Market Research – Spine Fusion Surgery

Trends in Spinal Fusion

Back pain and spine surgery: medical indications and utility

Spinal fusion (arthrodesis) is a medical procedure for conjoining adjacent vertebrates to prevent movement of the spine (Morrison & Vieweg, 2012). Spinal fusion surgeries were invented almost a century ago, and were first indicated for severe infections of the spine, such as tuberculosis and rare deformities (Lipson, 2004). Today most spinal fusions are indicated in conditions of severe back pain, a much more common condition. Up to 80% of the population will suffer from back pain at some time in life (Andersson, 1999). The annual prevalence of back pain ranges from 15% to 45%, with peaking incidence among adults 45 to 64 years old (Andersson, 1999). Back pain is the second most common cause for visiting a doctor, fifth for hospital admissions, and third for surgery in the USA (Andersson, 1999). Most back pain resolves in about three months with bedrest, pain killers, and physical exercise. Persistent low back pain lasting more than three months causes disability, unemployment and loss of income (Andersson, 1999). Despite ongoing research efforts, the exact causes of back pain, the best tools for diagnosis, and optimal treatment are not entirely clear. Most back pain cannot be attributed to a specific medical cause, while about a third is attributed to specific conditions such as spondylolisthesis, stenosis or disk degeneration. These conditions are the most common medical indications for the increasingly common spinal fusion surgery (**Table 1**).

- Spondylolisthesis, is a displacement of one or more vertebrates, often associated with a fracture of the vertebrate. Can be diagnosed by X-ray. Indicated in 27% of spinal fusions.
- In stenosis, narrowing of the nerve canal, within a vertebrate, creates pressure on the nerve roots leading to severe back and leg pains. Diagnosed by CT or MRI, indicated in 13% of spinal fusions.
- In disk degeneration, the cartilage disc that separates bony vertebrae is eroded, creating painful friction points between vertebrates. Diagnosed by diskography, and indicated in 39% of spinal fusions.

What is the utility of spinal fusions in these indications? In modern, evidence-based medicine assessment of utility relies on effective randomized double blind trials comparing outcomes in at least two experimental groups. Patients are assigned randomly to each group to avoid bias by sending sicker patients to one of the groups. Ideally, both patients and physicians are 'blinded' regarding the 'label' of the treatment, and only at the end of the experiment the labels are removes and the data is analysed to study the impact of the proposed new treatment. However, when it comes to back surgeries, several important issues hinder the conductance and comparative assessment of effectiveness by double blind clinical trials. The first issue is the lack of consensus in the literature regarding the proper outcomes to be measured in spinal surgeries, and the required durations of monitoring period. Each of the potential outcome measurements in

back surgeries are deficient, including pain relief (a subjective measure), walking ability (the distance, duration and posture are not well defined), return to work (not every patient is employed), while length of stay in the hospital, and readmission rate are defined but too general. The duration of the monitoring period in clinical trial could stretch from a month to five years. In general, with shorter observation periods there is larger advantage for spinal surgeries, but longer observation periods demonstrate less favourable for surgical outcome in back surgeries.

A second issue in the back surgery literature is the lack of agreement on the proper 'control group' for back pain patients. A control group of completely untreated patients is not ethical. Non-surgical treatments could be compared with surgical treatments, but there is a broad range of non-surgical options, including several types of physiotherapy, pharmaceutical injections, electrical stimulation, acupuncture, and cognitive training that can be applied. Scientifically, one treatment per experiential group is preferred, however, in practice often a plethora of non-surgical treatments are thrown together into one group. Another important consideration in the experimental design of clinical trials in spinal surgery is the potential effect of surgery itself, often called the 'placebo' effect. To control for this effect, some researcher suggested the use of a 'sham' procedure as the control group, a surgery that includes anesthesia and skin rupture, without spine manipulation. Other experts claim that exposing patients to the risks of anesthesia and infection risk in a sham procedure is not ethical (Horng & Miller, 2002). These are serious design issues that should be kept in mind when interpreting the results of clinical trials surveyed below.

The medical literature is split regarding the utility of spinal fusion in the conditions of spondylolisthesis and stenosis (Deyo, Nachemson, & Mirza, 2004). One experimental design that mitigated some of the control group challenges illustrated above is a prospective analysis of two groups of patients randomized to receive only a simple decompression surgery, or a decompression plus instrumental spine fusion. In a decompression surgery, a piece of vertebral bone that is pressuring a nerve is surgically removed in a procedure that is less complicated and less expensive (about $5,000 vs. $35,000). In 1991, a prospective study of fifty patents with spondylolisthesis and stenosis revealed a better outcome for patients receiving spinal fusion in addition to decompression (Herkowitz & Kurz, 1991). However, a follow up study of sixty seven patients followed for two years revealed an opposite trend, with better clinical outcome in the group receiving decompression only (Fischgrund et al., 1997). Another pivotal study in a large group of patients, concluded that the use of pedicle screws leads to longer operations, loss of blood and poor outcomes that do not justify the use of screws (Thomsen et al., 1997). In contrast, pedicle screws had significant advantage when compared with bone-grafts. A rare advantage of this study is that all patients were operated on by the same surgeon to eliminate technical variations among surgeons (Zdeblick, 1993).

Comparing surgical techniques (spinal fusions and decompression) with exercise in a randomized trial of 111 lumbar spondylolisthesis, revealed statistically significant better outcome for surgical patients (MÃ¶ller & Hedlund, 2000). A smaller study of forty-seven spondylolisthesis patients followed for seven years concluded that spinal fusion is clinically

beneficial (Kornblum et al., 2004). To resolve some of the controversy in the field, a large study of 600 patients operated across eleven US states was conducted in 2007 (J. N. Weinstein et al., 2007). The study compared the two surgical treatments (decompression and/or fusion) against multiple non-surgical treatments. There were several flaws in this study, including a switch from a randomized study design to observational non-random study, lack of unity in the non-surgical arm, and cross-over of patients between the experimental groups. Despite these flaws, the conclusion from this study was that patients receiving surgical treatment exhibited greater improvement in pain reduction and functional recovery (J. N. Weinstein et al., 2007). The consensus emerging from these studies is that for some patients exhibiting stenosis and/or spondylolisthesis (about 40% of fusion patients, **Table 1**) a surgical treatment that includes decompression and fusion is superior to non-surgical alternatives, at least in the short term.

In contrast to stenosis and spondylolisthesis, in disc degeneration, the source of pain is not in the boney vertebrates, but a degeneration of a gel-like disc separating one vertebrate from another. Discectomy is a surgical procedure that removes the affected disc and can reduce pain more rapidly than conservative non-surgical treatments (Peul et al., 2007). Of one hundred and twenty patients receiving anterior cervical discectomy with arthrodesis (fusion), fifty-three of the fifty-five patients who had a motor deficit had had a complete recovery, and the two remaining patients had had a partial recovery. Seventy-one of the seventy-seven patients who had had a sensory loss regained sensation (Bohlman, Emery, Goodfellow, & Jones, 1993). Note that this study did not include any control group, making interpretation challenging, since patients may recover anyhow or perhaps faster when treated by other modalities. When ninety patients undergoing cervical discectomy were randomized into groups testing spinal fusion in addition to discectomy, spinal fusion had no additional benefit (Savolainen, Rinne, & Hernesniemi, 1998). A similar randomized study of eighty four cervical discectomy patients reached similar conclusions against spinal fusion (Dowd & Wirth, 1999). In contrast, in a large Swedish study of 294 lumbar back-pain patients, surgical treatment including fusion was compared with non-surgical treatments (Fritzell, Hagg, Wessberg, & Nordwall, 2001). Pain relief was better in the group receiving surgical treatment (30% vs 7%). Several flaws and weaknesses can be detected in this study, including collapsing of three surgical treatment groups into one group, having a heterogeneous non-surgical treatment group, temporary pain relief labelled as desired outcome, and a non-satisfactory pain relief of 30% in the surgical group. Lately, a new procedure of cervical arthroplasty exhibited greater benefit for cervical discectomy patients (Murrey et al., 2009). Despite the overwhelming evidence against spinal fusion in disc conditions, about forty percent of USA spinal fusions are indicated for disc degeneration (**Table 1**).

Table 1. Spinal fusion - indications (US, 2011)					
			Number	%	
Spine degeneration					27.60%
	Lumbosacral Spondylosis		24,512	5.40%	
	Cervical Spondylosis with Myelopathy		30,334	6.60%	
	Cervical Spondylosis		24,701	5.40%	
	Acquired Spondylolisthesis		34,400	7.50%	
	Spondylolisthesis		12,258	2.70%	
Stenosis					13.30%
	Lumbar Spinal Stenosis		48,565	10.60%	
	Cervical Spinal Stenosis		16,265	3.60%	
Disc degeneration					39.00%
	Lumbar Disc Degeneration		51,319	11.20%	
	Lumbar Disc Displacement		38,630	8.40%	
	Cervical Disc Displacement		51,138	11.20%	
	Cervical Disc Disorder		22,739	5.00%	
	Cervical Disc Degeneration		14,695	3.20%	
Other indications					
	Idiopathic Scoliosis		11,183	2.40%	
	Complication of Internal Orthopaedic Device		5,202	1.10%	
	All Other Diagnoses		71,433	15.60%	
	Total		457,374	100.00%	

Medical indications for spinal fusion surgeries in the US. SSM is targeting lumbar indications (blue shaded, about 45% of all spine indications). Source: Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality.

The rise in spinal fusions and projections of future trends

Back pain is notoriously common in the population, creating a strong demand for a quick-fix in the form of back surgery. The supply of spinal surgeons, medical imaging and medical instrumentations likely synergize to create a self-feeding loop, enhancing the incidence of back surgeries. The market for spine-fusion surgeries has increased dramatically over time. About 20,000 annual lumbar (low back) fusions were reported in the early 1990s (Esses & Huler, 1992). In 1998, 174,223 spinal fusions were recorded in hospital discharges in the USA (Rajaee, Bae, Kanim, & Delamarter, 2012). In 2004, 300,000 operations grossing $16 billion in hospital charges, excluding physician fees were reported (Deyo, 2007). By 2008, the annual number of spine fusions climbed to 413,171 (Rajaee et al., 2012). Most recent data from the Healthcare Cost and Utility project (HCUP) indicates 431,577 spinal fusion cases in the USA. The compounded annual growth rate in spinal fusions appears to have slowed down from nearly 10% in the 1990s and early 2000s to about 2% in recent years (**Figure 1**).

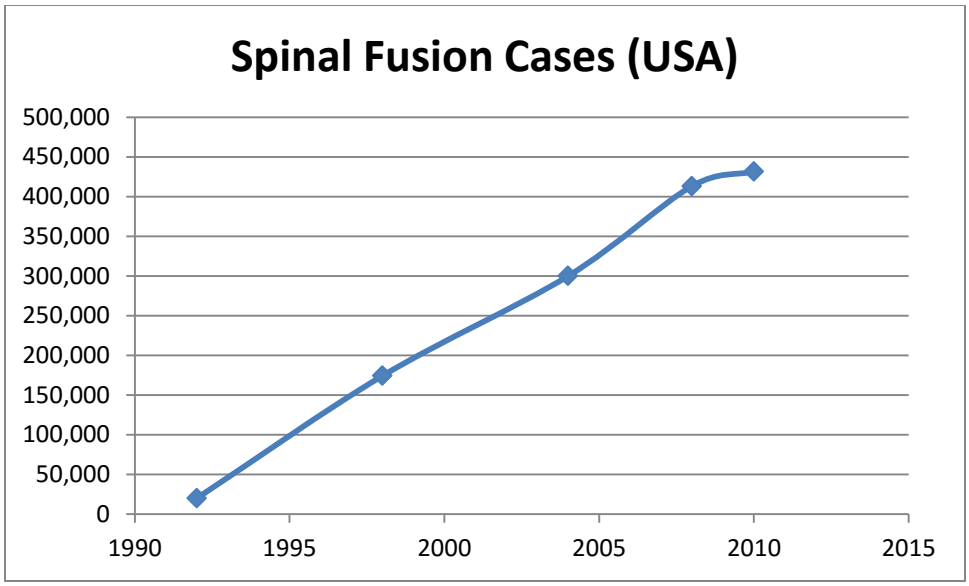

Figure 1: Spinal fusion cases in the USA. Data compiled from: (Esses & Huler, 1992), (Deyo, 2007), (Rajaee et al., 2012), and HCUP (2012).

What are the reasons for this dramatic increase in spine fusions? One important reason is increasing prescription of spinal fusions from rare infections and trauma in the 1990s to the more common conditions of stenosis, spondylolisthesis and disc hernia today. The increase in spinal fusions could be partially attributed to aging of the American population. However, the increase in spine fusions is much larger than increases in other 'elderly' orthopedics procedures of the knee or hip. For example: from 1996 to 2001, the number of lumbar fusions increased over 113%, compared with 13-15% increase for hip replacement and knee arthroplasty (Deyo & Mirza, 2006). Another reason for the increase in spinal fusion could be the increases in prevalence of medical imaging modalities such as MRI and CT. Increasing diagnosis of spinal stenosis and disc herniation indirectly increased the rate of fusions. However, the rate of spinal fusion surgery among 65 and older stenosis patients was stable at 140 per 100,000 Medicare patients from 2002 to 2007 (Deyo et al., 2010). The number of these patients in 2007 was 37,598, grossing $1.6 billion in hospital bills (Deyo et al., 2010), about 10% of total spine fusions in the USA. The dramatic growth in spine fusion during the 2000s could have been originated from operations in younger patients or due to other indications.

The decision to operate is often delegated by the patient to the surgeon, likely as a result of the large information asymmetry that exists between the patient and the surgeon (Wennberg, 2010). Currents trends that increase the quality of imaging technology (higher resolution at lower price) and the increase in quality of surgical instruments may have enhanced surgical rates by increasing the confidence of spine surgeons, contributing to the information gap. The patient-surgeon dynamics in spine-fusion created large market for surgeons, hospitals, payers and technology providers. It is difficult to envision continued high annual growth in spinal fusions in the USA; a more moderate growth rate of 2-3% is reasonably justified.

Readmission and revision rates among spinal fusion patients

Unplanned readmissions to hospitals are common, costly and avoidable events in many healthcare systems. In Canada, the rate of 30 day readmission among surgical patients is 9.3% (CIHI, 2012). In 2010 US hospitals discharge data, spinal fusion patients were the 11th largest surgical group, with 29,326 patients, or a 6.8% thirty days readmission rate (HCUP, Brief#154, 2010). The leading causes for readmissions are labelled as 'complication', with 31% of readmitted lumbar fusion patients readmitted due to complications (**Table 2**). Half of these patients (15%) suffer from infections and the rest from surgical complications (M. C. Wang et al., 2012). Interestingly, there are regional variation in readmission rates, with a higher rate of readmission in mid-Atlantic regions (M. C. Wang et al., 2012). There are variations in the length of stay and costs of readmissions, for example, a course of antibiotics as a treatment for infection can be relatively cheap in comparison to revision surgery in severe complications. The one year readmission rate is slightly higher in patients undergoing decompression with spinal fusion (9.7%) than patients who underwent decompression alone (7.2%)(Modhia, Takemoto, Braid-Forbes, Weber, & Berven, 2013). Extended observation periods of spinal fusion patient indicate that 20% of patients undergo a revision surgery within 5 year follow up (Sato et al., 2015). In this study alternative surgical approaches were not better when revision rates were considered; and laminectomy (decompression surgery) had a higher rate of revision at 30%. In an Australian study similar rates were reported with 9.2% surgical revision and 50% return to work in a study of patients with worker compensation (Harris, Dantanarayana, & Naylor, 2012). Surgical revisions themselves are not that effective, in one study up to 50% of revision patients indicated that their state was not improved following the revision surgery (Dede et al., 2015). Reducing readmission and revision rates in spinal fusions could reduce suffering of patients and reduce costs for payers and hospitals.

Table 2. Readmissions of spinal fusion patients in the US (2010)

	Lumbar (n=20,786), n (%)	**Cervical** (n=4,595), n (%)
Complications	6,452 (31.0)	1,076 (23.4)
Postoperative infection	3,155 (15.2)	264 (5.8)
Other complications	1,293 (6.2)	207 (4.5)
Hemorrhage complications	742 (3.6)	221 (4.8)
Implant Complications	521 (2.5)	203 (4.4)
Accidental puncture	79 (0.4)	3 (0.1)

Data source: (M. C. Wang et al., 2012).

Conclusions –medical market overview for pedicle screw navigation devices

Chronic back pain causes not only discomfort but also disability for many patients in western societies, leading to a large economic burden. In many cases, the causes of back pain remains undiagnosed, and the preferred course for treatment unclear. Technical advances in imaging and surgical instruments may have contributed to higher diagnoses rates of low back-pain patients with medical indications that warrant surgical interventions, including spinal fusion, decompression and various disc manipulations. However, there is little consensus among medical practitioners regarding the best selection criteria for patients for specific treatments, and assigning a treatment to a specific patient remains more art than science. In general, non-surgical treatments can reduce pain in some patients and are recommended as a first line of treatment, due to the lower cost and lower risk of these procedures. Surgical interventions are quicker and are effective in many cases, but they are also more expensive and carry a high risk of revision surgery. For some patients lumbar spinal fusion indeed is beneficial, but its results are highly variable and hard to predict for the individual patient. The US is the leading market for spinal fusion, with a surgical rate that is twice as high as any other country. However, the growth in spinal fusion rate in the US is slowing down from double digit growth to about 2%.