journal of Neurosurgery 2014: 30 studies were included in the analysis**
 - 12 data sets used conventional fluoroscopy, 8 data sets used 2D fluoroscopic navigation, and 20 data sets used 3D fluoroscopic navigation
 - 1973 patients with 9310 pedicle screws inserted
 - Conventional fluoroscopy: 2532 of 3719 screws inserted accurately (68.1%)
 - 2D fluoroscopic navigation: 1031 of 1223 screws inserted accurately (84.3%)
 - 3D fluoroscopic navigation: 4170 of 4368 screws inserted accurately (95.5%)
 - Accuracy rates when 3D was compared with 2D fluoroscopic navigation were also consistently higher throughout all individual spinal levels
- **Conclusion: Three-dimensional fluoroscopic image guidance systems demonstrated a significantly higher pedicle screw placement accuracy than conventional fluoroscopy or 2D fluoroscopic image guidance methods**

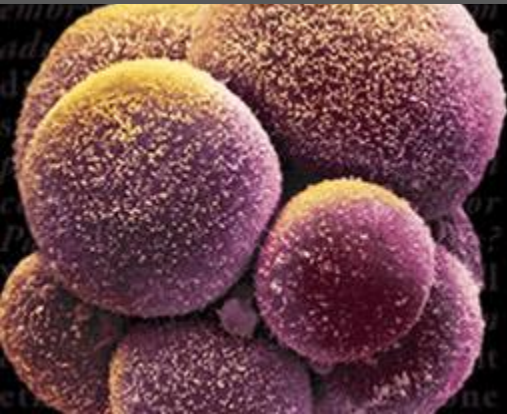
IMAGE GUIDANCE TO ROBOTS

- MazorRobotics and others
 - Open or MIS thoracolumbar surgery
 - Scoliosis and other complex spinal deformities
 - Pedicle screw fixation
- Da Vinci not suitable for robotic spine surgery
- Eur Spine J. 2011; 20(6): 860-868
 - 112 cases of robotic implants (55) vs freehand pedicle screws (57)
 - Improved robotic implant accuracy to 94.5% compared to 91.4%
 - Reduced fluoro time by 56%
 - Reduced complication rates including infections by 48%
 - Reduced re-operations, and post-op opioids
 - Reduced average length of stay by 27%



REGENERATIVE BIOLOGY

- Emory University announced Phase II international clinical trial: 100 patients with moderate to severe discogenic LBP
- Bone marrow stem cells (mesenchymal precursor cells) injections reduced LBP > 50% for at least 12 months
- Less need for pain meds, improvement in function, less need for surgical and non-surgical spine interventions



EVIDENCE BASED MEDICINE

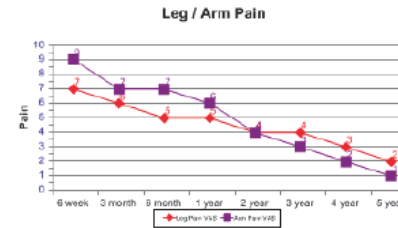
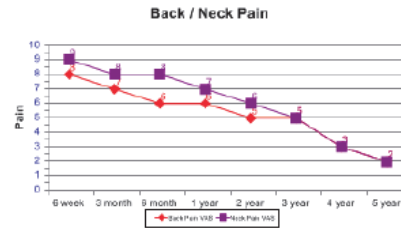
- More and more of what we do will be data driven
- Outcomes will be increasingly important
- QALYs
- Clinical outcomes
 - VAS
 - ODI
 - SF36
- Patient satisfaction

Demographics and Surgery Data

Diagnosis: Tumor	Surgery Date: 12/15/07
Gender: Male	Surgery Type (Primary or Revision): MISSING (Revision)
Age: 86	Length of Surgery: 10 minutes
DOB: 06/20/26	Length of Hospital Stay: 70 hours
Smoker: Yes, I use non-tobacco nicotine	Return to Work Date: MISSING
Pre-existing conditions: MISSING	

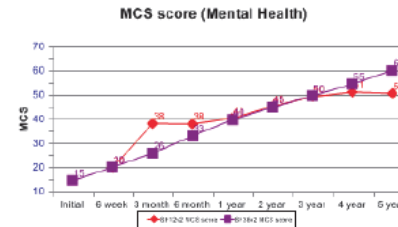
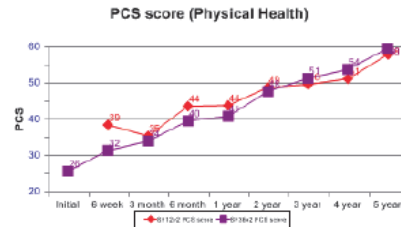
Pain Scale

The pain scale is scored from 0 to 10 with 0 being 'No pain' and 10 being 'Unbearable pain.'



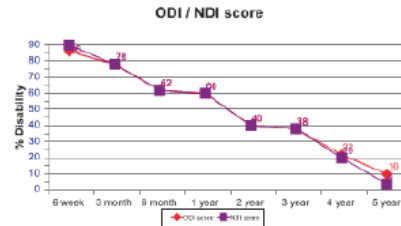
SF-12v2 and SF-36v2 Norm Based Scores

All scores are standardized to have a mean = 50 and a standard deviation = 10 in the general US population. (Ware, et al., 1998)



Disability Index Norm Based Scores

Patient's % of disability with activities of daily living



2. Cost Reduction Trends

Trend Analysis

- Site of service
(inpatient to outpatient)
- Pricing transparency
- Bundled payments
- Value Assessment Teams (VAT)
 - Implant management
 - Osteobiologics



INPATIENT TO OUTPATIENT

Inpatient Charge	Single Level ACDF	Cervical Arthroplasty	Outpatient Charge	Single Level ACDF	Cervical Arthroplasty
			Facility	\$28,636	\$22,891
Implants	\$32,613	\$29,500	Implants	\$2,375	\$8,125
Total Billed Charges	\$68,000	\$61,095	Total Billed Charges	\$31,011	\$31,016
Ave. Insurance Payment	\$48,960	\$43,988	Ave. Insurance Payment	\$14,500	\$17,000
			Average Co-pay	\$0	\$0

OUTPATIENT VS INPATIENT ACDF

- The Spine Journal 14 (2014) IS-183S
- Prospective quality improvement registry representing more than 150 hospitals, 1-3 level ACDFs
- Outpt vs Inpt ACDF is associated w/ improved patient safety: analysis of 7,288 pts from NSQIP Database
- Outpt ACDFs had 58% lower odds of having major morbidity and 80% lower odds of a return to OR within 30 days

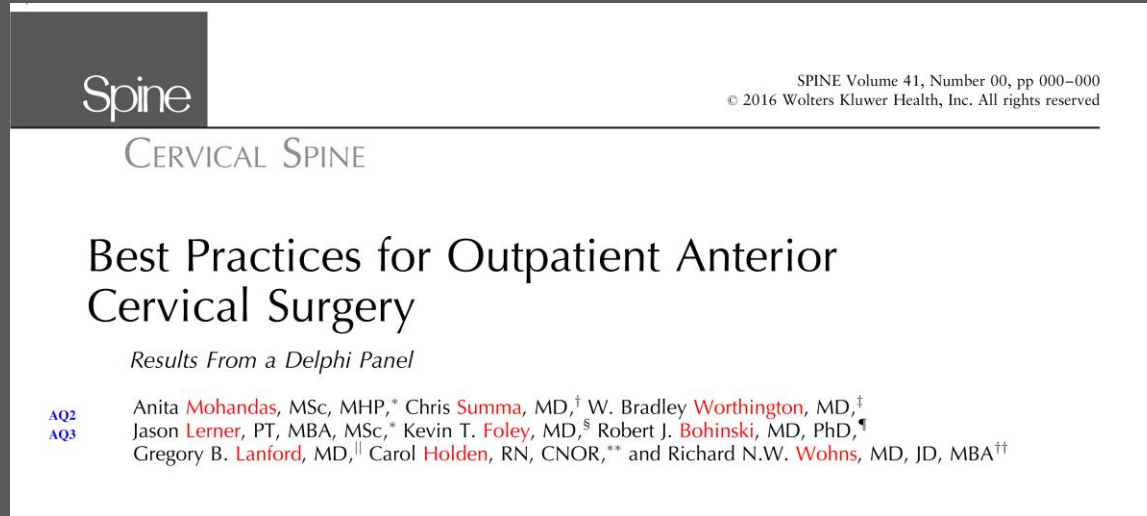


OUTPATIENT VS INPATIENT ACDF

- **Journal of Neurosurgery: Spine, Feb. 5, 2016; DOI: 10.3171/2015.8.SPINE14284**
- 1000 consecutive patients underwent ACDF in an outpatient setting
- Complications occur at a low rate (1%) and can be appropriately diagnosed and managed in a 4-hour ASC PACU window
- Comparison with inpatient ACDF surgery cohort demonstrated similar results, highlighting that ACDF can be safely performed in the outpatient ambulatory surgery setting without compromising surgical safety.
- In an effort to decrease costs of care, surgeons can safely perform 1- and 2-level ACDFs in an ASC environment.



OUTPATIENT ACDF



Conclusion. This study obtained expert-panel consensus on best practices for patient selection and peri-operative decision making for outpatient anterior cervical surgery (ACDF/CTDR). Given a paucity of guidelines and a lack of established care pathways for ACDF/CTDR in same-day, ambulatory settings, results from this study can supplement available evidence in support of local protocol development for providers considering a transition to the outpatient environment.

BUNDLED PAYMENTS

- **ASC Bundle**
 - Pro fee, technical fee, implant costs, anesthesia fee
- **Medicare Bundled Payment Program**
 - CMS “Pay for Performance” initiative
 - Surgeons directly control patients and receive all resulting savings
 - Surgeons would trump all hospitals, ACOs, ASCs for ultimate control of the bundle for 3 years from 1/1/15
 - Surgeons go at risk for DRG Bundles that are potentially profitable because surgeon is confident that he can complete care (90+ days after discharge) for a total \$ amount lower than the Bundle provided

SPINE BUNDLES

- **Huge variation in spine surgery costs**
- **Spine, Vol. 39, Issue 15, July 1, 2014:**
 - 196,918 patients with cervical or lumbar surgery, 2000-2009
 - At least 2-yr pre-op and 90-day post-op follow-up data
 - Significant variation between DRGs, ranging from \$11,180 (30-day bundle, DRG 491) to \$107,642 (30-day bundle, DRG 456)
 - Significant cost variations
 - Post-discharge care accounted for relative small portion of overall bundle costs (4%-8% in 90-day bundles)
 - Total bundle costs remained relatively flat as bundle-length increased (total average cost of 30-day bundle \$33,522 vs 90-day bundle, \$35,165.
 - Payments to hospitals accounted for the largest portion of bundle costs (76%)

ASCs

- Less expensive option for care
- Insurance companies may incentivize patients to use lower-cost ASC option
- If hospitals control the payments for the bundle, they are unlikely to refer patients out of their network



ASC BUNDLES

- Orthopedic Surgery Center of Orange County
 - Discectomy, laminectomy, laminotomy \$14,225
 - 2-level discectomy, laminectomy, laminotomy \$16,200
 - 1-level lumbar fusion and overnight stay \$30,000
 - 2-level lumbar fusion and overnight stay \$38,000
 - Facet joint injection, cervical/thoracic (1-level) \$ 2,100
 - Transforaminal epidural steroid, lumbar/sacral \$ 2,100
 - Radiofrequency ablation, cervical \$ 2,475

SUCCESS RATE

- >50% of hospitals that have tried bundled payments want to increase the number of procedures, care settings and partners including in the bundles
- 40% of hospitals reported savings of 5% or more
- >80% of hospitals w/ bundled experiences improved patient engagement, increased alignment w/ physicians and reduced administrative costs
- 60% of payers w/ bundles plan to expand their bundling efforts
- 57% of physicians say they will adopt bundles if their payers adopt them



3. Healthcare Trends

Trend Analysis

- Pre-ACO to ACO to MDHC
- Narrow networks
- Increasingly restrictive payors
- Reference pricing
- Growth of boutique spine practices



ACOs or Market Driven Health Care



NARROW NETWORKS

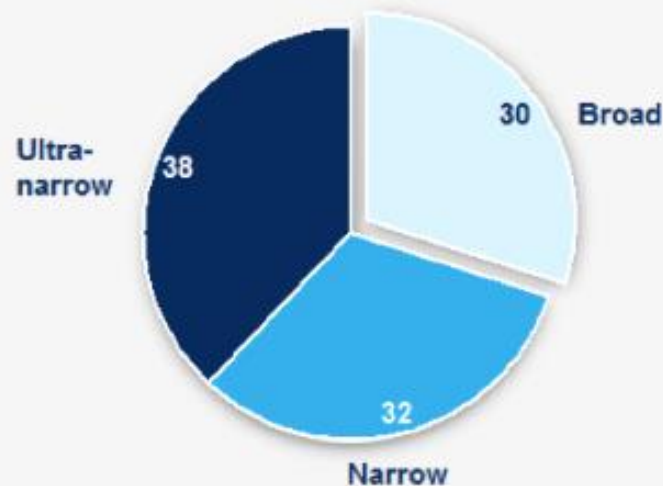
- Health insurance plans that place limits on the doctors and hospitals available to subscribers
- Do not pay for trips to doctors that aren't in the restricted network
- Insurance plans that work with a smaller number of providers would have more leverage to demand even lower prices from these hospitals and doctors
 - They promise to buy in bulk from a small set of doctors and can reduce the cost they pay for each visit
 - This allows them to offer lower premiums
- Health insurance plans charge higher co-payments to go to see a doctor who isn't in the "top tier"
 - Patients can go out-of-network, but will pay higher price

NARROW NETWORKS

70 percent of hospital networks on exchanges are narrow or ultra-narrow

Distribution of networks by network breadth¹

2014 individual exchange – Percent of analyzed silver networks (n = 120²)

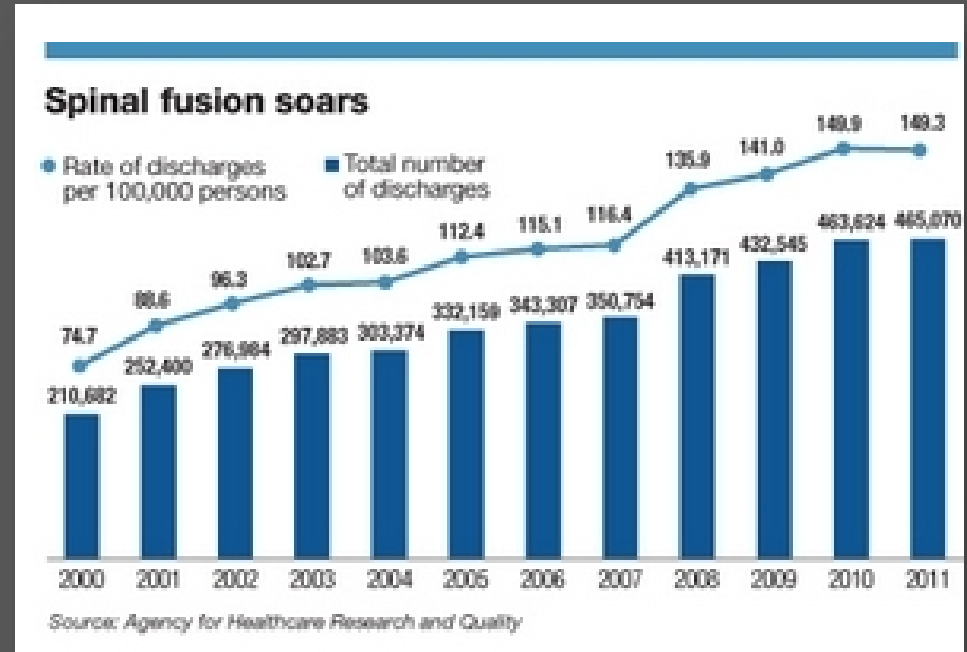


¹ Broad networks: less than 30% of largest 20 hospitals by number of beds are not participating, Narrow networks: 30-69% of largest 20 hospitals are not participating, Ultra-narrow networks: at least 70% of largest 20 hospitals are not participating

² Networks offered in silver in Atlanta, Bridgeport, Dallas, Nashville, Houston, Salt Lake City, Miami, Tampa, Louisville, Indianapolis, St. Louis, Los Angeles, San Jose, Pittsburgh, Denver, Philadelphia, Seattle, Chicago, Washington D.C., and Portland, ME

RESTRICTIVE PAYERS

Payers are changing their policies and services given the mounting research evidence that too many Americans are undergoing unnecessary spinal procedures and experiencing mixed outcomes.



COLLIDING FORCES

- Insurance guidelines vs clinical indications
 - Attempts to limit medically necessary spine surgeries simply put off the inevitable, leading to higher costs when medically necessary procedures are delayed (Eur Spine J (2007) 16:329-337)



FUSION BETTER THAN NON-SURGICAL TREATMENT

Critically Appraised Papers

Fusion surgery is slightly better than non-surgical treatment in patients with severe chronic non-specific low back pain

Synopsis

Summary of Fritzell P, Hägg O, Wessberg P, Nordwall A, and the Swedish Lumbar Spine Study Group (2001): Lumbar fusion versus non-surgical treatment for chronic low back pain. A multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group. *Spine* 26: 2521-2534. [Prepared by Gro Jamtvedt and Kåre Birger Hagen, National Agency for Health and Social Welfare, Norway.]

Question: Does fusion surgery reduce pain and disability more than conservative treatment in patients with severe chronic low back pain? **Design:** Multicentre randomised controlled trial. **Setting:** Nineteen orthopaedic departments in Sweden. **Patients:** Two hundred and ninety-four patients aged 25-65 years with chronic low back pain (CLBP). Criteria for inclusion were pain duration at least two years, back pain more pronounced than leg pain, sick leave for at least one year, no success with previous conservative treatment and a score of at least 7 out of 10 points on a pain and function scale where 10 points was "severe pain and no function". Exclusion criteria were psychiatric illness, spine surgery in the last two years, and specific radiological findings such as spondylolisthesis and spinal stenosis. Five patients (2%) were lost to follow-up after two years. **Interventions:** Two hundred and twenty-two patients were allocated to the surgery group and 72 to a non-surgical group. The non-surgical program was constructed on a consensus basis and used as a guideline with the possibility of local modifications and variations. The main components were different physiotherapy modalities such as information and education, TENS, cognitive and functional training, coping strategies, in addition to acupuncture and injections. **Outcomes:** Primary outcomes included 1) back and leg pain measured on a visual analogue scale; 2) functional disability measured with the Oswestry, Million and General Function Scale disability questionnaires; 3) patient overall assessment; and 4) work status. Outcomes were assessed at two years by an independent observer, and analysed according to the intention-to-treat principle. **Result:** Groups were comparable at baseline. Back pain reduced by 33% in the surgical group compared with 7% in the non-surgical group ($p < 0.001$). Leg pain reduced by 18% in the surgical group compared with a 21% increase in the non-surgical group ($p = 0.005$). Disability, as measured by the three different instruments, was reduced from 25% to 31% in the surgical group compared with 4% to 8% in the non-surgical group (p values from 0.015 to 0.004). In the surgical group, 63% rated themselves as "much better or "better" compared with 29% in the non-surgical group ($p < 0.001$). In the sub-group of those not in work before inclusion, 39% returned to work in the surgical group compared with 23% in the non-surgical group ($p = 0.049$). **Conclusion:** In patients with severe chronic low back pain, lumbar fusion provides greater improvement in pain, disability and work status than uncontrolled non-surgical treatment.

Commentary

The search for effective treatment for patients with CLBP makes this study very important and highly needed for both patients and society. Many CLBP patients consider surgery as "a magic bullet", but back surgery has so far not been compared with conservative treatment in a randomised controlled trial. The main purpose of Fritzell's study was to evaluate whether lumbar fusion could reduce pain and decrease disability more effectively than commonly recommended non-surgical treatment in patients with severe chronic low back pain.

Before randomisation, the patients were told by the surgeon that no treatment method, as far as was known, was superior to any other. The non-surgical treatment program was constructed on a consensus basis and used only as a guideline with the possibility of wide modifications and variations. The inclusion period extended over six years (1992-1998), a period during which several systematic reviews on conservative treatment of CLBP were published, which may have changed the therapists' approaches considerably during the study period. The modalities, the specific dose of treatment and compliance is unknown. The non-surgical group should therefore be considered a control group rather than an alternative treatment group.

Statistically, all primary outcome measures were significantly in favour of surgery. On average, however, both groups still suffered from pain and disability two years after treatment, indicating that even lumbar fusion did not cure this selected group of patients completely. Thirty-seven per cent of the patients in the surgical group rated their result as unchanged or worse. Fusion surgery may be a valid option for patients with longstanding lumbar pain, but this study alone does not provide conclusive evidence to support increased use of lumbar fusion.

Additionally, the placebo effect following surgery is known to be more powerful than non-surgical treatment methods. The fact that many of the patients in the non-surgical group probably had been through conservative treatment in an earlier phase, with an unsuccessful result, may to a certain degree explain the differences between the groups.

Scientifically valid studies comparing surgical fusion with well defined multidisciplinary treatment programs are therefore needed.

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National Hospital, Oslo

COST-EFFECTIVE SPINE SURGERY IMPROVES QALY

- “Surgery improves health with persistent quality-adjusted life year differences” SPORT Trial, 634 patients, 414 underwent surgery either initially or during 4-year f/u period
 - Spinal stenosis: \$77,600 at two years to \$59,400 at four years
 - Degenerative spondylolisthesis: \$115,600 at two years to \$64,300 at four years
 - TLIF: \$42,854 at two years
 - HNP: \$34,355 at two years to \$20,600 at four years

REFERENCE PRICING

- A form of defined contribution health benefits where health plans pay a fixed amount or limit contributions toward the cost of a specific health care service, and health plan members must pay the difference in price if a more costly health care provider or service is selected.
- Fronstin and Roebuck, Employee Benefit Research Institute, April 2014, No. 398



BOUTIQUE SPINE PRACTICE

- Response to ACA for independent doctors to maintain autonomy: “American medicine is rapidly heading to a two-tier system similar to many other countries, like England and Australia,” Scott Blumenthal, MD, Co-Director of the Boutique Spine Program at TBI
- Concierge services: access to specialists 24/7, personal services, travel arrangements, telemedicine, self-pay, no insurance company restrictions
- Surgeons must prove consistently better service and surgical outcomes than competitors
- Surgery for lumbar DDD will not be routinely covered by payers, and patients with disabling LBP will seek out boutique spine practices for high quality care

THE FUTURE IS OUTPATIENT

- **SG2 projected 22% increase in ASC services from 2010 to 2019**
 - More than 50% of all spine surgeries can be safely performed outpatient
- **Macroeconomic forces**
 - Outpatient is 30-60% less expensive than inpatient
- **Clinical innovations**
 - Minimally invasive is more and more suited for ASCs
- **Popularity with patients**
 - Outpatient leads to higher patient satisfaction
 - Fewer complications including infection



Your Choice!

You can become extinct ...

... or soar like an eagle



Thank You!

