Outpatient Instrumented Minimally Invasive Lumbar Fusion

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Lumbar Fusion – Traditionally Inpatient Surgery

- Trends in outpatient lumbar surgery
  - 4 to 13 % of all lumbar surgery cases performed on an outpatient basis from 1994 to 1996
  - Outpatient procedures accounted for an increased 9% - 17% in 1997 – 2000
  - 90% of cases were discectomies and just below 1% - fusions

Gray et al, Spine 2006

Trends Are Changing

- Contributing Factors
  - Increasing health care cost
  - Development of less invasive surgical techniques
  - Advancements in anesthesia
  - Growing medical staff and surgeons' confidence
  - Realization that hospitalizations increase the rate of complications

Minimally Invasive Surgery

- The size of incision is ONLY cosmetic
- What makes a clinically significant difference?
  - Tissue trauma and blood loss is minimized
  - Less epidural scarring
  - Postoperative pain is minimized
  - Hospital stay is minimized = outpatient surgeries
  - Decreased recovery time, but not at the expense of clinical outcomes

Changing Clinical Environment

- Hospital-acquired infections
  - Almost 100,000 deaths/year are caused by hospital acquired infections in the United States (The Association for Professionals in Infection Control and Epidemiology Economic Survey, 2009)
  - Antimicrobial resistance was found to be significantly higher for inpatients (Archibald et al, Clin Infect Dis, 1997)
  - A single non-compliant health care worker could cause a 73% – 238% increase in infections/month (Temime et al, Proc Natl Acad Sci USA, 2009)

Venous Thromboembolism

- A prospective cohort of almost 1 million middle-aged women was studied (Sweetland et al, BMJ, 2009)
- A 7-fold increased risk after inpatient compared to outpatient surgeries in the first 6 weeks was found
- Higher risk was associated with joint replacement or cancer surgeries, but hospital admission remained an important factor

Systematic Review

- A diverse group of outpatient surgeries was analyzed (Wu et al, Anesthesiology, 2002)
- Studies published from 1966 – 2000
- Patients complained:
  - Pain - 45%
  - Drowsiness - 42%
  - Fatigue - 21%
  - Dizziness - 18%
  - Nausea - 17%
  - Nonspecific headaches - 17%
  - Vomiting - 8%
- No critical or life-threatening problems were reported
- No infections, acute respiratory distress syndrome or thromboembolic complications were reported

Advantages vs. Disadvantages

- Prolonged hospital stays may better address such problems as:
  - Inadequate pain control
  - Urinary retention, constipation
  - Nausea, vomiting
- Disadvantages
  - Rising health care cost
  - Increased risk of infections
  - Pneumonia
  - Thromboembolic complications
  - UTIs

Patient "Home-Readiness"

- A total 500 patients were randomly selected that underwent various ambulatory surgeries (Chung, Anest Analg, 1995)
- The majority of patients were ready to be discharged
  - 82% after 2 hours
  - 96% after 3 hours
- The discharge delays were due to personal, non-medical reasons in 50% of the patients

Clinical Study

- Objectives
  - Analyze our results to determine if it is safe and effective to perform instrumented lumbar interbody fusion on an outpatient basis
  - Identify the need for prolonged observation for complications in the immediate postoperative period

Patients

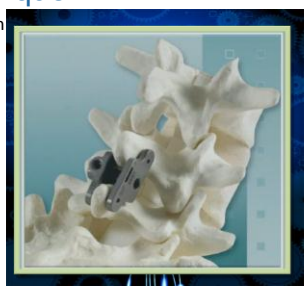
- A total of 52 one-level TLIF surgeries with instrumentation were performed on an outpatient basis from 2003 – 2009
- Ambulatory Surgery Center (ASC) = 27 patients
- Hospital Outpatient Department (HOD) = 25 patients
- The mean age was 49.8 years (range, 19 – 72)
- M/F ratio 28:24

Methods

- Safety - complications
  - Discharge – 7 POD (0 - 7POD)
  - 7 days – 6 months (>7POD)
  - Hospital readmissions, visits to ED
  - UTI, pneumonia, thromboembolic complications
- Efficacy – pain relief
  - Pre- and postoperative VAS (0 – 100) scores were compared for lower back and extremity pain
- Follow-up – at least 6 months
- Surgeries
  - MI Tubular-Assisted Surgeries (MITS; n = 9)
  - Mini-open (n = 23)
  - Open (n = 20)

Surgical Technique

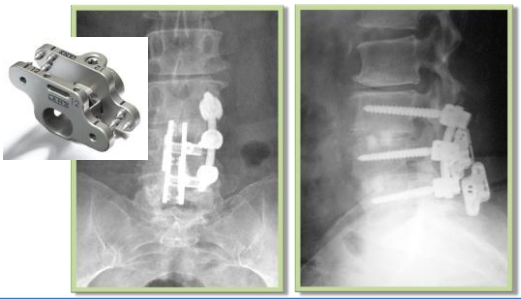
- Interspinous Process Fixation Systems
  - Less invasive than pedicle screw fixation
    - Smaller incision
    - No additional lateral exposure
  - Easy to implant
    - No fluoroscopic guidance required
    - No risk of neural injury
    - Feasible alternative to pedicle screw fixation



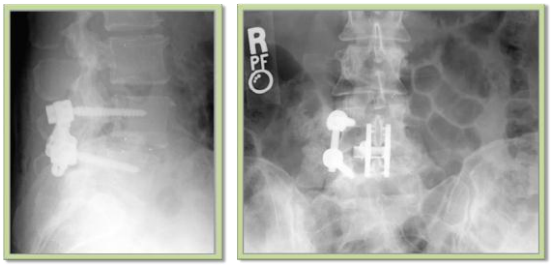
Rationale

- Pros
  - Pedicle screw fixation increases fusion rates
  - Stabilizes spine
- Cons
  - Increases complication rates (e.g. neural injury, need for re-operation)
  - Radiation exposure
  - Increased OR time

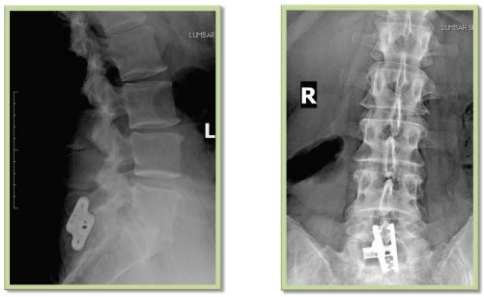
Interspinous Process System



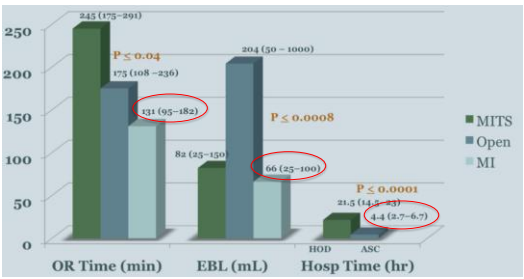
Interspinous Process System



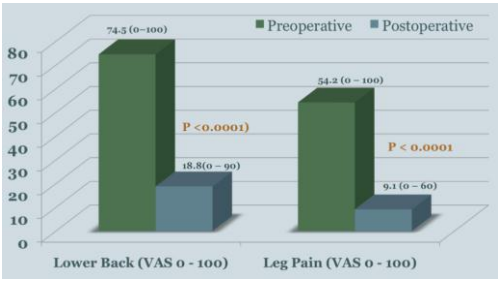
Interspinous Process System



Surgical and Hospitalization Data



Effectiveness



Complications

	ASC (n = 27)	HOD (n = 25)	Total
Hospital readmissions (0-7POD)	1 pain control #1 1 wound infection #3	1 delirium tremens #3	3
Visits to ED (0 -7 POD)	1 constipation #2 1 CSF leak #3	-	2
Other Complications (> 7POD)			
CSF leak	2 (#35/H and #8)	1 (#10)	3
Allograft malposition	1 (#45/H)	1 (#90/H)	2
Pedicle screw malposition	1 (#8/H)	-	1
Pericarditis	1 (#14/H)	-	1
Total:	9 (33%)	3 (12%)	12 (23%)

Postoperative Complications According to Surgery Location (# - number of days after discharge; H – hospitalization was required)

Complications

	Open (n=20)	MITS (n=9)	Mini-Open (n=23)	Total
Hospital readmissions (0-7POD)	1 delirium tremens #3/H	-	1 pain control #1/H 1 wound infection #3/H	3
Visits to ED (0 -7 POD)	1 constipation #2	-	1 CSF leak #3	2
Other Complications (> 7POD)				
CSF leak	-	1 (#10)	2 (#35/H and #8)	3
Allograft malposition	1 (#90/H)	-	1 (#45/H)	2
Pedicle screw malposition	-	1 (#8/H)	-	1
Pericarditis	-	-	1 (#14/H)	1
Total:	3 (15%)	2 (22%)	7 (30%)	12 (23%)

Postoperative Complications According to Surgery Location (# - number of days after discharge; H – hospitalization was required)

Cost Analysis

- Inpatient (Patel et al, J Spinal Disord Tech, 2008)
  - $45,184 incl. rhBMP-2
  - One-level TLIF surgeries
  - Average hospital stay – 3 days
  - Direct costs - OR time, inpatient room costs, nursing staff wages ($17,898)
  - Indirect costs – hospital overhead, maintenance, administration ($11,362)
- This study (ASC)
  - $18,420
  - $29,983 incl. the cost of implants and rhBMP-2

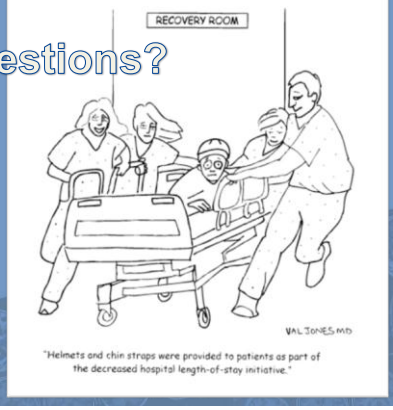
Conclusions

- Appropriate patient selection
  - Absence of significant commorbidities
  - Age
  - Adequate postoperative home care
- Time under anesthesia
- Blood loss
- Postoperative pain control

Conclusions

- This is the first study of it's kind to evaluate outpatient instrumented lumbar fusion surgery
- Additional confirmation is needed, but these results strongly suggest 2 things:
  - That it is safe and efficacious to perform instrumented lumbar interbody fusions as outpatient procedures
  - There is significant cost savings associated with outpatient procedures as compared to inpatient

Questions?


RECOVERY ROOM
VAL JONES MD
"Helmets and chin straps were provided to patients as part of the decreased hospital length-of-stay initiative."