MACQUARIE UNIVERSITY

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DEVELOPMENT OF A MODEL FOR ASSESSMENT AND PREDICTING OUTCOME IN SURGERY FOR DEGENERATIVE DISORDER OF THE LUMBOSACRAL SPINE

by

DR. SABARUL AFIAN MOKHTAR, MD (UKM), MS (Orth)

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ABSTRACT

Degenerative lumbosacral disorders involve the gradual loss of normal structure and function of the spine over time. The growth of the ageing population has led to an increase in the number of spinal surgery for degenerative lumbosacral disorder recommended when conservative treatment fails. Yet the clinical benefit of this surgery remains controversial when a significant number of patients fail to achieve the expected beneficial outcome.

The overall aim of any surgical intervention in degenerative lumbosacral disorders should be to eliminate the primary pathology of the disease (e.g. loss of sagittal balance) to achieve an outcome that restores or improves patients' health-related quality of life (HRQL). In order to assess health-related quality of life, a plethora of outcome measures are employed in the speciality of spinal surgery. The ability to measure outcome of surgery and to predict which patients will have a good outcome from surgery is important for patients and the healthcare systems as a whole.

The concept of maintaining or restoring spinal sagittal balance is essential in managing degenerative lumbosacral spine disorders. The focus of spinal fusion and deformity correction techniques are obtaining fusion of the diseased spinal column in the optimal balanced alignment in order to improve the long-term outcome of surgery. The spinal sagittal balance is characterized by both pelvic and spinal parameters. No single measurement can accommodate the entire spectrum of spinal curvatures. All methods available for assessing the spine in the sagittal plane have their strengths and caveats.

The purpose of my PhD research is to establish that spinal surgery is a worthwhile surgical procedure in improving the health-related quality of life outcome for degenerative lumbosacral disorders by using the comparison model utilizing the generic HRQL outcome measure instrument (i.e. SF-12) to benchmark with established surgical procedures (i.e. total joint replacement surgery for osteoarthritis of the knees and hips). I also intend to develop a model for a simple and practical pre-operative assessment method utilizing the SF-12 scores as predictors of favourable outcome for patients with degenerative lumbosacral disorder undergoing spinal surgery. Another model would investigate the correlation of a simple VAS score with the lengthy and sophisticated outcome measures instruments used to monitor outcome of patients post-operatively. The final part of the thesis is to analyze the concept of sagittal balance as the biological factor in terms of its value and compensatory mechanism that affect the outcome of spinal surgery.

My research developed the following models:

1. Comparison model for benchmarking the outcome of certain spinal surgical procedures (on a homogenous group of spinal disorder) with other established surgical procedure (e.g primary spinal fusion, large joint replacement surgery) using the generic HRQL outcome measure instruments (e.g SF-12).
2. Prediction model for pre-operative screening of biopsychosocial factor of patients planned for spinal surgery by using the pre-operative scores of SF-12(both the PCS-12 and MCS-12 scores).
3. Visual pain scale(VAS) score model for assessment of follow-up patients to replace the administration of multiple, lengthy outcome measures instruments in certain clinical setting where resources are limited (e.g. private surgical practice audit).

4. The compensatory mechanism model for spondylolisthesis:
    a. Type I - hyperlordosis above the slipped level, observed in the younger patients with otherwise flexible lumbar spines.
    b. Type II - increase in pelvic angulation may be a less energy efficient secondary compensation mechanism that is adopted by older patients with stiffer spines
    c. Type III - combined hip and knee flexion may represent a third compensation mechanism, which is used once the capacity of Type I and II mechanisms to correct sagittal imbalance is exceeded.

STATEMENT OF CANDIDATE

I certify that the work in this thesis entitled "Development of a Model for Assessment and Predicting Outcome in Surgery for Degenerative Disorder of the Lumbosacral Spine" has not previously been submitted for a degree nor has it been submitted as part of requirements for a degree at any other university or institution other than Macquarie University.

I also certify that the thesis is an original piece of research and it has been written by me. Any help and assistance that I have received in my research work and the preparation of the thesis itself have been appropriately acknowledged. The additional authors included in the papers were involved in the research at a supervisory level and collaboration with other researchers are stated in Appendix A (List of authors and contribution list). This thesis includes two original papers published in peer reviewed journals and four unpublished publications. All of the papers have been presented as oral presentation at international level conferences (List of proceedings).

In addition, I certify that all information sources and literature used are indicated in the thesis.

The research presented in this thesis was approved by Macquarie University Ethics Review Committee (reference number: HE24OCT2008-D06141) on the 13 January 2009.

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Sabarul Afian Mokhtar (Student ID: 41406176)

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List of Articles

This thesis is based on the following articles:

I Health-related quality of life: a comparison of outcomes after lumbar fusion for degenerative spondylolisthesis with large joint replacement surgery and population norms.(Published - The Spine Journal, Volume 10, Issue 4 , Pages 306-312, April 2010)

II Health-Related Quality Of Life Following Revision Surgery For `Failed Back Surgery Syndrome´ – A Comparison with Results Following Primary Spinal Fusion And Large Joint Arthroplasty.

III Independence of Clinical Outcome Measurement Instruments in Spinal Surgical Practice.

IV Preoperative Health-Related Quality of Life Scores as Predictor of Clinical Outcomes after Degenerative Lumbar Surgery

V Lumbo-pelvic Lordosis and the Pelvic Radius Technique in the Assessment of Spinal Sagittal Balance: Strengths and Caveats.(Published-European Spine Journal Volume 20, Supplement 5, Pages 591-60,August 2011)

VI Compensatory Mechanisms and the Effect of Age on Sagittal Balance in Degenerative and Isthmic Spondylolisthesis: An Analysis Utilizing the Pelvic Radius Technique

List of Proceedings

1 Health-Related Quality of Life Following Further Surgery For 'Failed Back Surgery'. *In Proceedings of Spine Society Of Australia Conference 2009*, Brisbane, Queensland, Australia, April 2009.

2 Independence of spinal surgery clinical outcome measurement instruments - an analysis of 9,600 paired outcome measures. *In Proceedings of 24th Annual Meeting North American Spine Society (NASS*), San Francisco, USA, November 2009.*

3 Health-related Quality of Life following further surgery for 'Failed Back Surgery' – a comparison with results following primary spinal fusion and large joint arthroplasty. *In Proceedings of 24th Annual Meeting North American Spine Society (NASS*), San Francisco, USA, November 2009.*

4 Preoperative Health-Related Quality of Life Scores as Predictor of Clinical Outcomes After Degenerative Lumbar Surgery. *In Proceedings of Spine Society Of Australia Conference 2010*, Christchurch, New Zealand, April 2010.

5 Preoperative Health-Related Quality of Life Scores as Predictors of Clinical Outcome After Degenerative Lumbar Surgery. *In Proceedings of 25th Annual Meeting North American Spine Society(NASS*), Orlando, USA, October 2010**.(Best Paper Presentation)***

6 Correlation of Age with Spino-Pelvic Balance in Degenerative Lumbo-Sacral Disorder. *In Proceedings of Spine Society Of Australia Conference 2011*, Melbourne, Victoria, Australia, April 2011.

7 Compensatory Mechanisms and the Effect of Age on Sagittal Balance in Degenerative and Isthmic Spondylolisthesis: An Analysis Utilizing the Pelvic Radius Technique. *In proceedings of 12th International Society for the Advancement of Spine Surgery* A*nnual Meeting* March 20-23, 2012, Barcelona, Spain.

8 Compensatory Mechanisms and the Effect of Age on Sagittal Balance in Degenerative and Isthmic Spondylolisthesis: An Analysis Utilizing the Pelvic Radius Technique. *In proceedings of 47th Annual Meeting & Course of SRS (The Scoliosis Research Society*) September 5-8, 2012, Chicago, Illinois, USA,

9 Compensatory Mechanisms and the Effect of Age on Sagittal Balance in Degenerative and Isthmic Spondylolisthesis: An Analysis Utilizing the Pelvic Radius Technique. *In proceedings of 56th Annual Meeting of the Korean Orthopaedics Associatio.* October 17-20, 2012, Seoul, South Korea.

** North American Spine Society (NASS) Annual Meeting is one of the three largest spine specialty meetings in the world. Presentations compiled from these meetings are thought to represent the bulk of the current research which are subjected to a peer-review composed of the program committee, which is made up of multiple individuals who review each submission in a blinded fashion.(sources :(The Publication Rates of Presentations at Major Spine Specialty Society Meetings (NASS, SRS, ISSLS) by Wang, Jeffrey C. MD; Yoo, Stephen BA; Delamarter, Rick B. MD Spine:1 March 1999 - Volume 24 - Issue 5 - pp 425-427)*

Abbreviations & Definitions

95% CI – 95% confidence interval

Disease specific – Referred to outcome instruments, it indicates a tool (usually a questionnaire) focusing on one or more aspects (function, impairment etc) of a specific health problem that is affecting the person.

Generic – Referred to outcome instruments, it indicates a tool (usually a questionnaire) which is applicable to a general population, regardless of the specific health problem that is affecting the person.

FBSS – failed back surgery syndrome

HRQL – Health-Related Quality of Life.

MCIDs – Minimal clinically important differences

Outcome – The end result of a clinical intervention.

Outcome assessment – The clinical activity of collecting outcomes in a standardised fashion to be able to interpret personal results.

PROM – Patient's response outcome measures.

Questionnaire – A set of questions submitted to persons receiving health care in order to share their view on the treatment received and perform an outcome evaluation, usually patient administered.

SF-12 – Medical Outcomes Study 12-Item Short-Form Health Survey

SF-36 – Medical Outcomes Study 36-Item Short-Form Health Survey

PCS - Physical Component Summary

MCS - Mental Component Summary

PCS-12 - Physical Component Summary for SF-12

MCS-12 - Mental Component Summary for SF-12

PCS-36 - Physical Component Summary for SF-36

MCS-36 - Mental Component Summary for SF-36

VAS – Visual analogue scale, usually a 10 cm horizontal line where a dimension can be marked. (quantified as 0–10)

EQ-5D - European Quality-of-Life 5-Dimension questionnaire

SIP- Sickness Impact Profile

ODI - Oswestry Disability Index

LBOS - Low Back Outcome Score

RDQ- Roland–Morris Disability Questionnaire.

QALY- Quality-Adjusted Life Year

ISSLS - International Society for the Study of the Lumbar Spine

NASS – North American Spine Society

HA - hip axis

PA - pelvic angulation

PR technique – pelvic radius technique

PRS1 - pelvic lordosis

PI – pelvic incidence

PT - pelvic tilt

SI – sacral inclination

SS - sacral slope

PRT12 – total lumbopelvic lordosis

T12S1 - total lumbosacral lordosis

ISPL - isthmic spondylolisthesis

DSPL - degenerative spondylolisthesis

Chapter 1

THESIS INTRODUCTION

Primum Non Nocere

"First Do No Harm"

-Hippocratic Oath-

PREFACE

The exponential growth of the ageing population has raised the incidence of degenerative spinal disorders and potentially they may become an epidemic of this century. Many of these patients will progress to symptomatic degenerative lumbosacral disorder that will interfere with activities of daily living. This will also have a significant and growing impact on both human resources and financial health costs. This effect is already evident in the increasing number of patients undergoing spinal surgery for degenerative spinal disorders.

In general, the current surgical management for symptomatic degenerative spinal disorder involves either spinal decompression alone, or a combination of spinal decompression and fusion. Over the years there has been considerable advancement in spinal surgical intervention, with the rapid development of surgical techniques and implant technology. However, considerable controversy remains about the clinical benefit gained from these surgical interventions. Particularly when adding cost-benefits of surgery to the equation as these surgical interventions require implants that potentially present significant cost to any healthcare system.

Assessing the outcome of surgery, as well as identifying factors that might predict favourable outcome, depend largely on the ability to measure and record the change of signs and symptoms of the patients after surgery. Various studies have looked into factors that can predict the *outcome of surgery. These factors will guide the decision making on which patients with degenerative lumbosacral disorders that would benefit from spinal surgery. Currently, there are no gold standard outcome assessments in the field of spinal surgery.*

Restoring patients' health-related quality of life (HRQL) is now a fundamental concept in medical interventions including spinal surgery. There is a plethora of instruments used to measure HRQL, and now it is essential health outcome indicators.

HRQL is assessed based on the "biopsychosocial model". This model has gained widespread acceptance and has altered the ways in which clinicians and carers think about and treat patients, including those with degenerative spinal disease. As a result, a conceptual shift has occurred from the traditional pathology-based disease model to a model with a more dynamic set of interactions between patients' biologic, psychological and social factors. Each factor and the interaction of these factors are crucial in affecting patients' response towards the disease and management of the disease.

The success of a surgical intervention not only depends on the patient selection but also the surgical technique. The concept of maintaining spinal sagittal balance is becoming essential in the management of degenerative disease of the lumbosacral spine. Thus, the current focus of spinal fusion and deformity correction techniques is obtaining fusion and correction of the diseased spinal column in the optimal spinal sagittal balance, in order to improve the long-term outcome of surgery. The spinal sagittal balance is characterized by measuring both the pelvic and spinal parameters. Currently there is no single measurement that can accommodate the entire spectrum of spinal curvatures assessment. All methods available for assessing the spine in the sagittal plane have their strengths and caveats.

The Ageing Spine

The ageing population is rapidly increasing throughout the world, especially in the developed countries. Australians' life expectancies are among the longest in the world. Between 2010 and 2050, the number of population aged 65 to 84 years is expected to be more than double. In contrast, the number of children is expected to increase only by 45%. This means that the proportion of people aged 65 years or over is projected to increase from 13% in 2010 to 23% by 2050. (Figure 1)[1] This demographic transformation would profoundly affect the health and socio-economic development of any nation with the inevitable increase in health problems associated with the physiological ageing process.[2-10]

	2010	2020	2030	2040	2050
Population projections					
Population (millions)	22.2	25.7	29.2	32.6	35.9
0-14	4.2	4.9	5.4	5.7	6.2
15-64	15.0	16.6	18.2	20.0	21.6
65-84	2.6	3.7	4.8	5.6	6.3
85 and over	0.4	0.5	0.8	1.3	1.8
Life expectancy at birth					
Male	80.1	82.5	84.5	86.1	87.7
Female	84.4	86.2	87.8	89.2	90.5
Total fertility rate	1.95	1.9	1.9	1.9	1.9
Dependency ratios					
Aged to working-age ratio	20.0	25.3	31.0	34.7	37.6
Child to working-age ratio	28.3	29.3	29.4	28.4	28.5
Net migration to population ratio	0.9	0.7	0.6	0.6	0.5

Figure 1: Demographic Projection of Population in Australia (2010 to 2050)
- Ministry of Finance, Australian Government's 2010 Intergenerational Report.

In this thesis, the focus is degenerative disorders of the lumbosacral spine. The mechanism of this disease may be due to the effects of ageing and secondary to trauma or "wear and tear". The disease commonly presents with the clinical picture of pain and disability. The disease processes involves the intervertebral discs, the vertebrae and/or the associated facet joints, resulting in the associated pathologies or clinical syndromes of instability, spinal stenosis and/or degenerative spondylolisthesis. This disorder has also been termed lumbar spondylosis or degenerative disc disease. Collectively, I have termed these conditions as "degenerative lumbosacral disorders". [7,11,12]

Surgical treatment for symptomatic degenerative lumbosacral disorder, after failed conservative treatment, has been ever more recommended.[13-16] The question for the clinician is whether surgery in the elderly patients is worthwhile and would it restore their quality of life. Review of the literature fails to clarify the issue, with conflicting reports regarding the outcome of lumbar spine surgery with results ranging from 10% to 90% success rate.[17-25]

Many studies have emphasised the morbidity associated with surgical treatment of lumbar stenosis in the elderly and thus have recommended non-surgical treatment. [26-31] Deyo et al demonstrated a substantial complication rate among patients 75 years of age or older and suggested the need for further study of the relative efficacy of surgery in degenerative spinal disorder.[26,27] Katz et al reported that 20% to 40% of patients who had surgery for degenerative lumbar spinal stenosis have a poor outcome.[28] The author noted that lumbar fusion in the presence of osteoporotic bone and advanced age may lead to significant peri-operative morbidity.

Nevertheless, there are emerging studies that support the benefit of surgery in the elderly.[32-36] Jakola and colleagues reported, in a prospective cohort of patients 70 years and older, that with proper patient selection, a clinical meaningful improvement of Health-Related Quality of Life (HRQL), functional status and pain following lumbar surgery can be achieved. [35] Crawford et al similarly demonstrated 35 patients (> 75 years of age) who had undergone instrumented lumbar arthrodesis, had statistically significant improvement in the HRQOL outcome measures Oswestry Disability Index (ODI) and Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) at 2 years post-operatively.[33] Shabat et al in their study of 357 patients greater than 65 years of age, who underwent revision surgery for lumbar spinal stenosis, confirmed significant improvement in pain perception and functional status.

Evolution of Spinal Surgery

The concepts of spinal surgery have evolved over the last few decades. This evolution coincides with the advancement in three medical specialities:

1. Diagnostic technology
2. Surgical technology
3. Disease conception

The advancement of diagnostic technology, primarily in radiological imaging, enhanced the clinician's visualisation of the pathological spine. The uses of computed tomography scan (CT scan) and more recently magnetic resonance imaging (MRI) have supplemented the plain radiography and myelography investigation. The correlation between the clinical-radiographic-pathologic findings became synonymous with disease model (or biomedical model) practiced by clinicians.[37,38]

A classical example of the evolution of the disease model is seen in the management of low back pain secondary to disc pathology. The pathology was first recognized through an autopsy carried out by Valliex (1841) and Virchow (1857). Following that, Oppenheim and Krause excised a disc herniation, diagnosing it as a chondroma in 1909. In 1934, Mixter and Barr performed the first discectomy with rupture of the intervertebral disc pathology in mind. Thus, "intervertebral disc herniation" emerged as a disease entity which could be diagnosed.[39,40] The diagnostic criteria, initially purely clinical on the basis of radicular pain to the leg, with time progressed to associating clinical presentation with plain radiography and myelogram and more recently, supplemented by computed tomography and MRI.[38]

Similarly, “spinal canal stenosis” emerged as the disease causing neurogenic claudication, and, despite continuing controversy regarding the scientific validity of associations between its assessments, diagnosis, treatment, and outcomes, “degenerative disc disease” emerged as the primary diagnosis of persistent low back pain. Currently, spinal canal stenosis is probably the most common indication for spinal surgery for degenerative disease of the lumbosacral spine. After more than 90 years, there are continued debates as to whether lumbar fusion is an appropriate and effective method of treating back pain in this group of patients. This controversy is the result of insufficient data, such as diagnostic criteria, natural history, indication for surgery, choices of surgical procedures and clinical characteristic associated with a favourable outcome.[8,41]

Advancement of diagnostic imaging technology, especially MRI, allows other pathological spinal entities, such as discogenic pain, internal disc disruption and facet joint syndrome to be diagnosed.[38] Pathologies identified by imaging modalities are used for the development of new surgical implants and surgical techniques. However, the down side of this advancement, as spinal disease is more “visualised”, more often the indication for surgery may be based on radiological findings only without clearly defining the underlying pathophysiology of the disease.

Another major breakthrough in the evolution of spinal surgery was the integration of medical science with biomechanical engineering and material science. This led to more powerful instruments and more durable implants able to withstand the physiological load of the spinal column. The combination of improved general surgical techniques, instruments, implants, and spinal surgery expertise, has created a range of new possibilities where surgeons could advance their field of operation. [8,42]

Finally, with the recent conceptual shift from pathologically based biomedical model, to the contextually based illness within the biopsychosocial model, has altered the ways clinicians think about and treat patients with spinal disorder. Through a century of modern medicine, as proposed by Virchow, the idea of pain had been associated with tissue damage. The disease model, or biomedical model, assumes tissue damage produces inflammations which manifests as pain. (Figure 2)This has been the basis of the explaining most disease entities. For this reason, the concept of spinal disorder evolved around finding the "pain generator". Other concepts have been forwarded to explain the problem of low back pain, from the concept of stability or instability, which was made popular in the 80's by White and Panjabi, to the concept of degenerative disc as the "pain generator". The biomedical model can explain a lot of pathology, but it is evident that there is limitation in the context of spinal disorders and the clinical presentation of back pain.[37,43-46]

Pain = tissue injury

Tissue damage →→*impairment* →→*disability*

"if we cure the pain, then the disability will recover"

Figure 2: Disease model (base on Virchow, 1858)

A change was seen in the mid-1980s when Waddell proposed the concept of a biopsychosocial model for treatment of spinal disorder.[47] It was originally developed by Adolf Meyer as a concept of "multicausality" in the psychiatric disorder. It was recognised that psychosocial factors on top of biological factors, influence the course and outcome of most somatic diseases. (Figure 3)

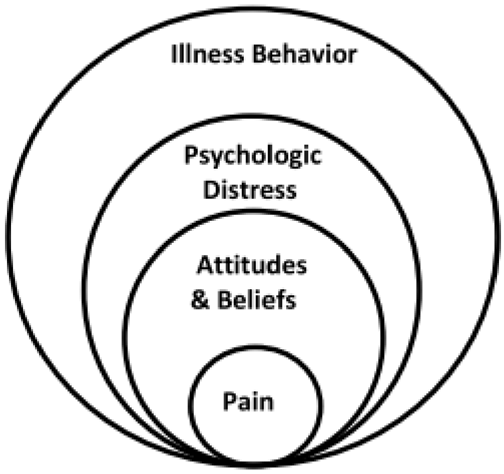

Figure 3: A biopsychosocial model of the clinical presentation and assessment of low back pain and disability. (Waddell et al, 1987)

The proponents of this model believe that the complex, multidimensional nature of persistent spinal problems do not lend themselves to the clean reductionist program of the disease model. Instead of totally focussing on the underlying pathophysiology, the patient's unique biologic, psychological, and social factors (e.g. socio-economic concerns, emotional reaction-fear and depression, illness beliefs, coping strategies), carry equal, if not primary, weight in the presentation of disease and illness, and the response to treatment.[43,47]

Although the biopsychosocial model has gained widespread acceptance within the spine care community, clinicians still adopt the patho-anatomically based disease categories for daily practice, research and treatment.(Table 1) The disease categories are just too useful to be discarded, especially when they allow physicians to group patients into disease groups, as an easy tool for looking at trends and costs.

Traditional assumptions (based on a disease model approach)	**A biopsychosocial model approach**
Etiology	
Low back pain is an injury **Often work related** **Pain = disability**	Physical dysfunction(not really an injury) Not really 'caused' by work Pain and disability are not the same thing
Activity/work causes	
Increased pain **Re-injury** **Recurrence and risk of chronicity**	Reduced pain in the long run (It isn't really an injury) Fewer recurrences and less risk chronicity
Treatment	
Rest **Activity limitation** **Routine sick certification**	Stay active Temporary activity modification Stay at work if at all possible

Table 1**:** Disease model versus biopsychosocial model approach

Outcome Assessment Instruments in Spine Surgery

The effectiveness of any surgical intervention is assessed by its outcome. The traditional clinical indices of health outcome are often negative in their focus, such as mortality rates, morbidities, complications, biochemical investigations, physical conditions, symptoms and return to work.[48]

The measurement of health outcome has moved away from these clinical measures towards more sophisticated patient-based outcome measures.[49-52] Among the most important health care development made during the past decades, was an increasing consensus regarding the centrality of the patient's point of view in monitoring medical outcome.[53-55] There is now greater focus on a broader, more positive concept of health rather than a narrow, negative and disease-based focus.[56]

Generally there are two categories of these patient based outcome measures. They are:

1) Generic Health-Related Quality Of Life (HRQL) Questionnaires
2) Disease-specific quality of life questionnaires.

The generic HRQL outcome measures are aimed at assessing all dimensions of health-related quality of life. The World Health Organisation (WHO) Quality-of-Life group has recommended that five dimensions should be assessed in any generic quality of life survey: physical health, psychological health, social relationship perceptions, function and well-being. Generic outcome measures are used across a wide range of medical and surgical specialties. Their purpose goes beyond just measuring intervention outcomes; they are also used for research to compare surgical techniques, patient selections and types of peri-operative care. Audits can also be done using these measures, allowing comparison of different surgeons, institutions or healthcare systems.[48,57,58]

Commonly used generic measures are:

- Medical outcomes study 36-item short-form health survey (SF-36)
- Medical outcomes study 12-item short form health survey (SF-12)
- European Quality-of-Life 5-Dimension (EQ-5D) questionnaire
- Sickness Impact Profile(SIP).[59]

The commonly used disease-specific measures for lumbar disorder are:

- Oswestry Disability Index (ODI)
- Low Back Outcome Score (LBOS)
- Roland–Morris Disability Questionnaire (RDQ)

Summary of each outcome measure instruments are elaborated in Appendix C.

Choosing the appropriate outcomes to measure in everyday practice is a decision the clinician must make taking into consideration many factors including the characteristics of these measures. Investigator preference for either the generic or the disease-specific measures depends on the purpose and period of assessment (e.g. clinicians involved in clinical trials often request outcome measures specifically tailored to the intervention under investigation or related to major clinical outcome).[49] When choosing between a generic or a disease-specific instrument, one will have to look at the advantages and disadvantages of the instruments. When deciding which measure to use, the investigator should assess: the type of scoring and whether the scores can be easily analyzed in relation to other variables; the reliability, validity and sensitivity of the scale; the appropriateness of the instrument for the study population; and the acceptability of the instrument to the group study.[48] There is also a demand of speed, efficiency and acceptability to both doctors and patients. In addition in clinical research and trials, there is the need of precision and specificity.[52]

It is important to not to omit a measure of overall patient satisfaction. Limitations should be recognised. Single item measures have at least two problems, the ceiling and floor effects. That is, problems of substantial numbers of people getting the highest or lowest possible scores in one population or another.

The most popular health surveys are likely to be those that achieve brevity and comprehensiveness. Commonly used measures of back-specific function are the Oswestry Disability Index (ODI) and the Roland-Morris Disability Questionnaire (RDQ). Among the generic measures, the SF-12 strikes the best balance between length, reliability, validity, responsiveness and experience in large populations of patients with back pain. In addition to the five recommended domains, preference-based health outcome measures, including the patient's utilities, may be useful when there is a need to value alternative health outcomes.

Outcome measures are important tools for clinicians, patients and policy makers to assess the effectiveness of medical interventions. However, there will be no single measure of patient satisfaction that will be the preferred choice for all these stakeholders.

Using SF-12, Chapter 2 investigates the worthiness of spinal fusion in patients with degenerative lumbosacral disorders, by comparing their surgical outcomes to the outcomes of patients with osteoarthritis having large joint replacement surgeries. Chapter 3 extends the investigation of spinal fusion results by looking at the most difficult group of patients who have not improved after initial spinal surgery, known as "failed back surgery syndrome". Outcome of further surgery for these “failed back surgery syndrome” patients are compared to the outcomes of patients having primary spinal fusion and also both primary and revision large joint replacements. The studies demonstrated a model of measuring clinical outcomes in a homogeneous group of spinal disorder (e.g. cases of unstable degenerative spondylolisthesis patients in chapter 2 and “failed back surgery syndrome” patients in chapter 3) using a specific spinal fusion technique.

The model is possible by the using generic Health-Related Quality Of Life (HRQL) Questionnaires (i.e. SF-12) score and comparing the clinical outcomes after treatment with those of established surgical procedures (e.g. large joint replacement surgeries) or disease entity(e.g. large joint osteoarthritis).The model of assessment also can be compare with known HRQL score of normal population. Similar model can be use to compare other homogenous group of spinal disorders (e.g degenerative scoliosis, degenerative scoliosis and iatrogenic flat-back syndrome) with known HRQL outcome measures within the same studied population.

Chapter 4 explores the value administrating multiple patients response outcome measures(PROM) instruments when assessing patient outcomes following spinal surgery. To achieve this, the correlation between the scores by various types of clinical outcome measurement instruments was examined. By using Visual Analogue Scale (VAS) for pain and comparing with a generic outcome measures instrument SF-12 and two disease-specific measures instruments, ODI and LBOS, the independence of these outcome measures will be investigated. The study looked into developing a model for assessment clinical outcome without the need for multiple, complex questionnaires.

Predictors of Outcome in Spine Surgery

Regardless of the technical success of spinal surgical intervention, a significant proportion of patients with spinal disorder developed unfavourable outcome. Studies showed the outcomes of spinal surgery have a diverse range of success rates of between 50% and 90%.[17,24] It is even more unpredictable with revision surgery, with favourable outcomes ranging from 10% to 80%.[18-25] It is usually considered that the outcome of repeat lumbar surgery is rarely as successful as that of primary surgery.[24,60] To improve spinal surgery outcomes, there have been attempts to identify predictors of outcome in individual patients with relevant prognostic factors.[58,61-65]

The main categories of predictors in the literature are socio-demographic (e.g. age, gender), clinical signs or symptoms (e.g sensory loss, straight leg raising test), radiological parameters, and work-related parameter(e.g work compensation) and psychological factors.[58,62-65] Despite the numerous studies that have sought to identify the criteria for the “ideal” patient for a favourable outcome, there are conflicting results and no consensus on the matter. For instance, when considering age, younger patients have often been thought to recover from spinal surgery better than older patients. However, a number of studies were unable to agree on the significant correlation between age and surgical outcome. [26-36]

Mannion and colleagues highlighted numerous factors that result in this inconsistent results. One of the main reasons for this uncertainty is that there is no existing universally accepted method for assessing predictor of outcome in spinal surgery. This is especially reflected in the design of the studies. The differences in the study design include statistical methods used to identify predictors which includes the number and type of predictor factors being investigated in the study and their prevalence within the group under investigation. Other major factors are the outcome measures employed to assess success and the end-point at which a ‘‘successful outcome’’ is defined.Even when similar types of outcome measures are utilized, the proportion of patients with good outcomes is highly dependent on how the measurement was used (e.g. successful outcome could variously be defined as any improvement in symptoms, achieving pain-free state or reaching a pre-specified level of pain such as pain score less than 2 on a 10-point scale). Each definition in the methodology would lead to a different estimate of successful or poor outcome.[58]

Mannion and colleagues have also emphasised the importance of homogeneity of the specific spinal condition to avoid inconsistencies. Surgical outcome is highly variable when heterogeneous groups of spinal disorders are clumped into a single entity (e.g low back pain patients).[66] It is essential to define and delineate the patients according to specific pathology under investigation. This stresses the importance of identifying the surgical pathology carefully with appropriate surgical strategies. This is to assure a more predictable outcome of surgery.[67,68]

Spangfort et al demonstrated that the success of surgical treatment for sciatica and back pain due to disc herniation depends on the degree of herniation during operative findings(Table 2). The best prognostic factor in terms of pain relief is accuracy of the diagnosis. The intra-operative findings of complete disc herniation demonstrated the best outcome. Vice versa was also found, a negative findings of disc herniation will have poorer outcome with less than 50% pain relief in term of both sciatica and back pain.[67]

Operative findings	Relief of Sciatica (%)		Relief of Back Pain (%)
	Complete (%)	Partial (%)	
Complete herniation	90	9	75
Incomplete herniation	82	16	74
Bulging disc	63	26	54
No herniation	37	38	43

Table 2 : Relief of sciatica and back pain according to the degree of disc herniation found at surgery (Spangfort, 1972)

More recent publications on this subject indicated that the outcome of spinal surgery is determined by multiple biopsychosocial factors.[43,47,58,65,69-71] These findings offer a preliminary opportunity to focus on certain aspects of patient selection . Chapter 5 will discuss further the application of the established generic health-related quality of life questionnaire, SF-12, as a pre-operative screening tool for biopsychosocial factor assessment to identify patients most likely to benefit from spinal surgery for degenerative lumbosacral disorder.[43,63,71-74] It will provide a basis for a model of utilizing existing HRQL outcome measure as a predictor tool of biopsychosocial aspect of a patient before going for surgery.

Concept of Spinal Sagittal Balance and Outcome of Spinal Surgery

The Riddle: What goes on four legs in the morning, on two legs at noon, and on three legs in the evening?

The Answer:

Human,

who crawls on all fours as a baby,

walks on two legs as an adult,

and walks with a cane in old age.

-The Sphinx (Egyptian Mythology)-

The concept of spinal sagittal balance has been accepted at face value by most spinal surgeons. It stresses on the importance of sagittal alignment and the restoration of sagittal contour of the spine.[75-89] Although these beliefs are widely held, there are only a few studies to support the existence of a relationship between sagittal balance and clinical outcome.[85,88,89]

Sagittal imbalance with displacement of the patient’s center of gravity anteriorly or rarely posteriorly to the sacrum, due to spinal disease, is biomechanically disadvantageous. It may cause significant pain and ambulatory difficulty. In some cases, it may be the primary spinal pathology causing pain and disability.

Part of any pre-operative planning must involves careful study to determine the correct location and degree of sagittal angulation that needs to be achieved to create optimum neutral sagittal balance. Increasing emphasis has been placed on the preservation or restoration of neutral upright sagittal spinal balance.[90-92] This involves a careful assessment of the whole spinal column which mainly consists of the cervical lordosis, thoracic kyphosis, lumbar lordosis and pelvic morphology. The regional and global alignment of the spine after fixation and fusion is increasingly recognized as a significant factor in post-operative clinical outcomes. Intuitively, restoring the sagittal balance should be associated with less pain and better function, particularly among patients who have previously undergone surgery and those with post-traumatic or osteoporotic fracture.[85]

A study by Glassman and colleagues demonstrated that restoration of normal sagittal balance is the critical goal for any reconstructive spine surgery. Sagittal balance is the most important and reliable radiographic predictor of clinical health status, as patients with positive sagittal imbalance reported worse self-assessment in pain, function, and self-image domains. Coronal imbalance (plumb line offset more than 5 cm in the coronal plane) was not as critical parameter as compared to sagittal imbalance in prediction of outcome after surgery.[93] Conversely, Winter et al showed that sagittal balance did not correlate with health status or disability of patients with de novo degenerative scoliosis. And the degree of patients' disability was also independent of the magnitude of the scoliosis in patients with degenerative lumbar scoliosis.[94]

Another study by Glassman et al examined the outcome of 752 adult patients with spinal deformity. A total of 352 patients had positive sagittal balance (anterior deviation of the C7 plumb line measurement anterior to the posterosuperior margin of the S-1 end plate). The study found positive sagittal balance was associated with greater pain, worse function, worse self-image, and poorer social function. They concluded even mildly positive sagittal balance had a negative effect on health outcome in a linear fashion with progressive sagittal imbalance.

Another important finding was that kyphosis is more favourable in the upper thoracic region but very poorly tolerated in the lumbar spine.[78]

Equally important is the preservation of neutral sagittal alignment in patients without pre-existing sagittal imbalance that undergo fusion in which instrumentation is placed from the lumbosacral spine to the pelvis; these patients possess minimal ability to compensate for any sagittal imbalance postoperatively. Although there is a long history of surgical treatment of sagittal plane deformities and sagittal imbalance (e.g. scoliosis surgery in adolescence), there is still lack of evidence demonstrating a more favourable outcome with restoration of normal lumbar lordosis during lumbar fusion procedures in degenerative lumbosacral disorder.[32,89,95,96] The additional benefit of improving surgical outcome by restoring sagittal balance to non-deformity pathological entities has not been established. The question is, should all lumbar decompressions due to degenerative stenosis be performed with instrumented fusions in order to maximize segmental lordosis and minimize the risk of developing sagittal imbalance (such as iatrogenic flat-back deformity)? Thus, the aim of surgery would be to obtain optimum sagittal alignment in the spinal column during fusion surgery to improve long term outcome.

In the past, the validity of the method of measuring curvature in the sagittal plane via Cobb techniques was questioned. Voutsinas and colleagues demonstrated from standardized radiographs of 670 normal subjects that the Cobb method has its limitations. Although it is an accepted method in coronal deformities, in the sagittal plane it is unable to represent an actual arc and reflects changes in the end vertebral bodies, rather than changes within the curve itself. [97]

Kuntz and colleagues presented the results of their review and analysis of neutral sagittal spinal alignment from previously published studies of various authors who reported measures of spinal alignment using plumb line from the occiput to the pelvis. They identified sagittal spinal balance was maintained in a narrow range for alignment of the spine over the pelvis and femoral heads (measured by either the relationship of a C2 or C7 plumb line to the sacrum or by the angular displacement of T1 or T9 relative to the hip axis) in asymptomatic adults. Significant limitation of their review was that differences with ethnicity and comorbid medical conditions were not taken into account. They also did not analyze neutral standing sagittal occiput–pelvis alignment in the same group of patients.[92]

For the context of this thesis, I concentrated the basis of the study of sagittal balance on references to the hip axis. During et al first reported the pelvisacral angle as a constant pelvic measurement for morphology using standing lateral radiographs.[98] This angle assessed the fixed orientation for the proximal sacrum between the iliac bones. The measurement relied on determining the central axis through the hip joints and finding the length of the superior S1 endplate.

Duval-Beaupe`re et al reproduced this prior methodology in their studies, but they measured the complement angle to that of During et al. This angle was termed the pelvic incidence (PI).[99,100] The authors described pelvic incidence as the angle between a line perpendicular to the sacral plate and a line joining the sacral plate to the axis of the femoral heads. A review of these publications showed that the mean acute angles for During et al and Duval-Beaupe`re et al when added together, equaled about 90°.

Duval-Beaupe`re et al proposed that PI appears to be the main axis of sagittal balance of the spine and controls the adaptability of the other parameters.[100] PI equates the sum of the sacral slope (SS) and pelvic tilt (PT): PI = SS + PT. Due to this arithmetical equation between PI, SS and PT, the morphology of the pelvis, as quantified by PI, is a strong determinant of the spatial position of the pelvis in the standing position (i.e. the greater PI, the greater has to be SS, PT, or both).[100]

Jackson et al similarly described a specific pelvic radius technique, which involved locating a midpoint between the hip centers called the pelvic hip axis, and drawing a line from this axis to a point on the sacrum. This line segment was named the pelvic radius because the sacrum rotates around the hip axis along an arc that could be defined by this radial line. The pelvic lordosis (PRS1) similar to pelvic incidence is considered a specific feature of an individual which remain constant after reaching adulthood.[101,102]

Jackson et al also illustrated the pelvic radius technique as a simple way of rapidly and accurately assessing lumbopelvic sagittal balance on a standard lateral lumbar radiograph and assessing the degree of correction required. It is nearly a complementary angle to pelvic incidence (i.e. PRS1≈ 90-PI). Based on his studies, pelvic radius technique yielded better inter-observer and intra-observer reliability on patients with degenerative disorders, compared with the commonly used pelvic incidence techniques described by Duval-Beaupère.[100-107]

Despite the differences in the application of the techniques, both methods stress that the anatomical position and orientation of the sacrum in relation to the hip axis is relatively fixed throughout adult life and a fundamental determinant of the shape of the spinal curves above. Nevertheless both methods have strengths and caveats.[100-102,104-115]

Chapter 6 reviews the pelvic radius technique that is used in our institution and compares our results to published data using the technique, specifically to indicate potential errors which can be made if the pelvic radius technique is not used correctly. Chapter 7 aims to analyze the correlations between age and measures of spino-pelvic sagittal alignment in patients with spondylolisthesis and secondly, whether sagittal imbalance compensation mechanisms differ as patients age. It also analyzes the differences between the subgroups of degenerative spondylolisthesis, isthmic spondylolisthesis and published data of asymptomatic volunteers.

Thesis Research Objectives

Objectives:

- To investigate whether spinal surgery is a worthwhile surgical procedure in improving the health-related quality of life outcome for degenerative lumbosacral disorders.
- To develop a model of simple and practical assessment of patients with degenerative lumbosacral disorder that is applicable to the clinical setting and to apply this for the purpose of patient selection for surgery.
- To analyse the concept of sagittal balance in terms of its value and compensatory mechanism that might affect the outcome of spinal surgery.

To reach these objectives this thesis intends to:

- investigate if primary spinal surgery can return patients' health-related quality of life by comparing with that of age-matched population norms and established surgical procedures (e.g. total hip and knee joint replacement surgery)
- investigate the health-related quality of life outcomes following surgery in 'failed back surgery syndrome' patients and to compare these outcomes with primary spinal surgery outcomes and established surgical procedures (e.g. total hip and knee joint replacement surgery).
- identify a model of using an existing simple assessment method for outcome assessment by exploring the independent value of administering available multiple clinical outcome measurement instruments following spinal surgery.
- identify a model of simple and practical screening tool for predicting outcome of spinal surgery by evaluating the property of pre-operative generic outcome measures (i.e.

Medical Outcome Study Short Form 12-Item Questionnaire (SF-12) scores) as predictors of outcome in fusion surgery for degenerative lumbar disorders.

- identify factors that affect the results of sagittal balance, not correlating with health status outcomes, by assessing the strengths and weaknesses of a sagittal balance measurements parameters (i.e. pelvic radius technique – PR techniques) after reviewing published measures made using the PR technique. This technique will then be compared with other techniques (i.e. pelvic incidence methods).
- identify the compensation mechanisms for defective sagittal balance that might be influenced by patients' age. This was done by investigating correlations between patients' age and measures of spino-pelvic alignment, in a series of patients with spondylolisthesis.

Note:

For the context of this thesis, a model is defined as "*a thing (a system, procedure, method etc.) used as an example to follow or imitate*"

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Chapter 2

Health-Related Quality of Life: A Comparison of Outcomes After Lumbar Fusion for Degenerative Spondylolisthesis with Large Joint Replacement Surgery and Population Norms

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Clinical Study

Health-related quality of life: a comparison of outcomes after lumbar fusion for degenerative spondylolisthesis with large joint replacement surgery and population norms

Sabarul A. Mokhtar, MD, MS (Orth)[a,*], Peter F. McCombe, MBBS, FRACS[b], Owen D. Williamson, MBBS, GradDipClinEpi, FRACS, FAOrthA[c], Michael K. Morgan, MD, MMedEd, FRACS[d], Gavin J. White[e], William R. Sears, MBBS, FRACS[a]

[a]*Department of Spinal Surgery, The Australian School of Advanced Medicine, Macquarie University, Level 1, Dow Corning Building, 3 Innovation Rd, Sydney, New South Wales 2109, Australia*

[b]*Brisbane Spine Centre, Watkins Medical Centre, Level 9, 255 Wickham Terrace, Spring Hill, Brisbane, Queensland 4000, Australia*

[c]*Department of Epidemiology & Preventive Medicine, Faculty of Medicine, Nursing & Health Sciences, Monash University, Melbourne, Victoria 3800, Australia*

[d]*The Australian School of Advanced Medicine, Macquarie University, Level 1, Dow Corning Building, 3 Innovation Rd, Sydney, New South Wales 2109, Australia*

[e]*Medtronic Sofamor Daneks, Memphis, TN 38132, USA*

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Abstract

BACKGROUND CONTEXT: Degenerative spine disease will become an increasing health problem, and a significant number of patients will be considered for surgery. Spinal surgeries have evolved since the last decades, and there is a positive impact on the clinical outcomes. Few works in the literature have reviewed the outcome compared with large joint replacement surgery, which is considered a benchmark for operative restoration of patients' quality of life.

PURPOSE: The purpose of this study was to investigate if spinal fusion can return patients' health-related quality of life to that of age-matched population norms and yield outcomes comparable with those of total hip and knee joint replacement.

STUDY DESIGN: This is a prospective cohort study.

PATIENT SAMPLE: The sample consists of 100 consecutive patients who were enrolled between December 1997 and January 2007.

OUTCOME MEASURES: The 12-item Short Form Health Survey (SF-12) was chosen for outcome measurement.

METHODS: All patients underwent wide decompressive laminectomy and single-level posterior lumbar interbody fusion for spinal stenosis associated with degenerative spondylolisthesis.

RESULTS: The preoperative and postoperative physical component summary (PCS)-12 scores of the spinal fusion patients were comparable with those of both the total knee and hip replacement patients. The mean improvement in PCS-12 scores after spine surgery was 11 (95% confidence interval [CI]: 9–14, $p<.0001$). It was equal to that after total hip replacement surgery, which was 11 (95% CI: 9–13), and higher than that of total knee replacement patients, which had an improvement of 8 (95% CI: 7–9). The postoperative mean and 95% CI of the PCS-12 scores for the three surgical procedures approached the population norm value of 44 (95% CI: 43–46).There was no statistical difference between the postoperative mental component summary-12 score among all the three surgical groups, which approached similar to the population norm value of 54 (95% CI: 53–54).

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* Corresponding author. Department of Spinal Surgery, The Australian School of Advanced Medicine, Macquarie University, Level 1, Dow Corning Building, 3 Innovation Rd, New South Wales 2109, Australia. Tel.: (612) 985-0400 (office); (614); fax: (612) 985-04010.

E-mail address: drsam2020@yahoo.com (S.A. Mokhtar)

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CONCLUSIONS: The current study demonstrated that spinal surgery can return patients' HRQL to that of age-matched population norms and yield outcomes comparable with those of total hip and knee joint replacement patients.

Keywords: Outcome assessment; Quality of Life; Spondylolisthesis; Spinal fusion; Arthroplasty; Replacement

Introduction

As the population ages, degenerative spine disease will become an increasing health problem, and an increasing number of patients will be considered for surgery [1]. Although the evolution of spinal surgery (facilitated by developments in diagnostic technology, spinal implants, and surgical techniques) is likely to have a positive impact on clinical outcomes, debate exists as to the role of surgery in the treatment of patients with degenerative spine disease [1–3].

Large joint replacement surgery is considered a benchmark for operative restoration of patients' health-related quality of life (HRQOL) [4,5]. The recent literature contains a number of studies comparing the clinical outcomes of spine procedures with those of large joint replacement and other surgeries [6,7]. These studies have shown improvements in self-reported quality of life after surgical interventions for lumbar spinal stenosis or low back pain, which are comparable with those after large joint replacement surgery.

The above-mentioned studies have compared a mix of spinal disorders and/or spinal surgical techniques with benchmark nonspinal surgeries. Clinical outcomes may vary, however, according to the disorder studied or the surgical technique used. We believe that the current study is the first to compare the capacity of a specific and current surgical technique of spinal decompression and fusion to restore quality of life in patients suffering from degenerative lumbar spinal stenosis, associated with an unstable spondylolisthesis, with published HRQOL outcomes of total hip and knee joint replacement surgery and with published age-matched Australian population norms.

Materials and methods

Study design and participants

A prospective study was undertaken of all patients who underwent primary spinal decompression and fusion surgery for neurogenic lower limb pain associated with lumbar spinal stenosis and degenerative spondylolisthesis.

The inclusion criteria for surgery were symptoms of neurogenic spinal claudication; unresponsive to conservative treatment; symptoms attributed to single-level lumbar spinal canal stenosis; and an unstable degenerative spondylolisthesis (assessed radiologically)—Meyerding Classification Grade I or II (Fig. 1) [8,9]. Patients with previous history of spinal surgery were excluded from the study.

Surgical technique

All patients underwent wide decompressive laminectomy and posterior lumbar interbody fusion. After removal of the lower half of the laminae of the cephalad vertebra and medial facetectomy, the spondylolisthesis and any associated loss of segmental lordosis were corrected using intervertebral disc space distraction and titanium pedicle screw instrumentation. Complete discectomy was followed by insertion of "insert and rotate" lordotic interbody spacers [10]. Before December 2001, carbon fiber "Ramp" posterior lumbar interbody fusion spacers (DePuy Spine, Raynham, MA, USA) were used and, subsequently, PEEK "R90/Hourglass" spacers (Medtronic Sofamor Daneks, Memphis, TN, USA). Before November 2005, autologous bone graft was harvested from the iliac crest and placed between the posterior lumbar interbody fusion spacers and over the partially decorticated posterior elements. From November 2005, morselized laminectomy bone was used as bone graft rather than iliac crest graft, after mixing it with a bone morphogenic protein-2 (Infuse; Medtronic, Minneapolis, MN, USA).

Data collection and analysis

Data were collected prospectively. Patient demographics (age and sex) were recorded. All patients completed the 12-item Short Form (SF-12) preoperatively and at 3, 6, 12, and 24 months postoperatively. The SF-12 is a self-reported generic HRQOL measure consisting of 12 questions that can be scored to provide a physical component summary (PCS-12) score and a mental component summary (MCS-12) score [11].

A systematic literature review was performed to obtain similar preoperative and postoperative PCS-12 and MCS-12 data for patients undergoing total hip replacement (THR) and total knee replacement (TKR) surgery. The Ovid Medline computerized literature databases were searched for articles published between 1950 and March 2008 and using the MeSH terms: "Arthroplasty, Replacement, Hip" or "Arthroplasty, Replacement, Knee" and the keyword "SF-12." Articles were excluded from further analysis if there were insufficient data to enable calculation of preoperative and postoperative means and 95% confidence intervals (95% CIs).

Population norms for PCS-12 and MCS-12 were obtained from the surveys conducted by the South Australian Department of Human Services, Population Research and Outcome Studies [12].

EVIDENCE & METHODS

Context
Hip arthroplasty for arthritic conditions is associated with substantial quality of life improvements. Quality of life outcomes following surgery for specific spinal pathology can be compared with hip replacement as a benchmark.

Contribution
For primary radicular or claudicant symptoms due to spinal canal stenosis with degenerative spondyolisthesis, the authors found changes in quality of life following decompression, instrumentation, and posterior interbody fusion compare favorably with total hip replacement surgery.

Implications
The efficacy of surgical intervention for lumbar stenosis and degenerative spondylolisthesis has been demonstrated in controlled trials with improvement in overall quality of life. It is not well-established that these patients uniformly need decompression *and* fusion *and* instrumentation *and* interbody cages. Determining whether similar or better outcomes can be achieved with less extensive surgical strategies should be a research priority.

—*The Editors*

Fig. 1. (Left) Plain erect lateral radiograph of a 52-year-old woman with a single-level L4–L5 degenerative spondylolisthesis, claudication sciatica, and back pain. (Right) Postoperative plain radiograph of posterior lumbar interbody fusion demonstrating restoration of the lumbar lordosis. (Below) Computed tomography scans showing the narrowing of the spinal canal at L4–L5 region.

Descriptive statistics including means and ranges or 95% CIs were used to provide a summary of the participant demographics, preoperative and postoperative PCS-12 and MCS-12 scores, and change scores. Preoperative and postoperative scores were compared using the Wilcoxon signed-rank test.

Data were extracted from relevant articles for calculation of mean and 95% CI PCS-12 and MCS-12 scores. PCS-12 and MCS-12 scores before and after spine surgery were compared with the corresponding scores before and after hip and knee replacement surgery and with population norms. Overlapping 95% CIs were interpreted as indicating lack of significant difference in outcomes between the spine patients and the published results in the other groups. Analyses were performed using the XLSTAT version 7.5.3 software. The study protocol was approved by the university's human ethics committee.

Results

Of the 105 consecutive patients who were enrolled between December 1997 and January 2007, 100 (95%) were available for review at a minimum of 12 months after surgery.

The mean age at surgery was 67 (range: 46–90) years. There were 27 men and 73 women. The median postoperative follow-up was 24 (range: 12–60) months.

Relevant information could be extracted from two articles on hip joint replacement surgery and three articles on knee joint replacement surgery (Table 1). The two published articles containing SF-12 data for total hip joint replacement surgery reported results in a total of 307 patients from four hospitals [13,14]. The mean age in the combined data was 62 (range: 22–89) years, and there was a slight male predominance (55%). In the three articles with SF-12 data for total knee joint replacement, there were a total of 879 patients enrolled [15–17]. The weighted mean age was 69 (range: 29–93) years, and there was a slight female predominance (58%).

The follow-up periods for the spine surgery and joint replacement patients were similar in three of the five articles (12–24 months). In the total knee arthroplasty article, where the follow-up was substantially longer (mean 9.5 years, 728 patients), the clinical outcomes reported at 2 years, 5 years, and last follow-up were similar [15].

Although the mean ages for the three surgical groups were similar, the lower limits of the age range for the large joint replacement patients (22 and 29 years) were younger

Table 1
Summary of studies included in analysis of THR and TKR surgery using Short Form-12

Author	Published (study dates)	Procedure/study type	Number of patients	Mean age (range), y	Mean follow-up (range)	Indication (all primary surgery)	Implant
Current study		PLIF/prospective observational	**100** (two hospitals)	**67** (46–90)	**24 mo** (12 mo to 5 y)	Single-level, degenerative stenosis with spondylolisthesis	Pre December 2001—“Ramp” PLIF spacers (DePuy Spine, Raynham, MA, USA), Post December 2001—“R90/Hourglass” PLIF spacers (Medtronic, Memphis, TN, USA)
Danesh-Clough et al. [13]	2007 (December 1996 to December 1999)	THR/prospective observational	193 patients (210 hips)	58 (22–85)	6.25 y (5–8 y)	Primary osteoarthritis (83%); inflammatory (2%); uni- or bilateral	Synergy Stem—3rd Generation Implant—proximal ingrowth, uncemented (Smith and Nephew, Memphis, TN, USA)
Ostendorf et al. [14]	2004 (April 1999 to December 2000)	THR/prospective observational	114 (three hospitals)	68 (36–89)	12 mo	Primary osteoarthritis (83%); no inflammatory; unilateral only	Prosthesis details not provided; 103 cemented; 11 uncemented
Primary THR summary			**307**		**1–8 y**		
Bourne et al. [15]	2007 (February 1996 to December 2001)	TKR/prospective observational	728 patients (843 knees)	68 (29–93)	9.5 y (5–11 y)	Osteoarthritis (93%); inflammatory (5%); uni- or bilateral	Genesis II—fourth-generation implant (Smith & Nephew, Memphis, TN, USA); cruciate-retaining or post-and-cam cruciate-sacrificing, cemented
Hartley et al. [16]	2002 (1997–1999)	TKR/prospective, nonrandomized, primary vs revision surgery	100 (primary surgery patients only)		12 mo	Primary surgery patients: osteoarthritis (85%); inflammatory (15%); unilateral	Cruciate-retaining, Anatomic Modular Knee (Depuy, Warsaw, IN, USA); femoral component porous, tibial component cemented
Muller et al. [17]	2006 (RCT—study dates)	TKR/prospective RCT, two prostheses	40 (both prosthesis types) included	74 (65–89)	24 mo	Osteoarthritis (92%); inflammatory (8%); unilateral only	Prospective randomized comparison of: cruciate-retaining condylar PFC-Σ: all-polyethylene (Depuy, Warsaw, IN, USA)—third generation with, cruciate-retaining condylar PFC-Σ: metal backed (Depuy, Warsaw, IN, USA)—third generation
Primary TKR summary			**879**		**12 mo to 11 y**		

PLIF, posterior lumbar interbody fusion; RCT, randomized controlled trial; THR, primary total hip replacement; TKR, primary total knee replacement.

Table 2
Demographic differences of the three groups of patient underwent different surgical procedures: primary spinal fusion, THR, and TKR

Procedure	Number	Mean age (range), y	Male	Female
Primary spinal fusion	100	66.9 (46–90)	27	73
THR	307	61.8 (22–89)	167	140
TKR	879	69 (29–93)	358	511

THR, primary total hip replacement; TKR, primary total knee replacement.

when compared with that of the spinal fusion patients (46 years). The upper limit of the age range for all the three groups was similar (Table 2).

The mean preoperative and postoperative PCS-12 scores for all groups are summarized in Table 3. The mean improvement in PCS-12 scores after spine surgery was 11 (95% CI: 9–14, $p<.0001$), which was equal to that after total hip joint replacement surgery of 11 (95% CI: 9–13). Total knee joint replacement patients had an improvement of 8 (95% CI: 7–9). The preoperative and postoperative PCS-12 scores of the spinal fusion patients were comparable with those of both the total knee and hip joint replacement patients (Fig. 2, top). The postoperative mean and 95% CI of the PCS-12 scores for the three surgical procedures (spinal fusion, TKR, and THR) approached the population norm value of 44 (95%CI: 43–46) [12].

The mean preoperative and postoperative MCS-12 scores for all groups are summarized in Table 4. The spinal fusion and THR patients had a lower preoperative MCS-12 mean score as compared with the TKR patients. All the three groups had no differences in the postoperative MCS-12 scores, which approached the population normative value of 54 (95% CI: 53–54). The mean improvement in MCS-12 scores after spine surgery was 4 (95%CI: 2–6, $p<.0001$). The TKR patients did not show any improvement in the mean MCS-12 score (Fig. 2, bottom).

Discussion

The current study has shown that spinal decompression and fusion surgery for degenerative lumbar spondylolisthesis with stenosis, unresponsive to conservative measures is able to generate significant and substantial improvements in patients' HRQOL outcome measures. The surgery returned the SF-12 measures of the patients studied to values approaching and perhaps not clinically different from those of the age-matched normal population. Total large joint replacement surgery has been described as the benchmark of patient-oriented success for surgical intervention [4,18]. Within the limitations of the literature review, the HRQOL improvements after fusion surgery appeared equivalent to those after total hip and knee joint replacement surgery.

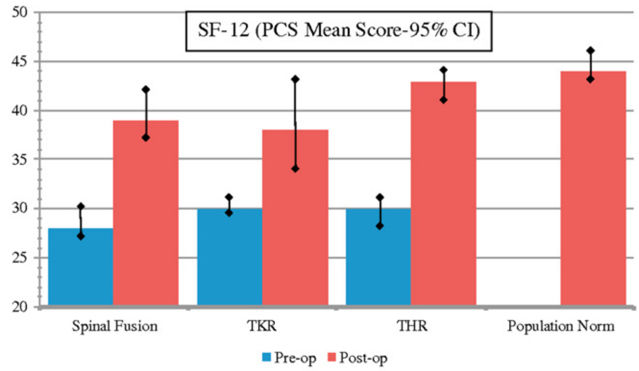
The heterogeneity of pathological conditions being treated by spinal decompression and fusion surgery needs to be considered when evaluating previously reported results. Polly et al. [6] compared SF-36 HRQOL outcome measures before and after spinal fusion for ''low back pain'' with published results of total hip and knee joint replacement and coronary artery surgery. They noted similar improvements in HRQOL measures for the spinal fusion and large joint replacement patients to those found in the current study. Their fusion procedures were for ''low back pain'' rather than for a specific spinal disorder. A variety of fusion techniques were used in their series including anterior interbody, posterior interbody, and transforaminal interbody. Rampersaud et al. [7] examined HRQOL in the surgical treatment of lumbar spinal stenosis. They used the SF-36 HRQOL instrument to prospectively compare outcomes with hip and knee joint replacement surgery. Although their study reported similar findings to the current study, it involved a mixture of spinal surgical procedures, with and without fusion. The current study examined treatment of degenerative lumbar spinal stenosis associated with spondylolisthesis. Surgical decompression of the stenotic spine may aggravate an associated spondylolisthesis and lead to poor outcome through increasing deformity and recurrent stenosis [1].

The current study aimed to measure clinical outcomes in cases of unstable degenerative spondylolisthesis using a specific spinal fusion technique and is the first to compare the clinical outcomes after treatment of a single condition and using a single spinal fusion technique with those after large joint replacement surgeries and with population

Table 3
Mean Short Form-12 physical summary scores and 95% confidence intervals for primary spinal fusion, THR, TKR, and Australian population norm

	Physical component score (95% confidence interval)		
Procedure	Preoperative	Postoperative	Improvement
Primary spinal fusion	28 (27–30)	39 (37–42)	11 (9–14)
TKR	30 (29–31)	37 (34–43)	8 (7–9)
THR	30 (28–31)	43 (41–44)	11 (9–13)
Normal population	44 (43–46)		

THR, primary total hip replacement; TKR, primary total knee replacement.



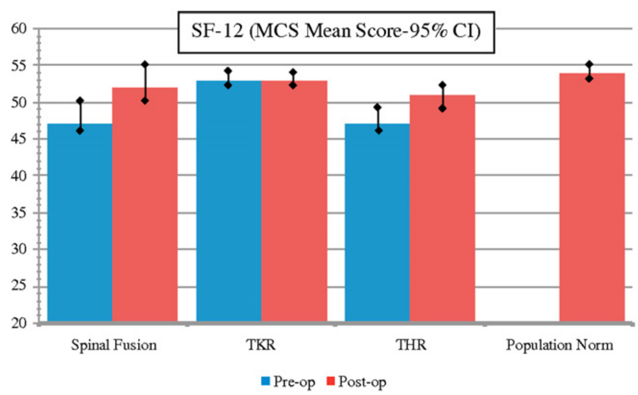


Fig. 2. (Top) Comparative preoperative and postoperative mean Short Form (SF)-12 physical summary scores and 95% confidence intervals for spinal fusion patients, published knee and hip replacement, and South Australian population norms. (Bottom) Comparative preoperative and postoperative mean SF-12 mental summary scores and 95% confidence intervals for spinal fusion patients, published knee and hip replacement, and South Australian population norms.

norms. The surgical technique was consistent throughout the period of study and between the two surgeons with the exceptions of a change in the interbody prosthesis type in December 2001 and the introduction of bone morphogenic protein-7 osteogenic protein use (OP1; Stryker, Kalamazoo, MI, USA) from June 2004 till November 2005 and bone morphogenic protein-2 (Infuse; Medtronic) after November 2005.

The SF-12 was chosen for outcome measurement because of its high degree of patient compliance and has been ranked by some to be the best questionnaire for assessment of general health because of its simplicity and high degree of compliance [11,19–22]. It is a validated instrument whose scores have been shown to be highly correlated with SF-36 summary measures and able to reproduce at least 90% of the variance in the physical and mental subscales of SF-36 [11]. Being a generic, quality-of-life measure, the SF-12 is not disease or treatment specific and provides a valuable method of comparing the efficacy of treatments of different diseases. It has been validated as an outcome measure for joint replacement patients. It can also be used to compare treatment outcomes with the normal population [11].

The literature search provided only five joint arthroplasty publications that contained sufficient baseline and follow-up SF-12 data for valid comparison with the patients from the current study (Table 1). Nevertheless, when combined, a substantial number of patients were reported—307 THR patients and 879 TKR patients. The largest TKR and largest THR articles were from the same high-volume academic unit, and consecutive patients were enrolled [13,15]. The 114 patients from the other THR article were from one university and two regional hospitals [14]. Given the primary and consecutive nature of the patients reported, it would seem reasonable to consider these patients representative of joint replacement patients in general.

The preoperative PCS-12 and MCS-12 scores of the patients in the current study indicated substantial impairment of their quality of life, comparable with that reported for patients before undergoing total knee or hip joint replacement surgery. The improvements in PCS-12 scores in the spinal fusion patients studied were equal to the published results for THR and tended to be higher than those of TKR.

The postoperative mean PCS-12 scores of the spinal fusion patients, 39 (95% CI: 37–42), approached the published age-matched South Australian population norm of 44 (95% CI: 43–46). Copay et al. [23] have demonstrated the minimum clinically important difference for changes in PCS-36 scores to be 5. Accordingly, any statistically discernable difference in the HRQOL PCS-12 scores between the spinal fusion patients and the population norms may not be clinically important [23].

With regard to the MCS-12 scores, all three surgical groups demonstrate comparable mean MCS-12 scores postoperatively. The mean postoperative score for the spinal fusion patients of 52 (95% CI: 50–55) was not statistically different from the published age-matched South Australian population norm of 54 (95% CI: 53–55) [12]. The baseline

Table 4
Mean Short Form-12 mental summary scores and 95% confidence intervals for primary spinal fusion, THR, TKR, and Australian population norm

	Mental component score(95% confidence interval)		
Procedure	Preoperative	Postoperative	Improvement
Primary spinal fusion	47 (46 to 50)	52 (50 to 55)	4 (2 to 6)
THR	53 (52 to 54)	53 (52 to 54)	0 (−1 to 1)
TKR	47 (46 to 49)	51 (49 to 52)	1 (−1 to 3)
Normal population	54 (53 to 55)		

THR, primary total hip replacement; TKR, primary total knee replacement.

mean scores for spinal fusion and THR patients were lower when compared with the TKR patients.

A limitation of the current study is the potential for errors in comparison of outcome measures for the spinal fusion patients with those of the published literature for large joint arthroplasty, given the variations in the published reporting methods and other possible measurement or demographic differences. Different patient populations could respond differently to the same outcome measures. A prospective collaborative trial with other surgical disciplines would enhance the veracity of our conclusions.

Conclusion

Spinal fusion surgery for degenerative lumbar stenosis with spondylolisthesis should be considered to be a significant medical treatment that is able to improve patient's quality of life. Although the evidence points to a return of fusion patients' HRQOL to levels approaching those of age-matched population norms and outcomes comparable with those of large joint replacement surgery, broader scale studies and longer follow-up trials will provide more definitive results.

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Chapter 3

Health-Related Quality of Life Following Revision Surgery for `Failed Back Surgery Syndrome´ : A Comparison with Results Following Primary Spinal Fusion and Large Joint Arthroplasty

ABSTRACT

STUDY DESIGN: Retrospective cohort study and comparison with results of systematic literature review.

OBJECTIVES:

1. To measure health-related quality of life outcomes following surgery in 'failed back surgery syndrome' patients.
2. To benchmark these outcomes with primary spinal fusion and large joint arthroplasty outcomes.

BACKGROUND: 'Failed back surgery syndrome' presents a management challenge and many surgeons advise against further surgical intervention for these patients. One of the reasons for this is that there has not been convincing evidence that surgery will be of benefit. On the other hand, [1-5]large joint arthroplasty is widely regarded as a worthwhile and cost-effective procedure. The discrepancy between attitudes towards surgery for 'failed back surgery syndrome' and large joint arthroplasty is significant. However, part of this gap is clouded by the lack of evidence of outomes following surgery for 'failed back surgery syndrome'. Specifically health-related quality of life measures have not been benchmarked with well regarded procedures such as large joint arthroplasty.

METHODS: 45 consecutive patients (mean age: 68 years, range: 26-83) underwent posterior lumbar interbody fusion (PLIF) for 'failed back surgery syndrome'. The median number of previous surgeries was 2 (range:1-5). 12-item Short Form Health Surveys (SF-12) were completed pre-operatively and post-operatively with last follow-up at a median of 32-months.

The SF-12 results of the ‘failed back surgery syndrome’ patients were compared with those of a similar cohort of primary fusion patients and the published results of primary and revision total hip arthroplasty (THA) and total knee arthroplasty (TKA). Overlapping 95% Confidence Intervals (95%CI) were interpreted as indicating lack of significant outcome difference between groups.

RESULTS: The pre-operative and post-operative SF-12 scores (both physical component: PCS-12 and mental component: MCS-12) of the ‘failed back surgery syndrome’ patients were similar to the scores of the primary fusion patients. The PCS-12 change-score for the ‘failed back surgery syndrome’ patients was significantly better than published change-scores following revision total knee arthroplasty but not as good as following primary total hip arthroplasty. ‘Failed back surgery syndrome’ patients had similar change-scores to primary total knee arthroplasty and revision total hip arthroplasty patients with overlap in the 95%CIs amongst these groups.

CONCLUSION: In selected ‘failed back surgery syndrome’ patients, further surgery can lead to an improvement in health-related quality of life comparable to the well regarded surgical interventions of large joint arthroplasty and primary spinal fusion.

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INTRODUCTION

'Failed back surgery syndrome' (FBSS) is a common problem encountered in the field of spinal surgery.[1-6] It presents a challenge in terms of its diagnosis and treatment. The reported success rates of revision surgery for FBSS have been highly variable, ranging from 10% to 80%.[1-8] It has been observed that the outcome after repeat lumbar surgery is rarely comparable to that of primary surgery.[5,9] Indeed some surgeons have maintained that because patients failed to respond to the primary surgery, the prospect of further surgical treatment being successful is poor.[8] However, recent literature has demonstrated substantial success rates dependent on a better understanding of the specific pathology causing the pain, proper patient selection, and targeted surgical treatment.[6,10-13]

Generic health-related quality of life (HRQL) outcome measures, which enable assessment of treatment efficacy, also allow comparative assessments of a variety of medical conditions and improvements following different treatments.[14] They have the ability to assess both physical and mental health aspects consistent with the bio-psychosocial model of disease.

Various studies have demonstrated that primary lumbar spinal fusion for degenerative disorders can achieve improvements in HRQL equivalent to results following widely accepted surgical intervention such as total hip arthroplasty (THA), total knee arthroplasty (TKA), and coronary artery bypass surgery.[14-18] Large joint arthroplasty has been regarded as a highly efficacious and cost-effective procedure in restoring HRQL to values approaching age-matched population norms.[15,16]

To the author's knowledge, the capacity of further surgery to achieve worthwhile improvements in HRQL following failed previous spine surgery has not been benchmarked with any procedures such as primary or revision large joint arthroplasty.[10,12] The aims of this study was to determine the HRQL outcome following surgery in FBSS patients and assess whether revision surgery in selected FBSS patients is worthwhile by comparing their HRQL with outcomes in patients following primary spinal fusion procedures and the published results of large joint arthroplasty.

METHODS

A retrospective cohort study was carried out on 47 consecutive patients who underwent posterior lumbar interbody fusion (PLIF) as a revision procedure for FBSS during the period September 2000 to October 2007. Data was sourced from an observational database of all patients who had undergone PLIF surgery for degenerative spine disease during the study period.

Study patients were selected based on the following inclusion criteria:

- Diagnosis of FBSS - defined as severe pain or disability that was unrelieved or aggravated by one or more previous spinal surgeries.
- Revision surgery in the form of a PLIF procedure was performed.
- Patients who were not receiving compensation (e.g. from insurance for a previous back injury).

The pre-operative diagnosis was based on history, physical and neurological examination. Symptoms and signs were correlated with the results of diagnostic imaging, which consisted of plain radiographs (including dynamic views) and either CT scan and/or MRI scan.

The minimum follow up period was 12 months with median follow up period of 32 months (range:12-78). Mean age of the patients was 68 years (range:26-83). The median number of previous surgeries was 2 (range:1-5) with median symptom duration of 21 months (range: 3-96) from the last surgery. The principle diagnoses are summarized in Table 1.

Surgical Procedure.

All surgical procedures involved posterior interbody fustion (PLIF) and were done by one surgeon (WRS). A wide decompression was undertaken prior to restoring sagittal and coronal alignment using either an ‘Insert & Rotate’ spacer PLIF technique or pedicle subtraction osteotomy (in the case of severe flat back deformity). (Figure 1 and Figure 2) Stabilization included polyaxial pedicle screw instrumentation.

Outcome Measures.

Patients completed health outcome questionnaires pre-operatively and then post-operatively at 6 weeks, 3 months, 6 months,12 months, 24 months and 36 months. The study used the 12-item Short Form Heath Survey(SF-12) generic HRQL outcome measure. Both the Physical Component Summary(PCS-12) and Mental Component Summary(MCS-12) scores were examined. Visual analogue pain scores (VAS) were recorded.

Patient satisfaction was also surveyed with the two questions:

- “Was the operation worthwhile?”
- “Would you repeat the operation if the same circumstances were to exist again?”

Literature Review.

A systematic review of the Ovid Medline database was undertaken, searching for articles, published between 1950 and 2008, using the MeSH terms: SF-12, total knee replacement/arthroplasty, total hip replacement/arthroplasty, primary and revision. Inclusion criteria for the studies included:

- Clinical studies with pre-operative and post-operative SF-12 data able to be used for calculating the point estimate of SF-12 scores and 95% confidence intervals (95%CI)
- English language publications
- Human studies

The generic SF-12 results of the FBSS patients were compared with the author's previously reported 'primary fusion' patient results and the results obtained from the published literature of primary or revision THA and TKA.[18-22] Non-parametric statistics were used for assessment of skewed continuous variables. Overlapping 95%CIs were interpreted as indicating lack of significant in outcome difference between the groups. The minimal clinical important difference (MCID) was defined as the smallest change that is important to the patients. [23,24] Based on study by Copay, et al, the MCID value for PCS in lumbar spine surgery is 4.9.[25]

RESULTS

The mean pre-operative VAS score for the study group was 59 (range: 52-66) and at last follow up, had reduced to 32 (95%CI, 24-40): a 46% reduction (*P* <0.0001).(Figure 3). Mean pre-operative PCS-12 score of 28 (95%CI: 26-30) improved to 35 (95%CI: 32-39) at last follow up (*P*<0.0001). The pre-operative mean PCS-12 score in the FBSS patients was similar to that previously reported in our study of primary PLIF for degenerative spondylolisthesis which was 28 (95%CI ,27-30).[18] Although the 95% confidence interval of the last follow up PCS-12 scores of these two groups overlapped, the improvement in the failed back patients was lower than that observed in the degenerative spondylolisthesis patients which was 39 (95%CI: 37-42).(Figure 4)

The published SF-12 results for primary and revision total knee and hip arthroplasty are summarized in Tables 2 and 3. The FBSS study patients had a mean PCS-12 change-score (pre to post-op) of +8 (95%CI, 5-11). This was similar to published change-scores following primary TKA and revision THA of +8 (95%CI: 7-9) and +8 (95%CI: 5-12), respectively. Although higher than the change-score following revision TKA of +5(95%CI,2-9), the difference was non significant. The primary spinal fusion and primary THA had the highest change-score of +11(95%CI, 9-14) and +11(95%CI, 9-13) respectively. However, because there is overlapping of the confidence interval , it is not possible to make any inference about statistical significance between this difference. All the change-scores were clinically significant in terms of MCID (Figure 5).

Mean MCS-12 for the pre-operative FBSS patients was 45(95%CI,42-49) and at last follow up was 51(95%CI,48-55, P<0.0001). The final outcomes are similar to all the other surgical procedures that we have compared. It was noted that the pre-operative MCS-12 score of the FBSS patients was the lowest among all the surgical groups.

It was noted in response to the patient satisfaction survey, that at last follow-up, 44 of the 47 (94%) FBSS study cohort felt the revision surgery was worthwhile.

DISCUSSION

In the literature there is no precise or well accepted definition of “failed back surgery syndrome” (FBSS). [6,8,11,12,26-28] Each practising surgeon or physician would have their own set of definitions. It is a term that generally implies the outcome of spinal surgery did not meet the expectations of both the patient and the surgeon, which had been established before surgery.[29] FBSS is a well documented spinal disorder of which the health community should be aware and be able to reach to a consensus in terms of its management.[30]

The best recommendation for achieving a favourable outcome is to firstly ensure that the indications for surgery are absolutely clear-cut and importantly that surgically remediable pathology exists.[31] With the advancement of current imaging and diagnostic tools, the structural cause of FBSS can be elicidated in over 90% of the patients.[6,11,29] It is important to delineate this cause of FBSS, as treatment should be individualized according to the cause of the pain. Also awareness of the common causes of FBSS would perhaps also minimize its frequency.[8,11]

The etiology of FBSS is multi-factorial. The most commonly recognized structural pathologies are foraminal stenosis, recurrent disc herniation, pseudoarthrosis, and neural fibrosis.[6,11,12,26,29] In our study, the main problems identified were foraminal stenosis, followed by non-union.

These are pathologies that are considered correctable with surgery. It is crucial to identify the cause of FBSS, as treatment should be chosen according to the pathology(e.g mechanical compression, instability, neuropathic pain), irrespective of whether the patient is a suitable candidate for either surgery or non-surgical treatment.[6,11,28]

Patient selection is also an important factor in decision making for further treament of FBSS. It is well established in the literature that patients with a poor psychological profile, abnormal pain behaviour, clinical depression, or involvement in workers' compensation or litigation claims, have poorer result after lumbar surgery.[10,12,28]

The management of FBSS should be targeted at the specific underlying pathology. In this series, all the patients underwent fusion surgery (i.e. PLIF) as the treatment of choice based on the pathology present. It is still debatable whether spinal fusion procedures performed during revision surgery provide added benefits in terms of outcome. However, there are a few studies which demonstrate patients who underwent fusion surgery had a more favourable outcome compared to those without fusion.[4,10,12]

Fritsch et al studied 182 cases of revisions surgery on failed back surgery syndrome. 44 patients (34%) were revised multiple times. He noted that recurrent sciatic pain and neurologic deficiency due lumbar instability led to reintervention surgery. Recurrent lumbar disc herniation mainly was found at the first reintervention. In multiple revision patients the rate of epidural fibrosis and instability increased to greater than 60%. The study concluded that a trend toward poor results after recurrent spinal surgery seems to be fateful because of the development of epidural fibrosis and instability and spinal fusion seems to be a more successful intervention.[4]
Wong et al retrospectively reviewed 124 consecutive patients who underwent revision surgery

for FBSS. The study also recommended performing spinal fusion and achievement of solid fusion in repeated low back surgery.[10] Skaf et al prospectively studied 50 patients with FBSS. The underlying pathology was identified and all the patients were treated surgically. Redo surgery was targeted at correcting the underlying pathology: removal of recurrent or residual disk, release of adhesions with neural decompression, and fusion with or without instrumentation. Successful outcome (defined as pain relieves more than 50%) could be achieved in 92% of the patients at 1 year follow-up.[12]

In our study, there was a significant improvement in the mean visual analogue scale (VAS) for pain score from the pre-operative score of 59 to the post-operative score of 32. (Figure 3) This is a reduction of 27 points in the pain scale, nearly half of the pre-operative score. Farrar and colleagues suggested that on an 11-point pain scale for chronic pain, an improvement in VAS score of 1.8 units, equivalent to a change in pain of about 30%, is a fairly satisfactory result and an improvement in VAS of 3 or more, equivalent to a change in pain of 50%, is an extremely satisfactory result. He concluded that the association of satisfaction and improvement in the VAS is highly consistent over multiple trials regardless of the disease causing the chronic pain, the treatment administered (drug or placebo), the trial outcome (positive or negative), or the patient factors of age or gender.[32] The result of the current study has demonstrated almost an excellent satisfaction.

The baseline mean PCS-12 scores are equal for the FBSS patients and our previous series of spondylolisthesis patients who underwent primary fusion.[18] Similar baseline PCS-12 scores were also observed in primary knee and hip joint arthroplasty patients. Post-operatively, FBSS patients demonstrated a significant improvement which was similar to the improvement in TKA patients. When comparing the change-score of the physical component, the FBSS patients had the same mean scores as the primary TKA and the revision THA patients. The mean change-score was higher than the revision TKA patients but the difference was not significant. The primary spinal fusion and primary THA groups had a higher change-score even though there was overlapping of the 95% confidence interval. Therefore, we cannot conclude that they are significantly different from one another. This is not surprising since numerous prospective studies have demonstrated superiority of THA as compared to other orthopaedic procedures.[15,33]

In terms of the MCS-12, the outcome of all the compared surgical interventions are similar at the end-point. This difference was not statistically different to the normal population.[34] It is noted that the FBSS patients had the lowest baseline mean score among all the surgical groups.

The SF-12 instrument is not a disease specific tool, hence its ability to compare outcomes across diverse diseases and treatments. It has been ranked by some to be the best questionnaire for assessment of general health because of its simplicity and high degree of compliance. [35-39] In our study, the SF-12 was chosen for outcome measurement because of this high degree of patient compliance.   It is a validated instrument that has been correlated with SF-36 summary measures and is able to reproduce at least 90 per cent of the variance in the physical and mental subscales of SF-36.[36] The use of SF-12 had some limitations in our study due to the limited reports in the literature of its use in other studies, especially in large joint arthroplasty. This limited the number of results available for comparison with our data. Further study of a prospective nature is needed using similar outcome measure instruments for different surgical intervention.

CONCLUSION

The results of this study demonstrated that in selected failed back surgery syndrome patients, where an identifiable cause of pain can be established, an improvement in HRQL can be achieved. The quality of life gains are comparable to published results following primary total knee arthroplasty and revision total hip arthroplasty. Even though the improvement did not achieve as favourable an outcome as the primary spinal fusion and primary total hip arthroplasty, the differences between the results of these procedures were stastically inconclusive.

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Appendix

Table 1. Principal diagnosis identified in the ‘failed back surgery syndrome’ patients (n=47).

Diagnosis	Numbers	(%)
Foraminal stenosis	21	44.7
Non-union	17	36.2
Painful deformity	13	27.7
Instability	7	14.9

Figure 1: (a) Plain erect radiographs of a 66-year-old lady presenting with painful deformity, right sided sciatica and back pain.

(b) Axial computed tomography scans showing the narrowing of the right foramen at the level of L4–L5.

(c) Post-operative erect plain radiograph demonstrating correction of the deformity by posterior lumbar interbody fusion.

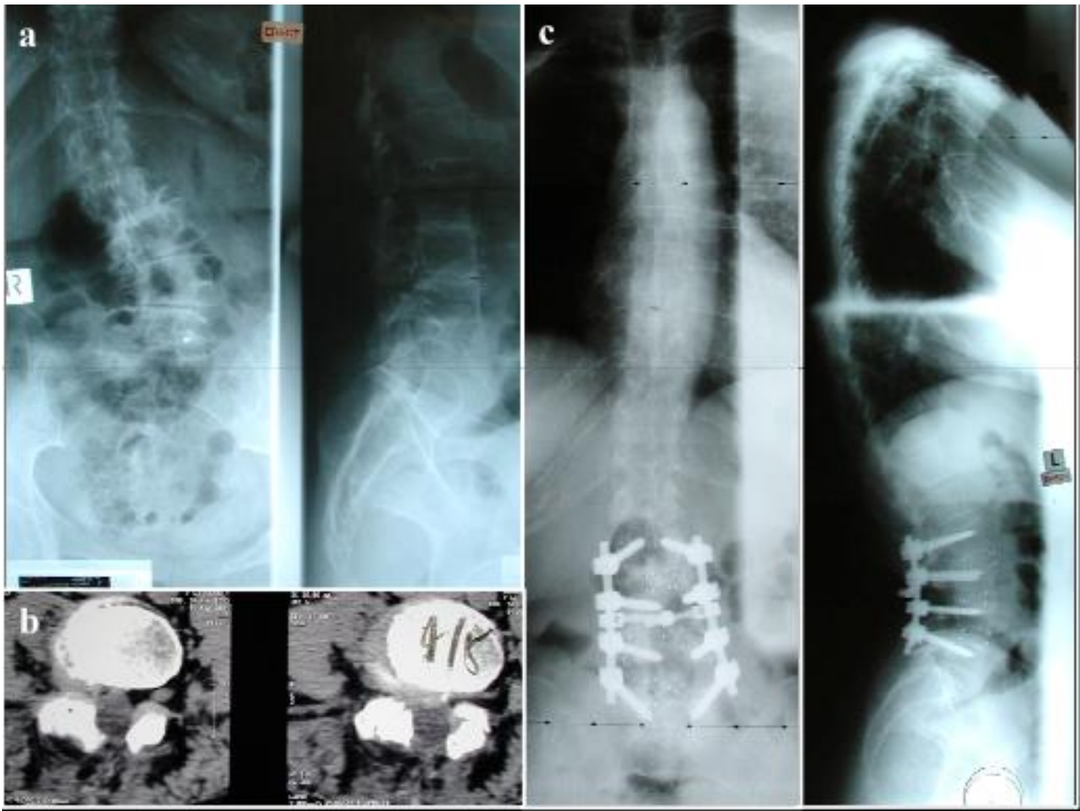


Figure 2: (a) Plain erect radiographs of a 68-year-old lady presenting with back pain and radicular leg pain. She had previous posterior decompression and posterolateral fusion. (b) Post-operative erect plain radiograph demonstrating correction of the deformity by pedicle subtraction osteotomy at L4 vertebrae and posterior lumbar interbody fusion (PLIF).

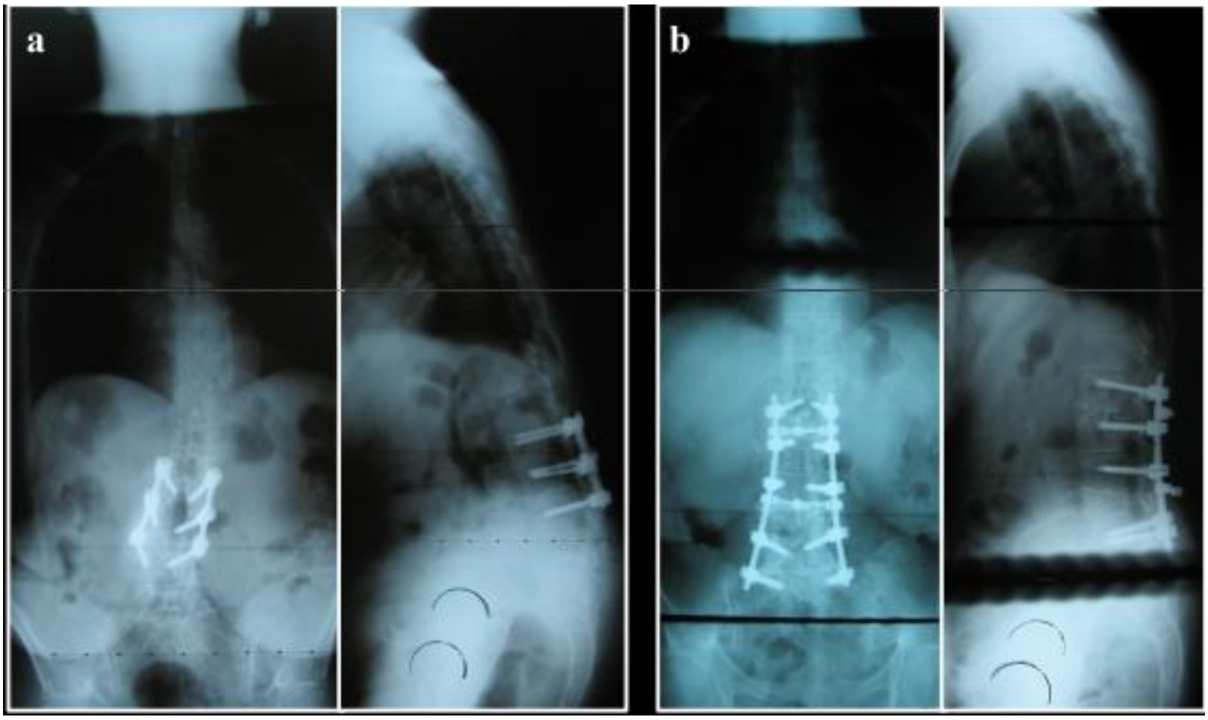


Figure 3: Improvement in the mean VAS pain score from pre-operative score (Pre-op) to post-operative score (Post-op).

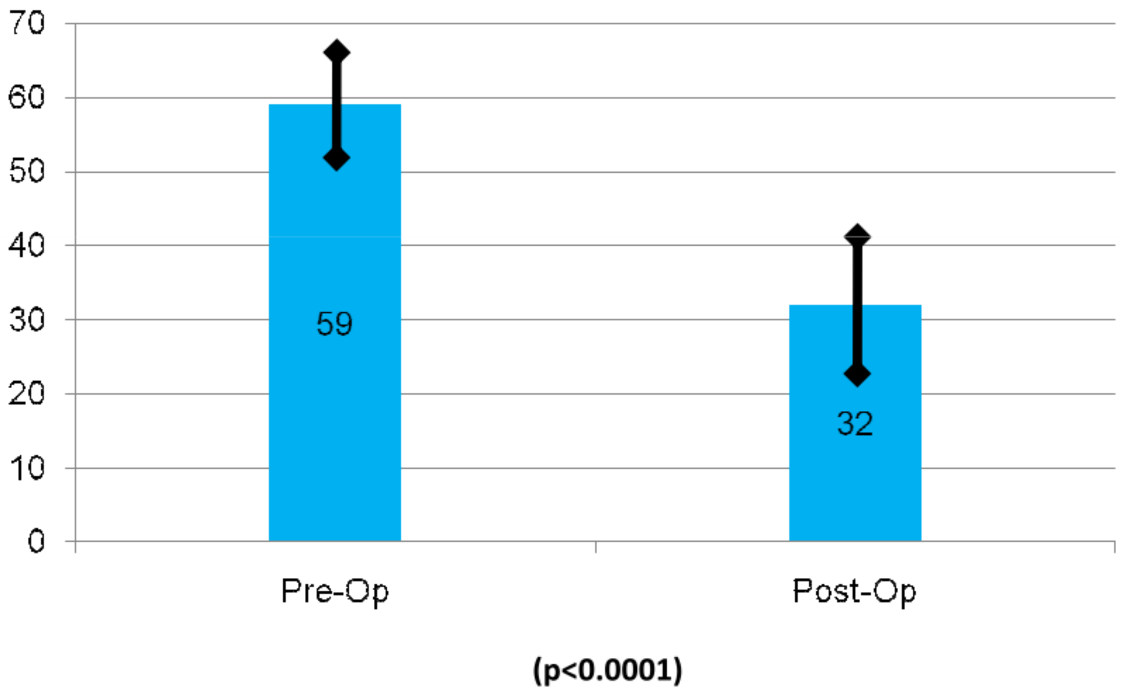
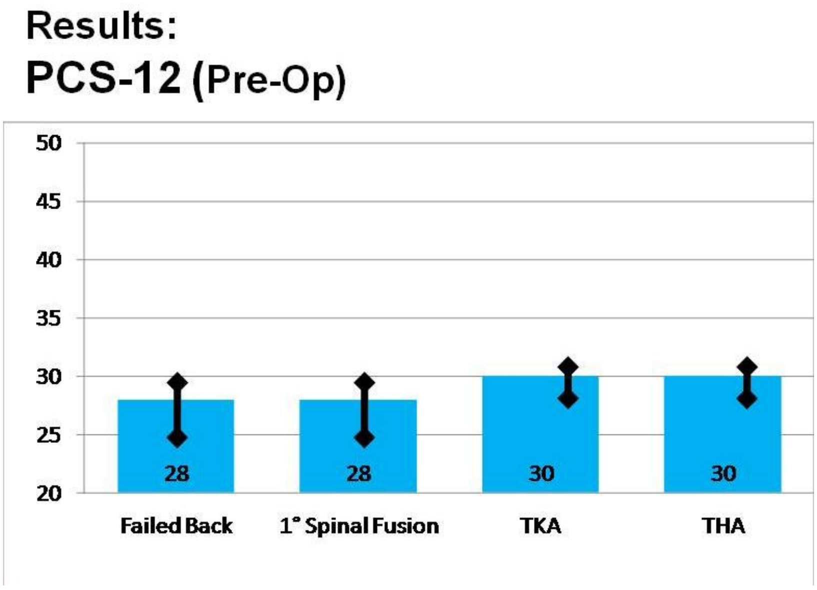


Figure 4: Pre-operative (a) and post-operative (b) PCS-12 score of 'failed back surgery syndrome', primary spinal fusion, primary total knee arthroplasty, primary total hip arthroplasty and normal population. The red horizontal bar represents the 95% CI of failed back surgery syndrome post-operative PCS-12 score.

(a)



(b)

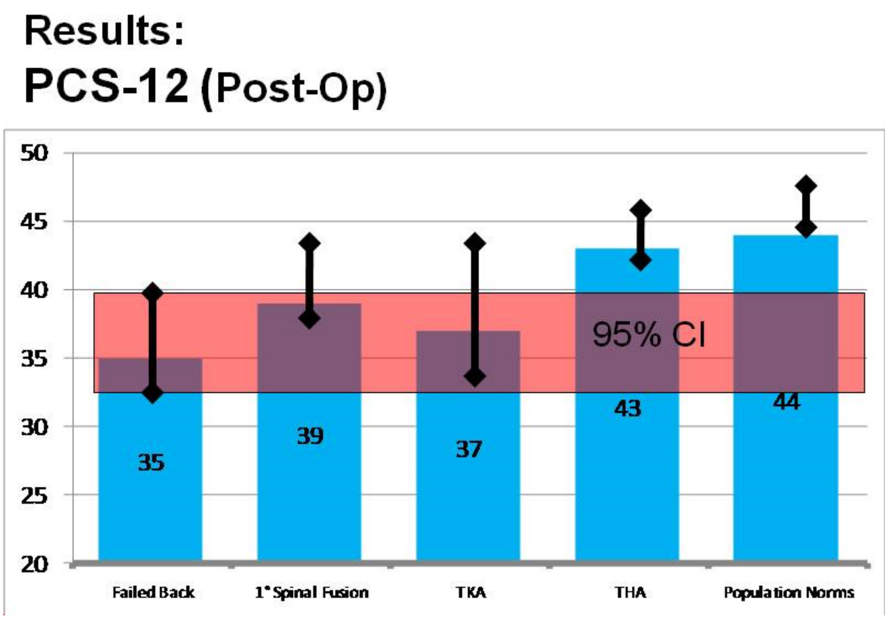


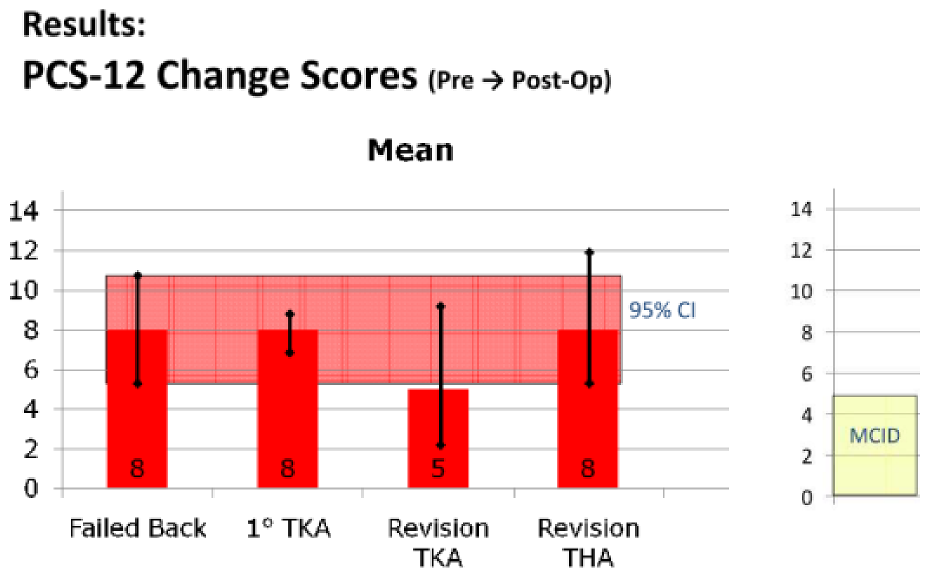
Table 2: SF-12 Scores for Revision Total Knee Replacement

Study	Year	Patients	Post-op PCS	Post-op MCS
Hartley et al	2002	60	35	53
Meek et al	2006	55	36	49

Table 3: SF-12 Scores for Revision Total Hip Replacement

Study	Year	Patients	Post-op PCS	Post-op MCS
Garbuz et al	2006	189	38	51
Garbuz et al	2006	31	41	56
Higuera et al	2006	53	39	55

Figure 5: Mean change score for PCS-12 of the primary and revision total joint arthroplasty compared with failed back surgery syndrome.



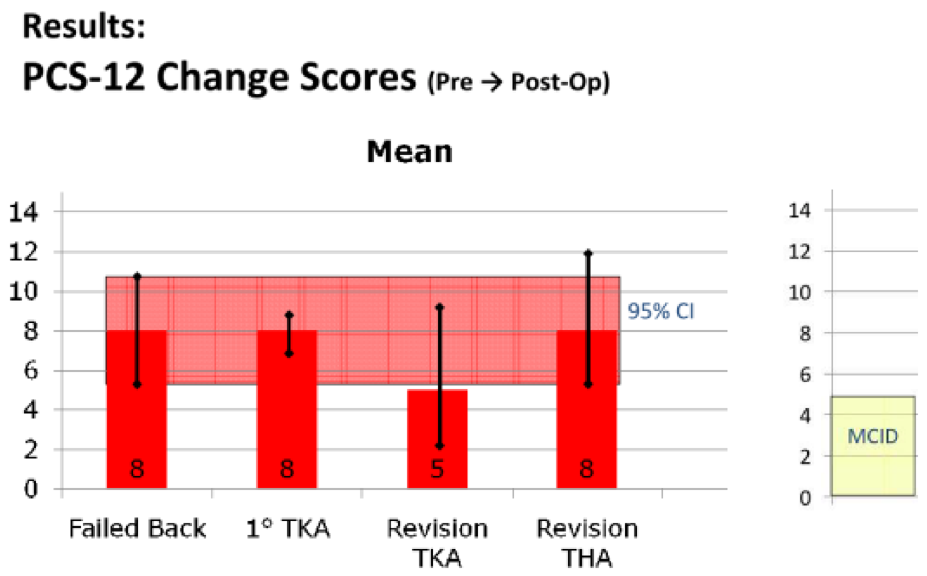
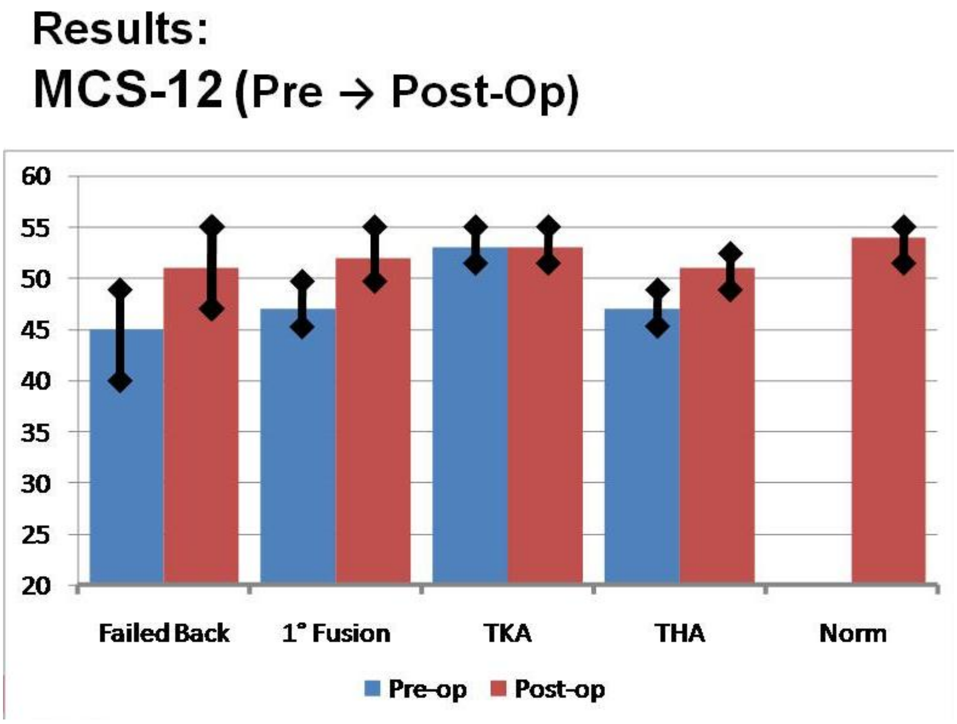


Figure 6: Mean pre-operative and post-operative MCS-12 score of failed back surgery syndrome with the other surgical group and population norm.



Chapter 4

Independence of Clinical Outcome Measurement Instruments in Spinal Surgical Practice.

ABSTRACT

OBJECTIVES: The aim of the study was to explore the independent value of administering multiple clinical outcome measurement instruments following spinal surgery, by examining the extent of correlation between the scores provided by various types of measurement instruments.

BACKGROUND: The use of clinical outcome measurement instruments in spinal surgical practice is becoming increasingly important. As healthcare costs rise, there is an increased requirement for surgeons to monitor patient outcomes and show justification of treatment methods. However, the generic or disease specific outcome measurement instruments used to monitor outcomes are time consuming and expensive.

METHODS: Prospectively collected patient-reported outcome measures from consecutive patients between 2000 and 2008 were compared. These included:

- Visual Analogue Scale for pain (VAS for pain)
- Illness-specific - Oswestry Low Back Disability Index (ODI)

  - Low Back Outcome Scale (LBOS)
- Generic - 12-item Short Form Health Survey (SF-12)

  - physical component (PCS-12)

  - mental component (MCS-12)
- Patient satisfaction question - “Was the operation worthwhile?”

Uni-variate correlations were assessed using Spearman´s non-parametric test and logistic regression analysis examined relationships between outcome scores and patient sastifaction.

RESULTS: 9600 patient-reported outcome measures from 690 consecutive patients were compared. The strongest correlation was between ODI and LBOS (r=0.88). The VAS scores for pain correlated with LBOS (r=0.80), ODI(r=0.73) and PCS-12(r=0.59). MCS-12 had the weakest correlations with other instruments (VAS:r=0.40, ODI:r=0.41, LBOS:r=0.47, SF-12:r=0.13). The only significant predictor of patient with surgery satisfaction was the ‘change-score’ for VAS for pain (odds ratio=1.98, 95% confidence interval=1.15-3.38, P=0.013).

CONCLUSION: The current study demonstrated strong to moderate correlations between VAS for pain scores and both generic and illness-specific patient-reported outcome measures instruments. The VAS ‘change-score’ was the only significant predictor of patient satisfaction. This suggests that for the purpose of outcome audit in the surgical practice setting, a single-item questions, such as global satisfaction or pain scale assessment, be adequate and it may not be necessary to administer multiple, lengthy outcome measurement instruments.

INTRODUCTION

Outcome assessment is important in the setting of spinal surgical practice for a number of reasons. Outcome assessment is an essential tool of clinical research. Also, the increasing costs of healthcare associated with an ageing population and the rising number of patients undergoing spinal surgery, will likely lead to pressure from government and third party payers for monitoring of spinal surgical outcomes.[1-3] Surgical outcome audit has become a practice requirement of many regulatory boards such as the Royal Australasian College of Surgeon (RACS)[4]. Surgical outcome results are useful in providing patients with information necessary for their informed consent. Furthermore, outcome audit enables surgeons to improve their practice by benchmarking with available standards or published outcomes. Thus, outcome assessment will become more important, especially in single surgeon or small surgical group practice, as third party payers and patients demand evidence of success or failure of management practices.[3,5,6]

To achieve a meaningful outcome assessment requires the use of established and well regarded outcome measurement instruments. This will also be essential if these assessments are to be used to compare outcomes between different surgeons or between different management treatments. The trend in published outcome assessments following spinal surgery, has been towards patient-reported outcome measures (PROM).[3 6,7] These measures attempt to take account of a broad range of factors including: pain, impairment of daily activities, and the ability to work.

PROM instruments, for the measurement of quality of life, may be classified into generic measures (some with separate mental and physical components) and disease-specific measures.

Generic measures are designed to assess functional status, regardless of an individual's disease or disorder. Disease-specific measures are designed to be sensitive to the specific diagnostic groups or disease/disorder of interest. These quality of life measurement instruments contain a diverse range of questions. The questions are intended to explore the independent and important components of an individual's health-related quality of life (HRQL), which when combined, will yield a valid and reliable global measure. In the research setting, one or more HRQL instruments is usually employed, depending upon the amount, quality and type of data considered neccessary to obtain meaningful results.[8-10] The number, variety and length of the instruments will, however, affect the time and cost of a study and may impact on patient compliance and accuracy of the assessment.[10,11]

The aim of the current study was to explore the value of or the need for the administration of multiple PROM instruments when assessing patient outcomes following spinal surgery. The correlation between the scores provided by various types of clinical outcome measurement instruments was examined. In particular, the author was interested in the degree to which different instruments generate independent measures in a single-surgeon clinical practice and whether it may be possible to adequately audit clinical outcome in such a setting, without the need for multiple, complex questionnaires.

MATERIAL AND METHODS

The study analysed the results of a prospectively acquired database of self-reported clinical outcome measures in 690 consecutive patients who underwent spinal surgery for degenerative lumbar disorders, by a single surgeon (WRS), between September 2000 and December 2008.

Questionnaires were administered pre-operatively and then post-operatively at 6 weeks, 3, 6, 12 and 24 months. Outcome measures included: the Visual Analogue Scale (VAS) for pain,[12] Oswestry Low Back Disability Index (ODI),[13] Low Back Outcome Scale (LBOS),[14] 12-item Short Form Health Survey (SF-12) - physical component summary scores (PCS-12) and mental component summary scores (MCS-12).[15] Patients' satisfaction with the surgery was assessed through the question, "Was the operation worthwhile?", with the possible answers: "Yes" or "No".

Uni-variate correlations between time and patient matched outcome scores were assessed using Spearman´s non-parametric test. Strengths of correlation were defined as 'strong' if 0.8 or more, 'moderate' for values between 0.5 and 0.8 and 'weak' for values of 0.5 or less.[16]

Logistic regression analysis was performed to examine relationships between final outcome scores or outcome "change scores" (i.e difference between pre-operative scores and scores at last follow-up) and patient satisfaction (at last follow-up).

Significance was set at $P < 0.05$. Statistical analysis was undertaken using the Statistical Package for the Social Science software, IBM SPSS v19.0 (IBM Corporation, Somers, NY). The study protocol was approved by the university's human ethics committee.

RESULTS

Of the 690 consecutive patients studied, there were 421 females and 269 males with a mean age of 65 years (range: 26 – 93). The average body mass index was 27.6 ± 4.9 kg/m^2 . The most frequent diagnoses were: spinal instability (30.9%), spinal stenosis (28.8%) and spinal deformity (13.5%).

There were 3420 follow-up visits with each visit resulting in an average of four completed outcome questionnaires. In total, 9626 outcome questionnaires were administered and collated. The mean outcome scores (± standard deviations) are summarized in Table 1: pre-operative, last follow-up and change scores.

The correlation co-efficients between time and patient matched scores for each of the outcome instruments are shown in Table 2. The strongest correlation was found between the two disease-specific outcome instruments, ODI and LBOS (r = 0.88). The VAS for pain scores were found to correlate strongly with the LBOS (r = 0.80). They had a moderate correlation with ODI (r = 0.73) and the generic, PCS-12 (r = 0.59). The PCS-12 scores had a moderate correlation with both of the disease-specific outcome instruments, ODI (r = 0.73) and LBOS (r = 0.74). The generic measure, MCS-12 had weak correlations with all the other instruments (VAS: r = 0.40, ODI: r = 0.41, LBOS: r = 0.47). The weakest correlation was between the PCS and MCS components of the SF-12 (r = 0.13).

93.4% of patients indicated satisfaction with the surgery, at last follow-up. Tables 3a and 3b show the results of the logistic regression analysis, which examined final scores or change-scores as predictors of patient satisfaction. The only substantial and significant predictor of patient satisfaction was the change-score for VAS for pain (odds ratio = 1.98, 95% confidence interval = 1.15-3.38, P = 0.013). No final scores (at last follow-up), for any of the outcome measures, were found to be significant predictors of patient satisfaction.

DISCUSSION

In a series of patients undergoing surgery for degenerative spine disease, the current study has demonstrated moderate or strong correlations between a variety of different HRQL PROM instruments, with the exception of the mental component scale of the SF-12 generic outcome measure. To the author's knowledge, there are few reported studies in the spinal surgical literature that have examined such correlations. Turner, et al, showed that the illness-specific, Roland Morris Disability questionnaire (RMDQ) displayed excellent correlation with the SF-12 and 36-item Short Form Health Survey (SF-36) scores, in patients with work-related back injuries: PCS-12 ($r = 0.80$), MCS-12 ($r = 0.52$), SF-36 physical function ($r = 0.85$), SF-36 role-physical ($r = 0.70$), SF-36 bodily pain ($r = 0.74$) and SF-36 mental health ($r = 0.60$).[17] Mousavi and colleagues demonstrated an overall good correlation between physical component of SF-36 with ODI ($r = 0.66$), RMDQ ($r = 0.62$) and Quebec Back Pain Disability Scale-QDS ($r = 0.69$).[18]

The VAS pain score is a simple, objective and validated tool, which is popular among different medical specialties.[12,19] The current study has demonstrated significant correlations between VAS pain scores and scores derived from several more lengthy HRQL outcome measurement instruments [ODI ($r = 0.73$), LBOS ($r = 0.80$), PCS-12 ($r = 0.59$) and MCS-12 ($r = 0.40$), all $p < 0.05$]. The strong correlation between VAS pain scores and LBOS, found in the current study may, at least in part, be due to the VAS pain score being a component of the LBOS questionnaire. Zanoli and colleagues have shown that VAS pain scores correlate better with patient satisfaction than scores calculated through more complex, questionnaire based instruments ($r=0.60$, $p<0.05$).[19] Haro, et al, showed similar correlations between VAS pain scores and ODI ($r = 0.75$) and with SF-36 ($r = 0.6$). Hagg and colleagues also demonstrated that a simple global assessment question has significant correlations with other clinical outcome measures: VAS ($r= 0.69$), General Function Score ($r = 0.66$), Million Scale ($r = 0.75$), ODI ($r = 0.73$) and Zung Depression Scale($r = 0.51$), $p<0.05$.[11]

In the current study, only the VAS 'change-score' was found, to be a significant predictor of patient satisfaction. Final scores, including the VAS pain score and the complex generic and disease-specific outcome measures were not significantly correlated with patients' sastifaction with surgery. Djurasovic and colleagues demonstrated few factors to be significant predictors of clinical success in revision spinal surgery, as measured by achievement of the minimum clinically important difference (MCID) thresholds. With respect to ODI, they found that the only factor that predicted success with revision surgery was whether the patient reported improvement from their last previous surgery (based on patients global assessment answer). With respect to SF-36, only the presence of worker's compensation and high preoperative narcotic use predicted a failure to reach MCID.[20]

The administration of generic HRQL or disease specific outcome measurement instruments may be time consuming and expensive.[10,21,22] Some instruments require the use of sophisticated scoring algorithms. Several commonly used instruments, such as the SF-12 or SF-36, may require annual license fees, the purchase of administration manuals or personnel training in survey administration and scoring.[23] Given the time and expense required to administer multiple questionnaires, the question arises as to whether such multiple instruments are necessary? Might a smaller number of simpler, single-item questions, such as global satisfaction or pain scale assessment, be adequate in certain settings, such as surgical practice audit? Shorter questionnaires may also increase patient compliance, known to be problematic with longer questionnaires.[11] While global satisfaction assessments by patients are intended to provide an aggregate of the important dimensions contained in multiple measurement instruments, their validity has been questioned, as they are a single-state retrospective recording with potential for recall bias and often results in an overestimation of improvement.[24]Walsh et al analyzed responsiveness of the ODI, MODEMS scales and summary scales of the SF-36 for 970 patients with low back pain/leg symptoms. The MODEM scales were when patients provided an overall assessment of their progress on a five-point scale:"Compared to when you last completed this questionnaire, is your musculoskeletal condition 1) much better now; 2) somewhat better now; 3) about the same; 4) somewhat worse now;5) much worse now." And physicians provide an independent assessment on a five-point scale: "Patient progress 1) major improvement; 2) minor improvement; 3) no change; 4) minor worsening; 5) major worsening."The study demonstrated that MODEM scales appear to be the most responsive measures in patients with low back pain. There were no significant differences between the disease-specific outcome measures scores(i.e. ODI) and generic health outcome score (i.e. SF-36).[22]

The strong correlations between VAS pain scores and HRQL PROM instruments found in the current study might suggest that a simple measure of pain is sufficient for outcome assessment. However, an important element of HRQL in patients suffering degenerative spinal disorders is their level of disability associated with the disorder. While pain may be the main factor contributing to patients' disability, other factors such as neurological deficit may predominate.

In these circumstances, a measure of pain only may underestimate impairment of HRQL and a generic or illness specific PROM instruments is likely to provide a better assessment.

It is apparent that there is no simple answer to the best way to assess or monitor clinical outcome following spinal surgery. In clinical trials, a combination of outcome measures is likely to continue with at least one measure from each of the generic quality-of-life measures, disease-specific measures, pain intensity scales and patient global satisfaction assessments. In the surgical practice setting where resources are limited (e.g audit officer, time with patients in clinic), a simpler and practical assessment tool are necessary.

It is the intention of the authors to suggest the possibility of assessment for patient's outcome based on the value of 'simple' questionnaires consisting of three components only. Two components could be VAS based patient self assessments of pain and disability. The third component could be a question regarding patient global satisfaction. Such an outcome assessment instrument would be time and cost saving. Furthermore, the small number of questions would assist with better patient compliance and hence, potentially yield a more accurate response. This would be the recomendation for future studies.

CONCLUSION

The rapid increase in the numbers of spinal surgical procedures and the resulting impact on health care costs is an important driver in the effort to build an evidence-based approach to spinal surgery. Thus surgical outcome measures are important in spinal surgical practice. The current study has shown a strong to moderate correlations between a simple VAS pain score with both generic and illness-specific PROM instruments, with the exception of the mental component of the SF-12 (MCS-12). It is also noted that the VAS 'change-score' was the only significant predictor of patient satisfaction to surgery. This suggest that for the purposes of outcome audit in the surgical practice setting where resources are limited, it may not be necessary to administer multiple, lenghthy outcome measurement insruments.

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APPENDIX

Table1: Mean Value (± Standard Deviation) of pre-operative, post-operative (last follow-up) and change-score.			
Outcome measures	**Pre-operative**	**Last Follow Up**	**Change score**
VAS	6.55 ± 2.30	3.13 ± 2.77	3.59±3.02
ODI	46.77 ± 15.89	26.00 ± 19.55	21.09±19.17
LBOS	23.35 ± 12.29	39.51 ± 17.12	16.18±15.62
PCS-12	28.73 ± 7.40	37.31 ± 11.30	8.42±10.34
MCS-12	46.19 ±11.49	51.28 ± 11.12	5.36±10.34

VAS = Visual Analogue Scale for pain , ODI = Oswestry Low Back Disability Index , LBOS = Low Back Outcome Scale PCS-12= SF-12 - physical component summary scores (PCS-12) and MCS-12 = SF-12 mental component summary scores.

Table 2: Correlation between VAS, ODI, LBOS, PCS-12 and MCS-12 (P < 0.05)

Outcome Measures	VAS	ODI	LBOS	PCS-12	MCS-12
VAS		0.73	0.80	0.59	0.40
ODI	0.73		0.88	0.73	0.41
LBOS	0.80	0.88		0.74	0.47
PCS-12	0.59	0.73	0.74		0.13
MCS-12	**0.40**	**0.41**	**0.47**	**0.13**	

Table 3a: Results of Logistic Regression Analysis of last follow-up outcome scores for "Satisfaction of the Surgery". (Question: Was the Operation Worthwhile? Answer : Yes/No)				
Variables	**Odds Ratio**	**95%CI for Odds Ratio**		***P***
		Lower	Upper	
VAS –last f/u	0.97	.910	1.025	0.248
ODI –last f/u	1.01	.909	1.120	0.868
LBOS –last f/u	1.01	.888	1.148	0.884
PCS –last f/u	1.03	.968	1.101	0.332
MCS –last f/u	0.69	.466	1.025	0.066

Table 3b: Results of Logistic Regression Analysis for Satisfaction of the Surgery. (Question: Was the Operation Worthwhile? Answer : Yes/No)				
Variables	**Odds Ratio**	**95%CI for Odds Ratio**		***P***
		Lower	Upper	
VAS changes	1.976	1.154	3.384	0.013
ODI changes	1.102	1.011	1.200	0.026
LBOS changes	.991	.894	1.099	0.862
PCS changes	.949	.849	1.060	0.353
MCS changes	.964	.895	1.039	0.340

Chapter 5

Pre-operative Health Related Quality of Life Scores as Predictor of Clinical Outcomes after Lumbar Fusion for Degenerative Lumbar Disorder

ABSTRACT

STUDY DESIGN: A prospective longitudinal cohort study.

OBJECTIVE: The aim of this study is to evaluate the pre-operative Medical Outcome Study Short Form 12-Item Questionnaire (SF-12) scores as predictors of outcome in fusion surgery for degenerative lumbar disorders.

BACKGROUND: Measures of health-related quality of life (HRQL) are routinely used in clinical studies to evaluate treatment effectiveness. However, the study of their use as a predictive tool has been limited.

METHODS: Retrospective analysis of a prospectively collected data. Questionnaires were filled pre-operatively and one year post-operatively by patients with degenerative lumbar disorders who underwent posterior lumbar interbody fusion (PLIF) surgery between September 2000 and September 2008. Outcome measures in the assessment were SF-12 (physical component summary score: PCS-12 and mental component summary score: MCS-12), the Oswestry Disability Index (ODI) and the Low Back Outcome Score (LBOS). Multivariate linear regression analysis was performed to determine the effect of pre-operative PCS-12 and MCS-12, on the change in the generic SF-12 and illness specific outcome measures, ODI and LBOS, at one year after surgery. Significance was set at $P < 0.05$.

RESULTS: 636 patients were enrolled with mean age of 66.2 ± 13.5 years. There were significant correlations between pre-operative outcome measures PCS-12 and MCS-12, and change in PCS-12, ODI and LBOS scores ($P < 0.05$). Change in MCS-12 was only correlated with pre-operative MCS-12 ($P < 0.05$) but not with pre-operative PCS-12.

CONCLUSION: This study demonstrated patients with worse physical impairment, as shown by the lower PCS-12 score, but not mentally distressed, as measured by the higher MCS-12 score, may be better candidates for favourable outcome with fusion surgery.

Keyword: Predictors of Outcome; SF-12; Health-Related Quality of Life; Lumbar Fusion

INTRODUCTION

Degenerative lumbar spinal disorders are inevitable with ageing. As our ageing population continues to grow and remain active, degenerative lumbar spinal disorders are becoming a significant healthcare concern. Despite the advancement of diagnostic and surgical techniques in the field of spinal surgery, unfavourable outcome in some patients remains a problem with degenerative spinal disorders. Studies have demonstrated success rates from lumbar surgery of 50% to 90%.[1-9] The subject of patient selection for surgery has been the focus of numerous studies. Several studies have sought to identify predictors of outcome, in an attempt to distinguish patients who would benefit from surgery and those who will not.[10-25]

There is growing evidence that biopsychosocial factors can predict the outcome of spinal surgeries. Instead of focussing entirely on the underlying spinal pathology, the patients' unique biologic, psychological, and social factors have gained recognition and may play significant roles in the outcome of surgery. However, biopsychosocial assessment usually involves a complex workout.[11,12,25-27] The question is "Is there a simple and practical tool which is useful as a predictor of surgical outcome?"

Measures of health-related quality of life (HRQL) are routinely used in clinical studies to evaluate treatment effectiveness. There is a plethora of outcome assessment instruments used in the field of spinal surgery. The Medical Outcome Study Short Form 12-Item Questionnaire (SF-12) is a generic patient-based outcome measure frequently utilised in medical research. It measures the physical and mental health by the physical component score (PCS-12) and the mental component score (MCS-12). It is a validated instrument used in orthopaedics and spine surgery literature to assess patients' satisfaction and quality of life improvement following surgical intervention. However, the study of their use as a predictive tool has not been reported.

The aim of this study is to evaluate the pre-operative 12-Item Short-Form Health Survey (SF-12) scores as predictors of treatment effectiveness in fusion surgery for degenerative lumbar disorders.

METHODS

The study is a retrospective analysis of a prospectively collected database. Consecutive patients with degenerative lumbar disorders who underwent posterior lumbar interbody fusion (PLIF) surgery between September 2000 and September 2008 were identified. Patients who had completed questionnaires pre-operatively and at one year post-operatively were included in the study. Patients with history of trauma, infection or neoplasm to the spinal column were excluded. The study was approved by University's Human Ethical Committee.

Outcome measure instruments used in the questionnaires for this study were the SF-12 (both the physical component summary score: PCS-12 and mental component summary score: MCS-12) as a measure of general health-related quality of life; and the Oswestry Disability Index (ODI) and the Low Back Outcome Score (LBOS), as instruments to measure disease-specific outcome.

The designated limit for clinical outcome to differentiate between a good or poor score for SF-12 was based on the reported survey of normal population of South Australia(PCS-12 = 48.9 ± 10.2 and MCS-12 = 52.4 ± 8.8).[28] Based on the cut-off value at one standard deviation below the mean value of the general population, the set value was designated at 38.7 for PCS-12 and 43.6 for MCS-12. The score above the set value is considered as a good score.

Responsiveness to surgical treatment was assessed by the amount of change from their baseline score pre-operatively to their score at one year post-operative follow up. Patients who were considered to achieve good or favourable outcome were those who achieved Minimum Clinically Important Difference (MCID) or more. MCID is defined as the smallest change in an outcome measure that represents a change that would be considered meaningful by the patient. [29,30] Based on literature, the published value of MCID for ODI is 10.0 and LBOS is 7.5.[31,32]

Statistical analysis was performed using the Statistical Package for the Social Science (SPSS v17.0) software (SPSS Inc., Chicago, Illinois, USA). Multivariate linear regression analysis was performed to determine the effect of pre-operative SF-12 components (PCS-12 and MCS-12) on the change in the generic SF-12 and illness specific outcome measures (ODI and LBOS) at one year after surgery. Significance was set at $P < 0.05$.

RESULTS

A total of 636 patients were enrolled and completed the questionnaires at pre-operatively and one year post-operative follow-up. There were 389 females (61.2%) and 247 males (38.8%). Mean age was 66.2 ± 13.5 years (range: 15.5-92.6 years). The indications for surgery included foraminal stenosis (36%), instability (36%), flat-back deformity (15%), adjacent segment disease (5%), non-union (4%), recurrent disc herniation (2%) and others (2%). The mean pre-operative PCS-12 and MCS-12 scores were 28.6±7.3 and 46.2±11.3 respectively. The mean post-operative PCS-12 and MCS-12 scores were 38.1±11.9 and 52.1±10.8 respectively. The pre-operative mean value for ODI was 46.7±16.1 and LBOS was 23.4±12.3. The mean post-operative ODI score was

23.8±19.3 and LBOS was 40.2±16.2. Mean change-scores for PCS-12, MCS-12, ODI and LBOS were 9.6±10.6, 5.5±11.8, 22.6±18.2 and 17.2±14.8, respectively. (Table 1)

Linear regression analysis showed the correlation co-efficient of pre-operative PCS-12 for change in PCS12, ODI and LBOS scores were 0.15, 0.37 and 0.28 respectively ($P < 0.05$). Pre-operative PCS-12 was not significantly correlated with change in MCS-12 score. (Table 2) The correlation co-efficient of pre-operative MCS-12 for change in PCS-12, MCS-12, ODI and LBOS scores were 0.18, 0.56, 0.18 and 0.27($P<0.05$). (Table 3)

With the result of the linear regression analysis, there is significant correlation between pre-operative PCS-12 and MCS-12 with change score of disease-specific outcome measures (i.e. ODI and LBOS). The next question is “What preoperative PCS-12 and MCS-12 score should a patient about to undergo lumbar spine fusion have so that he/she can expect improvement in his/her ODI or LBOS?” Thus, pattern of the pre-operative PCS-12 and MCS-12 of the patients that are predictive of a patient achieving MCID for ODI and LBOS were sought. To achieve this, a scatter plot diagram is utilized to visualize the pattern of distribution.

A scatter plot of pre-operative PCS- 12 and change in ODI and LBOS are presented in figure 1a and 1b respectively. The vertical line in the scatter-plot graph is marked at 38.7 which is the set value for PCS-12 based on normal South Australian population.[28] In figure 1a, the horizontal line is marked at the MCID of ODI which is 10.[30] Majority of the plots are at the left upper quadrant of the graph, which illustrated majority of the cases that had improvement of ODI score more than 10 have a pre-operative PCS-12 value of less than 38.7.

In figure 1b, the horizontal line is at the MCID of LBOS which is 7.5.[32] The scatter plot graph of change in LBOS and pre-operative PCS-12 also demonstrated majority of the plots are at the left upper quadrant of the graph, which indicated majority of the cases that had improvement of LBOS score more than 7.5 also had a pre-operative PCS-12 value of less than 38.7.

A scatter plot of pre-operative MCS-12 and change in ODI and LBOS are presented in figure 2a and 2b respectively. The vertical line on the graph represents the set value of MCS-12 at 43.6 which is based on normal Australian population.[28] In figure 2a, the horizontal line is at the MCID of ODI which is 10. The scatter plot of change in ODI and pre-operative MCS-12 shows most number of plots are at the right upper quadrant indicating that patients with improvement of ODI score more than the MCID had a pre-operative MCS-12 value of more than 43.6.

In figure 2b, the scatter plot of change in LBOS and pre-operative MCS-12, where the horizontal line is at the MCID of LBOS which is 7.5. The highest numbers of the plots are also concentrated at the right upper quadrant which indicates that majority of the patients that had improvement of LBOS score more than MCID have a pre-operative MCS-12 value of more than 43.6.

DISCUSSION

The role of spinal surgery to treat a range of spinal pathologies and deformities has been questioned due to the failure of surgery to achieve satisfactory outcomes in a proportion of patients especially those with degenerative diseases. The significant distress suffered by patients who do not improve after surgery and the associated cost to the healthcare system have prompted numerous studies to attempt to identify predictors of outcome in patients undergoing spinal surgery. Many biomedical factors (e.g. pre-operative pain status and straight leg raising) and the socio-demographic factors (e.g. gender, age and body weight), have been identified. Some of these results have been conflicting.[33] Overall, it is increasingly recognised that careful patient selection for surgery for degenerative spinal disorder is the most important predictor of success,.[34-37]

The biopsychosocial model is gaining acceptance in spinal disorder and has provided a basis for screening measurements and treatment interventions.[25,26,38] This has gradually replaced the disease model that assumes pain and disabilities are products of tissue damage and once the damaged tissue is removed, the pain and subsequently the disability will recover. The biopsychosocial model allows all the physical (biological), psychological and social elements to be considered in the management of spinal disorders. Unfortunately, biopsychosocial assessment may involve more interviews or a series of workouts, combined with physical and psychological examinations, attempting to assess all the issues of the patients.[25,26,38]

Health-related quality of life (HRQL) instruments have been well established and validated as generic tools conventionally used for assessment of treatment outcome. Among the commonly used in the field of spinal surgery is the SF-12 for its simplicity and high degree of correspondence.[39-43] It is also a validated generic patient-based outcome measure which is frequently used to monitor progress. It is widely used to assess the overall health status in various medical conditions. The instruments measure two components: the physical health (physical component summary, PCS-12) and the mental health (mental component summary, MCS-12).

Our study demonstrated significant correlations between the change-score (i.e. improvement from SF-12 pre-operative score and post-operative score). The pre-operative PCS-12 score have the strongest correlation with improvement in the ODI score (r = 0.37) and LBOS score (r = 0.28). The pre-operative MCS-12 score has the strongest correlation with the improvement in the ODI score (r = 0.56); and has similar correlation with the improvement in PCS-12 score (r = 0.18) and LBOS score (r = 0.18). The change-score for MCS-12 correlate with pre-op MCS-12 score (r = 0.27) but no significant correlation with pre-operative PCS-12 score (r = 0.03).

The scatter plot diagrams of pre-operative scores for both components of the SF-12 (PCS-12 and MCS-12) demonstrated well a distinctive prognostic pattern. Patients with lower pre-operative PCS-12 score have a better improvement in terms of ODI and LBOS outcome score. On the other hand, patients with higher pre-operative MCS-12 score have a better improvement in terms of ODI and LBOS outcome score. These findings can be interpreted as patients with worse physical impairment, which is reflected by lower pre-operative PCS-12 scores, but still not mentally distressed, which is reflected by the higher pre-operative MCS-12 scores, achieved greater improvement outcome in terms of the ODI and LBOS scores.

Psychological factor plays an important role in the outcome of spinal surgery. Greenough et al reported similar findings in their study of 151 patients that underwent lumbar spinal fusion for intractable back pain. Despite the solid bony fusion obtained in 76% of the patients, only 40% achieved a good or excellent result on objective low back pain outcome score. Psychological disturbance in patients had a profound unfavourable effect on surgical outcome and patient satisfaction ratings. Their study concluded that “psychological distress” was predictive of a poor outcome in lumbar fusion surgery.[44] Carragee et al also demonstrated that the ability to rapidly relieve pain may limit the morbid effects of psychological distress seen in many back pain syndromes. Prolonged pain and emotional distress may significantly decrease the positive impact of surgical intervention.[20]

My study shows that SF-12 is a simple and practical assessment tool of predictor of surgical outcome for lumbar fusion in degenerative spinal disease. By using the same measure instrument as the predicting tool and for outcome assessment, we are reducing the time and effort of the clinician and patient of filling in multiple sets of questionnaire or pre-operative assessment forms. Due to its generic nature, SF-12 might also be applicable for use in other spinal treatment intervention. Furthermore, SF-12 potentially could be used to screen biopsychosocial risk levels that could compromise a patient’s ability to benefit from spinal surgical intervention. Once these patients were identified, appropriate interventions could be implemented to try to improve these risks, and leave the patient better prepared to achieve a successful outcome from surgery. On the other hand, if an unfavourable outcome is predicted, the indication for surgical intervention should be re-evaluated. It may be that this group of patients should be considered for treatment modalities other than surgery. This treatment may include continuing observation, conservative treatment and psychological support therapy.

Junge et al in his study of 381 patients undergoing discectomy for disc herniation demonstrated that in addition to the clinical and radiological assessment, the Hannover-Mobility questionnaire (12 questions to calculate a total mobility score) and the Beck depression inventory (to measure the intensity of depression) should be included in the routine pre-operative assessment. The calculation of the overall score gave an overall appropriate prediction of 80%.[14,45] Glassman et al, in 235 patients undergoing fusion surgery, demonstrated higher score in the social function and pain domain score in the SF-36 questionnaire for patients with good outcome as compared to patients who need further revision surgery.[15] Carreon et al, in her study with pre-operative SF-36 demonstrated that patients with good pre-operative mental score in the SF-36 and worse pre-operative ODI score had better improvement after lumbar fusion surgery.[46]

We would recommend that further studies are necessary to verify our findings and their application to clinical decision making. One limitation of our study is that we only had a single review of patients at one year post-operative period. Whether this will be beneficial in the long-term requires further study. Nonetheless, the pre-operative SF-12 scores maybe useful as part of the objective assessment and screening factors in recommending or withholding surgery.

CONCLUSION

This study indicates pre-operative HRQL scores such as the SF-12 scores are able to be used as a predictor tool for treatment effectiveness in fusion surgery for degenerative lumbar disorders. Findings demonstrated patients with worse physical impairment, as shown by the lower PCS-12 score, but not mentally distressed, as measured by the higher MCS-12 score at their pre-operative assessment, may be better candidates for a favourable outcome with surgery.

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APPENDIX

Table 1: Mean pre-operative, post-operative (one year) and change score of the patients.

Outcome Measures	Pre-Operative (Mean ± SD)	Post-Operative (Mean ± SD)	Change in Score (Mean ± SD)
PCS-12	28.6 ± 7.3	38.1 ± 11.9	**9.6** ± 10.6
MCS-12	46.2 ±11.3	52.1 ± 10.8	**5.5** ± 11.8
ODI	46.7 ± 16.1	23.8 ± 19.3	**22.6** ± 18.2
LBOS	23.4 ± 12.3	40.2 ± 16.2	**17.2** ± 14.8

Table 2: Correlation co-efficient of pre-operative PCS-12 score with change score.

Change Scores	Correlation (r)	Significance
PCS-12	0.15	$P < 0.05$
ODI	0.37	
LBOS	0.28	
MCS-12	0.03	*Nil*

Table 3: Correlation co-efficient of pre-operative MCS-12 score with change score.

Change Scores	**Correlation (r)**	**Significance**
PCS-12	0.18	$P < 0.05$
ODI	0.56	
LBOS	0.18	
MCS-12	0.27	

Figure 1a: Scatterplot of pre-operative PCS-12 score and change score in ODI.

(Set value for PCS-12 = 38.7 and MCID of ODI = 10.0)

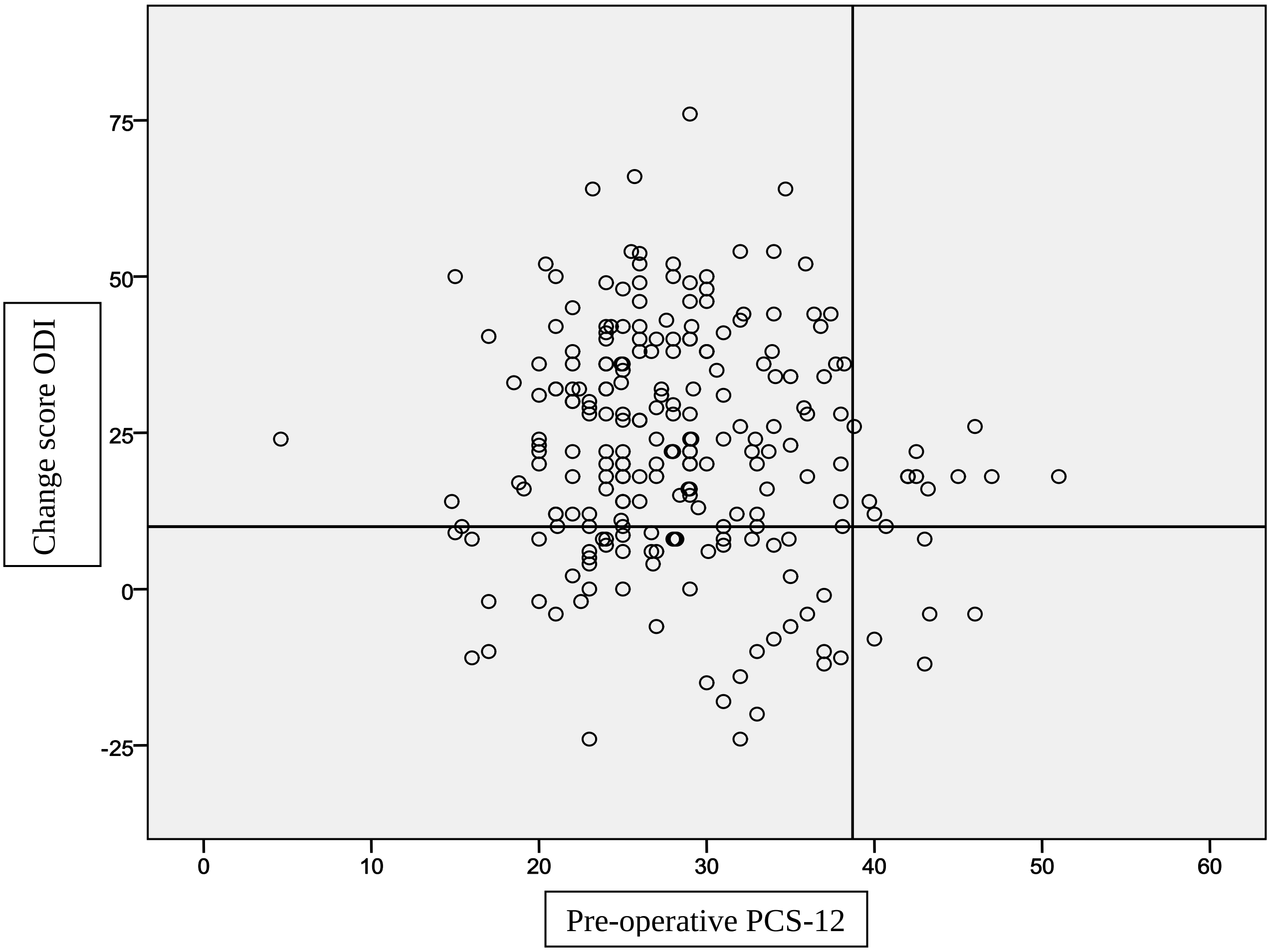


Figure 1b: Scatterplot of pre-operative PCS-12 score and change score in LBOS.

(Set value for PCS-12 = 38.7 and MCID of LBOS = 7.5)

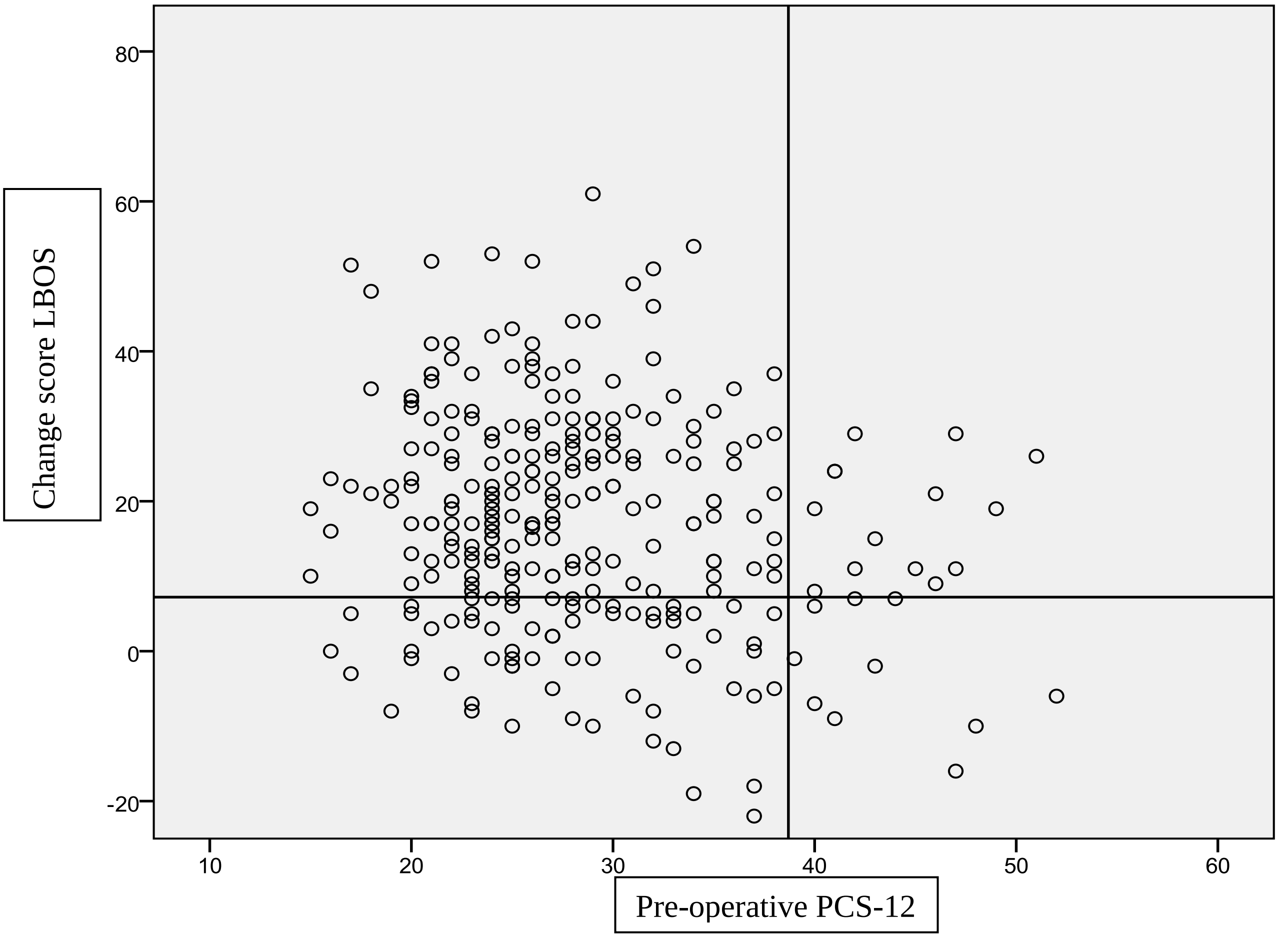


Figure 2a: Scatterplot of pre-operative MCS-12 score and change score in ODI.

(Set value for MCS-12 = 43.6 and MCID of ODI = 10.0)

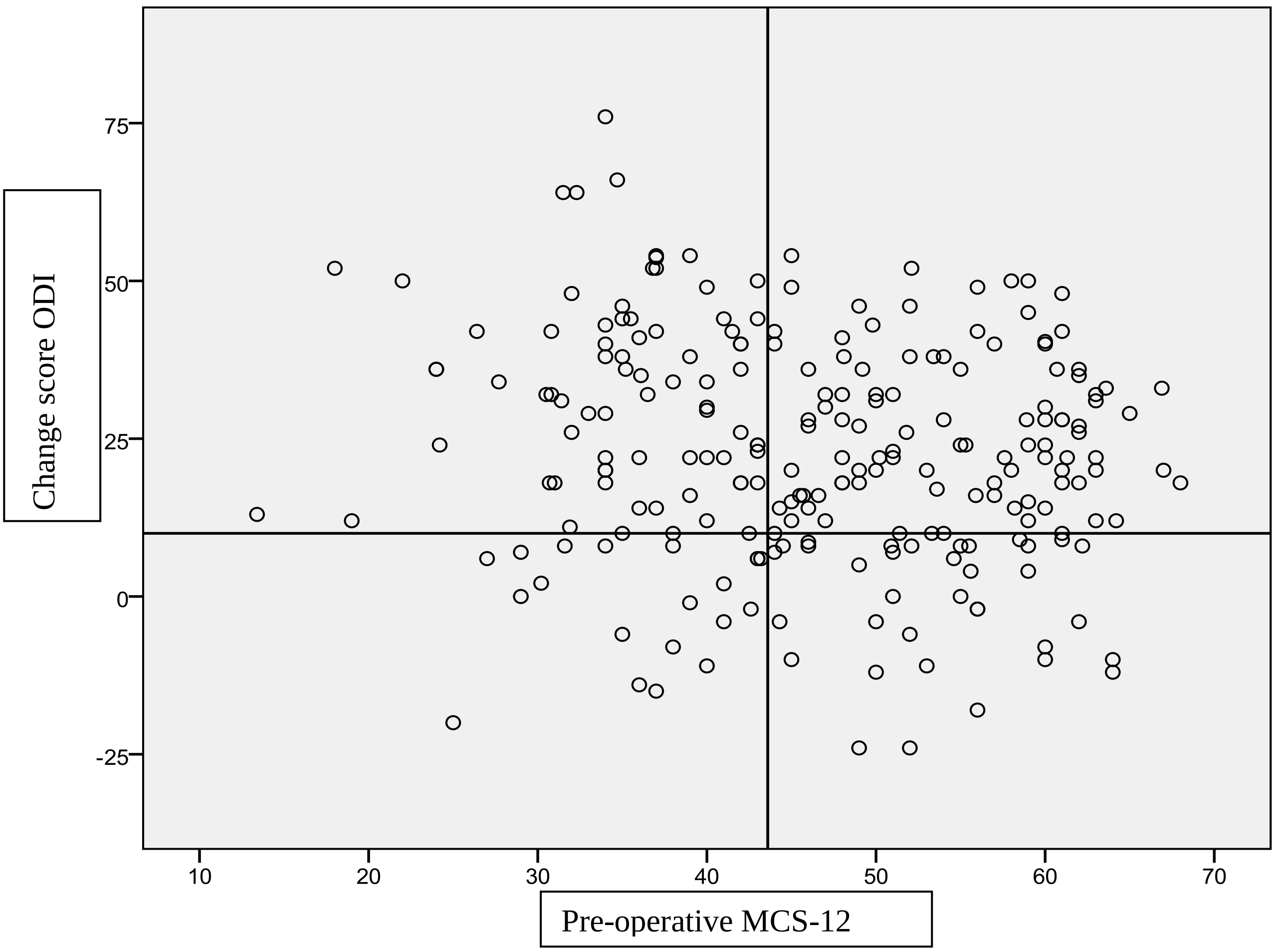
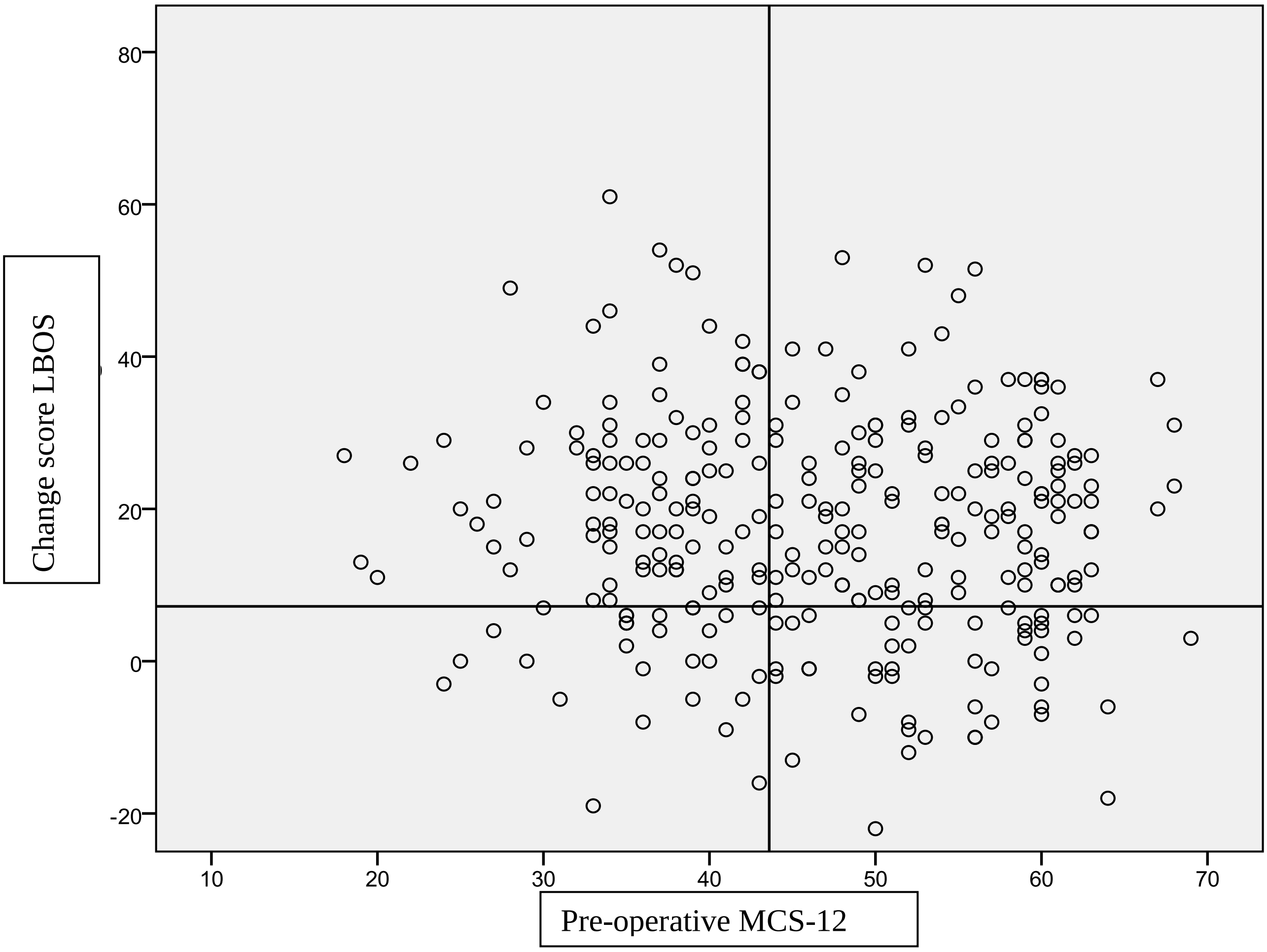


Figure 2b: Scatterplot of pre-operative MCS-12 score and change score in LBOS.

(Set value for MCS-12 = 43.6 and MCID of LBOS = 7.5)



Chapter 6

Lumbo-Pelvic Lordosis and The Pelvic Radius Technique

In The Assessment of Spinal Sagittal Balance:

Strengths and Caveats

Pages 117-127 of this thesis have been removed as they contain published material. Please refer to the following citation for details of the article contained in these pages:

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Chapter 7

Compensatory Mechanisms and the Effect of Age on Sagittal Balance in Degenerative and Isthmic Spondylolisthesis: An Analysis Utilizing the Pelvic Radius Technique

ABSTRACT

STUDY DESIGN: Cross-sectional observational study.

OBJECTIVES: The aims of this study are to investigate correlations between age and measures of spino-pelvic sagittal alignment in patients with spondylolisthesis and secondly, whether sagittal imbalance compensation mechanisms differ as patients age.

BACKGROUND: Few studies have investigated the effect of age on spino-pelvic sagittal alignment and to the authors' knowledge, none have examined this effect in patients with spondylolisthesis. Knowledge of aging and sagittal alignment in the degenerating spine may aid our understanding of the compensatory mechanisms, which patients adopt.

METHODS: Measures of sagittal alignment were acquired from the pre-operative radiographs of 382 consecutive patients with spondylolisthesis (isthmic-85 and degenerative-297) using the pelvic radius technique. Pearson's univariate correlations were tested between age and measured parameters. Compensation mechanisms were explored by examining correlations between spino-pelvic parameters – for all patients and after stratifying into three age groups (<45-years, 45-60 and >60-years).

RESULTS: No significant correlations were found between age and any parameters in the degenerative spondylolisthesis patients. In the isthmic spondylolisthesis patients, correlations were found between age and total lumbopelvic lordosis (r=-0.45) and between age and pelvic angulation (r=0.44). In the younger (<45years), isthmic subgroup, a strong correlation (r=-0.58, p=0.02) was found between focal lordosis at the slip level and the lumbar lordosis above.

Correlations between total lumbopelvic lordosis and pelvic angulation were observed in the degenerative ($r=-0.74$, $p<0.001$) and isthmic ($r=-0.69$, $p<0.001$) spondylolisthesis patients.

CONCLUSIONS: The hyperlordosis observed in younger patients (above a spondylolisthesis) may represent the primary compensation mechanism for focal loss of sagittal alignment (Type I), while an increase in pelvic angulation (pelvic retroversion) appears to be a secondary compensation mechanism adopted by older patients, with stiffer spines (Type II). It is postulated that combined hip and knee flexion may represent a third compensation mechanism (Type III), which is used once the capacity of Type I and II mechanisms to correct sagittal imbalance is exceeded.

INTRODUCTION

Spinal sagittal alignment may play an important role in the development and progression of degenerative spine disease, especially spondylolisthesis.[1-5] Various studies have shown differences in parameters of spino-pelvic alignment between normal volunteers, patients with low back pain and patients with more specific pathology such as spondylolisthesis.[3,4,6-10] Barrey et al recently reviewed the compensatory mechanisms observed in patients suffering disorders of sagittal balance associated with spinal degenerative disease. [11] They noted the importance of recognising compensatory mechanisms in order to avoid underestimating the severity of imbalance associated with a spinal degenerative disorder.

With advances in spinal fusion and deformity correction techniques, the ability to fuse the diseased spinal column in balanced sagittal alignment may improve the long-term outcomes of fusion surgery.[5,9,12] If so, an understanding of the natural history and magnitude of progressive disturbances of sagittal balance, with age and in various degenerative spinal disease states, will be important in formulating appropriate management strategies for surgical correction.[6,7,13-15]

Pelvic incidence (PI), a parameter of pelvic morphology, has been shown to evolve in growing children and mean values have been found to differ between certain degenerative conditions.[16-18] Other factors have been shown to affect or alter parameters of spinal alignment, including race, gender, weight and pelvic morphology. However, to the authors' knowledge, few studies have investigated the effect of age on changes in spino-pelvic sagittal alignment in adults[8,19] and none have examined this effect in patients with spondylolisthesis.

The purposes of the current study were to firstly, determine whether correlations exist between age and measures of spino-pelvic alignment in patients with spondylolisthesis and secondly, to use this data to investigate whether the compensation mechanisms, which patients use in cases of sagittal imbalance, differ as they age.

MATERIALS AND METHODS

A cross-sectional observational study was undertaken of the pre-operative radiographic data taken from a prospectively acquired database of consecutive patients with lumbar or lumbosacral spondylolisthesis, both isthmic and degenerative, who underwent surgery between September 2000 and September 2010. Patients were excluded if they had one or more of the following clinical and/or radiological criteria: traumatic or pathologic spondylolisthesis (e.g. tumor, infection), concomitant coronal deformity (e.g. idiopathic or degenerative scoliosis), previous lumbar fusion surgery or past history of fracture, tumors or infection to the spinal column.

The radiographic data was acquired by manual measurement of patients' pre-operative, erect standing 36-inch long lateral radiographs of their whole spine and pelvis, including both hips (i.e. full view of the femoral heads).[1,10] Spondylolisthesis slip severity was measured according to the Meyerding grade[20] and Taillard percentage techniques (% slip).[21]

The measurements of spinal sagittal alignment were obtained using the pelvic radius (PR) technique, described by Jackson et al.[7,22,23] The technique employs measurements based on

a line (the pelvic radius or PR) drawn from the hip axis (HA) and extending through the posterior superior corner of S1. The PR parameters measured were (Figure 1):

pelvic lordosis (PRS1) - angular measurement between the PR line and a tangent line along the S1 endplate, intersecting at the posterior superior corner of S1.

total lumbosacral lordosis (T12S1) - angular measurement between a tangent line along the inferior endplate of the T12 vertebral body and a tangent line along the superior endplate of S1.

total lumbopelvic lordosis (PRT12) - angular measurement between the PR line and a tangent line along the inferior endplate of the T12 vertebral body.

pelvic angulation (PA) – an angular measure of rotational pelvic balance, influenced by sacral translation in the sagittal plane, measured between a vertical line through the hip axis (HA) and the PR line.

distances of sagittal plumb lines from the hip axis (HAS1 and HAT4) - horizontal measures of pelvic balance reflecting sacral translation from the HA, measured in millimeters between vertical lines through the HA and the posterior superior corner of S1 and the center of T4 vertebrae, respectively.

Other measures analyzed included the focal lordosis at the slip level (focal lordosis) and the lumbar lordosis above the slip (lordosis above). Reliability of radiographic measurements was assessed using inter-observer and intra-observer correlations on subsamples of 30 and 16 patients, respectively. The independent t-test was used to assess differences in the spino-pelvic parameters between the two subgroups, isthmic and degenerative spondylolisthesis.

Univariate relationships between age and the measured parameters were then assessed using Pearson's correlation for the combined as well as for the separate isthmic and degenerative spondylolisthesis subgroups.

The compensation mechanisms used by patients for maintaining sagittal balance (in the presence of a spondylolisthesis, with or without an associated loss of focal lordosis) were explored by examining correlations between focal lordosis, lumbar lordosis above, total lumbar lordosis (T12S1), total lumbopelvic lordosis (PRT12) and pelvic angulation (PA).[11] Correlations were further examined following stratification of the patients into three age groups: (Group I: less than 45 years old; Group II: 45 to 60 years old and Group III: more than 60 years old). Differences between the mean values of the spino-pelvic parameters for the stratified age groups were assessed by analysis of variance (ANOVA) within both the isthmic and degenerative spondylolisthesis patient subgroups.

Statistical analysis was performed using the SPSS software version 19.0 (IBM Corporation, Somers, NY). The significance level was set at $P < 0.05$. The study protocol was approved by the university's ethics committee.

RESULTS

The study included 382 patients with spondylolisthesis, both isthmic (85 patients) and degenerative (297 patients). There were 255 females and 127 males. The mean age was 66 ± 14 years. (Table 1)

The degenerative spondylolisthesis patients were Meyerding grade I (74.1%) and grade II (25.9%). The isthmic spondylolisthesis patients were grade I (39.7%), grade II (50%) and grade III (10.3%). The mean degree of slippage in patients with degenerative spondylolisthesis (19.6%) was less than in patients with isthmic spondylolisthesis (29.3%). No patients had grade IV or spondyloptosis in our series. (Table 1)

The mean values (± standard deviations) for the spino-pelvic parameters for all spondylolisthesis patients, as well as for the degenerative spondylolisthesis and isthmic spondylolisthesis subgroups, are summarized in table 2. Significant differences were found between the two subgroups for age and for the parameters: PRS1, T12S1, PRT12, PA and HAS1. For comparative purposes, table 2 also includes Jackson and colleagues' published results of 75 healthy volunteers – 44 males and 31 females with a mean age of 39 years (range: 20-63 years) and Jackson's 75 spondylolisthesis patients – 33 males and 42 females with a mean age of 44 years (range: 14-78 years).[22]

The correlation coefficients between age and the spino-pelvic parameters for the combined spondylolisthesis patients were significant. Correlations were found between age and T12S1 (r = 0.26), PRT12 (r = - 0.24), PA (r = 0.31) and HAS1 (r = - 0.26). No correlations were found in the combined spondylolisthesis patients or in the isthmic or in the degenerative subgroups between age and PRS1 or HAT4.

In the isthmic and degenerative spondylolisthesis subgroup analysis, significant correlations of moderate strength were found in the isthmic subgroup between age & PRT12 (r = -0.45), between age & PA (r = 0.44) and between age & percentage slip.(Table

3a) No significant correlations were found between age and any of the spino-pelvic parameters in the degenerative spondylolisthesis subgroup. (Table 3b)

Analysis of variance (ANOVA) of the mean values of spino-pelvic parameters for the stratified age groups showed no significant difference in either the isthmic or degenerative spondylolisthesis subgroups.

Among the younger age group (<45 years) of the isthmic spondylolisthesis patients, a strong correlation (r = -0.58, p = 0.02) was found between the focal lordosis at the level of the slip and the lumbar lordosis above. (Figure 2)

Correlations between PRT12 and PA were observed: in the subgroup degenerative spondylolisthesis (r = -0.74, P <0.001) and in the subgroup isthmic spondylolisthesis (r = -0.69, p<0.001). The scatter-plot graphs of the correlations between PRT12 and PA are shown in figure 3.

DISCUSSION

The authors have used the pelvic radius technique for the current study. This technique, described by Jackson et al,[7] is one of the two principal techniques that have been advanced for the measurement of spino-pelvic sagittal alignment. The other, described by Duval-Beaupe`re et al is based on the pelvic incidence (PI).[14,24] The pelvic radius technique uses measurements based on the pelvic radius line (PR), which is drawn from the hip axis and continued through the posterior superior corner of S1. Jackson et al described the pelvic lordosis (PRS1); an important angle formed by the intersection of the PR with a tangent line along the endplate of S1. Like the pelvic incidence, PRS1 reflects the alignment of the sacrum within the pelvis. PRS1 is approximately equivalent to the complementary angle to the PI (i.e. PRS1 ≈ 90-PI); the relatively small difference resulting from use of the different measures: Pelvic Angulation (in the PR technique) and Pelvic Tilt (in the PI technique).[14,24,25].

Previous studies have shown changes in pelvic morphology in growing children (using the measure, PI).[16,17] While the current study is a cross-sectional one, the lack of any correlation between age and measures of pelvic morphology (here measured by PRS1) would appear to confirm the belief that once skeletal maturity has been reached, pelvic morphology remains constant for an individual and does not change during adulthood. (Table 3)

The subgroup analysis of the degenerative spondylolisthesis patients showed no significant correlations between age and any of the spino-pelvic parameters. This was despite the relatively large number of patients examined (n=297). It is possible that the older and narrower age range within this subgroup (mean age: 69 ±10 years) contributed to the lack of statistically significant correlations, when compared with the younger and wider age range for isthmic spondylolisthesis patients (mean age: 53 ±17 years).(Table 1) Moreover, the slower and less severe degree of slippage in the degenerative spondylolisthesis subgroup, when combined with the narrow age range, may result in less potential for the slip to affect other parameters of sagittal alignment. Matsunaga et al studied the natural history of 145 patients with degenerative spondylolisthesis (>10 years follow-up) and showed that progression of the slippage occurred in only 30% of cases. Rarely did the slip exceed 25% to 30% of the width of the subjacent vertebra.[26]

The pelvic radius technique is able to describe the total lumbopelvic lordosis, through the single angular measure, PRT12. PRT12 is the sum of the pelvic lordosis (PRS1) and the total lumbosacral lordosis (T12S1): PRT12 = PRS1 + T12S1.(Figure 1) Jackson noted, amongst normal volunteers, that values for PRS1 and T12S1 approach complementary angles, such that PRT12 is normally maintained at approximately 90 degrees (± 10 degrees standard deviation).[22] (Figure 1)

The current study found that in the isthmic spondylolisthesis subgroup, total lumbopelvic lordosis (PRT12) reduced and pelvic angulation (PA) increased as patients aged. (Table 3) Strong correlations were found between total lumbopelvic lordosis and pelvic angulation for both the isthmic and degenerative subgroups ($R=-0.69$ & $R=-0.74$, respectively, $P<0.001$, Figure 3), with a loss of lumbopelvic lordosis being associated with an increase in pelvic angulation. As well as this association, the young isthmic spondylolisthesis patient sub-group was the only group to demonstrate a significant correlation between the focal lordosis (at the level of the spondylolisthesis) and the lordosis above. (Figure 2) The direction of this effect was such that a loss of focal lordosis at the spondylolisthesis level was associated with an increase in the lordosis above. It would therefore seem likely that young patients with a flexible spine are able to maintain their sagittal spinal balance by increasing the lordosis of the segments above the slip. (Figure 4a-d)[6,11,27] However, older patients with relatively stiff spines (due to degenerative disease) may be unable to compensate in this way. Indeed, they may have lost the ability to maintain their normal lordosis (reflected in a low PRT12 value) and must compensate by extending or retroverting their pelvis around the hip axis. (Figure 4e-f)[2,4,6,11,23,27] This compensation mechanism is reflected in the increased PA value. (Figure 4c-d)

It is suggested that hyperlordosis of the segments above a focal loss of lordosis is the first or Type I compensatory mechanism, which is employed in cases of lumbar sagittal imbalance. The younger patients in the current series were observed to adopt this as their preferred compensation mechanism. It is postulated that the Type I mechanism requires less energy input than the alternative mechanism of pelvic extension, if the remainder of the spine has not become abnormally stiff (e.g. through degenerative disease). In the current series, hip joint extension (otherwise referred to as pelvic retroversion) appeared to be a second or Type II compensation mechanism and the preferred compensation strategy as patients aged. It is postulated that in the older patients, with stiffer spines, the energy required to increase the lordosis of a stiff spine (above a spondylolisthesis) is greater than that required to extend the pelvis around the hip joints. In the presence of fixed flexion deformity of the hips and/or maximal pelvic retroversion, a final or Type III compensation mechanism (and perhaps the most energy inefficient) may be for the patient to combine flexion of the hips and knees (along with ankle dorsiflexion) in order to bring the trunk center of gravity back over the axis of the hips and feet.[11,28,29]

In the setting of degenerative spinal deformity, structural or iatrogenic modifications to spinal alignment should be considered in respect to the findings in the current study. Spinal malalignment challenges balance mechanisms used for maintenance of an upright posture. Sagittal balance is necessary to maintain the basic human needs of preserving level visual gaze and retaining the head over the pelvis. Progressive severity in skeletal malalignment will result in greater recruitment in muscular effort and greater energy expenditure to maintain the erect posture as well as use of compensatory mechanisms. Spinal malalignment to the extremes of the "Cone of Economy" might leads to extreme muscular demand, fatigue, and significant pain as well as disability. Once a spinal deformity has reached the level of marked loss in function and quality of life, surgical intervention is often recommended and requested.[29-33]

The current study did not examine the relationship between lower limb joint alignment and spinal sagittal balance. This, as well as other factors such as thoracic flexibility and kyphosis, is likely to alter with increasing age. Further studies are required to examine the roles that these potential confounding factors play in affecting spinal sagittal balance. The information generated by such studies should enable a better understanding of the evolution of compensatory changes, which are seen on patients' radiographs, and a more accurate surgical correction of sagittal alignment. Perhaps, newer digital x-ray scanning technology, such as the EOS imaging system (Biospace Med, Paris, France) with low radiation, improved visibility of the cervico-thoracic junction and the ability to see the entire erect vertebral column, pelvis and lower limb alignment will contribute to a better understanding of the overall spinal balance.[13]

CONCLUSION

As anticipated, the current study found that pelvic lordosis (measured by PRS1) did not vary with age in either isthmic or degenerative spondylolisthesis patients. No correlations were found between increasing age and pre-operative measures of sagittal spinal alignment in 297 patients with degenerative spondylolisthesis. However, in 85 patients with isthmic spondylolisthesis, total lumbopelvic lordosis was found to decrease and pelvic angulation (PA) was found to increase as patients aged. In younger patients with isthmic spondylolisthesis (< 45 years), loss of focal lordosis at the level of the spondylolisthesis was found to correlate with increasing lumbar lordosis above the level of the spondylolisthesis. Pelvic angulation was found to increase with loss of total lumbopelvic lordosis (PRT12) in all patients. The hyperlordosis above, observed in the younger patients with otherwise flexible lumbar spines, may represent the primary mechanism used to compensate for a focal loss of sagittal alignment (Type I), while an increase in pelvic angulation may be a less energy efficient secondary compensation mechanism that is adopted by older patients with stiffer spines Type II). The authors postulate that combined hip and knee flexion may represent a third compensation mechanism (Type III), which is used once the capacity of Type I and II mechanisms to correct sagittal imbalance is exceeded.

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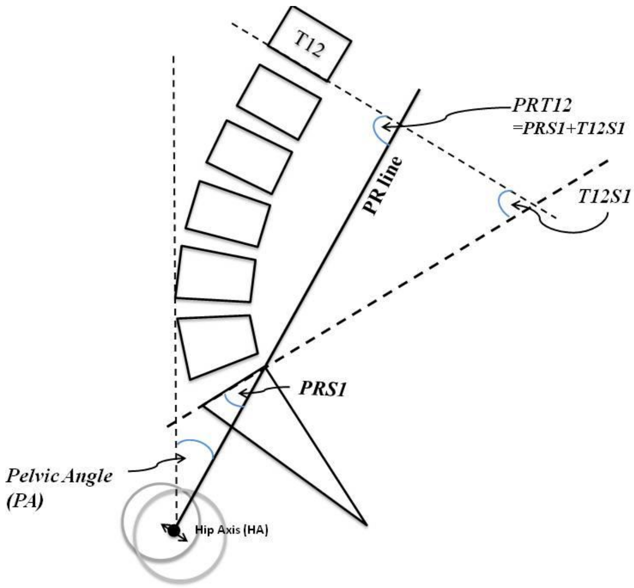
APPENDIX:

Figure 1: Pelvic Radius (PR) parameters: a) spino-pelvic angular measures and b) sagittal plumbline measures.

a)



b)

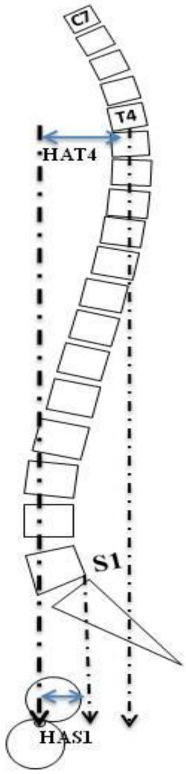


Table 1: Patient details – combined spondylolisthesis and sub-groups (isthmic and degenerative spondylolisthesis).

Variables	Combined Spondylolisthesis	Degenerative Spondylolisthesis	Isthmic Spondylolisthesis
N	382	297	85
Age in years (mean ±SD)	66 ±14	69 ±10	53 ±17
Gender	N	N	N
Male	127	86	41
Female	255	211	44
Subgroups (Age)			
Less than 45 years	30	6	24
45 to 60 years	77	47	30
More than 60 years	275	244	31
The classification of the spondylolisthesis			
Mean degree of Slip **(Talliard et al 1976)**	22.0	19.6	29.3
Meyerding Classification **(Meyerding et al 1931)**	%	%	%
I	65.4	74.1	39.7
II	32.0	25.9	50.0
III	2.6	-	10.3
IV	-	-	-

Table 2: Mean values (± Standard Deviation) for the combined spondylolisthesis patients and sub-groups, degenerative spondylolisthesis and isthmic spondylolisthesis. For comparison, previously published values are shown for 75 normal asymptomatic volunteers and 75 patients with isthmic spondylolisthesis.

Groups	Age (years)	PRS1 (degrees)	T12S1 (degrees)	PRT12 (degrees)	PA (degrees)	HAS1 (mm)	HAT4 (mm)
Study patients							
Combined Spondylolisthesis (n=382)	66 ± 14	23 ± 10	-54 ± 14	83 ± 13	28 ± 8	-62 ± 19	-74 ± 36
Degenerative Spondylolisthesis (n=297)	69 ± 10	25 ± 10	-51 ± 13	82 ± 13	29 ± 8	-64 ± 16	-73 ± 36
Isthmic Spondylolisthesis (n=85)	53 ± 17**	19 ± 9**	-64 ± 13**	87 ± 10*	24 ± 7**	-56 ± 24*	-79 ± 35[#]
Published Jackson measures[#]							
Asymptomatic Volunteers* (n=75)	39 (range: 20–63)	31 ± 10	-63 ± 12	94 ± 10	16 ± 6	-41 ± 14	-72 ± 22
Isthmic Spondylolisthesis* (n=75)	44 (range: 14–78)	14±9	-75±11	89±10	21±6	-52±15	-70±29

(Comparison of means between Degenerative and Isthmic Spondylolisthesis patient groups – Independent T-Test: *p < 0.05, *p ≤ 0.001,[#]Not significant)

Note: Asymptomatic volunteers and spondylolisthesis patients from Jackson et al.”Pelvic lordosis and alignment in spondylolisthesis”.Spine 2003*

Table 3: Co-efficients of correlation between age and between parameters of spino-pelvic alignment for a) degenerative spondylolisthesis and b) isthmic spondylolisthesis. (Pearson Correlation Coefficient Analysis, with p values – 2-tailed. Significant values shown in bold (*p < 0.05, **p ≤ 0.001)

a: Co-efficients of Correlations: Isthmic Spondylolisthesis

	Age	PRS1	T12S1	PRT12	PA	HAS1	HAT4	% Slip	Focal Lordosis	Lumbar Lordosis Above Slip
Age		0.00	0.21	**-0.45****	**0.44****	-0.30	-0.01	**-0.24***	-0.11	0.09
PRS1	0.00		-0.04	0.23	-0.27	0.02	**-0.49***	0.06	-0.01	-0.07
T12S1	0.21	-0.04		-0.33	0.16	0.14	-0.34	-0.20	0.13	**0.69****
PRT12	**-0.45****	0.23	-0.33		**-0.69****	**0.52****	-0.24	-0.18	-0.01	0.06
PA	**0.44****	-0.27	0.16	**-0.69****		**-0.73****	-0.21	0.28	0.08	-0.03
HAS1	-0.30	0.02	0.14	**0.52****	**-0.73****		0.11	-0.27	-0.16	0.25
HAT4	-0.01	**-0.49***	-0.34	-0.24	-0.21	0.11		0.02	0.02	-0.34
% Slip	**-0.24***	0.06	-0.20	-0.18	0.28	-0.27	0.02		0.19	**-0.49****
Focal Lordosis	-0.11	-0.01	0.13	-0.01	0.08	-0.16	0.02	0.19		-0.18
Lumbar Lordosis Above Slip	0.09	-0.07	**0.69***	0.06	-0.03	0.25	-0.34	**-0.49****	-0.18	

b: Co-efficients of Correlations: Degenerative Spondylolisthesis

	Age	PRS1	T12S1	PRT12	PA	HAS1	HAT4	% Slip	Focal Lordosis	Lumbar Lordosis Above Slip
Age		-0.08	0.02	-0.09	0.16	-0.12	0.07	-0.02	-0.13	0.07
PRS1	-0.08		**0.42****	**0.26****	**-0.38****	**0.29****	-0.12	-0.14	-0.18	0.07
T12S1	0.02	**0.42****		**-0.61****	**0.32****	**-0.40****	**0.31****	0.04	-0.12	-0.04
PRT12	-0.09	**0.26****	**-0.61****		**-0.74****	**0.71****	**-0.43****	-0.13	0.02	0.09
PA	0.16	**-0.38****	**0.32****	**-0.74****		**-0.92****	-0.07	**0.21****	0.14	-0.15
HAS1	-0.12	**0.29****	**-0.40****	**0.71****	**-0.92****		0.09	**-0.20***	-0.12	0.13
HAT4	0.07	-0.12	**0.31****	**-0.43****	-0.07	0.09		0.05	-0.09	0.07
% Slip	-0.02	-0.14	0.04	-0.13	**0.21****	**-0.20***	0.05		0.01	-0.08
Focal Lordosis	-0.13	-0.18	-0.12	0.02	0.14	-0.12	-0.09	0.01		-0.14
Lumbar Lordosis Above Slip	0.07	0.07	-0.04	0.09	-0.15	0.13	0.07	-0.08	-0.14	

Figure 2: Scatter plot graph of focal lordosis at the level of the spondylolisthesis (slip) versus lumbar lordosis above the slip, for isthmic spondylolisthesis patients – Group I: less than 45 years ***(n=24, mean and 95% confidence interval lines shown. Increasing negative values indicate increasing lordosis angle)***

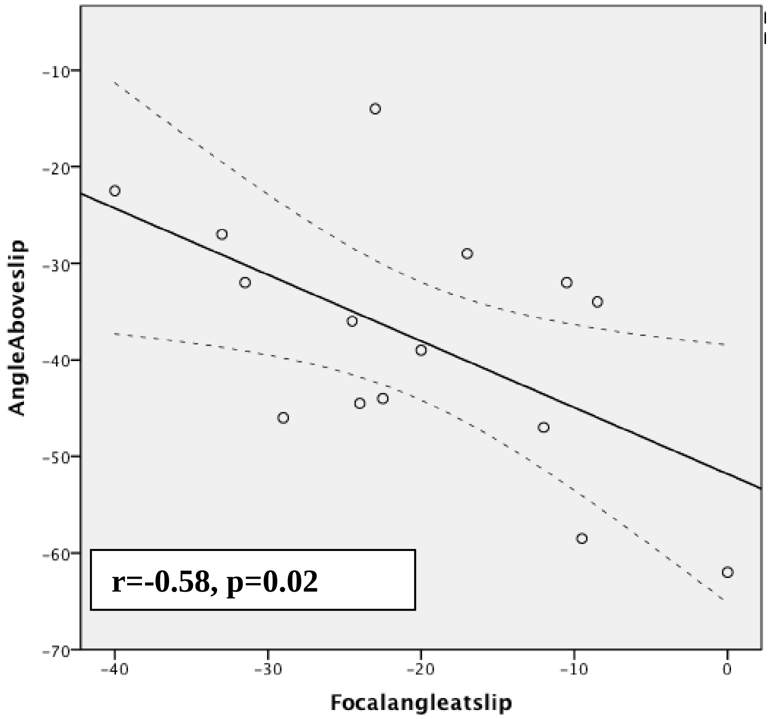
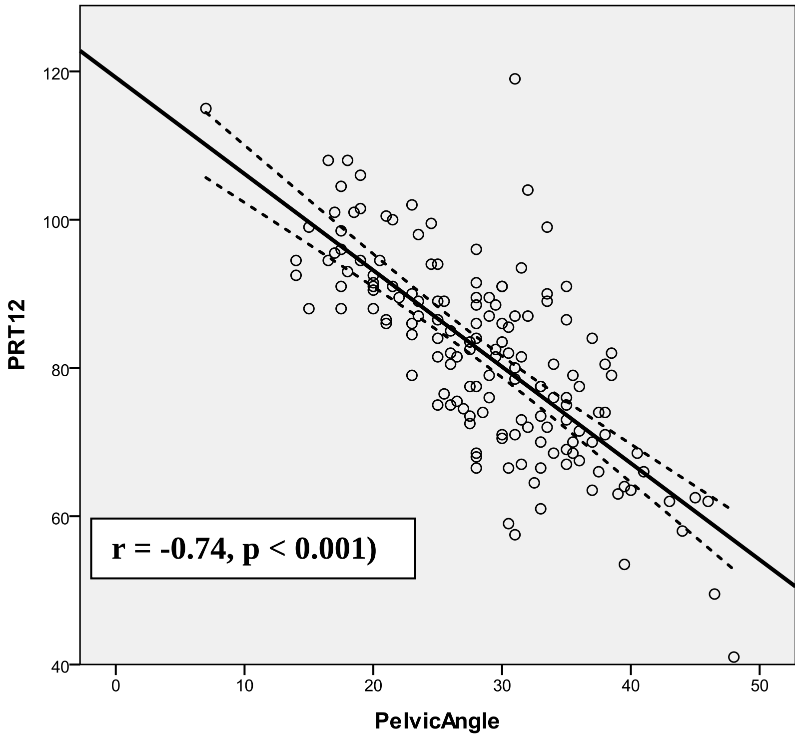


Figure 3: Scatter plot graph for PA versus PRT12 a) Degenerative Spondylolisthesis (all age group) and b) Isthmic Spondylolisthesis (all age group). Mean and 95% confidence interval lines shown.

a: Degenerative Spondylolisthesis(all age group)



b: Isthmic Spondylolisthesis(all age group)

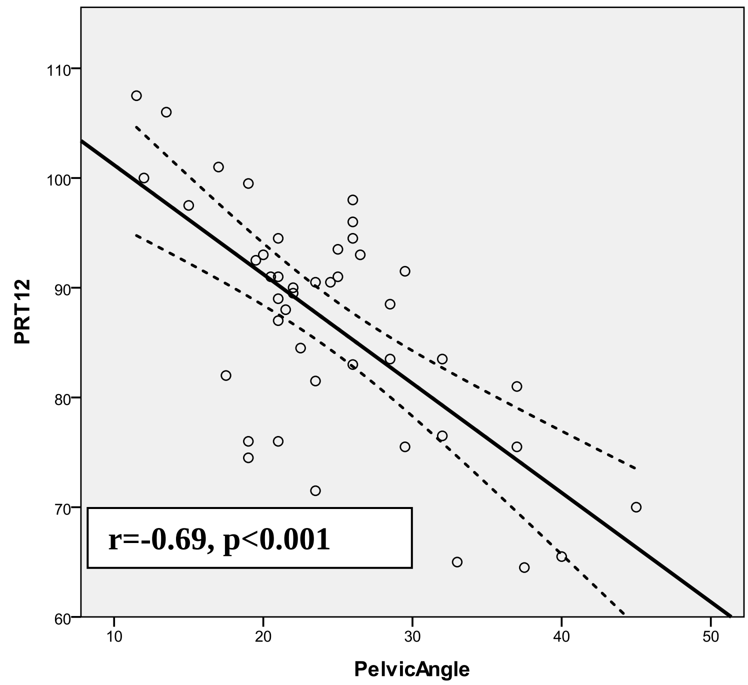
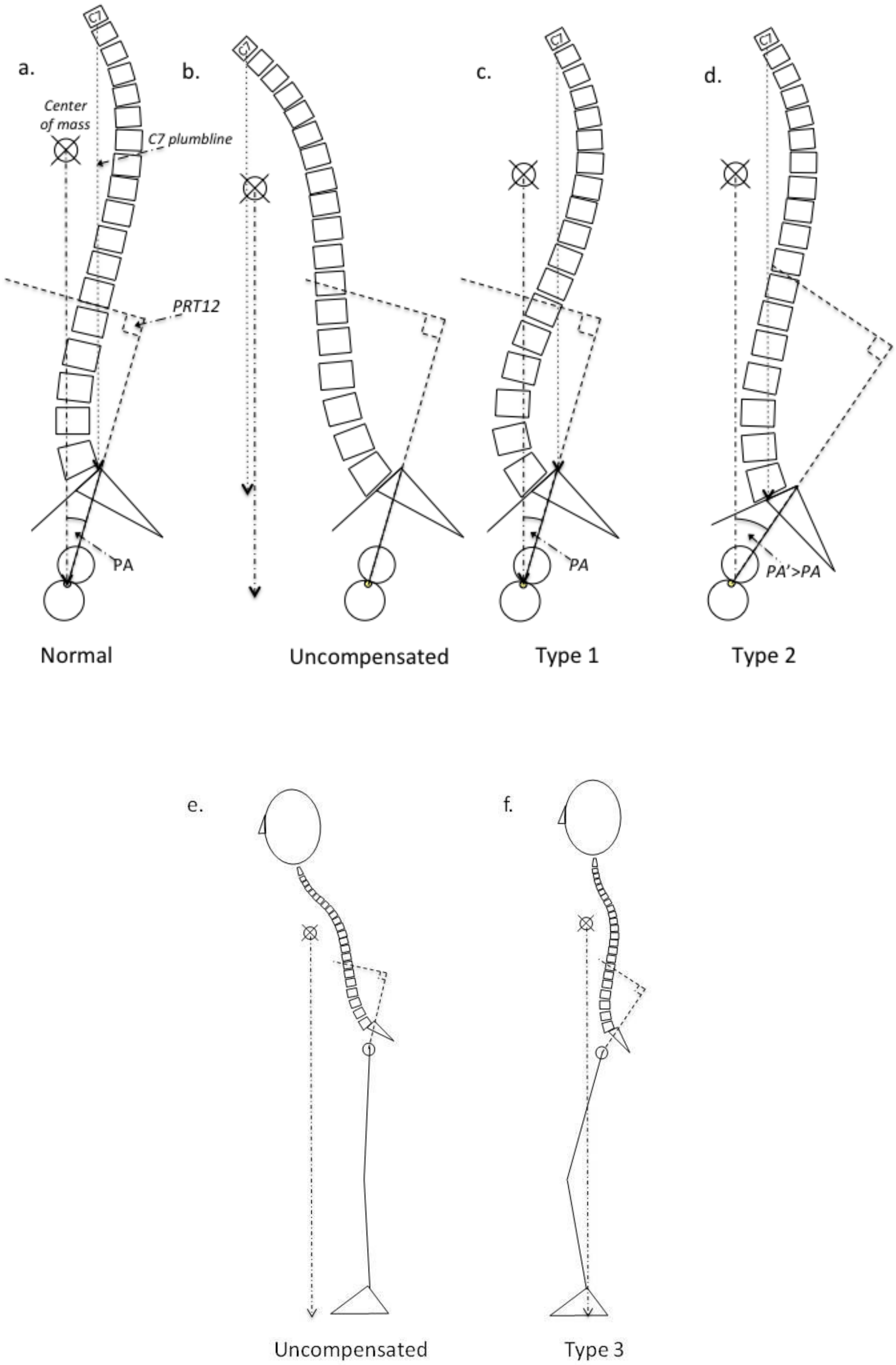


Figure 4: Schematic diagrams showing sagittal imbalance compensation mechanisms – Types 1, 2 & 3.

a. **Normal erect thoraco-lumbar spine**
b. **Uncompensated sagittal imbalance associated with spondylolisthesis and focal kyphosis at L5/S1**
c. **Compensation mechanism Type 1 – hyper-extension +/- retrolisthesis of segments above L5/S1**
d. **Compensation mechanism Type 2 – pelvic extension or retroversion**
e. **Uncompensated sagittal imbalance associated with spondylolisthesis and focal kyphosis at L5/S1 and normal lower limb alignment**
f. **Compensation mechanism Type 3 – knee/hip flexion +/- ankle extension**



Chapter 8

THESIS DISCUSSION AND CONCLUSION

DISCUSSION

"Simplicity is the ultimate sophistication."

- Leonardo da Vinci-

The thesis aimed at developing and investigating models for simple and practical methods of predicting and assessing patients' outcome used for spinal surgery for degenerative lumbosacral disorders. In the context of this thesis, a model is defined as "*a thing (a system, procedure, method etc.) used as an example to follow or imitate*" by Oxford Dictionary. Besides using the biopsychosocial analysis, the generic outcome measure of HRQL, this thesis also investigated the concept of spinal sagittal balance as a factor in predicting and determining the outcome of spinal surgery. The analyses were mainly by utilizing a prospectively collected database in the study centre.

Over the last few decades the evolution of spine care has undergone a rapid transformation. Increasingly, care has shifted from the older, traditional disease-based model of spinal disorder, where the management had been governed by associating clinical signs and symptoms with the spinal pathology identified by imaging modalities, to a more holistic approach of the biopsychosocial model. The biopsychosocial model emphasises patients' unique biologic, psychological and social factors, each playing an important role in influencing the spinal disease and management. Although the disease-based model is being replaced in spine care, it still remains the mainstay of the management concept in many other diseases (e.g. coronary artery disease and renal failure), where the failure of the damaged tissue or organ is the cause of signs, symptoms and abnormal investigative results.

This shift to a biopsychosocial model in spinal care is reflected in the current use of health-related quality of life (HRQL) measurements forming the basis of assessment for surgical outcome. This trend has resulted in an increase in spinal surgery publications with patient reported outcomes.

With this trend, there has been increased interest in the ways to measure HRQL and an increase number of measure instruments. Those involved in spinal care, both in the clinical and research setting, need to decide which of the many measure instruments that are routinely utilized in the field of spine care that are valid, accurate and useful in their practice. My research looked at the value of HRQL measurement instruments in degenerative disorders of the lumbosacral spine and how these HRQL measures are used to report on spinal fusion outcomes. In this research, Medical Outcomes Study 12-Item Short-Form Health Survey (SF-12), Oswestry Disability Index Scale (ODI) and Low Backpain Outcome Score (LBOS) were applied. These HRQL measures have been validated for measuring outcome in spinal surgical intervention and are increasingly being accepted in spinal research, based on their ability to measure biopsychosocial change.

The advantages of using HRQL instruments, especially the generic HRQL, are that they allow comparison of outcomes of different medical conditions and treatments. This research took a straight forward approach to analysing the worthiness of a certain procedure, which is spinal fusion, by comparing it to established procedures that have been regarded as “gold standard” in restoring patient’s HRQL. In this research, large joint replacement surgery for osteoarthritis was chosen because it is accepted as an established surgical procedure in improving HRQL of aging patients. To approximate the worthiness of spinal fusion surgery, comparisons were made with previously published SF-12 outcomes scores of large joint replacement surgery for osteoarthritis of the hip and knee with the SF-12 outcome score of spinal fusion surgery in this research. This allowed generation of league tables to compare and analyse (i.e. comparative study model) any measurable benefit among these different surgical treatments. This approach may also provide a basis for further detailed study looking at the issues surrounding cost-effectiveness of spinal fusion surgery. In Chapters 2 and 3, using this comparative study model, it was demonstrated that lumbar fusion surgery yielded favourable outcomes.

In addition to reasons mentioned earlier, large joint replacement surgery were also chosen as comparison as osteoarthritis and degenerative spine disease are common musculoskeletal impairments in a similar group of the ageing population. Furthermore, the similarity in clinical manifestation of both of these conditions, with pain as the main symptom followed by disability, makes it relevant for their comparison. The only setback for the selection of large joint replacement is the fact that the surgical procedure still preserves the mobility or movement of the joint. Improvement of pain is also associated with improvement of movement in certain cases but the range of motion for whole joint is still restricted as compared to a normal hip or knee joints. It our series where fusion was performed at a single functional spinal unit, the restriction of mobility of the spinal column is unaffected due the mobility of other adjacent segments. Thus the significance of maintaining sagittal spinal balance in fusion surgery to yield a favourable long term outcome has become the aim of some studies. The incidence of adjacent segment disease has been implicated as the complication of such phenomenon.

Large joint osteoarthritis is a single pathology disease due to thinning of the articular cartilage. Total joint replacement surgery is currently the established treatment modality where the worn out articular cartilage is removed and replaced with an endo-prothesis. On the other hand, degenerative spinal disorders are a heterogeneous group with various pathologies, resulting in numerous treatment options. The indication for spinal surgery is not specific and involves many factors. Furthermore, the surgical outcome for spinal surgery is unpredictable and does not always result in favourable outcomes. This research has attempted to address these problems and offer a solution that would be practical in the clinical setting and result in better outcomes after spinal surgery. By stratifying the diagnosis of the spinal disorder into homogenous sub-groups, we would be able to understand better the specific pathology. This would also help with a more precise treatment targeted at the pathology.

The efficacy of lumbar interbody fusion as a specific surgical intervention for lumbar stenosis and instability secondary to degenerative spondylolisthesis has been proven in controlled trials. My research employed the strict selection criteria of a single level degenerative spondylolisthesis to identify a subgroup of patients within the larger group of degenerative spinal disease. As a result of this strict selection criteria and specific surgical intervention (i.e. primary spinal decompression and fusion surgery), my published article (Chapter 2) illustrated improvement in HRQL after surgery to levels approaching those of age-matched normal population and outcomes comparable to those of large joint replacement surgical patients.

The research used the same comparative study model, to look at the difficult group of spinal patients who have not had improvement after surgery, collectively known as the "failed back surgery syndrome" (FBSS) patients. As demonstrated in Chapter 3, the results of this research indicated that in selected failed back surgery patients, where an identifiable cause of pain can be established, an improvement in HRQL can be achieved by surgery. These improvements in the HRQL are comparable to published results following primary total knee arthroplasty and revision hip arthroplasty. The HRQL improvements did not achieve the better outcomes of primary spinal fusion and primary total hip arthroplasty, however, these differences were stastically inconclusive.

As discussed earlier, the increase in concerns of healthcare costs has been an important driver in the effort to build an evidence-based approach to surgical intervention especially in the area of spinal surgery. This has led to an increasing number of outcome measurement instruments being developed for research and clinical care in spine surgery. The focus of the instruments has moved towards patients' response to the surgery in terms of pain and disability, rather than the surgeons' perception of good or poor outcome based on improvement on radiological examination or clinical assessment. In the clinical research setting more than one instrument is usually employed. The number of instruments used depends on the amount, quality and type of data considered necessary to obtain meaningful results. However, the number, variety and length of the instruments will affect the time and cost of implementing these instruments and may impact on patient's compliance and ultimately the accuracy of the assessment.

Outcome measure instruments available tend to be lengthy and complex and can be a time consuming and tiring exercise for both the patient and the clinician. There is a need to identify a shorter and simpler assessment tool to be used in clinical practice. Therefore, I selected the common and easily used pain rating scale, the visual analogue pain scale (VAS for pain), and correlated it with both generic outcome measures and specific back pain measures. The generic measures used were, SF-12, both the Physical Component Summary for SF-12 (PCS-12) and the Mental Component Summary for SF-12 (MCS-12). Back pain measures used were patient's response outcome measures (PROM), the Oswestry Disability Index (ODI) and the Low Back Outcome Score (LBOS). In Chapter 4 this research detected correlations between the generic outcome measure instrument PCS-12 of SF-12 as well as the back pain specific PROM measure instruments ODI and LBOS with the visual analogue pain scale. In other words, the shorter and simpler assessment tool of the visual analogue pain scale was demonstrated to correlate with the lengthier and more complex assessment tools SF-12, ODI and LBOS. The research did not demonstrate a correlation of the visual analogue pain scale with the MCS-12 of SF-12.

These findings implied the visual analogue pain scale is sufficient to assess patients' HRQL following spinal fusion. This will be important in busy clinical practices or where resources are limited, as the visual analogue pain scale is more convenient and will result in better compliance and better response.

Furthermore, these findings suggest future development of a simpler measure instrument. As a result of my research, I would propose that such an assessment tool should involve only three components. The first two components should be assessing pain and disability by the patient using a visual analogue scale. The third component should be a question on patients' global satisfaction.

Patient selection, especially in surgery for low-back degenerative conditions, has always been regarded as important for a successful surgical intervention. Significant numbers of studies have looked into identifying predictors of outcome for lumbosacral surgery. These predictors include socio-demographic factors (e.g. age, gender), clinical factors (e.g. pain, severity of straight leg raising test, body mass index), work-related factors, and psychological factors. At present, there is no agreement on pre-operative predictors that can assist in selecting patients for surgery. This may be due to the fact that spinal surgery outcome is influenced by multiple factors, recognised as biopsychosocial factors.

On the basis that biopsychosocial factors influence the surgical outcome, I examined the ability of the HRQL measure instrument, SF-12, as a predictor of surgical outcome in patients with degenerative lumbosacral disorder. SF-12 is a validated generic patient based measure, which is readily available to monitor patients' progress and widely used in assessment of outcomes in medical interventions. Referring to Chapter 5, this research demonstrated that SF-12 could specifically be used as a predictor of surgical outcome for patients with degenerative lumbosacral disorders. This research demonstrated that pre-operative components of SF-12, the PCS-12 and MCS-12 scores, correlated with the surgical outcome. Patients with lower pre-operative PCS-12 scores and higher pre-operative MCS-12 scores achieved greater PCS-12, ODI and LBOS improvement post-operatively. Thus, this research implied that patients with worse physical impairment, as shown by the lower PCS-12 score, but not mentally distressed, as measured by the higher MCS-12 score, would be better candidates for spinal fusion surgery and have more favourable outcomes.(Figure1)

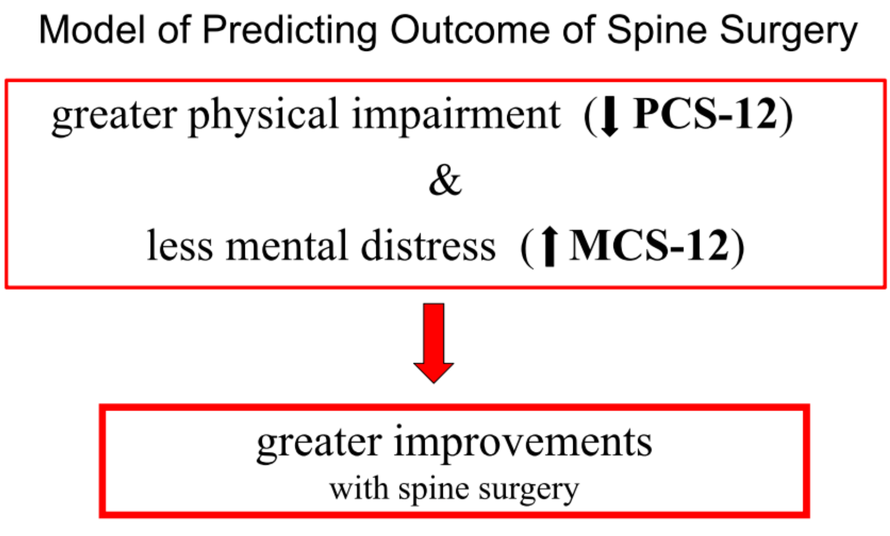


Figure 1: A schematic model demonstrating the pre-operative SF-12 scores predicting the outcome of surgery in degenerative lumbar disorder.

Over the last decade, maintaining or restoring spinal sagittal balance has been increasingly recognized as important in the care of patients with spinal problems. It is essential that clinicians have a way of assessing and describing spinal sagittal balance and alignment to aid in diagnosis, pre-operative surgical planning and post-operative assessment. Currently there is no single measurement that can accommodate the entire spectrum of spinal curvatures. All methods available for assessing the spine in the sagittal plane have their strengths and weaknesses. Addressing this problem, Chapter 6 is a review article on the strengths and caveats of the pelvic radius technique, described by Jackson et al, in assessing the spino-pelvic alignment. The pelvic radius technique was chosen due to its simple method of application and its reliability (good inter-observer and intra-observer reliability) of measuring sagittal balance of the spine by implementing the concept of spino-pelvic parameters.

Based on Chapter 6 (published review article), there are potential errors if the pelvic radius technique is not used correctly. In a balanced spine, the lumbar lordosis is affected by the thoracic kyphosis and vice versa. The prerequisite in measuring total lumbopelvic lordosis (PRT12) is that it must not be evaluated in isolation from the thoracic spine. This is seen in the example where a pathological large thoracic kyphosis (e.g. Scheuermann's disease or thoracic wedge fractures), and the pelvic radius measures for the lumbar spine may appear to be appropriate. In such an example the lumbar lordosis may need to be substantially larger and the PRT12 may need to be significantly greater than 90º in order for the spine to be in balance.

Various factors such as race, gender, weight and pelvic morphology affect the spinal sagittal balance. Limited studies have been carried out specifically looking at the effect of age on the spinal sagittal balance. To investigate this area, my research in Chapter 7 investigated relationships that may exist between age and spino-pelvic parameters in patients with isthmic spondylolisthesis and degenerative spondylolisthesis. The research identified that age correlated with changes in total lumbopelvic lordosis (PRT12) and pelvic angulation (PA) in patients with isthmic spondylolisthesis. These changes are related to the smaller total lumbopelvic lordosis (PRT12), which inversely causes larger pelvic angulation (PA) with increasing age. This compensatory mechanism is due to the decreased ability of the lumbar spine to maintain flexibility with age and the role of hip extension on standing to maintain the sagittal alignment of the spine. However, there was no correlation of age and spino-pelvic parameters in patients with degenerative spondylolisthesis. This is due to the narrower age range in the group studied and their older age (more than 60 years).

This research also identified significant differences in spino-pelvic parameters between the subgroups of isthmic spondylolisthesis and degenerative spondylolisthesis. These parameters result in the distinctive and diverse mechanisms of compensation to maintain spinal sagittal balance. Patients with isthmic spondylolisthesis, due to their younger age and ability to extend the lumbosacral spine, compensate with increasing total lumbosacral lordosis (T12S1). Patients with degenerative spondylolisthesis, comprised of older patients, have less flexibility of their lumbar spine motion segment, and hence have more significant compensation with hip extension, which is reflected by their larger pelvic angulations (PA).

Various studies have acknowledged that there are differences in the value of pelvic lordosis (PRS1) between patients with spondylolisthesis and normal volunteers. It is widely accepted that PRS1, measured using the pelvic radius technique, remain constant. My research also confirmed this finding by demonstrating PRS1 did not vary with age in both isthmic and degenerative spondylolisthesis patient subgroups. I would also like to emphasize that because of the independent nature of PRS1 and its constant value throughout adulthood, it may be the ideal prognostic indicator of development and natural progression of spondylolisthesis. The dynamic process of spondylolisthesis, signifying the disease progression results in changes of parameters measured.

This research illustrated smaller PRS1 in patients with isthmic spondylolisthesis in comparison to patients with degenerative spondylolisthesis. This finding may be explained by the theory of increased shear stress at the lumbosacral junction due to increased vertical orientation of the S1 endplate. The orientation of the S1 endplate is predetermined and directly related to the pelvic lordosis of an individual. Patients with isthmic spondylolisthesis have more flexibility of the spine (i.e. good disc height and no osteophytes). Furthermore, the biomechanical stress is greater in isthmic spondylolisthesis causing failure of the pars interarticularis resulting in the lytic appearance and progression of the slip.

In degenerative spondylolisthesis, due to the natural loss of disc height and formation of osteophytes, the magnitude of loading and forward translation is less, causing a more gradual change to the increasing load or stress. These secondary changes, and in particularly the osteophytes, provide a natural tendency to restabilize the motion segment. It is noted that rarely does the slip exceed 25% to 30% of the width of the subjacent vertebra. The long-standing effect of the posterior tilt of the pelvis and loss of lordosis might enhance the development of the facet joint arthritis, which is evident in degenerative spondylolisthesis.

CLINICAL IMPLICATION

In Chapters 2 and 3, I have used a study model utilizing SF-12, a generic HRQL questionnaire, to compare the efficacy of spinal fusion surgery in degenerative lumbosacral disorder with published results in total large joint replacement surgery. This is a simple and practical model for comparison of spinal surgical intervention with a well-established procedure that is known to restore patient's HRQL. The study model could also be applied for other comparisons between different homogenous groups in degenerative lumbosacral disorders.

My research, described in Chapter 4, demonstrated strong correlations between the simpler visual analogue scale pain scores and both generic outcome measure instruments and illness-specific patients' response outcome measure instruments. This is important for the purpose of outcome audit of surgical practice, as it suggests that a single simple visual analogue scale assessment is adequate to replace the complex administration of multiple, lengthy outcome measurement instruments.

Referring to Chapter 5, the research identified that the pre-operative SF-12 scores are useful as a predictor tool for effectiveness in fusion surgery for degenerative lumbar disorders. Having it readily available in practice, where it is also used for outcome assessment, is an advantage in terms of cost and burden for both assessor and patients. The application of this method will avoid the need for using more intricate workouts for biopsychosocial assessment.

The pelvic radius technique, which was described by Jackson and associates, is a simple and reliable technique. The research identified that the caveat of this technique is that the measuring of total lumbopelvic lordosis (PRT12) must not be in isolation from the thoracic spine. This is because the lumbar lordosis is affected by the thoracic kyphosis and vice versa.

My research in Chapter 7 indicated that compensation mechanism for sagittal balance changes with age. As for surgeons who perform fusion surgery for degenerative lumbosacral disorder, there is a need to be aware that only by understanding the differences in sagittal balance parameters between different types of pathology and age of the patient, that optimal correction of sagittal alignment can be made.

THESIS LIMITATION

Although the evidence indicated that after spinal fusion surgery, patients with degenerative spondylolisthesis and failed back surgery syndrome will have a statistical improvement of HRQOL to a satisfying level, broader scale studies and longer follow-up trials are required to provide more definitive results. The limitation of the research, using the comparative study model, is that the comparisons made with the total large joint replacements were based on reported literature outcomes. It would be preferable if the comparison data of the two groups were within the same population and would allow comparison within the same biopsychosocial background.

The average follow up for the patients in this study is two years. This is the usual duration of follow-up after surgery in majority of the patients in our study center. The longer period of follow-up will be more beneficial in looking at the long term outcome of surgery but it is not feasible in terms of cost and time for both patients and surgeons.

The “gold standard” of any clinical trial would be to perform a randomized control trial (RCT). RCT is considered the most powerful method currently available in clinical practice to demonstrate differences between treatment regimes. But the design and execution of RCT is not easy and practical, particularly if surgical treatment is involved. It involves more resources, in terms of time and human resources. The issue of difficulty in the recruitment of patients have been highlighted. Both surgeons and patients might not be satisfied with the loss of autonomy implied by randomization of treatment. Our studies are mainly retrospective analysis of prospectively collected database. Based on this, the studies could be considered as a level II evidence studies. (Table 1)

Levels of Evidence	
Ia	Systematic reviews (with homogeneity) of randomized controlled trials
Ib	Individual randomized controlled trials (with narrow confidence interval)
Ic	All or none randomized controlled trials
IIa	Systematic reviews (with homogeneity) of cohort studies
IIb	Individual cohort study or low quality randomized controlled trials (e.g. <80% follow-up)
IIc	"Outcomes" Research; ecological studies
IIIa	Systematic review (with homogeneity) of case-control studies
IIIb	Individual case-control study
IV	Case-series (and poor quality cohort and case-control studies)
V	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

Table 1: Levels of evidence based on Centre for Evidence- Based Medicine, Oxford University

FUTURE DIRECTION

It is my future intention to conduct a prospective collaborative trial with other surgical disciplines mainly large joint replacement surgery for osteoarthritis. This is to compare the effectiveness of spinal surgery with large joint replacement surgery in the same demographic population background. This would allow more standardization of the study methodology and patients selection with similar socio-demographic background and thus enhance the veracity of the conclusions.

Based on the finding in Chapter 4, that a simple VAS score is sufficient to assess patients' HRQL following spinal fusion, it would be my intention to use a VAS score in clinical practice. The use of VAS as a simple outcome assessment would be more convenient for the patients and assessors, especially in a busy practice or where resources are limited, and thus result in better compliance. It is my intention to study further about the development of a simpler questionnaire with only three components. Two components of the questionnaire would consist of two VAS scores, each for for assessing pain and disability. The third component should be a question on patients' global satisfaction. The clinical application of this simpler instrument would likely be time and cost saving, consequently improving patients' compliance hence yielding more accurate response.

My research detected components of the Medical Outcomes Study 12-Item Short-Form Health Survey (SF-12), a validated generic patient based HRQL outcome measure instrument that is commonly used in monitoring progress, can also be used in the pre-operative assessment of patients with degenerative lumbosacral disorders to predict patient outcome after spinal surgery. Therefore, SF-12 can be employed for the important role of selecting patients that are more likely to have a favourable outcome as well as assessing progress for these patients. I would plan to apply this finding in a future prospective study looking at the efficacy of the screening method and compare it hand-in hand with the more sophisticated neuropsychological assessment of biopsychosocial factor for patients planned for surgery.

In terms of sagittal balance, greater research is needed to look further into compensation mechanism especially the effects of the other complex variables such as thoracic curvature proximally, and hip flexibility distally. This will be important, as these variables are likely to be risk factors contributing to the progression of spinal disorder and contribute to the long term outcome of fusion surgery.

THESIS CONCLUSION

The thesis proposed the following models:

1. Comparison model for benchmarking the outcome of certain spinal surgical procedures on a homogenous group of spinal disorder with other established surgical procedure (e.g primary spinal fusion, large joint replacement surgery) using the generic HRQL outcome measure instruments (e.g SF-12).
2. Prediction model for pre-operative screening of biopsychosocial factor of patients planned for spinal surgery by using the pre-operative scores of SF-12(both the PCS1-12 and MCS-12 scores).
3. Simple single visual pain scale(VAS) score model for assessment of follow-up patients to replace the administration of multiple, lengthy outcome measures instruments in certain clinical setting where resources are limited (e.g. private surgical practice audit).
4. The compensatory mechanism model for spondylolisthesis:
    a. Type I - hyperlordosis above the slipped level, observed in the younger patients with otherwise flexible lumbar spines.
    b. Type II - increase in pelvic angulation may be a less energy efficient secondary compensation mechanism that is adopted by older patients with stiffer spines
    c. Type III - combined hip and knee flexion may represent a third compensation mechanism, which is used once the capacity of Type I and II mechanisms to correct sagittal imbalance is exceeded.

APPENDIX A

List of authors and contribution to the studies

Contribution of Authors

Article Title:
Health-Related Quality of Life: A Comparison of Outcomes after Lumbar Fusion for Degenerative Spondylolisthesis with Large Joint Replacement Surgery and Population Norms

Author Names and Order:
1. Sabarul A. Mokhtar, MD, MS (Orth)
2. Peter F. McCombe, MBBS, FRACS
3. Owen D. Williamson, MBBS, GradDipClinEpi, FRACS, FAOrthA
4. Michael K. Morgan, MD, MMedEd, FRACS
5. Gavin J. White
6. William R. Sears, MBBS, FRACS

Author Number	**1**	**2**	**3**	**4**	**5**	**6**
Conception and design	X	X		X		X
Acquisition and data	X	X			X	X
Analysis and interpretation of data	X					X
Drafting of the manuscript	X					
Critical revision of the manuscript for important intellectual content	X	X		X		X
Statistical analysis	X		X			
Administrative, technical or material support					X	
Supervision		X	X	X		X

Contribution of Authors

Article Title:
Health-Related Quality Of Life Following Revision Surgery for `Failed Back Surgery Syndrome´–A Comparison with Results Following Primary Spinal Fusion And Large Joint Arthroplasty

Author Names and Order:

1. Sabarul A. Mokhtar, MD, MS (Orth)
2. Owen D. Williamson, MBBS, GradDipClinEpi, FRACS, FAOrthA
3. Michael K. Morgan, MD, MMedEd, FRACS
4. Gavin J. White
5. William R. Sears, MBBS, FRACS

Author Number	1	2	3	4	5
Conception and design	X	X		X	X
Acquisition and data	X		X		X
Analysis and interpretation of data	X	X			X
Drafting of the manuscript	X				
Critical revision of the manuscript for important intellectual content	X	X		X	X
Statistical analysis	X	X			
Administrative, technical or material support			X		
Supervision		X		X	X

Contribution of Authors

Article Title:
Independence of Clinical Outcome Measurement Instruments in Spinal Surgical Practice

Author Names and Order:

1. Sabarul A. Mokhtar, MD, MS (Orth)
2. Michael K. Morgan, MD, MMedEd, FRACS
3. William R. Sears, MBBS, FRACS

Author Number	**1**	**2**	**3**
Conception and design	X	X	X
Acquisition and data	X		X
Analysis and interpretation of data	X		X
Drafting of the manuscript	X		
Critical revision of the manuscript for important intellectual content	X	X	X
Statistical analysis	X		
Administrative, technical or material support			
Supervision		X	X

Contribution of Authors

Article Title:
Preoperative Health-Related Quality of Life Scores as Predictor of Clinical Outcomes after Degenerative Lumbar Surgery

Author Names and Order:

1. Sabarul A. Mokhtar, MD, MS (Orth)
2. Michael K. Morgan, MD, MMedEd, FRACS
3. William R. Sears, MBBS, FRACS

Author Number	**1**	**2**	**3**
Conception and design	X	X	X
Acquisition and data	X		X
Analysis and interpretation of data	X		X
Drafting of the manuscript	X		
Critical revision of the manuscript for important intellectual content	X	X	X
Statistical analysis	X		
Administrative, technical or material support			
Supervision		X	X

Contribution of Authors

Article Title:
Lumbo-pelvic Lordosis and the Pelvic Radius Technique in the Assessment of Spinal Sagittal Balance: Strengths and Caveats

Author Names and Order:

1. Ioannis G. Sergides MBBS, BSc, FRCS
2. Peter F. McCombe, MBBS, FRACS
3. Gavin J. White
4. Sabarul A. Mokhtar, MD, MS (Orth)
5. William R. Sears, MBBS, FRACS

Author Number	**1**	**2**	**3**	**4**	**5**
Conception and design	X	X		X	X
Acquisition and data	X		X	X	X
Analysis and interpretation of data	X			X	X
Drafting of the manuscript	X			X	
Critical revision of the manuscript for important intellectual content		X		X	X
Statistical analysis	X			X	
Administrative, technical or material support			X		
Supervision		X			X

Contribution of Authors

Article Title:
Compensatory Mechanisms and the Effect of Age on Sagittal Balance in Degenerative and Isthmic Spondylolisthesis: An Analysis Utilizing the Pelvic Radius Technique

Author Names and Order:
1. Sabarul A. Mokhtar, MD, MS (Orth)
2. Peter F. McCombe, MBBS, FRACS
3. Michael K. Morgan, MD, MMedEd, FRACS
4. William R. Sears, MBBS, FRACS

Author Number	**1**	**2**	**3**	**4**
Conception and design	X	X	X	X
Acquisition and data	X			X
Analysis and interpretation of data	X			X
Drafting of the manuscript	X			
Critical revision of the manuscript for important intellectual content	X	X	X	X
Statistical analysis	X			
Administrative, technical or material support				
Supervision		X	X	X

APPENDIX B

Questionnaire Form for the Studies

Thoracolumbar Questionnaire

To be completed by the PATIENT POSTOPERATIVELY

Directions: *The following questionnaires have been designed to give the doctor information about your general health and how your back/leg pain has affected your ability to manage your everyday life.* ***Please answer every question. Mark only one answer for each question****. Where a range of statements are provided, please mark only the one that most closely describes your situation.*

Place patient label sticker here

Office use only

VAS ave	
VAS (Back)	
VAS (Leg)	
OLBP	
SF-12	
LBOS	

NAME: ____________________ DOB: ____________ TODAYS DATE: ____________

1. **Have you been able to return to your normal daily activities (work *or* home duties) since your surgery?**
   - O Yes, full time at normal duties
   - O Yes, full time at lighter duties
   - O Yes, part time
   - O No

2. **Based on your own expectations, how would you rate the success of your operation?**

O	EXCELLENT:	Very satisfied, complete or almost complete relief of symptoms
O	GOOD:	Fairly satisfied, a good deal of relief
O	FAIR:	Not very satisfied, only a little relief
O	POOR:	Failure, no relief of symptoms
O	WORSE:	Failure, worse than before the operation

3. **Was the operation worthwhile?** O Yes O No

4. **Would you repeat the operation if the same circumstances were to exist again?** O Yes O No

5. **Please list the type and frequency of the pain relief medication you have used *on average during the last week* for your back/leg pain.**

	Usage			
	None/ Occassionally	Some Days	Everyday (once or twice)	Several times a day
(i) Prescription medication	O	O	O	O
(ii) Non-prescription medication	O	O	O	O

6. **Is your current health predicament now the subject of a workers compensation or third party accident insurance claim?** O Yes O No

Please turn page to continue the questionnaire

Visual Analogue Pain Scale Questionnaire

To be completed by the PATIENT

Directions: *for the following questions please mark your response on the lines provided. Please answer all questions.*

Today's Date (DD/MM/YY): ☐☐ / ☐☐ / ☐☐

1. **With regard to your *BACK* pain, for which you had surgery, please mark (with a "X" on the lines below) the amount of pain you have had in the last week:**

NOT APPLICABLE (no back pain) ☐

a. **At its least painful**

0 ——————————————— 10

No pain at all — Maximum pain possible

b. **On average**

0 ——————————————— 10

No pain at all — Maximum pain possible

c. **At its most painful**

0 ——————————————— 10

No pain at all — Maximum pain possible

2. **With regard to your *LEG* pain, for which you had surgery, please mark (with a "X" on the lines below) the amount of pain you have had in the last week:**

NOT APPLICABLE (no leg pain) ☐

a. **At its least painful**

0 ——————————————— 10

No pain at all — Maximum pain possible

b. **On average**

0 ——————————————— 10

No pain at all — Maximum pain possible

c. **At its most painful**

0 ——————————————— 10

No pain at all — Maximum pain possible

Please turn page to continue the questionnaire

Oswestry Low Back Pain Disability Questionnaire

Today's Date (DD/MM/YY): ☐☐ / ☐☐ / ☐☐

Directions: *please answer all questions. Mark only **one** answer for each question.*

1.**Pain intensity** *(mark only one answer)*

- O I can tolerate the pain I have without having to use pain killers.
- O The pain is bad but I manage without taking pain killers.
- O Pain killers give complete relief from pain.
- O Pain killers give moderate relief from pain.
- O Pain killers give very little relief from pain.
- O Pain killers have no effect on the pain and I do not use them.

2.**Personal Care (washing, Dressing, etc.)** *(mark only one answer)*

- O I can look after myself normally without causing extra pain.
- O I can look after myself normally but it causes extra pain.
- O It is painful to look after myself and I am slow and careful.
- O I need some help but can manage most of my personal care.
- O I need help everyday in most aspects of self care.
- O I do not get dressed, wash with difficulty and stay in bed.

3.**Lifting** *(mark only one answer)*

- O I can lift heavy weights without extra pain.
- O I can lift heavy weights but it gives extra pain.
- O Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g. on a table.
- O Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
- O I can lift only very light weights.
- O I cannot lift or carry anything at all.

4.**Walking** *(mark only one answer)*

- O Pain does not prevent me walking any distance.
- O Pain prevents me walking more than 2 kilometres.
- O Pain prevents me walking more than 1 kilometre.
- O Pain prevents me walking more than ½ a kilometre.
- O I can only walk using a stick or crutches.
- O I am in bed most of the time and have to crawl to the toilet.

5.**Sitting** *(mark only one answer)*

- O I can sit in any chair as long as I like.
- O I can only sit in my favourite chair as long as I like.
- O Pain prevents me sitting more than one hour.
- O Pain prevents me from sitting more than thirty minutes.
- O Pain prevents me from sitting more than ten minutes.
- O Pain prevents me from sitting at all.

Please turn page to continue the questionnaire

Oswestry Low Back Pain Disability Questionnaire Cont.

6.**Standing** *(mark only one answer)*

O I can stand as long as I want without extra pain.
O I can stand as long as I want but it gives me extra pain.
O Pain prevents me from standing for more than one hour.
O Pain prevents me from standing for more than thirty minutes.
O Pain prevents me from standing for more than ten minutes.
O Pain prevents me from standing at all.

7. **Sleeping** *(mark only one answer)*

O Pain does not prevent me from sleeping well.
O I can sleep well only by using tablets.
O Even when I take tablets I have less than six hours sleep.
O Even when I take tablets I have less than 4 hours sleep.
O Even when I take tablets I have less than two hours sleep.
O Pain prevents me from sleeping at all.

8. **Sex life** *(mark only one answer)*

O My sex life is normal and causes no extra pain.
O My sex life is normal but causes some extra pain.
O My sex life is nearly normal but is very painful.
O My sex life is severely restricted by pain.
O My sex life is nearly absent because of pain.
O Pain prevents any sex life at all.

9. **Social life** *(mark only one answer)*

O My social life is normal and gives me no extra pain.
O My social life is normal but increases the degree of pain.
O Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. dancing, etc.
O Pain has restricted my social life and I do not go out as often.
O Pain has restricted my social life to my home.
O I have no social life because of pain.

10. **Travelling** *(mark only one answer)*

O I can travel anywhere without extra pain.
O I can travel anywhere but it gives me extra pain.
O Pain is bad but I manage journeys over two hours.
O Pain restricts me to journeys of less than one hour.
O Pain restricts me to short necessary journeys under thirty minutes.
O Pain prevents me from travelling except to the doctor or hospital.

Fairbank J, Couper J, Davies J, et al. The Oswestry low back pain questionnaire. Physiotherapy 1980; 66: 271-3.

Please turn page to continue the questionnaire

SF-12 Health Survey

To be completed by the PATIENT

Directions: *please answer **all** questions. Mark only **one** answer for each question.*

Today's Date (DD/MM/YY): [|] / [|] / [|]

1. In general, would you say your health is:
   O **Excellent** O **Very Good** O **Good** O **Fair** O **Poor**

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

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	O	O	O
3. Climbing **several** flights of stairs	O	O	O

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
4. Accomplished less than you would like	O	O
5. Were limited in the kind of work or other activities	O	O

During the past 4 weeks, how much of the time 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
6. **Accomplished less** than you would like	O	O
7. Did work or activities less **carefully** than usual	O	O

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
   O **Not at all** O **A little bit** O **Moderately** O **Quite a bit** O **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 of the time	Most of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	O	O	O	O	O
10. Did you have a lot of energy?	O	O	O	O	O
11. Have you felt downhearted and blue?	O	O	O	O	O

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

All of the time	Most of the time	Some of the time	A little of the time	None of the time
O	O	O	O	O

Please turn page to continue the questionnaire

Low Back Outcome Scale Questionnaire

To be completed by the PATIENT

Directions: *please answer all questions. Mark only* ***one*** *answer for each question.*

Today's Date (DD/MM/YY): [ ][ ] / [ ][ ] / [ ][ ]

1. **Please mark on the line below (with a "X") how much back/leg pain you have had on average during the past week:**

0 ———————————————— 10

No pain at all — Maximum pain possible

2. **Do you have to rest during the day because of pain?**	O Not at all	O A little	O Half the day	O More than half the day
3. **How often do you have a consultation with a Doctor or have treatment (eg physiotherapy) for your pain?**	O Never	O Rarely	O Approximately once a month	O More than once a month
4. **How often do you have to take pain killers?**	O Never	O Occasionally	O Almost every day	O Several times each day
5. **At present, are you working?**	O Full time at usual job	O Full time at a lighter job	O Part time	O Not working
6. **At present, can you undertake sports or active pursuits (eg dancing)**	O As much as usual	O Almost as much as usual	O Some, much less than usual	O Not at all
7. **At present, can you undertake household chores or odd jobs?**	O Normally	O As much as usual, but slowly	O A few, not as many as usual	O Not at all

Please mark the box that describes best how much your back/leg pain affects each of the following six activities:

	No effect	**Mildly/ not much**	**Moderately/ difficult**	**Severely/ impossible**
8. **Sex life**	O	O	O	O
9. **Sleeping**	O	O	O	O
10. **Walking**	O	O	O	O
11. **Sitting**	O	O	O	O
12. **Travelling**	O	O	O	O
13. **Dressing**	O	O	O	O

Greenough CG, Fraser RD. Assessment of outcome in patients with low back pain. Spine 1992;17:36-41.

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

APPENDIX C

Outcome Measure Instrument in Spine Surgery

Outcome Measure Instrument in Spine Surgery

- Generic Health-Related Quality Of Life (HRQL) Questionnaires
    1. Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)
    2. Medical Outcomes Study 12-Item Short-Form Health Survey (SF-12)
    3. European Quality-Of-Life 5-Dimension (EQ-5D) Questionnaire
    4. Sick Impact Profile (SIP)
- Disease-specific quality of life questionnaires
    1. Oswestry Disability Index (ODI) Questionnaires
    2. Low Back Outcome Score (LBOS)
    3. Roland-Morris Disability Questionnaire (RMDQ)

Generic Health-Related Quality of Life (HRQL) Questionnaires

Generic quality of life or health status is a broad concept representing individual responses to the physical, mental and social effects of illness on daily living, which influence the extent to which personal satisfaction with life circumstances can be achieved.[1-3] The evaluation of health-related quality of life through a validated and patient-completed questionnaire has become the preferred approach.[4]

Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)

The SF-36 questionnaire is now the most frequently used, generic, patient report, measure of health status across the world.[2,5-7] It was developed by the Rand Corporation in the USA with the aim of assessing the effect of different health financing plans on the health status of the general population.[6-8] The SF-36 has been commonly used in studies assessing health status outcomes in spine disease. It is also popular among social gerontologist investigating the quality of life of the older people.[2] It is also recommended for use in health policy evaluations, general population surveys, clinical research, and clinical practice.[5]

The scale itself measures health status in 8 different areas that are considered relevant to many disorders. The 8 different scales measures are:

1. limitations in physical activities because of health problems
2. limitations in social activities because of physical or emotional problems
3. limitations in usual role activities because of physical health problems
4. bodily pain
5. general mental health
6. limitations in usual role activities because of emotional problems
7. vitality
8. general health perceptions

The scales are combined to form two summary measures the Physical Component Summary score (PCS) and the Mental Component Summary score (MCS). The 8 scales provide a comprehensive profile of health status. However, the two summary measures are more advantageous from a clinical trials perspective because they have a number of features. They have smaller confidence intervals around sample mean scores and individual persons scores (i.e., better measurement precision), smaller floor and ceiling effects, and superior responsiveness (at least in theory). In addition, a reduction in the number of analyses required from eight scale scores to two summary scores avoids the problems associated with multiple testing.[9] It is considered a good global index of patient whole function in terms of psychometric properties.[2] Studies had demonstrated that SF-36 has high levels of internal validity, internal consistency and good test-retest properties.[10-12] The questionnaire has advantages over, for example, the Sickness Impact Profile (SIP), in that it is considerably shorter, and the Nottingham Health Profile, which has been found to be insensitive to lower levels of dysfunction and disability.[10,13,14]

Gatchel and colleagues demonstrated that there is a role limitation of physical scale (PCS-36) score in terms of the floor effect or clustering of low scores in samples of disabled, chronic spinal disorder patients. This may suggest that SF-36 may not be sensitive enough to the impact of spinal disorders on a patient's ability to complete various physical activities of daily living.[15] Zanoli and colleagues noted that there are no specific studies dealing with Minimal Clinically Important Differences (MCIDs) of deviations from SF-36 normative values in lumbar disorder, but suggested that 10–20% of the highest possible value should represent a clinical difference: in our case, it would mean that a score which has a mean difference of more than 20 points from the norm probably represents a population which is clinically different from the normal population regarding that particular SF-36 domain.

Medical Outcomes Study 12-Item Short-Form Health Survey (SF-12)

SF-12 generic questionnaire is derived from the SF-36 questionnaire (shorter version of SF 36). It is used to assess the overall health status and measures two components, physical health (physical component summary scale-PCS) and the mental health (mental component summary scale-MCS). The questionnaire does not generate domain scores such as in SF-36 but only provides summary scores (PCS-12 and MCS-12). SF-12 is ranked the best questionnaire for assessment for the general health because of its simplicity and high degree of correspondence. [16-20] It is a reliable and validated outcome measure. Their psychometric properties were able to reproduce at least 90 per cent of the variance in the physical and mental subscales of SF-36 and reproduced the profile of the eight dimension of SF-36.[17] The compliance is better because of its shorter form. It is recommended to be suitable for the physically impaired, especially in filling out the questionnaire (e.g. rheumatoid arthritis, elderly) and in the out-patient clinic setting. It is also being reported as having better reliability and validity as compared to SF 36.[17]

There is a study which demonstrated age was somewhat positively correlated with the Mental Health Component (MCS) of the SF-12 but was not significantly correlated with the Physical Component Summary (PCS) score. In other words, older subjects tended to report higher levels of mental health HRQOL but age did not seem to make a difference in terms of physical HRQOL. The finding that age is positively correlated with higher levels of mental HRQOL is consistent with the literature of older persons in the general population reporting higher levels of overall HRQOL and well-being than younger persons.[21]

European Quality-Of-Life 5-Dimension (EQ-5D) Questionnaire

The EQ-5D is a generic, multidimensional health profile, designed to generate a single index value for health status. It was designed to be self-administered and short enough to be used in conjunction with other measures. Extensive cultural and language evaluations have been made.[22,23] Section one consist of five single-item dimensions covering mobility, self-care, usual activities, pain/discomfort and anxiety depression, each with a three-point response scale to indicate the level of problems (no, mild to moderate and severe). Hence, this descriptive system contains 243 combinations, or health states. For each of these combinations, one can assign health state utility indices (or ‘‘preference weights’’) which are based on different value sets yielding an index score based on a scale from 0 (death) to 1.0 (perfect health). The index score must be multiplied by the time spent in the health state to produce a Quality-Adjusted Life Year (QALY) measure. The aim was intended to complement other health-related quality of life measures. The instrument was to provide a standardized, non-disease-specific survey instrument and to generate a cardinal index of health for describing HRQL and for use in economic evaluation.[24]

The second section contains 100-point visual analogue scale. The patients rate their health state by drawing a line from a box marked ‘‘your health state today’’ to the appropriate point on the 20 cm VAS scale, which ranges from 0 to 100 (worst to best imaginable health) on which the respondents are asked to mark how good or bad their own health is today.[2,25]

Solberg and colleagues (2005) showed that the EQ-5D was reliable and performed well compared to the ODI in HRQL evaluations of patients who were operated on for disorders in lumbar spine. The EQ-5D performed better in identifying patients with an unfavourable outcome.

This indicates that the EQ-5D is more capable to identify patients who have deteriorated.[26] In some studies involving non-surgical patients, the EQ-5D has been less responsive.[27,28]

The EQ-5D is brief, efficient to administer and highly acceptable to investigators and respondents. Especially in the clinical setting, it is important that the questionnaires are short in order to secure a high response rate. However, the developers of the EQ-5D have recommended that it should be supplemented by a disease-specific questionnaire in studies that focus on the specific concerns and problems of the patients, rather than overall treatment effects.[24]

Sick Impact Profile (SIP)

The SIP is a well established, standardized questionnaire that indicates changes in a person's behaviour due to sickness.[29] It consists of 136 items grouped into 12 categories:

1. ambulation
2. mobility
3. body care and movement
4. social interaction
5. alertness behaviour
6. emotional behaviour
7. communication
8. sleep and rest
9. eating
10. work
11. home management
12. recreation

These categories are subdivided into two dimensions which are physical dimension (ambulation, mobility, and body care categories) and psychosocial dimension (social interaction, alertness, emotional, and communication categories). The remaining five categories are independent scores. An overall score for the entire instrument can also be calculated: Higher scores indicate increasing dysfunction or poorer health. The SIP consists of statement such as, "I am not working at all" or "I sit during much of the day," and the respondents check those statements that apply to them "today" because of their illnesses. The SIP thus measures the performance of specific behaviour, rather than judgements of capacity and assesses dysfunction without a positive formulation of health.[29] The SIP has been extensively studied in populations of patients with back pain and other musculoskeletal conditions.[2]

Disease-Specific Quality Of Life Questionnaires

Disease-specific health status measures are commonly used as outcome measures in clinical trials and clinical practice. It is designed to assess specific diagnostic groups or patient populations. It is often used to assess patient "clinically important" responsiveness or progress in treatment. The two commonly used condition specific measure for back pain are the Roland–Morris Disability Questionnaire (RDQ) or the Oswestry Disability Index (ODI). These two measures have been used in a wide variety of situations over many years, and each is available in a number of languages.[30]

Oswestry Disability Index (ODI) Questionnaires

Development of the Oswestry Disability Index (ODI) was initiated by John O'Brien in 1976 in a specialist referral clinic in which a large number of patients with chronic low back pain were seen. The index was designed as a measure for both assessment and outcome. The first version of the questionnaire was published in 1980 and widely disseminated after the 1981 meeting of the International Society for The Study of the Lumbar Spine (ISSLS) in Paris.[31,32]

ODI was designed on the basis of patients' self-reports and symptoms of chronic low back pain. It shows moderate correlation with pain measures such as a visual analogue scale.[33] The ODI has been used to validate most of the disability measures such as the Pain Disability Index and the Low Back Outcome Score. The ODI also correlates with Generic Health outcome measures such as the SF-36.[34] ODI is a better predictor of return to work than the other two different methods of lumbar spine assessment. It predicted isokinetic performance, isometric endurance and performance with sitting and standing (but not with lifting) in a study involving secret observation. Physical tests correlate with the ODI, but range of movement does not.[31]

Low Back Outcome Score (LBOS)

The Low Back Outcome Score is a 13-item questionnaire intended as a comprehensive rating system for patients with back pain. It includes weighted questions that pertain to current pain, employment, domestic and sport activities, use of drugs and medical services, rest, sex life, and daily activities.[35]

Overall scores can vary from 0 (very disabled) to 75 (not at all disabled). Patients are placed in one of four outcome categories depending on their overall pure scores: 65 or higher (excellent), 50 or higher (good), 30 or higher (fair), and lower than 30 (poor). The appendix presents the LBOS in full. A previous study showed that the LBOS has concurrent validity against the Oswestry Low Back Pain Disability Score and the Waddell Disability Index.[35,36]

Taylor and colleagues compared the responsiveness of the LBOS with that of the ODQ and SF-36 in patients with low back pain or sciatica. The results depended on the method of calculating effect size and the direction of self-reported change. Overall, the LBOS seemed more responsive than the SF-36, but less responsive than the ODQ.[34] The LBOS compares favourably with other established measures of low back pain in terms of both internal consistency and test–retest reliability, even when tested more rigorously. Therefore, the LBOS is a reliable instrument for clinical use.[37]

Roland-Morris Disability Questionnaire (RMDQ)

The Roland-Morris Disability questionnaire is a health status measure designed to be completed by patients to assess physical disability due to low back pain. It was originally designed for use in primary care in the United Kingdom but has been used in a variety of other settings such as in research (e.g. as an outcome measure for clinical trials) and for monitoring patients in clinical practice.[38]

The RDQ was derived from the Sickness Impact Profile (SIP), which is a 136-item health status measure covering all aspects of physical and mental function. The twenty-four items selected from the SIP were related specifically to physical functions that were likely to be affected by low back pain. Each item was qualified with the phrase "because of my back pain" to distinguish back pain disability from disability due to other causes—a distinction that patients are in general able to make without difficulty. [38,39] The total scores range from 0 (no disability) to 24 (maximum disability). Although designed for administration on paper, the RDQ has also been satisfactorily administered on computer and by telephone.[40,41]

The statements in the RDQ focus almost exclusively on physical function, with only one question on mood (statement number 22). The questionnaire covers limited range of the problems faced by patients with back pain and it does not address psychological or social problems. Some aspects of physical function are not included (e.g lifting and twisting or turning). These features are both strength and a weakness in the RDQ content validity. The RDQ should be combined with specific measures of these functions. Due to its restricted nature of the domains, the scores are easy to understand and interpret.[31]

The RDQ is short, simple to complete, and readily understood by patients.[42] Stratford and colleagues found fewer incomplete or ambiguous responses to the RDQ than to the Oswestry questionnaire.[43] These characteristics, along with evidence of its scientific validity, have led to its widespread use. It is now available in the 12 languages and there are no restrictions on its use.

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