Update on Lumbar Stenosis and Spondylolisthesis:
Back pain and neurogenic claudication

A. Nick Shamie, MD

Professor and Chief, Orthopaedic Spine Surgery

UCLA Department of Orthopaedic Surgery and Neurosurgery

UCLA Health

Safety of Spine Surgery

- Over 1200 spine surgeries last year at UCLA
- 80+% patient satisfaction
- Better understanding of the pain generators
- Better techniques and instrumentation
- Multidisciplinary approach and collaboration
  - Orthopaedic Surgery
  - Neurologic Surgery
  - Pain medicine and Anesthesia
  - Neurology etc.

Common Spine Surgeries

- Decompression
  - Taking the pressure of the nerves (decompressing nerves)
  - Performed when the patient experiences shooting pain or nerve problems like balance issues
- Fusion (and arthroplasty)
  - Anchoring one or more vertebra against others in the spinal column
  - For either pre-existing instability for bone destructive process or for iatrogenic instability (severe stenosis, tumors, infections etc.)

Lumbar Spinal Stenosis

- 8 - 11% Incidence of LSS in the U.S.[1]
  - 1.2 million Americans diagnosed
- LSS is the most common reason for spine surgery in older people[2]
- More than 500,000 laminectomy procedures were performed for LSS annually
- The financial impact and lost work hours reaches billions of dollars each year in this country[4]

1. Murphy et al, BMC musculoskeletal Disorders, 2006, Jennis et al, Spine 2000.
2. Murphy et al, BMC musculoskeletal Disorders, Szpalski, European Spine Journal, 2003
3. The Ortho FactBook™; U.S. 5th Edition; Solucient, LLC and Verispan, LLC
4. Knowledge Enterprises, Inc.

Clinical Presentation of Lumbar Spinal Stenosis

- Pain, numbness, tingling and weakness in the legs with ambulation

- **Patients lean forward while walking to ambulate more comfortably**

- Sitting relieves symptoms

Lumbar Spinal Stenosis (LSS) Affects Your Patients

LSS: narrowing of spinal canal causes pain, weakness, and immobility,

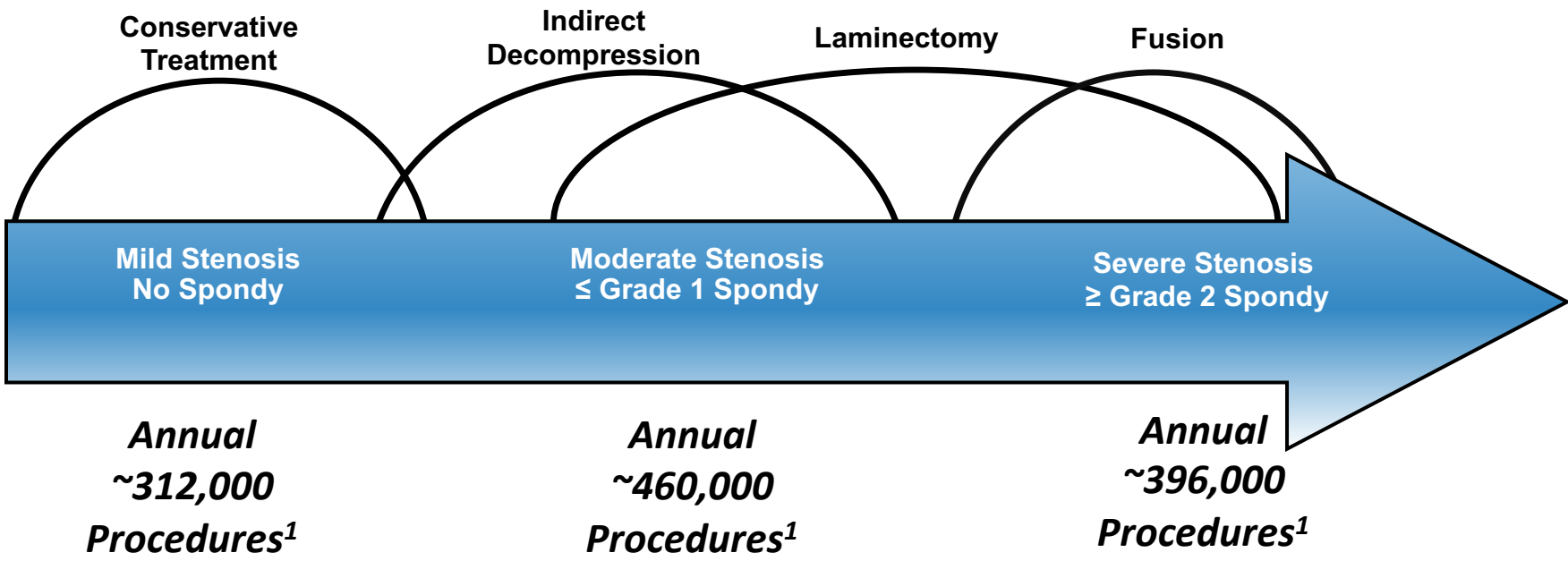
1.2M annual US diagnoses [1]

- 1.5M ESIs provide only temporary relief [2]
- >175K decompression surgeries [2]
- #1 reason for spine surgery in elderly [3]
- LSS surgeries: fastest growing type of lumbar surgery in US [4]

[1] American Association of Neurological Surgeons.
[2] American Medical Association's RBRVS Data Manager Program 2013.
[3] Deyo et al. 2010.
[4] Weinstein et al. 2008.

UCLA Health

Treatment Options for LSS: The Continuum of Care



[1]Qessential Medical Market Research, 2015.

Surgical vs. Nonsurgical Care

- SPORT (Weinstein et al. NEJM 2007)
  - Spondylosithesis
  - 303 Randomized to Lami +/- fusion vs. no surgery (including epidural)
  - 304 in observation cohort arms
  - 13 centers in 11 states, randomized and Outcome measures: SF-36 and ODI
  - Nonsurgical: PT 68%, ESI 55%, Chiro 25%, NSAIDS 63%, Opioids 30%.
  - Surgical patients had fusion w/ICBG, +/- implants

SPORT Results

- High Crossover between Randomized and observational
- Point improved on SF-36
  - 18.1 Bodily Pain
  - 18.3 Physical Function
- ODI -17.6
- Significant improvement at 2yrs vs. nonoperative care.

Laminectomy

- Does not stop progression of disease
- Discs continue collapsing
- Disc protrudes in the Lateral recess and neural foramina
- Does disease progression lead to recurrence of stenosis?

Laminectomy is not perfect!

- Spinal Stenosis - complications
  - ICL 2000 Garfin, Herkowitz, Mirkovic
- Epidural Hematoma (acute or delayed)
  - Sokolowski MJ, Dolan M, Aminian A, Haak MH, Schafer MF. JSDT 2006
- Dural Tear (10% in SPORT)
- Revision surgery for restenosis (4% at 2yrs SPORT)
- Epidural Scarring
  - Cause of neuropathy
  - Challenging revision surgery

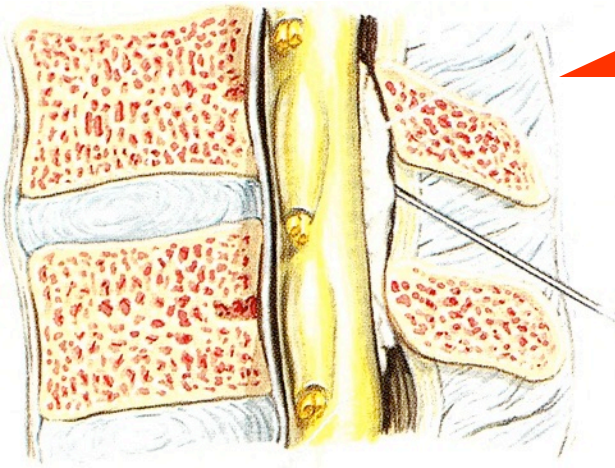
Less Invasive ALTERNATIVE

Non-Operative Care

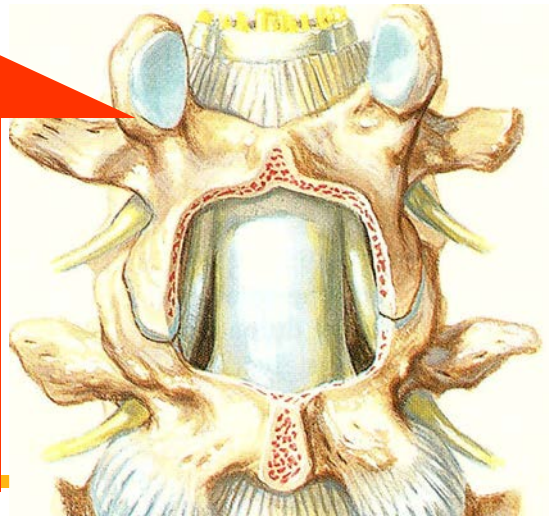
- **Epidural injections**
- **Physical therapy**
- **NSAIDs other drugs**
- **Lifestyle modification**

Surgical Decompression

- Laminectomy
- Laminectomy with fusion
- Laminotomy/facetectomy
  - Minimally Invasive Techniques

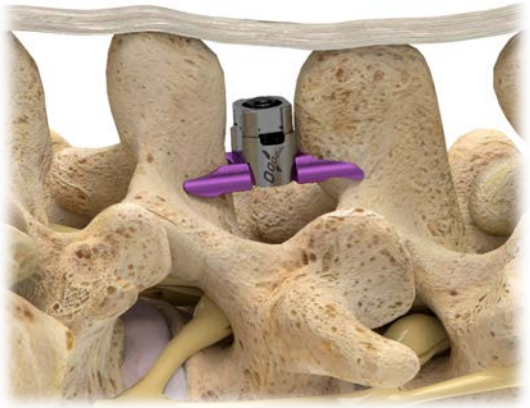


IPD



UCLA Health

This outpatient procedure features a reduced operative time and involves no tissue or bone resection, minimal blood loss and no destabilization of anatomical structures.



The deployed Superion®. The implant fits between the spinous processes and the wings help prevent the implant from moving.

- A clinically proven, less invasive alternative for lumbar stenosis
- Does not limit future treatment options
- No general anesthesia, small incision
- Lower rate of serious peri-and-post operative complications
- **Clinical improvement comparable to "gold standard" laminectomy**

Superion® Compares Favorably to Laminectomy

Superion® Data vs Literature Reports of Laminectomy[1]

All Clinical Outcome Measures Favor Superion®

Outcome Measure	% Improvement from Baseline (24 mo)	
	Superion®	Laminectomy
Back Pain	**65%**	52%
Leg Pain	**70%**	62%
ODI	**51%**	47%
ZCQ Symptom Severity	**37%**	29%
ZCQ Physical Function	**36%**	32%

More Favorable Outcomes

The outpatient procedure requires only local anesthesia and a small incision.

[1]Lauryssen C, *et al.*: Stand-alone interspinous spacer versus decompressive laminectomy for treatment of lumbar spinal stenosis. *Expert Rev Med Devices* 2015; 12(6):763-769.

UCLA Health

FDA-Defined Complex Composite Endpoint

% of Subjects Meeting Success Criteria			
Primary Endpoint Components	24 mo	36 mo	48 mo
Success in 2 of 3 ZCQ domains	81.7%	88.0%	84.3%
No re-operations / revisions	80.0%	78.4%	75.8%
No major related complications	86.3%	87.4%	86.3%
No confounding additional treatments	86.8%	84.2%	83.7%

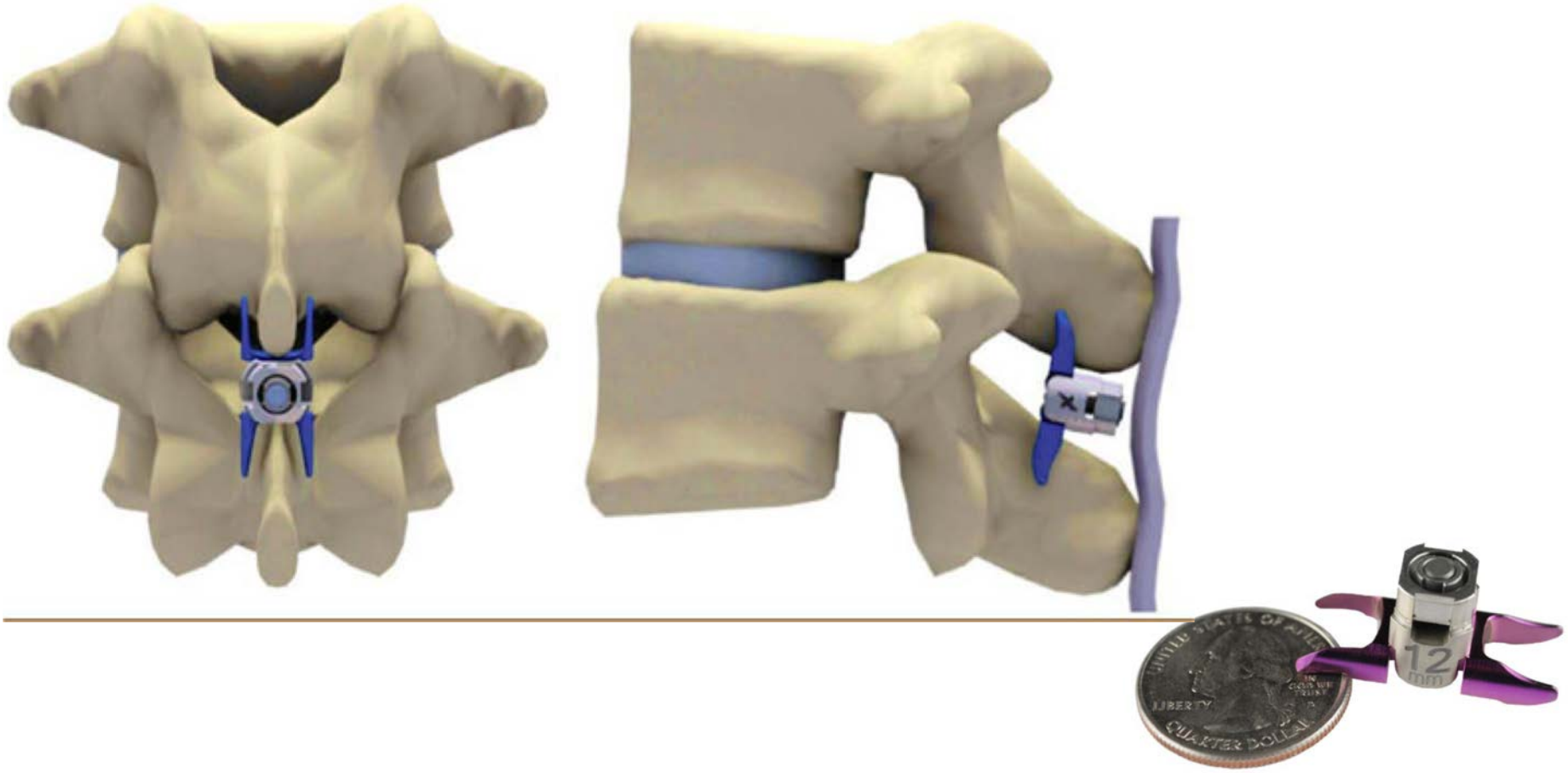
Results – Secondary Outcomes

Individual Outcomes Positive at 2 yrs, Improved at 3 yrs

% of Subjects Meeting Success Criteria			
	24 mo	36 mo	48 mo
ZCQ Physical Function domain	72.5%	79.6%	78.7%
ZCQ Symptom Severity domain	77.1%	84.3%	83.1%
ZCQ Patient Satisfaction domain	84.0%	91.7%	86.5%
VAS (Leg Pain)	75.7%	80.3%	77.3%
VAS (Back Pain)	67.4%	75.2%	67.0%
ODI	60.9%	62.8%	61.7%

Establishes clear durability of effectiveness through 48 months

Superion Spacer



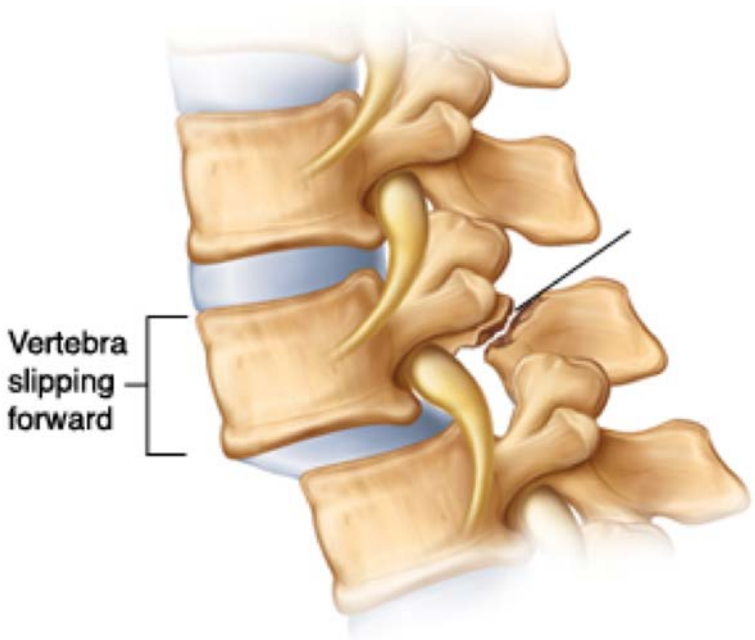
Boston Scientific gets into spine with $465 Vertiflex buy

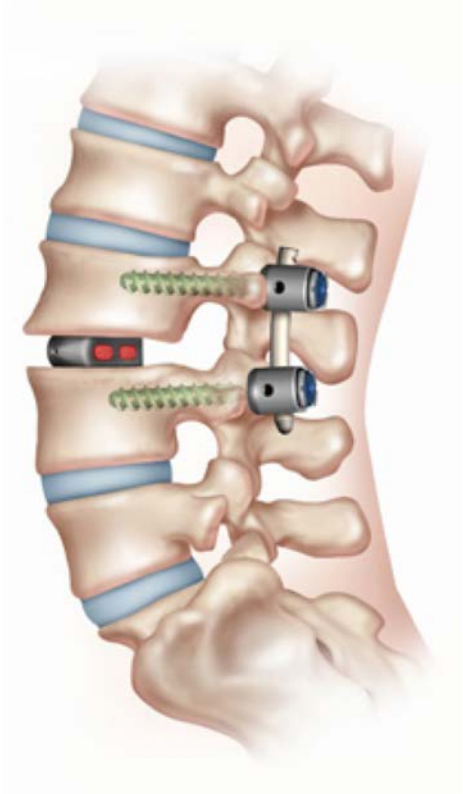
MAY 9, 2019 BY BRAD PERRIELLO — LEAVE A COMMENT

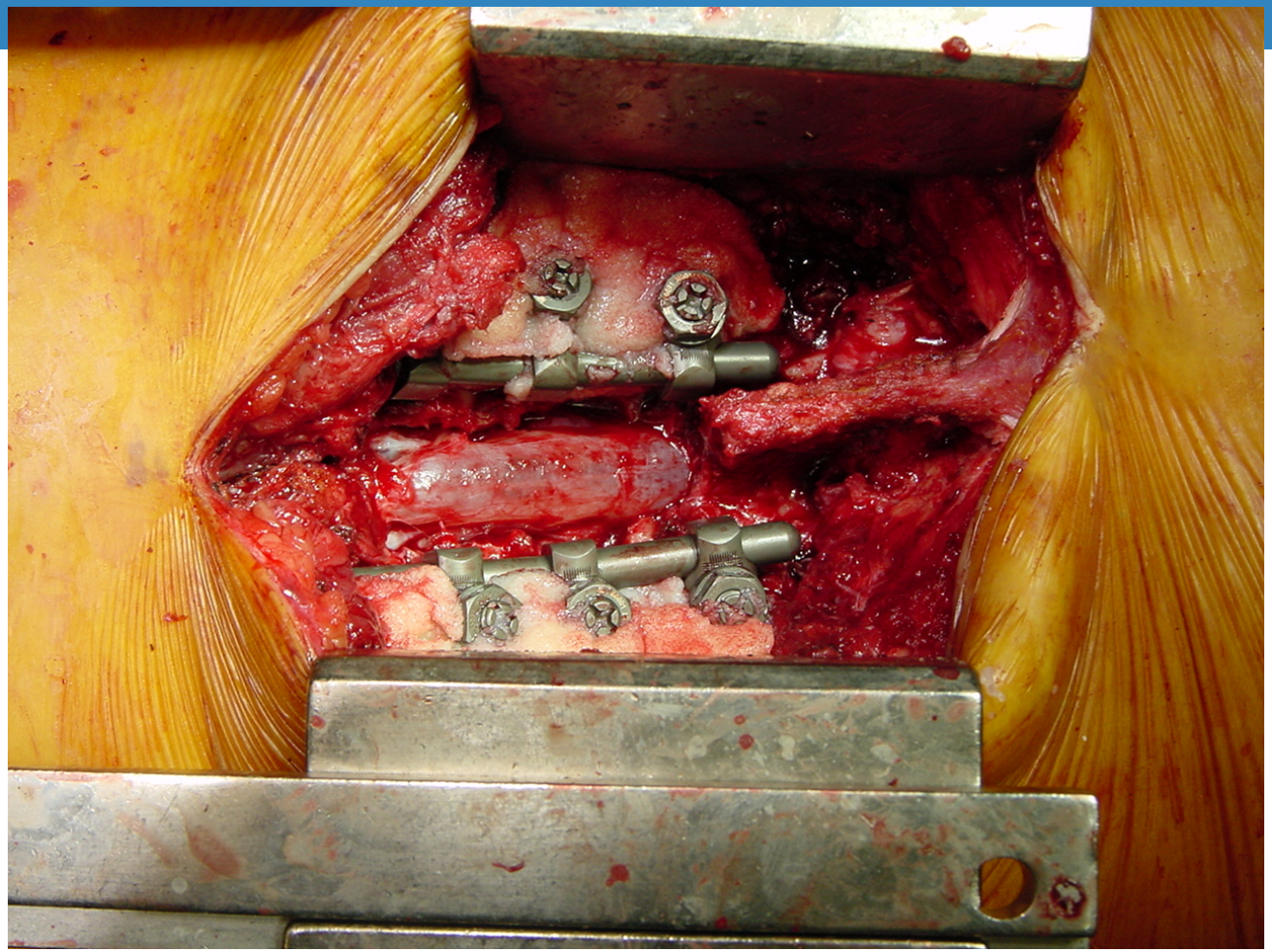
Boston Scientific (NYSE:BSX) moved into the orthopedics space with a $465 million buyout of spinal implant maker Vertiflex.

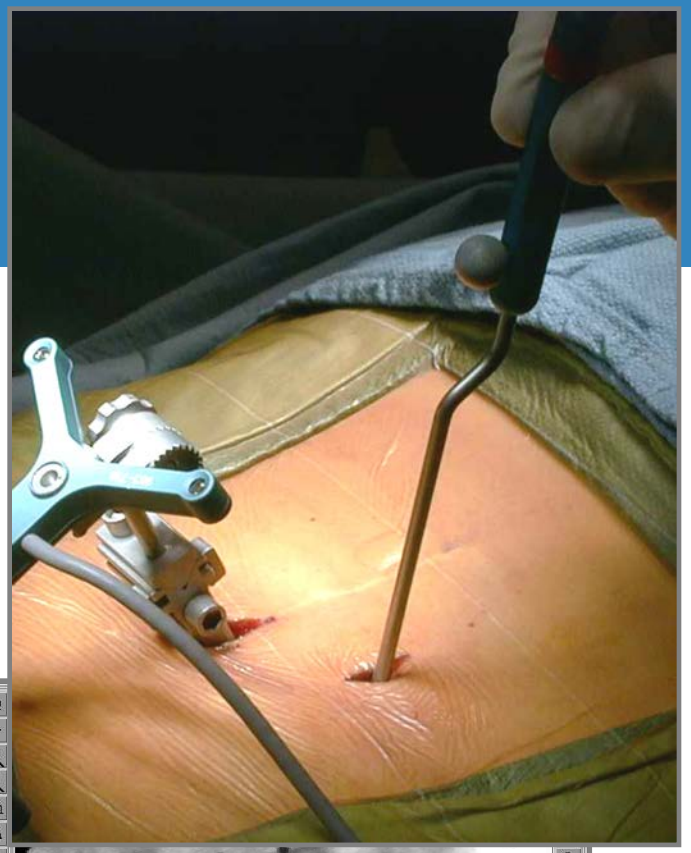
The deal, announced this morning and expected to close late in the second quarter of 2019, includes commercial milestones spaced out over three years. Carlsbad, Calif.-based Vertiflex makes the Superion decompression device for treating lumbar spinal stenosis, which won pre-market approval from the FDA in May 2015. Boston Scientific said it plans to integrate Vertiflex, which employs about 100 people, into its pain management portfolio. Superion sales are slated to hit $60 million this year, Boston said.

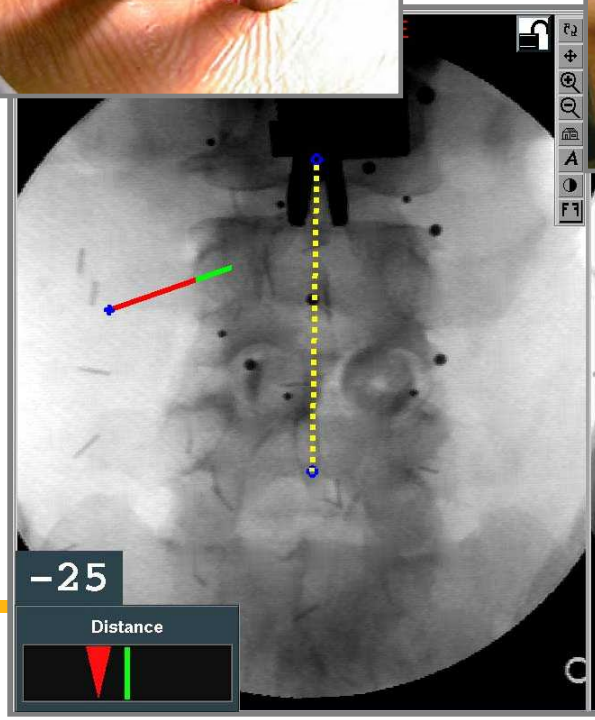
Spinal Fusion

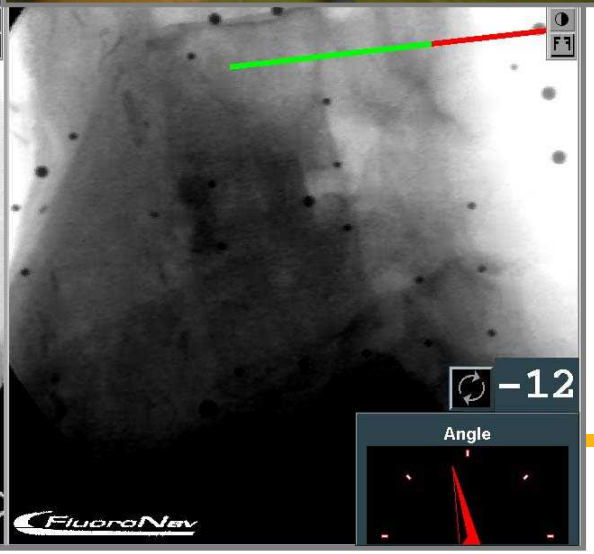




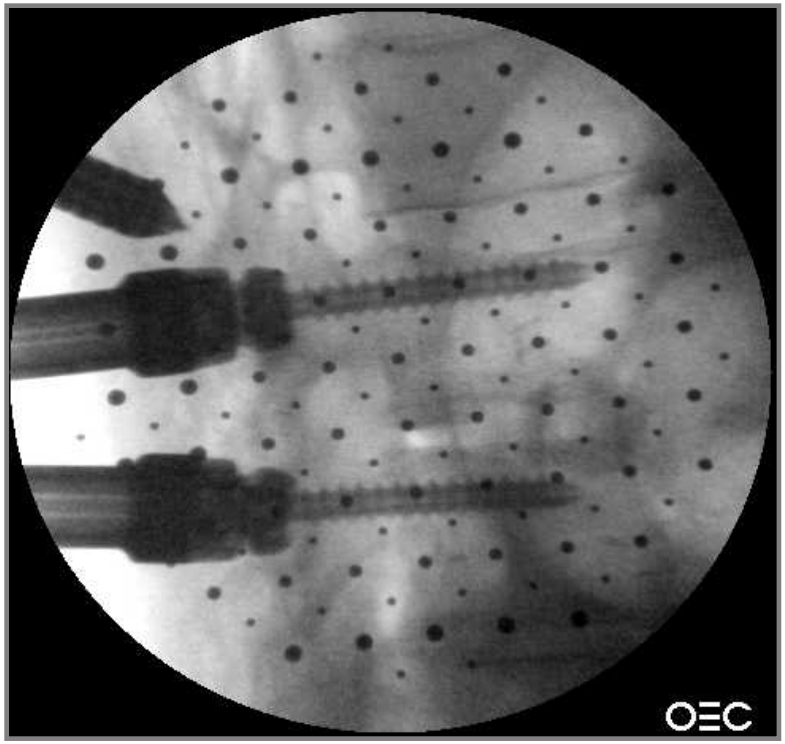


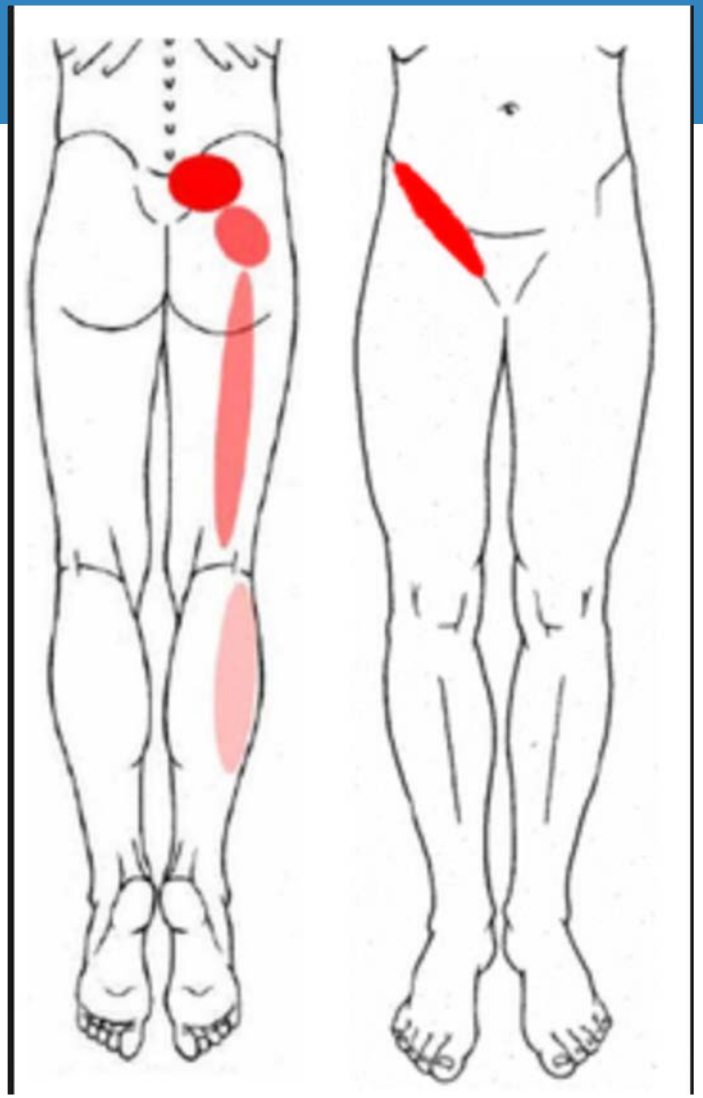






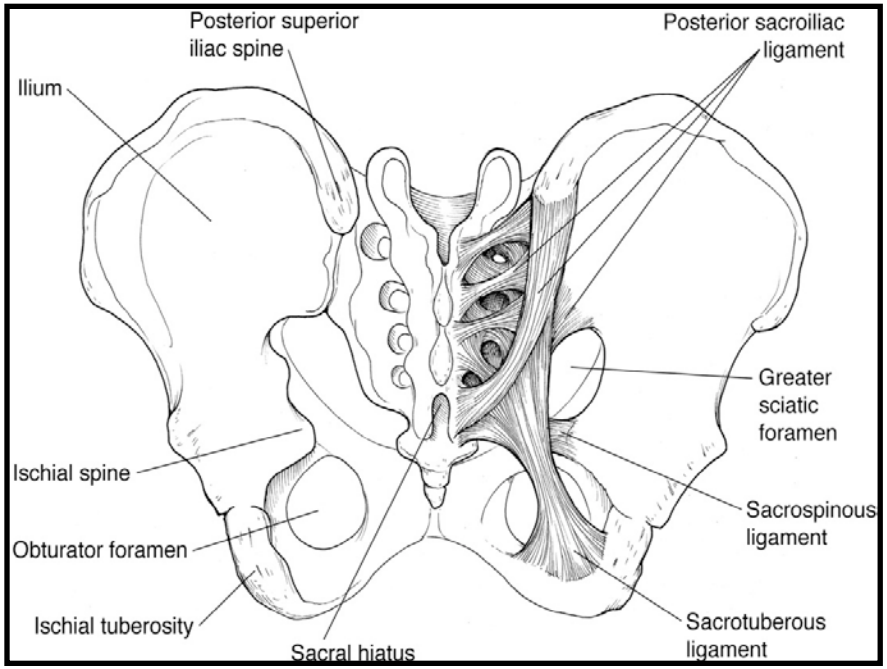
UCLA Health


OEC



Sacroiliac Joint

- Largest axial, synovial joint in body ~ 17.5 cm^2
- Stronger posterior ligaments
- Morphology changes with age, bony ridges and depressions

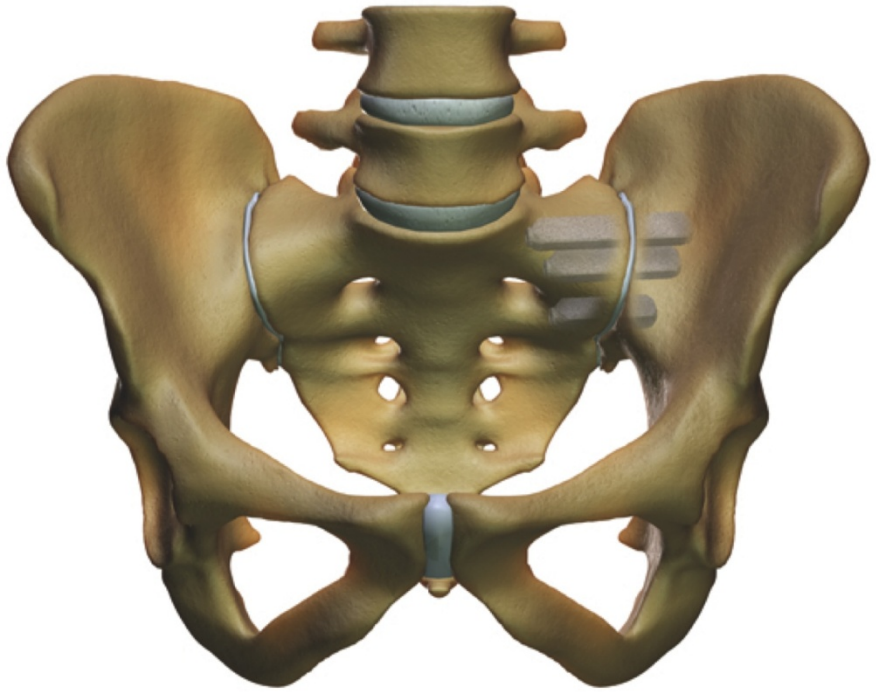


SI Dysfunction

- >22% of 1,200 pts presenting with LBP have SIJ-related problems
  - *–Bernard, Kirkaldy-Willis, Clinical Ortho & Related Res 1987*
- SIJ disease should strongly be considered in differential diagnosis of LBP
  - *–Weksler, Archives Ortho Trauma Surg 2007*
- SIJ is potential source of pain post-lumbar surgery
  - *–Liliang, Pain Med 2011*
- 75% of post-lumbar fusion patients had imaging changes showing SIJ degeneration 5 years post-op
  - *–Ha, et al, Spine 2008*

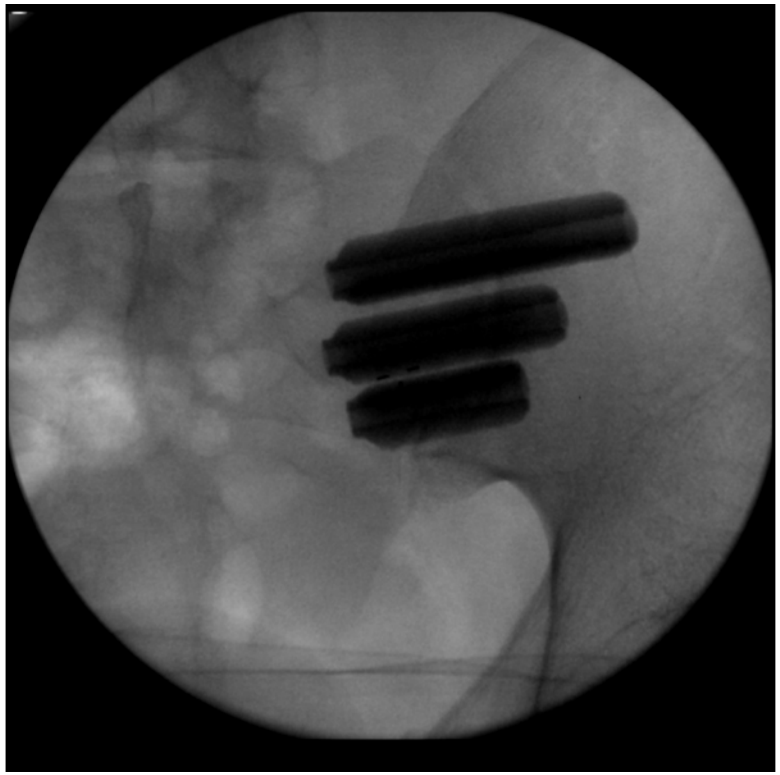
MIS SI Joint Implant:

- Intramedullary titanium implant coated w/ porous plasma spray
  - -Interference fit minimizing implant motion
  - -Immediate stabilization
- 7mm Implant strength vs. 8mm screw
  - -3X stronger in bending
  - -3 X stronger in shear



MIS SI Joint Procedure:

- Posterior-lateral approach
- Prone
- One hour procedure
- Instrumentation:
  - -Guide pin
  - -Soft tissue protector
  - -Drill
  - -Broach
  - -Implant



3 implants

Outpatient Spine Surgery?

Outpatient Surgery

- Pros
  - Efficiency
  - environment
  - Ancillary revenue
  - Lower overall cost
- Cons
  - Payor coverage of services
  - Availability of various services
  - Unfamiliar for spine surgeons

Efficiency in ASC

- Not a new phenomenon
- Not driven purely by $

Market Pressures

- Ancillary Revenue
  -  Hospital reimbursement
  -  Surgeon reimbursement
  - Surgeons buying shares

History of ASC

- Health care professionals and government officials begin calling for affordable, accessible outpatient surgery alternatives that can continue to deliver top-quality patient care.
- 1966-67 –Facilities dedicated to providing ambulatory surgical care open in conjunction with hospitals in California and Washington, D.C.
- 1968– Wallace Reed, MD, and John Ford, MD, commit their idea for a freestanding ambulatory surgery facility to paper for the first time and develop objectives for the facility. They begin collecting endorsements from the governmental bodies and members of the health care community they need to obtain financing for the project.

Hospital involvement

- 90% of ASCs partially owned by surgeons
- Hospital with ownership interests in 21% of ASCs
- 3% of ASCs are fully owned by hospitals

Economic Impact

- $90B in 2009
- $5.8 Billion tax payments
- 111,700 full-time employees

Oxford Outcomes ASC Impact Analysis, 2010.

Safety

- The ASC Quality Collaboration collected data from more than 1,000 ASCs, representing every state except Vermont and West Virginia, regarding patient admissions for the third quarter of 2010. The data showed, per 1,000 patient admissions, that:
- the patient fall rate in participating ASCs is 0.167
- the rate of patient burns is 0.033
- the rate of hospital transfers/admissions is 1.183
- the rate of wrong site, side, patient, procedure, implant events is 0.0247

Appropriate cases for ASC

- Non-instrumented spine surgery, microdiscetomies and/or nerve decompressions;
- Anterior cervical decompression;
- Anterior cervical fusion — 1 & 2 Levels;
- Cervical artificial disc replacements — 1 & 2 Levels;
- Anterior lumbar fusion — 1 Level
- Lumbar artificial disc replacement — 1 Level
- Posterior lumbar fusion -if >24 stay possible (esp. w/convalescent license)
- Minimally invasive spine surgeries ie. X Stop, Coflex, SI Fusion etc.

Figure ES1. ASC Share of Medicare Allowed Charges by Service Category, 2007

Source: KNG Health analysis of PSPS files. Includes FFS Medicare claims only.

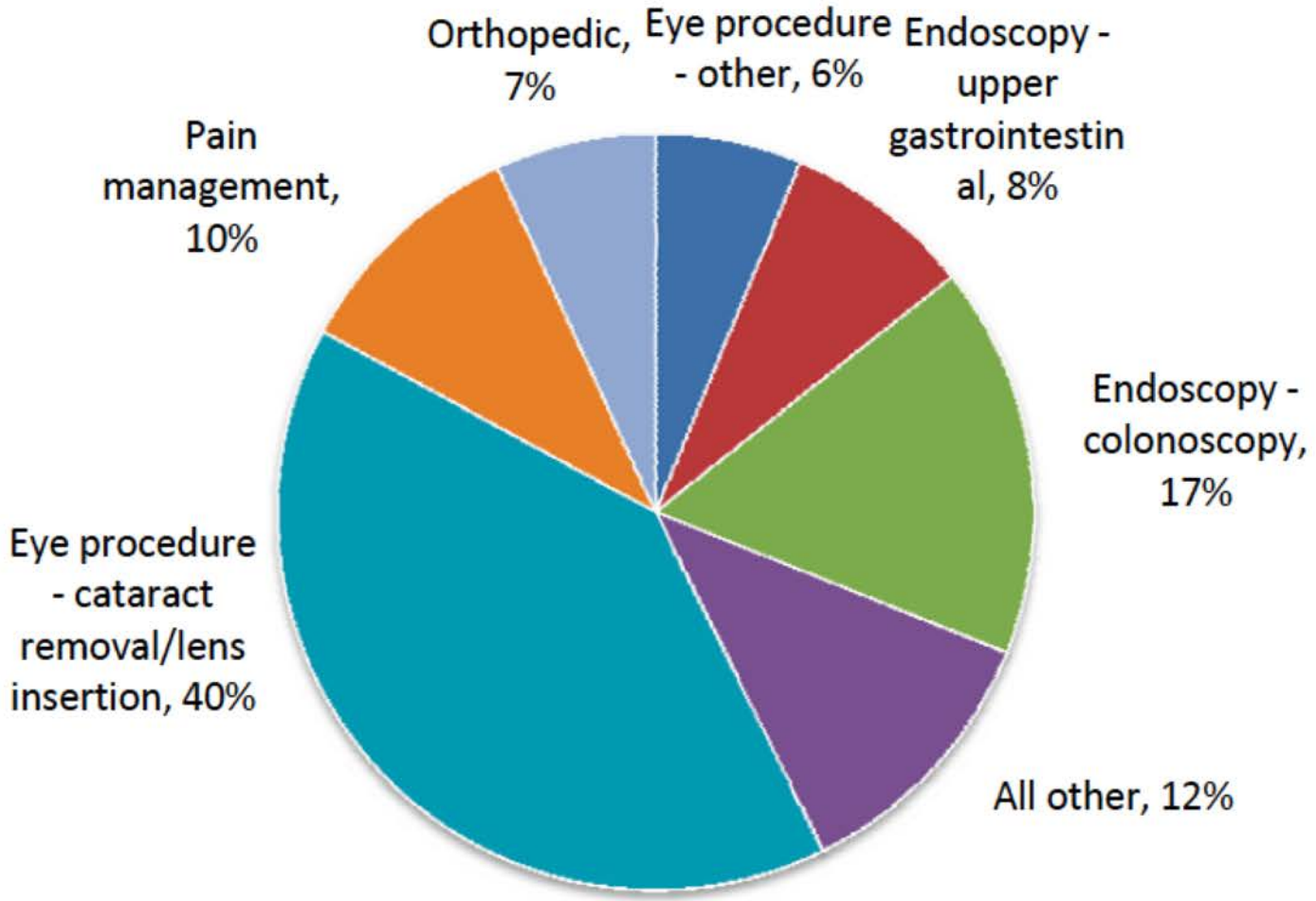


Figure ES2. Average Annual Growth in Medicare Allowed Service per Beneficiary by Place of Service, 2000 to 2007

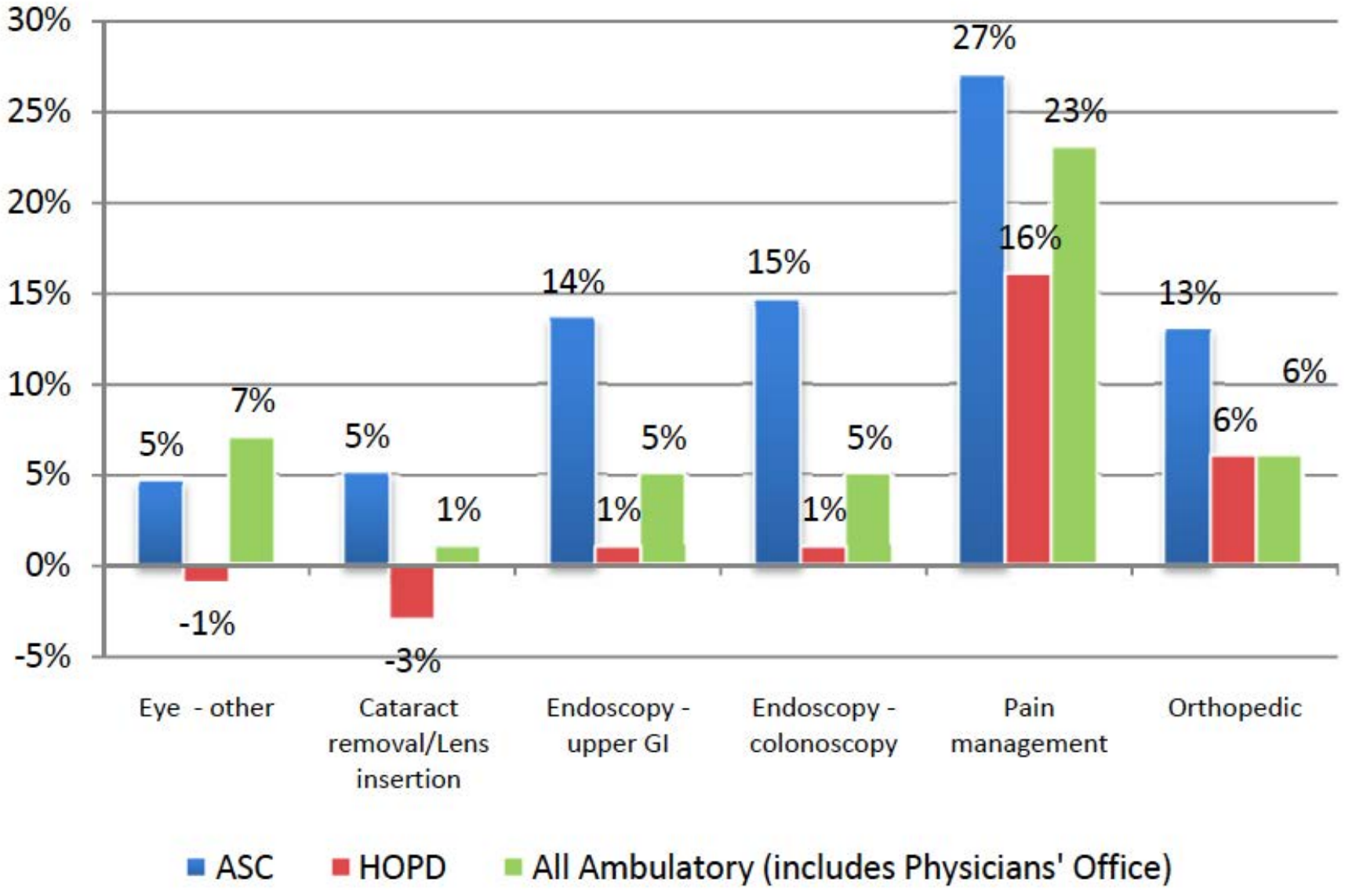
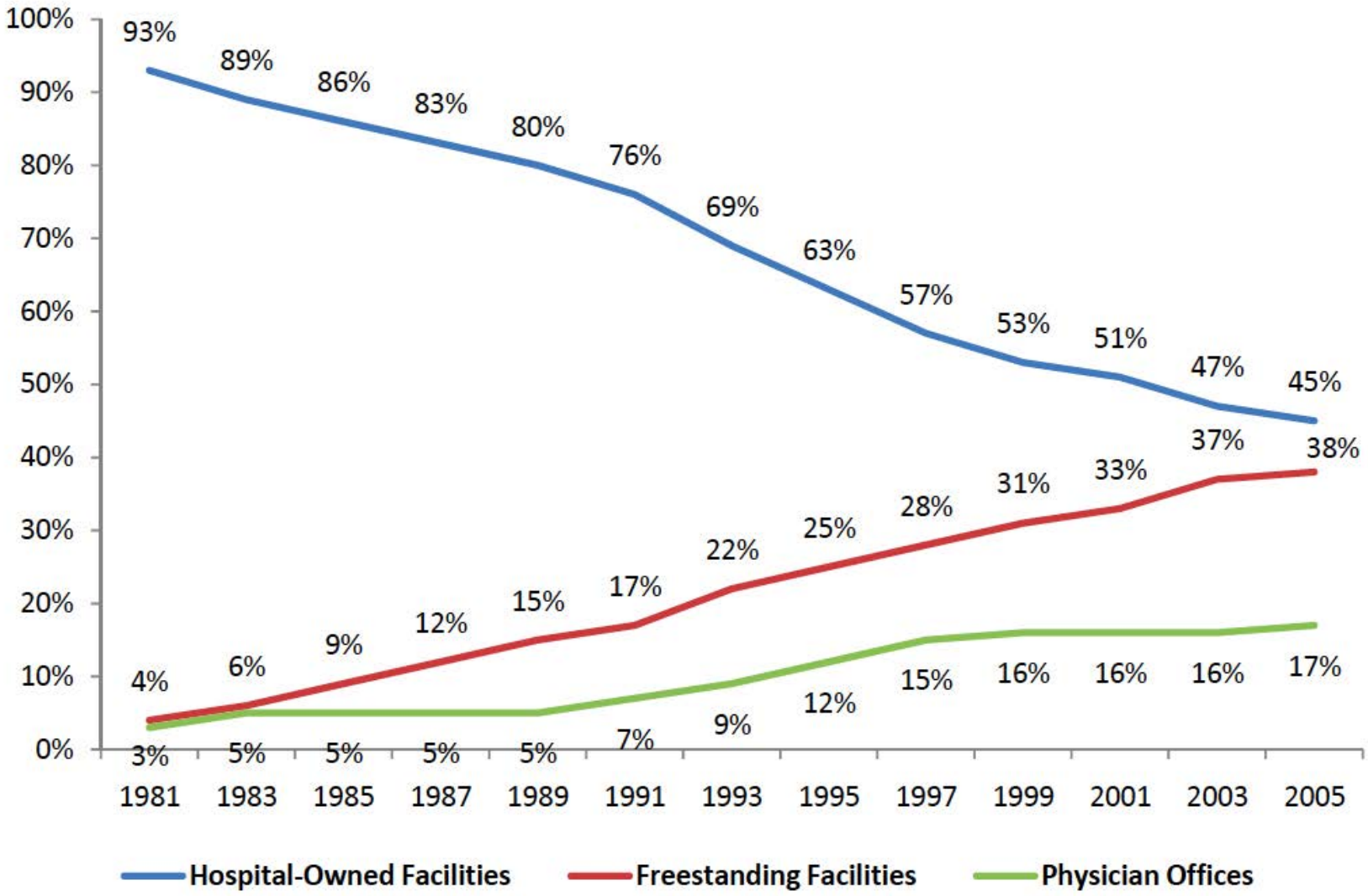


Figure 1. Percent of Outpatient Surgeries by Facility Type

Source: AHA, Trendwatch Chartbook, 2008, Supplementary Data Tables, Organizational Trends



Dr. A. Nick Shamie
Professor & Chief, Orthopaedic Spine Surgery

THANK YOU!!!

UCLA Health