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Factors Associated With Clinical Outcomes After Lumbar Interbody Fusion With a Porous Nitinol Implant

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Abstract

Study Design: A retrospective cohort study.

Objective: The aim of this study is to assess the association of demographic and perioperative factors with clinical outcomes of lumbar interbody fusion with a porous nitinol (TiNi) implant for degenerative disc disease.

Methods: Forty-one patients with degenerative lumbar disease were prospectively followed for a mean of 4.8 years. All patients were instrumented with porous TiNi interbody fusion devices. The Oswestry Disability Index (ODI) and return to work were used to assess clinical outcomes. Factors including age, body mass index, smoking status, insurance status, number of comorbidities, duration of surgery, estimated blood loss, number of levels fused, time since surgery, and preoperative ODI score were assessed. A multiple linear regression analysis was performed to look for demographic and perioperative factors associated with clinical outcome.

Results: All patients except one (98%) showed complete fusion on radiography at 1 year. Estimated blood loss and duration of surgery were significantly associated with higher postoperative ODI scores ($P = .002$ and $P = .019$, respectively). Smoking status, salary insurance status, age, body mass index, number of comorbidities, number of levels fused, time since surgery, and preoperative ODI score were not significantly associated with outcome.

Conclusions: Porous nitinol permitted fusion rates similar to those reported in the literature for alternative fusion cages. Poor functional outcome of patients was strongly associated with intraoperative blood loss and duration of surgery. We believe that estimated blood loss should be carefully evaluated in studies of postoperative outcome, as it may affect midterm outcomes.

Level of Evidence: Level 3

Keywords

lumbar fusion, predictor, clinical outcome, nitinol cage

Introduction

Spinal fusion is a standard treatment for many spinal disorders, with degenerative causes being the most common indication.[1] The goal of surgery is to achieve successful fusion and to improve functional outcomes while limiting a patient's morbidity. Interbody implants used for fusion have evolved to achieve optimal fusion results and good functional outcomes by promoting intervertebral fusion, neuroforaminal distraction, and preservation of interbody height.[2,3] The development of novel fusion devices has been driven by the reported decrease

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in fusion rates without instrumentation.[4,5] Structural allografts and autografts have traditionally been used for anterior column support when performing spinal fusions.[6] Nevertheless, the morbidity of harvesting autografts for implantation has led to the widespread use of allograft bone substitutes. However, the possibility of infection and immunological incompatibility of allografts has led to the development of various synthetic interbody devices such as threaded titanium, nonthreaded titanium, polyetheretherketone (PEEK), and carbon fiber cages. On the other hand, using these devices can be associated with complications such as subsidence, migration, and pseudarthrosis.[7-11]

Porous nickel-titanium (porous nitinol [NiTi]; Actipore, Biorthex, Inc, Boucherville, Quebec, Canada) is a titanium-rich biocompatible intermetallic alloy with desirable biomechanical properties. These properties include a good safety profile and rapid osseointegration.[12,13]

Multiple factors have been identified to affect functional outcome after lumbar fusion. These include psychosocial factors, smoking, body mass index (BMI), workers' compensation, and preoperative functional scores.[14-21] To date, however, the factors affecting clinical outcomes with use of the nitinol interbody fusion implant remain unclear. In this retrospective cohort analysis of prospectively collected data, we investigated possible factors associated with clinical outcomes in a series of patients who underwent lumbar interbody fusion with a porous nitinol device.

Table 1. Summary of Patients' Demographic and Clinical Data.

	Range	Mean	Standard Deviation
Age (y)	30-73	52.4	11.25
Body mass index (kg/m^2)	18-39	27.3	4.6
No. of comorbidities	0-4	1.02	1.15
Estimated blood loss, cm^3	250-1700	780.24	407.83
Operative time, min	128-270	196.95	37.13
No. of spine levels	1-2	1.12	0.33
Last follow-up in months	236-260	252.9	8.89
Preoperative ODI score	32-82	53.02	15.99
Last follow-up ODI score	0-64	22.73	20.14

Abbreviation: ODI, Oswestry Disability Index.

Table 2. Different Diagnoses of This Cohort of Patients.

Diagnosis	No. of Patients
Degenerative spondylolisthesis	18
Isthmic spondylolisthesis	8
Iatrogenic spondylolisthesis	1
Post-discectomy syndrome	5
Recurrent disc herniation	4
Central disc herniation	3
Degenerative disc disease (DDD) adjacent to previous fusion	1
Discogenic low back pain (LBP)	1
Total	41

Material and Methods

After approval by the McGill University Health Centre Ethics Board, we carried out a retrospective cohort study of prospectively collected data. Forty-one patients who were operated on between December 2002 and April 2006 by a single surgeon (senior author) were included in the study. The inclusion criteria were a lumbar interbody fusion between L3 and S1 for degenerative lumbar disc disease and demonstration of one or more of the following: instability, spondylolisthesis, arthropathy or osteophyte formation at a facet joint(s) or endplate(s), decreased disc height, herniated nucleus pulpous, and spinal stenosis. The exclusion criteria were an Oswestry Disability Index (ODI) preoperative score of less than 30, cancer, recent vertebral infection, osteoporosis, fracture as primary diagnosis at the affected level, and more than 2 levels of pathology. In addition, patients who demonstrated 3 or more Waddell's signs were excluded from surgery.[22] A total of 492 patients were screened in a general spine clinic considered for this study. A total of 451 patients met at least one of the exclusion criteria. A total of 41 patients were included in the study: 25 females (61%) and 16 males (39%). The patients' demographic and clinical characteristics are summarized in Table 1. The patients' different underlying diagnoses are shown in Table 2. All patients were treated conservatively for at least 6 months prior to surgery, and 11 of the 41 patients had undergone 12 prior spine surgeries (discectomy and laminectomies). Thirty-three of the procedures (80%) were carried out using the posterior lumbar interbody fusion "PLIF" technique, while 8 (20%) were performed using the transforaminal lumbar interbody fusion "TLIF" technique. All patients, except the first case, had supplemental posterior instrumentation that included 8 patients (20%) with unilateral pedicle screws and rod, 28 patients (68%) with bilateral pedicle screws and rods and 4 patients (10%) with translaminar facet screws.

A standard open midline posterior approach was used in all cases.[23] Thirty-five patients (85%) had the procedure performed at a single level, whereas 6 patients (15%) had the fusion at 2 consecutive levels. Complications were recorded for evaluation of the safety profile. Radiographic evaluation consisted of standing posterior-anterior (PA) and lateral plain radiographs, together with flexion/extension films or computed tomography scans in selected cases in which evaluation with plain radiographs was difficult. Fusion was defined by the following: visible bridging bone across the disc space, less than 50% circumferential radiolucency (halo) around the cage on static X-rays, and less than 5° of motion on dynamic flexion/extension X-rays.[24-27] Patients had serial lumbar spine X-rays at 6 weeks, 3 months, 6 months, and 1 year to assess for fusion. Computed tomography scans were done for selected cases in which evaluation with plain radiographs was difficult and there was a clinical suspicion for psuedoarthrosis. Clinical outcomes for low back pain were assessed by using the ODI.[28] Estimated blood loss was the sum of the volume of blood suctioned from the operative field (from which irrigation fluid was subtracted), blood loss collected on sponges (as determined by weight), and approximate estimates of blood loss on drapes and gowns.

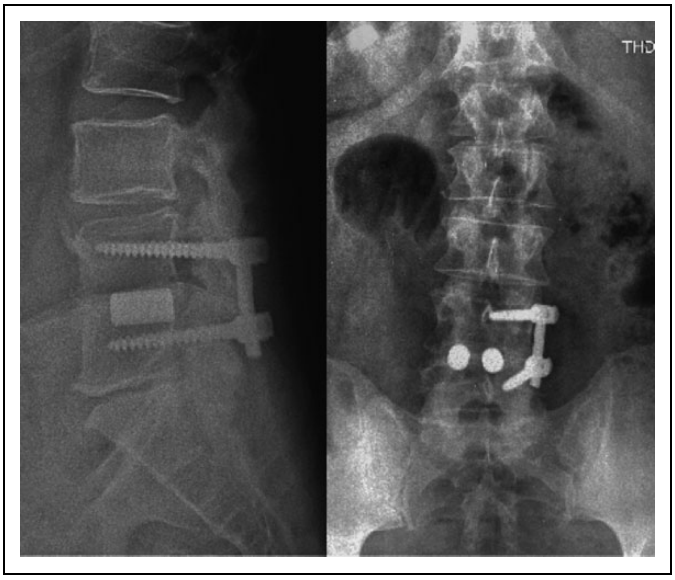

Figure 1. One-year post–posterior lumbar interbody fusion (PLIF) using porous nitinol implants augmented with posterior instrumentation using unilateral pedicle screws and a rod. Solid fusion is evident between L4 and L5.

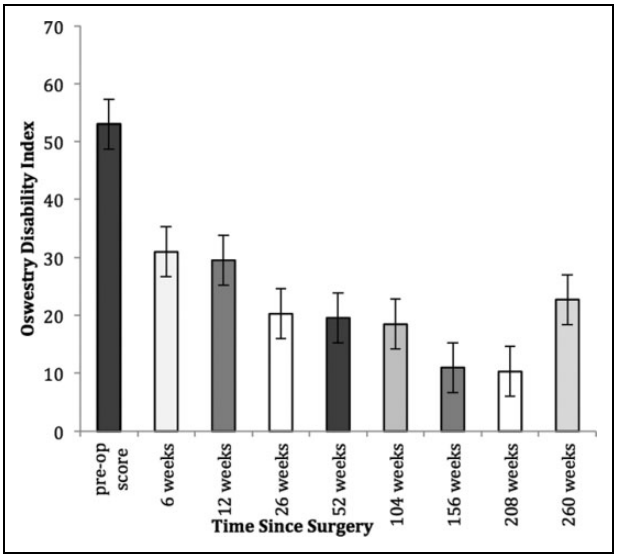

Figure 2. Change in Oswestry Disability Index with time.

Statistical Analysis

Mean and standard deviation (SD) were used for descriptive statistics. A univariate analysis was performed by using a paired *T* test and chi-square test to detect a significant difference between continuous and categorical variables, respectively. Multiple linear regression analysis was used to determine the relationship between demographic factors, perioperative factors and the ODI scores. A *P* value <.05 was considered a statistically significant result. SPSS software (version 20.0; IBM Corp, Armonk, NY) was used for all statistical analyses.

Results

The mean operative time was 197 minutes (range, 128-270 minutes) with an SD of 37 minutes. The average blood loss was 780 cm^3 (range, 250-1700 cm^3; SD, 407) and the average hospital stay was 4.8 days (range, 2-12 days). Average follow-up was 4.8 years (range, 4.5-5 years). All patients except one (98%) showed complete fusion on radiographs at 1 year (Figure 1).

The ODI averaged 53 preoperatively (SD, 15.99) and had decreased to a mean of 22.73 (SD, 20.14) at the final follow-up. The postoperative ODI score at 4 years (208 weeks) was significantly different from the preoperative score. At the last follow-up at 5 years, however, the score was not significantly different ($P > .05$) despite an average change from 53.02 preoperatively to 22.73 postoperatively (Figure 2).

The multiple linear regression analysis of all factors (age, BMI, smoking status, insurance status, number of comorbidities, duration of surgery, estimated blood loss, number of levels fused, time since surgery, and preoperative ODI score) showed that estimated blood loss and duration of surgery had a significant association with the ODI score with *P* values of .002 and .019, respectively (Table 3). Salary insurance or workers' compensation showed marginal statistical significance with a *P* value of .053. A significant positive correlation was found between ODI score and estimated blood loss (regression coefficient 0.475) and duration of surgery (regression coefficient 0.365), as shown in Figures 3 and 4, respectively. There was no difference in clinical outcome (ODI) between the different groups either before ($P = .708$) or after the surgery ($P = .282$).

Table 3. Results of the Multiple Linear Regression Analysis of All Factors.

Demographic and Perioperative Factors	*P*
Sex	.118
Age	.376
Body mass index	.840
Smoking	.589
Number of comorbidities	.459
Previous operations	.292
CSST/Salary insurance	.053
Estimated blood loss	.002
Operative time	.019
Complications	.144
Number of levels	.101
Duration of follow-up	.343
Preoperative ODI score	.437

Abbreviations: CSST, de la santé et de la sécurité du travail; ODI, Oswestry Disability Index.

We considered a complication as a categorical variable and assessed the presence of a complication for its effect on the outcome score. A total of 14 complications were observed: 4 required reoperation, and only 1 reoperation was for cage migration (Table 4). None of the complications had a significant effect on functional outcome on the basis of the multiple linear regression analysis ($P = .144$).

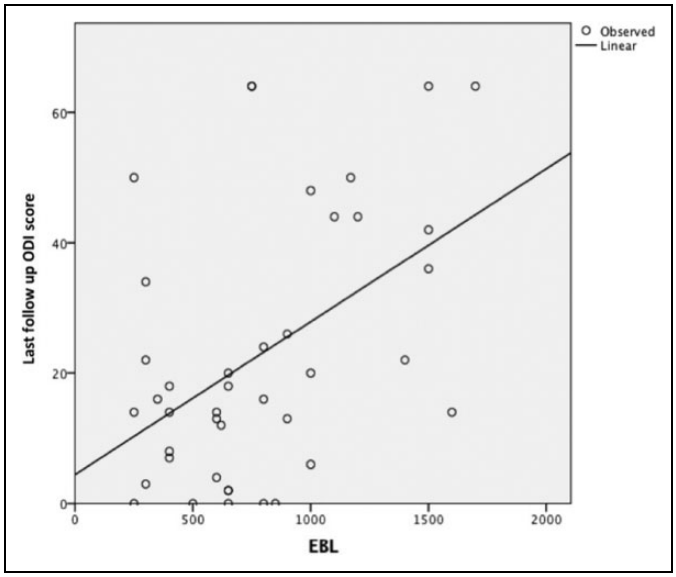

Figure 3. Scatterplot showing the relation between estimated blood loss (EBL) and the Oswestry Disability Index (ODI) score at the last follow-up by use of multiple linear regression analysis. The straight line is the line of unity.

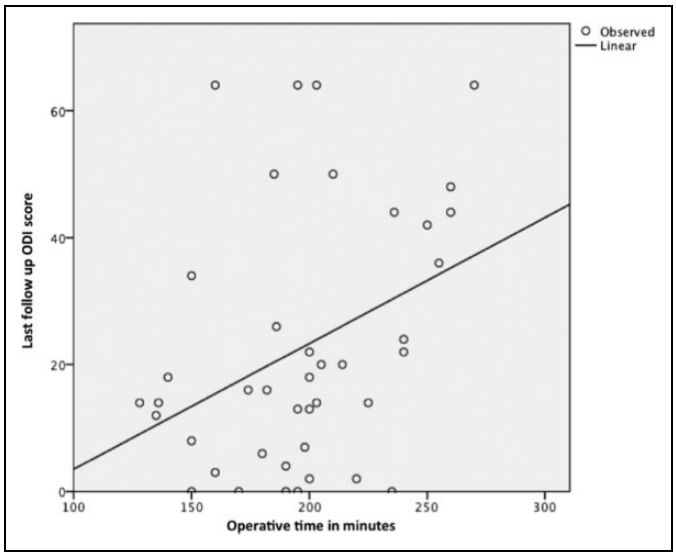

Figure 4. Scatterplot showing the relation between the duration of surgery in minutes and the Oswestry Disability Index (ODI) score at the last follow-up by use of multiple linear regression analysis. The straight line is the line of unity.

Discussion

In the past decade, an evolution has taken place in the fusion techniques using interbody cages for the treatment of degenerative lumbar disc disease. In our study, we used porous nitinol implants in patients undergoing lumbar fusions and examined the factors affecting functional outcomes by use of a multiple linear regression analysis of demographic and perioperative factors. These factors included estimated blood loss and duration of surgery. Currently, there are no clear studies examining the relationship between medium-term functional outcome and blood loss in spine surgery.[29] Our study showed significant association between the estimated blood loss during lumbar spine fusions and future clinical outcome based on the ODI.

Table 4. List of Complications During and After Surgery Using Porous Nitinol.

Complication	Incidence, No. of Patients (%)	Treatment
Infection	1 (2.4)	Irrigation and debridement
Seroma	1 (2.4)	Drainage
Misplaced pedicel screw	1 (2.4)	Revision of pedicle screw
Cage migration	1 (2.4)	Reoperation to adjust cage position
Dural tears	5 (12.1)	Treated by immediate intraoperative dural repair
Neurapraxia	3 (7.3)	Resolved spontaneously
Venous thromboembolism (DVT/PE)	2 (4.9)	Treated with anticoagulation therapy
Total	14	

Abbreviations: DVT, deep vein thrombosis; PE, pulmonary embolism.

The relation between the duration of spine fusion surgery, intraoperative bleeding,[30] and the rate of infection is well established.[31-33] Although linking these factors with final outcome may be intuitive, we are not aware of any literature to support the relationship blood loss and functional outcome. Intraoperative blood loss can lead to postoperative anemia, which is associated with lower functional recovery scores, higher transfusion rates, and longer hospital stays in arthroplasty patients.[34,35] Jiang et al[33] performed a meta-analysis of studies of spinal surgery patients and found obesity to be associated with a higher risk of surgical site infection, a higher risk of venous thromboembolism, more blood loss, and longer surgical time. However, those authors did not correlate these variables to functional outcome.[36] Another 3 studies that examined early and late functional results of patients who had lumbar spinal surgery correlated obesity with a worse surgical outcome.[19,20,37] In our study, BMI did not affect functional or other clinical outcomes. This may have been due to the small number of obese patients included in the present study (only 31% had a BMI > 30 kg/m^2). Other studies have shown that smoking is a negative predictive factor for outcome and patient satisfaction.[38-40] Our study at an average follow-up of 4.8 years did not show smoking status to have a significant effect on patient outcome. This could again be due to the small sample size. In addition, several studies have examined the relationship of insurance status and short-term outcome and have shown that the results of spinal fusion in workers' compensation patients are inferior to the results in non–workers' compensation patients.[41-44] In the medium term (<5 years), our present study suggests insurance status does not affect outcome. This may be due to the selection process or the fact that most insurance claims are resolved 5 years after surgery.

Talking about implants used for lumbar interbody fusion, many options are available including iliac crest tricortical bone

grafts, allograft spacers, synthetic mesh cages and ceramics. Synthetic porous implants have a biomorphological structure similar to bone and have demonstrated consistent osseointegration. But few synthetic structures have been able to mimic the mechanical and elastic properties of living bone. Some of the commonly used inter-body biomaterials, such as polyetheretherketone (PEEK) and titanium, have a modulus of elasticity considerably higher than cancellous bone and cannot osseointegrate without supplemental graft material.[45] Porous nickel-titanium (NiTi, porous nitinol, Actipore Biorthex, Inc, Boucherville, Quebec, Canada) is a titanium-rich biocompatible intermetallic alloy which gained significant interest as an alternative orthopedic implant.[12,13] In addition to the biomechanical properties, its memory shape effect, corrosion resistance, and biocompatibility have extended the applications of these implants in spine surgery. Also, they appear to be nontoxic and nonsensitizing to the dura mater.[46] Applications have included distraction rods for scoliosis, compression plates, staples, clamps, nails, anchors, and hooks as well as lumbar interbody implant.[45,47] When constructed as a porous structure, nitinol has been found to be an excellent osteoconductive material for fusion,[48-50] which enhances lumbar fusion without supplemental bone graft.[50,51] It is characterized by 65% porosity, 250-μm average pore size, and mechanical properties similar to that of cancellous bone, which does not require any filling grafts and provides the best environment for bone ingrowth and subsequent fusion. Animal studies have shown that porous nitinol has an excellent bone implant contact and achieved a high level of bone ingrowth in rabbits and rats.[52,53] In a sheep model of spine fusion, Assad et al[48,49] have shown excellent osteogenic cell integration to support the osteoconductive role of porous nitinol. Although nitinol does not demonstrate significant shape memory effect when fabricated as a porous structure, it does exhibit super elastic property and modulus characteristics with low stiffness almost identical to cancellous bone that may minimize periprosthetic stress shielding and improved osseointegration.[45,54] Assad et al[49] and Likibi et al[55] have shown that porous nitinol provides higher bone ingrowth stimulation, which further increases with time due to its cellular, bone-like architecture, without the need of additional bone grafting. One year after implantation, complete bone bridging across the full porous implant with inherent vascularization and intimate bone attachment on the porous surface was observed. Qualitative (macroscopic and microscopic) and quantitative (histomorphometric) histological analysis were carried out and the results indicated that a porous nickel-titanium had obtained a better osseointegration than the conventional titanium implants.[55] The use of PLIF cages in large series, reported greater than 95% fusion rate, regardless of whether carbon fiber–reinforced cages, polymer cages, vertical titanium mesh cages, allograft bone spacers, or standalone cylindric threaded cages have been used.[56-58] Brantigan et al[59] have shown that using a cage with autograft has achieved a quicker and more reliable fusion rates compared to allograft spacer alone in goats. This is attributed to the loss of osteoinductive function of those allografts. Moreover, there is a concern with allograft breakage and failure under high loads.[59] In our series, we achieved 98% fusion rate without using supplemental bone graft, which is comparable to other cages filled with bone grafts. Kok et al[60] found a 100% fusion rate with improved functional outcomes after using nitinol interbody fusion implants in 25 patients.

Reviewing the literature on dural tear revealed an incidence that ranges from 2% to 14% (average is 7.3%) and our incidence was 12%.[61] The explanation for this finding is that the rough surface texture of the porous cage is great for fusion but not dura friendly, requiring extra care during cage insertion.

The present study may be the first to demonstrate a moderate relationship between blood loss and patient outcome postoperatively. Because blood loss and operating time are related, an increase in one may increase the other, efforts should be made to streamline surgery and reduce blood loss. Techniques know to reduce blood loss such as minimally invasive surgery, decreasing abdominal pressure with proper positioning, hypotensive anesthesia, not using blood transfusion at predetermined levels of hemoglobin, rigorous hemostasis[30] and antihemolytic agents to reduce blood loss,[62-64] may be warranted in light of these results.

Nevertheless, in the present study, the mean ODI at 5 years was 23 and remained stable from year 4 to year 5. Although this score represents a significant improvement from preoperative values, the lack of further improvement may be related to the beginning of adjacent-level disease.[65] The limitations of the present study include the retrospective nature of the study, selection bias, absence of a control group, small number of patients, and the involvement of a single surgeon and one center.

Conclusions

We believe that intraoperative blood loss and long surgical time are associated with worse midterm functional outcome after lumbar fusion, as shown by the results of the present study. These results need to be verified in larger multicenter databases.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: J.O. receives grants from AO Foundation, DePuy Synthes and personal fees from DePuy Synthes, outside the submitted work.

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