The Efficacy of Lumbar Surgery

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Spinal Surgery in the US

- The likelihood of having spinal surgery in the US is 5 times higher than that of the United Kingdom, and at least twice than the surgery rates of Australia, Canada and Scandinavian countries.

Increased Lumbar Fusions

- Between 1996 – 2001
  - Spinal fusions rose by 77%
  - Total hip arthroplasty (THA) and total knee arthroplasty (TKA) rose by 13%

Increase in Spinal Surgery

- **Patients with DDD:**
  - Between 1990 – 1993: 9.4% underwent spinal fusion
  - Between 1997 – 2000: 19.1% underwent spinal fusion
    (> 200% increase)

- In addition to a rising rate of lumbar fusion surgery, it seems an increasing proportion of all spine operations include a fusion procedure:
  - For spinal stenosis, spine fusions quadrupled.


Cage Updates:

- Fusions with cages increased from 3.6% in 1996 to 58.1% in 2001.
  (1500% increase)

Outpatient Ambulatory Surgery

- Discectomies performed on outpatients rose from 4% in 1994 to 26% in 2000
- 650% increase


Before we examine outcomes of surgery...

- Spine surgery patients only care about:
  - Loss of Pain
  - Improved Function
  - No complications

Patient’s don’t give a $%^ about fusion rates

- To compare the outcomes of the 3 fusion methods and find a useful fusion method.
- Complications included deep infection in 3 cases, transient nerve palsy in 4, permanent nerve palsy in 1, and donor site pain in 6.
- No significant differences in clinical results and union rates were found among the 3 fusion methods.


Patient’s don’t give a $%^ about migration (unless it’s birds)

Long-term outcome of surgical and non-surgical treatment of LSS: 8-10 year outcomes:

• After 8 to 10 years:
  – LBP improved: 53% surgery vs. 50% nonsurgical
  – Predominant symptom (either back or leg pain) improved: 54% surgery vs. 42% nonsurgical
  – Satisfied with their current status: 55% surgical vs. 49% nonsurgical

• By 10 years:
  – 23% of surgical patients: Undergone another surgery
  – 39% of nonsurgical patients: Undergone surgery


Laminectomy/Laminotomy

• Forty-five patients (84.9%) were satisfied with the treatment result after a follow-up period of 15.7 months (12-24).
• ODI improved from 64.3 to 16.7.
• There were 11 surgical complications: dural tear in 5, wrong level operation in 2, and transient neuralgia in 4 patients.

Laminectomy/Laminotomy

• Treatment effects (defined as mean change in surgery group minus mean change in non-operative group) for:
  – Bodily pain 12.6
  – Physical function 8.6
  – Oswestry Disability index -9.4

• Early advantages for surgical treatment for secondary measures such as bothersomeness, satisfaction with symptoms, and self-rated progress were also maintained.

In group A, at the final evaluation, the overall results were good to excellent in 89% of the patients, fair 11%, and poor 0%.

In group B, at the final evaluation, the overall results were good to excellent in 63% of the patients, fair 30%, and poor 7%.


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**Table 3. Outcomes Comparison Between Group A and Group B**

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
<th>P</th>
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</thead>
<tbody>
<tr>
<td>Ages</td>
<td>57.78 ± 4.91</td>
<td>57.47 ± 5.07</td>
<td>0.709*</td>
</tr>
<tr>
<td>Decompression levels</td>
<td>2.07 ± 0.97</td>
<td>1.98 ± 0.88</td>
<td>0.384*</td>
</tr>
<tr>
<td>Follow-up duration</td>
<td>40.64 ± 8.15</td>
<td>40.55 ± 8.14</td>
<td>0.945*</td>
</tr>
<tr>
<td>VAS of back pain</td>
<td>Before surgery</td>
<td>1.14 ± 0.96</td>
<td>0.91 ± 0.91</td>
</tr>
<tr>
<td>VAS of leg pain</td>
<td>Before surgery</td>
<td>4.41 ± 1.12</td>
<td>4.53 ± 1.32</td>
</tr>
<tr>
<td>ODI</td>
<td>Before surgery</td>
<td>39.26 ± 6.54</td>
<td>38.76 ± 6.94</td>
</tr>
<tr>
<td>Leg numbness eliminated and improved</td>
<td>100% (64/64)</td>
<td>97% (62/64)</td>
<td>0.491T</td>
</tr>
<tr>
<td>Leg weakness resolved and improved</td>
<td>100% (11/11)</td>
<td>94% (15/16)</td>
<td>1.0001</td>
</tr>
<tr>
<td>Good to excellent (at the final interview)</td>
<td>89%</td>
<td>63%</td>
<td>0.0001T</td>
</tr>
<tr>
<td>Good to excellent and fair (at the final interview)</td>
<td>100%</td>
<td>93%</td>
<td>0.058T</td>
</tr>
<tr>
<td>Poor (at the final interview)</td>
<td>0%</td>
<td>7%</td>
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Laminotomy

- 5.6 years post-op follow-up
  - 85.3% had an excellent-to-fair operative result.
  - Reoperation rate of 11.8%.

**Summary: Laminectomy/Laminotomy**

- Success rate ~ 80%
- Effective for leg symptoms – pain, neurological, etc.
- Most research – spinal stenosis
- Long-term slightly better than conservative care
- Indicated in neurological deficit

**Discectomy – very well studied**

- The reported success rate of lumbar disc surgery varies from 60% to 90% (Ave 80%)

Discectomy in Athletes

- **NBA**
  - Discectomy: 75% returned to play again in the NBA
  - Non-surgical: 88% returned to the NBA

- **NFL**
  - Discectomy: 78% returned to NFL

Microdiscectomy

- Have not yet shown any advantage over traditional discectomy

- Microdiscectomy gives broadly comparable results to open discectomy.
Discectomy – Summary

- 80% success rate
- Predominantly for leg pain due to HNP
- No difference between open vs. microdiscectomy

Fusions

- No conclusions are possible about the relative effectiveness of anterior, posterior, or circumferential fusion.

Spinal Fusion

– At least 10 patients (22%) required revision surgery.
– Ten patients (22%) had 14 total complications not requiring revision surgery.
– Seventy percent of patients had a fair or poor outcome
– 58% of patients had at least "severe disability" according to the Oswestry outcome scale.
– Fifty percent of patients were satisfied with their surgery


Spinal Fusion

• Only 46% of those with interbody fusion met all 4 criteria for success (54% of fusion patients did not meet success criteria)
• Even among the patients classified as having a successful result, most were still using narcotic medications at the 2-year follow-up, including 84% in the fusion group
• Complications were reported in 77.8% of the BAK fusion group (77 events in 99 patients)

**Reoperation rates significant following L-fusion**

- Patients who had surgery in 1990-93 had a 19% cumulative incidence of reoperation during the subsequent 11 years.
- After fusion surgery, 62.5% of reoperations were associated with a diagnosis suggesting device complication or pseudarthrosis.


**Cage Fusions**

- 63.9% overall disability rate at 2 years after fusion
- 22.1% reoperation rate
- Other complications 11.8%

Fusing previous back surgery patients

- ODI was significantly improved from 47 to 38 after fusion (REALLY?).
- The success rate was 50% in the fusion group (CAN WE CALL IT A SUCCESS RATE?)
- For patients with chronic low back pain after previous surgery for disc herniation, lumbar fusion failed to show any benefit over cognitive intervention and exercises.


Fusion – Summary

- At best – coin toss: 50% success rate
- Significant complications
  - Double risks compare to decompression surgery
  - Blood transfusion x 6
  - Double postoperative mortality

They may be getting the message

Spinal-Fusion Surgery — The Case for Restraint
Richard A. Deyo, M.D., M.P.H., Alf Nachemson, M.D., Ph.D., and Sohail K. Mirza, M.D.

N ENGL J MED 350:7 WWW NEJM.ORG FEBRUARY 12, 2004

Spinal-Fusion Surgery

Perspective

Spinal-Fusion Surgery — Advances and Concerns
Stephen J. Lipson, M.D.

N ENGL J MED 350:7 WWW NEJM.ORG FEBRUARY 12, 2004

Total Disc Arthroplasty

• 57% of the patients with disc replacement met all 4 criteria for success

• 64% still using narcotic medications at the 2-year follow-up, including 64%

Hold On…

• What were the criteria for success?
  – > 25% ODI improvement 24 months postop
  – No device failure
  – No major medical complications
  – No neurological deterioration


Lumbar Disc Replacement

• TDR with the CHARITE Artificial Disc – 106 follow-up
• Mean follow-up time 13.2 years
• 82.1% – “excellent or good clinical outcome”
• 89.6 % returned to work
• 7.5 % required posterior instrumented fusion
• 4.6% of postoperative facet arthrosis

Lumbar Disc Replacement

- 2 RCTs, 2 previous systematic reviews, 7 prospective cohort studies, 11 retrospective cohort studies and 8 case series

- **To date, no study has shown total disc replacement to be superior to spinal fusion in terms of clinical outcome**

- Long-term benefits of total disc replacement in preventing adjacent level disc degeneration have yet to be realized


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Lumbar Disc Replacement

- **Negative selection study**
  - 75 patients with persistent leg and back pain after insertion of an artificial disc
  - Complications – subsidence, wear, adjacent disc degeneration, facet joint degeneration and migration
  - 15 – posterior fusion without disc removal
  - 22 – removed prostheses and performed a posterior and anterior fusion

**Lumbar Disc Replacement**

- Global Assessment: 30% in the TDR group and 15% in the fusion group were totally pain-free at 2 years
- TDR patients had reached maximum recovery in virtually all variables at 1 year, with significant differences compared to the fusion group.
- Complications and reoperations were similar in both groups
- One year after surgery, TDR was superior to spinal fusion in clinical outcome, but this difference had diminished by 2 years, apart from (VAS for back pain and) numbers of pain-free.


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**Disc Replacement**

**Summary**

- Results not as impressive as expected
- Lot’s of “hype”
- Better than fusion (coin toss at best)
- At least 30-40% of patients experience persistent pain and disability
Kypho/Vertebroplasty

- Patients of the kyphoplasty group showed an immediate beneficial and significant effect postoperatively, and better outcomes 1 and 3 months after operation compared to the conservatively treated group in pain feeling, mobility and vertebral body height.
- After 12 months the difference between both groups was not significant excepting the vertebral body height.
- There was clinically asymptomatic cement leakages in up to 45% of which we do not know the consequences in long term.


Kypho/Vertebroplasty

- There are now prospective studies of low bias, with follow-up of 12 months or more, which demonstrate balloon kyphoplasty to be more effective than medical management of osteoporotic vertebral compression fractures and as least as effective as vertebroplasty.

Kypho/Vertebroplasty

- A large proportion of subjects had some pain relief, including 87% with vertebroplasty and 92% with kyphoplasty.
- Cement leaks occurred for 41% and 9% of treated vertebrae for vertebroplasty and kyphoplasty, respectively.
- New fractures of adjacent vertebrae occurred for both procedures at rates that are higher than the general osteoporotic population but approximately equivalent to the general osteoporotic population that had a previous vertebral fracture.
- CONCLUSIONS: Lack of comparative, blinded, randomized clinical trials.


Kypho/Vertebroplasty

- Vertebroplasty did not result in a significant advantage in any measured outcome at any time point.
- There were significant reductions in overall pain in both study groups at each follow-up assessment.
- Similar improvements were seen in both groups with respect to pain at night and at rest, physical functioning, quality of life, and perceived improvement.
- CONCLUSIONS: We found no beneficial effect of vertebroplasty as compared with a sham procedure in patients with painful osteoporotic vertebral fractures, at 1 week or at 1, 3, or 6 months after treatment.

Kypho/Vertebroplasty

- At 1 month, there was no significant difference between the vertebroplasty group and the control group in either the RDQ score or the pain rating.

- Although the two groups did not differ significantly on any secondary outcome measure at 1 month, there was a trend toward a higher rate of clinically meaningful improvement in pain (a 30% decrease from baseline) in the vertebroplasty group (64% vs. 48%, P=0.06).

- CONCLUSIONS: Improvements in pain and pain-related disability associated with osteoporotic compression fractures in patients treated with vertebroplasty were similar to the improvements in a control group.


Kypho/Vertebroplasty

- 26% of patients sustained 17 subsequent fractures.

- Of the 17 subsequent fractures, there were nine at the adjacent-above levels, four at adjacent-below levels, and four at remote levels.

- CONCLUSION: This study demonstrated a higher rate of subsequent fracture after kyphoplasty compared with natural history data for untreated fractures.

Kypho/Vertebroplasty

- Refractures of cemented vertebrae after vertebroplasty occurred in 63% of osteoporotic patients.


Kypho/Vertebroplasty

- **Summary**
  - No significant evidence over conservative care or placebo
  - High incidence of fractures above/below
  - Cemented vertebrae fractures also occur
  AND – various medical concerns: unknowns of cement leakage, intravascular leakage, embolisms, bleeding, etc.

US Insurance likely won’t cover the procedure
• By 12 months, 54% of the patients reported clinically significant improvement in their symptoms.
• 33% reported clinically significant improvement in physical function.
• 71% expressed satisfaction with the procedure.
• 29% of the patients required caudal epidural after 12 months after surgery for recurrence of their symptoms of neurogenic claudication.


• The mean VAS (leg pain) score in these 175 patients was reduced from 61.2% preoperatively to 39.0% at the first clinical follow-up examination at 6 weeks postoperatively. The mean VAS score at 24 months postoperatively was 39.0%.
• Oswestry score was 32.6% preoperatively, 22.7% at 6 weeks, and 20.3% at 24 months postoperatively on average.
• In eight out of the implanted 175 patients, the X-Stop had to be removed and a microsurgical decompression had to be performed because of unsatisfactory effect of the interspinous distraction device.
• The interspinous device does not replace microsurgical decompression in patients with massive stenosis and continuous claudication, but offers a save, effective and less invasive alternative in selected patients with spinal stenosis.

X-Stop

• Summary
  – Has yet to show long-term results
  – Likely limited time-frame due to progressive nature of LSS
  – Complications: Device failure and spinous process fractures

Summary

It can easily be stated that at least 1/3 of lumbar surgery patients continue to have significant persistent pain, disability and functional loss.
So – a Second Surgery will fix it…right?


So: No-One Should Have Back Surgery?

- There are VERY DEFINITE indications:
  - Progressive neurological deficit
  - Fractures
  - Cord Compression

  - Pain?
  - Instability?
  - Arthritis?
Instability

• What is it?
• How do you diagnose it?
• What percentage of “normal” people have a spondylolisthesis? (Treat the symptoms)

Arthritis?

• The Lumbar Spine starts aging at age 22-23
• Everyone in the audience is thus a candidate for surgery – so: don’t sneeze, bend or fart!

• Doing the same thing over and over again and expecting different results