Université de Montréal

# Lumbar-Sacral Pedicle Screw Insertion with Preoperative CT-based Navigation

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# Lumbo-sacral pedicle screw insertion with preoperative CT-based navigation

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# Résumé

***Objectif****:* Nous avons effectué une étude chez 135 patients ayant subis une chirurgie lombo-sacrée avec vissage pédiculaire sous navigation par tomographie axiale. Nous avons évalué la précision des vis pédiculaires et les résultats cliniques.

***Méthodes***: Cette étude comporte 44 hommes et 91 femmes (âge moyen=61, intervalle 24-90 ans). Les diamètres, longueurs et trajectoires des 836 vis ont été planifiés en préopératoire avec un système de navigation (SNN, Surgical Navigation Network, Mississauga). Les patients ont subi une fusion lombaire (55), lombo-sacrée (73) et thoraco-lombo-sacrée (7). La perforation pédiculaire, la longueur des vis et les spondylolisthesis sont évalués par tomographies axiales postopératoires. Le niveau de douleur est mesuré par autoévaluations, échelles visuelles analogues et questionnaires (Oswestry et SF-36). La fusion osseuse a été évaluée par l'examen des radiographies postopératoires.

***Résultats****:* Une perforation des pédicules est présente pour 49/836 (5.9%) des vis (2.4% latéral, 1.7% inférieur, 1.1% supérieur, 0.7% médial). Les erreurs ont été mineures (0.1-2mm, 46/49) ou intermédiaires (2.1 - 4mm, 3/49 en latéral). Il y a aucune erreur majeure (≥ 4.1mm). Certaines vis ont été jugées trop longues (66/836, 8%). Le temps moyen pour insérer une vis en navigation a été de 19.1 minutes de l´application au retrait du cadre de référence. Un an postopératoire on note une amélioration de la douleur des jambes et lombaire de 72% et 48% en moyenne respectivement. L'amélioration reste stable après 2 ans. La dégénérescence radiologique au dessus et sous la fusion a été retrouvée chez 44 patients (33%) and 3 patients respectivement (2%). Elle est survenue en moyenne 22.2 ± 2.6 mois après la chirurgie. Les fusions se terminant à L2 ont été associées à plus de dégénération (14/25, 56%).

***Conclusion**:* La navigation spinale basée sur des images tomographiques préopératoires est une technique sécuritaire et précise. Elle donne de bons résultats à court terme justifiant l’investissement de temps chirurgical. La dégénérescence segmentaire peut avoir un impact négatif sur les résultats radiologique et cliniques.

**MOTS CLÉS** • navigation par tomographie axiale • spondylolisthésis • vis transpédiculaires • fusion lombaire• dégénérescence segmentaire

# Abstract

***Objective:*** The authors studied 135 consecutive patients following a lumbo-sacral fixation using pedicle screws and CT-based navigation to evaluate pedicle screw accuracy and clinical outcomes.

***Methods***: The series included 44 men and 91 women (mean age 61 years, range 24-90 years). All 836 screws were planned with pre-operative CT-Scans in a navigation system (SNN, Surgical Navigation Network, Mississauga, Ontario, Canada) for diameter, length and direction. Fixation included the lumbar spines only (55), the lumbo-sacral spine (73) or the thoraco-lumbo-sacral spine (7). Pedicle perforation, screw length and spondylolisthesis were assessed on post-operative CT-Scan. Pain was surveyed using self-rated scales, visual analogue scales, Oswestry and SF-36 questionnaires. Bony union was assessed on post-operative follow-up radiographs.

***Results****:* Pedicle perforation was found in 49/836 (5.9%) screws (2.4% laterally, 1.7% inferiorly, 1.1% superiorly, 0.7% medially). The errors were minor (0.1-2mm, 46/49) or intermediate (2.1 – 4 mm, 3/49). All intermediate errors were lateral. There were no major errors (≥ 4.1mm). Some screws were judged too long (66/836, 8%). The average time to insert one screw with navigation was 19.1 minutes from application to removal of the reference frame. The amount of improvement at one year post-operation for self-rated leg and back pain were 72% and 48% respectively. The improvement was stable over 2 years. Above-level and below-level radiological degenerations were found in 44 patients (33%) and 3 patients respectively (2%) and occurred on average 22.2 ± 2.6 months after the surgery. Fusions ending at L2 had the most degenerations (14/25, 56%).

***Conclusion**:* CT-based preoperative navigation for lumbo-sacral pedicle screw insertion is accurate and associated with a good short term outcome, making it worth the investment of the additional time required. Segmental degeneration may have a negative effect on radiological and clinical outcomes.

**KEY WORDS** • CT-based spinal navigation • spondylolisthesis • transpedicular screws • lumbar fusion • segmental degeneration

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# Abbreviations

ASD: Adjacent segment disease
ALD: Above level degeneration

ALIF: Anterior lumbar interbody fusion

ABLD: Bellow level degeneration

DDD: Degenerative disc disease

Inf: Inferior

Lat: Lateral

Med: Medial

MRI: Magnetic resonance imaging

NSt: Not stated

NS: Not statistically significant

PLIF: Posterior lumbar interbody fusion

PSF: Pedicle screw fixation

SNN: Surgical Navigation Network

Sup: Superior

TLIF: Transverse lumbar interbody fusion

VAS: Visual analogue scale

XLIF: Extreme lateral interbody fusion

# Dedication

This thesis is dedicated to those who made it possible:

Julie, my wife; Elizabeth, Stephanie and Frederick, my children;

Jean-François, Louis, Lahbib, and Jacques.

> "Although a thorough knowledge of surgical anatomy and technique remains the most essential aspect of a spinal surgeon's navigational experience, the information acquired from image guidance can assist even the most experienced surgeon." Holly [47]

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# CHAPTER 1 - Introduction

## A) Motivation

Spine surgeons are confronted to treat many patients with instability to their spine. Causes of spine instability can be: degenerative, infectious, tumoral, traumatic and iatrogenic. These conditions are often associated with narrowing of the spinal canal and foramen causing pain and neurological deficits. The surgery for these conditions has 3 goals: decompression, stabilization and realignment of the spine [87]. Decompression is done by a laminectomy or a discectomy. Stabilization is done by fixation, which in the lumbar spine, typically consists of pedicle screws that are fixed with rods and bolts. A bone graft is inserted in addition to the screws to create a bony fusion as screws alone will become loose over time. Realignment of the spine is done with maneuvers on the rods and insertion of spacers into the disc spaces.

Pedicle screw insertion is challenging as the pedicle itself consists of only a narrow passage of bone into which the screws need to be inserted. This funnel of bone has hard cortical bone outside and softer cancellous bone inside through which the screw is passed. Beyond the pedicle, the screw anchors in the vertebral body. If a screw is misplaced, it may injure the spinal nerves around the pedicle or the vessels or soft tissues in front of the vertebral body [85].

One of the difficulties with this type surgery is that the pedicle is hidden under the lamina and the facet joints. The sides and the front of the vertebral body including the pedicle are not usually exposed in lumbar fusion surgeries. The surgeons have to rely on the anatomy of the bone exposed to evaluate the best screw path. Classic screw entry points have been described to guide the entry point of the screw.  Often, in the lumbar spine, the pedicles are bigger in size and allow many options in screw directions.

Despite this more favorable anatomy compared to the thoracic and cervical spine, many pedicle screws inserted with traditionally anatomical landmarks have failed to be properly placed.  Using such anatomical landmarks, surgeons have reported high rates of pedicle perforations.  Fortunately the problem of accuracy of pedicle screws has led to only a few neurological injuries.  For the rare patient that has pain or neurological deficit, an improperly inserted screw is an important problem.

In the search for accuracy, surgeons have used many techniques: Pedicle sounding (palpation), laminotomy, laminectomy, intraosseous endoscopy, saline challenge, pedicle impedance testing (electromyography), intra-operative fluoroscopy, 2D-fluoroscopy, preoperative CT-based navigation and intraoperative CT-Scan.  Each of these techniques has associated inaccuracies, risks, cost and limitations.  Simple techniques such as fluoroscopy and non-imaging techniques did not have high accuracy levels of screw insertion.

More advanced imaging techniques as 2D-fluoroscopy rely only on a lateral and antero-posterior radiological view taken during surgeries.  It does not allow a 3-dimension pre-operative planning and has a significant error rate reported in the literature.  Intra-operative CT-Scan has good accuracies, but until recently with the development of the O-Arm (Medtronics), this technique was not easily available in operating rooms.

The ideal system to do image-guided surgery should have many qualities.  It should image the patient with minimal or no radiation.  It should adequately image the bony structures required for screw insertion and allow visualization of any stenotic areas.  It should allow the planning of surgeries and could allow analysis of biomechanical scenarios.  It should do an automatic registration of the bone anatomy.  All instruments should be tracked and the insertion of the screw should be automated. The system should allow on site confirmatory imaging so that rare errors would be corrected during surgery. The system should be inexpensive, small and easy to use by surgeons.

When we started to look for a navigation system in our hospital in 2001, the closest solution to improve the accuracy of pedicle screw insertion was to use a pre-operative CT-Scan navigation system. It has the advantages of adequately imaging the bone, of pre-operative planning and showing 3D anatomy. It is available in most centers that perform cranial image-guided surgery. It has the disadvantage of requiring a lengthy and sometimes frustrating registration process and increases operating time. Also it does not allow reimaging of the patient during surgery and relies on navigation specialists to manage the system.

The literature has repetitively shown the superiority of CT-based navigation over anatomical landmark-based techniques, fluoroscopy or laminotomies for lumbar pedicle screw insertion. Intraoperative radiographs or fluoroscopy can help the surgeon to localize the pedicle but its usefulness has been questioned [123]. It is difficult for the reader to analyze the literature on pedicle accuracy as the authors used different methods to quantify screw errors and some failed to include small errors in their errors rates. Considering the difficulties with CT-based navigation and the low rate of complications of small and moderate pedicle errors, most surgeons use anatomical landmarks for screw insertion.

## B) Overview and organization of the thesis.

The thesis is based on a manuscript that will be submitted for publication. The other chapters of the thesis are developed to support the reader in the understanding of the article. The thesis will be organized in the following order: Chapter 1, Introduction; Chapter 2, Review of basic anatomy and ancillary surgical techniques; Chapter 3, Review of the literature on spinal image-guided surgery and on clinical measurements; Chapter 4, presentation of the manuscript; and Chapter 5, Discussions and conclusions. The primary goal of the study was to evaluate the accuracy of pedicle screw insertion. We quantified pedicle screw error in all four quadrants of the pedicle (medial, lateral, inferior and superior). We also measured the length of the screws respective to the anterior vertebral body wall. The pedicle error rate was about 6% per screw. All pedicle errors were judged inconsequential. Of all the screws, 8% were judged to be too long and screws were much too long (≥ 6mm) 3% of the time. None of the too long screws caused vascular injury. As secondary goals we evaluated clinical variables. Pain and clinical outcomes were assessed by self-reported scales, visual analogue scales, Oswestry disability index questionnaires and Short-Form 36 questionnaires. Radiological exams were reviewed to assess early and late radiological results. Lumbar fusions patients report good satisfaction rate, however, the vertebral level above the fusion has failed in the long term in some cases.

## C) Scientific contributions

- We presented the largest series on lumbar pedicle screws inserted with the pre-operative CT-based navigation.
- We confirmed the good clinical early results found in the literature for lumbar fusions.
- We confirmed that above level degeneration is a significant cause of long-term morbidity after a lumbar fusion.

# CHAPTER 2 – Spine anatomy, pathology, surgical technique and navigation techniques

Thorough knowledge of the specific anatomy of the patient to be operated is very important for the surgeon. This knowledge is acquired though reading of textbooks, practicing on spine models, through the training process, by analyzing the preoperative imaging and during surgery itself. Like an airplane pilot, the surgeon makes a plan of the procedure. The surgeon organizes the surgery into different stages. Each stage follows a routine, so the surgery can be performed safely and in an expedited way. The classic pedicle screw entry points are well mastered by experience surgeons but are sometimes difficult to see in much degenerated cases. Such specific circumstances are better to be known in advance. The navigation system allows a proper planning for the patient's specific anatomy. This section will cover A) Spine anatomy, B) Degenerative spine diseases, C) Surgical management of degenerative spine disease, D) Anatomical constraints of pedicle screw insertion, E) Description of the standard surgical technique, F) Navigation concepts and surgical techniques, G) Validation and verification of the errors and H) Assessment of bony union.

## A) Spine anatomy

The spine has 7 cervical vertebrae, 12 thoracic vertebrae, 5 lumbar vertebrae, a sacrum composed of 5 fused segments and the coccyx composed of 4 fused segments (Figure 2.1). The spinal curves (cervical lordosis, thoracic kyphosis and lumbar lordosis) distribute the axial load and allows the spine to be 30 times more elastic than if was straight [29]. Each vertebra has a specific shape with variations between levels and between different patients. The typical lumbar vertebra has an anterior vertebral body that connects through two pedicles and a posterior arch (figure 2.2). Inside there is a spinal canal and a foramen on each side through which pass the spinal cord and spinal nerves roots respectively (figures 3 and 4).

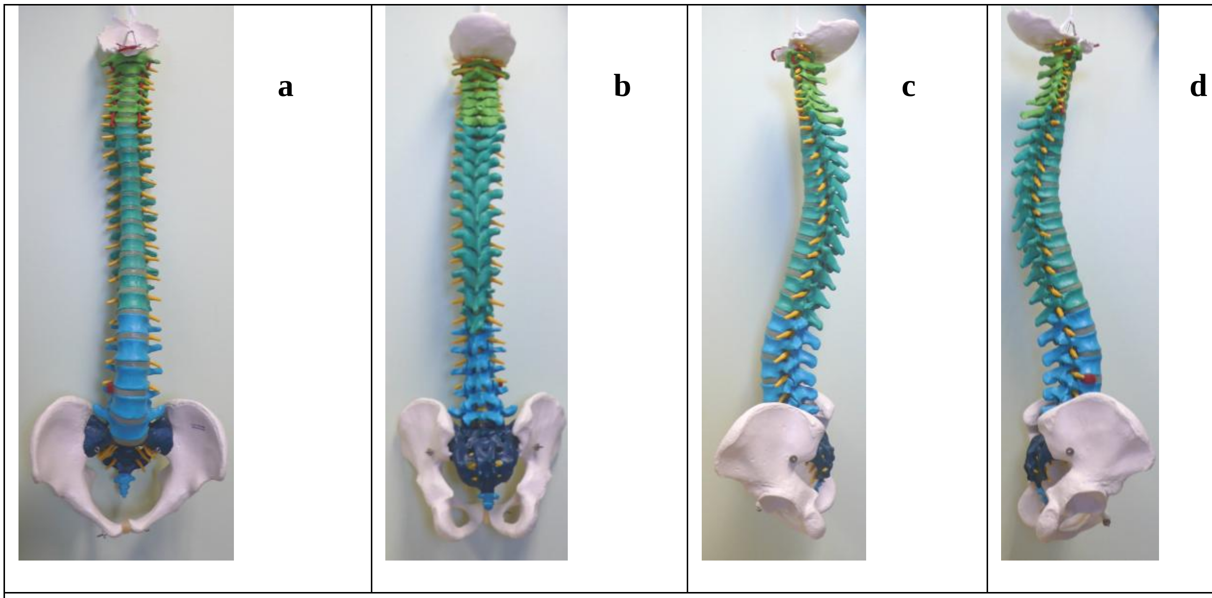

**Figure 2. 1 Spine curvatures**

**a.** Anterior view of a plastic spine model **b.** Posterior view c**.** Left lateral view **d.** Right lateral view

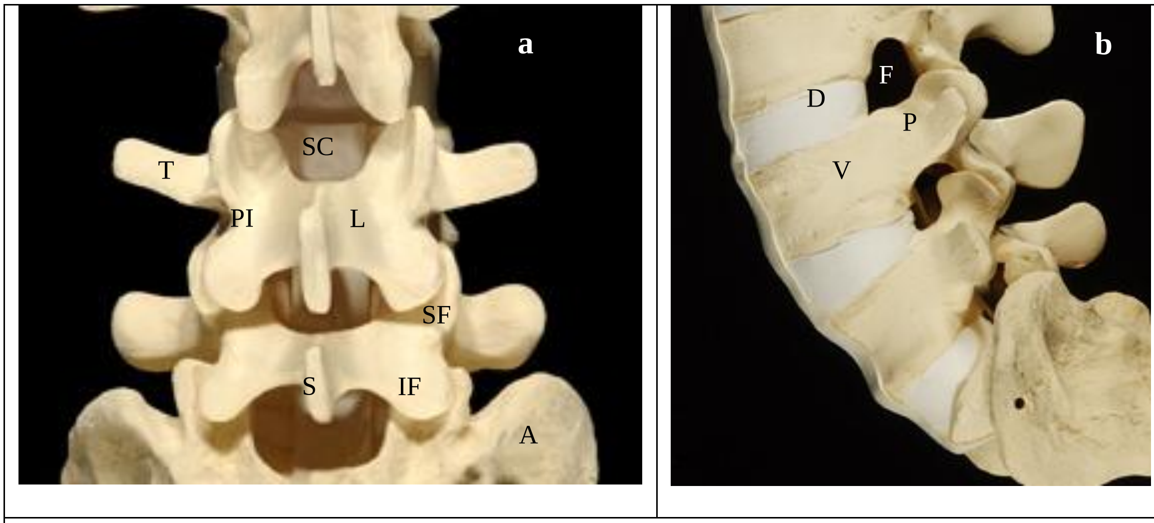

**Figure 2. 2 Lumbar vertebral anatomy**

**a,b.** Close up of a sawbone spine model. Posterior view of L3, L4, L5 vertebrae and upper sacrum with transverse process (T), spinous process (S), lamina (L), superior facet (SF), inferior facet (IF), pars interarticularis (PI), spinal canal (SC), pedicle (P), foramen (F), vertebral body (V), disc (D) and ala of sacrum (A). The pedicle is in the superior 1/2 of the vertebra. A pedicle screw is usually closer to the facet above than below.

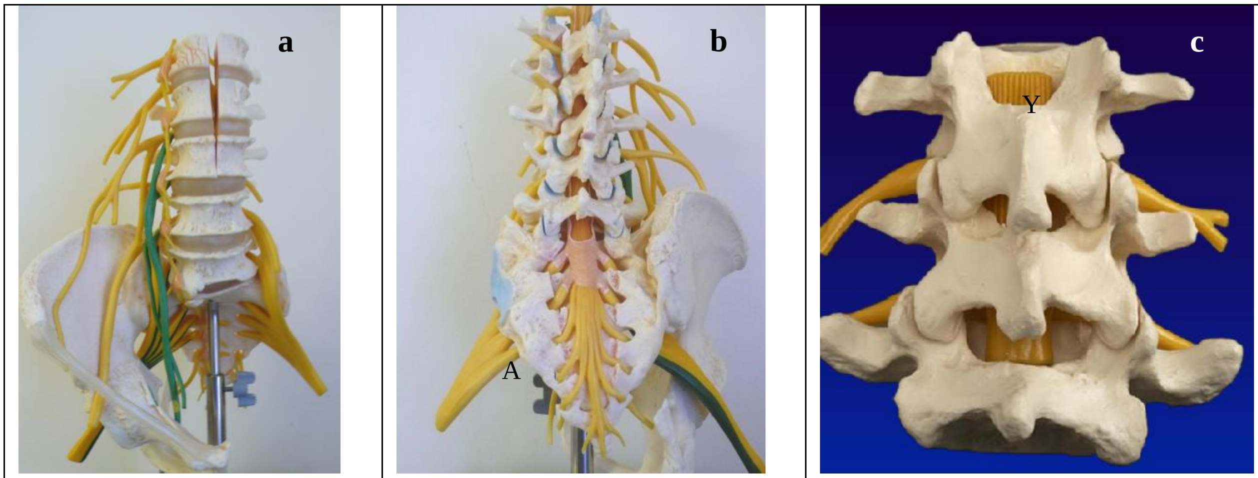

**Figure 2. 3 Anterior and posterior nerve anatomy**

**a.** Anterior view of the lumbar spine showing the nerves grouping to create the lumbar-sacral plexus. **b.** Posterior view of the lumbar spine with the posterior part of the sacrum removed to show the dural sac and sacral nerves. **c.** Posterior view of the spine showing on top the yellow ligament (Y) and at the bottom the dural sac between the laminae. On the side the nerves come out the foramen in front and above the transverse processes.

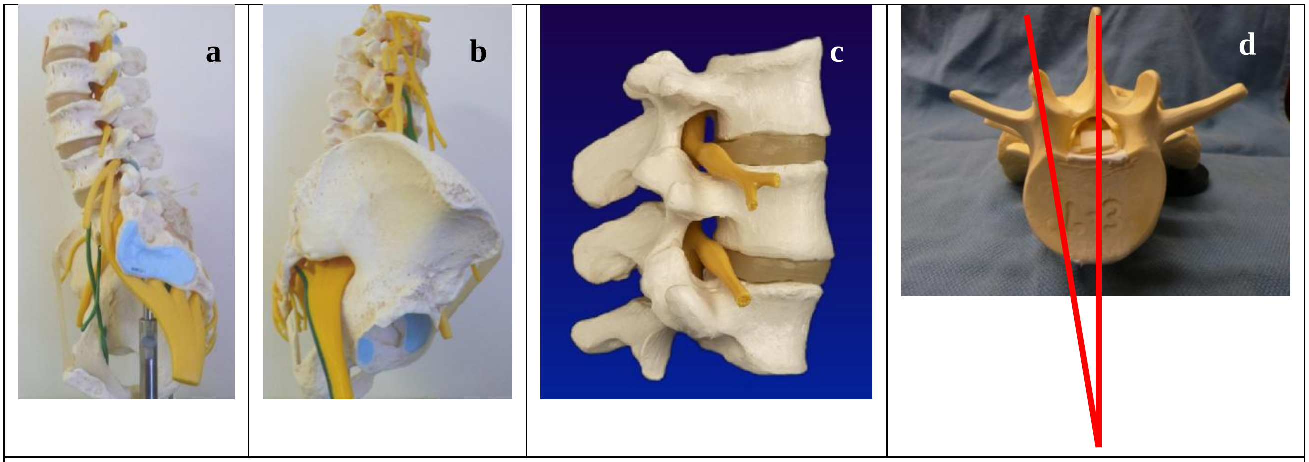

**Figure 2. 4 Lateral spine nerve anatomy**

**a.** The spine is showed without the iliac bone. The sciatic nerve comes out the sciatic notch. **b.** The pelvic bone hides the side of the spine. **c.** In the foramen the nerves enlarge at the location of the dorsal root ganglion. **d.** Axial view of L3 vertebral body. Approximate angle of pedicle respective to the sagittal axis (red lines).

The anatomy of the pedicle and it's variations were well described by Saillant in 1976 [108] and Zindrick in 1987 [134]. In the lumbar spine, the transverse (horizontal) diameter of the pedicle increases from L1 (approximately 8mm [108,134]) to L5 (16 -18 mm [108,134]). The pedicle vertical diameter (height) is more constant throughout the lumbar spine measuring approximately 15 mm. The angle between the sagittal axis and the pedicle in more pronounced in L5 at about 30°and decreases progressively from L5 to L1 at about 0°- 10° depending on the study (Figure 2.4) [108,134]. The length of bone accessible for screw fixation (vertebral body and pedicle length) is quite constant in the lumbar spine (43 - 50 mm [108 ,134]).

## B) Degenerative spine disease

Instability of the spine can be caused by trauma, tumors, infections, degeneration or after decompressive surgery. The most frequent cause of instability in an elective practice is degeneration of the spine. Causes of spine degeneration include chronic overload, chronic multi-traumatism and sequelae of acute trauma [29]. In the lumbosacral spine, L4-L5 and L5-S1 are the most frequent levels involved because this area has the highest dynamic and static loads.

Degeneration of the vertebrae creates "spondylolis deformans" shown on radiographs as osteophytosis or bone spurs. They are found in 60% of women and 80% of men after age 50. The facet joints are frequently involved in osteoarthritis. Facet joint osteoarthritis is seen in imaging as joint space narrowing, subchondral sclerosis and cysts, osteophytosis, ligament thickening, intra-articular vacuum (gas in the facet joints) and joint fluid. Severe facet osteoarthritis can cause lateral recess, neural foramen stenosis, central canal stenosis and or instability. Facet instability can cause an anterior degenerative spondylolisthesis with one vertebra slipped against the other. Degenerative spondylolisthesis is found in about 4% of the elderly population. So degeneration of the spine is a continuous process.

Spondylolisthesis is most often found at L4-L5 and L3-L4 levels because of the more sagittal orientation of the joints. L5-S1 is protected by the lumbo-sacral ligaments. Anterior spondylolisthesis is classified in 4 grades according to Meyerding: grade 1 (slippage 1% to 25%; most frequent), grade 2 (26% to 50%), grade 3 (51%-75%)

and grade 4 (76% -100%).[86] Spondyloptosis, sometimes called grade 5, describes a vertebra in front of the other. Posterior spondylolisthesis, found less frequently, is associated with loss if disc height and facet sliding and is usually mild. We find spondylolisthesis in about 3% to 7% of the population.

Stenosis is a narrowing that can be localized centrally (middle of canal), in the lateral recess (sides of the canal) or in the foramen (exits for nerve roots). A stenosis can be caused by degenerated discs, facet joints, osteophytes at the edges of a vertebral body, spondylolisthesis, spondylosis, and hypertrophy of the ligamentum flavum [29,38].

Fissures in the radial direction can rupture the annulus fibrosus (outside hard part) and extend in the nucleus pulposus (inside soft part) causing a disc herniation. Disc herniation is a localized displacement of the nucleus pulposus outside the limits of the normal disc. A bulging disc is broader and follows the contours of the annulus fibrosus usually less than 3 mm beyond the edges of the vertebral body.

## C) Surgical management of degenerative spine disease

In patients with sciatic leg pain, the first goal of spine surgery is decompression [87]. For central canal stenosis without instability, a simple laminectomy is the most frequently used operation. Patients with spondylolisthesis are most frequently managed by a decompression and stabilization. Pedicle screws and rods have become the main way to fix the spine. When performing pedicle screw fixation variability in pedicle width, height and orientation [134] should be considered.

To increase the strength of a posterior fusion and help with the reduction, the disc space can be fused as well. This intersomatic fusion can be achieved through an anterior approach (ALIF, anterior lumbar interbody fusion), a postero-lateral approach (TLIF, transverse lumbar interbody fusion), posterior approaches (PLIF, posterior lumbar interbody fusion) or a lateral approach (XLIF, Extreme lateral interbody fusion).

Instrumentation alone without bone graft or bone substitute may fail over time. Best results of union are obtained with the patient's own bone. Because of morbidity of iliac crest harvesting and insufficient amount of bone collected from laminectomy, other substitute such as allograft, demineralized bone matrix and bone promoting proteins are used with certain success.

## D) Anatomical constraints of pedicle screw insertion

The pedicle is like a tube [103]. Depending on the size of the pedicle and the screw size, different trajectories can be used to insert the screw without breaching the sides of the pedicle. Rampersaud described possible variation in screw direction for translation (sideway variation) and rotation from C2 to L5 [103]. Of all the vertebrae, the maximal variability was at L5 where 3.8 mm of sideway translation and 12.7º of rotation was anatomically possible [103]. L1 has only 0.65 mm of possible translation and 2.1° of rotation allowed [103]. This specific anatomy would make L5 the easiest vertebra to instrument. In reality L5 is a difficult vertebra to instrument due to its deeper location in the lordosis of the lumbar spine.

In the lumbar spine there is 2mm of epidural space between the nerves and the pedicle allowing a safety margin while inserting pedicle screws [32]. In the thoracic spine, there was no space found between the pedicle and the dura [20]. The average distance of the pedicle to the superior root ranged from 1.9 to 3.9mm and the distance from the pedicle to the inferior root ranged from 1.7 to 2.8mm. In the thoracic spine, the spinal cord is more at risk than nerve roots that give intercostals nerves.

S1 pedicle screws pose different problems. Typically the screw is inserted bi-cortically, across the anterior vertebral cortex, for a good fixation. The S1 pedicle is softer and the fusion to S1 has a higher rate of non-union. The entry point is usually at the inferior and lateral corner of L5-S1 facet joint. This point is also defined with navigation. The screw is directed medially. The screw usually ends in the medial zone of the sacrum called the safe zone, just below the S1 promontory [87]. It allows for screw placement away from the sacro-iliac joint and the neurovascular structures located more laterally.

S1 screws pose a second problem. The iliac crest can block the trajectory for a midline S1 screw insertion in 76% of males and 85% of females [54]. In reality, such a classic midline trajectory is not often feasible due to the insufficient possible muscle retraction necessary. Alternatively, the screw can aim be inserted laterally, through the smaller lateral safe zone of Mirkovic [87].

The success of pedicle screw insertion depends on identification of landmarks, surgeon experience, spine level of fixation and screw size. To understand the pedicle anatomy surgeons study before the surgery the pedicle anatomy on plain X-rays, CT-Scans or MRI’s. More information during the surgery can be taken from the palpation of the pedicle after a laminectomy or laminotomy.

## E) Description of the standard surgical technique

For lumbo-sacral fusions, patients are positioned prone with the hips in slight extension to keep an adequate lumbar lordosis (Figure 2.5). The incision is midline (Figure 2.6). The autologous bone graft is resected in the pelvic bone at the postero-infero iliac crest area trough the same incision by following the thoraco-lumbar fascia (Figure 2.6). The spinous processes, the laminae, the facet joints and the transverse processes are exposed and the muscles are retracted to allow screw insertion (Figure 2.7).

**Figure 2. 5 Surgical positioning and incision planning**

**a.** Positioning for lumbo-sacral fusions in the operating room. **b.** Incision drawing with buttock on right side. Inferiorly, there is marking of postero-superior iliac crest site harvesting.

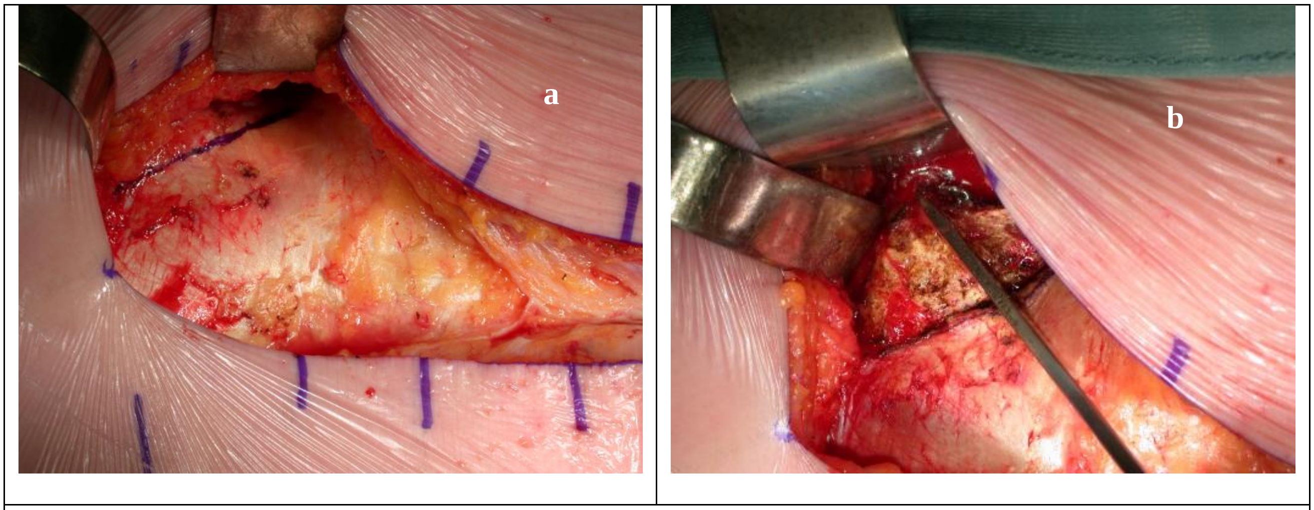

**Figure 2. 6 Iliac crest preparations**

**a.** Midline incision and left iliac crest site harvesting marked with felt pen. **b.** Resection of lateral margin of left iliac crest with an osteotome.

After iliac crest closure, the spine is exposed with dissection of the muscles at the levels to be decompressed and fused. The capsule of facets not to be fused is preserved. The interspinous ligaments of levels not fused are also preserved to prevent adjacent level degeneration (Figure 2.7).

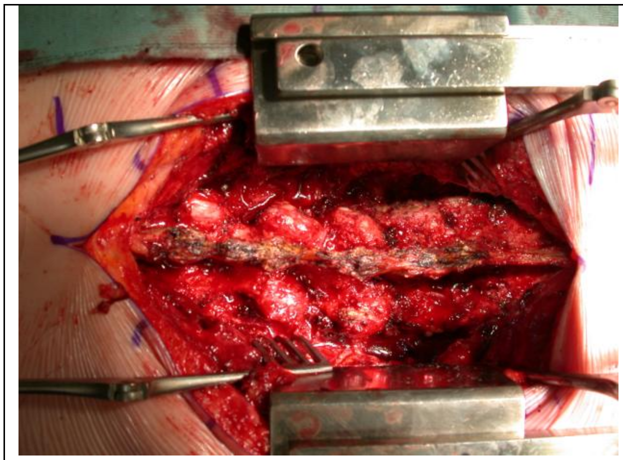

**Figure 2.7 Spine exposure**

Exposed lumbar spine with retractors holding muscles. In midline there are the spinous process and laterally the facet joints.

In the lumbar spine, the classic entry point for pedicle screws insertion is found at the junction of the mid-part of the transverse process and the mamillary process found at the base of the superior articular process (Figure 2.8).

Two main classic entry points have been described in the literature. The Roy-Camille entry point is 1 mm below the facet joint and the screw is directed straight (0°) in the pedicle and the vertebra [107]. The Weinstein entry point is more lateral at the base of the superior facet in the mamillary process and the direction in angled more medially (Figure 2.8) [123]. A too medial approach can injure the facet and a too lateral approach can break the pedicle laterally [71]. The Weinstein entry point is the most frequently used by spine surgeons. In a cadaveric experiment Weinstein showed that their technique had 7% of pedicle perforation compared to 21% with the Roy-Camille technique. The Weinstein technique was more accurate in the L3-S1 area and the Roy-Camille technique was better in the T12-L2 area [123] where the pedicle angle is closer to 0º as described earlier.

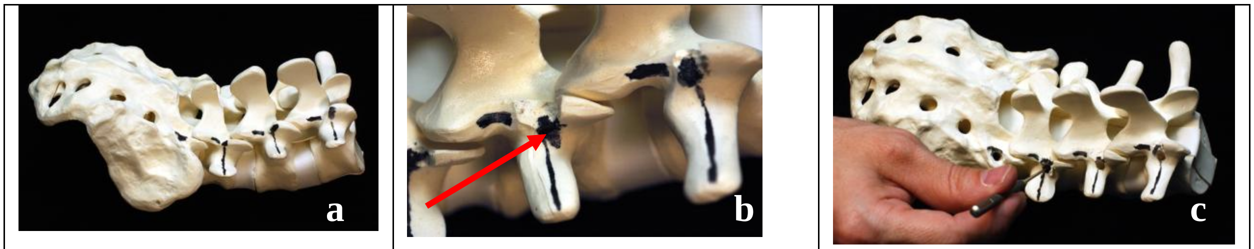

**Figure 2. 8 Pedicle entry point**

**a.** Sawbone phantom right lateral view with black markings of the transverse process and the inferior portion of the superior articular process (mamillary process). **b.** Close up of the entry point (red arrow) for a classic pedicle screw entry in line with the transverse process section and the mamillary process nibbled away. In real surgery just the entry point is filed away preventing injury to the facet joint. **c.** Pilot hole for the screw created by the pedicle finder (not showed) and palpation of the pedicle with a ball tip.

The pedicle is entered with a flat probe (pedicle finder) in the direction of the screw planning. That non-sharp instrument can redirect itself somewhat within the confines of the pedicle cortex. In cases of very sclerotic pedicles (ossified pedicles) a drill bit is used to complete the trajectory. George [31] demonstrated that preparing that pedicle with a probe or a drill had no significant difference in screw pull-out. After the pilot hole is done, a ball tip instrument is used to feel that the wall of the pedicle is intact in all 4 quadrants: medial, inferior, lateral and superior (Figure 2.8). The anterior margin of the vertebra is felt to evaluate the maximal length of screw possible (Figure 2.8).

Typically in the thoracic and lumbar spine, the anterior cortex is not crossed by the screw to avoid injury of the aorta or inferior vena cava. The only exception is at the S1 level, where due to lower risk of vessel injury, the anterior cortex is engaged to increase screw pull-out strength. Also, S1 has a pedicle that is mostly cancellous and in which the pull-out strength can be weak. S1 is often the end of the construct where a lot of stress is applied. Before inserting the screw, preparation on the screw threads is done with a tap. Undertapping 1mm less than the screw size increases peak insertional torque and increases the fixation strength in the thoracic spine [64]. The insertion torque is correlated with the stability of the hardware [132]. The pedicle is responsible for 60% of the pullout strength and for 80% of the cephalocaudal stiffness. Misenhimer [89] wrote that the screws have their strength from cancellous purchase and not from cutting into the cortex of the pedicle. The inner pedicle diameter can be evaluated by CT-Scanning and is a few mm smaller than the outside cortex [89]. A too big screw will cause pedicle expansion (plasticity) before fracture of the pedicle. Fractures of pedicles occur more often laterally (72%) than medially (28%). Screw pull-out and insertional torque is increased with screws aimed at the superior endplate instead of going to the inferior endplate in the thoracic spine [75] . As shown in figure 2.9, the orientations of the screws are directed medially and converge posteriorly to follow the pedicle trajectories. The posterior convergence is due to the lordosis in the lumbar spine.

**Figure 2. 9 Pedicle tracts orientation**

**a.** Right side view of L3 to sacrum with red plastic tubes showing perforation of the anterior cortex in sacrum but not at other levels. **b.** Red plastic tube coming out at S1 on the right side. **c.** The red posts show the trajectories converge posteriorly.

Pedicle screw systems are available in different sizes, thread shapes, and different alloys. The screws heads are either polyaxial or monoaxial. Most surgeons now use cases polyaxial titanium screws for lumbar degenerative cases. The CD - Horizon M8 system (Medtronic Sofamor Danek, Memphis, TN) is available in 4.5, 5.0, 5.5, 6.5 and 7.5 mm diameters in a wide selection of lengths (Figure 2.10). XIA-II system (Xia-II; Stryker Spine, Allendale, NJ), is available in 4.0, 4.5, 5.0, 5.5, 6.5, 7.5 and 8.5 mm diameters, and in multiple lengths (Figure 2.10). The availability of multiple screw sizes allows for a better fit of the screw within the pedicle internal wall. Too big a screw may fracture a pedicle wall, thus weakening the construct. In big pedicles, a 6.5mm screw is usually mechanically strong enough and has a good purchase, except in osteoporosis. Too small screws might break or become loose, especially in osteoporotic bone. In osteoporotic bone, most surgeons will reinforce screw purchase with the addition of bone cement in the screw path. In S1, bigger screws of about 7.5mm in diameter are used for better bicortical purchase.

The ideal screw diameter is about 80% of the pedicle diameter [121]. If the pedicle cortical margin is violated the pullout strength was diminished by 11% in one study [31]. Zindrick [135] found that larger diameter, full-threaded screws and screws that cross the anterior cortex were the strongest to pull-out. In that study, a shorter screw with the tip at 50% of the vertebra had similar pull-out strength as a screw tip just close to the anterior cortex but not engaging it. The frequently recommended screw length is 70% of the vertebral antero-posterior length seen on the lateral radiograph [121]. Whitecloud [126] found that a screw at 80% of the vertebral perforation vertebral antero-posterior length was associated with no anterior cortex perforation at T12, L1, L2, L3 and S1 levels. At L4 and L5 levels, the authors reported 30% and 10% of anterior cortex perforation respectively.

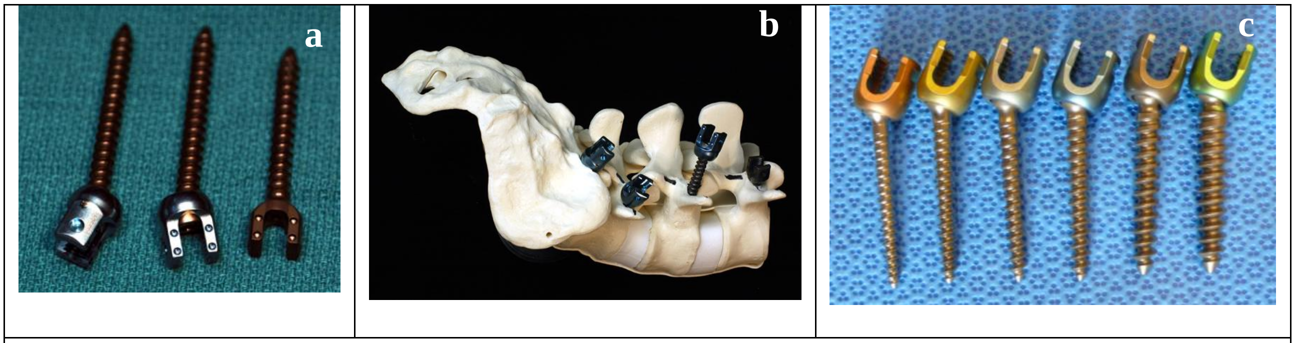

**Figure 2. 10 Pedicular screws**

**a.** CD Horizon M8 screws. On the left polyaxial screws head and on the right a fixed head screw. **b.** Screws inserted in the pedicles of L3, L4, L5 and S1. **c.** XIA-II system polyaxial screws with all sizes available.

An effort is made to insert the screws following a straight line to facilitate the rod insertion at the end of the procedure (Figure 2.11). The position of the retractor is regularly changed to diminish the muscular ischemic time. A laminectomy is performed after the insertion of the screws.

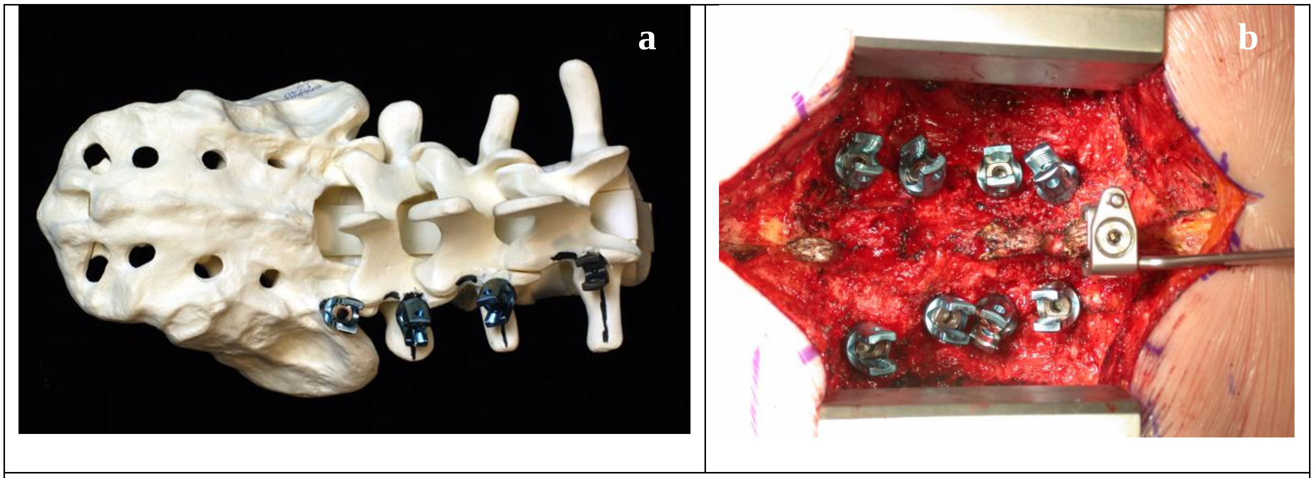

**Figure 2. 11 Screws inserted**

**a.** Sawbone with Horizon M8 screws at L3, L4, L5 and S1. **b.** Exposed spine with Horizon M8 screws at L3, L4, L5 and S1 with reference frame base on spinous process of L2. In his case we used a wide retractor. In more recent cases we use a smaller retractor blade.

Before inserting the rods, the bone surface of the transverse processes and facet joints are decorticated to promote bony union (Figure 2.12). This step can cause significant persistent bleeding and is typically done at the end of the procedure towards closure. The polyaxial screws are fixed on the screws with nuts (Figure 2.12). Depending on the screw system used different nut mechanisms exist. The XiA II system has a simple inside screwing nut and the

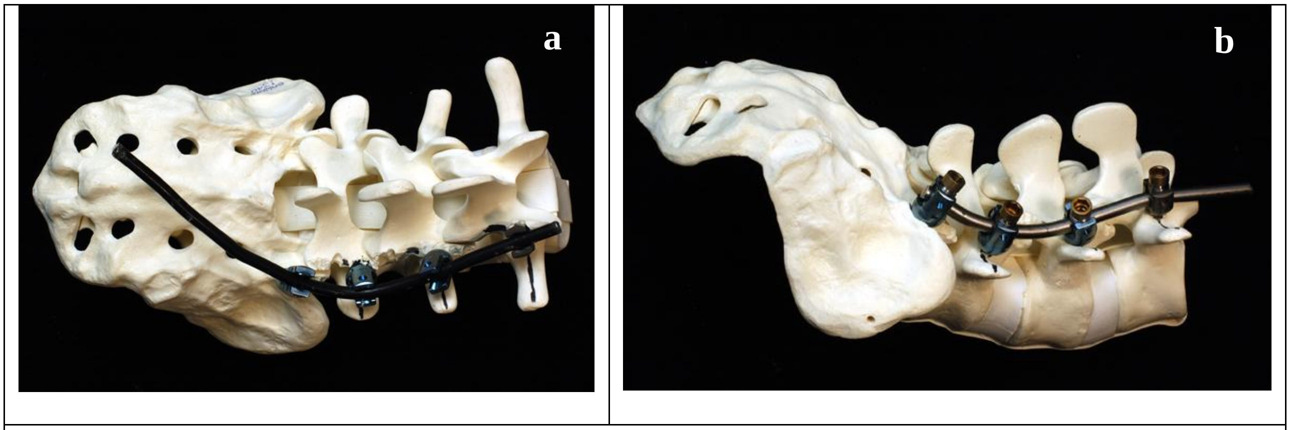

**Figure 2. 12 Rod insertion**

**a.** A malleable template is used is long construct to simplify of the understanding the rod configuration. **b.** The titanium rod is bent to the template contours. The rod is mounted on the screw heads and nuts are tightened.

Horizon M8 system has a screwing nut with a break off extension.

Most surgeons use cross-links to increase the strength of the construct (Figure 2.13). Multilayer closure is completed.

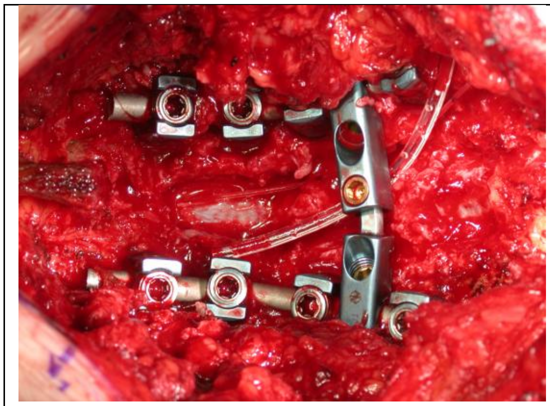

**Figure 2. 13 Final screws and rods construct**

Complete construct with screws, rods, nuts without their break off extension. There is a laminectomy defect in the middle. A cross link is inserted to strengthen the tortional stiffness of the construct. An epidural drain is inserted to drain excess fluid after surgery. An epidural catheter to inject Morphine is inserted under the lamina above the laminectomy for pain control.

## F) Navigation concepts and surgical techniques

Since the introduction of spinal pre-operative CT-based navigation by Nolte in 1995 [97,101], the principles of the technology have not change significantly. In this section the method of navigation using the SNN system (Surgical Navigation Network, Mississauga, Ontario, Canada) will be presented with case examples to illustrate the technique.

A pre-operative axial CT-Scan is performed a few weeks before the surgery using images 4mm thick with 2mm of overlap. The biomedical engineer or the navigation technician imports DICOM images on the Spinal navigation unit (SNN, Surgical Navigation Network, Mississauga, Ontario, Canada) to reconstruct a 3-D spine model, sagittal images and coronal images (Figure 2.14). Usually the day before the surgery, the surgeon plans the screw path on the navigation unit to accommodate for an entry point, the screw trajectory, the ending point (exiting point), the screw size and the screw alignment. The surgeon can do all the planning alone, but the help of navigation specialist is valuable and time saving.

A minimum of four points are selected on images of the spine for registration during surgery. Typically six points are selected to better represent the 3-dimensional representation of the vertebra. The surgeon can use any anatomical points that have features reproducible on the image and the patient. These points need to be easily found during surgery to match image and patient co-ordinates (Figure 2.14).

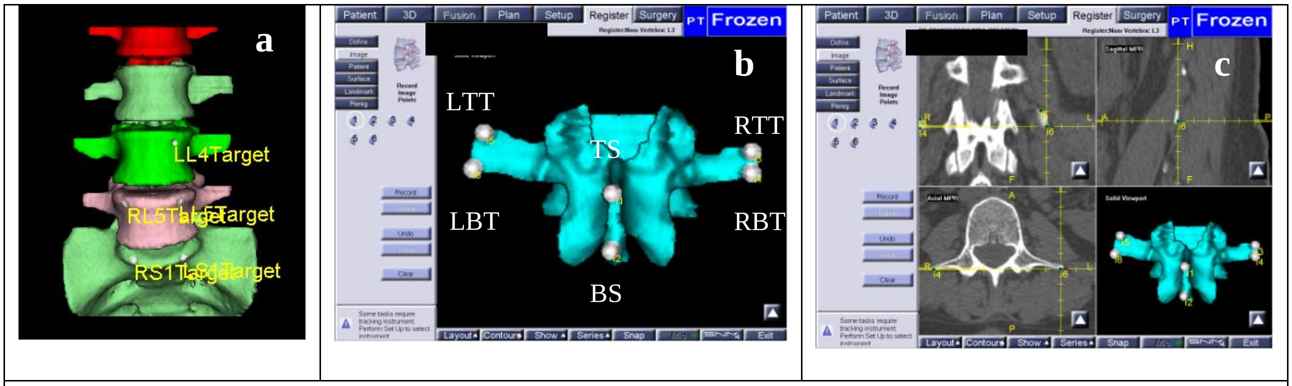
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**Figure 2. 14 Navigation planning**

**a.** View of the anterior spine form L2 to S1 with each vertebra reconstructed separately. The exiting points in gray (target) have been elongated to see if the screws would interfere with the anterior approach. **b.** Six registration points chosen on the 3-D model (TS = top of spinous process, BS = bottom of spinous process, RTT = right top (superior) transverse process, RBT = right bottom (inferior) transverse process, LTT = left top (superior) transverse process and LBT = left bottom (inferior) transverse process. **c.** Both 2-D and 3-D images are used to select the navigation points.

To establish the image-patient correlation the surgeon fixes a reference frame on a spinous process above the fusion level (Figure 2.15). The reference frame has to be solidly fixed on the spine and protected from any contact by the surgical team in an effort to keep the accuracy of the navigation system.

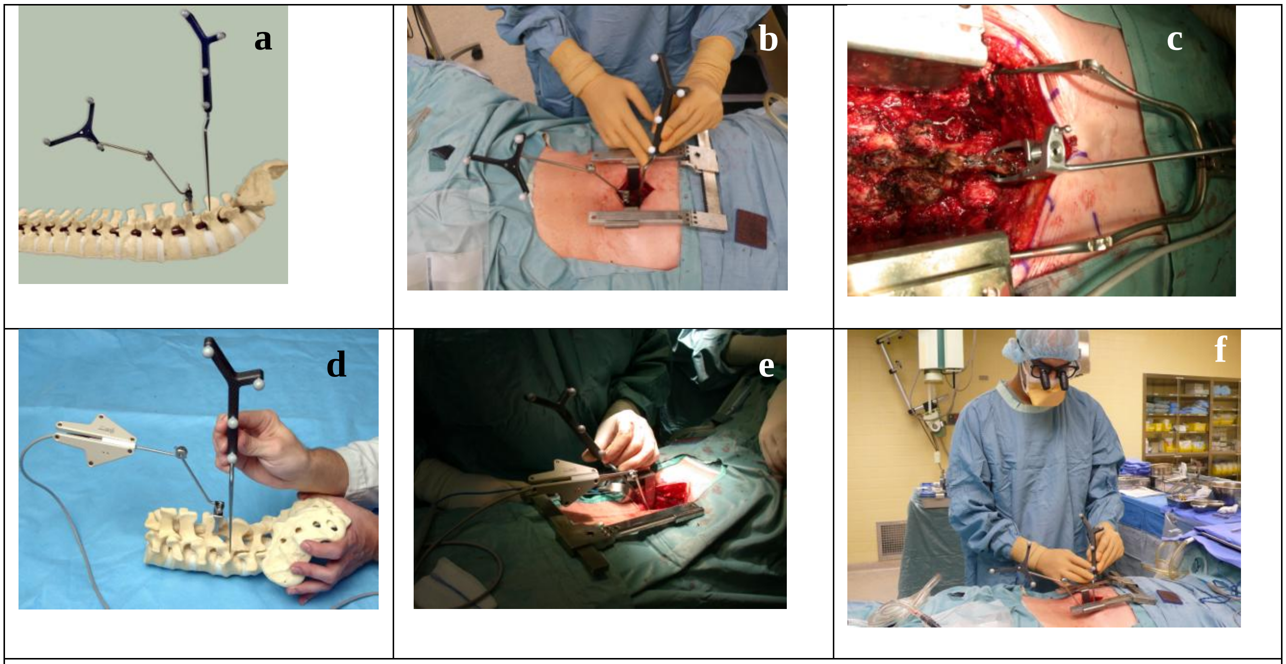

**Figure 2. 15 Navigation instruments**

**a.** The passive reference frame (patient tracker) is fixed on L3 spinous process of a sawbone and the pointer is directed laterally. The navigation pointer is touching the left L4 transverse process. Both the reference frame and the navigation probe have their reflection spheres pointing towards the navigation camera (not shown). **b.** During a live L5-S1 fusion case, the passive reference frame is fixed on L4 spinous process. **c.** The base of the reference frame is firmly attached on a spinous process above the fusion to avoid motion of the frame. **d.** An active (dynamic emitting diodes) reference frame is used with similar accuracy in navigation as a passive reference frame. **e.** Surgical set up with dynamic reference frame. **f.** The assistant is showing the tracked instruments to the camera while touching the spine anatomy.

An optic camera is used as an interface between the computer system and both the reference frame and the navigation pointer. The Polaris optic camera emits and receives infrared light. The information of the location of different tools is processes in the computer system (Figure 2.16). The image of the navigation pointer is represented on the screen superimposed on the pre-operative image of the patient spine. The images of the planned procedure are also displayed on the screen to allow execution of the procedure.

The camera needs to see both navigation instruments without obstruction from the operating room personnel and equipment (Figure 2.16). Adjustments in the camera position can be done during the procedure to track the changes in position of the navigation pointer. The camera has to be able to interact with the location of three spheres at all times. The passive reference frame has three spheres that reflect infrared light. The navigation probe (pointer) has 4 passive reflective spheres so 3 spheres can be seen at all times. To complete the registration the pointer is used to select anatomical points on the patient previously chosen on the images (Figure 2.14).

**Figure 2. 16 Spinal navigation set up**

**a.** The set-up includes the computer system on the left, a camera that is wired to the navigation system (red arrow), a reference frame (patient tracker) attached to the patient and a navigation pointer held by the surgeon (white arrow). **b.** The procedure is facilitated by navigation technician manipulating images. The images can also present on bigger screens (60 x 40 inches plasma) to facilitate the view of images by the surgeon. **c.** The infrared light emitted by the Polaris camera is reflected by the navigation instruments. In this case the assistant has to turn his head to see the screen. A Fluoroscopy machine was draped sterile in the operating field.

After registration of the preselected six anatomical points, an accuracy check is performed with the pointer touching any spine surfaces on the chosen vertebra (Figure 2.17). A routine for choosing surfaces is preferable to standardize the validation process and simplify the communication with the technician. The points should be chosen to evaluate a possible translation in all x, y and z axis. An error of 1mm in navigation accuracy is typically accepted in lumbar spine [22]. The quest for precision is restrained by surgical time. If accuracy is not obtained, other specific points are found on both the image and the patient. The innominate process at the base of the transverse process or features on the inferior articulate process are other good anatomical points that can be used. A high quality 3-D image is important to be able to find specific anatomic points. Some newer commercially available navigation systems do not have very good 3-D images. To increase the accuracy, a surface matching technique using a minimum of 20 surface points on the flat surfaces can be used. However, this technique has not been found to be often useful [46].

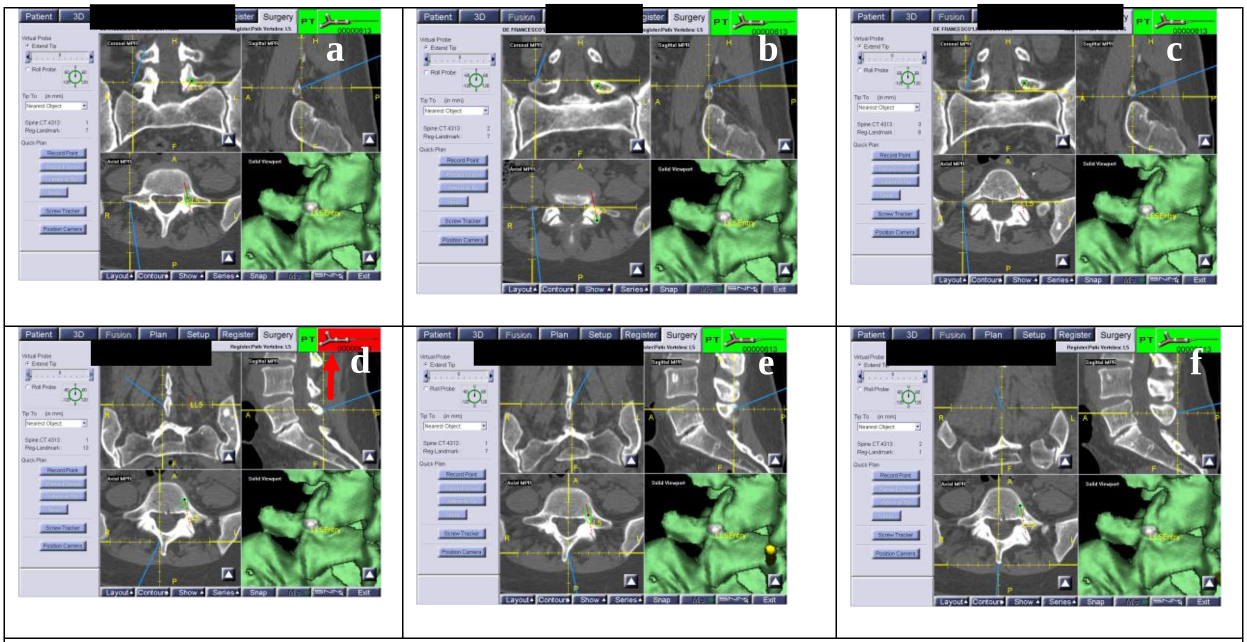

**Figure 2. 17 Accuracy check**

**a.** This is a snapshot picture of the navigation screen during surgery. The navigation probe represented by a blue line is in contact with the right transverse process. The accuracy is very good as shown by the contact of the blue line and the image of the transverse process. **b.** The pointer touches the superior aspect of the transverse process. **c.** The pointer touches the inferior aspect of the right transverse process. **d.** The pointer touches the right lamina. In this case, the navigation pointer is not seen because the icon of this instrument is in red (red arrow). The reference frame is seen as the PT (patient tracker icon is in green). **e.** The pointer touches medial aspect of the spinous process. **f.** The pointer touches the posterior aspect of the spinous process. The same accuracy check points are done on the left side.

When the iterative process of registration has reached a clinically acceptable accuracy, the procedure is carried out with insertion of the screws (Figure 2.18). The navigation probe is put in contact with the bone to simulate the screw trajectory. The entry point is reproduced and the bony cortex under it is drilled away with a high speed burr to expose the cancellous bone. The trajectory of the screw is then simulated with the navigation pointer (Figure 2.18). The planned trajectory is kept by the surgeon’s left hand fingers. With the right hand, the surgeon pushes the pedicle finder within the cancellous bone stopping at 40mm or less depending on the case. The pilot hole within the pedicle is sounded and the screw is inserted as described in the previous section. Small variations are sometimes found between the planned screw and the obtained screw path (Figure 2.18). If the screw has a clinically acceptable orientation, the screw is inserted following previously described techniques.

Adjustments with a curet to scrape the bone of the pedicle in a specific direction are sometimes necessary to readjust the trajectory. Considering that the pedicle is a tube, an alternate entry point can be used. The navigation system allows a simulation of any variations selected by the surgeon. Altering the classic entry point is often necessary at the top of the fusion to avoid the facet joint that does not need to be fused. Avoidance of the facet above the fusion is recommended to prevent post-operative adjacent level disease [92].

The screw head at the top level is brought inferiorly and laterally if muscle retraction allows this configuration. A second reason to change the classic entry point is to align all the screw heads for an easy rod insertion. A third cause of alteration in the planned trajectory is the inability to accommodate the screw trajectory due to insufficient exposure. The amount of possible muscle retraction allowed is subjectively evaluated by the surgeon during planning.

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Tip To (in mm)
Nearest Object
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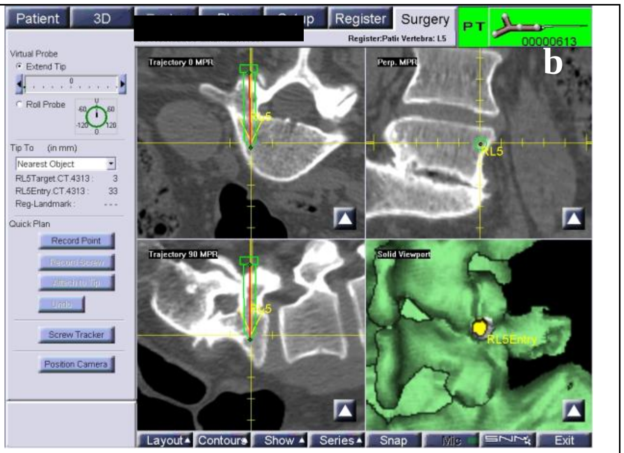
RL5Entry.CT.4313 : 5
Reg-Landmark : 6



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Tip To (in mm)
Nearest Object
RL5Target.CT.4313 : 3
RL5Entry.CT.4313 : 33
Reg-Landmark : - - -

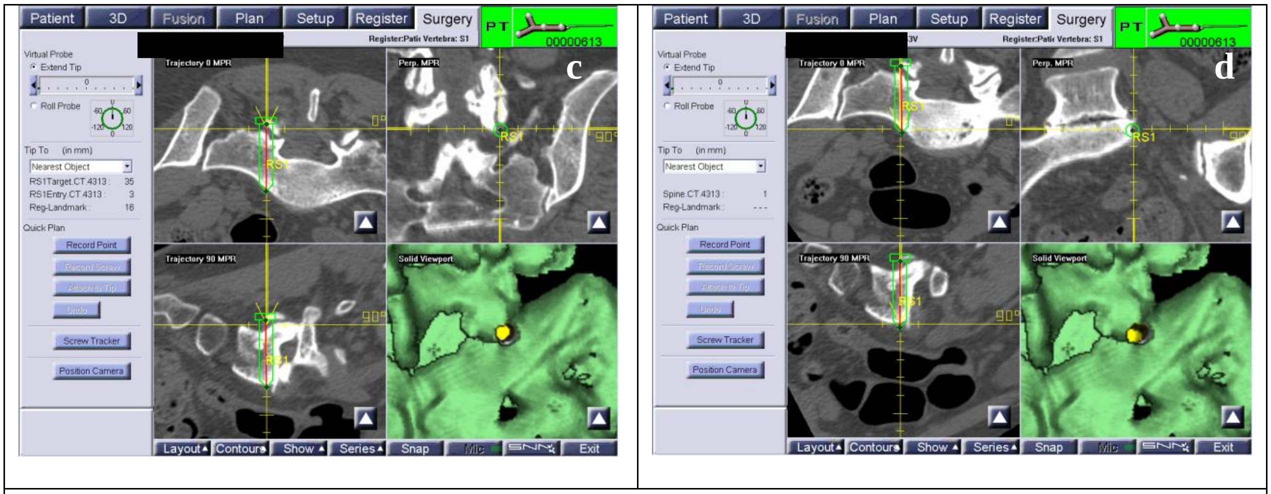


**Figure 2. 18 Intraoperative navigation images**

**a.** The right L5 screw image is showed in green and red. The yellow arrow with represent the position of the navigation probe. With this yellow arrow there is attached a coordinate system to help the surgeon with his (her) orientation. **b.** The navigation probe is inserted in the pedicle to show that the trajectory created is almost similar to the screw planned. **c.** The entry point of right S1 screw is simulated. It is located just at the inferolateral corner of the L5-S1 facet joint. **d.** The navigation probe is advanced into the pilot hole to visualize the screw trajectory and the residual amount of bone left to cross for a bicortical purchase.

## G) Validation and verification of the errors

As presented in the next section, errors are measured at the pedicle and at the anterior part of the vertebral body. The length errors and the pedicle medial and lateral errors are measured on axial CT-Scans (Figure 2.19). The superior and inferior pedicle errors are measured on the sagittal reconstructed images (Figure 2.19). The amount of errors is quantified in mm using the measurement tool of the Intelviewer software of the PACS system.

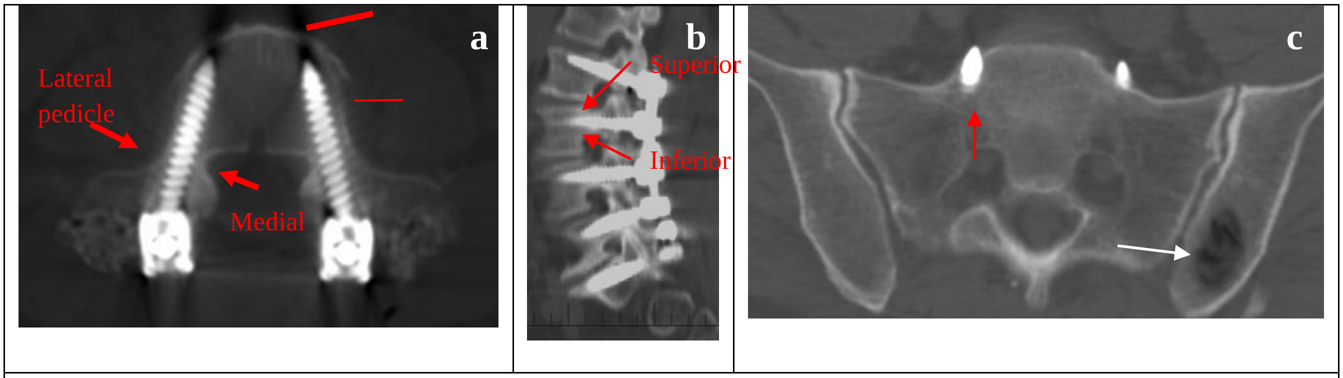


**Figure 2. 19 Screw error assessment**

**a.** The axial images of pedicle screws show preservation of medial and lateral pedicle walls (red arrows). The right screw is about 4 mm posterior to the anterior vertebral cortical wall (Thick red line) and the lateral vertebral body (Thin red line). The left screw is about 5mm from the vertebral anterior wall. On the sides there is morselized bone graft with adequate contact with the transverse processes. **b.** The Sagittal reconstruction images show intact superior and inferior pedicles at all levels. **c.** This is an axial image of the sacrum with bicortical screws (white arrow). On the right side of the image (left side of the patient) there is a defect in the iliac crest where a graft was resected (red arrow).

## H) Assessment of bony union

A solid bony union is not always easy to define. During surgery, bone graft is inserted in the facet joints, behind the transverse processes and sometimes in the disc space. Bony union is usually assessed between the transverse processes and between the vertebrae on plain radiographs or CT-Scan. An obvious bony fusion and pseudarthrosis are easier to define (figure 2.20). In an effort to quantify good bony union from the less obvious, bony union was divided in four categories. This was classification has not been validated in the literature.

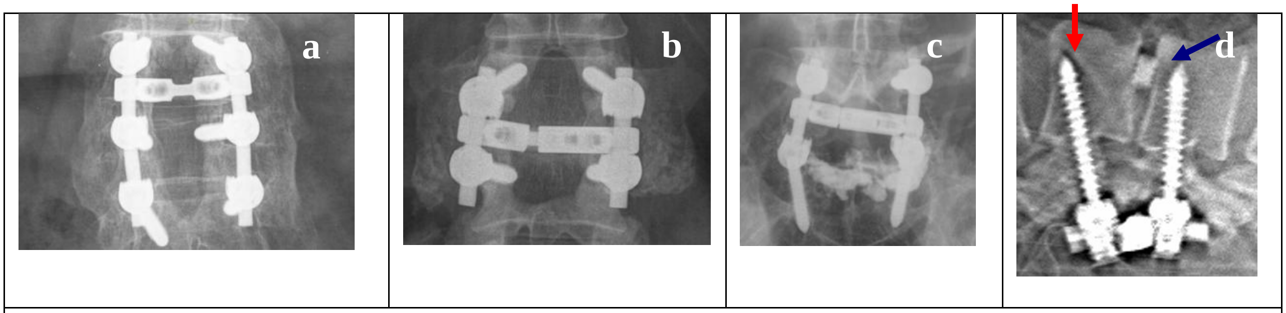


**Figure 2. 20 Bony union grading**

**a.** Obvious bony fusion (grade 4/4). There are 2 solid bridges of bone on both sides of the spine. The superior and inferior edges of the transverse processes are not well visible. There is no abnormal motion on flexion and extension X-rays (not shown). **b.** This case is probably fused (grade 3/4). The fusion mass is granulated and the superior or inferior edge of the transverse processes are visible. **c.** There is no bone union between the transverse processes. There is no motion on flexion and extension views. There are no signs of loosening around the screws. This is considered a fibrous union (grade 2/4). **d.** In this case there is a pseudarthrosis (grade 1/4). There is a hollow around the top screws (red arrow) and the allograft cage (blue arrow) does not seem to be incorporated. On AP views there is no bone mass between the transverse processes. On flexion and extension views there is no obvious motion. On CT-Scan there is widening and sclerosis of the screw tract indicating that the screws are mobile.

# CHAPTER 3 – Literature Review

## A) Introduction of the Literature Review

Computer-aided image-guided surgery has improved accuracy and safety of spinal fusion [47]. Spinal navigation and image-guided spinal surgery are accepted terminology used for this application.

Spinal navigation has its origins in cranial applications. David Roberts [127] in 1986 created for cranial surgery a stereotaxy system without a frame which used ultrasounds as the medium of transmission. Frameless image guided surgery using preoperative CT-Scan images were developed in early 1990's. Initially, both electromagnetic and optical cameras were used, but current technology has moved towards optics.

Nolte introduced the use of spinal CT-based navigation to the spine in 1995 [97,101]. Since then, pre-operative CT-based navigation principles did not change significantly. The literature on CT-based navigation shows a misplaced screw rate varying between 4 and 7% [8,52,53,70,84], as measured by postoperative CT- Scans. Computer-aided image guided surgery, has significantly improved the accuracy and safety of routine and complex spinal instrumentation procedures [47]. CT-based navigation, though accurate, is time consuming, needing the difficult process of registration of the vertebra. CT-based navigation is not adequate for the newer percutaneous procedures as registration points need to be taken on the anatomy of the patient.

Other technologies such as 2D-fluoroscopy, 3D-fluoroscopy, intra-operative CT-Scan, 2D-3D registration and intra-operative ultrasound registration of pre-operative CT-Scan, are being developed to avoid the step of manual registration. Robots have also been used for pedicle screw insertion. Different techniques of spinal navigation have been developed in this fast-evolving domain.

In this chapter, the literature related to pedicle screw instrumentation and navigation techniques will be presented. For most sections, a table is presented to summarize the results.

## B) Radiological Evaluation of Error

A uniform way to communicate the errors should be used to facilitate comparison between series. The error can be measured at the pedicle level or at the vertebral body level. The pedicle error is usually described anatomically following four quadrants: medial, lateral, superior or inferior (Table 3.1). The vertebral body error is less frequently reported and is usually described by the presence or absence of breach of the vertebral body anteriorly. The optimal screw length is controversial so an error length was less systematically studied. Errors have significance if they are associated with a worse clinical outcome. Some errors have been associated with bad consequences [10,32,115] but most series had 0% nerve root injuries. In a case of misplaced screw, it is not always easy to associate the screw error with a clinical radiculopathy.

Different tools to measure errors were used in the literature: plain radiographs, axial CT-Scan, sagittal CT-Scan, coronal CT-Scan [53,96]. In 1976, Saillant was the first to use X-Rays to report errors in pedicle screw insertion [77]. In one report, radiographs were successful in determining the position of the implant in only 41% of the cases [8]. In 1999, Sapkas [109] prospectively evaluatated the radiography and CT-Scans of 35 patients following lumbar and thoracic screw insertion. CT-Scans showed that 4% of the 220 screws were outside the pedicle, contrary to 1% with plain radiographs. Questionable screws were found in 2.5% of CT-Scans and in 3% of plain radiographs. In 1997, Yoo defined CT-Scan a sensitivity of 86%, a specificity of 88% and an accuracy of 87% to predict titanium pedicle screw misplacement. In the literature, CT-Scan was in general more reliable than radiographs to detect pedicle screw errors [123]. CT-Scan is considered the gold-standard in evaluating the pedicle screw error [25,131]. In our study we use axial and sagittal CT-Scan to evaluate the screw misplacements.

In a meta-analysis completed in 2007, Kostmopoulos found 35 different methods to define pedicle screw error [61]. The most frequently used method is in or out of the pedicle. The second most used method is to define the pedicle error in 2 mm increments. The Gertzbein method [32] has 6 categories: no pedicle breach, 0-2 mm medial pedicle breach, 2.1-4 mm medial pedicle breach, 4.1-6 mm medial pedicle breach, 6.1-8 mm medial pedicle breach and a lateral pedicle breach. The lateral error was not quantified and was not defined as in or out of the pedicle. There was no description of superior of inferior errors. This method is based on the anatomical observation that there is 2mm of epidural space between the pedicle and the neural structures and 2mm of arachnoid space form T10 to L4 [32]. Gertzbein wrote that 4 mm of canal encroachment can be tolerated without risk of the spinal cord or cauda equina injuries [32]. This 4 mm space was called the “safe zone” [32] . This can also be called the “tolerance zone”. Laine [71] (1991) used 2 mm increment measurements to define errors medially and laterally.

Ideally, the reporting method chosen should use mutually exclusive measures and avoid overlapping ranges (eg: 0-2, 2-4 and 4-6 mm). This classification is based on the anatomical measurements of epidural space. Reynolds measured the right lateral epidural space from T7 to L4 to be 2.4mm +- 0.2mm and the left side 2.3mm +- 0.2mm [105]. Values with 1 mm increments can have statistical advantages but this method was not widely used in the literature.

Some studies included the impression of the surgeon about the strength of screw purchase [10,102,106]. In pedicle precision studies, such subjectivity cannot be used to compare studies.

In our study we used a similar 2mm increment method of measuring the error in all 4 quadrants of the pedicle (medial, lateral, superior and inferior). We used axial and sagittally reconstructed images as per our radiology department protocol. Coronal images or images perpendicular to the axis of the pedicle were not part of our protocol.

**Table 3. 1 Methods of measurement of errors**

| Year, author | Error categories | Mutually exclusive | Medial, lateral error | Superior, inferior error | Length error |
|---|---|---|---|---|---|
| 1997, Liljenqvist[77] | Mm of error | Yes | Yes | Yes | Yes |
| 1995, Farber[25]<br>1995, Vaccaro[119]<br>1999, Sapkas[109]<br>2007, Schizas[111] | In / Out | Yes | Yes | No | No |
| 2000, Amiot [1] | 0.1-2.0mm<br>2.1-4.0mm<br>> 4mm | Yes | Yes | Yes | No |
| 2001, Belmont[7]<br>2008, Modi[91] | 0.1-2.0mm<br>2.1-4.0mm<br>4.1-6.0mm<br>6.1-8.0mm | Yes | Yes | Yes | Lateral and anterior vertebral wall |
| 2003, Mirza[88]<br>2007, Lekovic[76] | 0.1-1.9 mm<br>2.0-4.0 mm<br>> 4mm | Yes | Yes | No | Anterior<br>Airball<br>Tip-out lateral |
| 2001 Yakoulis[131] | ≤2mm<br>>2mm | Yes | Yes | Yes | No |
| 2005, Kuklo[65] | 0 - 2mm<br>2 - 4mm<br>>4mm | No | Yes | No | No |
| 2007, Merloz[85] | > 1mm-≤ 2mm<br>> 2mm<br>≤ 3mm | No | Yes | Yes | No |

## C) Anatomical Landmarks and/or Intraoperative Fluoroscopy

Most surgeons use anatomical landmarks (topography, free hand), with or without fluoroscopy, for screw insertion. Earlier series reported pedicle screw perforation in the range of 40% (table 3.2). With increased experience, lower rates of pedicle screw injuries were reported. Recent studies only rarely report high rates of errors and nerve injuries [115].

Data from table 3.2 (see below) shows that lumbo-sacral screws inserted using anatomic (free-hand) methods, with or without fluoroscopy, have a pedicle perforation rate varying from 0.2% - 62%. Studies that used only X-Rays for post-op evaluations, reported a perforation rate that varies from 0.02% to 5%. In studies using Axial CT-Scans for post-op evaluations, the perforation rate varied from 13-62%. The higher rates of perforation are found in studies reporting also the superior and inferior errors. The nerve root injury rate varied from 0-17% in these series and occurred more often when the screw error was ≥5mm. Following a misplaced screw, patients usually present with a new onset of leg pain and more rarely with weakness or drop foot. As an alternative to landmarks, surgeons have used the palpation of the pedicle after laminectomy as another way to try to improve screw accuracy. This technique was not found to significantly increase the error rate.

In 1990, Gertzbein [32] used Axial CT-Scans to report pedicle screw perforation. The authors used lateral fluoroscopy to help guide the alignment of the screws. The authors saw an improvement in the screw error rate over time, showing a learning curve. By extracting lumbo-sacral screw data from their tables, we found the errors were mostly medial (25%) and classified as such: 9% (0-2 mm), 9% (2.1-4.0 mm), 4% (4.1-6 mm), 2% (6.1-8.0mm). Only 3% of errors were laterally position to the pedicle. Only one patient, with a screw inserted 7 mm medially into the canal, developed a nerve root injury with paresthesia in L2 distribution.

In the thoracic spine, screws evaluated with CT-Scan have a pedicle error rate that varies from 2% to 41% (Table 3.3). Unfortunately some authors choose to exclude small errors from 0 to 2mm. As most errors occur in that zone, the real pedicle rate is not accurately stated. The reported rate only reflects large errors that have the potential of causing neurological injuries.

The results of thoracic screws in Gertzbein's were also extracted from their tables. The authors inserted 71 thoracic pedicle screws [32]. After analyzing their data, 26% of screws were too medial (0-2mm = 7/71, 2.1-4.0 mm = 6/71, 4.1-6.0 mm = 4/71 and 6.1-8.0mm). Only 4% of screws (3/71) were too lateral. It is not clearly stated if the second patient with neurological injury was in the thoracic group. One patient had headaches that lasted 2-3 days. There was no spinal cord compression in this group.

**Table 3. 2 Literature review for lumbo-sacral pedicle error with landmarks, radiography and fluoroscopy insertion techniques**

| Year, Author | # screws / # patients | % error per screw | Location errors | | | | % nerve injury from screw per patient | Method of insertion | Measurement method |
|---|---|---|---|---|---|---|---|---|---|
| | | | Med | Lat | Inf | Sup | | | |
| 1976, Saillant[108] | 375/56 | 10% | NSt | | | | NSt | Anatomical | Radiographs |
| 1991, West [124] | NSt/61 | NSt | NSt | | | | (2/61) 3% | Anatomical | NSt |
| 1992, Davne[15] | 2642/486 | NSt | NSt | | | | 3/486 pts (0.6%) | Anatomical | NSt |
| 1993, Esses [21,22] | 3949/617 | 5% (survey) | NSt | | | | 1% | NSt | NSt |
| 1993, Sjöström[116] | 82/21 | 16/82 (20%) | 10/82 (12%) | 6/82 (7%) | | | 0% | Anatomical | Axial CT-Scan |
| 1993, Steinmann [117] | 90/9 | 5/90 (6%) | 1/90 (1%) | 3/90 (3%) | 0% | 1/90 (1%) | NA cadavers | Anatomical | Palpation |
| 1995, Farber[25] | 74/16 | 46/74 (62%) | 20/74 (27%) | 18/74 (24%) | 6/74 (8%) | 2/74 (3%) | 0% | Anatomical | Axial and sagittal CT-Scan |
| 1996, Castro [10] | 42 / 4 | 10/42 (29%) | 10/42 (23%) | 0% | | | NA cadavers | Anatomical | Axial CT-Scan |
| 1996, Castro [10] | 123 / 30 | 49/123 (40%) | 35/131 (27%) | 14/131 (10%) | | | 5/30 patients (17%) | Anatomical | Axial CT-Scan |
| 1996, Pihlajamaki[99] | NSt/63 | NSt | NSt | | | | 3/63 patients | NSt | NSt |
| 1997, Brown, pediatrics[9] | 759/223 | 2/759 (0.2%) | 2/759 (0.2%) | | | | 2/223 patients (1%)<br>6/759 screws (1%) | Anatomical | NSt |
| 1997, Laine [71] | 35 / NSt | 5/35 (14%) | 3/35 (9%) | 1/35 (3%) | 1/35 (3%) | 0% | 1/35 screws (3%) | Anatomical | Coronal CT-Scan |
| 1999, Lonstein[79] | 4790/NSt | 5% | NSt | | | | 0.2% | Anatomical | Radiographs |
| 1998, Merloz [81] | 64/32 | 26/64 (41%) | 12/64(19%) | 14/64 (21%) | | | 0% | Anatomical | Axial CT-Scan |
| 2000, Amiot [1] | 544/100 T5 –S1 | 84/544 (15%) | 35/544 (6%) | 35/544 (6%) | 11/544 (2%) | 0% | 7% patients | Anatomical | MRI |
| 2004, Kim[57] | Mixed with thoracic | NSt | NSt | | | | NSt | Anatomical | Axial CT-Scan |
| 2005, Kim [58] | 157/NSt | NSt | Mixed with thoracic | | | | 0% | Anatomical | Axial CT-Scan |
| 2006, Karim [55] | 48/12 | NSt | NSt | | | | Cadaveric study | NSt | Axial CT-Scan |
| 2006, | NSt/36 | NSt | NSt | | | | 4/36 | NSt | NSt |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sengupta[115] | | | | | | | patients (11%) | | |
| 2006, Ringel [106] | 488/104 | 64/488 (13%) (≥2mm errors) | 64/488 10% | | | | NSt | Anatomical | Axial CT-Scan |
| 2007, Chin[12] | 428/65 | 10/428 (2%) | 8/428 2% | 2/428 (0.5 %) | | | 2% | Anatomical | Laminectomy and radiography |
| 2008, Kim[59] | 300/37 | 6/300 0.02% per-op | NSt | | | | 0% | Anatomical | Radiographs per and post-op |
| 2008, Modi[91] | 320/37 | 56/320 (18%) | 18/320 (6%) | 38/320 (12 %) | | | 0% | Anatomical | Axial CT-Scan |

*NSt = not stated. Med = Medial, Lat = Lateral, Inf = Inferior and Sup = Superior

**Table 3. 3 Pedicle screw errors in the thoracic spine with anatomical or spinal navigation**

| Year, Author | # screws / # patients | % error per screw | Location errors | | | | % nerve injury from screw | Method of insertion | Measurement method |
|---|---|---|---|---|---|---|---|---|---|
| | | | Med | Lat | Inf | Sup | | | |
| 1990 Gertzbein [32] | 71/40 | 21/71 (30%) | 18/71 (25%) | 3/71 (4%) | | | 1/40 (3%) | Anatomical | Axial CT-Scan |
| 1995, Vaccaro[119] | 90/5 cadavers | 37/90 (41%) | 21/90 23% | 16/90 (18%) | | | NA | Anatomical | Axial CT-Scan |
| 1996, Hamil[43] pediatrics | 103/22 | NSt | NSt | | | | 0% | Anatomical | NtS |
| 1997, Lijenqvist[77] | 120/32 | 29/120 (24% | 10/120 (8%) | 17/120 (14%) | 2/120 ( 2%) | 0% | 0% | Anatomical | Axial, sagittal? CT-Scan |
| 2000, Halm[42] | 104/20 | 24/104 (23%) | 9/24 (9%) | 15/24 (14%) | | | 0 (0%) | Anatomical | Axial CT-Scan |
| 2001, Suk[118] | 4604/462 | 67/4604 (1.5%) | 4/67 (0.1%) | 18/67 (0.4%) | 33/67 (0.7%) | 12/67 (0.2%) | 0.2% | Anatomical | X-ray mostly |
| 2001, Belmont[7] | 279/40 | 43% | 38/279 (14%) | 81/279 (29%) | 0% | 0% | 0% | Anatomical | Axial/sagittal CT-Scan |
| 2001, Reidy[104] | 90/17 | 8/90 (9%) | 1/90 (1%) | 5/90 (6%) | 2/90 (2%) | 0% | 0% | Anatomical | Axial/sagittal CT |
| 2001, Youkilis[131] | 224/52 | 19/224 (8%) | 3/224 (1%) | 13/224 (6%) | 2/224 (1%) | 1/224 (0.4%) | 0% | CT-based navigation | Axial, Coronal CT |
| 2004, Kim[57] | 577/45 | 36/577 (6%) | 10/577 (1.7%) | 26/577 (4.5%) | | | 0% | Anatomical | Axial CT |
| 2005, Kuklo[65] | 352/37 | 50/352 (14%) | 15/352 (4%) | 35/352 (10%) | | | 0% | Anatomical | Axial CT |
| 2005, Kim[58] | 789/49 | 80/789 (10%) | 30/789 (4%) | 50/789 (6%) | | | 0% | Anatomical | Axial CT |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2007, Schizas[111] | 60/13 (T1-T6) | 7/60 (12%) | 5/60) 8% | (2/60) 3% | | | 0% | Anatomical | Axial CT |
| 2007, Kotani[62] | 57/20 | 1/57 (2%) | 0% | (1/57) 2% | | | 0% | CT-based navigation | Axial CT |
| 2007, Kotani[62] | 81/25 | 9/81 (11%) | 8/81 (10%) | 1/81 (1%) | | | 0% | Anatomical | Axial CT |

## D) CT-based Navigation

Early reports on CT-based navigation were on cadaveric experiments and cases series. The error rate of CT-based navigation varies in patients showed a pedicle error rate varying form 2.7 to 9% (Table 3.4). Cadaveric studies have error rates varying from 0 to 5.2%. The pedicle screw error rate with pre-operative CT-based navigation in the lumbar spine is better than when using the anatomical techniques. This is a strong argument to recommend CT-based navigation for pedicle screw insertion. The percentage of nerve injuries is also 0%, not much different from the anatomical technique.

Nolte [97] was the first in 1995 to report the results of lumbar pedicle screw insertion in cadavers with CT-based navigation. They used the Optotrak 3020 (Northern Digital, Waterloo, Canada) and used with light-emitting diodes to track the dynamic reference base and their instruments. They used paired-point registration and when not accurate, they used 30-60 surface matching points. Using coronal images through the pedicles they found an ideal position in 91% (70/77) of cuts and no pedicular cortex encroachment (100% accurate). Kalfas [52] was the first in 1975 to report clinical results on a series of 30 patients. Of the 150 screws inserted, 13 (8.7%) had a suboptimum but satisfactory placement with lateral pedicle violation or anterior body violation.

Glossop [37], compared the accuracy of the registration of three different techniques: four implantable fiducial markers, paired-point matching and paired-point matching with surface matching (30-35 points) in the lumbar spine (L1-L4). The reported navigation error was 1.3 mm with fiducial marker, 3.7 mm for paired-point matching and 2.8

mm for paired-point combined with surface matching. Five main critiques of this landmark article were made by Holly [48]: a mechanical arm was used, measurements were done with calipers, some errors could not be recorded, a limited number of vertebrae were studied and a statistical analysis was not performed. Similar to our experience, Holly did not find surface matching useful to increase the navigation accuracy [48].

Comparative studies carried out to determine the accuracy of CT-based navigation in the spine have shown the superiority of CT-based navigation. These studies are presented in more detail due to their more informative value. Laine [71] compared the results of pedicle screw insertion in 30 adult patients using CT-based navigation (139 screws) to cases where navigation could not be used (35 screws). The reasons for not using CT-based navigation were the absence of landmarks due to a previous laminectomy or a mechanical problem with the dynamic reference frame or other problems with the light-emitting diodes (LEDs). This study does not compare similar groups. With CT-based navigation 4.3% (6/139) of the screws encroached the pedicle compared to 14.3% (5/35) of screws inserted without navigations ($p=0.03$). The error for the CT-based navigation group was small (0.1 to 2.0 mm; 4/6 errors) or moderate (2.1 - 4.0 mm; 2/6 errors). All CT-based navigation errors were laterally located. The majority of errors of non-CT based were medial or inferior (4/5).

Yoo [130] compared anatomical and CT-based navigation techniques for screw insertion. They found that 40% of patients in the anatomical group had at least one screw perforation in the medial or inferior cortex compared with only 2.4% for patients in the computer-assisted group.

Merloz [81] compared spinal navigation (64 patients) and a control anatomical landmarks group (64 patients). It is not clearly stated how patients were assigned to each group. With anatomical landmarks there was 41% of pedicle errors (0-2mm errors = 0%, 2.1-4mm errors = 41%). With navigation there was 10.5% of pedicle errors (0.1-2mm errors = 1.5%, 2.1-5 mm errors = 9%). The anatomical group had 9% of cases with too long screws compared to 5% in the navigation group (3/64 cases). The authors caution about avoiding gaps in the CT-Scan data to avoid errors of navigation.

Laine [70] randomized 91 consecutive patients having pedicle screw fixation, to assess 50 patients with anatomical landmarks and fluoroscopy and 41 patients with CT-based navigation. The pedicle perforation rate was 13.4% in the conventional group (4-6mm errors = 1.4%; medial) and 4.6% with CT-based navigation (4-6mm = 0%; lateral) (P = 0.006).

Amiot[1] compared a historical cohort of patients operated by anatomical landmarks with patients newly operated with navigation. The error rate was 15% for the historical control group (83/544; 5 screws more that 4mm; 17/100 neurological complications) compared to 5% for the navigation group (16/294 screws; all 0.1 to 2mm; no neurological complications). Errors were quantified by MRI. They cautioned that MRI might overestimate errors compared to CT-Scan.

Schlenzka [113], compared anatomical landmarks to CT-based navigation. They found respectively 15.9% (23/145) and 4.1% (4/98) of pedicle perforation. CT-Scan images were done perpendicular to the screw.

Assaker [3] compared lateral fluoroscopy to CT-based navigation and found respectively 2 medial and 1 lateral perforations. Their CT images protocol used slices of 2 mm thick with 1.3 mm interval. The clinical accuracy required was 1 mm. They aimed to have the screw tip close to the anterior vertebral cortex. The length between the screw tip and the anterior vertebral wall was on average 10.7 and for the fluoroscopy group and 5mm for the navigation group. The insertion of a screw took 4 minutes for the fluoroscopy and 13.5 minutes for navigation. The author states that CT-based navigation is not absolutely necessary in lumbosacral spine but is very helpful in the thoracic and cervical spine.

In a cadaveric study, Austin[4] compared fluoroscopy and lamino-foraminotomy (to feel the pedicle) and CT-based navigation. They found a perforation rate of 14.29%, 10% and 0% respectively.

Concerns exist about the surgical time necessary to insert a screw. In a workshop in 2000, a registration time of 5 minutes per vertebra in open fusions was considered acceptable [14]. Kalfas [51] wrote in a review article that it takes 10-15 seconds to do the registration for pair-matching and 10-15 minutes for surface matching. However, surface matching registration was often inaccurate.

Kosmopoulos [61] performed a Meta-analysis of pedicle screw placement accuracy. They reviewed 130 studies on 37,337 pedicle screws and found in the lumbar spine that 864 screws were inserted with navigation and 1674 screws inserted without navigation. A weighted accuracy of 92.1% was found for navigation and 87.3% without navigation for the lumbar spine.

CT-based navigation for cervical and thoracic spine has showed high rates of pedicle perforations. In the cervical spine the 24% of the pedicles were perforated (13.4% small cortical breach, and 10.6% had a critical breach) [80]. CT-based navigation was superior to foraminotomy or anatomical landmarks (CT versus anatomical p=0.001, CT versus foraminotomy p=0.006). In a thoracic spine cadaver study, 19.2% of the pedicles were perforated [56].

**Table 3. 4 Literature review for lumbar pedicle error with pre-operative CT-Scan technique**

| **Year, Author** | **# screws / # patients** | **pedicle error %** | **Location of error** | **% nerve injury from screw** | **Insertion Method** | **Measurement method** |
|---|---|---|---|---|---|---|
| 1995, Nolte [97] * | 77/2 | 0% | NSt | NA cadavers | Preop CT-Scan | Coronal CT-Scan |
| 1995, Kalfas [52] | 150/30 | 13/150 (9%) with anterior | NSt | 0% | Preop CT-Scan | CT-Scan |
| 1996, Glossop [37] | 8/4 | NSt | NSt | NA cadavers | Preop CT-Scan | CT-Scan |
| 1997, Schwarzenbach [114] | 133/29 | 4/133 | Medial: 0% | 0% | Preop CT- | CT-Scan |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | (3%) | Lateral: 3/133 (2%)<br>Inferior: 1/133 (0.8%)<br>Superior: 0% | | Scan | |
| 1997, Laine [71] | 139/30 | 6/139 (4%) | Medial: 0%<br>Lateral: 6/139 (4%)<br>Inferior: 0%<br>Superior: 0% | 1% | Preop CT-Scan | Coronal CT-Scan |
| 1997, Yoo [130] | 36/6 | NSt | NSt | NA cadavers | Preop CT-Scan | CT-Scan |
| 1998, Merloz [81] | 64/32 | 5/64 (8%) | Medial: 3/64 (5%)<br>Lateral: 2/64 (3%) | 0% | Preop CT-Scan | Axial CT-Scan |
| 1999, Girardi [35] | 171/35 | 3/171 (2%) | Medial: 0%<br>Lateral: 3/171 (2%) | 0% | Preop CT-Scan | Axial , sagittal CT-Scan |
| 2000, Amiot [1] | 294/50<br>T2-S1 | 16/294 (5%) | Medial: 8/294 (3%)<br>Lateral: 4/294 (1%)<br>Inferior: 4/294 (1%)<br>Superior: 0% | 0% | Preop CT-Scan | MRI |

## E) Anterior error

The anterior error is not as frequently categorized in the literature. In the lumbar spine such errors occurred 3-10% of the screws compared to 4-6% for the thoracic screws (Table 3.5). The significance of such errors is uncertain.

Vaccaro[119] showed on post-operative CT-Scan after thoracic screw inserted in cadavers that many critical structures (diaphragm, aorta, azygos vein, esophagus, hemiazygos vein, inferior vena cava, right and left atria, parietal pleura and lung) were found within 5 mm of the anterior cortex. Liljenqvist [77] found one screw abutting the aorta in a series of 120 screws inserted in the thoracic spine using anatomical landmarks. That screw was removed to prevent aortic erosion.

**Table 3. 5 Anterior vertebral error for all techniques**

| Year, Author | Too long screws | Insertion Technique | Measurement Technique | Notes |
|---|---|---|---|---|
| 1996, Castro[10] | 13/131(10%) lumbar | CT-Scan | Axial CT-Scan | |
| 1997, Liljenqvist[77] | 3/120 (3%) lumbar | Anatomical | Axial, sagittal? CT-Scan | All in concavity of scoliosis |
| 1998, Merloz [81] | 6/64 (9%) lumbar | Anatomical | CT-Scan | |
| 1998, Merloz [81] | 2/64 (3%) lumbar | CT-Scan | CT-Scan | |
| 2001, Belmont | 17/279 (6%) thoracic | Anatomical | Axial/sagittal CT-Scan | Association with lateral pedicle perforation $p<0.0005$ |
| 2008, Modi | 27/320 (8%) lumbar | Anatomical | Axial CT-Scan | |
| 2008, Modi | 30/689 (4%) thoracic | Anatomical | Axial CT-Scan | |

## F) 2D-fluoroscopy Navigation

The 2D-fluoroscopy has been less studied than CT-based navigation (Table 3.6). The pedicle screw error of this technique is about 10% in the lumbar spine and 30% in the thoracic spine. The thoracic spine usually yields worse quality radiographs than 2D-fluoroscopy images. In the Rampersaud series, most of the pedicle errors with 2D-fluoroscopy were less than 2mm [102]. The author also found that for 49% of the screws, the diameter of the screw was bigger than the pedicle itself. The lack of 3D images for proper screw size planning in 2D-fluoroscopy is probably responsible for this phenomenon.

Studies using 2D-fluoroscopy navigation are presented here.

Merloz [83] compared the accuracy of pedicle screws using anatomical landmarks and conventional fluoroscopy (2004, 26 cases, 138 screws, T11-L5) to 2D-fluoroscopy (2004-2005, 26 cases, 140 screws, T8-L5). The definition for incorrect placement was a perforation greater than 1mm. The anatomical group had 13% of pedicle perforations (medial 7/140, 5%; lateral 7/140, 5%; and inferior 5/140, 4%) compared to 5% for the 2D-fluoroscopy group (medial 4/140, 3% and lateral 3/140, 2%). The amount of fluoroscopy time was less for 2D-fluoroscopy (mean 3.5seconds) compared to the anatomical landmark and fluoroscopy group (mean 11 minutes 30 seconds). The time to insert screw in one vertebra (2 screws) was 12 minutes for the 2D-fluoroscopy group compared to 10 minutes for the anatomical landmark group.

Sasso [110] compared the surgical time of a L5-S1 fusion in 43 patients (1995 to 2002) operated with anatomical landmarks and serial radiography to 59 patients (2000 to 2004) operated with 2D-fluoroscopy (FluoroNav). The average surgical time was 201 minutes for the anatomical landmark group compared to 162 minutes for the 2D-fluoroscopy group. The 2D-fluoroscopy has the advantage to not require a manual registration explaining partly the economy in surgical time. The authors have compared the results of 4 techniques for screw insertion: 2D-fluoroscopy using a single-reference frame (FluoroNav version 2.2), 2D-Fluoroscopy using multiple-reference frames (FluoroNav version 2.3.2), standard Fluoroscopy and CT-based navigation (Stealth Station). The radiation exposure to the specimens was 44 mrem, 2317 mrem, 121 mrem and 1833 mrem for those four techniques respectively. The error rate including anterior perforations was 69%, 14%, 26% and 31% respectively. The average time for inserting one screw was 3.3 min, 3.7 mm, 1.6 min and 6.8 mm, respectively. The authors concluded that navigation is not justified for insertion of thoracic pedicle screws considering the small improvement in accuracy, the increased surgical time (6X) and the increased radiations (20X) with these systems [88].

Lekovic studied compared the accuracy of 183 thoracic pedicle screws inserted 2D-Fluoroscopy (Fluoro-Nav) and 94 screws inserted with 3D-fluoroscopy (Iso-C-arm, Siremobil Iso-C 3D, Siemens AG, Erlangen, Germany). The authors found comparable accuracy when excluding lateral breaches (5.3% of errors with Iso-C and 8.7% with Fluoro-Nav)[76].

**Table 3. 6 Results of 2D-Fluoroscopy for insertion of lumbar screws**

| Year, Author | # screws / # patients | pedicle error % per screw | Location of errors | | | | % nerve injury from screw | Insertion Method | Measurement method |
|---|---|---|---|---|---|---|---|---|---|
| | | | Med | Lat | Inf | Sup | | | |
| 2000, Nolte[96] | 11/3<br>lumbar | 19 % of | 2/11<br>(18%) | 0/11<br>(0%) | 1/11<br>(9%) | 0/11<br>(0%) | 0% | 2D Fluoroscopy | CT-Scan |
| 2003, Euler [23] | NSt/12<br>cadavers | 17% of patients | NSt | | | | NA | 2D Fluoroscopy | NSt |
| 2003, Mirza[88] | 99/6<br>cadavers<br>thoracic | 69% | 0/99<br>(0%) | 37/99<br>(37%) | 67/99<br>(67%) | 0/99<br>(0%) | NA | FluoroNav single-reference | CT-Scan, inspection |
| 2003, Mirza[88] | 70/4<br>cadavers<br>Thoracic | 14% | 0/70<br>(0%) | 3/70<br>(4%) | 3/70<br>(4%) | 0/70<br>(0%) | NA | FluoroNav multiple-reference | CT-Scan, inspection |
| 2005, Rampersaud[102] | 360/45 | Lumbar 10.3%<br>Thoracic 31.6% | 25/360<br>(7%) | 30/360<br>(8%) | | | 0% | 2D Fluoroscopy | CT-Scan |
| 2006, Quiñones-Hinojosa [101] | 32/7<br>lumbar | 0% | 0% | | | | 0% | 2D Fluoroscopy | Radiography |
| 2007, Sasso[110] | NSt/59<br>L5-S1 | NSt | NSt | | | | NSt | 2D Fluoroscopy | CT-Scan |
| 2007, Merloz[85] | 140/26<br>T11-L5 | 5% | 4/140<br>(3%) | 3/140<br>(2%) | | | 0% | 2D Fluoroscopy | CT-Scan |
| 2007, Lekovic[76] | 277/25<br>thoracic | 35/277<br>(13%) | 4/277<br>(1%) | 18/183<br>(11%) | | | 0% | Anatomical | Axial CT-Scan |
| 2008, Kim[59] | NSt/10 | 0% | 0% | | | | 0% | 2D Fluoroscopy | CT-Scan |

## G) 3D-fluoroscopy Navigation

The only reports of 3D-fluoroscopy put the error in the range of 19% (Table 3.7). More clinical comparative studies are needed with this technology to comment on its superior accuracy.

In 2007, Lekovic [76] studied the accuracy of 94 thoracic pedicle screws inserted in 12 patients with 3D-fluoroscopy (Iso-C-arm, Siremobil Iso-C 3D, Siemens AG, Erlangen, Germany). The authors compared the results with 277 screws inserted with 2D-fluoroscopy (Fluoro-Nav virtual fluoroscopy). The results were presented in the thoracic section. There were 19% errors in the thoracic spine with Iso-C if we included both medial and lateral errors. Considering that there is no preoperative planning with Iso-C, some of the errors might have been related to oversize screws. The author confirms that the highest rate of pedicle perforations occurred in pedicles diameters ≤ 4mm diameters. The author also states the advantages of Iso-C: No preoperative CT-Scan (the lack of planning might not be an advantage), minimal exposure of radiation for the surgeon (same as pre-operative CT-Scan) and the ability of keeping the reference frame in one position (same as most pre-operative CT-Scan cases and of minimal benefit).

**Table 3. 7 3D-rotational radiographs for thoracic pedicle screws**

| **Year, Author** | **# screws / # patients** | **% error per screw** | **Location errors** | **% nerve injury from screw** | **Method of insertion** | **Measurement method** |
|---|---|---|---|---|---|---|
| 2007, Lekovic | 94/12 | 20/94 (19%) | Medial : 2/94 (2%)<br>Lateral: 18/183 (17%) | 0% | Anatomical | Axial CT-Scan |

## H) Intraoperative CT-Scan

Hamberland used 3 fiducial markers on the spine and proceeded with an intra-operative CT-Scan. He obtained a 1.9% perforation of the cortex. The technique is accurate but not easily available [40].

Holly wrote that the spine can be navigated intraoperatively with a CT-Scan [47]. The use of 2 mm diameter marker screws (implanted fiducials) on the spine simplifies the registration and increases the accuracy. This technology is costly, requires the use of a special operating room table and creates a difficulty with sterility.

## I) Ultrasound

Ultrasound has been studied mostly in the brain to solve the difficult problem of brain shift. Its application in spine surgeries is experimental. The team of Louis Collins is trying to find a solution for an automatic registration of preoperative CT-Scan image with an intraoperative ultrasound 3D data. To obtain images, the surgical field needs to be filled with water. This can easily be done in the spine. Quality of images is diminished by fat droplets, blood and residual soft tissue on the spine. Retractors to hold the muscles often block the view of the transverse processes.

Three different approaches to obtain 3D data are: slicing, volume rendering and geometric rendering [95]. From the reconstructed volume we can extract both orthogonal and oblique slices that help the observer understand the localization of the surgical tool like a biopsy forceps or an ultrasonic aspirator. Tools can be tracked and seen in the images.

Systems used for brain surgery are standard optical tracking system (NDI Polaris) and standard ultrasound devices. Lindner in 2006 used a 7.5 MHz probe and intraoperative 3D-Ultrasound during brain tumour resection to correct the brain shift [78]. The fusion of 3D-Ultrasound with pre-operative CT-Scanning is a 3D image registration problem. 3D intraoperative lower quality intraoperative images are augmented with preoperative CT higher quality images. As of 1999, ultrasounds were not creating good pictures, but improvement in the quality of ultrasound images could lead to more developments of this technology [14].

Nagelhus Hernes [95] showed that 4-8 MHz probes give high image quality at a distance of 2-6 cm from the probe within in the range of one vertebra. Recently, ultrasound images have improved in quality, thus making it worthwhile to investigate its application in the spine.

Muratore [93] used probes of 4.5 to 7.5 MHz. and did fusions with different CT-Scan slice thickness. System accuracy (average target registration error) was best with the thinnest slice thickness of the CT-Scan (2mm>3mm>5mm).

## J) Surgical Outcomes

### Clinical Outcomes and Measures

Recent literature uses the self-reported scales visual analog scale (VAS), Oswestry Disability Index and the Short Form 36 (SF-36) in assessing clinical outcomes.

The visual analogue scale measures outcome on a 10 cm line that the patient scores. The Oswestry Disability Index is divided in 5 categories: 1) Excellent (minimal disability) with a score of 0-20%, 2) Good (moderate disability) with a score of 21-40%, 3) Fair (severe disability) with a score of 41-60%, 4) Poor (completely disabled) with a score of 61-80% and 5) Very poor (bed-bound) 81-100%. These categories are interesting but arbitrary. The SF-36 includes more questions that need to be analyzed with software sold by a company (100% is healthy indicator). The value of these measures is obtained by comparing the preoperative state and the post-operative state.

The scales above are standardized and validated. They can be used to compare different surgeries and are for now some of the best outcome measurement tools available [36]. The best reported measurements came from Food and Drug Administration (FDA) studies [36]. Trials on intersomatic cages, artificial discs and bone morphogenetic protein-2 used Oswestry and SF-36 questionnaire for FDA approval. In 1993 when pedicle screws were evaluated by the FDA, these questionnaires were not available.

Glassman 2006 [36] used the Oswestry and SF-36 questionnaires. The authors reviewed 497 patients who were operated for a lumbar fusion of two or three vertebrae by 5 different surgeons. After a lumbar fusion both 1 and 2 years postoperative SF-36 and ODI demonstrated a significant improvement (p=.001). SF-36 Physical Composite Score (PCS) showed 9.9 points of improvement on average in 497 patients at 1 year and 9.5 points in 225 patients at 2 years. The Oswestry Disability Index showed 22.2 points improvement in 418/497 patients one year postoperatively and 22.1 points improvement in 141/497 two years postoperatively. Interestingly, the authors saw no difference between results at one year and two years after surgery. Patients with previous surgery had worse preoperative Oswestry Disability Index score and a worse outcome after surgery. At what score do we judge a significant improvement? A decrease of 10-points and more in the Oswestry Disability Index is considered as a significant improvement [36]. The FDA requires 15 points to define a good or excellent outcome. For SF-36 PCS scores, improvement or stabilization are accepted as an excellent or good result by the FDA.

In the same line of thought, a large series has been published (Swedish Lumbar Spine Study) [27,28]. The study included 294 patients with worse chronic (>2 years) low back pain than leg pain [67]. They found at 2 years postoperatively an improvement in the Oswestry Disability Index of 1.8 points in the fusion group with bone graft only, 14.8 points for the fusion with pedicle screws and graft and 8.8 points after a 360º surgery. Considering that the 360º group had a more solid fixation, this report shows that too extensive surgery is not always beneficial. Iliac crest graft site pain was present in 4.3% of patients after surgery.

**Fusion and Graft**

Significant post-operative morbidity comes from iliac crest bone harvesting. This is thought to be the best fusion material. Some recent reports are looking at alternatives to iliac crest graft. The recommendations on alternatives are difficult to follow as some of these trials are company sponsored and the criteria to determine a bony union is not clear.

Dimar [19] studied the results after a 2 vertebrae posterolateral lumbar fusion with pedicle screws and recombinant human bone morphogenic protein-2. The bone morphogenic group had less blood loss and a better fusion rate than the iliac crest bone graft group. Patients with residual iliac crest graft site pain after 6 weeks still had pain after 2 years.

Jenis [50] studied the use of autologous growth factors (AGF) in lumbar interbody fusion. CT-Scan done at 6 months showed a 56% (18/32 levels) fusion rate for autograft and 68% (15/22 levels) with AGF. The plain radiographs showed bony union in 85% for autograft and 89% with AGF (p=NS). The author stated that nearly 800,000 of bone grafting procedures are done in the US each year. Of these about 55% are done for spinal fusion and about 2/3 are done with iliac crest graft harvesting. Iliac crest graft complications include: pain, infection, hematoma and pelvic fracture. Iliac postoperative pain incidence ranges from 2.5% to 49%.

Sengupta [115] compared the outcome of local bone versus autogenous iliac crest bone graft in posterolateral fusions. The authors stated that iliac crest graft harvesting the complication of harvesting bone ranges from 1 to 39%. The authors compared 40 cases with local bone graft from decompression and 30 cases from iliac crest autograft during posterolateral fusion and pedicle screws. Solid bony union was found in 65% of the local bone group and 75% in the iliac crest bone graft group. Longer fusions had less bony union in the local group due to the lower amount of bone used. Blood loss was significantly less in the local bone group.

### Adjacent Level Degeneration

After a lumbar fusion, there is a significant risk of degeneration of the disc above and less often below. This phenomenon is dramatic as it can turn a patient with a good quality of life into an invalid. Theories to explain this are: the natural history, biomechanics, and above facet injury by a screw, rod or dissection. These articles try to find a reason for this problem. Most reports are retrospective. The estimated rate of developing adjacent segment disease is about 35% (Table VIII).

Biomechanical studies show that fusions increases the pressure of discs on non-fused segment [45]. Quinnell [100] showed in a biomechanical study of a floating fusion (not including L5-S1) that after fusion that the movement is transferred to the disc below and not above. This finding goes against the clinical observation that degenerations occur usually in the disc above the fusion. Yang [129] showed in a biomechanical experiment on human cadavers that the combination of compression and bending increased stress at the level adjacent to the fusion. Compression-torsion did not cause such stress. Nagata [94] showed in dog's cadavers that facet loading and lumbosacral motion were increased adjacent to a fixation with wire and methylmathacrylate. As the number of immobilized segments increased the load on the last disc (L7-S1 joint in dogs) progressively increased. Bastian [6] showed in a biomechanical study that after a T12, L1 and L2 fusion that only the level above had increased mobility contrary to the level bellow. Some interesting clinical studies have also been presented in the literature.

Schlegel [112] evaluated 58 patients who had adjacent segment disease and new surgery. Most degeneration occurred above the fusion. The most frequent diagnosis were stenosis (n=50), spondylolisthesis (n=13) and herniated disc herniation (n=7). In 36/58 (62%) two levels above the fusion had also degenerated. The symptom-free period was on average 13 years (2.6-40.0 years). This article included only surgical cases and do not represent patients where less severe degeneration. This type of study does not include patients that do not want surgery.

In 2004, Ghiselli [33] reported on a series of 223 patients with an average follow-up of 6.7 years after a fusion involving the lumbar spine. New disease occurred at a constant rate of 3.9% per year. The authors stated that adjacent segment disease is either caused by the natural effect of spinal degeneration or by iatrogenic effect of the fusion on non-fused segments.

Moshirfar [92] reviewed the rate of above facet joint violation by the implant after surgery on CT-Scan. He classified facet violation when the screw or the rod were clearly within the facet, were abutting or within 1mm of the facet. They found violation of the facet joint in 24% of patients and 15% of the screws. The most frequent level of injury was L5 after a L5-S1 fusion. Longer fusions were not as significantly affected. They concluded that this facet violation might be responsible for early degeneration.

In 2006, DeWald [16] presented on the complications for multilevel fusions. The study included more than 5 levels in patients over 65 years old. Iliac screws were used in 12/47 cases. They found 13% (6/47) of early (6 weeks) postoperative complications related to instrumentation. The average time to early complication was 7 weeks (range 1.5 - 12 weeks). A second early complication involved fracture of the adjacent cephalad vertebral body. Most complications were cephalad. Late progressive kyphosis was found in 32% of patients.

**Table 3. 8 Adjacent level disease**

| **Date, Author** | **# cases** | **ASD / ALD / BLD / time average** | **Levels most involved** | **Correlation** |
|---|---|---|---|---|
| 1988 Lee[74] | 18 ASD | 100% / NSt / NSt / 8.5 yrs | NSt | NSt |
| 1994 Whitecloud[125] | 14 ASD | 100% / NSt / NSt / 11 yrs | L3-L4 | |
| 1995 Penta[98] | 38/anterior lumbar | 32% / 32% / NS / 10 yrs | NSt | Not related to length of fusion |
| 1996Schlegel[112] | 58 ASD | 100% / NS / NS / 13 yrs | NSt | Adjacent level 100%<br>Adjacent to adjacent 62% |
| 1999 Wiltse[128] | 52/lumbar | 38% / NS / NS / 7 yrs | NSt | Less ASD with pedicle |

| | | | | |
|---|---|---|---|---|
| | | | | screws than non-instrumented fusion |
| 2001 Miayakoshi[90] | 45 / L4-L5 | NSt | NSt | |
| 2004 Lai [69] | 101/ L3-L5 | NSt/ 6.5% / 0% / 6 yrs if posterior ligaments preserved<br>NSt/ 24.3% / 5.6% / 6 yrs if posterior ligaments not preserved | NSt | |
| 2004 Ghiselli [33] | 215/ lumbar | 27.4% / NSt / NA / 6.7 years | NSt | 3.9% per year<br>Within 10 years new surgery 27% |
| 2006 Wai [121,122] | lumbar anterior fusion mostly L5-S1 | 74.3% / NSt / NA /20 years | NSt | MRI study. Normal discogram before surgery. Advanced degeneration was found in 30.7%. |
| 2007 Cheh [11] | 188 lumbar/thoracolumbar fusions | 43%/ 89%) /8%/7.8 years | L1, L2 and L3 | Increased ASD Patients aged more than 50 years, 4 levels disease |

ASD = Adjacent segment disease, ALD = Above level degeneration and BLD = Bellow level degeneration.

**Time for screw insertion**

The time to insert a screw is frequently indicated in the literature as a factor disfavoring the use of CT-based navigation (Table 3.9). The insertion time per level is less than 15 minutes per level with CT-based navigation and 5 minutes with anatomical landmarks.

**Table 3. 9 Time for screw insertion**

| **Year, Author** | **Time per level (min)** | **Time for 4 screws (min)** | **Time for 6 screws** | **Method** |
|---|---|---|---|---|
| 1992, Davne[15] | | 20-30 | 30-45 | Anatomical |
| 1997, Faraj [24] | 4 lumbar<br>6 thoracic | | | Anatomical |
| 1999, Girardi[35] | 13 lumbar | | | CT-Scan |
| 2001, Suk[118] | 16 thoracic with opening | | | Anatomical |

## Infection rate

In the literature the deep and superficial infections rate after a lumbar fusion are both around 1% (Table 3.10).

**Table 3. 10 Infection rate**

| **Year, Author** | **# screws / # patients** | **% infection per patient** | **% Deep infection per patient** | **% Superficial infection per patient** | **% Iliac crest site infection per patient** |
|---|---|---|---|---|---|
| 1992, Davne[15] | 2642/486 | 14 (3%) | 3 (0.6%) | 6 (1%) | 5 (1%) |
| 1996, Hamill[43] | 103/22 | NSt | 0% | NSt | NSt |
| 1997, Brown[9] | 759/223 | 1 (0.4%) | NSt | NSt | NSt |
| 2001, Suk[118] | 4604/462 thoracic | 9(2%) | 1(0.2%) | 8(2%) | NSt |

# CHAPTER 4 - Manuscript Presentation, Clinical Material, Methods and Results

My interest in intra-operative spinal image-guided neurosurgery started during a fellowship training in spine surgery in Toronto (July 2000-June 2001). Under the supervision of Dr Michael Fehlings, neurosurgeon, we used CT-based navigation for C1-C2 screw fixation. We also used 2D-Fluoroscopy (Fluoronav) for thoracic and lumbar pedicle screw insertion under the supervision of Dr. Raja Rampersaud, orthopedist. After this fellowship, I applied CT-based navigation for pedicle screw insertion in the cervical, thoracic and lumbar spine. CT-based navigation is also used for insertion of C1-C2 screws and iliac screws and planning of anterior approaches when complex combined anterior and posterior approaches are performed.

In 2003, we reviewed the data of the first 25 patients that had lumbar pedicle screws inserted with pre-operative CT-based navigation and we presented the data on a poster at the Canadian Congress of Neurological Science (Appendix 1). In 2005, I presented the results of the first 50 patients in a spine course at the Canadian Congress of Neurological Sciences and at the Association of Neurosurgeons of Quebec. In 2007, I reviewed the literature on CT-based navigation methods and presented our results at the American Association of Neurological Surgeons (AANS) meeting. .

The review of our 135 patients who had pedicle screws inserted by CT-based navigation is presented in this chapter in the form of a manuscript to be submitted to the Journal of Neurosurgery. The tables and pictures of this section are found at the end of the thesis after the discussion and conclusions as defined by the thesis regulations. The contribution of each author is as followed: Benoit Goulet collected the data, analyzed the data and wrote most of the article. Jean-Francois Couture entered the data in the JMP software data bank and helped to analyze the data.

Julie Pelletier helped with the data collection and the writing of the thesis. Lahbib Soualmi prepared the navigation images and helped with the surgeries. Jacques de Guise is the thesis co-director. Louis Collins is the thesis co-director and supervised the writing of the article and thesis.

The title of the article is: **Lumbar pedicle screw insertion with preoperative CT based navigation**

Goulet BG, Couture JF, Pelletier J, Soualmi L, deGuise J., Schwartz Z and Collins DL.

***Objective:*** The authors studied 135 consecutive patients following a lumbo-sacral fixation using pedicle screws and CT-based navigation to evaluate pedicle screw accuracy the clinical outcome.

***Methods***: The series included 44 men and 91 women (mean age 61 years, range 24-90 years). All 836 screws were planned with pre-operative CT-Scans in a navigation system (SNN, Surgical Navigation Network, Mississauga, Ontario, Canada) for diameter, length and direction. Fixation included the lumbar spines only (55), the lumbo-sacral spine (73) or the thoraco-lumbo-sacral spine (7). Pedicle perforation, screw length and spondylolisthesis were assessed on post-operative CT-Scan. Pain was surveyed using self-rated scales, visual analogue scales, Oswestry and SF-36 questionnaires. Bony union was assessed on post-operative follow-up radiographs.

***Results****:* Pedicle perforation was found in 49/836 (5.9%) screws (2.4% laterally, 1.7% inferiorly, 1.1% superiorly, 0.7% medially). The errors were minor (0.1-2mm, 46/49) or intermediate (2.1 – 4 mm, 3/49). All intermediate errors were lateral. There were no major errors (≥ 4.1mm). Some screws were judged too long (66/836, 8%). The average time to insert one screw with navigation was 19.1 minutes from application to removal of the reference frame. The amount of improvement at one year post-operation for self-rated leg and back pain were 72% and 48% respectively. The improvement was stable over 2 years. Above-level and below-level radiological degenerations were found in 44 patients (33%) and 3 patients respectively (2%) and occurred on average 22.2 ± 2.6 months after the surgery. Fusions ending at L2 had the most degenerations (14/25, 56%).

***Conclusion:*** CT-based preoperative navigation for lumbo-sacral pedicle screw insertion is accurate and associated with a good short term outcome, making it worth the investment of the additional time required. Segmental degeneration may have a negative effect on radiological and clinical outcomes.

KEY WORDS • CT-based spinal navigation • spondylolisthesis • transpedicular screws • lumbar fusion • segmental degeneration

***Abbreviations used in this paper***

ASD: Adjacent segment disease

ALD: Above level degeneration

BLD: Bellow level degeneration

DDD: Degenerative disc disease

MRI: Magnetic resonance imaging

NS: Not statistically significant

PSF: Pedicle screw fixation

SNN: Surgical Navigation Network

VAS: Visual analogue scale

PLIF: Posterior lumbar interbody fusion

## Introduction

Since the clinical introduction of lumbar pedicle screws in 1986 by Roy-Camille [107], surgeons have tried to improve their accuracy [123]. The insertion of lumbar pedicle screws using anatomical landmarks aided by fluoroscopy has a high rate of misplacements varying between 13 and 55% when assessed by post-operative CT-Scan [10,25,70,84,102]. Spinal CT-based navigation was introduced by Nolte in 1995 [97,101], nine years after the introduction of frameless cranial stereotaxy by Roberts [127]. CT-based spinal navigation has a misplaced screw rate varying between 4 and 7% [8,52,53,70,84], when measured by postoperative CT-Scans. The role of preoperative CT-based navigation for pedicle screw insertion is being challenged by other navigation modalities: 2D-fluoroscopy [26,30,96,101], 3D-fluoroscopy [2,47,49], intra-operative CT-Scan [40,41,47], 2D-3D registration [72], intra-operative ultrasound registration [95] of pre-operative scans, and robotics [5]. CT-based navigation has the advantage to be available in most centers that perform cranial surgeries. The aim of this study was to present our results on our series of pedicle screw fixation implanted with the help of CT-based navigation. We also present long-term follow-up. To our knowledge this is the biggest series of lumbar pedicle screws inserted with CT-based navigation.

## Clinical Material and Methods

### *Patient population*

Between October 2001 and July 2007, 135 consecutive patients (about 22 patients per year, 44 men and 91 women; mean age 62, range 24-90) underwent a posterior lumbar instrumented fusion. In 55 patients, the fusion was confined to the lumbar spine. In 73 patients, the fusion was done in the lumbo-sacral spine. In 7 patients, the fusion was extended to thoracic vertebrae and/or included iliac screws: T10 to iliac (n=2), T10 to S1 (n=1), T11 to iliac (n=1), T12 to S1 (n=2) and L2 to iliac (n=1). We fused on average 3.28 vertebrae per patient (range 2-8). All procedures were performed by one of the authors at the Montreal Neurological Hospital and Institute. The clinical presentation was combined back pain and leg pain in 124 patients (92%), leg pain alone in 5 patients (4%), back pain alone in 3 patients (2%) and claudication alone in 3 patients (2%) (Table 4.1). The most common indications for lumbar PSF (Pedicle screw fixation) were stenosis and degenerative anterolisthesis (n=85; 63%) or retrolisthesis (n=3; 2%) followed by degenerative disc disease (n=23; 17%) (Table 4.2). Eighteen patients (13%) had a previous lumbar surgery (Table 4.3).

### *Preoperative radiographic evaluation and computer techniques*

All 135 patients had a preoperative MRI, plain X-Rays (AP, lateral, flexion, extension) and preoperative CT-Scan for navigation (Picker 6000, Cleveland, Ohio; axial cuts with no angulation, 4mm slice thickness, 2 mm overlap, FOV 180 mm, Matrix 1024x1024, scan time 2 seconds, 175mA, 130kV) (Appendix 2). DICOM CT-Scan images are imported in the Spinal navigation unit (SNN, Surgical Navigation Network, Mississauga, Ontario, Canada). The navigation specialist performed spine segmentation and identification of anatomical landmarks on the pre-operative CT-Scan images. The surgeon adjusts direction, size and length of the pedicle screws on the system considering the proximity of the facet joint above and the general alignment of the screws for easy rod insertion.

On preoperative and postoperative CT-Scans, the amount of anterior or posterior spondylolisthesis was measured on sagittal reconstructed views at the midline of each vertebra. The listhesis was graded from I to IV (Meyerdeen's classification [86]) and in percentage of vertebral slippage.

### *Preoperative and postoperative clinical evaluation*

Patients verbally self-rated their average lower back and leg pain using a numerical scale from 0 to 10 on every visit. Patients completed a VAS (Visual analogue scale) scale (10 cm long) for back pain at rest, back pain with activity, right and left leg pain and postoperative iliac crest graft harvesting site pain. Patients rated the percentage of overall improvement and rated their degree of satisfaction after surgery (very satisfied, satisfied, neutral, dissatisfied and very dissatisfied). Patients filled before and after surgery an Oswestry disability index (ODI) questionnaire (0% = no disability, 100% = total disability), and a SF-36 short form questionnaire (8 dimensions for physical and mental health; 0 = worst health state and 100 = best health state) [120].

***Surgical technique***

Under general anaesthesia, the patients are placed in the prone position on a Maquet Alphamaxx Surgical Table (Getinge USA, Bridgewater, NJ, USA) with bilateral padded bolsters. The head is immobilized with a three point Mayfield clamp to avoid eye compression. The legs are kept straight at the hips and bent at the knee to maintain lordosis. The arms are placed forward on foams and arm-rests. Cell-saver was used routinely. The skin is cut in the midline. Dissection between thoracolumbar fascia and the fat is done to expose the left iliac crest for bone graft harvesting. After the exposure of the lamina and part of the facets, radiography is done to define the location of the pedicle using a metallic marker. The transverse processes are exposed to the most lateral aspect to be able to use as surgical landmarks. The interspinous ligament and the facet capsules of the segment above the levels to be fused are preserved [17].

Navigation reference frame is fixed on the spinous process above the levels to be fused. After an electronic failure of the dynamic reference frame used for first 30 cases, a passive reference frame was used for the remaining cases. We found no difference in the application of the navigation. With the navigation probe, six pre-selected anatomical points on the pre-operative CT-Scan are found on the spine anatomy (paired-point registration): Spinous process (2 points) and transverse processes (2 points each). Accuracy is verified with the pointer touching flat surfaces and edges typically at the top of the spinous process (Fig. 4.1), the sides of the spinous process, the laminae, the posterior aspect of the transverse processes and the superior and inferior edges of the transverse processes. A maximum of 1 mm discrepancy was tolerated. Otherwise extra paired-points were selected like the innominate process, laminectomy edge or previous instrumentation. A good 3D model is important for this application. Surface matching with a minimum of 20 points was tried but was seldom useful.

After simulation of the screw trajectory with the navigation probe, the entry point is drilled with a burr to show cancellous bone. A 3.8mm pedicle finder is used to canulate the pedicle stopping posterior to the expected anterior vertebral body wall usually 35-40mm of the posterior entry point. In sclerotic pedicles, we started the hole with a 4 mm burr and continued the tract with a hand drill. A ball-tip is used to feel pedicle breaches and measure the length of the created path. The navigation probe is plunged in the burred hole to confirm the trajectory before tapping and inserting the screw.

From T10 to L5, we aim for unicortical fixation within 5mm of the anterior cortex. At S1, we aim for a bicortical screw fixation within 5 mm past the anterior cortex. In the first 120 patients, we used the M8 system (Medtronic Sofamor Danek, Memphis, TN) available in 4.5, 5.0, 5.5, 6.5 and 7.5 mm diameter screws of different lengths. In the last 15 patients, we used the XIA-II system (Stryker Spine, Allendale, NJ), available in 4.0, 4.5, 5.0, 5.5, 6.5, 7.5 and 8.5 mm diameters of different lengths. At S1, we use 7.5mm diameter screws. From T10 to L5 we aim to put a 6.5 mm diameter screw or smaller depending on the navigation planning. The median screw size used was 6.5 mm for T10, T11, T12, L1, L3, L4 and L5, 5.5mm for L2 and 7.5mm for S1. The numbers of screws used per levels was: T10=4, T11=4, T12=6, L1=17, L2=59, L3=125, L4=220, L5=242, S1=159, Iliac=8. Iliac screws were inserted by navigation as well. Almost all screws (834/836) were implanted with navigation only. Because of a difficult registration at the S1 level in one case, both S1 screws were inserted with lateral fluoroscopy supervision. After all screws are in place radiography is performed to show the final position for all screws.

A laminectomy alone was performed in 71 patients. Laminectomy and discectomy combined were performed in 37 patients, supplemented by a double or single posterior lumbar interbody fusion (PLIF) or by an anterior lumbar interbody fusion (ALIF). We used three different types of cages: (PLIF cages, Telemon from Medtronics, Ontario Canada for bilateral cases); (TLIF cages, T-PLIF from Synthes Canada, Missisauga, ON for unilateral cases); ALIF cages, SynCage from Synthes Canada, Missisauga, ON). If there was not enough space for a cage, autograft iliac crest bone was used alone in the disc space. Inter-transverse and facet joint fusion was completed with autograft and laminectomy bone. We used, at the most superficial layer, graft substitutes if autograft was not sufficient (Demineralized bone matrix, Musculoskeletal Transplant Foundation, Synthes, USA; femoral head allograft or CanMix, pre chipped human cancellous bone (Regional Tissue Bank, Halifax, Canada or Pathology & Laboratory Medicine, Toronto, Ontario, Canada). Rods, cross-links, epidural drains and epidural analgesia catheters were inserted before closure.

### *Postoperative clinical and radiographic evaluation*

An axial CT-Scan with sagittal reconstructions was obtained in all 135 patients within two days of the surgery. The screws were assessed retrospectively by the assistants and the primary surgeon. On the axial views, we looked for pedicle perforations (medial and lateral) and for vertebral perforations (lateral and anterior) (Fig. 4.2 and 4.3). The lateral perforation measurements were cumulated with the anterior errors. On sagittal views we assessed pedicle perforation (inferior and superior), vertebral endplate perforations (Fig. 4.4) and residual spondylolisthesis.

The pedicle perforations in the medial, inferior, lateral and superior directions (Fig. 4.4 and 4.5) were classified using 2mm increments: minor error (0.1mm-2.0mm), intermediate error (2.1mm-4.0mm) and major error (4.1mm and more). This system is based on the anatomical observations, considering a safety zone of 2mm of epidural space and 2mm of arachnoid space [20,32]. The anterior vertebral measurement used 1mm increments as there is not anatomical reason to use 2mm increments (Fig. 4.6).

Follow-up visits were done at 6 weeks (83/135; 61%), 3 months (91/135; 67%), 6 months (89/135; 66%), one year (90/135; 66%), two years (51/135; 38%) and three years (11/135; 8%) postoperatively. The reasons for a low follow-up rate were that patient failed to come at the follow-up or chose to delay their appointments outside the planned calendar. To correlate the long-term adjacent segment disease effect on clinical deterioration, charts and radiographs were reviewed a second time in April 2009 to evaluate from the history and the self-reported back and leg pain if there was a deterioration of the condition. This evaluation was done by the surgeon that followed all the patients.

Plain lumbar radiographs were obtained at 6 weeks (AP & lateral) and at 3, 6, 12 and 24 months postoperatively (AP lateral and flexion/extension views) to assess intertransverse fusion and complications. Radiographic bony union was rated in 4 categories: 0/3 pseudarthrosis (motion on dynamic radiographs, visible halo around a screw or fracture of a fused vertebra); 1/3 fibrous union (absence of bridging osseous trabeculae without hiding the transverse process); 2/3 incomplete union (fusion with disorganized and/or granulated bone though hiding the transverse process); 3/3 complete union (continuous bone between hidden transverse processes). Adjacent level disease was defined as any significant changes above or below the fusion visible on available radiological examinations (Radiography, CT-Scan or MRI). MRI or CT-Scan was requested as clinically necessary.

### *Statistical analysis*

Confidence interval of 0.95 was used for all measurements. A Student t test was used to compare the pre-operative status with different intervals: low back pain (VAS with activity, VAS without activity, mean self-reported on 10), leg pain (mean VAS, mean self-reported on 10), self-rated overall improvement in percentage, Oswestry disability index scores, SF-36 scores (eight separated components, physical component and mental component). Contingency table (Pearson Chi square) was used for: comparing number of above level radiological degeneration (L2, L3, L4 and L5) and radiological degeneration with sex. One-way ANOVA test was used for comparing radiological degeneration with age, number of levels fused and radiological follow-up. One-way ANOVA was also used to correlate the time of radiological and clinical deterioration with sex. A two-way ANOVA was used to compare the time of radiological and clinical deterioration with age at surgery and number of vertebrae fused. A two-way ANOVA and regression line were used to compare the number of levels fused with the navigation time and the blood lost. A two-way ANOVA was use to compare improvement in listhesis and improvement in pain. Statistical analyses were performed using JMP IN 8 software (SAS Institute, Inc., CA, USA).

## Results

### *Clinical outcomes*

The mean self-rated lumbar pain was 7.0/10 preoperatively and improved to 3.0/10 at six weeks postoperatively (Fig. 4.5). The mean self-rated lumbar pain was stable for two years after surgery (p=0.0002). After one year, 84.0% of patients reported improvement in their pain, 5.2% were the same and 10.8% were worse. The VAS for back pain with activity and back pain at rest were both similarly improved at many intervals post-operatively (87 patients).

The mean right and left leg self-reported leg pain was on average 5.5/10 preoperatively and improved on average to 1.5/10 six weeks postoperatively (108 patients) (Fig. 4.6). The improvement was also stable for two years ($p<0.0001$). Postoperatively after one year, 88% of patients had improved or were the same for their self-reported leg pain, while 12% were worse. The VAS for leg pain followed the trend of self-reported leg pain (87 patients, $p<0.0001$).

At 6 months, 84% of the patients reported to be very satisfied or satisfied with their surgery (Fig. 4.7). Their satisfaction level was also maintained over two years. Overall, patients reported that they were improved 75% after their surgery (Fig. 4.8). Pain was found in the iliac crest graft site in 37% of patients at 6 months postoperatively and in 50.0% after 1 year. The VAS of the iliac crest graft did not significantly change over time: 6 weeks = 1.6/10, 3 months = 1.4/10, 6 months = 1.6/10, 1 year = 2.3/10 and 2 years 1.8/10. Severe iliac crest graft site pain (7/10cm or more on VAS) was found in 8.5% of patients six months postoperatively and was thought to be disabling.

The mean preoperative Oswestry score was 50/100 points and improved to 30/100 points 3 months postoperatively and was stable for two years ($p < 0.0001$) (Fig. 4.8).

The physical component of the SF-36 score was on average 29.3 points preoperatively and improved to 38 points at 6 months, and maintained improvement at 1 year and 2 years postoperatively ($p < 0.0001$) (Fig. 4.9 and 4.10). The mental score was not significantly improved in the follow-up period (45.5 preoperatively, NS) (Fig. 4.10).

The self-reported pain values were available in 62% of patients one year postoperatively and in 38% of the patients two years postoperatively. Some patients did not yet complete this follow-up or did not show up for follow-up. At one year postoperatively, VAS, Oswestry and SF-36 are available in 64%, 43% and 34% of patients respectively. Slightly more patients with worse outcome at 6 months completed the 1 year follow-up (77% vs 73%).

There was no statistically significant relation between improvement of pain with age, sex, fusion status, improvement of listhesis, operative time, navigation time, number of levels fused, smoking, allograft type, blood loss or screw diameter.

***Radiographic outcome***

Out of 836 screws (135 patients), pedicle perforation was found in 49/836 (5.9%) of the screws (Table 4.4, 4.5). We found 46/836 minor errors of 0-2mm, 3/836 intermediate errors of 2.1-4mm (all lateral) and no major error ≥4.1mm. Stated differently, CT-Scan showed 6 medial breaches (0.7%; all minor), 20 lateral breaches (2.4%; 17 minor and 3 intermediate), 14 inferior breaches (1.7% all minor) and 9 superior breaches (1.1%; all minor). No patients had a radiculopathy that could be attributed to an incorrectly positioned screw. The percentage of pedicle screw errors per level is at T10 = 0%, T11 = 0%, T12 = 0%, L1 = 1/17 (6%), L2 = 4/59 (7%), L3 = 8/125 (6%), L4 = 13/220 (6%), L5 = 20/242 (8%), S1= 3/159 (3%). At L5 the pedicle error were medial (2/242), lateral (3/242), superior (8/242) and inferior (7/242).

Overall we measured 66/836 (8%) screws that were too long (Table 4.6). From T10 to L5, 47/677 (7%) screws were too long on average 4.1mm (range 1 to 9mm) behind the anterior vertebral cortex. In S1 the screw tip ended on average 1.7 mm in front of the anterior vertebral cortex. In S1, 12% (19/159) of the screws were too long, more than 5mm past the cortex and 17% (27/159) of the screws were judge too short (range -11 to -0.1 mm). Significantly long screws (6-10 mm) were found in L4 (2%; 4/220) in L5 (8%; 2/242) and S1 (16/159, 10%). Some very long screws (11-15 mm) were found in S1 (3/159; 2%). A total of 25/836 (3%) screws were long or very long.

We did not have any vessel injuries from long and very long screws. The review of the CT axial cuts did no show any contact of the screw with big vessels. Over the years there have been a steady decrease of pedicle errors from T10-S1 and a length error decrease from T10-L5. No learning curve was found by length errors at S1.

We used on average 6.5mm diameter screws in all levels except at L2 (5.5mm) and S1 (7.5mm). The greatest variation in screw diameter was in L2 (Fig. 4.11) due to smaller size pedicles. In three cases, 7.5mm diameter screws were inserted from L2 to L5 because of oversized pedicles, osteoporotic bone or a revision of a broken pedicle. The data taken from operating room logs was available in 87 patients (64%).

Anterolisthesis (main level of listhesis) was found in 108 patients (80%) preoperatively with a mean slip percentage of 18% (range 3 to 47%). These listhesis were grade I in 83/135 patients (61%) and grade II in 25/135 patients (19%). Postoperatively, the mean value of main listhesis was 13% (range 0 to 47%). There was no difference in improvement in the percentage of spondylolisthesis with the use of an intersomatic cage (4.9%) or autograft chips alone (4.6%).

A second less important listhesis at another level was found in 26/135 (19%) patients preoperatively, with a mean slip percentage of 12% (range 3% to 23%). Postoperatively, the mean value of secondary listhesis was 9% (range 0 to 19%). A third listhesis was found in one patient with a slip percentage of 3%. None of the secondary or the third listhesis were instrumented with an interbody fusion. There was no statistical relation between improvement of listhesis and improvement of back pain or leg pain.

The bony fusion was assessed in all 90 patients (100%; 90/90) that completed their one year follow-up and in 36 patients (71%; 36/51) that completed their two years follow-up. A complete bony union by our definition was found in 66% of patients at one year and 50% of patients at 2 years. The mean fusion rate evaluated by our method was 2.7/3 after one year and 2.4/3 after two years. There were no correlation between the fusion rate and age, sex, improvement of listhesis, operative time, navigation time, number of levels fused, smoking, use of allograft, blood loss or screw diameter. We found a complete bony intertransverse union in 69% of patients with intersomatic graft or cage, and in 61% of patients without intersomatic fusion at one year postoperatively.

### *Procedure-related outcomes and complications*

Our most common complication was an adjacent level disease of the disc just above (total 47/135, 35%). We also found degeneration (40/135, 30%); fracture of above vertebra (4/135, 3%) and below degeneration (3/135, 2%); Table 4.7). Of all patients who had a fusion with the screws stopping superiorly at L2 had 56% of above level degeneration compared to only 17% when the fusion stopped at L5 superiorly (Table 4.8). Comparisons between groups showed a statistical significance (Chi square = 0.02). The main diagnosis for above level degeneration was: spondylolisthesis (n=16, posterior = 9, anterior = 5 and lateral = 2), scoliosis (n=12), severe degenerated disc (n=7), herniated disc (n=4) and stenosis (1). Below level diagnoses were: synovial cyst, disc degeneration and herniated disc. Females had more frequent degenerations (p=0.05) but the separated analysis of degenerated patients versus age was not statistically significant (p=0.1) (Tables 4.9 and 4.10). Radiological degeneration occurred in average 2.2 ± 2.6 months after surgery but clinical deterioration occurred later on average after 25.9 ± 3.0 months after surgery (Table 4.10). Older age and the number of fused levels were associated with more radiological and clinical deteriorations. Each extra level fused was associated with a 6.1 ± 2.5 and 7.0 ± 2.8 months of earlier radiological and clinical degeneration (Table 4.10). Radiological follow-up was longer for degenerated patients (40.3 ± 2.8 radiological and 24.0 ± 2.0 months).

Of the 6 patients with a fusion ending at T10, T11 or T12, all 4 complications occurred at the bottom of the fixation (two cases of iliac screw failures, one insufficiency fracture of S2 and one L5 bilateral screw pull-out in a patient who had a previous L5-S1 bony fusion). Other complications were instrumentation failure and pseudarthrosis (10/135 7%), procedural errors (3/135, 2%), deep infections (3/135, 2%) and superficial wound infections (2/135, 1%).

We re-operated on 13 patients for above level degeneration (n=7), screw pull-out (n=1), fracture of the top fusion vertebra (n=1), CSF leak (n=1), revision of bilateral iliac screw pull-out (n=1), removal of bilateral loose iliac screws (n=1). Out of these, 8 patients were improved after the second surgery and 3 patients did not see any change in their pain.

The average operating time from skin incision to closure for a one level fusion (2 vertebrae) was 7 hours and 31 minutes (451 min). Each extra vertebra increased the operative time by 59 minutes on average, in a linear fashion ($R^2$=0.41). It took 38.2 ± 5.2 minutes per level operated. On average, it took the 19.1 minutes to insert one screw including all the navigation steps. (123 minutes per patient, 18 minutes for the first 4 screws and 22.5 minutes for subsequent screws). There was a statistical correlation ($p<0.0001$) between navigation time and number of levels to be fused ($R^2$ =0.47) (Fig. 4.12).

The mean blood loss for a one level fusion (2 vertebrae) was of 587.4cc and about 1000cc for 4 vertebrae. Each extra level fused increased blood loss by 207.8cc on average, in a linear fashion ($R^2$ = 0.25) (Fig.4.13). There was a statistically signification correlation ($p<0.0001$) between the operative time and the blood loss, and between the navigation time and the blood loss ($p<0.0001$). For every minute of surgery, the mean blood loss was 2.2 cc.

## *Discussion*

### *Screws*

We found a total of 5.9% pedicle errors (49/836 screws; accuracy 94.1%). Our pedicle error with preoperative CT-based navigation is comparable to literature with an error rate of 4-7% when errors were assessed with post-operative CT-scan [8,52,53,82,113]. The error rate of lumbar pedicle screw insertion with anatomical landmarks is higher when screw accuracy is evaluated by CT-Scan (range 13-62%) [106]. High rates of errors are also found in the thoracic spine with anatomical landmarks only when assessed by CT-Scan (9-30%) [32,57,58,65]. Some of the reports excluded errors of 0-2 mm and did not analyze the superior and inferior errors so the published error rates may be underestimated.

A Meta-analysis of pedicle screw placement accuracy reports a mean weighted accuracy of 92.1% (864 screws) for screws inserted by navigation and 87.3% (1674 screws) for screws inserted without navigation in the lumbar spine (in vivo) [61]. Out of 35 methods of assessment of pedicle error used in the literature, the “in and out” technique is the most used in reports followed by the 2 mm increment classification presented by Gertzbein and Robbins in 1990 [32]. The most used method today uses 2mm increments.

In our study there were no major errors (≥ 4.1mm) and all 3 screws with intermediate errors (2.1-4.0mm) were laterally directed. No complications could be attributed to these lateral screws. All other errors (46/49) were minor (0.1-2mm), 46/49) within the epidural space. Therefore 100% of the screws were judged to be safe in relation to nervous structures. Some screws were judged too long (66/836, 8%). It compares to the 5% rate found in the literature [84]. Assaker [3] found that for screws from T10 to L5 inserted with preoperative CT-Scan, the mean distance from the anterior cortex was -4.1 mm. None of the screws caused vascular injuries. Some of these errors could have been prevented by a more conservative choice of screw length. Zindrick[135] found that there was no difference between a screw at 50% of the cortex and a screw close to the cortex for pull-out strength.

None of the patients had a radiculopathy post-operatively. In older studies of Gertzbein [32] and Castro [10], 5/30 and 2/40 of the patients respectively had screw-related radiculopathy. All cases had errors that were ≥ 6 mm medially. In general, recent literature reports 0% of neural injury except for one contemporary series that reported 6.6% of nerve injuries from screw malposition [115]. The low rate of nerve injury with anatomical technique insertion is an argument against spinal navigation. Randomized studies to prove the clinical superiority of one technique over the other would require a lot of patients.

Overall 8% of all screws were too long. It compares with the 5% rate found of too long screws reported in the literature [3,84]. At S1, the screws were intentionally inserted longer and the bicortical tips were adequately across in the anterior vertebra (passed the vertebral border by 1.7 mm on average giving a better fixation in the promontory of S1 [87,2]). Very long S1 screws (11-15 mm, 3/159, 2%) could have caused sigmoid injury. More conservative choice of screws is recommended. We could not achieve fixation to the midline of the sacral promontory as recommended by Kaptanoglu [54] due to limited muscle retraction. Trying such a trajectory in S1 has increased the risk of medial pedicle violation.

The greatest variability in pedicle screw diameter was used at L2 where the screw size implanted varied from 4mm to 7.5mm with an average of 5.4 mm. The mean outside pedicle width found in the literature at L2 is 8.9 mm (ranges from 4.0 to 13.0 mm) [63,134]. The error rate of pedicle screws in the lumbar spine was about 6% per level and slightly higher at L5 (8%). In the literature, L5 is the largest lumbar pedicle with a width of 18 mm (range 9-29mm) [134]. The translational and rotational errors for L5 are the largest with 3.8mm and 12º respectively [103]. The favourable anatomy for L5 screws was not reflected in our results. L5 is the deepest vertebra. To align the screw for easy rod insertion, the L5 screws have to be inserted more medially.

The error rate has improved over time. Earlier on in our study, we used fewer points for the accuracy check. Anecdotally some lateral errors were created by an insufficient muscle retraction during the screw insertion. Tracked pedicle finder and pedicle screw driver might help to diminish this error.

### *Clinical outcomes*

We saw a significant improvement in most clinical measurements (self-reported pain, VAS, Oswestry, and SF-36) comparable to the literature (Figures 4.5, 4.6, 4,7 4.8, 4.9 and 4.10) [19,36]. The improvement was maintained for 2 years. The back pain at six months follow-up was improved on average by 56%. The mean self-reported back pain improved from 7.0/10 to 3.1/10. The leg pain was improved by 80% (mean self-reported pain 5.5/10 to 1.1/10) at six months postoperatively. For the leg pain, the self-reported pain corresponded very well with the VAS. At 1 year 61% of patients are very satisfied and 28% are satisfied with the result of their surgery (89%). Patients rated their overall self-rated improvement to about 75% at 6 months, 1 year and 2 years (Fig. 4.8). Our results compare well with a series of one level fusion series where improvement in leg pain was 50% at 6 months, 45% at 1 year and 36% at 2 years [18]. Severe iliac crest site pain at 6 months was present in 8.5% of patients. This result conflicts with those of Dimar [19], where residual iliac crest graft pain present at 6 weeks was still present after 2 years. Alternatives to iliac crest grafting should be sought [50,115].

The Oswestry Disability Index (ODI) was significantly improved by 24.6 points at 6 months, 24.2 points at 1 year, and 19.1 at 2 years (Fig. 4.8). We fused on average two levels (3 vertebrae). Dimar reported for one level fusion similar Oswestry scores: 22.8 points at 6 months, 25.2 points at 1 year, and 21.4 points at 2 years [19]. Glassman [36] reports a lower improvement in the ODI score for 2 levels fusion (18.1 points at 1 year; 21 points at 2 years) compared to one level fusion (21.4 points at 1 year; 22.9 at 2 years). Ghogawala, in a selected study of grade 1 degenerative spondylolisthesis, found an improvement of 27.5 points at 1 year and found lower effectiveness of surgery in older patients [34].

The SF-36 physical composite score improved 7.7 points (29.3 to 37 operatively) at three months postoperatively and was stable for two years. The mental score was not improved (45.5 preoperatively). In Glassman's [36] study the Physical Composite Score (PCS) improved 9.9 points at 1 year and 9.5 points at 2 years postoperatively. Ghogawala found an improvement of 15.9 points at 1 year postoperatively but this study was limited to the level of spondylolisthesis and excluded revision cases [34]. Our study included 4 extensive fusion cases and yet still compares well with other studies.

### *Spondylolisthesis*

In our series, there was only 5% improvement in the spondylolisthesis percentage with the use of an intersomatic fusion cage (4.9% improvement) or not (4.6% improvement). In a series of isthmic spondylolisthesis [68], the amount of spondylolisthesis improved by 25% with a posterior lumbar fusion (PLF) and 21.8% after a PLF and an interbody fusion (PLIF). The clinical outcome did not differ between the two groups. Our low percentage of reduction is perhaps due to our non-aggressive paradigm for the insertion of big cages.

### *Bony Union*

Bony union was complete in 69% of patients with intersomatic graft or cage, and in 61% of patients without intersomatic fusion. We found a rate of 9% pseudarthrosis in all patients and 7% in patients with interbody fusion. Our method of quantifying the fusion has not been validated. Obvious fusion and pseudarthrosis were easier to assess. Other subgroup of our classification might not be reproducible. Pseudarthrosis was defined as no continuity in the fusion mass. Flexion-extension radiographs demonstrated an angulation more than 2° or a sagittal motion more than 2 mm [60]. In the literature [60, 68, 34, 50], some reported rate of pseudarthrosis after a lumbar fusion varies 6% to 56%.

### *Complications*

The overall above level degeneration rate was 33% (44/135). The rate of degeneration was 56% when the top screw stopped at L2 compared to 17% when the fusion is limited at L5-S1. The below level degeneration rate was 3/135 (2%). The literature reports a rate of above level degeneration between 1.4% to 36 [13,66,16,67]. Whitecloud [126] reported that L3-L4 was the most frequent level to degenerate above fusions. We found that more females have degeneration than males but sub-analysis of this factor showed it was not statistically significant. We found a correlation between the older age and the risk of above level degeneration. We also found a correlation between the older age and the risk of above level degeneration. Radiological and clinical degenerations occurred on average 22 and 25 months after the first surgery respectively. Radiological deterioration occurred on average 3 months before radiological deterioration. Each extra level of fusion speed-up six and seven months the risk of radiological and clinical degeneration. Our rate compares to 38% and 27% rate of segmental degenerations reported by Wiltse[128] and Ghiselli [33] after 7 years of a lumbar fusion.

Segmental disease was a frequent cause of morbidity in our study. Considering the early occurrence of segmental disease, the iatrogenic cause for the degeneration is favoured over a natural progression of the disease though our study cannot prove this statement. The preservation of the spinous process, the interspinous ligament and the facet joints above the fusion are important to diminishes the rate of above fusion [92,13,69] but was not proven by the study.

Of the 135 patients, 10% (14/135) needed to be re-operated with good results achieved in 67% (8/14). This compares with the rate of 13% re-operations reported in the literature [39].

The superficial and deep infection rates were respectively 1% and 2%. This complication rate is low considering the increased in surgical time with spinal navigation. Ghogawala [34] reports a 7% rate of deep infection for degenerative spondylolisthesis surgery.

### *Operation and navigation time*

The average operating time for a one level fusion (2 vertebrae) was 451 minutes. A study on 2 to 3 vertebrae fusion reports a surgical time of 294±59 minutes [50]. The extra surgical time is related to the navigation but also to requested time needed for the exposure of the transverse processes for navigation landmarks. Working with a designated navigation specialist is important in this regard.

On average, the time to insert a screw was 19.1 minutes. The navigation time per screw was 13.5 minutes in Assaker's series [3]. Davne found that it takes between 5 and 6 minutes to insert a screw with anatomical landmarks [15]. For our study, there was a linear correlation between the time of surgery, blood loss and each extra level to be fused. The mean blood loss for 2 vertebrae fusion was 587.4 cc and for 4 vertebrae fusion was below 1000 cc. Each extra level took us 60 minutes to put screws in and increased the blood loss by 200 cc. In the literature the blood loss was 766 ± 498 cc for 2 to 3 vertebrae fusions [50,115]. Sengupta found a positive correlation between time of surgery and blood loss [115].

### *Limitations of the study*

We are aware of the limited sensitivity of 86% of CT-Scans to detect titanium pedicle screw errors and the tendency for CT-Scans to oversize screw measurement [70,133]. CT-scan is still today the best way to evaluate the pedicle errors. Missing follow-ups, questionnaires and radiographs weaken some results. An independent radiological assessment was also not done. CT-Scans and MRIs were not done systematically on every patient to assess fusion rate and the adjacent level degeneration rate.

### *Conclusions*

We found that navigation was very helpful in most cases to understand the pedicle size, the screw direction, the pedicle ossification, the length of the screw and the alignment of screws for easy rod insertion. Preoperative CT-based navigation was shown to allow safe and accurate pedicle screw insertion in the lumbo-sacral spine. New navigational technologies are needed to allow safe and faster navigation [3,72,127].

# FIGURES AND TABLES of article

### Figure 4.1 – Intraoperative images of navigation screen

CT-based navigation display of a coronal 2D image (top left), of an axial image (inferior left), of a sagittal image (top right) and of a 3D reconstruction (bottom right). The tip of the navigation pointer is touching the spinous process. Bellow we see artefacts of a previous successful fusion with wires and grafts at L4-L5-S1. Because of stenosis and a degeneration of the L3-L4 disc, the fusion was extended to L3-L4.

[redacted]

Register:Patient Vertebra: L3

Tip To (in mm): Nearest Object

Reg-Landmark : 13

### Table 4. 1 - Symptoms before surgery

| | Number of patients | Percentage |
|---|---|---|
| **Back pain and leg pain** | 124 | 92% |
| **Leg pain alone** | 5 | 4% |
| **Back pain alone** | 3 | 2% |
| **Claudication alone** | 3 | 2% |

**Table 4. 2 - Indications for surgery**

| | Number of patients | Percentage |
|---|---|---|
| **Degenerative anterolisthesis (retrolisthesis in 3 cases included)** | 88 | 65% |
| **Degenerative disc disease** | 23 | 17% |
| **Spondylolisis** | 9 | 7% |
| **Diskitis, malignant spine tumour, osteoporotic fracture, herniated disc, scoliosis, synovial cyst** | 15 | 11% |
| **Failure of previous surgery (see below)** | 18 | 13% |

**Table 4. 3 - Previous surgery**

| | Number of patients | Percentage |
|---|---|---|
| **Discectomy** | 7 | 5% |
| **Laminectomy** | 5 | 4% |
| **Foraminotomy** | 2 | 2% |
| **Fusion** | 2 | 2% |
| **Laminectomy and discectomy** | 2 | 2% |

**Figure 4. 2** – Pedicle and length error measurement on axial CT-Scan

Axial CT-Scan cut of a vertebra with pedicle screws well positioned. The thin white arrow indicates where the medial pedicle error is measured. It is in the smallest area of the pedicle. The thick white arrow indicates where the lateral pedicle error is measured. The thick white straight line shows the anterior cortex. The measurement for anterior length error is done in the projection of the screw towards the anterior cortex. The measurement of the lateral length error is showed by thin white straight line.

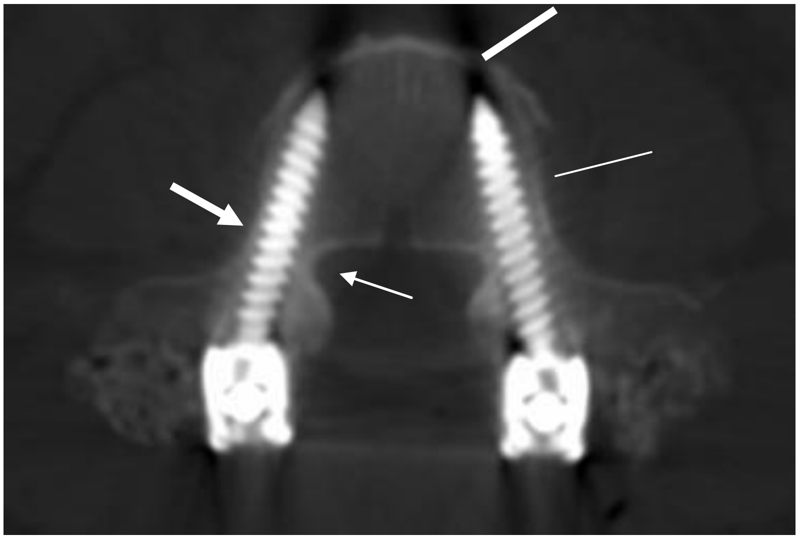


**Figure 4. 3** – S1 length errors

Axial CT-Scan cut of S1. Multiple axial views have to be studied to see the entire path of some vertebrae. The anterior length error of S1 screws is measured from the tip of the screw to the anterior vertebra (thick white arrow). The hypodensity in the left iliac crest represents the iliac crest site graft harvesting (Thin white arrow).

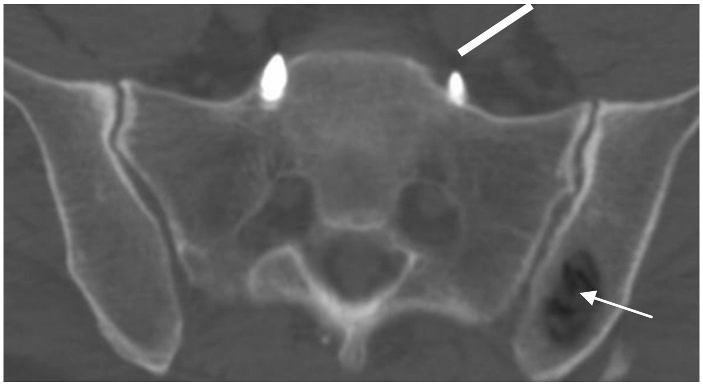


**Figure 4. 4** - T10-S1 sagittal pedicle error

CT-Scan sagittal reconstruction showing the superior pedicle error measurement (Thick white arrow) and the inferior pedicle error measurement method (thin white arrow).

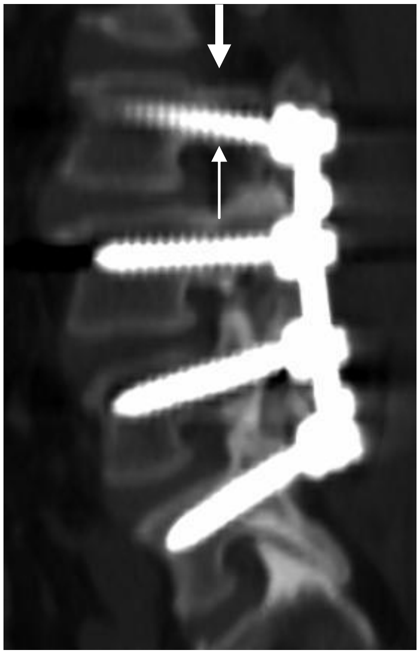
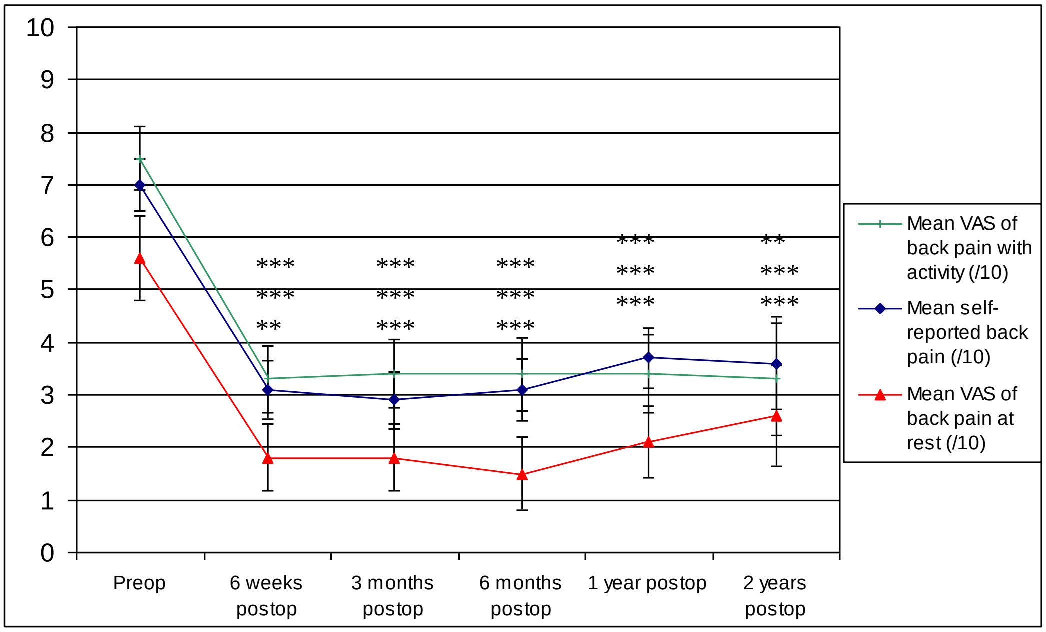


**Figure 4. 5 – Back pain measurements**

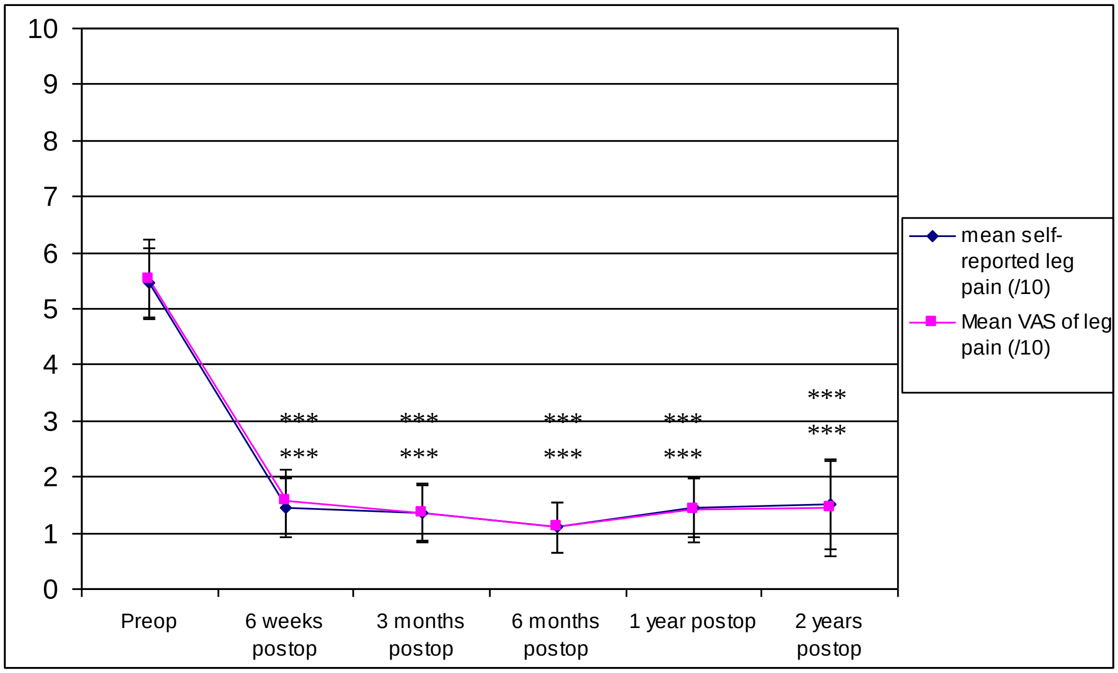
Mean values (0-10) and standard mean error of preoperatively and after five postoperative time periods.



** for p=0.0002 for each follow-up periods compared to pre-operatively, *** for p<0.0001 for each follow-up periods compared to pre-operatively

**Figure 4. 6** - Leg pain measurements

Mean values (0-10) and standard mean error of leg pain preoperatively and after five postoperative time periods.



*** for p<0.0001 for each follow-up periods compared to pre-operatively

**Figure 4. 7 - Satisfaction degree**

Percentage of patient's degree of satisfaction and standard mean error.

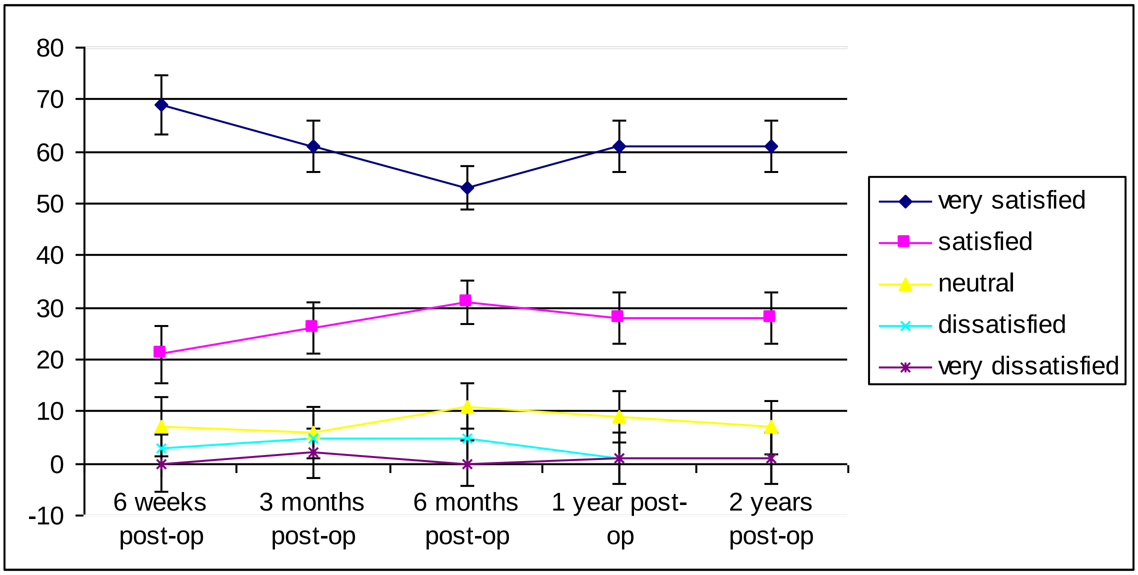
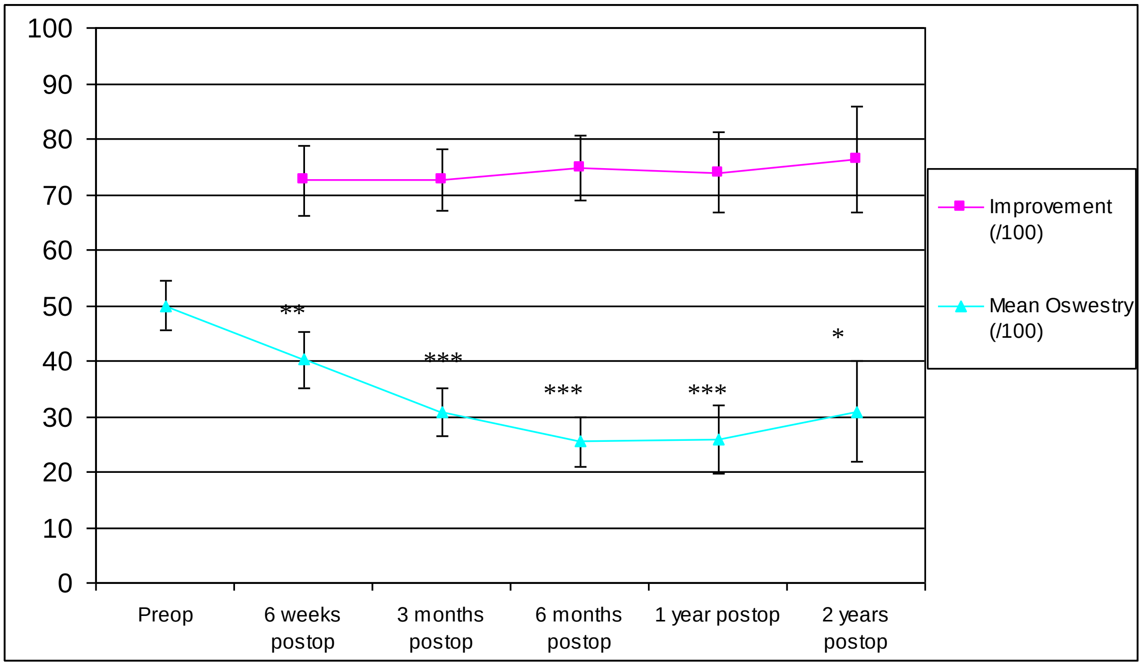


**Figure 4. 8** – Self-rated percentage of overall improvement & Oswestry Disability Index

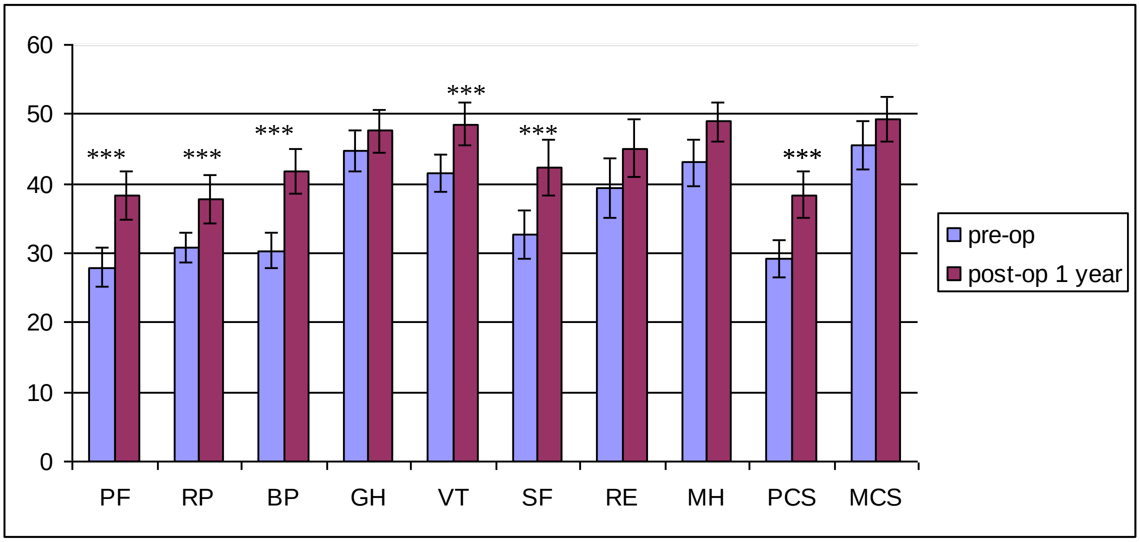
The top of the graph includes the mean overall improvement of the patients in percentage and the bottom is the value of the Oswestry Disability Index (0-100).



** for p<0.001 compared for each follow-up periods to pre-operatively, *** for p<0.0001 compared for each follow-up periods to pre-operatively, * for p<0.05 (p=0.002 at 2 years)

**Figure 4. 9** - Short Form SF-36 scores at 1 year follow-up

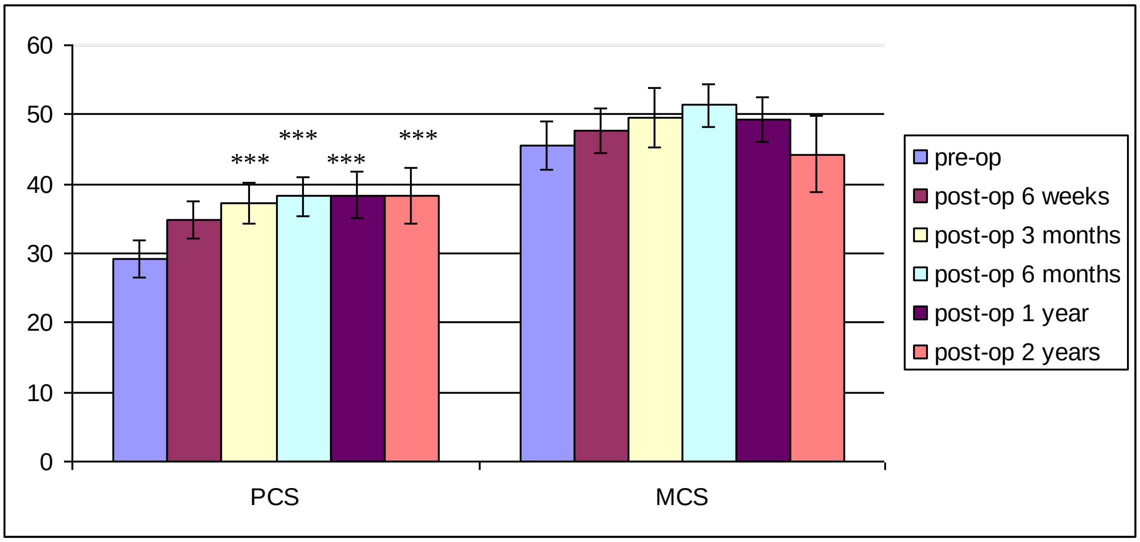
SF-36 preoperative and postoperative values after one year.



*** for p<0.0001 pre-operatively compared to post-operatively at 1 year

**Figure 4. 10 - Short Form SF-36 over time**

SF-36 physical and mental summaries preoperatively and postoperatively after 5 follow-up periods



*** for p<0.0001 preoperatively compared to each follow-up periods

**Table 4. 4** – Medial and lateral screw errors at pedicle level and length errors.

| | **Medial errors by categories** | | | | **Lateral errors by categories** | | | | **Total screws** |
|---|---|---|---|---|---|---|---|---|---|
| **Errors** | **Good screw** | **0.1-2.0mm** | **2.1-4.0mm** | **4.1 or more** | **Good screw** | **0.1-2.0mm** | **2.1-4.0mm** | **4.1 or more** | |
| T10 | 4 | | | | 4 | | | | 4 |
| T11 | 4 | | | | 4 | | | | 4 |
| T12 | 6 | | | | 6 | | | | 6 |
| L1 | 17 | | | | 16 | 1 | | | 17 |
| L2 | 58 | 1 | | | 56 | 3 | | | 59 |
| L3 | 124 | 1 | | | 119 | 6 | | | 125 |
| L4 | 220 | | | | 213 | 6 | 1 | | 220 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| L5 | 240 | 2 | | | 239 | 1 | 2 | | 242 |
| S1 | 157 | 2 | | | 159 | | | | 159 |
| Total | 830 | 6 | | | 816 | 17 | 3 | | 836 |

**Table 4. 5** - Superior and Inferior errors at pedicle level

| | Superior errors by categories | | | | Inferior errors by categories | | | | Total errors |
|---|---|---|---|---|---|---|---|---|---|
| | Good screw | 0.1-2.0mm | 2.1-4.0mm | 4.1 or more | Good screw | 0.1-2.0mm | 2.1-4.0mm | 4.1 or more | |
| T10 | 4 | | | | 4 | | | | 0 |
| T11 | 4 | | | | 4 | | | | 0 |
| T12 | 6 | | | | 6 | | | | 0 |
| L1 | 17 | | | | 17 | | | | 1/17 (6%) |
| L2 | 59 | | | | 59 | | | | 4/59 (7%) |
| L3 | 125 | | | | 124 | 1 | | | 8/125 (6%) |
| L4 | 220 | | | | 214 | 6 | | | 13/220 (6%) |
| L5 | 234 | 8 | | | 235 | 7 | | | 20/242 (8%) |
| S1 | 158 | 1 | | | 159 | | | | 3/159 (2%) |
| Total | 827 | 9 | | | 822 | 14 | | | 49/836 (6%) |

**Table 4. 6 - Length screw errors**

| | To long screws (n) | Average distance to cortex (mm) | Range (mm) |
|---|---|---|---|
| T10 | 1/4 (25%) | 0 | -4 to 1 |
| T11 | 0 | -5.5 | -7 to -3 |
| T12 | 0 | -5.0 | -10 to 0 |
| L1 | 0 | -4.9 | -7 to 0 |
| L2 | 0 | -4.9 | -14 to 0 |
| L3 | 5/125 (4%) | -4.5 | -13 to 9 |
| L4 | 13/220 (6%) | -4.2 | -17 to 7 |
| L5 | 28/242 (12%) | -3.5 | -14 to 7 |
| S1 | 19/159 (12%) | 1.7 | -11 to 12 |
| Total | 66 (8%) | | |

**Figure 4. 11 - Screw diameter per vertebra**

L2 vertebra had more variability in screw diameter than any other screws.

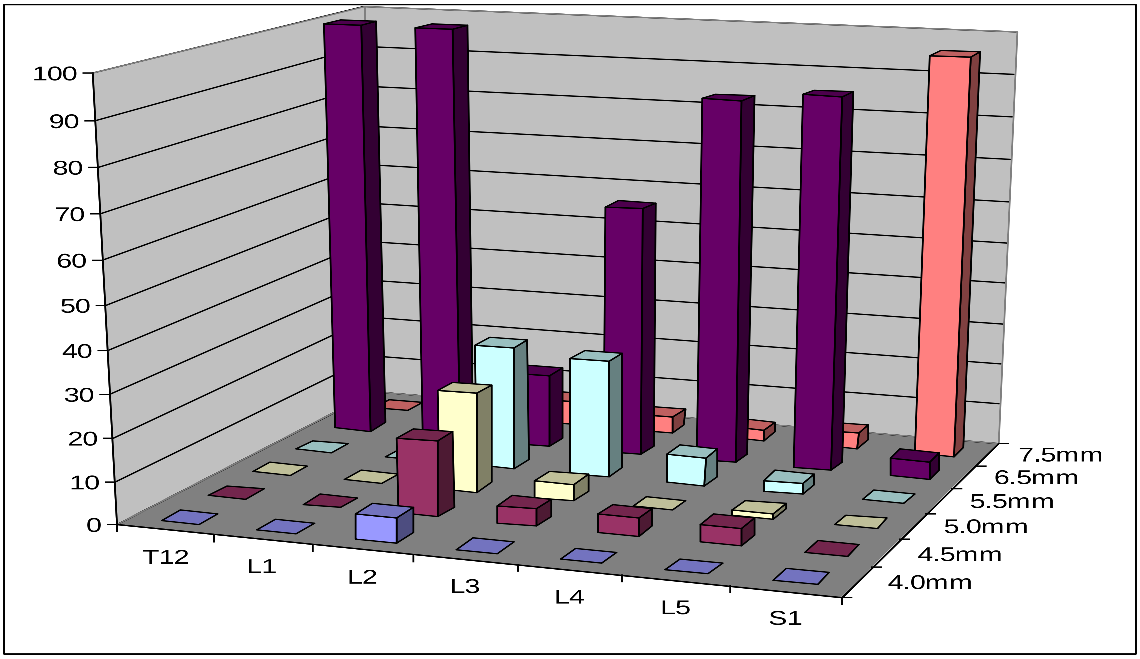


**Table 4. 7** - Major procedure-related complications

| | **NUMBER OF PATIENTS** | **PERCENTAGE** |
|---|---|---|
| **ADJACENT LEVEL DISEASE** | | |
| Above level degeneration | 40 | 30% |
| Above level fracture | 4 | 3% |
| Below level degeneration | 3 | 2% |
| **FUSION FAILURE (PSEUDARTHROSIS)** | | |
| Loosened bilateral iliac screws (halo around screw) | 2 | 1% |
| Iliac screw pull-out | 2 | 1% |
| Loosened pedicle screw (halo around screw) | 2 | 1% |
| Pedicle screw pull-out | 2 | 1% |
| Superior fused level vertebra fracture | 1 | 1% |
| Inferior fused level vertebra fracture | 1 | 1% |
| **PROCEDURAL ERROR** | | |
| L5 broken pedicle during screw insertion | 1 | 1% |
| Inadequate tightening of nut | 1 | 1% |
| Nut loosening in middle of fusion | 1 | 1% |
| **OTHER COMPLICATIONS** | | |
| Postoperative deep infection | 3 | 2% |
| Superficial wound infection | 2 | 1% |
| Below level fracture (deficiency fracture of S2) | 2 | 1% |
| Retro-psoas hematoma (Vessel close to transverse process) | 1 | 1% |
| Epidural hematoma (punctured post-op) | 1 | 1% |
| Postoperative mortality secondary to deep infection | 1 | 1% |
| Bilateral heal pressure wounds | 1 | 1% |
| Deep vein thrombosis | 1 | 1% |
| Misdiagnosed cause of pain: peripheral vascular disease | 1 | 1% |

**Table 4. 8** - Above level degeneration per level

Percentage of above level degeneration depending on superior fused vertebra: There is a progression of the percentage of above level degeneration as we approach L2.

| Levels | Highest screw (All cases) | Above level radiological degeneration per level | Lowest screw (All cases) | Below level radiological degeneration per level |
|---|---|---|---|---|
| T10 | 2 (2%) | 0 | | |
| T11 | 1 (1%) | 0 | | |
| T12 | 3 (2%) | 0 | | |
| L1 | 1 (1%) | 0 | | |
| L2 | 25 (19%) | 14/25 (56%) ** | | |
| L3 | 35 (26%) | 12/35 (34%) ** | | |
| L4 | 50 (37% | 16/50 (32%) ** | 9 (7%) | 1/9 (1%) |
| L5 | 18 (13%) | 2/18 (11%) ** | 47 (35%) | 2/47 (4%) |
| S1 | | | 79 (59%) | |
| Total | 135 | 44/135 (33%) | 135 | 3/135 (2%) |

** A contingency table of L2, L3, L4 and L5 showed that the Chi square = 0.02.

**Table 4. 9 - Comparison of levels with and without degenerations**

| | With radiological degeneration | Without radiological degeneration | Significance | |
|---|---|---|---|---|
| Number | 47/135 (36)% | 88/135 (64%) | | |
| F/M | 37/10 (76%) | 54/34 (62%) | p=0.04 | |
| Age | 64.3 ± 2.1 | 59.7 ± 1.6 | P=0.08 | |
| Number of levels | 3.2 ± 0.2 | 3.3 ± 0.2 | P=0.5 | |
| Radiological follow-up (mo) | 40.3 mo ± 2.8 | 24.0 ± 2.0 | p<0.0001 | |

**Table 4. 10 - Statistics on radiological and clinical degeneration cases**

| | Time of radiological deterioration | Time of clinical deterioration | Time of clinical-Radiological deterioration |
|---|---|---|---|
| Number / percentage | 47/135 (36%) | 39/135 (31%) | 39/135 (31%) |
| Surgery to deterioration (mo) | 22.2 ± 2.6 | 25.9 ± 3.0 | 3.3 ± 1.7 |
| Range (mo) | 1.0 -76 | 1.5 – 76 | -30 to 36 |
| Correlation with older age at surgery | P < 0.05 | P=<0.0001 | |
| For every year older, # mo sooner for degeneration | 0.4 ± 0.2 mo | 0.8 ± 0.2 | |
| Correlation with # of levels fused | P=0.02 | P=0.02 | |
| For every level fused number months sooner (mo) | 6.1 ± 2.5 | 7.0± 2.8 | |
| Correlation with sex | P=0.2 | P=0.3 | |

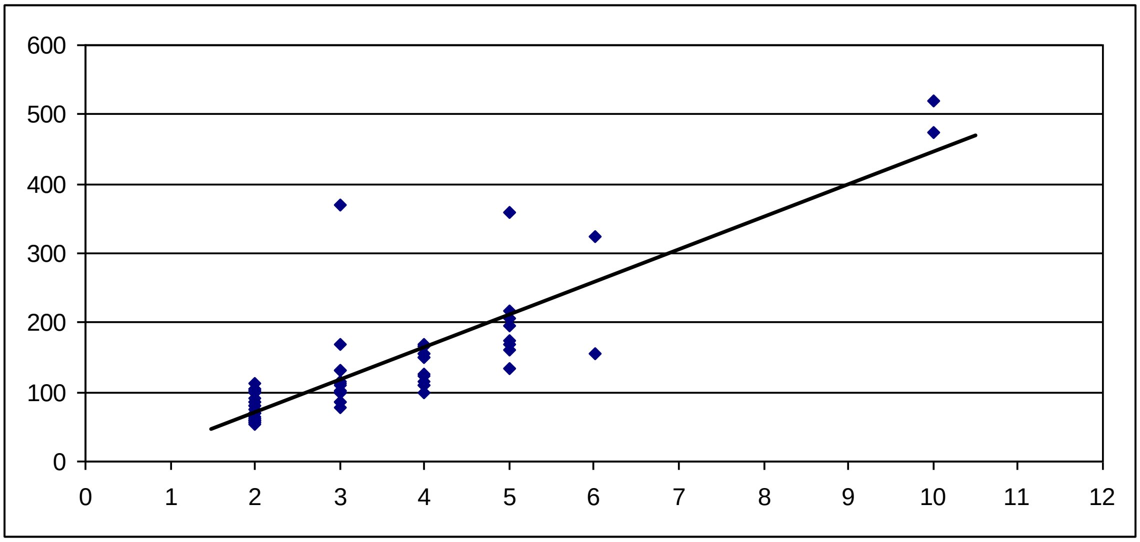


**Figure 4. 12** - Navigation time per number of vertebrae fused.

Navigation time (min) = 1.9 + 38.2 X number vertebrae. Test of variance Prob. > F <0001

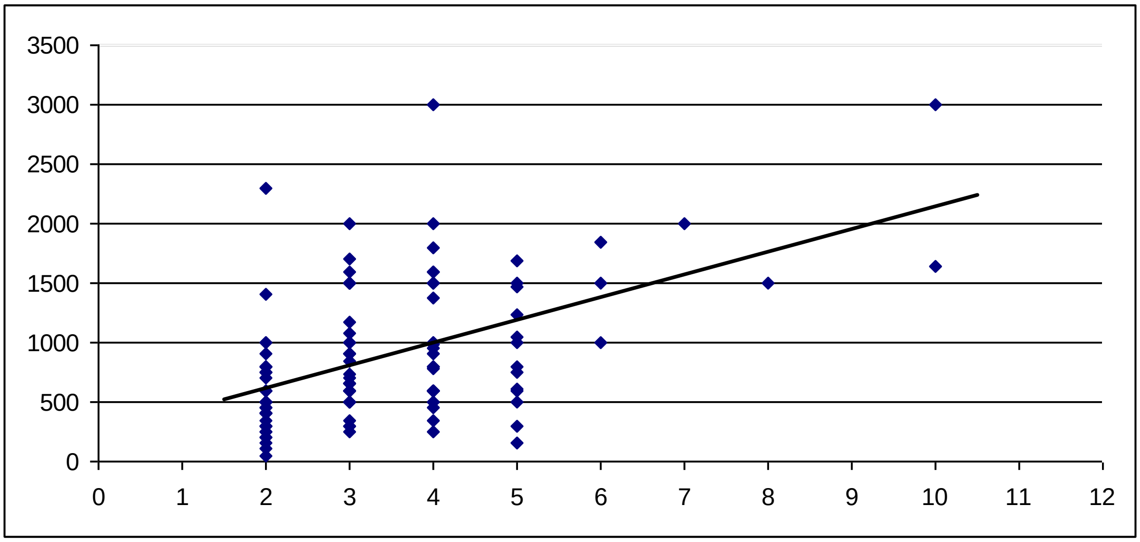


**Figure 4. 13 - Blood loss vs number of vertebrae fused.**

Navigation time (min) = 1.9 + 38.2 X number vertebrae. Test of variance Prob. > F <0001

# CHAPTER 5 – Discussion and Conclusion of the Thesis

## A) Historical perspectives

Spinal navigation has its origins in cranial applications. Zernov (1989), Horsley (1906) and Clark (1906) were pioneers in developing cranial navigation with a frame called stereotaxy [127]. Stereotaxy refers to the Greek words stereos meaning three-dimensional and taxy meaning organization. Nolte [97,101] introduced in 1995 spinal preoperative CT-based navigation in the spine. Since then, pre-operative CT-based navigation technologies did not change significantly.

## B) Discussion of our results

It is estimated in 1998 that about 250 000 spinal surgeries are performed every year in the United States [44]. In perspective, limited numbers of cases are being reported with the use of spinal navigation. A meta-analysis found a description of 37 330 pedicle screws inserted in the whole spine [61]. Of these, Kostopoulos analyzed only 864 screws that were inserted with navigation in the lumbar spine [61]. Our report was done on 836 screws inserted by the same surgeon with the same navigation system during a period of six years. To date this is the biggest series presented on lumbar pedicle screws inserted with CT-based navigation.

As stated earlier, the main problem of misplaced pedicle screws is the risk of nerve injuries, vascular injuries and mechanical failure. In the section on lumbar spine of this meta-analysis, the accuracy of pedicle screws inserted with anatomical landmarks aided with fluoroscopy was slightly inferior to screws inserted with pre-operative CT-

Scans. Respectively, the accuracies were 87.3% and 92.1% [61]. In studies using intra-operative fluoroscopy (or plain radiographies) for screw insertion, an error rate of 14-62% was reported when validated with on post-operative CT-Scans [10,32,81,113]. The variation between studies is explained by different time periods when the surgeries were done. Early reports include inexperienced surgeons. Also reports used different methods of measurements of pedicle screw errors. In studies using CT-based navigation for screw insertion, an error rate of 4-12% was reported on post-operative CT-Scans are used for validation [52,73,113,114]. Studies comparing manual insertion and pre-operative CT-based navigation showed less pedicle screw errors with CT-based navigation [1,70 ,53, 81 ,130,71].

The problem with the literature is that many different ways of measuring errors were used to quantify the errors. As stated by Kosmopoulos, there are 35 ways to quantify screw errors [61]. Fortunately, errors reported were rarely associated with nerve root injuries. The reported nerve root injuries usually occurred with the screws perforating the medial of inferior pedicle where the nerve roots are closest to the pedicle. Laterally and superiorly the nerve structures are far from the nerves and the dural sac. Most errors in the literature occurred when the screw is located ≥ 5 mm within the spinal canal or within the foramen. The classification of the pedicle error should include the location of the error in the pedicle with respect to these four quadrants. Most reports evaluated axial CT-Scan only without looking at sagittal or coronal reconstructions to assess the superior and inferior errors. These reports might have underestimated the true error rate of pedicle screws. Fortunately important pedicle errors are rare and explain why most series reported 0% nerve injury. In our series we found that the pedicle screws were accurately inserted within the pedicle in 94.1% of cases. None of the errors involved a nerve or had the potential to injure one.

In our report we used a modification of the system described by Gertzbein in 1990 [32] to better quantify error. Gertzbein divided the error medially and laterally but did not define the superior and inferior errors. The authors categorized the error using intervals of 2 mm: 0-2 mm, 2.1-4.0 mm, 4.1-6 mm and 6.1-8.0mm [32]. This method is based on the anatomical observation that there is 2mm of epidural space and 2mm of arachnoid space form T10 to L4 [32]. Gertzbein wrote that 4 mm of canal encroachment can be tolerated without risk of the spinal cord or cauda equina injuries and called this space the "safe zone"[32]. We think that the terminology of "tolerance zone" would be more appropriate. The lateral errors were only classified as in or out of the pedicle in Gertzbein's classification. The inferior and superior errors were not quantified. Some reports on thoracic screws have excluded errors of 0-2 mm and did not include the superior and inferior errors. These reports which are using the anatomical (free hand technique) underestimate the screw errors [57,58,65,104].

In our study we applied a 2 mm interval to quantify errors in all four quadrants of the pedicle. Using this classification, the pedicle errors were 2.4% laterally, 1.7% inferiorly, 1.1% superiorly and 0.7% medially. The majority of errors were within 0.1-2mm for 5.5% of the screws (46/836). Considering that the average screw measured 6.5 mm, a 2mm error constitutes a break by the screw threads only. In our series, only three screws (3/836, 0.4%) had breached the pedicle in the 2.1- 4 mm range (intermediate). Those three errors were all lateral. A lateral error of 4mm for a 6.5 mm diameter screw might have exposed the shaft of the screw and possibly cause a mechanical weakness. No clinical consequences were observed for these intermediate errors. Overall none of the screws had the potential for a nerve root injury.

Overall we found that 8% (66/836) of the screws were too long. From T10 to L5 measures, screws are routinely inserted monocortically. The thoraco-lumbar screws ended on average 4.1mm (range 1 to 9mm) posterior to the anterior vertebral border. Of the 677 of the thoraco-lumbar screws, excluding S1 screw, 47 screws were too long. Significantly long screws within the 6-10 mm range were found in 2% of L4 screws inserted and in 8% of L5 screws. The aortic and inferior vena cava bifurcations are located at about L4-L5 disc level. Any perforation above the bifurcation may have injured the aorta or inferior vena cava and any perforations could have injured the common iliac arteries and veins [84]. Length errors are thought to be related to the fact that bone over the screw entry point is often removed to expose the cancellous bone. The length of the screw was estimated by the navigation system, but the final length chosen was defined by a depth gage. The surgeon was also probably not conservative enough in the choices of screw length.

For S1 screws, most surgeons perform bicortical screw fixation. To obtain this extra cortical strength, just a few screw threads need to pass the anterior cortex. This represents a couple of millimetres. At the S1 level, the common iliac arteries and veins are lateral thus leaving the midline unoccupied by vessels. However, the sigmoid (colon) is located anteriorly to the sacral promontory with some fat protecting it from the screw tip. In our study we found that the screws were on average 1.7 mm in front of the anterior vertebral cortex. Screws too long, within 0 to 5 mm of the anterior cortex, were considered acceptable in our study. Overall 17% of the screws tips passed the anterior cortex by 6 to 10mm. Of concern 2% of the screws were very long by 11-15 mm. CT axial cuts were reviewed after the observation for all these screws. No screw tips did impede vascular structures seen as round shapes. S1 is more at risk of having too long screws. The antero-posterior length of the sacrum is longer closer to the endplate and diminishes rapidly inferiorly. If the screw is aimed too inferiorly a selected screw length will soon be too long. To avoid such length errors we are now more conservative, accepting screws that catch the anterior cortex with minimum perforation.

We could not achieve fixation to the midline of the sacral promontory as recommended by Kaptanoglu [54] due to limited muscle retraction in the majority of our cases. From our experience on 135 cases with pre-operative CT-Scan, we found that trying to aim at the midline would need excessive retraction on the muscles. This screw angle forces a more medially entry point and increases the risk for a medial error.

The average time to insert one screw with navigation was about 20 minutes from application to removal of the reference frame. That time to insert a screw is too long for most experienced spine surgeons. In scoliosis cases where many screws are inserted, the extra time for the navigation could be excessive. In shorter fixations at one or two levels, the increased surgical time might be out weighted by the benefits of navigation. The extra time to perform surgery did not have a significant effect on the infection rate. The causes for this long time of navigation include: the surgeon not personally registering the reference points on the images, the technician not finishing the registration points before the surgery, the anatomy not being exposed enough, the tip of the transverse process being too far, the navigation system shutting down, the system running slow due to the large amount of vertebrae imaged, the surgical team displacing the reference frame, the surgeon wanting more accuracy from the system, the screws are not ready or contaminated. Faster times should be aimed for.

The navigation time could be diminished if the team would be more ready, if the scans were of better quality, if the computer were faster, if the instruments were tracked or if the surgeon accepted less accuracy out of the system.

We did not systematically study in which clinical situation navigation was the most useful. Anecdotally we found navigation very useful when the pedicles were completely calcified as a consequence of degeneration, especially at L5. It is our opinion that without navigation these cases would have been done with difficulty considering that these patients had also very big facet joints and distorted anatomy. Navigation was also useful in previously operated patients who had laminectomies, when the pedicles were small and in males with a narrow pelvis. In this case, the screw will be aimed laterally. Navigation was also useful for planning the proper screw size and orientation.

The amount of improvement one year postoperatively of self-rated leg and back pain were 72% and 48% respectively. The improvement was stable over 2 years. These results compare favourably with the literature.

Of a less encouraging nature, 30% (40/135) of patient develop above level radiological degeneration, 3% (4/135) of above level fracture and 2% (3/135) of below level degeneration. We found that the clinical deterioration occurred about three months after the radiological deterioration. It is expected that radiological deterioration will occur before clinical deterioration. Females had degeneration more frequently than males. Degenerated patients were older, with a mean age of 64 yrs in degenerated cases and 60 years for non degenerated cases. The number of levels fused was similar for both degenerated (3.2) and non-degenerated (3.3) groups. The radiological follow-up was longer for degenerated groups (40 months) compared to non-degenerated groups (24 months). This can be explained by the fact that patients with degeneration symptoms will usually consult more often and for a longer period of time after surgery.

Degeneration above a fusion was frequent problem in our series. We found a high correlation between the development of radiological degeneration and the clinical deterioration. Adjacent segment disease affected the quality of life of many patients that had a good initial result with fusion surgery. The cause of this problem is not defined and good solutions are not clearly found in the literature. During the surgery, the surgeon should be careful with the facet joint capsule of the level above the last screw. The screws and rods should not interfere with the above facet. Above the fusion, the spinous process and interspinous ligaments should be preserved to diminish the risk of above level degeneration [13,46,69,92]. Limiting the number of levels to fuse is another option, however, it carries the risk of an accelerated degeneration. In our study, fusions ending at L2 had the most degenerations (14/25, 56%). It might be better to extend the fusion to the thoracic spine rather than ending the fusion at L2.

There are some limitations to preoperative CT-based navigation. In the spine and especially in the lumbar spine, navigation is not used routinely despite its accuracy. The long and difficult process of registration has prevented its wide-spread use. Because each vertebra has to be registered separately with paired-point matching and surface matching, the whole posterior anatomy has to be exposed. In the spine, only the posterior elements are available for registration limiting the full 3D representation of the volume. Spinal navigation involves expensive equipments and a trained navigation specialist and may not be available in centers that don't already use navigation for cranial surgery.

Inherent errors of the navigation system were not studied. The CT-Scan images are done with 4mm slice thickness and 2 mm overlap. The navigation systems have inherent errors also. The planning of screw by the surgeon is a source of errors. In our study we used a navigated pointer to define the trajectory of the screws and the entry points, but all other instruments were not tracked (pedicle finder, tap and screw driver). The planned trajectory might have been changed while using other non-navigated instruments. All right sided screws were inserted by the primary surgeon. Some of the screws on the left side of the patient were inserted by assistants and some were inserted by the primary surgeon depending on the difficulty of the screw and the operative experience of the assistant.

Considering that there was no log of who inserted the screw, this error factor was not studied. One of the advantages of navigation is that the primary surgeon can have some control over the screws inserted by the assistants.

We are aware that CT-Scans can overestimate screw size and give false measurements of errors [70,133]. CT-Scan is still the best way to eliminate pedicle errors.

Missing follow-ups, questionnaires and radiographs are a major concern about this study. This study was done with minimal funding. Busy spine clinics prevented the supervision of the handling of questionnaires. An independent radiological assessment was not done. CT-Scans and MRIs were not done routinely post-operatively but were requested if new significant symptoms were present. Almost all patients had plain radiographs done systematically at most visits. Serial plain radiography was useful to document significant progression in the degeneration process above or bellow operated levels.

Easier navigation is done with a computer engineer who takes care of images before and during surgery. A registration accuracy of 0.5mm to 1mm is desired. During our study, we found that paired-point registration was the most robust. It could be improved by extra discrete anatomical landmarks. Surface matching registration did not improve in most cases the correspondence between the patient and the navigation image. This was not quantified, but was repetitively observed.

## C) Other navigation techniques

In our literature review we presented other methods of navigation. Other means of navigation have been developed to complete an automatic registration. These techniques are new, expensive, incompletely validated, and surgeons do not have experience with them.

2D-fluoroscopy uses plain radiographs. Its accuracy is in the range of 90% for lumbar pedicle screws [102]. It also allows minimally invasive procedure to be performed. The main drawback is the absence of 3D view of the anatomy for planning. It does not predict screw sizes well [102].

The 3D-fluoroscopy has allowed 3D visualization of pedicle path and intraoperative updates. Images are still of low quality. Before considering acquisition of such a machine, surgeons need to visit other centers that have the technology to see in reality the results obtained with its use.

The 3D-3D registration with ultrasound is an avenue studied in our laboratory with recent improvement in ultrasound image quality. This might become a good solution for an automatic registration for centers that already have CT-based navigation capacities. The 2D-3D registration with radiographs has not yet reached the significant accuracy needed to be used clinically.

Intraoperative CT-Scanning with internal fiducials has the best clinical accuracy [40]. These machines are fixed on the floor and need special operating room tables. Newer portable intraoperative CT-Scans are available on the market.

This technology is expensive and the results of its use are not spread yet in the literature. Our institution bought an intraoperative CT-Scan (O-arm, Medtronics). We will soon start to use it for pedicle screw insertion. This could enhance our ability to do minimally invasive procedures in all parts of the spine. Robotic spine surgery is still in its infancy.

These new technologies have to be evaluated in detail before their acquisition. The cost-effectiveness is difficult to demonstrate and their application requires changes in the operating room and in the spine navigation unit. These new technologies will probably replace preoperative CT-based navigation in the future. CT-based navigation may remain as a planning tool.

## D) New research ideas

For adjacent level disease a randomized study can be done. Patients that need surgery for spondylolisthesis and stenosis might have other degenerated levels above and bellow the fusion. These patients can be randomized in two groups. One group of patients can have an extension of the fusion above or below the main degenerated levels. The other group would have fusion only of the most significant levels and observation of the other levels. Such a study will need long term follow-up with serial MRIs and radiography.

L5 has the most degree of freedom for alternate screw angulation and translation. In surgery this variation is limited by muscle retraction. Variation in the translation and angulation of the screw entry point can be measured and recorded with the navigation system and studied after the surgery for all vertebrae imaged.

We will also continue to study intraoperative 3D-Ultrasound in the laboratory of Professor Louis Collins. Finally pre-operative CT-based navigation can be compared to intraoperative CT-Scan in a randomized fashion.

## E) Conclusions

Despite superior accuracy with CT-based navigation found in the literature, why are not more surgeons using this technique? The major difficulty with CT-based navigation technology is the required manual registration of the spine. Spinal navigation is time consuming, needs a navigation system, needs technical support or is considered unnecessary by experienced surgeons. Intuitively, pedicle screw insertion should be 100% within the pedicle without any cortical wall violation.

Our results show that spinal image-guided surgery with the use of pre-operative CT-based-navigation can help safely and accurately insert pedicle screws in the lumbar spine. The increased surgical time is a concern. Ways to diminish the registration time are being tested, but registration is an unavoidable step of the technique. In the end, the time spent to obtain a good registration gave worthwhile radiological and clinical results.

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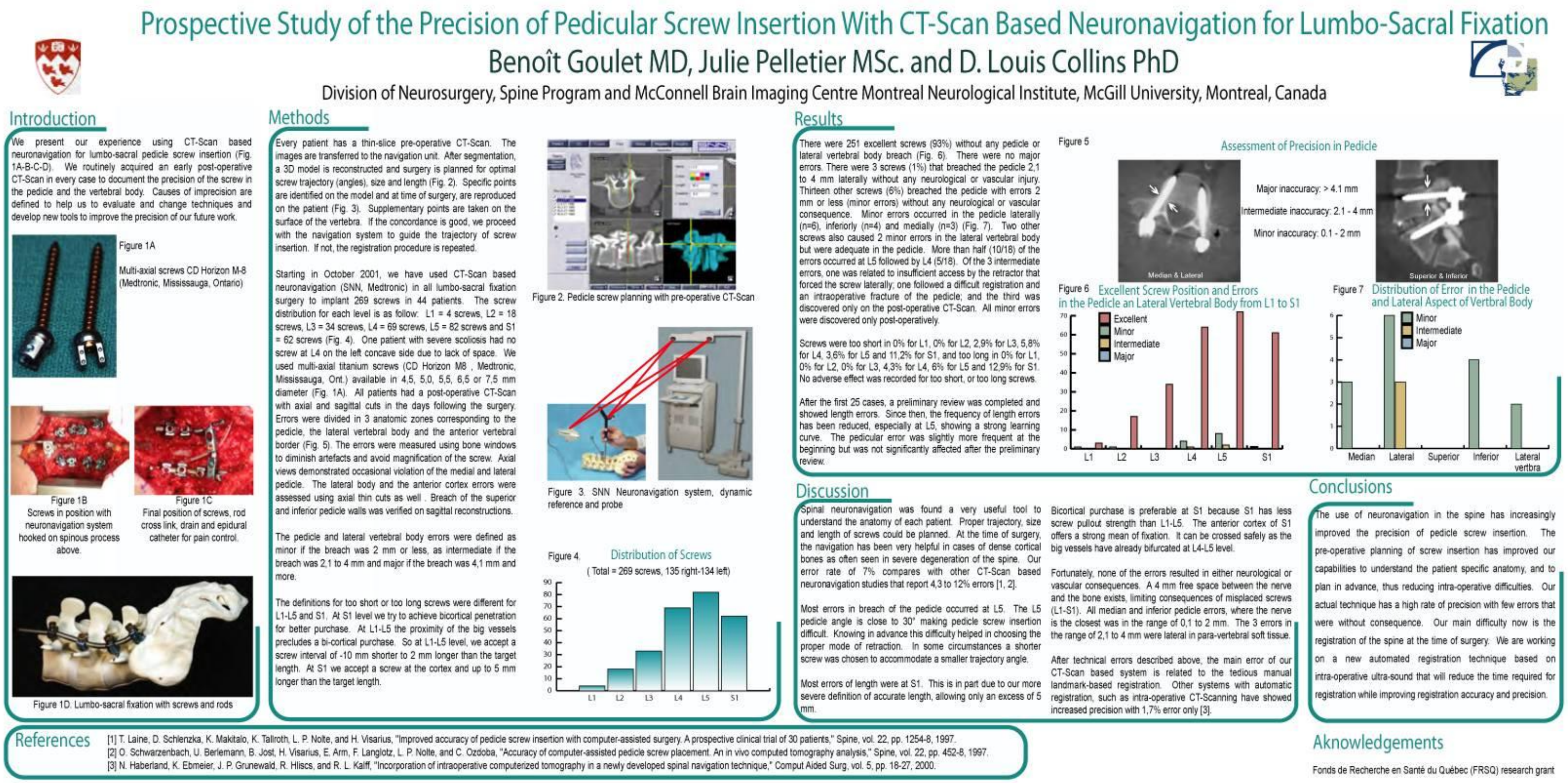
# ANNEX 1 – Poster Presentation



## Prospective Study of the Precision of Pedicular Screw Insertion With CT-Scan Based Neuronavigation for Lumbo-Sacral Fixation

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### Introduction

We present our experience using CT-Scan based neuronavigation for lumbo-sacral pedicle screw insertion (Fig. 1A-B-C-D). We routinely acquired an early post-operative CT-Scan in every case to document the precision of the screw in the pedicle and the vertebral body. Causes of imprecision are defined to help us to evaluate and change techniques and develop new tools to improve the precision of our future work.

Figure 1A

Multi-axial screws CD Horizon M-8 (Medtronic, Mississauga, Ontario)

Figure 1B
Screws in position with neuronavigation system hooked on spinous process above.

Figure 1C
Final position of screws, rod cross link, drain and epidural catheter for pain control.

Figure 1D. Lumbo-sacral fixation with screws and rods

### Methods

Every patient has a thin-slice pre-operative CT-Scan. The images are transferred to the navigation unit. After segmentation, a 3D model is reconstructed and surgery is planned for optimal screw trajectory (angles), size and length (Fig. 2). Specific points are identified on the model and at time of surgery, are reproduced on the patient (Fig. 3). Supplementary points are taken on the surface of the vertebra. If the concordance is good, we proceed with the navigation system to guide the trajectory of screw insertion. If not, the registration procedure is repeated.

Starting in October 2001, we have used CT-Scan based neuronavigation (SNN, Medtronic) in all lumbo-sacral fixation surgery to implant 269 screws in 44 patients. The screw distribution for each level is as follow: L1 = 4 screws, L2 = 18 screws, L3 = 34 screws, L4 = 69 screws, L5 = 82 screws and S1 = 62 screws (Fig. 4). One patient with severe scoliosis had no screw at L4 on the left concave side due to lack of space. We used multi-axial titanium screws (CD Horizon M8 , Medtronic, Mississauga, Ont.) available in 4,5, 5,0, 5,5, 6,5 or 7,5 mm diameter (Fig. 1A). All patients had a post-operative CT-Scan with axial and sagittal cuts in the days following the surgery. Errors were divided in 3 anatomic zones corresponding to the pedicle, the lateral vertebral body and the anterior vertebral border (Fig. 5). The errors were measured using bone windows to diminish artefacts and avoid magnification of the screw. Axial views demonstrated occasional violation of the medial and lateral pedicle. The lateral body and the anterior cortex errors were assessed using axial thin cuts as well . Breach of the superior and inferior pedicle walls was verified on sagittal reconstructions.

The pedicle and lateral vertebral body errors were defined as minor if the breach was 2 mm or less, as intermediate if the breach was 2,1 to 4 mm and major if the breach was 4,1 mm and more.

The definitions for too short or too long screws were different for L1-L5 and S1. At S1 level we try to achieve bicortical penetration for better purchase. At L1-L5 the proximity of the big vessels precludes a bi-cortical purchase. So at L1-L5 level, we accept a screw interval of -10 mm shorter to 2 mm longer than the target length. At S1 we accept a screw at the cortex and up to 5 mm longer than the target length.

Figure 2. Pedicle screw planning with pre-operative CT-Scan

Figure 3. SNN Neuronavigation system, dynamic reference and probe

Figure 4. Distribution of Screws
( Total = 269 screws, 135 right-134 left)

### Results

There were 251 excellent screws (93%) without any pedicle or lateral vertebral body breach (Fig. 6). There were no major errors. There were 3 screws (1%) that breached the pedicle 2,1 to 4 mm laterally without any neurological or vascular injury. Thirteen other screws (6%) breached the pedicle with errors 2 mm or less (minor errors) without any neurological or vascular consequence. Minor errors occurred in the pedicle laterally (n=6), inferiorly (n=4) and medially (n=3) (Fig. 7). Two other screws also caused 2 minor errors in the lateral vertebral body but were adequate in the pedicle. More than half (10/18) of the errors occurred at L5 followed by L4 (5/18). Of the 3 intermediate errors, one was related to insufficient access by the retractor that forced the screw laterally; one followed a difficult registration and an intraoperative fracture of the pedicle; and the third was discovered only on the post-operative CT-Scan. All minor errors were discovered only post-operatively.

Screws were too short in 0% for L1, 0% for L2, 2,9% for L3, 5,8% for L4, 3,6% for L5 and 11,2% for S1, and too long in 0% for L1, 0% for L2, 0% for L3, 4,3% for L4, 6% for L5 and 12,9% for S1. No adverse effect was recorded for too short, or too long screws.

After the first 25 cases, a preliminary review was completed and showed length errors. Since then, the frequency of length errors has been reduced, especially at L5, showing a strong learning curve. The pedicular error was slightly more frequent at the beginning but was not significantly affected after the preliminary review.

Figure 5 Assessment of Precision in Pedicle

Figure 6 Excellent Screw Position and Errors in the Pedicle an Lateral Vertebral Body from L1 to S1

Figure 7 Distribution of Error in the Pedicle and Lateral Aspect of Vertbral Body

### Discussion

Spinal neuronavigation was found a very useful tool to understand the anatomy of each patient. Proper trajectory, size and length of screws could be planned. At the time of surgery, the navigation has been very helpful in cases of dense cortical bones as often seen in severe degeneration of the spine. Our error rate of 7% compares with other CT-Scan based neuronavigation studies that report 4,3 to 12% errors [1, 2].

Most errors in breach of the pedicle occurred at L5. The L5 pedicle angle is close to 30° making pedicle screw insertion difficult. Knowing in advance this difficulty helped in choosing the proper mode of retraction. In some circumstances a shorter screw was chosen to accommodate a smaller trajectory angle.

Most errors of length were at S1. This is in part due to our more severe definition of accurate length, allowing only an excess of 5 mm.

Bicortical purchase is preferable at S1 because S1 has less screw pullout strength than L1-L5. The anterior cortex of S1 offers a strong mean of fixation. It can be crossed safely as the big vessels have already bifurcated at L4-L5 level.

Fortunately, none of the errors resulted in either neurological or vascular consequences. A 4 mm free space between the nerve and the bone exists, limiting consequences of misplaced screws (L1-S1). All median and inferior pedicle errors, where the nerve is the closest was in the range of 0,1 to 2 mm. The 3 errors in the range of 2,1 to 4 mm were lateral in para-vertebral soft tissue.

After technical errors described above, the main error of our CT-Scan based system is related to the tedious manual landmark-based registration. Other systems with automatic registration, such as intra-operative CT-Scanning have showed increased precision with 1,7% error only [3].

### Conclusions

The use of neuronavigation in the spine has increasingly improved the precision of pedicle screw insertion. The pre-operative planning of screw insertion has improved our capabilities to understand the patient specific anatomy, and to plan in advance, thus reducing intra-operative difficulties. Our actual technique has a high rate of precision with few errors that were without consequence. Our main difficulty now is the registration of the spine at the time of surgery. We are working on a new automated registration technique based on intra-operative ultra-sound that will reduce the time required for registration while improving registration accuracy and precision.

### Aknowledgements

Fonds de Recherche en Santé du Québec (FRSQ) research grant

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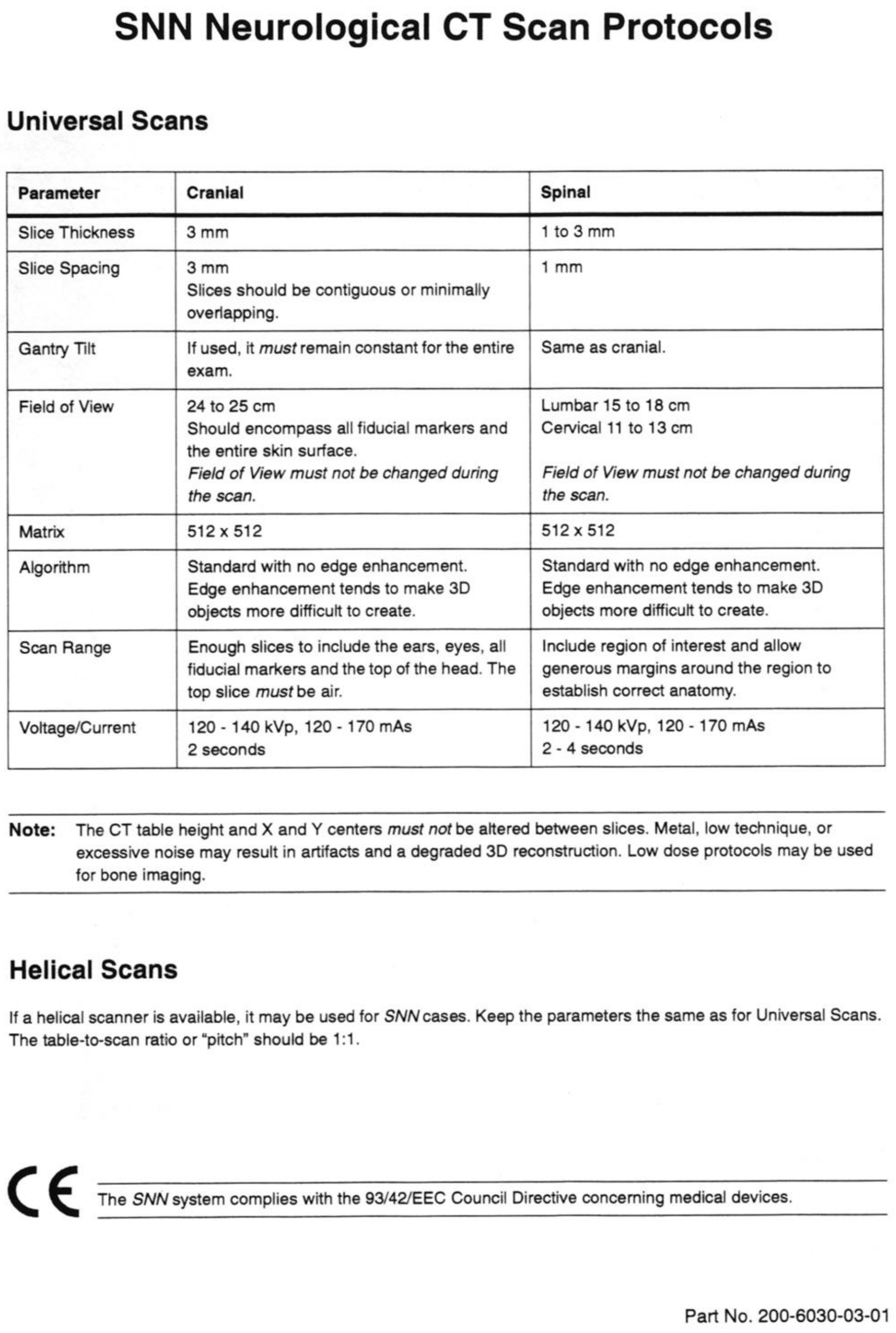
# ANNEX 2 - CT-Scan Protocol Recommended by SNN



## SNN Neurological CT Scan Protocols

### Universal Scans

| Parameter | Cranial | Spinal |
|---|---|---|
| Slice Thickness | 3 mm | 1 to 3 mm |
| Slice Spacing | 3 mm<br>Slices should be contiguous or minimally overlapping. | 1 mm |
| Gantry Tilt | If used, it *must* remain constant for the entire exam. | Same as cranial. |
| Field of View | 24 to 25 cm<br>Should encompass all fiducial markers and the entire skin surface.<br>*Field of View must not be changed during the scan.* | Lumbar 15 to 18 cm<br>Cervical 11 to 13 cm<br>*Field of View must not be changed during the scan.* |
| Matrix | 512 x 512 | 512 x 512 |
| Algorithm | Standard with no edge enhancement.<br>Edge enhancement tends to make 3D objects more difficult to create. | Standard with no edge enhancement.<br>Edge enhancement tends to make 3D objects more difficult to create. |
| Scan Range | Enough slices to include the ears, eyes, all fiducial markers and the top of the head. The top slice *must* be air. | Include region of interest and allow generous margins around the region to establish correct anatomy. |
| Voltage/Current | 120 - 140 kVp, 120 - 170 mAs<br>2 seconds | 120 - 140 kVp, 120 - 170 mAs<br>2 - 4 seconds |

**Note:** The CT table height and X and Y centers *must not* be altered between slices. Metal, low technique, or excessive noise may result in artifacts and a degraded 3D reconstruction. Low dose protocols may be used for bone imaging.

### Helical Scans

If a helical scanner is available, it may be used for *SNN* cases. Keep the parameters the same as for Universal Scans. The table-to-scan ratio or "pitch" should be 1:1.

The *SNN* system complies with the 93/42/EEC Council Directive concerning medical devices.

Part No. 200-6030-03-01

# CURRICULUM VITAE

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**General Neurosurgeon**, Centre Hospitalier Régional de Trois-Rivières. February 199 – July 2000

**Faculty Member** of AO Spine North America, 2006 - Present

## Administration

**Director of Spine Program**, September 2003 - Present

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## Present Research and Grants

Principal Investigator, McGill University Health Centre site on a drug trial project: Novartis study: BMD#06-046 **A Multi-center Cohort Study to Assess Feasibility, Acute Safety, Tolerability and Pharmacokinetics of 4 Dose Regimens of Continuous Intrathecal ATI355 Infusion in Acute Spinal Cord Injury Paraplegic Patients** (Protocol CATI355A2102). November 2006 - present

Principal Investigator, McGill University Health Centre site on an implant trial project: CeraPedics Inc: **P-15 Bone Putty in Anterior Cervical Fusion with Instrumentation**. May 2007 - Present

CO-Principal Investigation for research project. **Ultrasound for Registration of Spinal Column During Neuronavigation for Pedicle Screw Insertion**. Collaboration with Dr. Louis Collins PhD, co-principal investigator. Grant from the Canadian Institute of Health Research (CIHR) - 500, 000 CD$. April 2005 - April 2009

## Education

**Master** in the program of Biomedical Sciences, University of Montreal. Supervised by Professor Jacques Deguise and Professor Louis Collins September 2001 – Present

**Fellowship in Spine Surgery, Department of Neurosurgery, Toronto Western Hospital, University of Toronto.** July 2000 – July 2001

**Fellowship in General Neurosurgery and Spine Surgery** with Dr. Steven Freidberg, Neurosurgeon and Dr. Bernard Pfiefer, Orthopaedic Surgeon. Lahey Hitchcock Clinic, Burlington, Massachussets, USA. November 1995 – February 1996

**Neurosurgery Residency Training Program**, Laval University, Enfant-Jesus Hospital, Quebec City, Quebec, Canada. 1991 – 1995

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## Certifications and Licenses

**American Board of Neurosurgery** – Oral - Part 2, FACS, November 2006

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**Medical License**, College of Physicians and Surgeons of Ontario (75-543). Not active.

**Medical License**, Medicine College of Quebec (196-0210). 1996 - present

**Certificate of Specialization in Neurosurgery**, Royal College of Physicians and Surgeons of Canada, FRCSC, 1995

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## Publications and Textbook Chapters

Goulet, B.; Leblanc, R.: Frameless Stereotactic Biopsy. In Benzel E, Levy M, Steinbert G. et all. Neurosurgery (in press).

Goulet, B.; Pelletier, J.; & Fehlings, M.G.: **Reconstruction of the Unstable Craniocervical Junction and Atlanto-axial Region with Transarticular Screws: Clinical and Radiological Outcomes of 51 Consecutive Cases**. Will be submitted to the Journal of Neurosurgery, spine.

Goulet, B. & Guha, A.: **Management of Intradural Extramedullary Spinal Tumours.** Textbook chapter in Indian Medical Council Update in Neurosurgery, Singh, A. (Ed.): (textbook published in 2000)

Guay, J.; Gaudreault, P.; Tang, A.; Goulet, B.; & Varin, F*:* **Pharmacokinetics of Sufentanil in Normal Children**. Can J Anaesth 1992; 39:14-20

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