

Outcomes of Minimally Invasive Surgery Compared to Open Posterior Lumbar Instrumentation and Fusion

Abstract

Introduction: Degenerative spine disease is increasingly common. There are many spinal fusion techniques used to treat degenerative spine disease. This study aims to compare the functional outcome of open versus minimally invasive surgery (MIS) technique in posterior lumbar instrumentation and fusion in degenerative spine disease and to evaluate the perioperative outcome and complications between MIS and open surgery. **Materials and Methods:** This is an observational cross-sectional study conducted on all degenerative spine disease patients who underwent both methods of posterior lumbar instrumentation and fusion from 2010 to 2014 by the Orthopedic and Neurosurgery Department, Sarawak General Hospital. The analyzed variables were method of surgery and the levels involved, demographic data, estimated blood loss, duration of operation, length of hospitalization, visual analog scale of back pain and radicular pain preoperative, postoperative 1 month, 3 months, 6 months, 1 year, and functional outcome. **Results:** One hundred and twenty-two patients underwent posterior lumbar instrumentation and fusion from 2010 to 2014. Seventy patients were subjected to MIS transforaminal lumbar interbody fusion (TLIF) and 52 open TLIF. Total 89 patients underwent single level of lumbar fusion with sixty patients in MIS group and 29 in open surgeries. MIS TLIF has less estimated blood loss and shorter hospitalization and longer operation time compared to open TLIF, which were statistically significance. MIS TLIF has statistically significance better functional outcome based on Oswestry disability index, Modified NASS score, and RAND 36-item Health Survey 1.0 score. Complications such as infection, new onsets of neurological, and dural tear are equal in both methods of surgery. **Conclusion:** This study concluded that MIS has better functional outcome compared to open TLIF with shorter hospitalization, faster return to work, and less estimated blood loss.

Keywords: Minimally invasive surgery posterior lumbar instrumentation and fusion, Modified North American Spine Society Low Back Pain Outcome Instrument, open posterior lumbar instrumentation and fusion, Oswestry disability index, RAND-36 Item Health Survey 1.0, visual analog scale

Introduction

Degenerative spine disease is common as part of the aging process in human. Different operative techniques are invented to fix this problem and at the same time minimized the operative complications. Minimally invasive approaches are gaining popularity in spinal surgery.

King^[4] initially described instrumentation of the lumbar facets as a form of internal fixation that he placed small screws across the facet joints in conjunction with a posterior fusion. Boucher^[5] modified this technique using a longer screw directed toward the pedicle with additional cancellous bone graft, resulting in a lower rate of pseudarthrosis reported as 14%–17%.

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Pedicle screw systems provide the strongest fixation in spinal surgery as it engaged all three columns of spine that resist movements in all planes. Gaines^[6] reported that pedicle screw fixation can be effectively and safely used whenever a vertebral pedicle can accommodate a pedicle screw and does not produce severe or frequent complications. Yuan *et al.*^[7] reported that low pedicle screws fixation complication with screw breakage of 2.6% and screw loosening of 2.8% in 2153 patients treated for degenerative spondylolisthesis.

Magerl^[1] first reported percutaneous fixation technique using an external fixator for the management of spinal fractures and infections. Mathews and Long^[2] later reported using plates as the longitudinal connectors in percutaneous pedicle fixation

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operation. Lowery and Kulkarni^[3] described similar techniques in which rods were placed. With the increasing popularity of percutaneous techniques, the safety and reliability of this technique have been studied.

Advantages of percutaneous transpedicular system are as follows: It requires smaller skin incision (stab incision) with less scarring. The paraspinal muscles are bluntly split rather than divided, leading to potentially shorter periods of hospitalization, less postoperative pain, and recovery. Blood loss and tissue trauma are minimized.

The disadvantages of the percutaneous transpedicular system include misplaced screws, hardware failure, nerve root injury, spinal cord injury, pedicular fracture, and cerebrospinal fluid fistula which are about the same as conventional pedicular screws' operation. Percutaneous transpedicular operation has a steeper learning curve compared to open surgery.

Wiltse *et al.*^[8] first described paraspinal sacrospinalis muscle splitting to the lumbar spine. They found that this approach reduces bleeding and provided a more direct approach to pedicles. Wiltse *et al.*'s approach has been adapted for transforaminal lumbar interbody fusion (TLIF). Advantages of TLIF are as follows: Ideal lateromedial screw trajectory is much more easily accomplished, especially in bigger size patients as significant paraspinal tissue retraction is avoided. This procedure also allows the screws to be placed in a standard anatomic position, optimized the biomechanics of the fixation and allows the hardware to remain in place without irritating the superficial tissues of the low back and thus obviates routine hardware removal. TLIF procedures reduce the complications associated with posterior lumbar interbody fusion (PLIF) such as less dura or nerve root retraction. TLIF procedures can also avoid the risks of other approaches such as anterior lumbar interbody fusion technique (ALIF). The common risks of ALIF are vessels injury, sympathetic nerve injury, and injury to retroperitoneal and peritoneal structures.

Materials and Methods

Research design

This was an observational cross-sectional comparative study in a single center to compare the outcomes of minimally invasive surgery (MIS) versus open posterior lumbar instrumentation and fusion in degenerative spine disease. At the same time, we studied the difference in perioperative outcomes between these two types of surgical techniques and their complications. Figure 1 are the photos of intraoperative procedure perform on one of the subject in this study. There is no randomization of the types of surgery in view of an observational study. Both types of surgery have been done in Hospital Umum Sarawak (HUS) since 2002. The selection of type of surgery depends on patients and surgeons' preferences and cost. Patients' written consent is obtained for enrollment

of this study. The Malaysian Medical Research and Ethics Committee (NMRR 14-877-20145, reference: (17) KKM/NIHSEC/P14-976) has approved this study. It was carried out at the Orthopedics Neurosurgery Department in HUS.

Research locations and duration

This study was performed in HUS; two departments were involved, which are Orthopedics and Neurosurgery Departments. The duration of the study was over a total of 4 years from January 2010 to December 2014, follows with a 1-year follow-up.

Inclusion criteria

The followings are the inclusion criteria needed to be fulfilled before patient selection for the eligibility of the study.

1. Aged 12–80 years,
2. Recurrent single lumbar disc herniation with significant neurogenic claudication, Figure 3
3. Degenerative disc disease causing discogenic low back pain, not respond to conservative treatment (after 4–8 weeks) with rest, analgesia, non-steroidal anti-inflammatory drugs, and physical therapy,
4. Neurological deficit contribute by the single level of degenerative disc disease,
5. Grade 1-2 spondylolisthesis Figure 2.

Single level of foraminal stenosis associated with spinal deformity.

Exclusion criteria

The followings are the exclusion criteria for patients not eligible to be included in this study.

1. Aged <12 and >80 years,
2. Presence of complete disc desiccation,
3. Extensive osteophytes,
4. Trauma,
5. Grade 3 and 4 spondylolisthesis,
6. Multiple level of degenerative lumbar spine disease with bilateral involvement.

Method of research

In this study, we aimed to perform a direct comparison between MIS versus open posterior lumbar instrumentation and fusion in patients with single level of degenerative lumbar spine disease that fulfilled the inclusion criteria. We collected a total of 89 patients (60 in MIS group and 29 in open group), who fulfilled the inclusion and exclusion criteria from January 2010 to December 2014. The same team of surgeons conducted both groups of surgery technique, so the different surgeons success and complications rate are excluded in this study. General patient data including age, sex, race, associated medical conditions, and other risk factors were assessed before surgery. The visual analog scale (VAS) Appendix 2 back

pain, radicular pain, Oswestry Disability Index (ODI) Appendix 3, Modified North American Spine Society (NASS) Appendix 4 low back pain outcome instruments score, RAND-36 item health survey 1.0 Appendix 5 between open and MIS posterior lumbar instrumentation, and fusion are analyzed preoperatively. Perioperative outcomes such as level of instrumentation, operation time, estimated blood loss, and duration of hospital stay are analyzed in this study. Postoperative 12 h VAS back pain and radicular pain are measured. Follow-up at 1 month, 3 months, 6 months, and 1 year for assessment of VAS back pain, VAS radicular pain, ODI, Modified NASS low back pain outcome instruments, and RAND-36 item health survey score are analyzed. Good outcome was defined as VAS score of $<5/10$. Lower ODI, Modified NASS low back pain outcome measurement, and RAND-36 item health score have better outcome. All the information will be entered into data collection form Appendix 1.

Statistical analysis and estimated sample size

The data were analyzed using the computer software SPSS for Windows version 21.0. (Armonk, NY, IBM Corp). Exploratory data are tested before proceed with the further statistic test. All variables were expressed as mean \pm standard deviation ($X \pm SD$). Quantitative data were presented as means (range) and qualitative data were expressed in percentages. The differences of investigated parameters were analyzed with the Student's *t*-test, Pearson Chi-square test, and Mann-Whitney test. Pearson's Chi-square test is used for categorical variables' analysis between two groups of procedure. Independent continuous variables with normal distribution were analyzed using Student's *t*-test. Non-parametric tests were analyzed with Mann-Whitney test when the data distribution is not normal with skewness and kurtosis over 2 or <-2 . The calculated sample size was 20 patients in each group (power 90%) to demonstrate statistical differences in overall surgical outcome, perioperative outcome, and complications. Significance was assumed at a level of $P < 0.05$, (National Medical research Register [NMRR], www.nmrr.gov.my, Identifier: NMRR-14-877-20145).

Definitions

- MIS: Surgery minimizing surgical incision to reduce trauma to body. This type of surgery is usually performed using guide wires and endoscope to visually guide the surgery
- TLIF: A form of spine fusion surgery in which the lumbar disc space is fused from a posterior approach outside the facet joint. The surgical procedures involve removing a disc from between two vertebrae and fusing the vertebrae together
- PLIF: A form spinal fusion to fuse the disc space of the spine through entering from the back of the body
- VAS: Psychometric response scale, which can be used in questionnaire. It is a measurement instrument for

subjective characteristics or attitudes that cannot be directly measured

- ODI: An index derived from the Oswestry low back pain questionnaire by clinicians and researchers to quantify disability for low back pain. Fairbank *et al.*^[21] published this validated questionnaire in 1980
- Modified NASS low back pain outcome measures: It was first published by Daltroy *et al.*^[14] and is derived from a consensus of the NASS. It consists of 62 main question obtained from three different existing questionnaires: the SF36, a modified ODI, and a modified employment assessment published by Bigos RAND-36 item health survey 1.0: It is part of the medical outcomes study. It is a set of generic, coherent, an easily administered quality of life measures. These measures rely upon patient self-reporting and by Medicare.

Results

General demographics and patient characteristics

Table 1 Patient Demographics and Characteristics. Grand total of 122 patients underwent either type of surgery in the study periods. A total number of 89 subjects underwent single level of posterior lumbar instrumentation and fusion with 29 subjects in open surgery group and 60 subjects in MIS group. Others are excluded because of multiple levels of surgery involved. The most common level of surgery was L4/5 in both group with MIS 45 subjects (75.0%) and open 18 (62.1%) follow with L5/S1; MIS 12 subjects (20.0%) and open 8 subjects (27.6%) and L3/4; MIS 3 subjects (5.0%) and open 3 subjects (10.3%). There were a total of 34 females (56.7%) and 26 males (43.3%) in MIS group. Open group comprises 16 males (52.2%) and 13 females (44.8%). The mean age was 56 years in MIS group compared to 53 years in open group.

Perioperative outcomes

Table 2 Perioperative Outcomes. Duration of operations, estimated blood loss, and duration of hospitalization are studied in between two groups of surgery.

There was no significance difference in the duration of operation for MIS group (mean = 170.67 min, SD = 51.53) and open group (mean = 157.41 min, SD 49.38) ($t = 1.152$, $P = 0.126$).

There was a significant difference in the estimated blood loss for MIS group (mean = 211.33 mL, SD = 100.23) and open group (mean = 683.79 mL, SD = 116.10) (Mann-Whitney U, $z = -4.610$, $P < 0.001$).

There was a significant difference in the duration of hospitalization for MIS group (mean = 3.80 days, SD = 2.38) and open group (mean = 7.38 days, SD = 4.45) (Mann-Whitney U, $z = -4.985$, $P < 0.001$).

Table 1: Patient demographics and characteristics

	MIS	Open
Number of patients	60	29
Age (mean±SD)	55.88±11.37	52.90±9.67
Sex (%)		
Male	26 (43.3)	16 (55.2)
Female	34 (56.7)	13 (44.8)
Level of surgery (%)		
L3/4	3 (5.0)	3 (10.3)
L4/5	45 (75.0)	18 (62.1)
L5/S1	12 (20.0)	8 (27.6)

SD – Standard deviation; MIS – Minimally invasive surgery

Table 2: Perioperative outcomes

	MIS	Open	P
Duration of operation, mean (min)±SD	170.67±51.53	157.41±49.38	0.126
Estimated blood loss, mean (mL)±SD	211.33±100.23	683.79±1161.10	<0.001
Duration of hospitalization, mean (days)±SD	3.80±2.38	7.38±4.45	<0.001

SD – Standard deviation; MIS – Minimally invasive surgery

Table 3: Modified North American Spine Society low back pain outcome instrument

NASS	MIS	Open	P
Preoperative (mean±SD)	122.22±13.64	130.28±19.27	0.171
1-month postoperative (mean±SD)	68.22±10.24	105.34±10.01	0.016
3-months postoperative (mean±SD)	62.03±9.03	96.62±11.39	<0.001
6-months postoperative (mean±SD)	53.12±7.93	91.24±12.04	0.003
1-year postoperative (mean±SD)	43.48±7.40	78.79±13.00	<0.001

SD – Standard deviation; MIS – Minimally invasive surgery; NASS – North American Spine Society

Table 4: RAND 36-item Health Survey 1.0

RAND 36-item health survey	MIS	Open	P
Preoperative (mean±SD)	95.40±8.90	107.38±15.35	0.085
1-month postoperative (mean±SD)	80.67±10.27	97.28±9.13	0.413
3-months postoperative (mean±SD)	67.48±10.79	89.76±5.84	0.291
6-months postoperative (mean±SD)	56.55±9.70	82.17±5.37	0.112
1-year postoperative (mean±SD)	47.17±8.71	73.69±6.78	0.144

SD – Standard deviation; MIS – Minimally invasive surgery

Visual analog scale back pain

VAS was used to assess the preoperative back pain and radicular pain. It was later used to follow-up patient during 12-h, 1-month, 3-month, 6-month, and 1-year postoperation.

Good VAS score was defined as score < 5. The changes of score preoperative and postoperative are also important to define good outcome.

There was no significant difference in VAS back pain preoperative for MIS group (mean = 6.13, SD = 2.85) and open group (mean = 5.43, SD = 1.67) ($t = 1.456$, $P = 0.075$).

There was no significant difference in VAS back pain 12-h postoperation for MIS group (mean = 2.13, SD = 1.54) and open group (mean = 2.03, SD 1.40) ($t = 0.293$, $P = 0.385$).

There was no significant difference in VAS back pain 1-month postoperative for MIS group (mean = 1.57, SD = 1.530) and open group (mean = 1.90, SD = 1.35) ($t = -0.989$, $P = 0.163$).

There was no significant difference in VAS back pain 3-month postoperative for MIS group (mean = 1.25, SD = 1.34) and open group (mean = 1.31, SD = 1.31) ($t = -0.201$, $P = 0.421$).

There was a significant difference in VAS back pain 6-month postoperative for MIS group (mean = 0.90, SD = 1.13) and open group (mean = 1.55, SD = 1.66) ($t = -2.176$, $P = 0.016$).

There was a significant difference in VAS back pain 1-year postoperative for MIS group (mean = 0.53, SD = 0.83) and open group (mean = 1.14, SD = 1.22) ($t = -2.747$, $P = 0.004$).

Visual analog scale of radicular pain

There was a significant difference in the preoperative VAS radicular pain for MIS group (mean = 6.13, SD = 2.35) and open group (mean = 4.97, open 2.92) ($t = 2.028$, $P = 0.023$).

There was a significant difference in the postoperative 12-h VAS radicular pain score in MIS group 9 mean = 1.90, SD = 1.65) and open group (mean = 0.93, SD = 1.44) ($t = 2.699$, $P = 0.004$).

There was no significant difference in the 1-month postoperative VAS radicular pain for MIS group (mean = 0.90, SD = 1.32) and open group (mean = 0.62, SD = 1.08) ($t = 0.987$, $P = 0.163$).

The mean VAS radicular pain 3-month postoperative in MIS group and open group were 0.47 and 0.38, respectively; the distribution in the two groups showed no significant difference (Mann–Whitney $U = 845$, $P = 0.382$).

The mean VAS radicular pain 6-month postoperative in MIS group and open group were 0.33 and 0.10, respectively; the distribution in the two groups showed no significant difference (Mann–Whitney $U = 768.500$, $P = 0.074$).

The mean VAS radicular pain 1-year postoperative in MIS group and open group were 0.14 and 0.00, respectively; the distributions in the two groups showed no significant difference (Mann–Whitney $U = 768.500$, $P = 0.057$).

Table 5: Overall surgical complications within both groups

	MIS	Open	P
Overall complications (%)	3 (5.0)	3 (10.3)	0.312
Infection (%)	0	2 (6.9)	0.098
New neurology deficit (%)	3 (5.0)	1 (3.4)	0.500
Dura tear	0	0	

MIS – Minimally invasive surgery

Oswestry disability index

Lower ODI was defined to have a better outcome. ODI was used to measure the functional outcome in this study. Subjects were given ODI questionnaire by the principal investigator. Any uncertainties will be explained and translated by the principal investigator without validation. The principal investigator was trained to explain the questions in the questionnaire. It consists of total 10 questions and the score will be converted to percentage. The patients who failed to answer all questions in the questionnaire were excluded from the study.

There was no significant difference in the preoperative ODI for MIS group (mean = 50.95%, SD = 18.55) and open group (mean = 55.17, SD = 11.64) ($t = -1.309, P = 0.097$).

There was a significant difference in the 1-month postoperative ODI for MIS group (mean = 37.15%, SD = 16.21) and open group (mean = 53.71%, SD = 12.24) ($t = -5.312, P < 0.001$).

There was a significant difference in the 3-month postoperative ODI for MIS group (mean = 34.58, SD = 14.83) and open group (mean = 47.86, SD = 8.97) ($t = -5.191, P < 0.001$).

There was a significant difference in the 6-month postoperative ODI for MIS group (mean = 31.38%, SD = 14.01) and open group (mean = 43.21%, SD = 10.10) ($t = -4.538, P < 0.001$).

There was a significant difference in the 1-year postoperative ODI for MIS group (mean = 25.48%, SD = 12.92) and open group (mean = 36.41%, SD = 10.91) ($t = -3.927, P < 0.001$).

Modified North American Spine Society low back pain outcome instruments

This questionnaire studied pain and disability score, neurogenic symptoms, job dissatisfaction, job exertion, patients’ expectations, and satisfaction. The lower the score, the better is the outcome. Trend of score from pre to postoperative is studied.

Table 3: There was no Significant difference in the preoperative modified NASS score for MIS group (mean = 1222.22, SD = 13.64) and open group (mean = 130.28, SD = 19.27) ($t = -0.961, P = 0.171$).

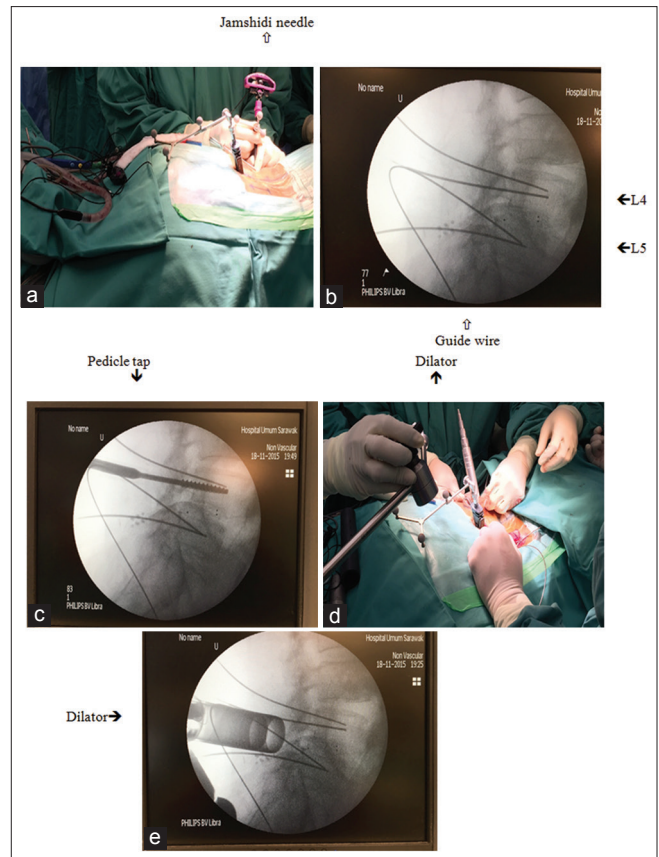


Figure 1: (a) Jamshidi needle inserted at the left L4 pedicle via the help of spinal navigation. (b) Fluoroscopy view of the guide wire inserted to the bilateral L4 and L5 pedicles following the Jamshidi needle track. (c) Fluoroscopy view showing the tapping of the pedicle before inserting the pedicle screws. (d) The different size of dilator inserted to dock on the facet joint of L4/5. (e) Fluoroscopy view showing the dilator dock on the L4/5 facet joint

Modified NASS score at 1-month postoperative in MIS and open group were 68.22 and 105.34, respectively; the distribution in two groups showed a significant difference (Mann–Whitney U = 625, $P = 0.016$).

There was a significant difference in the 3-month postoperative modified NASS score for MIS group (mean = 62.03, SD = 9.03) and open group (mean = 96.62, SD = 11.39) ($t = 4.281, P < 0.001$).

There was a significant difference in the 6-month postoperative modified NASS score for MIS group (mean = 53.12, SD = 7.93) and open group (mean = 91.24, SD = 12.04) ($t = 2.929, P = 0.003$).

There was a significant difference in the 1-year postoperative modified NASS score for MIS group (mean = 43.48, SD = 7.40) and open group (mean = 78.79, SD = 13.00) ($t = 4.536, P < 0.001$).

RAND 36-Item Health Survey 1.0

Table 4: RAND 36-item health survey 1.0 studies the subjects’ physical function, pain, role limitation secondary

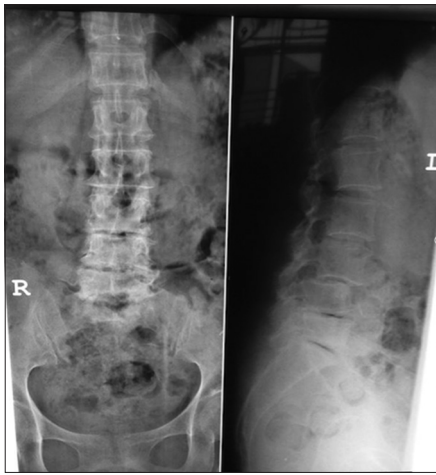


Figure 2: Lumbar-sacral anteroposterior and lateral view showing L3/4 and L4/5 spondylolisthesis with loss of L4 and L5 vertebra body height

to physical health, personal, or emotional problems. Emotional well-being, social functions, fatigability, and general health perceptions are also studied in this survey. However, the main aim to study with this survey is by looking at the trend preoperative and postoperative.

There was no significant difference in the preoperative RAND 36-Item Health Survey score for MIS group (mean = 95.40, SD = 8.90) and open group (mean = 107.38, SD = 15.35) ($t = -1.399$, $P = 0.085$).

There was no significant difference in the 1-month postoperative RAND 36-Item Health Survey score for MIS group (mean = 80.67, SD = 10.27) and open group (mean = 97.28, SD = 9.13) ($t = -0.223$, $P = 0.413$).

There was no significant difference in the 3-month postoperative RAND 36-Item Health Survey Score in the MIS group (mean = 67.48, SD = 10.79) and open group (mean = 89.76, SD = 5.84) ($t = -0.054$, $P = 0.291$).

There was no significant difference in the 6-month postoperative RAND 36-Item Health Survey score for MIS group (mean = 56.55, SD = 9.70) and open group (mean = 82.17, SD = 5.37) ($t = -1.226$, $P = 0.112$).

There was no significant difference in the 1-year postoperative RAND 36-Item Health Survey score for MIS group (mean = 47.17, SD = 8.71) and open group (mean = 73.69, SD = 6.78) ($t = -1.071$, $P = 0.144$).

Complications

The surgical complications [Table 5] were categorized into dural tear, infections, and nerve root injuries. These are the common complications reported in MIS TLIF. In MIS group, the overall complications rate was 5.0% where three patients developed new neurological secondary to nerve root injury postoperative and require repeated surgery for exploration. In open group, the overall complication rate was 10.3% with two patients having postoperative infection requiring antibiotics treatment and removal of implant. One patient had

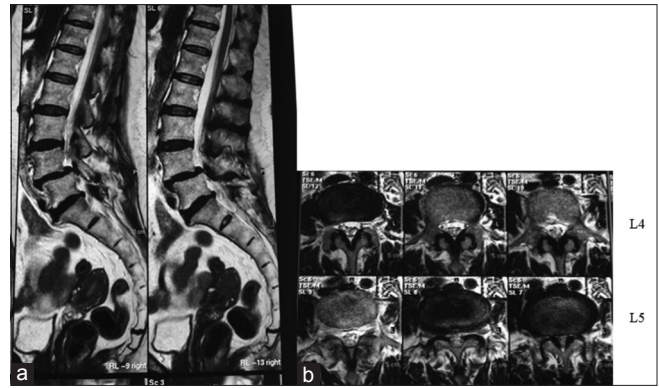


Figure 3: (a) Magnetic resonance imaging sagittal T2-weighted image lumbar-sacral showing L4/5 spondylolisthesis with disc prolapse. (b) Magnetic resonance imaging axial T2 lumbar showing disc protrusion with narrowing of right exit foramina and spinal canal stenosis

new neurology deficit secondary to nerve root injury because of the misplacement of the pedicle screw. Open group had higher complication rate compared to MIS group. However, the overall complications were not statistically significance between the two groups of surgery ($P > 0.05$). There was no dural tear in both groups of surgery. No mortality was detected in both groups of operation.

Discussion

Lumbar fusion is effective in treating spinal pathology such as spondylolisthesis, degenerative disc disease, spinal canal stenosis, and spinal instability. There are few methods of operation in lumbar fusion. These include posterior lumbar fusion, PLIF, TLIF, and ALIF. Minimally invasive spine procedures are gaining popularity in recent clinical practice. It reduces the blood loss and duration of hospitalization. However, minimally invasive procedures have steeper learning curve for surgeons.

Literature reviews on perioperative outcomes between MIS TLIF and open TLIF found that there are significant better perioperative outcomes in MIS TLIF compared to open TLIF. Villavicencio *et al.*^[10] reported lower estimated blood loss and shorter hospitalization in MIS (163 mL, 3 days) compared to open TLIF (366.8 mL, 4.2 days). However, operative times, mean change in VAS score, and functional outcome are better in open TLIF. In addition, the new neurology deficits' rate is higher in MIS group (10.2%, $P = 0.02$) compared to open TLIF (1.6%).

Our study was designed to compare the outcomes of MIS and open TLIF in local setting (HUS) and to demonstrate the efficacy of these two procedures in terms of pain relief and surgical complications. In this study, a single team of surgeons was involved in performing these two types of procedure to minimize any possible differences in the technical aspect of the surgery. Single investigator was employed to conduct the questionnaire session with the subject to reduce the possible bias during question answering or translation.

Perioperative outcomes

Dhall *et al.*^[12] retrospective data comparing MIS and open TLIF found a lower blood loss and shorter hospital stay in MIS TLIF compared to open TLIF. Villavicencio *et al.*^[10] retrospective data also have similar result. In our study, perioperative outcomes are favorable in MIS group compared to open group. The estimated blood loss is lower in MIS (211.3 mL) and open (683.8 mL). Length of hospitalization is shorter in MIS (3.8 days) versus open (7.4 days). However, the duration of operation is longer in MIS (170.7 min) compared to open (157.4 min). Peng *et al.*^[15] in their study comparing clinical and radiological outcomes of MIS versus open TLIF had similar result. This study found that MIS had longer operation time, shorter length of stay, and less blood loss. However, Scheufler *et al.*^[9] found that operative time is equivalent between MIS and open TLIF. Schizas *et al.*^[11] prospective data found that MIS TLIF has shorter hospital stay, less blood loss, and decreased pain but steeper learning curve. The majority of literatures show similar results.

In this study, the mean estimated blood loss, mean duration of operation, and mean duration of hospitalization are comparable to the literatures mentioned above. MIS group had less estimated blood loss (211.13 mL), longer duration of operation (170.67 min), and shorter duration of hospitalization (3.80 days) compared to open group – estimated blood loss (683.79 mL), duration of operation (157.41 min) and duration of hospitalization (7.38 days). The smaller incision in MIS operation caused less blood loss, faster recovery with shorter hospital stay.

Costs of the MIS group also lesser in view of shorter hospitalization but further study needs to be carried out for validation. Singh *et al.*^[23] study the costs of hospitalization for TLIF and found that open TLIF (average of \$ 4,038, 20.7%) were more expensive than MIS TLIF ($P < 0.001$). The implant costs made up most total direct costs and was similar between the two groups ($P = 0.686$). Most of the additional hospital cost in the open TLIF was due to the direct costs of surgical services, including operating room time, staff, anesthesia time, and non-implant supplies cost \$3,260 greater on average for the open cohort ($P < 0.001$). Other costs that were statistically greater for open TLIFs included room and board (+\$319; $P = 0.0012$), pharmacy (+\$ 176; $P < 0.001$), blood (+\$163; $P < 0.001$), and laboratory services (+\$ 46; $P < 0.001$).

Wong *et al.*^[22] found that MIS TLIF procedures were associated with significant increased radiation exposure to the patient, surgeon, and operating room personnel. There was a 2.5-fold increase in millisievert (mSv) per level for the MIS TLIF group of 1.90 versus 0.75 mSv for the open TLIF group ($P < 0.01$).

The duration of operation was longer in MIS group in view of steep learning curve. Wong *et al.*^[22] first described MIS TLIF in early 2002 with 100 MIS TLIF procedures

and found that the operation time was longer compared to open group. Subsequently, in their series of 144 MIS TLIF procedures representing surgical cases (years 2006–2008), they found that MIS TLIF group had shorter surgical times (2.05 h) than the open group (3.75 h). This was due to the surgeons involved had well past the initial learning curve of performing the MIS TLIF procedure.

Pain

Jang and Lee^[18] in their study found that there is a significant reduction in pain on patient underwent MIS TLIF. Park and Foley in their retrospective study of 40 patients who underwent MIS TLIF for spondylolisthesis also found that there was a significant reduction of back pain and leg pain or radicular pain from VAS 52 and 65 to 15 and 8. In our study, both the back pain and radicular pain significantly reduced from preoperative to 1-year postoperative. Mean preoperative back pain and radicular pain was 6.1 and 6.1 in MIS group and 5.4 and 5.0 in open group, respectively. Postoperative 1 year, the pain score drop to 0.5 (back pain) and 0.1 (radicular pain) for MIS group while 1.1 (back pain) and 0 (radicular pain) for open group. This shows that both types of operations have significantly help in reducing the pain with good outcome. Statistically for back pain, there was a significant reduction in pain score for MIS group compared to open group postoperative 6 months and 1 year ($P < 0.05$). This may be due to faster fusion rate in MIS group compared to open group. In our study, we unable to show fusion radiologically because most of the patients do not have postoperative CT scan which made the definition of fusion difficult.

Preoperative and 12 h postoperative VAS radicular pain were significant higher in MIS group ($P < 0.05$). This may be due to no randomization in selection of patients to undergo both types of surgery. MIS group had worse outcome in terms of radicular pain during 12 h postoperative which could be due to excessive retraction on muscle or nerve roots that causes neuropraxia.

Functional outcome

Functional outcome was measured with the trend of score using three sets of questionnaires: ODI, modified NASS low back pain outcome measures score, and RAND 36-Item Health Survey. Jang and Lee (2005: 3)^[18] in their prospective study of 23 patients found that there was a significant reduction of mean ODI score from 33.1 to 7.6 for patient underwent MIS TLIF. Deutsch and Musacchio^[19] in their prospective study of 20 patients also had similar results where they found that 85% had >20 point reduction in ODI after MIS TLIF. We manage to produce similar results in our study. Preoperative ODI for MIS group was 51 and dropped to 25.5 1-year postoperation. In open group, preoperative ODI was 55.2 and dropped to 36.4 1-year postoperative. Statistically, MIS had lower ODI score with better outcome postoperatively compared to open group

($P < 0.05$). This may be due to the shorter hospital stay in MIS group patients that allow early rehabilitation that affect the ODI score.

Modified NASS low back pain outcome measures score also showed the similar results with significant lower score in MIS postoperative compared to open surgery ($P < 0.05$). However, statistically for RAND 36-Item Health Survey score, there was no significant difference in between MIS and open group but the mean score in MIS group was lower than open group. Hence, we concluded that MIS has better outcome compared to open surgery.

Overall complications

Dhall *et al.*^[12] in their study of mini-open TLIF versus open TLIF found that mini-open surgery is more prone to neurological deficit and require revision (2 out of 42 patients). Statistically, it did not show any significance ($P > 0.05$). Schwender *et al.*^[17] also found similar result with 2 patients of 49 patients who had neurology deficit postoperation. Two patients had screws misplaced, which require revision. The overall complication rate reported as 8.2%. In our study, MIS group overall complication rate was 5.0% where all 3 patients had new neurology deficit postoperative and required revision surgery for the presence of new neurological deficit. Statistically, there was no significant difference in overall complications between MIS and open surgery ($P > 0.05$). Khan *et al.*^[20] reported overall complication rate of 28.9% (45 out of 114 patients) in their study of patients underwent open TLIF. The main complication was dural tear. In our study, open TLIF complication rate was 10.3% with 1 patient (3.4%) having new neurology deficit postoperative and 2 patients (6.9%) having infection postoperative. Our study complication rate was similar to other.^[10,16]

Clinical implications and recommendations

There is a lack of local data on the spinal fusion outcomes even though many journals studied the outcome of MIS versus open TLIF.^[10-12] MIS TLIF was first introduced in the 1980s and later gains popularity in 21st century. MIS TLIF is well known to have many advantages compared to open TLIF in terms of reducing muscle injury, smaller incision, and scar. However, MIS TLIF has a steeper learning curve for surgeons. This study was designed to study similar parameter and emphasize on functional outcome between both MIS and open TLIF. In our study, we managed to show similar result with better perioperative outcomes in terms of less blood loss, shorter hospital stay in MIS TLI compared to open TLIF. However, MIS TLIF had longer operation time compared to open TLIF. Our study statistically shows significant difference in perioperative outcome between MIS and open TLIF. We recommend other perioperative outcome, which can be studied, is the radiation exposure. We were unable to study this because our study was a cross-sectional study with half of the subjects underwent operation before we started to design the research.

Outcomes in terms of pain control, functional outcome measures from ODI, modified NASS low back pain outcome measures, and RAND 36-item Health Survey showed significant improvement from preoperative to postoperative in both groups of surgery. MIS was found to have better outcome with statistically significant. This result is similar to Park and Foley,^[13] Jang and Lee,^[18] and Deutsch and Musacchio.^[19] However, another control group can be included to study the outcome between conservative management versus operative treatment but ethics will be an issue. Usage of painkiller can also be studied before and after operation as part of the outcome measures. Another outcome can be studied in this research which is fusion radiology. In our study, we were unable to justify the fusion in view most of the patients only have X-ray postoperative. Muscle retraction also can be studied, as MIS TLIF is well known to reduce muscle retraction. MRI imaging measuring the muscle bulk or measuring the serum creatine kinase level can achieve this. Time of ambulation also can be studied.

Complication rate in our study is compatible to the literature review (Schwender *et al.*, 2005. p. 18).^[9,19] New neurology deficit is more common in MIS TLIF while infection is more common in open TLIF. Overall, MIS TLIF has lower complication rate (5%) compared to open TLIF (10.3%). These surgeries are safe with no mortality detected.

Cost between MIS and open TLIF can also be studied even though in MIS implant cost more, but overall including the medical expenses, it may cost less compared to open TLIF.

Limitations of study

This study is a cross-sectional study design and is not a randomized prospective design. We expect bias in terms of different severity of disease before operation and different outcome after operation. Only one center (HUS) is involved in this study with small sample size, perhaps multicenter with bigger sample size will shows different result.

The second limitation is that the follow-up duration is not long enough as spine operation needs at least 2-year follow-up to note the significant outcome. This happens because this is a study to fulfill criteria for the degree of Master of Surgery (Neurosurgery), so the duration of research is limited for routine monitoring and assessment of care outcomes in adult patients.

Summary and Conclusion

The present study aimed to study the functional outcomes of MIS TLIF versus open TLIF. This was a measure through pain score, ODI, modified NASS Low back pain outcome measure score, and RAND 36-Item Health Survey score. At the same time, the perioperative outcome in terms of estimated blood loss, duration of hospitalization, and duration of operation were measured. The complication and mortality rate were also studied.

Based on the results data of our study, we concluded as follows:

- Most common level of operation is L4/5, which is the most common level of degenerative changes
- MIS has less estimated blood loss and shorter hospital stay compared to open group, but has longer operation time
- Both surgeries have significant reduction in back pain and radicular pain score postoperative with MIS group having lower pain score compared to open surgery postoperative
- Both MIS and open TLIF show improved functional outcome with lower ODI, modified NASS low back pain outcome measure score, and RAND 36-item Health Survey Score postoperation
- Immediate complication (dura tear, excessive bleeding), infection, and new onset of neurology are not related to type of surgery.

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Conflicts of interest

There are no conflicts of interest.

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Appendices

Appendix 1

Data collection sheet

Open versus MIS TLIF

Epidemiology

Name
 RN/IC
 Age
 Sex Male/female
 Contact number
 Address
 Smoker
 Medical problems
 Weight (kg)
 Height (cm)

Indications of operation: Degenerative disc disease/Spondylolisthesis Grade 1 and 2/Foraminal stenosis with deformity/Recurrent disc disease/others, specify.

Preoperative assessment

Back pain Yes/no - VAS
 Type Mechanical/discogenic/stenotic/nonspecific
 Back pain duration (months)
 Radicular pain Yes/no - VAS
 Radicular pain duration (months)
 Weakness Yes/no specify side and level: R/L
 Numbness Yes/no specify side and level: R/L
 Anal tone Intact/lax
 Perianal sensation Intact/lax
 Conservative treatment durations
 Type of painkillers
 Any improvement VAS (pre): ___ VAS (post): ___

Operation: MIS/open date of operation:

Operated level L
 Surgical time (min)
 Estimated blood loss (mL)
 Size of incision/wound (cm)
 Length of hospital stay (days)
 Surgeon

Clinical outcome

Pain	Preoperative	12 h postoperative	1 month	3 months	6 months	1 year
VAS back pain	Preoperative	12 h postoperative	1 month	3 months	6 months	1 year
VAS radicular pain	Preoperative	12 h postoperative	1 month	3 months	6 months	1 year

Functional outcome

	Preoperative	1 month	3 months	6 months	1 year
Oswestry disability index (%)	Preoperative	1 month	3 months	6 months	1 year
Modified NASS score	Preoperative	1 month	3 months	6 months	1 year
RAND-36 health item survey 1.0	Preoperative	1 month	3 months	6 months	1 year

Complications

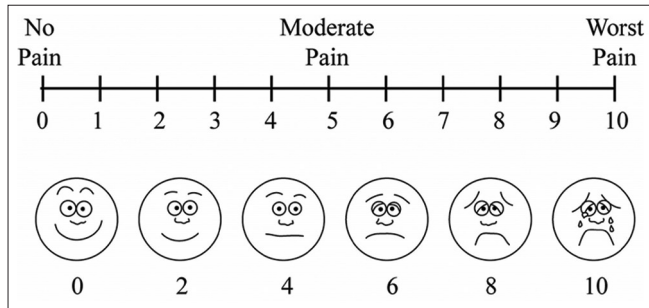
Infections	Yes/no Require further surgery? Yes/No Description
New neurology deficit	Yes/no Require further surgery? Yes/no Description
Dura tear	Yes/no Require further surgery? Yes/no Description
Others	

Appendix 2

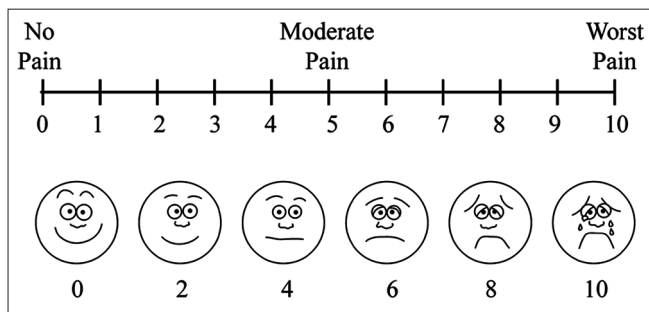
Visual Analog Scale

Please (X) on the line to indicate the intensity of pain

Back pain:



Leg pain:



Appendix 3

Oswestry disability index

Oswestry disability index - 2.0

Date:

Section 1: Pain intensity

- 0 - I can tolerate pain I have without having to use pain killers
- 1 - The pain is bad but I manage without taking pain killers
- 2 - Painkillers give complete relief from pain
- 3 - Painkillers give moderate relief from pain
- 4 - Painkillers give very little relief from pain
- 5 - Painkillers have no effect on the pain and I do not use them

Section 2: Personal care

- 0 - I can look after myself normally without causing extra pain
- 1 - I can look after myself normally but it causes extra pain

Patient's sticker

Section 6: Standing (remember, standing is NOT walking)

- 0 - I can stand as long as I want without extra pain
- 1 - I can stand as long as I want but it gives me extra pain
- 2 - Pain prevents me from standing for more than 1 h
- 3 - Pain prevents me from standing for more than 30 min
- 4 - Pain prevents me from standing for more than 10 min
- 5 - Pain prevents me from standing at all

Section 7: Sleeping

- 0 - Pain does not prevent me from sleeping well
- 1 - I can sleep well only by using tablets

2 - It is painful to look after myself and I am slow and careful	2 - Even when I take tablets I have <6 h sleep
3 - I need some help but manage most of my personal care	3 - Even when I take tablets I have <4 h sleep
4 - I need help every day in most aspects of self-care	4 - Even when I take tablets I have <2 h sleep
5 - I do not get dressed wash with difficulty and stay in bed	5 - Pain prevents me from sleeping at all
Section 3: Lifting	Section 8: Sex Life (by pain=for fear of causing pain)
0 - I can lift heavy weights without extra pain	0 - My sex life is normal and causes no extra pain
1 - I can lift heavy weights but it gives extra pain	1 - My sex life is normal but causes some extra pain
2 - Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned for example on a table	2 - My sex life is nearly normal but it is very painful
3 - Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned	3 - My sex life is severely restricted by pain
4 - I can lift only very light weights	4 - My sex life is nearly absent because of pain
5 - I cannot lift or carry anything at all	5 - Pain prevents any sex life at all
Section 4: Walking	Section 9: Social life
0 - Pain does not prevent me walking any distance	0 - My social life is normal and gives me no extra pain
1 - Pain prevents me walking more than 1 mile	1 - My social life is normal but increases the degree of pain
2 - Pain prevents me walking more than 0.5 miles	2 - Pain has no significant effect on my social life apart from limiting energetic interests such as dancing
3 - Pain prevents me walking more than 0.25 miles	3 - Pain has restricted my social life and I do not go out as often
4 - I can only walk using a stick or crutches	4 - Pain has restricted my social life to my home
5 - I am in bed most of the time and have to crawl to the toilet	5 - I have no social life because of pain
Section 5: Sitting ("Favourite chair" includes a recliner)	Section 10: Travelling
0 - I can sit in any chair as long as I like	0 - I can travel anywhere without extra pain
1 - I can only sit in my favourite chair as long as I like	1 - I can travel anywhere but it gives me extra pain
2 - Pain prevents me from sitting more than 1 h	2 - Pain is bad but I manage journeys over 2 h
3 - Pain prevents me from sitting more than 0.5 h	3 - Pain restricts me to journeys of <1 h
4 - Pain prevents me from sitting more than 10 min	4 - Pain restricts me to short necessary journeys under 30 min
5 - Pain prevents me from sitting at all	5 - Pain prevents me from travelling except to the doctor or hospital

Appendix 4

Modified North American Spine Society low back pain outcome instrument

Modified NASS Low Back Pain Outcome Instrument (Pre Op)

Patient's Sticker

- PID (IDET/Open/Micro/Endo or Percutaneous Discectomy/METRx/Disc Replacement)
- Spinal stenosis (Decompression Lami/-notomy/-nectomy)
- Spondylolisthesis/Spondylosis [Fusion – TLIF/PLIF/No instrument i.e., Alar fusion/Instrument (Cage only or Screws & Alar fusion)]
- Compression Fracture (Conservative/Vertebroplasty/Kyphoplasty)
- Face Joint OA (Radiofrequency/Facet Block)

Examination Date: Height: _____ cm

Surgeon: Weight: _____ kg

Preoperative diagnosis:

Operation planned:

Operation date:

Educational level	Marital status	Language	Household income	Activity level
None		English	<1000	Inactive
Primary	Single	Chinese	1000-2999	Moderately active
Secondary	Married	Others	3000-4999	Very active
Tertiary	Separated		≥5000	
	Widowed			

Work Status

- Currently working, but not back to work yet
 - Not working/retired
1. How long ago did your current episode begin?*
1. <2 weeks ago
 2. 2 weeks to<8 weeks ago
 3. 3 weeks to<3 months ago
 4. 3 months to<6 months ago
 5. 6–12 months ago
 6. More than 12 months ago
2. How did your current episode begin?*
1. Suddenly
 2. Gradually
3. Have you had back symptoms before your current episode?*
1. No (if no, go to question 6)
 2. Yes, one episode
 3. Yes, two or more episode

Question 4 and 5 are about your past back symptoms

4. Did you receive workers Compensation for your past back symptoms?*
1. No
 2. Yes
5. How much work did you miss because of your worst prior episode? *
1. None
 2. 1 day to 2 weeks
 3. More than 2–4 weeks
 4. More than 4–12 weeks
 5. More than 12–24 weeks
 6. More than 24 weeks
6. Have you had previous back surgery? *
1. No (if no, go to question 9)
 2. Yes: How many surgeries?_____
7. After your most recent surgery, did you return to work?*
1. No
 2. Yes, with limitations
 3. Yes, with no limitations
 4. Never stopped working
 5. Did not work
 - A. Homemaker
 - B. Student
 - C. Retired
 - D. Other
8. After your most recent surgery, did you return to full function?*
1. No
 2. Yes

There will be several questions about leg and back pain in this questionnaire. When we say leg, we mean your thigh, calf, ankle and foot. When we say back, we mean your low back and buttocks.

9. Which hurts you more, your legs or back?*
1. Legs hurt much more
 2. Legs hurt somewhat more
 3. Legs and back hurt about the same

4. Back hurts somewhat more
5. Back hurts much more

Please answer every question in the box below.

In the past week, how often you suffered	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
10. Low back and/or buttock pain	1	2	3	4	5	6
11. Leg pain	1	2	3	4	5	6
12. Numbness or tingling in leg and/or foot	1	2	3	4	5	6
13. Weakness in leg and/or foot (such as difficulty lifting foot)	1	2	3	4	5	6

Please answer every question in the box below.

In the past week, how bothersome have these symptoms been?	Not at all bothersome	Slightly bothersome	Somewhat bothersome	Moderately bothersome	Very bothersome	Extremely bothersome
14. Low back and/or buttock pain	1	2	3	4	5	6
15. Leg pain	1	2	3	4	5	6
16. Numbness or tingling in leg and/or foot	1	2	3	4	5	6
17. Weakness in leg and/or foot (such as difficulty lifting foot)	1	2	3	4	5	6

In the last week, please tell us how pain has affected your ability to perform the following daily activities. Mark the one statement that best describes your average ability.

18. Getting dressed (in the last week):

1. I can dress myself without pain.
2. I can dress myself without increasing pain.
3. I can dress myself but pain increases.
4. I can dress myself but with significant pain.
5. I can dress myself but with very severe pain.
6. I cannot dress myself.

19. Lifting (in the last week):

1. I can lift heavy objects without pain.
2. I can lift heavy objects but it is painful.
3. Pain prevents me from lifting heavy objects off the floor, but I can manage if they are conveniently positioned, for example on a table.
4. Pain prevents me from lifting heavy objects, but I can manage light to medium objects if they are on a table.
5. I can lift only light objects.
6. I cannot lift anything.

20. Walking (in the last week):

1. Pain does not prevent me from walking.
2. Pain prevents me from walking more than 1 h.
3. Pain prevents me from walking more than 30 min.
4. Pain prevents me from walking more than 10 min.
5. I can only walk a few steps at a time.
6. I am unable to walk.

21. Sitting (in the last week):

1. I can sit in any chair as long as I like.
2. I can only sit in a special chair for as long as I like.
3. Pain prevents me from sitting more than 1 h.
4. Pain prevents me from sitting more than 30 min.
5. Pain prevents me from sitting more than 10 min.
6. Pain prevents me from sitting at all.

22. Standing (in the last week):

1. I can stand as long as I want.
2. I can stand as long as I want but it gives me pain.

3. Pain prevents me from standing more than 1 h.
4. Pain prevents me from standing more than 30 min.
5. Pain prevents me from standing more than 10 min.
6. Pain prevents me from standing at all.

23. Sleeping (in the last week):

1. I sleep well.
2. Pain occasionally interrupts my sleep.
3. Pain interrupts my sleep half of the time.
4. Pain often interrupts my sleep.
5. Pain always interrupts my sleep.
6. I never sleep well.

24. Social and recreational life (in the last week):

1. My social and recreational life is unchanged.
2. My social and recreational life is unchanged but it increases pain.
3. My social and recreational life is unchanged but it severely increases pain.
4. Pain has restricted my social and recreational life.
5. Pain has severely restricted my social and recreational.
6. I have essentially no social and recreational life because of pain.

25. Travelling (in the last week):

1. I can travel anywhere.
2. I can travel anywhere but it gives me pain.
3. Pain is bad but I can manage to travel over 2 h.
4. Pain restricts me to trips of <1 h.
5. Pain restricts me to trips of <30 min.
6. Pain restricts me from travelling.

26. Sex (in the last week):

1. My sex life is unchanged.
2. My sex life is unchanged but causes some extra pain.
3. My sex life is nearly unchanged but is very painful.
4. My sex life is severely restricted by pain.
5. My sex life is nearly absent because of pain.
6. Pain prevents any sex life at all.

Question 27–31: Not important.

32. During the last week, how often have you taken medication for your back and/or leg pain?*

1. 3 or more times a day
2. Once or twice a day
3. Once every couple of days
4. Once a week
5. Not at all

Question 32–34: Compressed to form Q.32.

Question 35–40: Not applicable preoperatively.

Question 41–47: Not important.

Question 48–51: Not applicable preoperatively.

Question 52: Not important.

Question 53: Not applicable preoperatively.

Appendix 5

RAND 36-Item Health Survey 1.0

Instructions: This survey asks for your view about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:
 1. Excellent
 2. Very good
 3. Good
 4. Fair
 5. Poor
2. Compared to 1 year ago, how would you rate your health in general now?
 1. Much better now than 1 year ago
 2. Somewhat better now than 1 year ago
 3. About the same (as 1 year ago*)
 4. Somewhat worse now than 1 year ago
 5. Much worse now than 1 year ago

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Activities	Yes, limited a lot	Yes, limited a little	No, Not limited at all
3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing several flights of stairs (e.g., overhead bridge*)	1	2	3
7. Climbing one flight of stairs	1	2	3
8. Bending, kneeling or stooping	1	2	3
9. Walking more than a mile (more than 30 min*)	1	2	3
10. Walking several blocks (15-30 min*)	1	2	3
11. Walking one block (<15 min*)	1	2	3
12. Bathing or dressing yourself	1	2	3

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
13. Cut down on the amount of time you spent on your work or other activities	1	2
14. Accomplished less than you would like	1	2
15. Were limited in the kind of work or other activities	1	2
16. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
17. Cut down on the amount of time you spent on your work or other activities	1	2
18. Accomplished less than you would like	1	2
19. Didn't do work or other activities as carefully as usual	1	2

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20. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?
 1. Not at all
 2. Slightly

- 3. Moderately
- 4. Quite a bit
- 5. Extremely

21. How much bodily pain have you had during the past 4 weeks?

- 1. None
- 2. Very mild
- 3. Mild
- 4. Moderate
- 5. Severe
- 6. Very severe

22. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- 1. Not at all
- 2. A little bit
- 3. Moderately
- 4. Quite a bit
- 5. Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks:

	All off the time	Most of the time	A Good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of pep (life*)?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	
28. Have you felt downhearted and blue?	1	2	3		5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (such as visiting with friends, relatives, etc.)?

- 1. All of the time
- 2. Most of the time
- 3. Some of the time
- 4. A little of the time
- 5. None of the time

How TRUE or FALSE is each of the following statements for you.

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

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