Cervical Spondylotic Myelopathy: a prospective study of outcome after surgery

By

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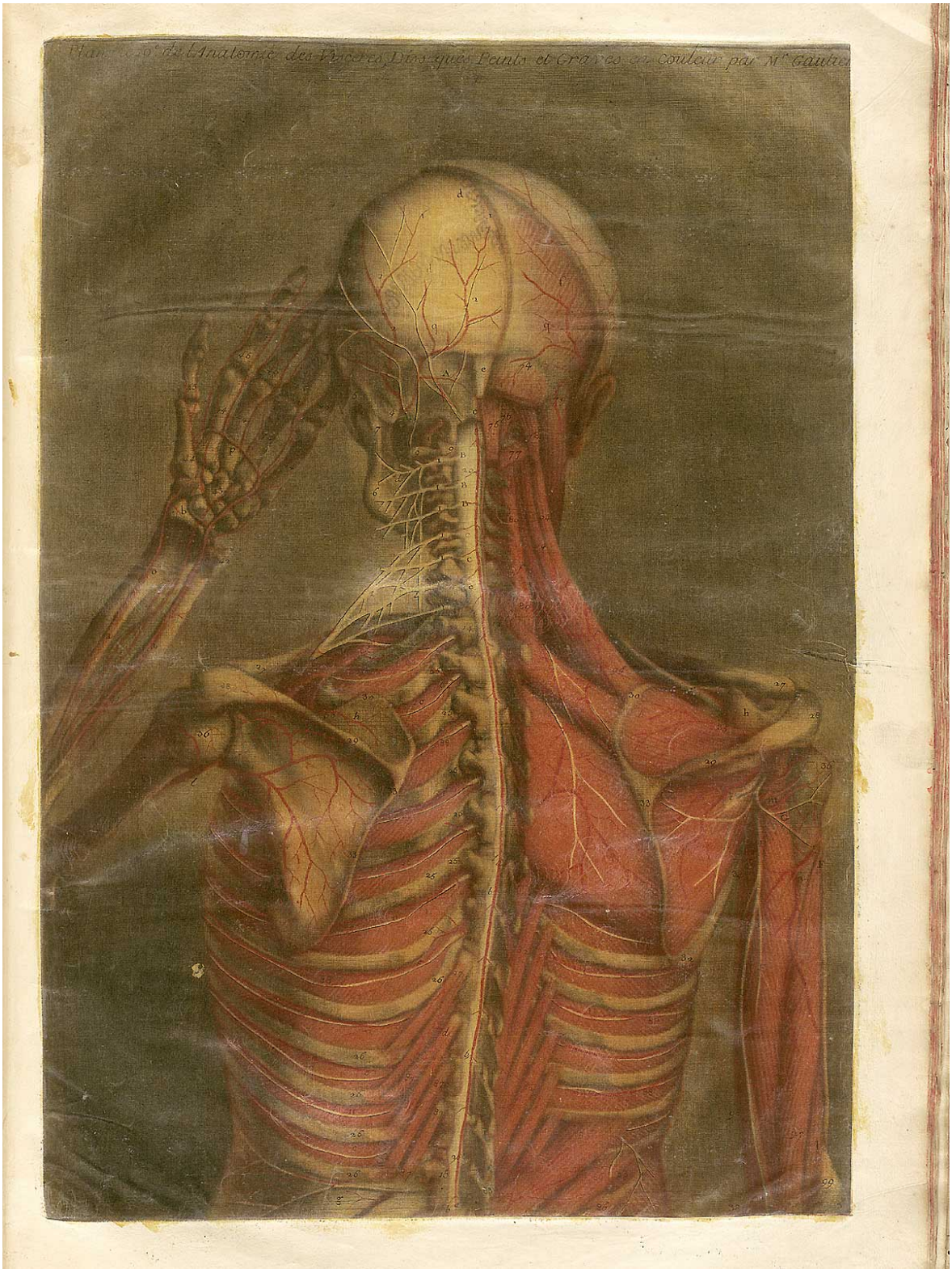

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ABSTRACT

Background: The natural history of cervical spondylotic myelopathy (CSM) is mixed. Surgical decompression is offered to patients with the aim of improving functional outcome. In some patients with chronic myelopathy, the aim is to prevent further deterioration. Despite surgical decompression, the functional status of some patients may deteriorate. CSM thus has a variable prognosis and it is difficult to predict neurological recovery after surgical decompression. There is a lack of consistency in the currently available literature regarding post-operative outcomes.

Objectives:

1. To prospectively assess and compare the pre and post-operative clinical and functional status of patients with CSM using the modified Japanese Orthopaedic Association (mJOA) scores and the modified Myelopathy Disability Index (mMDI) scores at baseline, 3, 6 and 12 months post surgery.
2. To prospectively assess the natural history of patients with CSM who did not undergo surgery using the mJOA and mMDI scores at baseline, 3, 6 and 12 months.
3. To identify factors which influence outcome.

Materials and Methods: All eligible patients in whom a diagnosis of CSM was made from 01 January 2011 to 31 December 2012 were evaluated. A neurologist (independent of the surgical team) performed baseline mJOA and mMDI scores. This was repeated at 3, 6, 12 and in some patients 24 months after surgery. Patients who refused or were not fit for surgery were also evaluated with mJOA and mMDI scores at baseline, 3, 6, 12 and in some, 24 months later by a

neurologist. These patients formed the natural history group. A minimum of 12 months follow up was obtained in all patients with a total of 540 months of follow up. The following factors were evaluated: age at presentation; gender; cigarette smoking; duration of symptoms; HIV status; presence of T2WI cord signal cord abnormality on MRI; number of cervical disc levels operated upon / affected; surgical approach used and post-operative complications. We also assessed recovery / progression of individual aspects of the mJOA: upper limb; lower limb; sensation and sphincters in both groups. Severity of CSM was assessed as mild if baseline mJOA score was ≥ 12 and moderate-severe if baseline mJOA score was < 12.

Results: Surgery was associated with significant improvement in clinical recovery as assessed by mJOA scores at 3, 6 and 12 months post-operatively with p-values of 0.0002, 0.0001 and 0.0067 respectively. Upper limb function improved after surgery as assessed by the upper limb component of the mJOA score at 3, 6 and 12 months with p-values of 0.0096, 0.0030 and 0.0459 respectively. Lower limb function also improved significantly as assessed by the lower limb recovery scores at 3, 6 and 12 months with p-values of 0.0256, 0.0011 and 0.0107 respectively. Sensation and sphincter function did not improve after surgery. There was significant functional recovery as assessed by mMDI scores at 3, 6 and 12 months after surgery with p values of 0.0001, 0.0001 and 0.0023 respectively. There was no significant clinical or functional improvement in the non-surgical group when looking at overall mJOA and mMDI scores at 3, 6 and 12 months. Furthermore, there was no improvement in upper limb, lower limb, sensation or sphincter function in the non-surgical group as assessed by individual components of the mJOA score at 3, 6 and 12 months.

When assessing factors that could predict outcome we found that the patients' age, gender, smoking status and duration of symptoms had no effect on outcome. The presence of T2WI cord signal abnormality on baseline MRI was associated with more severe CSM at presentation (p=0.036), but this did not affect outcome. Those with moderate-severe CSM at baseline had a better recovery at 12 months (p=0.025). The occurrence of intra-operative complications resulted in a worse outcome with both clinical and functional recovery rates worse at 3 months. Clinical recovery as assessed by mJOA score normalised at 12 months (p=0.235), but these patients were still functionally impaired as assessed by mMDI at 12 months (p=0.005).

Conclusions: Patients with CSM benefit from surgical decompression regardless of baseline severity, with significant clinical and functional improvement noted at least 12 months post-operatively. Upper and lower limb function improves significantly, but sensation and sphincter function do not recover. The occurrence of intra-operative complications results in a worse outcome and this negative effect is still seen 12 months post-operatively. Patients who are managed non-operatively do not show significant improvement and 42% have some clinical deterioration at 12 months. Identification of patients with mild CSM (mJOA score ≥ 12) who can be safely managed non-operatively remains a challenge, however it appears that this is a reasonable option in patients with mild CSM and no T2WI cord signal abnormality on MRI.

Plagiarism:

DECLARATION

I Rohen Harrichandparsad declare that:

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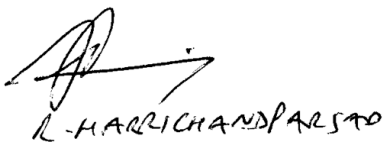
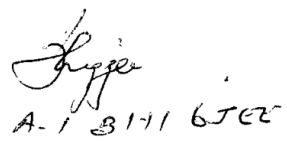
Signed:  R. HARRICHANDPARSAD

Supervisor: 

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The friendly staff at Consulens assisted me with adding the mJOA and mMDI templates onto Sorian, the in-hospital electronic patient file system.

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Writing a thesis is an incredibly time-consuming enterprise. I am lucky to have in Avashri, a supportive and understanding wife. Her encouragement, together with the support from Ravi, Annie and Bala has made it possible for me to complete this project. I also thank her for her astute proofreading of the final drafts. I am grateful to my parents Roy and Sabitha, for making me the person I am today. It is to my lovely girls Arushi, Kirana and baby Suhani and all these loved ones that I dedicate this thesis.

ETHICAL CONSIDERATIONS

Informed consent was obtained from all patients prior to enrollment in the study. Informed consent for surgery was obtained from all those in the surgical group, explaining expected benefits, potential risks and possible alternative management, as per current standard of practice. HIV testing was voluntary and pre and post-test counseling was offered as per current hospital standard of practice.

The expectation after analysis of data obtained from this study, is that the Departments of Neurosurgery and Neurology would be better equipped to obtain informed consent when explaining to patients what the expected benefits and risks from surgical decompression for CSM would be. As natural history of CSM is quite variable, we would be able to quantify expected outcomes in our patient population.

In addition, if we could identify subgroups of patients who do not benefit from surgical intervention, we would then be able to counsel such patients accordingly; thus avoiding the costs of unnecessary surgery.

This study would also serve as a self-audit to formally analyse surgical outcomes of patients with CSM at the Department of Neurosurgery, Inkosi Albert Luthuli Central Hospital (IALCH). No such analysis has previously been done within the Department of Neurosurgery, IALCH.

The study was conducted with ethical approval from the Biomedical Research Ethics Committee of the University of KwaZulu-Natal. Study approval number **BE244/09.**

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ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation	Description
CSM	Cervical Spondylotic Myelopathy
mJOA	Modified Japanese Orthopaedic Association
MDI	Myelopathy Disability Index
mMDI	Modified Myelopathy Disability Index
ACDF	Anterior Cervical Discectomy and Fusion
ACCF	Anterior Cervical Corpectomy and Fusion
IALCH	Inkosi Albert Luthuli Central Hospital
IOD	Injury on Duty
HIV	Human Immunodeficiency Virus
MRI	Magnetic Resonance Imaging
RR	Recovery Rate
PR	Progression Rate

Term	Description
Cervical osteophytes	"Bone spurs" which form in the neck as a result of degeneration in the ageing spine.
ACDF	Anterior neck surgery in which the intervertebral disc between two cervical vertebrae is removed and the resultant disc space is grafted with either autologous iliac crest graft or a synthetic graft.
ACCF	Anterior neck surgery in which a core of vertebra is removed along with the intervertebral discs above and below the vertebra. The resultant space is grafted with an autologous iliac crest strut graft.
Laminectomy	Posterior neck surgery in which the lamina of the vertebra is removed, aiming to create space for the spinal cord.
Laminectomy with fusion	Laminectomy combined with cervical spine stabilization techniques (interfacet wiring, wiring the bone onto the facet, or lateral mass fixation with plates or rods).
Laminoplasty	The laminae are cut on both sides at the affected level and then the freed flap is swung open, relieving the pressure on the spinal cord. The bone flap is then propped open using small pieces of bone such that the enlarged spinal canal will remain in place.

CHAPTER 1 INTRODUCTION

1.1 Background

Cervical spondylotic myelopathy (CSM) is the most common cause of spinal dysfunction in the elderly. It is also the most common cause of non-traumatic spastic paraparesis and quadriparesis and thus is a major cause of morbidity in this population. In one series, 23.6% of all patients presenting with non-traumatic myelopathic symptoms were found to have CSM (Moore & Blumhardt, 1997).

CSM results from the process of degeneration of the intervertebral discs and facet joints of the cervical spine. Symptoms related to myelopathy are caused by the formation of osteophytes, which compromise the diameter of the spinal canal. This compromise may also be partially developmental. The developmental process, together with the degenerative process, may cause mechanical pressure on the spinal cord at one or multiple levels. This pressure may produce direct neurological damage or ischemic changes and, thus, lead to spinal cord disturbances (Young & Baron, 2007). Thus symptomatic CSM results from a combination of static factors (congenitally narrowed cervical spinal canal, osteophytic spurs, hypertrophy of the ligamentum flavum, facet hypertrophy) and dynamic factors (spinal cord irritation and compression as a result of neck motion). The spinal cord stretches with neck flexion with resultant compression against osteophytic spurs and protruding intervertebral discs. With neck extension, the spinal cord may be “pinched” between the posterior margin of the vertebral body anteriorly and the ligamentum flavum or laminae posteriorly. Repetitive neck movements and trauma may accelerate the development of spondylosis (Toledano & Bartleson, 2013).

The natural history of cervical spondylotic myelopathy is mixed. It may present as a slow, stepwise decline or there may be a long period of quiescence (Matz et al., 2009). It is therefore a difficult condition to manage. Surgical decompression is offered to patients with the aim of improving functional outcome. In some patients with chronic myelopathy, the aim is to prevent further deterioration. Despite surgical decompression, the functional status of some patients may deteriorate. CSM thus has a variable prognosis and it is difficult to predict neurological recovery after surgical decompression. There is a lack of consistency in the currently available literature regarding post-operative outcomes.

There are few studies that prospectively assess neurological recovery in patients with cervical spondylotic myelopathy. One such study by Cheung et al. (2008) excluded a subgroup of patients with more than two stenotic levels with loss of cervical lordosis as seen on MRI scan because this group of patients have a higher complication rate. They do however form a significant portion of the patients seen locally with CSM, and were therefore included in this study.

The available literature focuses on American and Asian populations. These results may not be applicable to other population groups. There are currently no published South African studies assessing neurological outcome in patients with CSM.

1.2 The Natural History of CSM

In March 2006, the Joint Section on Disorders of the Spine and Peripheral Nerves of the American Association of Neurological Surgeons and Congress of Neurological Surgeons compiled an expert group to perform an evidence-based

review of the clinical literature on management of cervical degenerative spine disease. This process culminated in the formation of the *Guidelines for the Surgical Management of Cervical Degenerative Disease*. These guidelines were published in August 2009 in the Journal of Neurosurgery, Spine.

There are only a few studies regarding the natural history of CSM. Earlier studies described progressive disability and neurological function that never returned to normal (Young & Baron, 2007). Nurick (1972) however found that for the majority of cases of CSM, there is an initial phase of deterioration followed by a static period lasting for a number of years, during which the degree of disability does not change significantly for those mildly affected. Lees & Turner (1963) showed that patients with CSM who had moderate to severe disability were more likely to improve with surgical therapy than non-operative treatments, and those with moderate disability treated non-operatively were more likely to deteriorate than those treated surgically. Patients with mild disability were unlikely to worsen. This supports the role of intervention for progressive myelopathy because the natural course seems to be continued deterioration.

Other recent studies have had conflicting results. Kadanka et al. (2000) performed a study in patients with mild or moderate clinical myelopathy, studying conservative versus operative treatment. They found no significant deterioration in mJOA score in the two groups over the 3-year follow-up period. Although surgical treatment was not found to improve long term neurological outcome, overall pain and functional status improved significantly. When medical and surgical treatments were compared, surgically treated patients

seemed to have better outcomes, despite exhibiting a greater number of neurological and non-neurological symptoms and having greater functional disability before treatment.

Morgado & Welsh (2013) reviewed the natural history of CSM and the role of surgery and concluded that conservative management of patients with mild CSM is an option, while patients with functional impairment are best treated surgically.

On the other hand, excellent results for surgical management of CSM have been demonstrated in many studies. In the Cochrane review by Matz et al. (2009) it was found that patients with mild CSM (mJOA $\geq$ 12) responded to either surgical decompression or non-operative therapy in the short term (3 years), whilst more severe CSM responds to surgical decompression with benefits maintained at a minimum of 5 years and as long as 15 years post-operatively. However, there was no class I level of evidence to support these findings. In the recent prospective multi-centre study on the efficacy and safety of surgical decompression in patients with CSM, Fehlings et al. (2013) found that surgical decompression was associated with improvement in functional, disability-related, and quality-of-life outcomes at one year of follow-up for all disease severity categories.

On the basis of these reports, the natural course of CSM for any given individual is variable, and a precise prognostication is not possible. It would be useful for Neurosurgeons and Neurologists to assess the natural history of CSM in the South African context, in order to establish local guidelines for the management of our patients.

1.3 Surgical Techniques for the Treatment of CSM

In the *Guidelines for the Surgical Management of Cervical Degenerative Disease,* published in August 2009 in the Journal of Neurosurgery, Spine, Mummaneni et al. looked at cervical surgical techniques for the treatment of cervical spondylotic myelopathy. They concluded that there are a variety of techniques, which may be used in the surgical treatment of CSM. These include anterior or posterior approaches to the cervical spine. Anterior approaches include ACDF and ACCF. Posterior techniques include laminoplasty, laminectomy and laminectomy with fusion.

The anterior approach is favoured for CSM, particularly if the cord compression is primarily ventral, is localised to a single interspace or up to three interspaces, or there is associated kyphotic deformity requiring anterior cervical spinal realignment, reconstruction, internal fixation, and fusion. The posterior approach is used if the primary spinal cord compression is dorsal, or if more than 3 interspaces require decompression.

Based on the above guidelines, the anterior or posterior approach is chosen for a particular patient with CSM. If the anterior approach is used, there is no difference in outcome comparing ACDF and ACCF. If the posterior approach is chosen, there is no difference in outcome comparing laminoplasty, laminectomy or laminectomy with fusion.

1.4 Assessing Clinical and Functional Outcomes

Several outcome measures are available to assess CSM. Both the mJOA and MDI scores were found to be valid and reliable measures for assessing CSM (Holly et al., 2009).

The JOA Score assesses 4 key areas: upper limb motor function (scored from 0 to 5); lower limb motor function (scored from 0 to 7); sensory abnormalities (scored from 0 to 3) and sphincter disturbances (scored from 0 to 3).

Part of the original Japanese Orthopaedic Association scoring system as described by Hirabayashi et al. (1976) looked at the ability to feed oneself with chopsticks to assess upper limb motor function. This ability is culturally appropriate for the Japanese population, but is not widely applicable to other populations. Thus the JOA was modified by Benzel et al. (1991) to enable it to be used in populations that do not use chopsticks routinely. The score ranges from 0 (worst function) to 18 (normal function).

The MDI score as described by Casey et al. (1996) is a set of 10 questions that assesses activities of daily living and scores each response into one of four categories, depending on the patient's ability to perform these tasks. The total score ranges from 0 (normal function) to 30 (worst function). The MDI was developed as a functional scoring system for rheumatoid arthritis patients with cervical myelopathy and has also been validated by Holly et al. as a reliable scoring system for cervical spondylotic myelopathy patients (2009).

1.5 Objectives

Primary Objectives

1.5.1 To prospectively assess and compare the pre and post-operative clinical status of patients with cervical spondylotic myelopathy (CSM), using the modified Japanese Orthopaedic Association (mJOA) scores at baseline, 3, 6 and 12 months post surgery.

1.5.2 To prospectively assess and compare the pre and post-operative functional status of patients with cervical spondylotic myelopathy (CSM), using the modified Myelopathy Disability Index (mMDI) scores at baseline, 3, 6 and 12 months post surgery.

Secondary Objectives

1.5.3 To prospectively assess and compare the natural history of CSM in those patients who did not undergo surgery, using the mJOA scores at baseline, 3, 6 and 12 months follow up.

1.5.4 To prospectively assess and compare the natural history of CSM in those patients who did not undergo surgery, using the mMDI scores at baseline, 3, 6 and 12 months follow up.

1.5.5 To identify factors which influence outcome.

CHAPTER 2 METHODS

This was a prospective, observational study.

2.1 Study Population

The study population was recruited from patients with CSM referred to the Departments of Neurosurgery and Neurology at IALCH. The Neurosurgery department at IALCH is the only state neurosurgical centre in KwaZulu-Natal, providing a service to a population of approximately 10 million people. Patients with possible spinal cord disorders are referred to Neurosurgery or Neurology clinics at IALCH. If a diagnosis of cervical spondylotic myelopathy was made and the patient met the eligibility criteria, they were asked to participate in the study.

2.2 Sampling Strategy

All consecutive eligible patients, in whom a diagnosis of CSM was made, from 01 January 2011 to 31 December 2012, were asked to participate in the study.

2.3 Statistical Planning (Variables / Confounders)

All participants underwent assessment by a neurologist at baseline and were graded according to the mJOA scale as mild CSM (mJOA score ≥ 12) or moderate-severe CSM (mJOA score < 12).

In keeping with current practice in the Department of Neurosurgery, IALCH, all patients in whom a diagnosis of CSM was made, were offered surgical decompression, regardless of severity of CSM. In particular, participants with moderate-severe CSM were strongly encouraged to undergo surgery.

Participants with mild CSM who preferred non-operative management were given this option, as objectively measurable deterioration in function is rarely seen acutely in this group of patients. Non-operative management included cervical bracing with a hard collar, referral for physiotherapy and simple analgesia as needed.

Those participants who agreed to operative management (the surgical group) underwent surgical decompression by the neurosurgeons. These participants were then followed up at 3, 6 and 12 months post-operatively where the neurologists assessed mJOA and mMDI scores. A few participants also had follow up scores at 24 months, however a minimum of 12 months follow up was obtained in all participants.

Participants who were offered, but declined operative management and participants who were deemed unfit for surgery (the non-surgical group) were also followed up at 3, 6 and 12 months where the neurologists assessed mJOA and mMDI scores. At any point during follow-up, the participants who declined surgery had the option to accept operative management and cross-over into the surgical group. A few participants in the non-operative group also had follow up scores at 24 months. However, a minimum of 12 months follow up was obtained in all participants.

The participants in the surgical group formed the sample population used to assess the primary objective i.e. to assess neurological recovery following surgery in patients with CSM. The participants in the non-surgical group formed the sample population used to assess the secondary objective i.e. to assess the natural history in patients with CSM.

Both groups were assessed at baseline, and followed up at 3, 6, 12 (and in some 24) months using the mJOA and mMDI scores. Direct comparisons between the surgical and non-surgical groups was not thought to be possible, as we anticipated that the latter group would probably comprise those patients with mild CSM (single level disease with mild symptoms) who declined surgery, or patients with severe multi-level CSM in a poor clinical condition in whom the risk-benefit ratio would not justify major surgery. However, when doing the statistical analysis, the groups did not differ significantly, so comparison between the two groups was performed.

The following factors were considered:

- Age at presentation
- Gender
- Cigarette smoking
- Duration of symptoms
- HIV status (as it may affect wound healing and post-operative recovery). Pre-test counselling for HIV was offered to all participants following which ELISA testing was done for those participants who gave consent. If clinically indicated (by unexplained weight loss, diarrhoea or onset of opportunistic infections), participants were encouraged to undergo testing as they may be at a higher risk of post-operative complications. Post-test counselling was performed for those who consented to testing.
- Presence of T2 weighted image spinal cord signal hyperintensity (T2WI)
- Medical co-morbidities e.g. diabetes, hypertension and others
- Severity of CSM at baseline

- Number of cervical disc levels operated upon / affected
- Surgical approach used
- Intra/post-operative complications

2.4 Sample Size

This was a descriptive study, so no formula was needed to calculate the sample size. The key factor was whether the sample group was representative of the population being studied. Since consecutive patients in whom a diagnosis of CSM was made were recruited over a period of 2 years, the sample size was solely dependent on the rate of patients presenting with CSM. The length of sampling was fixed at 2 years, due to time constraints. Significant loss to follow-up was not expected, as participant follow-up is part of routine patient management.

The sample group obtained using this sampling strategy was representative of the population of KwaZulu-Natal, as IALCH is the only state Neurosurgical centre in the province. Patients with spinal cord disorders, from all state hospitals in the province, are referred to IALCH Neurosurgery and Neurology.

2.5 Inclusion / Exclusion Criteria

Inclusion Criteria:

- Adult patients (>18 years) in whom a clinical diagnosis of cervical myelopathy was made, who have MRI evidence confirming cervical spondylosis.
- The patient had to be willing and able to provide informed consent.

Exclusion criteria:

- Any patient who was deemed unfit for a general anaesthetic, due to severe medical co-morbidities (as assessed by an anaesthetist) were excluded from the surgical group.
- Patients with prior surgery for CSM.
- Patients who present as a result of an injury on duty, (as there are often issues of secondary gain).
- Patients who did not have baseline mJOA or mMDI scores.

2.6 Data Collection Methods and Tools

Data was collected using the Sorian computer system, which is used at IALCH for all patients. This is a password-protected system, ensuring that only relevant clinicians had access to participants' electronic files. mJOA and mMDI templates were created and added onto Sorian. These templates were accessible on all participants' files and were used by the neurologists when assessing participants at baseline, 3, 6, 12 and 24 months.

2.7 Data Analysis Techniques

Scores obtained on the mJOA scale were used to calculate the overall recovery rate pre and post-operatively. Those participants who did not undergo surgery had their mJOA scores assessed on follow up as a means to ascertain the natural history of CSM. By subdividing the mJOA components, we were able to assess upper limb, lower limb, sensation and sphincter recovery individually to determine whether there were different gains in neurological recovery **(Table 1)**.

TABLE 1: MODIFIED JAPANESE ORTHOPAEDIC ASSOCIATION SCORE[1]	
Score	**Definition**
Motor Dysfunction	
Upper extremities	
0	Unable to move hands
1	Unable to eat with a spoon but able to move hands
2	Unable to button shirt but able to eat with a spoon
3	Able to button shirt with great difficulty
4	Able to button shirt with slight difficulty
5	No dysfunction
Lower extremities	
0	Complete loss of motor & sensory function
1	Sensory preservation without ability to move legs
2	Able to move legs but unable to walk
3	Able to walk on flat floor with a walking aid (cane or crutch)
4	Able to walk up- &/or downstairs with aid of a handrail
5	Moderate-to-significant lack of stability but able to walk up- &/or downstairs without handrail
6	Mild lack of stability but walk unaided with smooth reciprocation
7	No dysfunction
Sensory Dysfunction	
Upper extremities	
0	Complete loss of hand sensation
1	Severe sensory loss or pain
2	Mild sensory loss
3	No sensory loss
Sphincter dysfunction	
0	Unable to micturate voluntarily
1	Marked difficulty in micturition
2	Mild to moderate difficulty in micturition
3	Normal micturition
[1]Benzel et al (1991)	

The mJOA scores were analysed using the Hirabayashi method:

$$\text{Recovery rate}^{*} = \frac{\text{Post-operative mJOA score} - \text{Pre-operative mJOA score}}{\text{Full score} - \text{Pre-operative mJOA score}} \times 100$$

*** Hirabayashi Method**

For example, if a patient presents with a baseline mJOA score of 8, which indicates moderate-severe CSM and the mJOA at 3 months improves to 11 post-operatively, then his recovery rate at 3 months is calculated as follows:

RR = [(11 – 8) / (18-8)] X 100

= (3/10) X 100

= 30%

To assess upper limb, lower limb, sensation and sphincter recovery individually, the individual categories in the mJOA score pertaining to each of these functions, were used to assess recovery rates for each modality.

Using the upper limb scores, we calculated upper limb recovery rate:

$$\text{Upper limb recovery} = \frac{\text{Post-op upper limb mJOA} - \text{pre-op upper limb mJOA}}{\text{Full upper limb score} - \text{pre-op upper limb score}} \times 100$$

Using the same example above, the baseline mJOA of 8 was obtained by adding the individual components: upper limb score 2, lower limb score 4, sensation score 1 and sphincter score 1. Post-operatively, if the patient improved to 11 with upper limb score 4, lower limb score 6, sensation score 1 and sphincter score 0, then the upper limb recovery can be calculated as follows:

Upper limb recovery = [(4-2) / (5-2)] X 100

= 2/3 X 100

= 67%

Using the lower limb scores, we calculated the lower limb recovery rate:

$$\text{Lower limb recovery} = \frac{\text{Post-op lower limb mJOA} - \text{pre-op lower limb mJOA}}{\text{Full lower limb score} - \text{pre-op lower limb score}} \times 100$$

Lower limb recovery using the same example would be calculated as:

Lower limb recovery = [(6-4) / (7-4)] X 100

= 2 / 3 X 100

= 67%

Using the sensation scores, we calculated the sensation recovery rate:

$$\text{Sensation recovery} = \frac{\text{Post-op Sensation mJOA} - \text{pre-op sensation mJOA}}{\text{Full sensation score} - \text{pre-op sensation score}} \times 100$$

Using the example: sensation recovery = [(1-1) / (3-1)] X 100

= 0 / 2 X 100

= 0 %

Similarly, using the sphincter scores, we calculated the sphincter recovery rate:

$$\text{Sphincter recovery} = \frac{\text{Post-op Sphincter mJOA} - \text{pre-op sphincter mJOA}}{\text{Full sphincter score} - \text{pre-op sphincter score}} \times 100$$

And sphincter recovery in the example would be calculated as:

Sphincter recovery = [(0-1) / (3-1)] X 100

= -1 / 2 X 100

= -50%

The recovery rates obtained (expressed as a percentage) were graded as follows:

75 – 100% = excellent recovery

50 – 74% = good recovery

25 – 49% = fair recovery

0 – 24% = unchanged

< 0 = worse

So, continuing with the above example, at 3 months, this patient had made a fair recovery overall (RR by mJOA = 30%), but upper limb recovery and lower limb recovery was good (UL RR = 67% and LL RR = 67%), while sensation was unchanged (sensation RR = 0%), and sphincter function worsened (sensation RR = -50%)

The modified Myelopathy Disability Index (mMDI) score was also used to calculate recovery rates pre and post-operatively, as well as to determine the natural history in patients who did not undergo surgery. The original MDI score **(Table 2)** grades each of 10 questions into one of 4 categories, depending on the patient's ability to perform everyday activities:

- "without any difficulty" → score of 0
- "with some difficulty" → score of 1
- "with much difficulty" → score of 2, and
- "unable to do" → score of 3

This is a better representation of what the patient can and cannot do. Thus, we termed this "functional recovery" as opposed to the recovery rate as calculated by the mJOA scores, which we termed "clinical recovery".

TABLE 2: MYELOPATHY DISABILITY INDEX (MDI)				
PLEASE TICK THE ONE IN RESPONSE WHICH BEST DESCRIBES YOUR USUAL ABILITIES OVER THE PAST WEEK				
	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	Unable to do
Score	**0**	**1**	**2**	**3**
Rising are you able to: **Stand up from an armless straight chair?** **Get in and out of bed?**	___ ___	___ ___	___ ___	___ ___
Eating are you able to: **Cut your meat?** **Lift a full cup or glass to your mouth?**	___ ___	___ ___	___ ___	___ ___
Walking are you able to: **Walk outdoor on flat ground?** **Climb up five steps?**	___ ___	___ ___	___ ___	___ ___
Hygiene are you able to: **Wash and dry your entire body?** **Get on and off the toilet?**	___ ___	___ ___	___ ___	___ ___
Grip are you able to: **Open jars which have previously been opened?**	___	___	___	___
Activities are you able to: **Get in and out of car?**	___	___	___	___
Total	**A**	**B**	**C**	**D**
Note: if aids or assistance from another is required to perform any of the above tasks please score the activity as "with much difficulty". Total score = A + B + C + D (range 0 – 30). The final score is expressed as a percentage				

The scores obtained were then totaled giving a range of 0 to 30 (with 0 being normal function and 30 being worst function). The MDI score was then expressed as a percentage.

Thus comparing the mJOA and MDI scores, one can see that a higher score in the mJOA scale equates to better function, whereas a higher score in the MDI scale equates to worse function. To facilitate ease of analysis, the MDI scale was modified for the purposes of this study **(Table 3)**.

TABLE 3: MODIFIED MYELOPATHY DISABILITY INDEX (mMDI)				
PLEASE TICK THE ONE IN RESPONSE WHICH BEST DESCRIBES YOUR USUAL ABILITIES OVER THE PAST WEEK				
	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	Unable to do
Score	**3**	**2**	**1**	**0**
Rising are you able to:				
Stand up from an armless straight chair?	___	___	___	___
Get in and out of bed?	___	___	___	___
Eating are you able to:				
Cut your meat?	___	___	___	___
Lift a full cup or glass to your mouth?	___	___	___	___
Walking are you able to:				
Walk outdoor on flat ground?	___	___	___	___
Climb up five steps?	___	___	___	___
Hygiene are you able to:				
Wash and dry your entire body?	___	___	___	___
Get on and off the toilet?	___	___	___	___
Grip are you able to:				
Open jars which have previously been opened?	___	___	___	___
Activities are you able to:				
Get in and out of car?	___	___	___	___
Total	**A**	**B**	**C**	**D**
Note: if aids or assistance from another is required to perform any of the above tasks please score the activity as "with much difficulty". Total score = A + B + C + D (range 0 – 30).				

The questions remained the same, but the responses were scored inversely, as follows:

- "without any difficulty" → score of 3 instead of 0
- "with some difficulty" → score of 2 instead of 1
- "with much difficulty" → score of 1 instead of 2
- "unable to do" → score of 0 instead of 3

The scores obtained were then totaled giving a range of 0 to 30 (with 0 being the worst function and 30 being normal). Instead of expressing the mMDI score as a percentage, we applied an equation analogous to the Hirabayashi method to calculate the functional recovery rate based on mMDI scores as follows:

$$\text{Functional recovery rate} = \frac{\text{Post-operative mMDI score} - \text{Pre-operative mMDI score}}{\text{Full score} - \text{Pre-operative mMDI score}} \times 100$$

The recovery rates obtained were subjected to the same grading scale:

75 – 100% = excellent recovery

50 – 74% = good recovery

25 – 49% = fair recovery

0 – 24% = unchanged

< 0 = worse

For the surgical group it was appropriate to speak of "recovery" rates as assessed by the mJOA and mMDI scores, however, this was not appropriate for the natural history group as no intervention was performed. We used the same formulas for calculating the change of disease from the baseline, and substituted the word "recovery" with "progression" and speak of "progression rate" instead. Thus the Hirabayashi method for calculating progression rate using mMDI scores was:

$$\text{Progression rate} = \frac{\text{Post mMDI score} - \text{Pre mMDI score}}{\text{Full score} - \text{Pre mMDI score}} \times 100$$

where the post mMDI score is the latter score chronologically (mMDI at 3, 6, or 12 months) and the pre mMDI score is the mMDI score at baseline.

Similarly, we applied the same terminology for recovery rates as calculated by the mJOA scores in the non-surgical group.

$$\text{Progression rate} = \frac{\text{Post mJOA score} - \text{Pre mJOA score}}{\text{Full score} - \text{Pre mJOA score}} \times 100$$

where the post mJOA score is the latter score chronologically (mJOA at 3, 6, or 12 months) and the pre mJOA score is the mJOA score at baseline assessment. The same substitutions were performed to calculate progression rates for upper limb, lower limb, sensation and sphincter function.

A problem occurred in some patients (four in the non-surgical group who declined surgery because of mild symptoms) when using the Hirabayashi method because these patients had a baseline score equal to the full score of 18. This results in the denominator being zero. Descriptive statistics were presented for these patients but they were excluded from the statistical analysis.

2.8 Statistical Analysis

Statistical analysis was done in conjunction with professional statisticians, affiliated to the University of KwaZulu-Natal. Tonya Esterhuizen was consulted during the study design and Fikile Nkwanyana assisted with the final data analysis.

Paired samples t-test was used to measure equality of means in two paired groups. Wilcox sign rank test was used to test for equality of distributions for recovery rates that were not normally distributed. Kruskal Wallis test was used to measure equality of distribution for non-normal continuous data when comparing more than two groups. Two independent sample t-test was used to

test equality of recovery rates between surgical and non-surgical patients. Mann Whitney U test was used to test the equality of distributions in cases where recovery rates were not normally distributed. Pearson chi-squared test or Fisher's exact test was used to test equality proportions. A p-value of < 0.05 was considered as statistically significant.

2.9 Study Location

This was a single centre, multi-disciplinary study conducted in the Departments of Neurosurgery and Neurology, IALCH, Durban.

2.10 Study Period

Recruitment – 01 January 2011 to 31 December 2012.

Follow up – a minimum of 1 year (up to December 2013).

A few patients who were recruited earlier in the study had follow up to 24 months as well.

2.11 Limitations of the Study

Participation was voluntary and hence bias in the selection of participants could not be obviated. Randomisation was not possible, as patients had to be given a choice regarding their management. Follow up was limited to a minimum of one year post surgery or initial assessment, due to time constraints. However, current evidence shows that neurological recovery plateaus at 6 months (Cheung et al., 2008). This was also a single center study, reflective of the population in KwaZulu-Natal, as IALCH services the entire province, however these results may not be generalisable to the entire South African population.

CHAPTER 3 RESULTS

3.1 Demographics

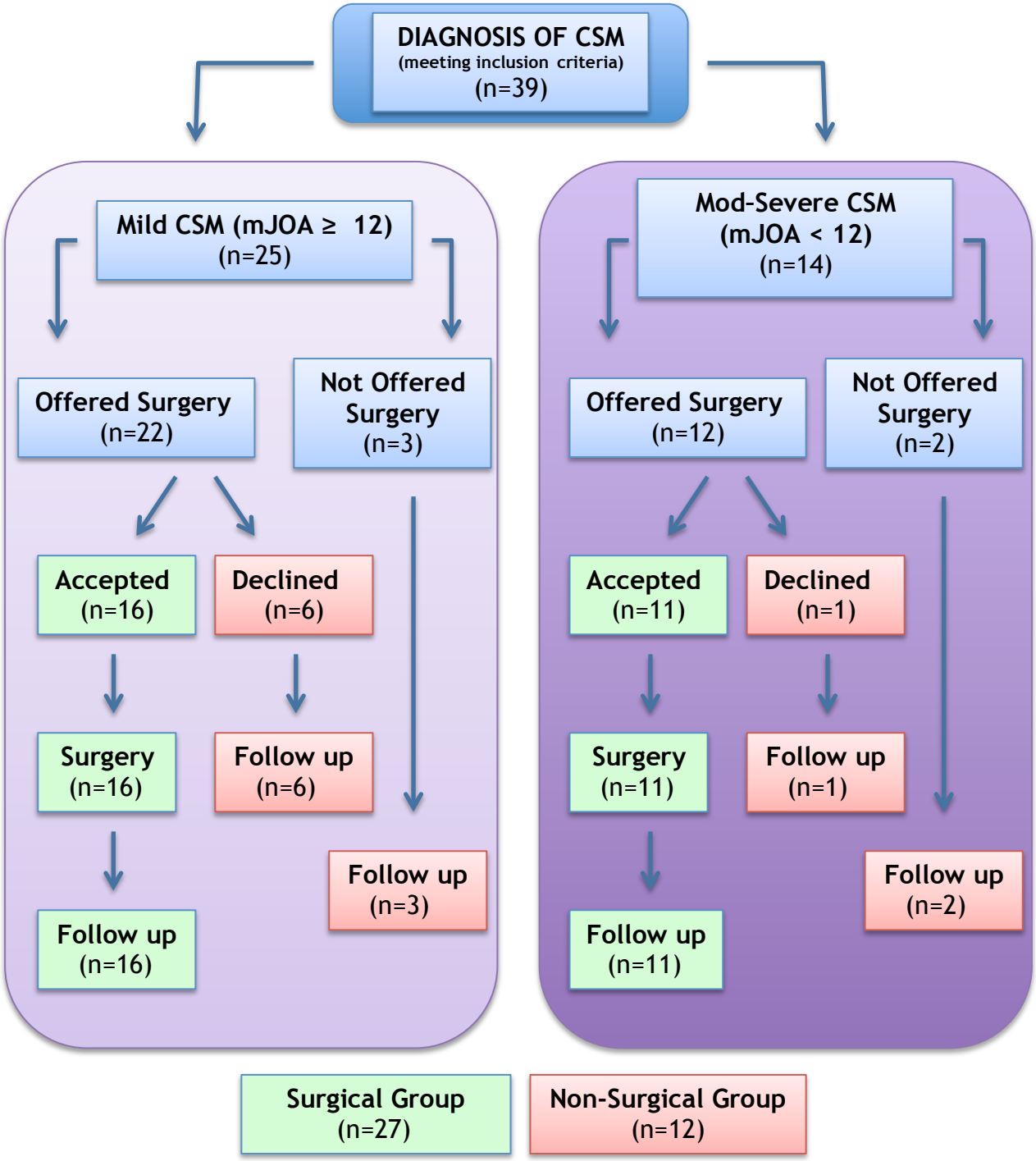

Figure 1: Stratification of patients into Surgical and Non-Surgical Groups

Figure 1 shows the distribution of patients into the surgical and non-surgical groups. There were 49 patients eligible but 10 were excluded because of incomplete baseline data. The remaining 39 were enrolled in the study. Of these, 25 had mild CSM as evidenced by mJOA score ≥ 12 and 14 had moderate-severe CSM with mJOA < 12. Of the 25 patients with mild CSM, 22 were offered surgery. 16 of these accepted surgical intervention and surgical decompression with subsequent follow up was performed. The remaining 6 declined surgery and were followed up. There were 3 patients with mild CSM who were not offered surgery as the treating surgeon felt that the disease was mild with only a single level affected. One of these patients had T2WI cord signal abnormality on the baseline MRI.

There were 14 patients with moderate–severe CSM and 12 of these were offered surgery. 11 of these accepted surgical intervention and surgical decompression with subsequent follow up was performed. The remaining patient declined surgery and was followed up. There were 2 patients with moderate–severe CSM who were not offered surgery. One was a 72-year old female with 3-level disease and a background of hypertension, diabetes and rheumatoid arthritis in a poor clinical condition. The other was a 79-year old male with 4-level disease, also in a poor clinical condition. It was felt that the risk-benefit ratio did not justify major surgery in either of these patients.

Thus, in the surgical group of 27 patients, there were 16 with mild CSM and 11 with moderate–severe CSM. In the non-surgical group of 12 patients, there were 9 with mild CSM and 3 with moderate–severe CSM. No patients crossed over from the non-surgical to the surgical group.

3.1.1 Age

Table 4 below shows the age, gender, smoking status, HIV status, duration of symptoms, presence of T2WI cord signal abnormality on MRI, number of levels operated or affected and severity of CSM at baseline in the surgical and non-surgical groups.

TABLE 4: DEMOGRAPHICS		
	Surgical Group (n=27)	**Non-Surgical Group (n=12)**
Age – Mean - Range	54.7 years 29 – 71 years	63.8 years 49 – 79 years
Gender – Males - Females	20 (74%) 7 (26%)	5 (42%) 7 (58%)
Smoking Status	12 smokers 15 non-smokers	8 smokers 4 non-smokers
HIV status – positive - negative - unknown	1 12 14	1 6 5
Duration of symptoms - Average - Range	12 months 2 – 36 months	12 months 3 – 24 months
T2WI cord signal abnormality on pre-op MRI	Yes – 23 (85%) No – 4 (15%)	Yes – 9 (75%) No – 3 (25%)
Number of levels affected / operated 1 level 2 levels 3 levels 4 levels	 12 (44.4%) 12 (44.4%) 2 (7.4%) 1 (3.7%)	 3 (25%) 6 (50%) 2 (16.7%) 1 (8.3%)
Severity of CSM at baseline Mild (mJOA ≥ 12) Moderate – Severe (mJOA < 12)	 16 (59%) 11 (41%)	 9 (75%) 3 (25%)

When comparing the above demographics between the surgical and non-surgical groups, the only statistically significant difference was age, with a mean age of 54.7 years in the surgical and 63.8 years in the non-surgical group ($p = 0.0127$).

3.1.2 The effect of gender on recovery / progression rates as assessed by mJOA scores

See appendix i for Gender vs. Recovery / Progression Rates by mJOA at 3, 6 and 12 months in the surgical and non-surgical groups.

TABLE 5: EFFECT OF GENDER ON OUTCOME

	Surgical Group (n=27)		Non-Surgical Group (n=12)	
RR / PR	Result	p – value	Result	p - value
At 3 months	No difference	p = 1.000	No difference	p = 0.364
At 6 months	No difference	p = 0.722	No difference	p = 1.000
At 12 months	No difference	p = 0.610	No difference	p = 0.747

RR = Recovery Rate
PR = Progression Rate

Conclusion: Gender had no effect on outcome in the surgical or non-surgical groups at 3, 6 or 12 months.

3.2 Effect of smoking on recovery / progression rates

See appendix ii for Smoking vs. Recovery / Progression Rates by mJOA at 3, 6 and 12 months in the surgical and non-surgical groups.

TABLE 6: EFFECT OF SMOKING ON OUTCOME

	Surgical Group (n=27)		Non-Surgical Group (n=12)	
RR / PR	Result	p value	Result	p value
At 3 months	No difference	p = 0.662	No difference	p = 1.000
At 6 months	No difference	p = 0.129	No difference	p = 1.000
At 12 months	No difference	p = 0.068	No difference	p = 1.000

RR = Recovery Rate
PR = Progression Rate

Conclusion: Smoking status had no effect on outcome in the surgical or non-surgical groups at 3, 6 or 12 months.

3.3 Effect of T2WI cord signal abnormality on MRI on the severity of CSM at presentation.

Patients were categorised as having mild CSM if the mJOA score at presentation was 12 or more. Those with a score of less than 12 indicated moderate-severe CSM. Of the 39 patients, there were 25 with mild CSM and 18 of these had T2WI cord signal abnormality on baseline MRI. There were 14 patients with moderate-severe CSM and all 14 patients had T2WI cord signal abnormality on the baseline MRI **(Figure 2)**.

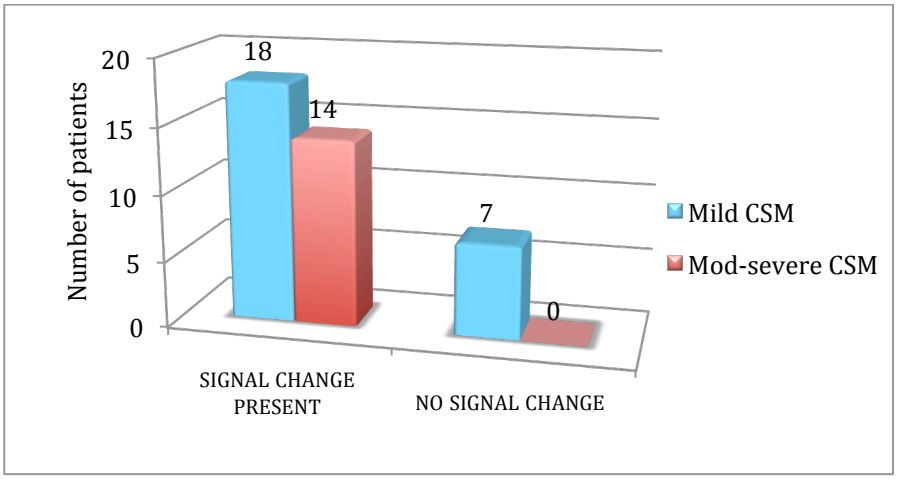

FIGURE 2: Distribution of T2WI cord signal abnormality and severity of CSM

Conclusion: If a patient had T2WI cord signal abnormality on baseline MRI, there was significantly higher probability of having moderate-severe rather than mild CSM (p value = 0.036).

3.4 Effect of T2WI cord signal abnormality on recovery / progression rates

See appendix iii for T2WI cord signal abnormality vs. Recovery / Progression Rates by mJOA at 3, 6 and 12 months in the surgical and non-surgical groups.

TABLE 7: EFFECT OF T2WI CORD SIGNAL ABNORMALITY ON OUTCOME				
	Surgical Group (n=27)		Non-Surgical Group (n=12)	
RR / PR	Result	p value	Result	p value
At 3 months	No difference	p = 0.269	No difference	p = 0.618
At 6 months	No difference	p = 0.870	No difference	p = 0.427
At 12 months	No difference	p = 1.000	No difference	p = 1.000
RR = Recovery Rate PR = Progression Rate				

Conclusion: T2WI cord signal abnormality on baseline MRI did not affect recovery /progression rates at 3, 6 or 12 months in both the surgical and non-surgical groups.

3.5 Effect of duration of symptoms on recovery / progression rates

See appendix iv for duration of symptoms vs. Recovery / Progression Rates by mJOA at 3, 6 and 12 months in the surgical and non-surgical groups.

TABLE 8: EFFECT OF DURATION OF SYMPTOMS ON OUTCOME				
	Surgical Group (n=27)		Non-Surgical Group (n=12)	
RR / PR	Result	p value	Result	p value
At 3 months	No difference	p = 0.0759	No difference	p = 0.5360
At 6 months	Better recovery in those with longer duration	p = 0.0221	No difference	p = 0.5834
At 12 months	No difference	p = 2569	No difference	p = 0.8845
RR = Recovery Rate PR = Progression Rate				

Conclusions: In the surgical group, those patients who had longer duration of symptoms, had a better outcome at 6 months. This effect was no longer evident at 12 months. In the non-surgical group, the duration of symptoms at time of presentation had no effect on outcome at 3, 6 or 12 months.

3.6 Effect of severity of CSM at baseline on recovery / progression rates

See appendix v for severity of CSM at baseline vs. Recovery / Progression Rates by mJOA at 3, 6 and 12 months in the surgical and non-surgical groups.

TABLE 9: EFFECT OF SEVERITY OF CSM AT BASELINE ON OUTCOME				
	Surgical Group (n=27)		Non-Surgical Group (n=12)	
RR / PR	Result	p value	Result	p value
At 3 months	No difference	p = 0.334	No difference	p = 1.000
At 6 months	No difference	p = 0.081	No difference	p = 1.000
At 12 months	Better outcome in moderate – severe CSM vs. mild CSM	p = 0.025	No difference	p = 1.000
RR = Recovery Rate PR = Progression Rate				

Conclusions: In the surgical group, patients who had moderate-severe CSM at baseline had better recovery at 1 year (p value = 0.025). In the non-surgical group the severity of CSM at baseline had no statistically significant effect on outcome.

3.7 Effect of co-morbidities on clinical and functional outcomes as assessed by mJOA and mMDI scores respectively

See appendices vi and xiii for tables with list of patients and co-morbidities in the surgical and non-surgical groups respectively.

TABLE 10: EFFECT OF CO-MORBIDITIES ON OUTCOME				
	By mJOA		By mMDI	
RR / PR	Result	p value	Result	p value
At 3 months	No difference	p = 0.681	No difference	p = 0.353
At 6 months	No difference	p = 0.120	No difference	p = 0.588
At 12 months	No difference	p = 0.134	No difference	p = 0.683
RR = Recovery Rate PR = Progression Rate				

Conclusion: Co-morbidities had no effect on clinical or functional outcome as assessed by the mJOA and mMDI scores respectively.

3.8 Effect of intra-op complications on clinical and functional outcomes in the surgical group as assessed by mJOA and mMDI score respectively (n=27)

See appendix vii for number of levels operated, surgical approach used and intra-operative complications.

TABLE 11: EFFECT OF INTRA-OPERATIVE COMPLICATIONS ON OUTCOME				
	By mJOA		By mMDI	
RR	Result	p value	Result	p value
At 3 months	Worse	p = 0.005	Worse	p = 0.044
At 6 months	Worse	p = 0.020	No difference	p = 0.54
At 12 months	No difference	p = 0.235	Worse	p = 0.005
RR = Recovery Rate				

Conclusions: Patients who had an intra-operative complication had significantly worse clinical recovery at 3 and 6 months as assessed by mJOA scores. At 12 months, mJOA scores showed no worse outcome, but functional recovery as assessed by mMDI remained worse at 12 months.

3.9 Overall recovery / progression rates as assessed by mJOA scores in the surgical and non-surgical groups

See appendices ix-xii, xvi-xix, xx and xxv for recovery / progression rates by mJOA in the surgical and non-surgical groups.

TABLE 12: RECOVERY / PROGRESSION RATES BY mJOA OVERALL				
	Surgical Group (n=27)		Non-Surgical Group (n=12)	
RR / PR	Result	p value	Result	p value
At 3 vs. 6 months	Improvement	p = 0.0002	No difference	p = 0.1100
At 6 vs. 12 months	Improvement	p = 0.0067	No difference	p = 1.000
At 3 vs. 12 months	Improvement	p = 0.0001	No difference	p = 0.1405
RR = Recovery Rate PR = Progression Rate				

Conclusions: In the surgical group there was statistically significant improvement in recovery rates after surgery at 3 vs. 6 months (p=0.0002). There was further improvement from 6 months to 12 months (p=0.0067). Comparing recovery rates at 3 vs. 12 months in the surgical group showed significant improvement (p=0.0001).

In the non-surgical group there was no improvement in progression rates at 3 vs. 6 months, 6 vs. 12 months or 3 vs. 12 months.

3.10 Upper limb recovery / progression rates in the surgical and non-surgical groups

See appendices ix-xii, xvi-xix, xxi and xxvi for upper limb recovery / progression rates by mJOA in the surgical and non-surgical groups.

TABLE 13: UPPER LIMB RECOVERY / PROGRESSION RATES

	Surgical Group (n=27)		Non-Surgical Group (n=12)	
RR / PR	**Result**	**p value**	**Result**	**p value**
At 3 vs. 6 months	**Improvement**	**p = 0.0096**	**No difference**	**p = 0.5035**
At 6 vs. 12 months	**Improvement**	**p = 0.0459**	**No difference**	**p = 0.3173**
At 3 vs. 12 months	**Improvement**	**p = 0.0030**	**No difference**	**p = 0.8575**

RR = Recovery Rate
PR = Progression Rate

Conclusions: When assessing upper limb recovery in the surgical group there was statistically significant improvement noted in recovery rates after surgery at 3 vs. 6 months (p=0.0096).

There was further improvement from 6 months to 12 months (p=0.0459). Comparing upper limb recovery at 3 vs. 12 months in the surgical group showed significant improvement up to 12 months post surgery (p=0.0030).

In the non-surgical group there was no improvement in upper limb progression rates at 3 vs. 6 months, 6 vs. 12 months 3 or vs. 12 months.

3.11 Lower limb recovery / progression rates in the surgical and non-surgical groups

See appendices ix-xii, xvi-xix, xxii and xxvii for lower limb recovery / progression rates by mJOA in the surgical and non-surgical groups.

TABLE 14: LOWER LIMB RECOVERY / PROGRESSION RATES

	Surgical Group (n=27)		Non-Surgical Group (n=12)	
RR / PR	**Result**	**p value**	**Result**	**p value**
At 3 vs. 6 months	**Improvement**	**p = 0.0256**	**No difference**	**p = 0.1590**
At 6 vs. 12 months	**Improvement**	**p = 0.0107**	**No difference**	**p = 0.5686**
At 3 vs. 12 months	**Improvement**	**p = 0.0011**	**No difference**	**p = 0.1389**

RR = Recovery Rate
PR = Progression Rate

Conclusions: Lower limb recovery in the surgical group showed statistically significant improvement in recovery rates after surgery at 3 vs. 6 months (p=0.0256).

Further improvement was noted from 6 months to 12 months (p=0.0107). Comparing lower limb recovery at 3 vs. 12 months in the surgical group showed significant improvement up to 12 months post surgery (p=0.0011).

In the non-surgical group there was no improvement in lower limb progression rates at 3 vs. 6 months, 6 vs. 12 months or 3 vs. 12 months.

3.12 Sensation recovery / progression rates in the surgical and non-surgical groups

See appendices ix-xii, xvi-xix, xxii and xxviii for sensation recovery / progression rates by mJOA in the surgical and non-surgical groups.

TABLE 15: SENSATION RECOVERY / PROGRESSION RATES				
	Surgical Group (n=27)		Non-Surgical Group (n=12)	
RR / PR	Result	p value	Result	p value
At 3 vs. 6 months	No difference	p = 0.3173	No difference	p = 1.000
At 6 vs. 12 months	No difference	p = 1.000	No difference	p = 1.000
At 3 vs. 12 months	No difference	p = 0.3173	No difference	p = 1.000
RR = Recovery Rate PR = Progression Rate				

Conclusions: There was no improvement whatsoever in recovery of sensation at 3 vs. 6 months, 6 vs. 12 months or 3 vs. 12 months. This was true for both the surgical and non-surgical groups.

3.13 Sphincter recovery / progression rates in the surgical and non-surgical groups

See appendices ix-xii, xvi-xix, xxiii and xxix for sphincter recovery / progression rates by mJOA in the surgical and non-surgical groups.

TABLE 16: SPHINCTER RECOVERY / PROGRESSION RATES				
	Surgical Group (n=27)		Non-Surgical Group (n=12)	
RR / PR	Result	p value	Result	p value
At 3 vs. 6 months	No difference	p = 0.3173	No difference	p = 1.000
At 6 vs. 12 months	No difference	p = 1.000	No difference	p = 1.000
At 3 vs. 12 months	No difference	p = 0.3173	No difference	p = 1.000
RR = Recovery Rate PR = Progression Rate				

Conclusion: There was no improvement whatsoever noted in sphincter recovery at 3 vs. 6 months, 6 vs. 12 months or 3 vs. 12 months. This was true for both the surgical and non-surgical groups.

3.14 Functional recovery / progression rates as assessed by mMDI in the surgical and non-surgical groups

See appendices ix-xii, xvi-xix, xxiv and xxx for mMDI recovery / progression rates in the surgical and non-surgical groups.

TABLE 17: FUNCTIONAL RECOVERY / PROGRESSION RATES BY mMDI

	Surgical Group (n=27)		Non-Surgical Group (n=12)	
RR / PR	**Result**	**p value**	**Result**	**p value**
At 3 vs. 6 months	**Improvement**	**p = 0.0001**	**No difference**	**p = 0.5842**
At 6 vs. 12 months	**Improvement**	**p = 0.0023**	**No difference**	**p = 0.9048**
At 3 vs. 12 months	**Improvement**	**p = 0.0001**	**No difference**	**p = 1.0000**

RR = Recovery Rate
PR = Progression Rate

Conclusions: Functional recovery in the surgical group showed statistically significant improvement in recovery rates after surgery at 3 vs. 6 months (p=0.0001). Improvement was also noted when comparing recovery at 6 vs. 12 months (p=0.0023). This significant improvement was again noted comparing recovery at 3 vs. 12 months (p=0.0001).

In the non-surgical group there was no improvement in functional progression rates at 3 vs. 6 months, 6 vs. 12 months or 3 vs. 12 months.

3.15 Comparison between recovery / progression rates in the surgical and non-surgical groups

TABLE 18: COMPARISON OF RECOVERY / PROGRESSION RATES BETWEEN THE SURGICAL AND NON-SURGICAL GROUPS		
		P value
Age	Older patients in non-surgical groups with mean age 54.7 years in surgical vs. 63.8 years in non-surgical group	0.0127
Severity of CSM at baseline	No difference between groups	0.344
mJOA at 3 months	No difference between groups	0.2102
mJOA at 6 months	No difference between groups	0.2405
mJOA at 12 months	Better outcome in the surgical group	0.0434
UL recovery at 3 months	No difference between groups	0.2294
UL recovery at 6 months	No difference between groups	0.4114
UL recovery at 12 months	No difference between groups	0.2160
LL recovery at 3 months	No difference between groups	0.8489
LL recovery at 6 months	No difference between groups	0.1422
LL recovery at 12 months	Better recovery in the surgical group	0.0155
Sensation at 3 months	No difference between groups	0.4701
Sensation at 6 months	No difference between groups	0.3657
Sensation at 12 months	No difference between groups	0.3657
Sphincters at 3 months	No difference between groups	0.1266
Sphincters at 6 months	No difference between groups	0.5127
Sphincters at 12 months	No difference between groups	0.5127
mMDI at 3 months	No difference between groups	0.1169
mMDI at 6 months	No difference between groups	0.9462
mMDI at 12 months	No difference between groups	0.9695

3.16 Comparison of actual mJOA and mMDI scores

TABLE 19: COMPARISON OF mJOA AND mMDI SCORES BETWEEN THE SURGICAL AND NON-SURGICAL GROUPS		
		P value
mJOA at 3 months	No difference between groups	0.1376
mJOA at 6 months	No difference between groups	0.3346
mJOA at 12 months	No difference between groups	0.8180
UL recovery at 3 months	No difference between groups	0.4671
UL recovery at 6 months	No difference between groups	0.4657
UL recovery at 12 months	No difference between groups	0.3368
LL recovery at 3 months	Non-surgical group had better scores	0.0402
LL recovery at 6 months	No difference between groups	0.2240
LL recovery at 12 months	No difference between groups	0.5208
Sensation at 3 months	No difference between groups	0.1778
Sensation at 6 months	No difference between groups	0.2394
Sensation at 12 months	No difference between groups	0.2394
Sphincters at 3 months	No difference between groups	0.6494
Sphincters at 6 months	No difference between groups	0.8041
Sphincters at 12 months	No difference between groups	0.4739
mMDI at 3 months	No difference between groups	0.3499
mMDI at 6 months	No difference between groups	0.7022
mMDI at 12 months	No difference between groups	0.7944

Conclusions: Comparison of recovery / progression rates and actual mJOA and mMDI scores between the surgical and non-surgical groups did not show any significant differences in outcome between the two groups.

CHAPTER 4 DISCUSSION

4.1 Demographics

4.1.1 Age

When the study was planned, we anticipated that direct comparisons between the surgical and non-surgical groups would not be possible as we expected the latter group to consist of patients with either mild CSM who refuse surgery as their disease does not significantly impact their lifestyle; or patients with severe debilitating CSM who are bed-bound in whom we thought surgery would not be of benefit to the patient. There is only one patient with moderate-severe CSM who was offered surgery but declined. The aim is to assess outcomes in the surgical group after surgical decompression and follow up the non-surgical group in order to obtain an idea of the natural history in our patients. However, when comparing the surgical and non-surgical groups, we find that the only statistically significant difference is age, with the non-surgical group having a mean age 9.1 years older than the surgical group. Therefore, we are able to compare outcomes between the two groups. The sample size is small with 27 in the surgical group and only 12 in the non-surgical group, so the level of evidence for the comparison between the groups is not robust.

4.1.2 The effect of gender on outcome

When assessing the effect of gender on recovery / progression rates calculated using the mJOA scores at baseline, 3, 6 and 12 months, there is no difference in the surgical and the non-surgical groups.

4.2 Effect of smoking on outcome

The negative effect of smoking on clinical recovery after surgery for cervical myelopathy has been documented (Hillbrand et al., 2001). This is presumed to be on the basis of an increased rate of pseudoarthrosis in smokers. While this effect is seen after posterolateral lumbar spine grafting, the same effect has not been conclusively proven in the cervical spine. The literature offers no conclusive evidence of smoking as an independent predictor of outcome. Kim et al. (2008) assessed the effect of diabetes and smoking on outcome after surgery and found that smoking did not affect outcome. The recent prospective, multi-centre North American AOSpine study assessing outcome after surgery, concluded that smoking among other factors is associated with a decreased probability of a successful outcome (Fehlings et al., 2014*)*. When assessing recovery rates at 3, 6 and 12 months, we find no difference between the smokers and non-smokers in both the surgical and the non-surgical groups.

4.3 Effect of T2WI cord signal abnormality on MRI on the severity of CSM at presentation, and

4.4 Effect of T2WI cord signal abnormality on recovery rates in the surgical and non-surgical groups

A sizeable body of literature examines the role of imaging, in particular pre-operative MRI, in predicting response to surgery (Toledano & Bartleson, 2013*)*. In a recent AOSpine survey of spinal surgeons, 86% responded "yes" to the question "Does Magnetic Resonance Imaging (MRI) provide prognostic information". It was the international AO respondents' general consensus that T2WI cord signal hyperintensity is the most significant MRI factor when predicting outcome after surgical decompression in patients with CSM (Tetreault

et al., 2013). However when analysing the literature, a recent systematic review concluded that there is controversy in the literature regarding the ability of MRI to predict surgical outcome (Tetreault et al., 2013). Some studies have found that T2WI cord signal hyperintensity MRI is not a prognostic factor after surgery and that this finding on MRI indicates reversible changes on MRI such as oedema and ischaemia. T1 weighted image cord signal hypointensity however, is more suggestive of chronic, irreversible changes such as necrosis, syrinx formation or cavitation and these may be associated with a worse prognosis after surgery. There are five reported relevant studies, but the evidence for this is low (Benzel et al., 2014). In addition, the number of levels where T2-signal change is evident, the height of signal intensity on T2, the ratio of T2-T1 signal change, the ratio of T2 normal signal-to-high signal areas and the transverse area of the spinal canal dimensions at the affected level are MRI factors, which have all been considered, to predict outcome in patients undergoing surgery for CSM. The level of evidence to support any MRI finding as a predictor of outcome after surgery is low at best.

Findings in our study show that patients who have T2-signal change on baseline MRI have significantly higher probability of having moderate-severe as opposed to mild CSM. This however has no effect on outcome, as there is no difference in recovery / progression rates in those patients who have, vs. those who do not have, signal change. This is true for both the surgical and non-surgical groups.

Findings in our study show that patients who have T2WI cord signal abnormality on baseline MRI have significantly higher probability of having moderate-severe as opposed to mild CSM. This however has no effect on outcome, as there is no

difference in recovery / progression rates in those patients who have, vs. those who do not have, signal change. This is true for both the surgical and non-surgical groups.

The question of how to manage patients who present with mild CSM but with T2WI cord signal abnormality on MRI is controversial. Literature suggests that these patients do not deteriorate during conservative treatment, but the level of evidence for this is low (Tetreault et al., 2013). The results in our study population show that of the 12 patients treated conservatively, 9 have T2WI cord signal abnormality on MRI. There is no difference in outcome in these patients vs. those with mild CSM treated surgically. Of the patients who are treated conservatively, one is worse at 3 months, three are worse at 6 months and five (42%) show deterioration in mJOA progression rates at 12 months. All except one of the patients who are worse have T2WI cord signal abnormality on the baseline MRI. This patient only shows deterioration at 12 months. It appears that patients with mild CSM and T2WI cord signal abnormality on MRI are at risk of clinical deterioration and these patients should be followed up more regularly.

Conversely, those with mild CSM and no T2WI cord signal abnormality on MRI do not appear to rapidly deteriorate. The only patient with mild CSM and no signal change to deteriorate did so only at 12 months. It is therefore reasonable to advocate conservative treatment in patients with mild CSM and no signal change on MRI.

4.5 Effect of duration of symptoms on outcome

Duration of symptoms at time of presentation is obtained from the history taken when the patient is first assessed. This is taken as the time at which the patient first noted symptoms referable to the cervical myelopathy. These include, but are not limited to: limb stiffness, limb weakness, limb pain, altered limb sensation, diminished manual dexterity, and altered gait. Symptoms referable to cervical spondylosis (neck stiffness, neck pain) were not used as the sole markers of onset of symptoms.

In the surgical group, those who have longer duration of symptoms (median of 17.5 months) have a better outcome at 6 months after surgery ($p=0.0221$). This is contrary to findings in literature where patients with longer duration of symptoms do worse than patients who present earlier (Sunago, 1982; Holly, 2009; Fehlings, 2013; Tetreault, 2013; Benzel, 2014). Most studies focus on the 12-month period as the clinically relevant threshold (Benzel, 2014). The findings in our study may indicate a more indolent or insidious course in those patients who have longer duration of symptoms. Because their symptoms progress slowly, they seek medical attention later as they presumably have a milder form of disease. This is in contrast to those who have a shorter duration of symptoms where symptoms progress more rapidly and may indicate a more severe form of disease. This better outcome with longer duration of symptoms is only evident at 6 months after surgery and this effect is no longer evident at 12 months. In the non-surgical group, there is no effect of duration of symptoms on outcome / progression of disease.

4.6 Effect of severity of CSM at baseline on outcome in the surgical and non-surgical groups

Outcome as assessed by recovery or progression rates calculated using mJOA scores show that in the surgical group there is no difference in outcome in the mild vs. moderate-severe CSM at 3 or 6 months. However, at 12 months, those patients who have moderate-severe CSM at baseline have a better recovery (p=0.025). This may indicate that this group of patients takes longer to show significant improvement. In the non-surgical group, severity of CSM at baseline, has no effect on outcome at 3, 6 or 12 months.

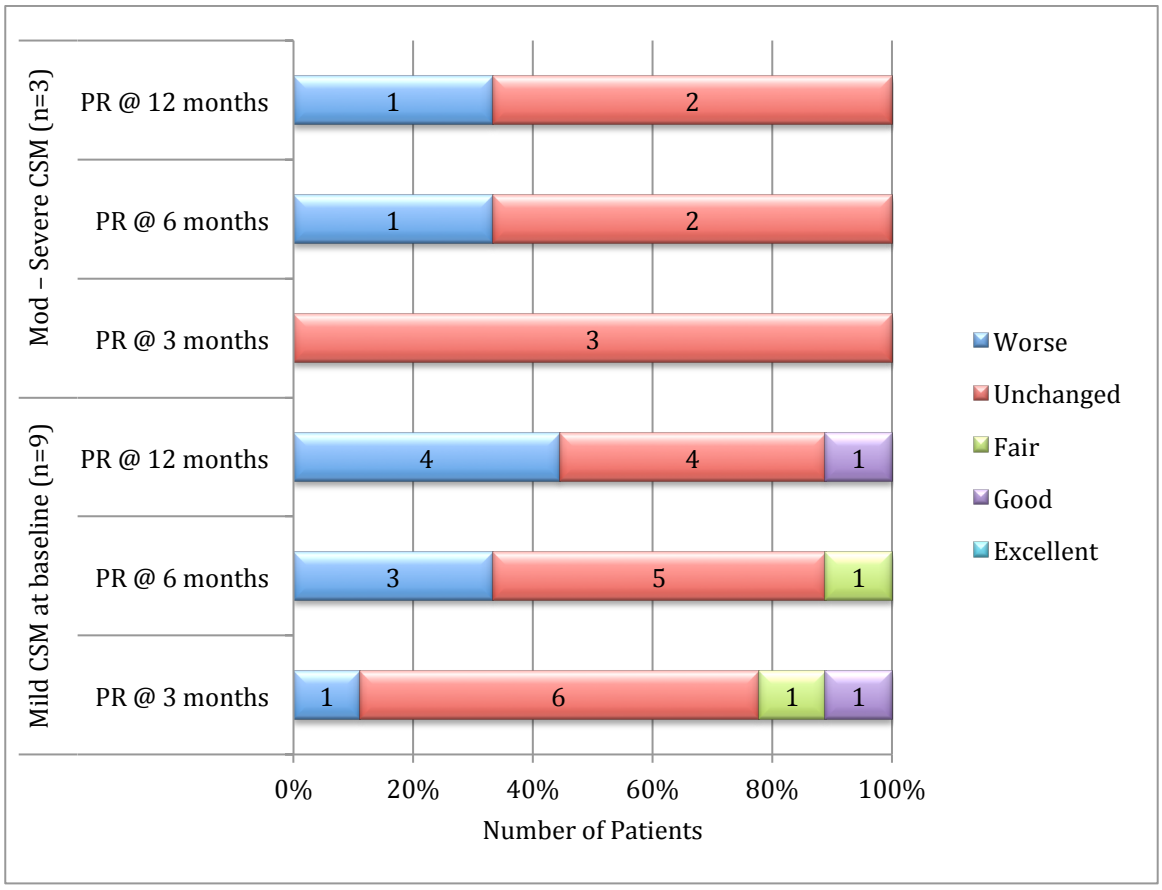

Figure 3: Progression Rates in Mild vs. Moderate-Severe CSM in the non-surgical group

While there is no statistically significant difference in outcome between mild vs. moderate-severe CSM in the non-surgical group, the graph above shows that 33%

of those with moderate-severe CSM are worse at 6 and 12 months, while the rest are unchanged. In those with mild CSM 44.4% are worse at 12 months, the same number are unchanged and only 11% have a good outcome. There are 12 patients in the non-surgical group, with 9 having mild CSM and 3 with moderate-severe CSM **(Figure 3).** Larger numbers are required to make statistically significant conclusions regarding the effect of severity of CSM at baseline on the natural history.

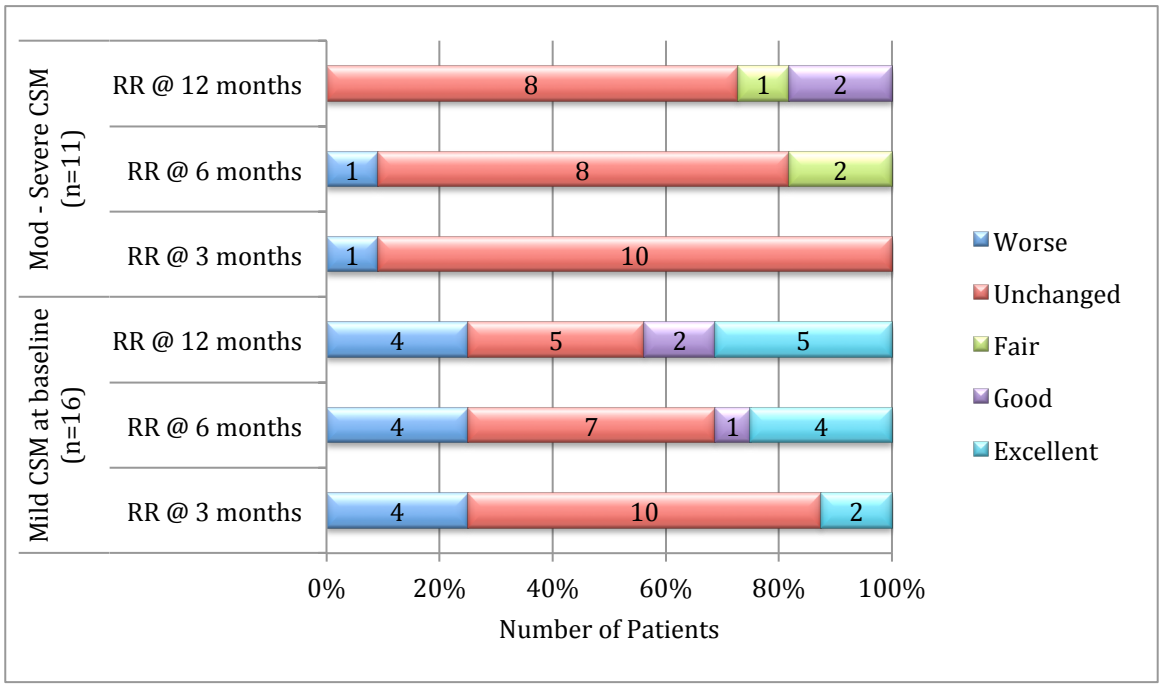

Figure 4: Recovery rates in Mild vs. Moderate-Severe CSM in the surgical group

In the surgical group, benefit from surgery is noted regardless of severity of CSM **(Figure 4)**. There are two extensive systematic reviews looking at the effect of baseline severity score on outcome. Holly et al. (2009) summarised the findings of 14 studies and found low class III level evidence that age and duration of symptoms had prognostic value in predicting outcome after surgery. Tetreault et al. (2013) reviewed 91 studies and found that duration of symptoms and baseline severity score had predictive value in determining outcome after surgery. A mJOA<12 is used as the threshold baseline score below which

there is a negative impact on surgical outcome (Benzel, 2013). Other surgeons have used mJOA<10 as a cut-off (Kadanka, 2002). The mJOA score represents a range of severities and the scale has not been validated, so slight variations between surgeon classifications are acceptable (Benzel, 2014).

4.7 Effect of co-morbidities on clinical and functional outcomes as assessed by mJOA and mMDI scores respectively

Pre-op co-morbidities have no effect on clinical or functional recovery as assessed by the mJOA and mMDI scores respectively. 27 of the 39 patients have at least one co-morbidity with the commonest being hypertension. Other co-morbidities noted are diabetes, dyslipidaemia, osteoarthritis, rheumatoid arthritis, schizophrenia, torticollis, angina pectoris, previous myocardial infarction, epilepsy, poliomyelitis, asthma, previous stroke, carpal tunnel syndrome, hypothyroidism, psoriatic arthritis, incidental frontal meningioma and congenital hydrocephalus. Most of these reflect the medical conditions prevalent in the general older / elderly population group. When surgeons ranked co-morbidities in terms of their significance to predict outcome after surgical decompression, diabetes, neurological disease including neuromuscular disorders, stroke and paralysis and psychological issues were the most important predictors (Tetreault et al., 2014). However, these perceptions are not supported by the available literature. Although diabetes as a predictor of outcome has been assessed in four studies, two have found that it is associated with a worse outcome while the other two have found that it does not significantly affect outcome (Kawaguchi, 2000; Kawaguchi, 2003; Choi, 2005; Chen, 2009). In their commentary on the AOSpine study, Fernando & Benzel (2014) concluded that there exist no studies specifically and solely dedicated to

assessing individual co-morbidities so there is no level-one evidence to support the effect of any co-morbidity on outcome after surgery. Fehlings et al. (2014) assessed co-morbidities as part of the AOSpine North American multicenter prospective study and found that mild diabetes is not a contraindication for surgical decompression in cervical spondylotic myelopathy. This is the only study that attempts to grade the severity of diabetes in terms of its effect on outcome. The major limitation of this study is that the majority of patients enrolled have mild, well-controlled diabetes with only 2% of patients having moderate diabetes and no patients with severe diabetes with end-organ damage. Thus, the only conclusion that can be made is that mild diabetes is not a contraindication to surgery in patients with CSM. However the effect of diabetes itself on outcome is still not fully defined. In our study, 7 of the 39 patients are diabetic (18%), however, most have multiple co-morbidities, so the effect of any one factor cannot be independently analysed. The sample size is also too small to draw definitive conclusions regarding different co-morbidities. Overall, in this study, the presence of co-morbidities, is not a predictor of worse outcome.

4.8 Effect of intra-operative complications on clinical and functional outcomes in the surgical group as assessed by mJOA and mMDI score respectively (n=27)

Patients who have an intra-operative complication have significantly worse clinical recovery at 3, 6 and 12 months as assessed by mJOA scores. Patients who have intra-operative complications have significantly worse functional recovery at 3 and 12 months, but not 6 months as assessed by mMDI scores.

Intra-operative complications are encountered in three of the twenty-seven patients (11%). These are intra-operative cerebrospinal fluid (CSF) leak in one patient, a dural rent without CSF leak in another and malpositioning of the cage in a third patient. This third patient manifested with worsening lower limb function in the immediate post-operative period. Urgent MRI scan showed the malpositioned cage with worsening T2WI cord signal abnormality. The patient was taken back to theatre for re-exploration and repositioning of the cage. All three patients who have intra-operative complications experience worse clinical and functional outcomes after surgery as compared to the non-complication sub-group.

While it is predictable that patients who have intra-operative complications will have a worse outcome, the severity and duration of these ill effects have not been studied. We find that at 3 months, these patients have worse clinical and functional outcomes as assessed by mJOA and mMDI scores respectively. At 12 months the clinical outcomes as assessed by mJOA scores have equalised between the group that have complications and those that do not, but the patients are still functionally worse at 12 months as assessed by mMDI scores.

When taking consent from patients with CSM prior to decompressive surgery, we use the typical adage that one-third of patients may deteriorate, one-third will stay the same and one-third will improve. Therefore, the aim of surgery may not be improvement, but rather to halt progression of disease. There is no scientific basis for this, but it is helpful when counseling patients prior to surgery.

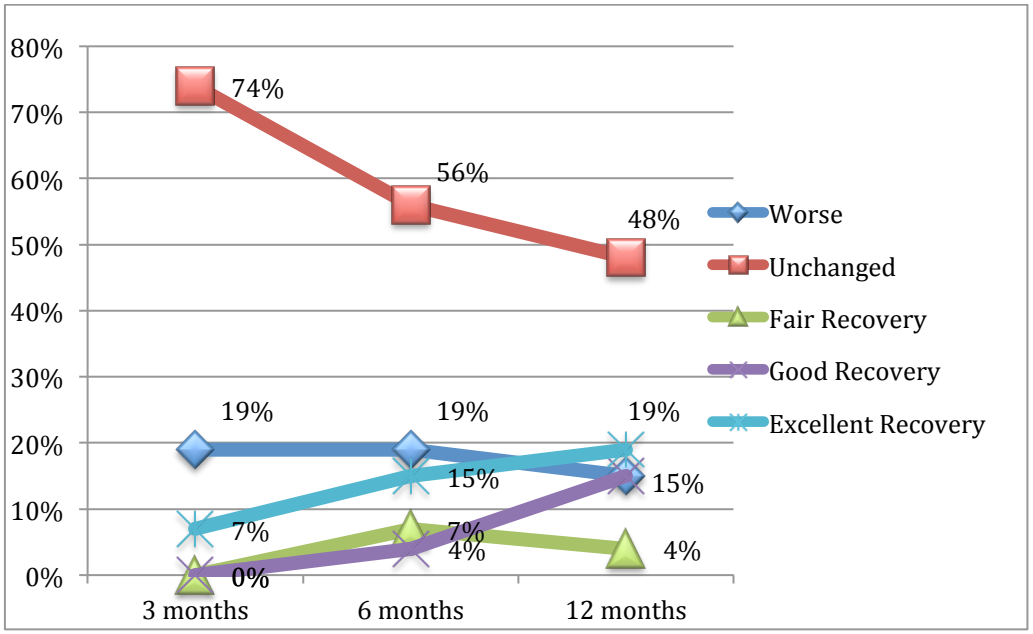

Figure 5: Recovery Rates in the Surgical Group at 3, 6 and 12 months (n=27)

Figure 5 above shows that those patients who are going to deteriorate after surgery, do so immediately. This is as a result of intra-operative complications and this deterioration remains constant at six months with only 4% overall improving at 12 months.

The majority of patients are unchanged at 3 months. At 6 months, patients start to show improvement and the proportion of patients from the unchanged group decrease as the proportion of patients who improve increase. This effect is still seen at 12 months. Contrary to other studies (Cheung, 2008) which show that improvement after surgery plateaus after 6 months, our patients show further improvement at 12 months.

Longer term follow up of all patients at 24 months and beyond, to assess the long term recovery, would be interesting, however is outside the scope of this current study.

4.9 – 4.14 Recovery / progression rates in the surgical and non-surgical groups as assessed by overall mJOA score, upper limb recovery rate, lower limb recovery rate, sensation recovery rate, sphincter recovery rate and functional recovery as assessed by mMDI scores

In the surgical group, there is statistically significant improvement in overall clinical and functional recovery as assessed by mJOA and mMDI scores. This improvement is noted at 3, 6 and 12 months after surgery. When assessing individual components of the mJOA score, upper limb and lower limb recovery both improve from 3 months with further improvement at 6 and 12 months after surgery. Sensation and sphincter function do not show any significant improvement after surgery. This is useful information when counseling patients prior to decompressive surgery for CSM because we can advise that patients can expect improvement in upper and lower limb function but sensation and sphincter function do not improve. If a patient presents with sphincter involvement, surgery will not reverse the damage already done. Cheung et al. (2008) showed similar results with upper limb recovery being the best followed by lower limb and poor recovery of sphincters. However, they found that recovery reached statistical significance at 3 months and plateaued at 6 months. We find continued recovery at 12 months post surgery. Fehlings et al. (2013) in their recent prospective multi-centre study on the efficacy and safety of surgical decompression in patients with CSM, conclude that surgical decompression is associated with improvement in functional, disability-related, and quality-of-life outcomes at one year of follow-up for all disease severity categories. Follow up was limited to one year and individual aspects of the mJOA score were not analysed to ascertain the pattern of recovery after surgical decompression.

Longer follow up of all our patients would be interesting, but is beyond the scope of this current study.

In the non-surgical group no clinical or functional improvement as assessed by mJOA or mMDI scores is noted. In addition, there is no improvement in upper limb, lower limb, sensation or sphincter function. This is noted at 3, 6 and 12 months after the baseline assessment.

Conservative management of CSM is associated with significant deterioration over a period of time **(Figure 6).**

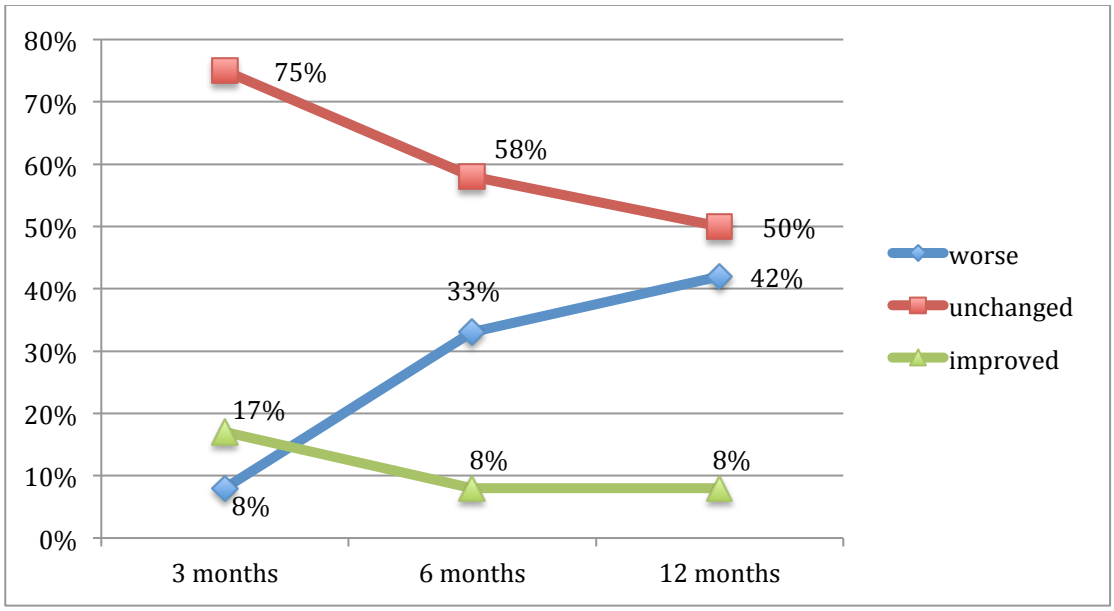

Figure 6: Progression Rates in the non-surgical group at 3, 6 and 12 months (n=12)

The majority of patients at 3 months are unchanged, but at 12 months only fifty percent of patients are unchanged. At 6 months one-third of patients are worse and this increases to forty-two percent at 12 months. These findings highlight the potential danger of conservative management of patients with CSM. The ability to predict who will deteriorate and who will remain unchanged is something that remains elusive. One also has to consider that the majority of patients managed non-operatively had mild CSM.

Patients may deteriorate by 1 point in the mJOA score and be regarded as being "worse" yet still have mild CSM.

The findings are reflective of our patient population and are a more useful guide when counseling patients with CSM regarding expected outcomes after surgery and natural history of the disease. This has to, however, be individualised as other factors such as age, duration of symptoms, severity of CSM, number of levels affected and presence of signal change on baseline MRI also have to be considered.

4.15 – 4.16 Comparison between recovery / progression rates in the surgical and non-surgical groups and comparison of actual mJOA and mMDI scores

When the study was planned we did not anticipate that direct comparison between the surgical and non-surgical groups would be possible as we expected that the two groups would not be comparable. Patients who were anticipated to form the non-surgical group would be those with mild CSM who refused surgery or those who were severely debilitated in whom we did not think surgery would offer any benefit when weighed against the associated risks. Only one patient with moderate-severe CSM declined after being offered surgery. However, when the data is analysed, the only factor that is found to be statistically significant between the groups is older age in the non-surgical group. Aside from better recovery in the surgical group when assessing mJOA scores at 12 months, ($p=0.0434$) and better lower limb recovery in the surgical group at 12 months ($p=0.0155$) there are no statistically significant differences in recovery or progression rates between the two groups at 3, 6 and 12 months.

Comparing actual mJOA and mMDI scores rather than recovery / progression rates, also shows no significant differences between the two groups.

The non-surgical group has only twelve patients and four of those patients are excluded from statistical analysis because of the problem experienced with using the Hirabayashi method where patients start with the full score. This results in the denominator in the equation being zero. We are able to include these patients in the descriptive statistics. Those who have mJOA scores that are less than the baseline are categorised as worse; and those with mJOA scores that are the same as the baseline score are categorised as unchanged. As a result of this, only 8 patients from the non-surgical group are included in the statistical analysis comparing the surgical and non-surgical groups.

We do not think that these small numbers are sufficient to draw convincing conclusions when comparing the two groups. While this would have been useful information, it is not the primary objective of this study as the non-surgical group was not intended to be a control group, but rather an opportunity to study the natural history of CSM in our patients.

CHAPTER 5 CONCLUSIONS, LIMITATIONS AND RECOMMENDATIONS

Conclusions:

Surgery is associated with statistically significant improvement in clinical recovery as assessed by mJOA scores at 3, 6 and 12 months post-operatively.

The pattern of recovery that can be expected is predictable in that upper limb and lower limb function show statistically significant recovery as assessed by the upper and lower limb components of the mJOA scores respectively. Sensation and sphincter function does not recover after surgical decompression in patients with CSM.

There is statistically significant functional recovery after surgical decompression in patients with CSM as assessed by mMDI scores at 3, 6 and 12 months after surgery.

There is no significant clinical or functional improvement of patients with CSM who are managed non-operatively as assessed by overall mJOA and mMDI scores at 3, 6 and 12 months. Furthermore, there is no improvement in upper limb, lower limb, sensation or sphincter function in the non-surgical group as assessed by individual components of the mJOA at 3, 6 and 12 months.

When assessing factors that can predict outcome: age, gender, smoking status and duration of symptoms have no effect on outcome. The presence of T2WI cord signal abnormality on baseline MRI is associated with statistically significant probability of having moderate-severe CSM at presentation, but this in itself, does not confer a worse outcome.

The occurrence of intra-operative complications results in a worse outcome with both clinical and functional recovery rates immediately worse at 3 months. Clinical recovery as assessed by mJOA normalises at 12 months, but these patients are still functionally impaired as assessed by mMDI at 12 months.

Limitations:

The sample size is small with only 12 patients in the non-surgical group. A number of potential patients are excluded from the study because pre-operative mJOA and mMDI scores were not performed. The natural history of these patients cannot be fully elucidated. Furthermore, direct comparisons between the surgical and non-surgical groups are not beneficial.

The effect of T1-signal hypointensities on baseline MRI was not studied. While radiologists at IALCH, when assessing cervical MRIs of patients with suspected CSM, always make a comment about T2WI cord signal abnormality, T1 weighted image spinal cord signal change is not routinely commented upon. It would have been interesting to study the effect of T1WI cord signal hypointensity on outcome in our patients.

Recommendations:

Patients with moderate-severe CSM should be offered surgical decompression.

Non-operative management is an option in patients with mild CSM, however, close clinical follow up is recommended to identify those who show early signs of deterioration.

Identification of patients with mild CSM who can be safely managed non-operatively remains a challenge and the decision has to be individualised, based on the patient's age, duration of symptoms, number of levels affected, the presence of signal change on baseline MRI and the patient's wishes. It appears reasonable to recommend non-operative management of patients with mild CSM and no T2-signal change on MRI.

Longer follow up of this cohort would be useful to assess the time at which benefit from surgery plateaus as well as to assess the long-term natural history in those patients in the non-surgical group.

APPENDICES

Patient Data

i. Gender vs. Recovery / Progression Rates by mJOA at 3,6 and 12 months

TABLE 20: GENDER VS OUTCOME						
Surgical Group (n=27)						
	Males (n=20)			**Females (n=7)**		
	RR @ 3 months	RR @ 6 months	RR @ 12 months	RR @ 3 months	RR @ 6 months	RR @ 12 months
Worse	4	4	3	1	1	1
Unchanged	14	10	8	6	5	5
Fair	0	1	1	0	1	0
Good	0	1	3	0	0	1
Excellent	2	4	5	0	0	0
Total	**20**	**20**	**20**	**7**	**7**	**7**
Non-Surgical Group (n=12)						
	Males (n=5)			**Females (n=7)**		
	PR @ 3 months	PR @ 6 months	PR @ 12 months	PR @ 3 months	PR @ 6 months	PR @ 12 months
Worse	1	2	3	0	2	2
Unchanged	3	3	2	6	4	4
Fair	0	0	0	1	1	0
Good	1	0	0	0	0	1
Excellent	0	0	0	0	0	0
Total	**5**	**5**	**5**	**7**	**7**	**7**
RR = Recovery Rate **PR = Progression Rate**						

ii. Smoking vs. Recovery / Progression Rates by mJOA at 3, 6 and 12 months

TABLE 21: SMOKING STATUS VS OUTCOME						
Surgical Group (n=27)						
	Smokers (n=12)			**Non-smokers (n=15)**		
	RR @ 3 months	RR @ 6 months	RR @ 12 months	RR @ 3 months	RR @ 6 months	RR @ 12 months
Worse	1	1	0	4	4	4
Unchanged	10	5	5	10	10	8
Fair	0	2	0	0	0	1
Good	0	1	3	0	0	1
Excellent	1	3	4	1	1	1
Total	**12**	**12**	**12**	**15**	**15**	**15**
Non-Surgical Group (n=12)						
	Smokers (n=8)			**Non-smokers (n=4)**		
	PR @ 3 months	PR @ 6 months	PR @ 12 months	PR @ 3 months	PR @ 6 months	PR @ 12 months
Worse	1	3	3	0	1	2
Unchanged	5	4	4	4	3	2
Fair	1	1	0	0	0	0
Good	1	0	1	0	0	0
Excellent	0	0	0	0	0	0
Total	**8**	**8**	**8**	**4**	**4**	**4**
RR = Recovery Rate **PR = Progression Rate**						

iii. T2WI cord signal abnormality vs. Recovery / Progression Rates by mJOA at 3, 6 and 12 months

TABLE 22: T2WI CORD SIGNAL ABNORMALITY VS OUTCOME						
Surgical Group (n=27)						
T2WI signal change present (n=23)				**No signal change (n=4)**		
	RR @ 3 months	RR @ 6 months	RR @ 12 months	RR @ 3 months	RR @ 6 months	RR @ 12 months
Worse	4	4	3	1	1	1
Unchanged	18	13	11	2	2	2
Fair	0	2	1	0	0	0
Good	0	1	4	0	0	0
Excellent	1	3	4	1	1	1
Total	**23**	**23**	**23**	**4**	**4**	**4**
Non-Surgical Group (n=12)						
T2WI signal change present (n=9)				**No signal change (n=3)**		
	PR @ 3 months	PR @ 6 months	PR @ 12 months	PR @ 3 months	PR @ 6 months	PR @ 12 months
Worse	1	4	4	0	0	1
Unchanged	7	4	4	2	3	2
Fair	1	1	0	0	0	0
Good	0	0	1	1	0	0
Excellent	0	0	0	0	0	0
Total	**9**	**9**	**9**	**3**	**3**	**3**
RR = Recovery Rate PR = Progression Rate						

iv. Duration of symptoms vs. Recovery / Progression Rates by mJOA at 3, 6 and 12 months

TABLE 23: DURATION OF SYMPTOMS (in months) VS OUTCOME						
	N	min	p25	p50	p75	max
At 3 months						
worse	6	4	6	13	16	18
unchanged	29	2	3	7	12	36
fair recovery	1	12	12	12	12	12
good recovery	1	22	22	22	22	22
excellent recovery	2	17	17	17.5	18	18
At 6 months						
worse	9	3	6	12	14	18
unchanged	22	2	3	5	13	36
fair recovery	3	2	2	12	12	12
good recovery	1	30	30	30	30	30
excellent recovery	4	12	14.5	17.5	20	22
At 12 months						
worse	9	3	4	12	14	18
unchanged	19	2	3	5	14	36
fair recovery	1	12	12	12	12	12
good recovery	5	2	3	12	12	30
excellent recovery	5	12	12	17	18	22

v. Severity of CSM at baseline on recovery / progression rates by mJOA at 3, 6 and 12 months

TABLE 24: SEVERITY OF CSM AT BASELINE VS OUTCOME						
Surgical Group (n=27)						
	Mild CSM at baseline (n=16)			**Mod – Severe CSM (n=11)**		
	RR @ 3 months	RR @ 6 months	RR @ 12 months	RR @ 3 months	RR @ 6 months	RR @ 12 months
Worse	4	4	4	1	1	0
Unchanged	10	7	5	10	8	8
Fair	0	0	0	0	2	1
Good	0	1	2	0	0	2
Excellent	2	4	5	0	0	0
Total	**16**	**16**	**16**	**11**	**11**	**11**
Non-Surgical Group (n=12)						
	Mild CSM at baseline (n=9)			**Mod – Severe CSM (n=3)**		
	PR @ 3 months	PR @ 6 months	PR @ 12 months	PR @ 3 months	PR @ 6 months	PR @ 12 months
Worse	1	3	4	0	1	1
Unchanged	6	5	4	3	2	2
Fair	1	1	0	0	0	0
Good	1	0	1	0	0	0
Excellent	0	0	0	0	0	0
Total	**9**	**9**	**9**	**3**	**3**	**3**
RR = Recovery Rate **PR = Progression Rate**						

vi. Table showing age, gender, smoking status and co-morbidities in the surgical cohort (n=27)

TABLE 25: AGE, GENDER, SMOKING STATUS AND CO-MORBIDITIES				
Patient	Age	Gender	Smoker	Co-morbidities
1	36	Male	No	Congenital hydrocephalus. VP shunt at birth. 5 revisions
2	48	Female	No	Incidental frontal meningioma --> observed
3	64	Female	No	Hypertension, psoriatic arthritis
4	58	Female	No	Hypertension, diabetic, dyslipidaemic, carpal tunnel, angina, hypothyroidism
5	60	Male	No	Nil
6	56	Male	No	Nil
7	67	Male	No	Asthma, hypertension, angina previous stroke --> recovered
8	49	Male	No	Dyslipidaemia
9	54	Male	Yes	Nil
10	66	Male	No	Nil
11	71	Male	No	Demyelinating neuropathy, diabetic
12	49	Male	Yes	Nil
13	49	Male	Yes	Diabetic, asthmatic
14	41	Female	Yes	Nil
15	49	Male	Yes	Nil
16	47	Male	No	Nil
17	64	Male	No	Previous left sided hemiparesis and spasticity due to poliomyelitis
18	65	Female	Yes	Hypertension
19	51	Male	Yes	Nil
20	54	Male	No	Hypertension, diabetic
21	67	Female	Yes	Hypertension, dyslipidaemia, previous myocardial infarction
22	29	Male	Yes	Nil
23	51	Male	Yes	Nil
24	68	Male	Yes	Hypertension, angina, previous myocardial infarction, epilepsy
25	56	Female	No	Hypertension
26	48	Male	Yes	Hypertension, torticollis
27	60	Male	No	Schizophrenia

vii. Table 26 showing duration of symptoms in months, HIV status, presence of T2WI cord signal abnormality on MRI, number of cervical levels operated upon, surgical approach used and intra-operative complications in the surgical cohort (n=27)

Patient	Duration of symptoms (months)	HIV status	Signal change on MRI	Number of levels	Surgical approach	Complications
1	12	Negative	Yes	1	C4/5 ACDF and cage	Cage malpositioned
2	2	Unknown	No	1	C5/6 ACDF and cage	Nil
3	6	Unknown	Yes	2	C4/5 and C5/6 ACDF and cage	Nil
4	3	Negative	Yes	1	C4/5 ACDF and cage	Nil
5	18	Negative	No	2	C5/6 and c6/7 ACDF and cages	Nil
6	16	Unknown	No	2	C5/6 and c6/7 ACDF and cages	CSF leak intra-op
7	7	Unknown	Yes	2	C3/4 and C4/5 ACDF and cages	Nil
8	3	Unknown	Yes	2	C3/4 and C5/6 ACDF and cages	Nil
9	13	Unknown	Yes	1	C4/5 ACDF and cage	Nil
10	18	Unknown	Yes	2	C3/4 ACDF and cage, C5 corpectomy and plate	Dural rent intra-op
11	12	Unknown	Yes	1	C5/6 ACDF and cage	Nil
12	12	Negative	Yes	2	C5/6 and C6/7 ACDF and cages	Nil
13	30	Unknown	Yes	2	C5 corpectomy and iliac graft and plate	Nil
14	2	Positive	Yes	1	C5/6 ACDF and cage	Nil
15	22	Negative	Yes	2	C5/6 and C6/7 ACDF and cages	Nil
16	5	Negative	Yes	3	C3/4 and C4/5 and C5/6 ACDF and cage	Nil
17	4	Unknown	Yes	2	C4/5 and C5/6 ACDF and cage	Nil
18	12	Unknown	Yes	1	C4/5 ACDF and cage	Nil
19	2	Negative	Yes	1	C4/5 ACDF and cage	Nil
20	4	Negative	Yes	2	C4/5 and C5/6 ACDF and cage	Nil
21	7	Negative	Yes	4	C4 and C5 corpectomy and C6/7 ACDF + 4 level plate	Nil
22	12	Negative	Yes	1	C5/6 ACDF and cage	Nil
23	14	Negative	Yes	1	C3/4 ACDF and cage	Nil
24	3	Unknown	Yes	3	C3/4 and C4/5 and C5/6 ACDF and cage	Nil
25	36	Negative	No	1	C5/6 ACDF and cage	Nil
26	17	Unknown	Yes	2	C4/5 and C5/6 ACDF and cage	Nil
27	5	Unknown	Yes	1	C3/4 ACDF and C3 laminectomy	Nil
ACDF – Anterior Cervical Discectomy and Fusion						

viii. Table 27 showing severity of CSM at baseline, baseline mJOA score with the individual component scores (upper limb, lower limb, sensation and sphincter), and the baseline mMDI scores in the surgical cohort (n=27)

Patient	Severity of CSM at baseline	Baseline mJOA score	Baseline upper limb score	Baseline lower limb score	Baseline sensation score	Baseline sphincter score	Baseline mMDI
1	Mild	13	4	4	2	3	25
2	Mild	16	5	6	2	3	24
3	Mild	14	4	4	3	3	24
4	Mild	17	5	7	2	3	30
5	Mild	14	5	4	2	3	27
6	Mild	16	4	6	3	3	25
7	Mod-severe	11	3	3	2	3	22
8	Mild	12	4	4	2	2	21
9	Mod-severe	7	2	4	1	0	19
10	Mild	14	4	5	2	3	20
11	Mod-severe	11	4	3	2	2	24
12	Mild	17	5	6	3	3	30
13	Mild	16	5	6	2	3	29
14	Mod-severe	3	1	1	1	0	5
15	Mild	17	5	6	3	3	30
16	Mod-severe	6	2	3	1	0	14
17	Mild	13	4	3	3	3	17
18	Mod-severe	10	1	3	3	3	5
19	Mod-severe	9	2	2	2	3	7
20	Mild	13	4	4	2	3	20
21	Mod-severe	11	3	3	2	3	22
22	Mild	17	5	6	3	3	28
23	Mod-severe	11	3	4	2	2	14
24	Mod-severe	7	1	2	1	3	4
25	Mild	13	4	4	2	3	22
26	Mild	13	3	6	1	3	26
27	Mod-severe	8	2	2	2	2	2

ix. Table 28 showing mJOA scores with the individual component scores (upper limb, lower limb, sensation and sphincter), and mMDI scores in the surgical cohort at 3 months (n=27)

Patient	mJOA at 3 months	Upper limb score at 3 months	Lower limb score at 3 months	Sensation score at 3 months	Sphincter score at 3 months	mMDI at 3 months
1	11	3	3	2	3	20
2	16	5	6	2	3	23
3	13	4	4	2	3	19
4	17	5	7	2	3	30
5	18	5	7	3	3	30
6	13	4	3	3	3	20
7	11	3	3	2	3	22
8	12	4	4	2	2	23
9	7	2	4	1	0	18
10	10	3	2	2	3	15
11	11	4	3	2	2	25
12	17	5	6	3	3	30
13	16	5	6	2	3	29
14	3	1	1	1	0	5
15	17	5	6	3	3	30
16	6	2	3	1	0	14
17	13	5	3	2	3	23
18	10	1	3	3	3	5
19	9	2	2	2	3	7
20	13	4	4	2	3	20
21	11	3	3	2	3	22
22	17	5	6	3	3	28
23	9	2	3	2	2	13
24	7	1	2	1	3	4
25	13	4	4	2	3	22
26	18	5	7	3	3	30
27	9	3	2	2	2	4

x. Table 29 showing mJOA scores with the individual component scores (upper limb, lower limb, sensation and sphincter), and mMDI scores in the surgical cohort at 6 months (n=27)

Patient	mJOA at 6 months	Upper limb score at 6 months	Lower limb score at 6 months	Sensation score at 6 months	Sphincter score at 6 months	mMDI at 6 months
1	12	4	3	2	3	22
2	16	5	6	2	3	23
3	13	4	4	2	3	19
4	17	5	7	2	3	30
5	18	5	7	3	3	30
6	13	4	3	3	3	21
7	12	4	3	2	3	23
8	13	5	4	2	2	27
9	7	2	4	1	0	18
10	11	3	3	2	3	16
11	12	5	3	2	2	27
12	18	5	7	3	3	30
13	17	5	7	2	3	29
14	3	1	1	1	0	5
15	18	5	7	3	3	30
16	7	3	3	1	0	16
17	13	5	3	2	3	24
18	12	3	3	3	3	10
19	12	3	4	2	3	14
20	14	5	4	2	3	21
21	11	3	3	2	3	23
22	17	5	6	3	3	29
23	9	2	3	2	2	13
24	8	2	2	1	3	5
25	13	4	4	2	3	23
26	18	5	7	3	3	30
27	10	2	2	3	3	12

xi. Table 30 showing mJOA scores with the individual component scores (upper limb, lower limb, sensation and sphincter), and mMDI scores in the surgical cohort at 12 months (n=27)

Patient	mJOA at 12 months	Upper limb score at 12 months	Lower limb score at 12 months	Sensation score at 12 months	Sphincter score at 12 months	mMDI at 12 months
1	13	4	4	2	3	24
2	16	5	6	2	3	23
3	13	4	4	2	3	19
4	17	5	7	2	3	30
5	18	5	7	3	3	30
6	13	4	3	3	3	22
7	12	4	3	2	3	24
8	16	5	7	2	2	28
9	7	2	4	1	0	19
10	11	3	3	2	3	16
11	13	5	4	2	2	27
12	18	5	7	3	3	30
13	17	5	7	2	3	29
14	3	1	1	1	0	5
15	18	5	7	3	3	30
16	7	3	3	1	0	18
17	12	5	2	2	3	22
18	14	4	4	3	3	18
19	14	4	5	2	3	20
20	14	5	4	2	3	22
21	12	4	3	2	3	24
22	18	5	7	3	3	29
23	11	3	4	2	2	14
24	9	2	3	1	3	6
25	14	4	5	2	3	24
26	18	5	7	3	3	30
27	10	2	2	3	3	12

xii. Table 31 showing mJOA scores with the individual component scores (upper limb, lower limb, sensation and sphincter), and mMDI scores in the surgical cohort at 24 months (n=2)

Patient	mJOA at 24 months	Upper limb score at 24 months	Lower limb score at 24 months	Sensation score at 24 months	Sphincter score at 24 months	mMDI at 24 months
17	10	3	2	2	3	19
18	18	5	7	3	3	30

xiii. Table 32 showing age, gender, smoking status and co-morbidities in the non-surgical cohort (n=12)

Patient	Age	Gender	Smoker	Co-morbidities
1	72	Female	No	Hypertension, diabetic, rheumatoid arthritis
2	79	Male	Yes	Hypertension
3	76	Female	No	Hypertension, osteoarthritis
4	64	Male	Yes	Hypertension, Chronic obstructive pulmonary disease
5	59	Male	No	Hypertension
6	53	Female	Yes	Diabetic
7	73	Male	Yes	Hypertension
8	49	Female	Yes	Hypertension
9	56	Female	No	Diabetic
10	60	Female	Yes	Asthma
11	58	Male	Yes	Hypertension, diabetic, dyslipidaemia
12	67	Female	Yes	Nil

xiv. Table 33 showing duration of symptoms in months, HIV status, presence of T2WI cord signal abnormality on MRI, number of cervical levels affected and reason for not operating in the non-surgical cohort (n=12)

Patient	Duration of symptoms (months)	Hiv status	Signal change on MRI	Number of levels affected	Reason for not operating
1	5	Unknown	Yes	4	Severe multilevel CSM in poor grade patient
2	3	Negative	Yes	3	Severe multilevel CSM in poor grade patient
3	3	Negative	Yes	3	Declined surgery
4	4	Negative	Yes	2	Declined surgery
5	14	Unknown	No	2	Declined surgery
6	3	Unknown	Yes	2	Declined surgery
7	12	Negative	Yes	2	Declined surgery
8	12	Unknown	Yes	2	Declined surgery
9	24	Positive	Yes	1	Mild single level disease
10	14	Negative	No	1	Mild single level disease
11	22	Negative	No	1	Mild single level disease
12	12	Unknown	Yes	2	Declined surgery

xv. Table 34 showing severity of CSM at baseline, baseline mJOA scores with the individual component scores (upper limb, lower limb, sensation and sphincter), and the baseline mMDI scores in the non-surgical cohort (n=12)

Patient	Severity of CSM at baseline	Baseline mJOA score	Baseline upper limb score	Baseline lower limb score	Baseline sensation score	Baseline sphincter score	Baseline mMDI
1	Mod-severe	6	2	1	3	0	2
2	Mod-severe	7	2	2	3	0	6
3	Mild	15	4	6	2	3	27
4	Mild	16	5	6	3	2	20
5	Mild	13	3	6	1	3	18
6	Mild	18	5	7	3	3	29
7	Mild	18	5	7	3	3	30
8	Mild	14	2	7	2	3	22
9	Mild	18	5	7	3	3	30
10	Mild	18	5	7	3	3	28
11	Mild	16	4	7	2	3	30
12	Mod-severe	7	1	3	0	3	8

xvi. Table 35 showing mJOA scores with the individual component scores (upper limb, lower limb, sensation and sphincter), and mMDI scores in the non-surgical cohort at 3 months (n=12)

Patient	mJOA at 3 months	Upper limb score at 3 months	Lower limb score at 3 months	Sensation score at 3 months	Sphincter score at 3 months	mMDI at 3 months
1	8	3	2	3	0	9
2	7	2	2	3	0	6
3	15	4	6	2	3	27
4	15	5	4	3	3	21
5	13	3	6	1	3	18
6	18	5	7	3	3	29
7	18	5	7	3	3	30
8	15	3	7	2	3	23
9	18	5	7	3	3	30
10	18	5	7	3	3	30
11	17	5	7	2	3	30
12	7	1	3	0	3	8

xvii. Table 36 showing mJOA scores with the individual component scores (upper limb, lower limb, sensation and sphincter), and mMDI scores in the non-surgical cohort at 6 months (n=12)

Patient	mJOA at 6 months	Upper limb score at 6 months	Lower limb score at 6 months	Sensation score at 6 months	Sphincter score at 6 months	mMDI at 6 months
1	8	2	2	3	0	6
2	8	3	2	3	0	9
3	14	4	5	2	3	26
4	14	4	4	3	3	20
5	13	3	6	1	3	18
6	18	5	7	3	3	29
7	16	4	6	3	3	28
8	15	3	7	2	3	24
9	18	5	7	3	3	30
10	18	5	7	3	3	30
11	16	4	7	2	3	30
12	5	1	2	0	2	7

xviii. Table 37 showing mJOA scores with the individual component scores (upper limb, lower limb, sensation and sphincter), and mMDI scores in the non-surgical cohort at 12 months (n=12)

Patient	mJOA at 12 months	Upper limb score at 12 months	Lower limb score at 12 months	Sensation score at 12 months	Sphincter score at 12 months	mMDI at 12 months
1	6	2	1	3	0	3
2	9	3	3	3	0	12
3	14	4	5	2	3	25
4	14	4	4	3	3	20
5	12	3	5	1	3	17
6	18	5	7	3	3	30
7	13	4	4	3	2	25
8	16	4	7	2	3	25
9	18	5	7	3	3	30
10	18	5	7	3	3	30
11	16	4	7	2	3	30
12	5	1	2	0	2	6

xix. Table 38 showing mJOA scores with the individual component scores (upper limb, lower limb, sensation and sphincter), and mMDI scores in the non-surgical cohort at 24 months (n=4)

Patient	mJOA at 24 months	Upper limb score at 24 months	Lower limb score at 24 months	Sensation score at 24 months	Sphincter score at 24 months	mMDI at 24 months
6	18	5	7	3	3	30
7	12	4	3	3	2	23
10	18	5	7	3	3	30
11	16	4	7	2	3	30

xx. Table 39 showing recovery / progression rates as assessed by mJOA in the surgical and non-surgical groups

RECOVERY / PROGRESSION RATES BY OVERALL mJOA						
SURGICAL GROUP (n=27)						
	Worse	Unchanged	Fair Recovery	Good Recovery	Excellent Recovery	Total
3 months	5	20	0	0	2	27
6 months	5	15	2	1	4	27
12 months	4	13	1	4	5	27
24 months	1	0	0	0	1	2
NON-SURGICAL GROUP (n=12)						
3 months	1	9	1	1	0	12
6 months	4	7	1	0	0	12
12 months	5	6	0	1	0	12
24 months	2	2	0	0	0	4

xxi. Table 40 showing upper limb recovery / progression rates in the surgical and non-surgical groups

UPPER LIMB RECOVERY / PROGRESSION RATES						
SURGICAL GROUP (n=27)						
	Worse	Unchanged	Fair Recovery	Good Recovery	Excellent Recovery	Total
3 months	3	21	1	0	2	27
6 months	2	15	3	2	5	27
12 months	1	15	2	3	6	27
24 months	1	0	0	0	1	2
NON-SURGICAL GROUP (n=12)						
3 months	0	9	2	0	1	12
6 months	2	8	2	0	0	12
12 months	2	8	1	1	0	12
24 months	1	3	0	0	0	4

xxii. Table 41 showing lower limb recovery / progression rates in the surgical and non-surgical groups

LOWER LIMB RECOVERY / PROGRESSION RATES						
SURGICAL GROUP (n=27)						
	Worse	Unchanged	Fair Recovery	Good Recovery	Excellent Recovery	Total
3 months	4	21	0	0	2	27
6 months	4	17	1	0	5	27
12 months	3	13	3	1	7	27
24 months	1	0	0	0	1	2
NON-SURGICAL GROUP (n=12)						
3 months	1	11	0	0	0	12
6 months	4	8	0	0	0	12
12 months	5	7	0	0	0	12
24 months	1	3	0	0	0	4

xxii. Table 42 showing sensation limb recovery / progression rates in the surgical and non-surgical groups

SENSATION LIMB RECOVERY / PROGRESSION RATES						
SURGICAL GROUP (n=27)						
	Worse	Unchanged	Fair Recovery	Good Recovery	Excellent Recovery	Total
3 months	2	23	0	0	2	27
6 months	2	22	0	0	3	27
12 months	2	22	0	0	3	27
24 months	1	0	0	0	1	2
NON-SURGICAL GROUP (n=12)						
3 months	0	12	0	0	0	12
6 months	0	12	0	0	0	12
12 months	0	12	0	0	0	12
24 months	0	4	0	0	0	4

xxiii. Table 43 showing sphincter recovery / progression rates in the surgical and non-surgical groups

SPHINCTER RECOVERY / PROGRESSION RATES						
SURGICAL GROUP (n=27)						
	Worse	Unchanged	Fair Recovery	Good Recovery	Excellent Recovery	Total
3 months	0	27	0	0	0	27
6 months	0	26	0	0	1	27
12 months	0	26	0	0	1	27
24 months	0	2	0	0	0	2
NON-SURGICAL GROUP (n=12)						
3 months	0	11	0	0	1	12
6 months	1	10	0	0	1	12
12 months	2	9	0	0	1	12
24 months	1	3	0	0	0	4

xxiv. Table 44 showing functional recovery / progression rates as assessed by mMDI

RECOVERY / PROGRESSION RATES BY mMDI						
SURGICAL GROUP (n=27)						
	Worse	Unchanged	Fair Recovery	Good Recovery	Excellent Recovery	Total
3 months	7	17	1	0	2	27
6 months	7	12	2	4	2	27
12 months	5	9	6	4	3	27
24 months	0	1	0	0	1	2
NON-SURGICAL GROUP (n=12)						
3 months	0	10	1	0	1	12
6 months	3	7	1	0	1	12
12 months	4	4	2	0	2	12
24 months	1	1	0	0	2	4

xxv. Table 45 showing mJOA scores in the surgical and non-surgical groups

mJOA SCORES IN SURGICAL GROUP			
	At 3 months	At 6 months	At 12 months
N	27	27	27
min	3	3	3
p25	9	11	11
p50	12	13	13
p75	16	17	17
max	18	18	18
mJOA SCORES IN NON-SURGICAL GROUP			
	At 3 months	At 6 months	At 12 months
N	12	12	12
min	7	5	5
p25	10.5	10.5	10.5
p50	15	14.5	14
p75	18	17	17
max	18	18	18

xxvi. Table 46 showing upper limb scores in the surgical and non-surgical groups

UPPER LIMB SCORES IN SURGICAL GROUP			
	At 3 months	At 6 months	At 12 months
N	27	27	27
min	1	1	1
p25	2	3	3
p50	4	4	4
p75	5	5	5
max	5	5	5
UPPER LIMB SCORES IN NON-SURGICAL GROUP			
	At 3 months	At 6 months	At 12 months
N	12	12	12
min	1	1	1
p25	3	3	3
p50	4.5	4	4
p75	5	4.5	4.5
max	5	5	5

xxvii. Table 47 showing lower limbs scores in the surgical and non-surgical groups

LOWER LIMB SCORES IN SURGICAL GROUP			
	At 3 months	At 6 months	At 12 months
N	27	27	27
min	1	1	1
p25	3	3	3
p50	3	4	4
p75	6	6	7
max	7	7	7
LOWER LIMB SCORES IN NON-SURGICAL GROUP			
	At 3 months	At 6 months	At 12 months
N	12	12	12
min	2	2	1
p25	3.5	3	3.5
p50	6.5	6	5
p75	7	7	7
max	7	7	7

xxviii. Table 48 showing sensation scores in the surgical and non-surgical groups

SENSATION SCORES IN SURGICAL GROUP			
	At 3 months	At 6 months	At 12 months
N	27	27	27
min	1	1	1
p25	2	2	2
p50	2	2	2
p75	3	3	3
max	3	3	3
SENSATION SCORES IN NON-SURGICAL GROUP			
	At 3 months	At 6 months	At 12 months
N	12	12	12
min	0	0	0
p25	2	2	2
p50	3	3	3
p75	3	3	3
max	3	3	3

xxix. Table 49 showing sphincter scores in the surgical and non-surgical groups

SPHINCTER SCORES IN SURGICAL GROUP			
	At 3 months	At 6 months	At 12 months
N	27	27	27
min	0	0	0
p25	2	3	3
p50	3	3	3
p75	3	3	3
max	3	3	3
SPHINCTER SCORES IN NON-SURGICAL GROUP			
	At 3 months	At 6 months	At 12 months
N	12	12	12
min	0	0	0
p25	3	2.5	2
p50	3	3	3
p75	3	3	3
max	3	3	3

xxx. Table 50: mMDI scores in the surgical and non-surgical groups

mMDI SCORES IN SURGICAL GROUP			
	At 3 months	At 6 months	At 12 months
N	27	27	27
min	4	5	5
p25	14	16	18
p50	22	23	23
p75	28	29	29
max	30	30	30
mMDI SCORES IN NON-SURGICAL GROUP			
	At 3 months	At 6 months	At 12 months
N	12	12	12
min	6	6	3
p25	13.5	13.5	14.5
p50	25	25	25
p75	30	29.5	30
max	30	30	30

Letters of Approval

UNIVERSITY OF
KWAZULU-NATAL

03 August 2010

Professor Al Bhigjee
Department of Neurosurgery
IALCH

Dear Professor Bhigjee

PROTOCOL: "Cervical spondylotic myelopathy: a prospective study of outcome after surgery." Student: R Harrichandparsad, student number: 963082468. (Neurosurgery).

The Postgraduate Education Committee ratified the approval of the abovementioned study on 3 August 2010.

Please note:

- The Postgraduate Education Committee must review any changes made to this study.
- The study may not begin without the approval of the Biomedical Research Ethics Committee.

May I take this opportunity to wish the student every success with the study.

Yours sincerely

Professor SJ Botha
Chair Postgraduate Education Committee

CC. Dr R Harrichandparsad

Ms D Ramnarain
Biomedical Research Ethics Committee
Westville Campus

Postgraduate Education Administration,
Medical School Campus

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Founding Campuses: Edgewood Howard College Medical School Pietermaritzburg Westville

DEPARTMENT OF HEALTH

PROVINCE OF KWAZULU-NATAL

INKOSI ALBERT LUTHULI CENTRAL HOSPITAL
OFFICE OF THE MEDICAL MANAGER
800 Bellair Road, Mayville, 4058
Private Bag X03, Mayville, 4058
Tel: 031 240 1059 Fax. 031 240 1050
Email: Ursulanun@ialch.co.za

8 June 2010

Dr RH Harrichandparsad
Dept of Neurosurgery
IALCH

Dear Dr Harrichandparsad

Re: Ref No: BE 244/09: Cervical Spondylotic Myelopathy: A Prospective study of the outcome after surgery.

As per the policy of the Provincial Health Research Committee (PHRC), you are hereby granted permission to conduct the above mentioned research once all relevant documentation has been submitted to PHRC inclusive of Full Ethical Approval.

Kindly note the following.

1. The research should adhere to all policies, procedures, protocols and guidelines of the KwaZulu-Natal Department of Health.
2. Research will only commence once the PHRC has granted approval to the researcher.
3. The researcher must ensure that the Medical Manager is informed before the commencement of the research by means of the approval letter by the chairperson of the PHRC.
4. The Medical Manager expects to be provided feedback on the findings of the research.
5. Kindly submit your research to:

   The Secretariat
   Health Research & Knowledge Management
   330 Langaliballe Street, Pietermaritzburg, 3200
   Private Bag X9501, Pietermaritzburg , 3201
   Tel: 033395-3123, Fax 033394-3782

Yours faithfully

.....

Dr M E L Joshua
Medical Manager

DEPARTMENT OF HEALTH

PROVINCE OF KWAZULU-NATAL

INKOSI ALBERT LUTHULI CENTRAL HOSPITAL

OFFICE OF THE MEDICAL MANAGER
800 Bellair Road, Mayville, 4058
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Tel.: 031 240 1059 Fax. 031 240 1050
Email. ursulanun@ialch.co.za

Reference: BE244/09
Enquiries: Dr M E L Joshua

Dear Dr Harrichandparsad

RE: PERMISSION TO CONDUCT RESEARCH AT IALCH

I have pleasure in informing you that permission has been granted to you by the Medical Manager to conduct research on

Kindly take note of the following information before you continue:

1. Please ensure that you adhere to all the policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. This research will only commence once this office has received confirmation from the Provincial Health Research Committee in the KZN Department of Health.
3. Kindly ensure that this office is informed before you commence your research.
4. The hospital will not provide any resources for this research.
5. You will be expected to provide feedback once your research is complete to the Medical Manager.

Yours faithfully

.....
Dr M E L Joshua
Medical Manager

HEALTH
KwaZulu-Natal

Health Research & Knowledge Management sub-component
10 – 103 Natalia Building, 330 Langalibalele Street
Private Bag x9051
Pietermaritzburg
3200
Tel.: 033 – 3953189
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Email.: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

Reference : HRKM165/10
Enquiries : Mrs G Khumalo
Telephone : 033 – 3953189

25 October 2010

Dear Dr R Harrichandparsad

Subject: Approval of a Research Proposal

1. The research proposal titled '**Cervical Spondylotic Myelopathy: A Prospective study of outcome after surgery'** was reviewed by the KwaZulu-Natal Department of Health.

   The proposal is hereby **approved** for research to be undertaken at **Inkosi Albert Luthuli Central Hospital**

2. You are requested to take note of the following:
   a. Make the necessary arrangement with the identified facility before commencing with your research project.
   b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.

3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Mrs G Khumalo on 033-3953189.

Yours Sincerely

Mrs E Snyman
Interim Chairperson, Health Research Committee
KwaZulu-Natal Department of Health
Date: 28/10/2010

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

30 January 2013

Dr RH Harrichandparsad
Dept of Neurosurgery, IALCH
Private Bag X03
Mayville
4058

PROTOCOL: Cervical spondylotic myelopathy:a prospective study of the outcome after surgery.
REF: BE244/09

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 20 October 2009.

The study was provisionally approved pending appropriate responses to queries raised. Your responses dated 23 June 2013 and personal discussion with BREC Chair and Deputy Chair dated 24 January refers.

The study is approved with effect from 25 October 2010. The lapse is taken as a good faith error.

Approvals are valid for one year. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be **RATIFIED** by a full Committee at its next meeting taking place on **12 February 2013.**

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

Professor D.R Wassenaar
Chair: Biomedical Research Ethics Committee

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23 December 2013

Dr RH Harrichandparsad
Dept of Neurosurgery, IALCH
Private Bag X03
Mayville
4058

PROTOCOL: Cervical spondylotic myelopathy:a prospective study of the outcome after surgery. REF: BE244/09

RECERTIFICATION APPLICATION APPROVAL NOTICE

Approved: 25 October 2013
Expiration of Ethical Approval: 24 October 2014

I wish to advise you that your application for Recertification dated 17 December 2013 for the above protocol has been noted and approved by a sub-committee of the Biomedical Research Ethics Committee (BREC) for another approval period. The start and end dates of this period are indicated above.

If any modifications or adverse events occur in the project before your next scheduled review, you must submit them to BREC for review. Except in emergency situations, no change to the protocol may be implemented until you have received written BREC approval for the change.

This approval will be **ratified** by a full Committee at its next meeting taking place on 11 **February 2014.**

Yours sincerely

Mrs A Marimuthu
Senior Administrator: Biomedical Research Ethics

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