PATIENT-REPORTED OUTCOMES POST-DISCECTOMY FOR LUMBAR DISC HERNIATION AT HOSPITALS IN ELDORET TOWN, KENYA.

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DECLARATION

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DISCLOSURE

The researcher did not receive any outside funding or grants in support for this study. Neither he nor a member of his immediate family received payments or other benefits, or commitment or agreement to provide such benefits from a commercial entity.

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DEDICATION

The author dedicates this research work to his loving family wife and children for their endless support and prayers.

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I would like to appreciate all the patients in this study.

ABBREVIATIONS AND ACRONYMS USED

CT : COMPUTED TOMOGRAPHY.

IP NO : INPATIENT NUMBER.

IREC : INSTITUTIONAL RESEARCH ETHIC COMMITTEE.

LBP : LOW BACK PAIN

LDH : LUMBAR DISC HERNIATION

MMED : MASTERS IN MEDICINE

MRI : MAGNETIC RESONANCE IMAGING.

MTRH : MOI TEACHING AND REFERRAL HOSPITAL.

NSAIDs : NON STEROIDAL ANTI-INFLAMMATORY DRUGS

POST-OP **:** POST OPERATIVE

PRE-OP : PRE OPERATIVE

ODI : OSWESTRY DISABILITY INDEX

OPD : OUT-PATIENT DEPARTMENT.

QUE : QUEBEC BACK PAIN DISABILITY SCALE

SPORT : THE SPINE PATIENT OUTCOMES RESEARCH TRIAL

SPSS : STATISTICAL PACKAGES FOR SOCIAL SCIENCES.

VAS : VISUAL ANALOGUE SCALE

ABSTRACT

BACKGROUND: Lumbar disc herniation can be managed operatively by discectomy, which significantly reduces the pain in these patients. The outcomes of these surgeries have been measured using physician based scores but it is important to understand patients' own perspective using a patient-reported outcome score thus enabling physicians to better manage patient expectations.

OBJECTIVE: To describe patient-reported outcome scores following discectomy for lumbar disc herniation using the Oswetry disability index (ODI) and Visual analogue scale (VAS) tools at hospitals in Eldoret town.

METHODS: A descriptive prospective study was carried out on patients treated at Moi Teaching and Referral hospital, Reale Hospital and St. Luke Orthopedic Hospital in Eldoret town for lumbar disc herniation with discectomy. Fifty-eight patients were recruited in the study. Data was collected between January 2016 and March 2017 using patient administered questionnaire. A baseline ODI and VAS scores were taken pre-operatively and then at 6 and 12 weeks post operatively, and then compared with the score at first contact. At 12 weeks, patients were to state if they were satisfied or not with their outcome. Data was analyzed using STATA version 13 at 95% confidence level.

RESULTS: The mean age of 42 ±8.6 years with a range of 18-58 years. There were 30 males and 28 females. Up to 86.2% of the herniation were classified as posterolateral herniation by site while the extruded type was diagnosed in 48.3% of the patients. The most common level of surgery was L4/L5 disc (25.9%) for single level while for two level surgery was L4/L5 and L5/S1 discs (44.8%). The baseline mean ODI score was 69.2(±11.1) while at 6 and 12 weeks it was at 39.4(±13.1) and 23.9(±10.4) respectively. The change in mean ODI (-45.1) at 12 weeks was statistically significant ($p < 0.001$). The baseline mean VAS score for back and leg pain were 7.3(±1.5) and 5.3(±2.1) respectively. At 6 weeks, the VAS score for back and leg pain was 3.8(±1.3) and 2.6(±1.7), while at 12 weeks it was 2.3 (±1.1) and 1.3(±1.1) respectively. The change in back pain and leg pain mean at 12 weeks of -59.7 and -41.8 respectively was significant ($p < 0.001$). There was no association between age, gender, type of herniation and surgery level to the change in ODI score or VAS scores for back and leg. Eighty-six percent of patients were satisfied with the outcome of their surgery despite residual pain.

CONCLUSION: There was significant change (reduction) in the ODI score and the VAS score for back and leg pains after discectomy for patients with lumbar disc herniation.

RECOMMENDATION: Discectomy should be encouraged as it is effective in reduction of pain in patients despite residual pain. Further studies with longer duration of follow up for these patients.

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CHAPTER ONE

1.0 INTRODUCTION

1.1 Background of the study

Disc herniation is one of the common causes of low back pain with herniation signs and symptoms seen in all age groups but have a peak incidence in patients between the ages of 35 and 45 years (Junaid, Rashid, Afsheen, Bukhari and Kulsoom, 2016). Disc herniation can occur in any disc in the spine, but the two most common forms are lumbar disc herniation and cervical disc herniation with the lumbar disc herniation type being the most common because of its weight load together with a wide range of motion. In the lumbar spine, it usually occurs at L4/L5, compressing the L5 nerve root, or L5/S1, compressing the S1 nerve root (Amin, Andrade and Neuman, 2017; Duckworth and Blundell, 2010).

Patients present typically with a history of lifting heavy objects then they suddenly experience severe low back pain with radiation to the foot (radiation pain). This is seen usually after a period of weeks of the patient complaining of low back pain which is an indication of nerve compression by the herniated disc.

Straight leg raise test on the affected side is reduced with positive tension signs (exacerbation of leg symptoms on dorsiflexion at the ankle joint) (Amin et al., 2017). Pain radiating to the foot is often severe but in most cases settles in a period of 2 – 3 months (Gregory, Seto, Wortley and Shugart, 2008).

Various diagnostic modalities are used for the diagnosis of lumbar disc herniation. Magnetic resonance imaging (MRI) is used routinely to confirm the diagnosis (Berg et al., 2011).

Many interventions have been employed in the treatment of disc herniation which can either be operative or non-operative modalities. Majority of the patients recover with non-operative treatment, and very few patients will require operative care. There is no single treatment option that provides definitive and long-term improvement in chronic low back pain for all patients. Some of the non-operative options include epidural steroid injections (ESI), nerve root blocks and facet joint injections (Benzakour, Igoumenou, Mavrogenis and Benzakour, 2018). The goal of these treatments is to reduce pain, improve function and to minimize the need for operative management in these patients. With sufficient regular analgesia and avoiding prolonged bed rest, most patients often get relief. Patients are however, referred for operative intervention if symptoms are worsening and cannot be controlled with oral analgesia or if the symptoms are not abating after 6 – 8 weeks despite non-operative treatment being administered (Benzakour et al., 2018; Gregory et al., 2008).

Lumbar disc herniation surgery is usually performed on an elective basis in patients whom conservative therapies have failed to offer significant improvement of leg and back pain and disability. Lumbar discectomy will significantly improve the leg pain in up to 93% of patients (Sedighi and Haghnegahdar, 2014). In the western countries this is treated in an outpatient setting and patients are back to work usually in 4 – 8 weeks. Radicular pain of the upper limb is usually managed with anterior cervical discectomy and fusion, again with very good outcomes (Duckworth and Blundell, 2010).

Co morbidity is significantly associated with a higher incidence of complications arising during spine surgery and poorer treatment outcome (Mannion, Fekete, et al., 2014).

Various studies on the outcomes of lumbar disc herniation surgery have been reported. The Spine Patient Outcomes Research Trial (SPORT) findings are consistent with other studies on outcomes of surgeries, that have shown that operative management for disc herniation produces better outcomes than non-operative treatment (Weinstein et al., 2008). However, prior studies have not taken into account improvements post-surgery from the patient's perspective (Weinstein et al., 2008). Measurement of the patient's reported outcomes apart from being used to measure the outcomes of an intervention can also give an indication of the quality of care after the specific intervention has been applied. It is a valuable tool for clinician also to mark the progress of their patients in managing their expectations and outcomes. With the help of visual analogue scale and Oswestry disability index (ODI), patient's reported outcome can be measured.

VAS is one way in which pain can be measured subjectively in a scale rated 0-10, and it is usually used in the clinical practice for assessment of pain after operative and/or non-operative interventions. The intensity of leg pain and low-back pain can be recorded with use of a 100-mm scale, with a score of 0 indicating no pain and a score of 100 indicating the worst conceivable pain.

The Oswestry Disability Index (also known as Oswestry Low Back Pain Disability Questionnaire) is a crucial tool that is utilized by clinicians to measure a patient's functional disability. The ODI is a condition-specific measure of disability which is used extensively in studies of low back pain, and has demonstrated validity and reliability in this context (Fairbank and Pynsent, 2000).

The Oswestry Disability Index (ODI) as a self-administered tool, is divided into ten sections to assess limitations of daily living activities. Each section is scored on a 0–5 scale, with 0 representing normal function and 5 representing the greatest disability.

The index is then expressed as a percentage by calculating sum scores divided by the total possible score and multiplied by 100 (Fairbank and Pynsent, 2000). A higher score indicates a higher level of physical disability (Mehra, Baker, Disney and Pynsent, 2008).

1.2 Problem Statement

A good number of spinal surgeries are done every year. The 2014 data from the hospital records of Moi Teaching and Referral Hospital (MTRH), St. Luke Orthopaedic and Trauma Hospital (SLTH) and Reale Hospital shows that the number of patients with disc herniation referred for discectomy ranged from 4-6 per month giving a total of approximately 48-72 cases per year. MTRH in the year 2014 had a total of 15 patients while SLTH operated on 55 patients while Reale hospital operated on a total of 22 patients in the same year. A few studies have described patient's reported outcome scores but most of these studies are mainly in the western countries. Patient's VAS score for pain recorded significant improvement of up to 90% in the immediate post-operative period (Sedighi and Haghnegahdar, 2014).

1.3 Justification

Our population earn their daily living by carrying out strenuous activities that involve lifting of heavy loads. The professionals also sit for prolonged period at their offices as well as living a sedentary lifestyle. All these predisposes the population to increased risk of disc prolapse thus the need to study the outcomes of patients treated at our hospitals.

Generally, patients are becoming more aware of their health care needs and in order to better manage patient's expectation post-surgery, it has become necessary to measure the outcome scores from the patient's perspective. Worldwide, measuring health care quality among healthcare providers and consumers is becoming prevalent and

patient's reported outcome scores are one of the important indicators of health care quality.

Traditionally outcome scores have been measured based on professional practice standards relying on radiological or biochemical changes or physician own rating in reference to the patient's functional outcome. Using various tools, it is possible to measure and assess whether there was success of the intervention applied, if the patient is able to resume work and other activities. When evaluating outcome of treatment options available to the patient, patient's reported outcome scores have been used as an objective outcome instrument. Managing patient's expectation is a good measure of the outcome of surgery (Mannion, Mutter, et al., 2014).

By measuring patient's outcome scores post discectomy, this study aims to provide clinicians with data on the outcome scores of the discectomy intervention from the patient's own perspective and this would help clinicians better meet the needs and expectations of patients in the pre-surgery, during surgery and in the recovery period, post-surgery. Besides being a quality of care indicator, immediate postoperative patient outcome scores may bring a new insight into clinical practice, as a predictor of self-perceived health status after surgery. It is also a critical component of performance improvement and efficiency of our clinical services as well as enable the clinicians able to counsel their patients in the pre-operative period.

In their study, Cramm, Strating and Nieboer, (2012) concluded that patients who report better outcome scores and had higher satisfaction levels in the post-operative period, generally have a better quality of life.

1.4 Research questions

What is the patient reported outcome scores following discectomy for lumbar disc herniation at hospitals in Eldoret town using the ODI and VAS tools?

1.5 Objectives

1.5.1 Broad objective

To describe patient reported outcome scores following discectomy for lumbar disc herniation at hospitals in Eldoret town using the ODI and VAS tools.

1.5.2 Specific objectives

1. To determine the level of Oswestry disability index score post discectomy at 6 and 12 weeks.
2. To determine the VAS (low back pain) scores post discectomy at 6 and 12 weeks.
3. To determine the VAS (leg pain) scores post discectomy at 6 and 12 weeks.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Overview

2.1.1 Anatomy of the spine

The spine consists of 7 cervical, 12 thoracic and 5 lumbar vertebrae with the sacrum and coccyx. Each vertebra is composed of a vertebral body, pedicles, laminae, transverse processes and a spinous process. There are intervertebral discs that lie between each vertebra which allow movement anteriorly and, posteriorly at the two facet joints (Duckworth and Blundell, 2010).

Figure 1: Diagram of lumbar spine

Adapted from Atlas of human anatomy, 6th edition (Netter, 2017).

Intervertebral disc is composed of an outer annulus fibrosus and inner nucleus pulposus (Benzakour et al., 2018).

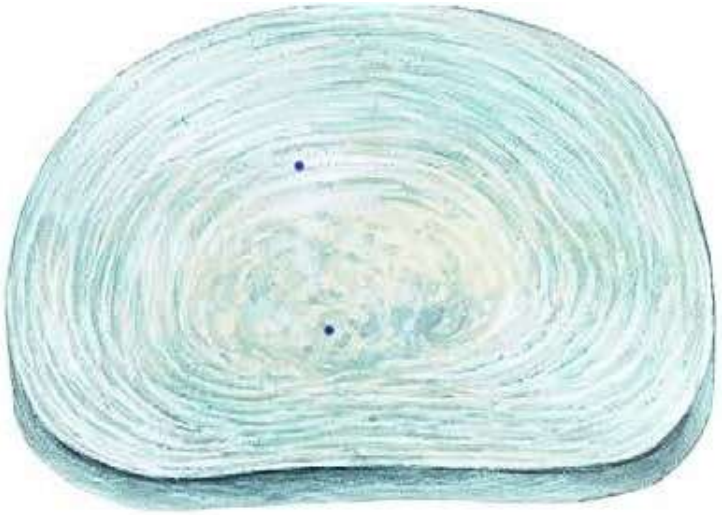

Figure 2: Intervertebral disc

Adapted from Atlas of human anatomy, 6th edition (Netter, 2017).

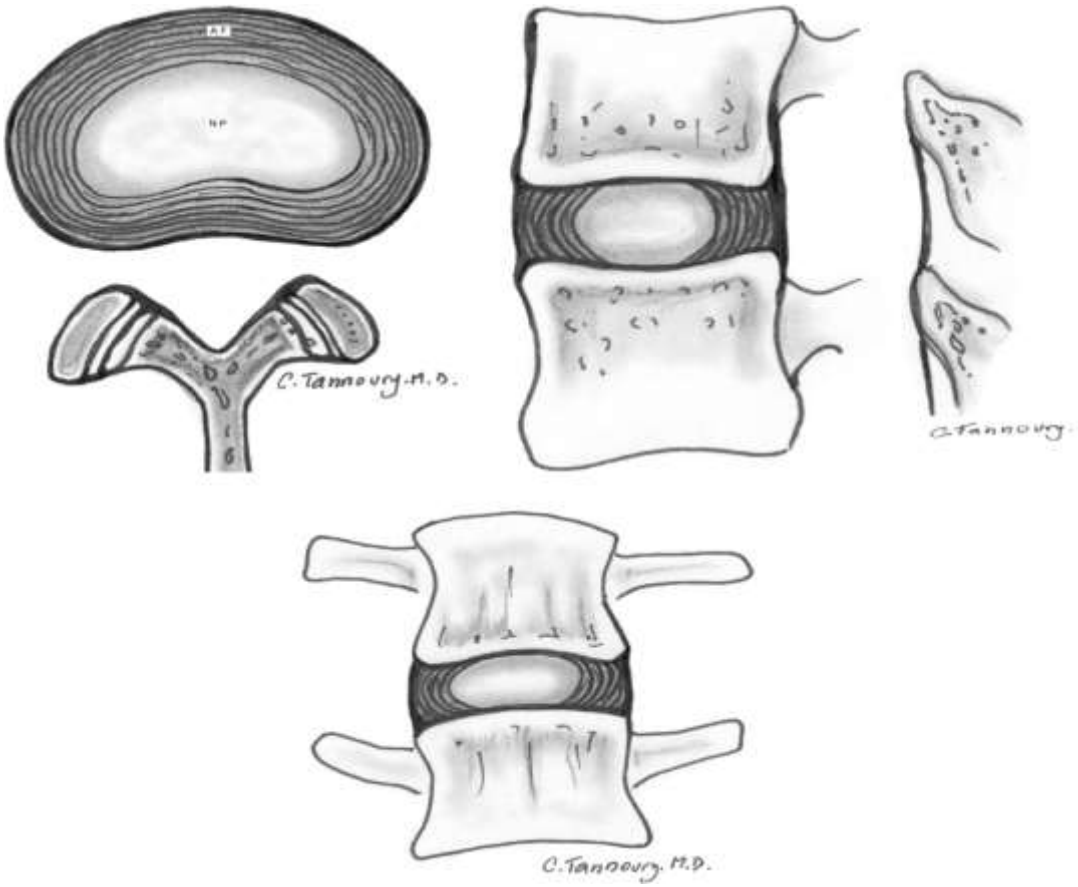

Fig 3: Normal lumbar disc. (Top Left) Axial, (Top Right) sagittal, and (Bottom) coronal images demonstrating the normal disc. (Adapted from Fardon et al., 2014)

Spinal disc herniation is a condition whereby there is damage to the outer, fibrous ring of an intervertebral disc hence the soft, central portion protrudes out beyond the torn outer ring of the spine compressing on the nerve roots (Benzakour et al., 2018; Ma et al., 2013). According to the recommendations of the combined task forces of the North American Spine Society, the American Society of Spine Radiology and the American Society of Neuroradiology, "a herniated disc is the general term used to denote displacement of disc material and localized displacement of nucleus, cartilage, fragmented apophyseal bone, or fragmented annular tissue beyond the intervertebral disc space" (Fardon et al., 2014).

Disc herniation is usually as a result of aging degeneration of the annulus fibrosus, although other etiological factors include trauma, lifting injuries, or straining have been implicated (Ma et al., 2013). The repetitive loading on the disc by bending, twisting and lifting causes abnormal pressures on the disc which can injure the annulus. Tears are almost always in the postero-lateral region because the presence of posterior longitudinal ligament in the spinal canal prevents posterior tears (Lurie et al., 2014).

2.1.2 Types of Disc Herniation

Disc herniation can occur in any disc in the spine, but the two most common forms are lumbar disc herniation and cervical disc herniation with the lumbar disc herniation type being the most prevalent form seen by clinicians (Azimi, et al., 2016).

2.1.2.1 Lumbar disc herniation

Lumbar disc herniation occurs in the lower back, most commonly between the fourth and fifth lumbar vertebral bodies or between the fifth and the sacrum spines. Patients' symptoms include pain in the lower back, buttocks, thigh, anal/genital region and the

pain may radiate to the feet and/or toes. The sciatic nerve is the nerve most commonly affected, causing symptoms of sciatica (Ma et al., 2013). The femoral nerve may also be affected and cause the patient to complain of numbness, tingling sensation throughout one or both legs and even feet or even a burning sensation in the hips and legs (Junaid et al., 2016).

The commonest affected sites are the lower lumbar discs at L4-L5/ L5-S1 levels (Ma et al., 2013). In the SPORT study, of all the patients who had been assigned to the surgical group, 7% had herniation of the L2/L3 and L3/L4 disc space while 34% and 59% had disc prolapse at L4/L5 and L5/S1 discs respectively (Weinstein, Tosteson, Lurie et al., 2006). While comparing the long term effects of various surgical options for patient with lumbar disc herniation, Dohrmann and Mansour, (2015) observed that a total of 95% of the recruited patients had a disc prolapse at either L4/L5 or L5/S1 while only 5% had a prolapse at L1/L2, L2/L3 and L3/L4 disc levels. In the study by Junaid et al., (2016), which reported on all patients with disc prolapse at two centers, for patients who had single level disc prolapse, the commonest level involved was L5/S1 (34.6%) followed by L4/L5 (33.4%). For two level disc involvement, L4/L5 and L5/S1 were the commonest levels involved (19.5%) followed by L3/L4 and L4/L5 (4.7%). Only 2.7% of the patients had a three level disc prolapse at L3/L4, L4/L5 and L5/S1.

2.1.2.2 Cervical disc herniation

Except for the upper 2 intervertebral spaces, cervical disc herniation may occur in any of the other intervertebral discs. Herniated disc may cause nerve symptoms of weakness, numbness, tingling sensation and pain radiating into the arm (Duckworth and Blundell, 2010).

2.1.2.3 Intradural disc herniation

Intradural disc herniation is a rare form of disc herniation with an incidence of 0.26-0.30% (Jain, Sundar, Sharma, Goel and Gupta, 2012). Preoperative imaging though helpful, one may require intra-operative findings to confirm this diagnosis (Ducati, Silva, Brandão, Romero and Zanini, 2012).

2.1.3 Epidemiology

Disc herniation can occur in any disc in the spine, but the two most common forms are lumbar disc herniation and cervical disc herniation with the lumbar disc herniation type being the most common form seen, causing lower back pain (lumbago) and often leg pain (sciatica) (Jacobs et al., 2011). The radicular pain radiates below the knee and to the feet and toes and this is due to the herniated disc compressing the nerve root (Jacobs et al., 2011; Valat, Genevay, Marty, Rozenberg and Koes, 2010).

The following spine vertebral levels have no discs and are therefore cannot have a disc herniation:

- the upper two cervical intervertebral spaces,
- the sacrum, and
- The coccyx.

Most disc herniation occurs when a person is in their thirties or forties when the nucleus pulposus is still a gelatin-like substance (Schoenfeld et al., 2010; Sedighi and Haghnegahdar, 2014). As the person ages, the nucleus pulposus changes and the risk of herniation is greatly reduced (Benzakour et al., 2018). In the SPORT study, the mean age for the patients recruited in the study was 42 years of with a standard deviation of 11 years (Weinstein et al., 2006). Similar findings of the mean ages were found in other studies (Aichmair et al., 2014; Almeida, Poletto, Milano, Leal and

Ramina, 2007). The study by Azimi, Benzel and Montazeri, (2016) had a slightly older population whose mean was 49.6 ±9.3 years. This was also similar to the study by Porchet et al., (2009) which also had a mean of 48 ±14.1 years. In the study by Siddiq, Ali, Jan and Dil, (2011), the range of the patients studied was 20- 65 years old.

After the ages of 50 or 60, spondylosis and spinal stenosis are the most likely causes of low back pain or leg pain. With aging the incidences of herniation generally decreases (Ma et al., 2013). This is attributed to the decrease in pressures exerted on the disc despite disc generally aging, losing moisture hence the strength and resilience as well as the size of the nucleus becomes small.

Generally, males have a slightly higher incidence than females (Jordan, Konstantinou, and Dowd, 2011; Junaid et al., 2016; Peul et al., 2007; Weinstein et al., 2008). But in one series, Almeida et al., (2007) observed a male to female ratio of 2:3 while the study by Azimi et al., (2016) reported a slight female preponderance (52%). In the Porchet et al., (2009) study, they observed a male to female ratio of 2:1 while in another study, the male to female ratio was 3:1 (Siddiq et al., 2011).

2.1.4 Diagnosis

2.1.4.1 Clinical diagnosis

Diagnosis of disc herniation is made by a clinician based on the history of symptoms and physical examination. Some of the signs and symptoms in patients presenting with lumbar disc herniation include low back pain, sciatica, sensory abnormalities in the lower limbs and weakness in the lumbosacral dermatomes (Amin et al., 2017; Junaid et al., 2016). In the physical examination, the straight leg raise may be positive and this test is regarded as one of the sensitive test for lumbar disc herniation (Amin

et al., 2017; Gregory et al., 2008). Up to 71 % of patients have a positive straight leg raise test (Peul et al., 2007).

Most patients would complain of either having a low back pain with radiation pains to the lower limbs. In the SPORT study all recruited patients had radiculopathy symptoms. In the Aichmair et al., (2014) and Azimi et al., (2016) studies, all their patients reported both lower back pains and radiculopathy symptoms.

2.1.4.2 Imaging

X-ray: this is considered to be first line imaging modality when treating patients with low back pain. Plain radiographs are limited in their ability to image soft tissues but can be used to confirm or exclude other causes of low back pain such as tumors, infections and fractures and enable the clinician to raise his/her index of suspicion.

Computed tomography scan (CT scan): can be used to show the shape and size of the spinal canal, its contents and the structures around it including soft tissues. Visual confirmation of a disc herniation can be difficult to demonstrate with a CT scan.

Magnetic resonance imaging (MRI): this is considered a gold standard in the diagnosis of disc herniation and has a diagnostic accuracy of 97% (Amin, Andrade and Neuman, 2017). An MRI usually provides the most conclusive evidence for diagnosis of a disc herniation. The T2-weighted images allow for clear visualization of protruded disc material in the spinal canal (Berg et al., 2011).

By site, lumbar disc herniation can either be classified as central, postero-lateral/paramedian/paracentral or far/extreme lateral. The posterolateral herniation is the commonest location for lumbar disc herniation (Benzakour et al., 2018; Lurie et

al., 2014). In the SPORT study, a total of 78% of the patients recruited into the study had a posterolateral herniation (Weinstein et al., 2006).

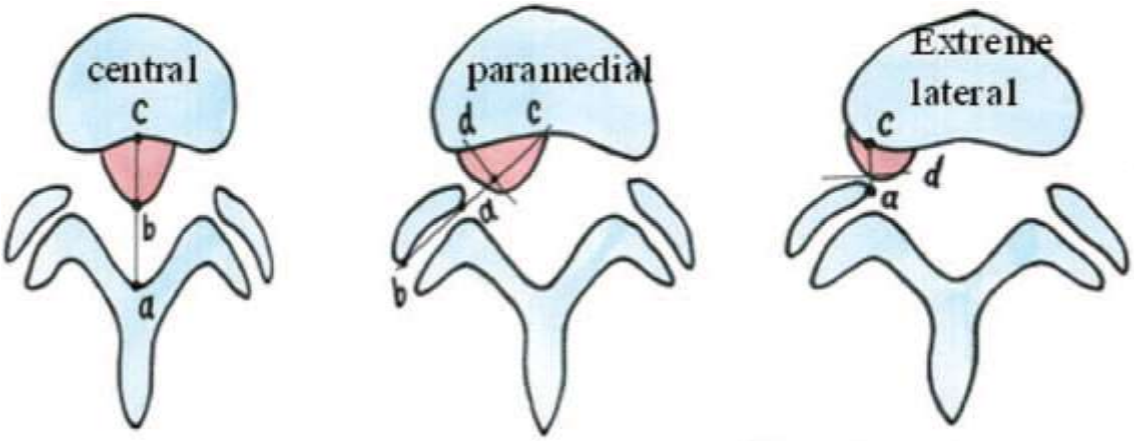

Figure 4: Classification of herniation types

Adapted from (Hao, Duan, Liu, Liu, & Wang, 2017)

Using MRI, the herniated disc can be classified as either being protruded, extruded or sequestered type based on the shape of the herniated material (Benzakour et al., 2018; Fardon et al., 2014). In the SPORT study, on recruitment, all patients had an MRI done and classified as either protruding type (25%) or extruded type (67%) or sequestered type (7%) (Weinstein et al., 2006). The study by Azimi et al., (2016) observed sequestration type (29%), extrusion type (38%), sub ligamentous type (24%) and protrusion (9%). In both these studies, only single level disc surgery was studied.

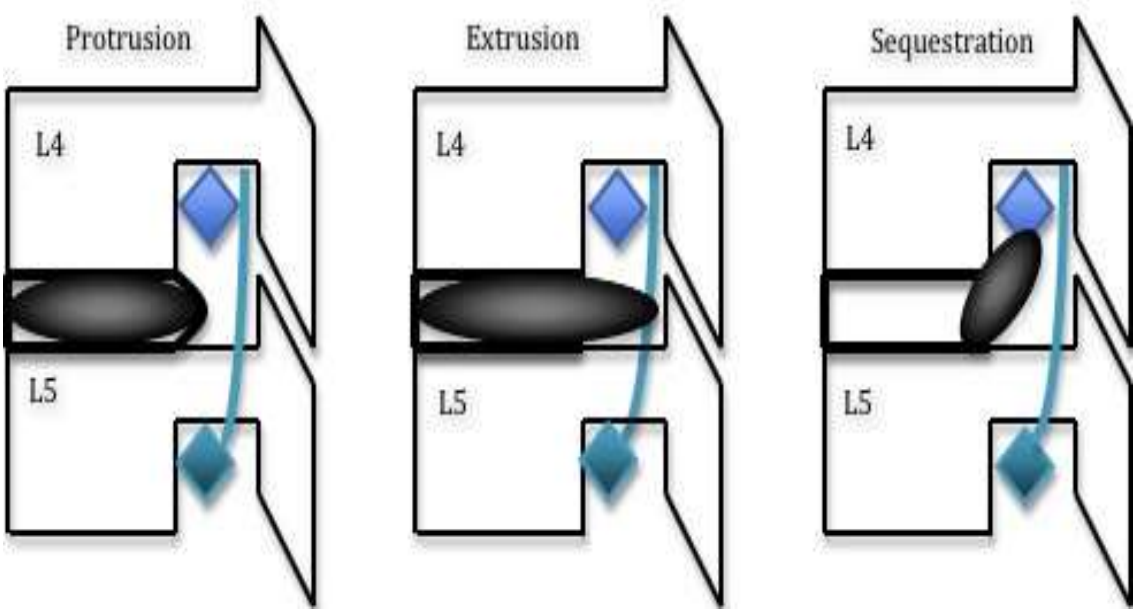

Figure 5: Pictorial classification of lumbar herniation types. Sagittal diagram of the L4-L5 disc segment. Blue diamond = L4 nerve root. Turquoise diamond = L5 nerve root (adapted from https://www.orthopaedisone.com/display/MSKMed/lumbar+Disc+Herniations)

2.1.5 Treatment Modalities

2.1.5.1 Non operative

In majority of cases, spinal disc herniation patients are managed non-operatively. Initial treatment usually consists of pain medications such as non-steroidal anti-inflammatory drugs (NSAIDs) (Benzakour et al., 2018) This would alleviate the pain and allow the patient to begin exercises and routine work early (Gregory et al., 2008). Epidural steroid injections with or without local anesthetics provide an improvement in those with low back pain and sciatica in up to 60-70% of the patients with lumbar disc herniation especially when non-operative management have failed (Manchikanti, Singh, Cash, Pampati and Falco, 2014)

Majority of the patients suffering from sciatica due to lumbar disc herniation do respond to non-operative management (Gregory et al 2008). Ekstrude, (2008) presented two cases of patients who had large extruded lumbar disc herniation that

regressed spontaneously with remission of their symptoms without any operative treatment.

However, Pearson et al., (2008) noted that for patients with low back pain due to herniated disc, outcome was much better for those who had been managed operatively than those managed non-operatively. Post-operative, most of these patients did not report low back pain although this benefit afforded by surgery would diminish over time (Jacobs et al., 2011).

2.1.5.2 Operative

Discectomy, which is the partial removal of a disc that is protruding, can provide pain relief sooner than non-surgical treatments. Lumbar discectomy is one of the most common surgical procedure performed in the US for patients suffering from back pain and sciatica, with over 300,000 discectomy procedures done yearly (Atlas et al., 1996; Weinstein et al., 2006). Mixter and Barr (1964) described the standard discectomy as a surgical management to neural compression caused by lumbar disc herniation in the year 1934 while Caspar, (1977) and Yasargil, (1977) described the micro-discectomy technique in the year 1977. This involved the use of an operating microscope.

Disc herniation surgery is commonly indicated in those patients whom non-operative therapies have failed to produce significant relief of leg pain and disability in patients with herniated disc (Berjano, Pejrona and Damilano, 2013). Elective lumbar disc herniation is usually scheduled 6 weeks after failed conservative management (Porchet et al., 2009). There is significant improvement in disability (83%) in the first 6 weeks as compared to the duration between 6 weeks and one year post-operatively (Häkkinen et al., 2006).

The presence of cauda equina syndrome, which is characterized by incontinence, weakness and genital numbness is considered an emergency requiring immediate attention (Korse, Jacobs, Elzevier and Vleggeert-Lankamp, 2013). In the study by Siddiq et al., (2011), they reported 3 cases of patients with cauda equine who had disc prolapse.

A good outcome in spinal surgery is achieving the patients' expectations with the results, pain relief, the alleviation of disability and social reintegration. The therapeutic role of surgery for sciatica is to provide faster recovery and relief of back and leg pain (Toyone, Tanaka, Kato and Kaneyama, 2004). The SPORT study, a prospective multicenter study, showed improved clinical outcomes (pain, physical function, and disability) for patients who had surgery for lumbar disc herniation relative to non-operative treatment (Weinstein et al., 2008).

Discectomy apart from reducing disability and pain, it also improves depressive symptoms and overall quality of life (Tharin, Mayer and Krishnaney, 2012). Other studies have shown significant improvement for patients with relief of pain and disability (Asch et al., 2002; Fizikel, 2013; Suri et al., 2011). There is no relationship between level of pain control and patient satisfaction as most patients were either satisfied or very satisfied with their outcomes despite their pain scores post-operatively (Phillips, Gift, Gelot, Duong and Tapp, 2013).

There are benefits to operative management in terms of earnings and missed workdays and as long as the operation is done in an outpatient setting (Koenig, Dall, Gu, Saavoss, and Schafer, 2014).

Patients who have a higher level of back pain in the pre-operative stage seem to have poor outcomes in the post-surgery period and therefore the need to assess the patient's

complaints and pain levels pre-operatively to better inform these patients on the possible outcome (Kleinstueck et al., 2011). This may help to improve patient's outcomes scores by altering their expectations. In other studies patient's expectation in the pre-surgery period had no relationship with the outcome of the operative management (Licina, Johnston, Ewing, and Pearcy, 2012).

Patients who had lumbar disc prolapse and have been operated on, show a significant decrease in leg pain (within a month) and this decrease continues in the subsequent periods post-surgery as measured with VAS (Porchet et al., 2009). There is also a reduction in the back pain in the post-operative period (Toyone et al., 2004).

2.1.5.3: The Surgery

Patients lie on their back on the operative table and are given anesthesia. then are rolled onto their stomach with the chest and sides supported by pillows. The area where the incision will be made is cleansed and prepped.

In an open discectomy, a skin incision is made down the middle of your back over the affected vertebrae The length of the incision depends on how many discectomies will be performed. A single-level surgery incision is about 1 to 2 inches long. The back muscles are retracted on one side to expose the bony vertebra. An X-ray is taken to verify the correct vertebra.

A small opening of the lamina, above and below the spinal nerve, is made with a drill or bone-biting tools. A laminetomy is done on one (unilateral) or both (bilateral) sides, or on multiple vertebrae levels.

With the lamina removed, the surgeon gently retracts the protective sac of the nerve root. The surgeon looks for the herniated disc. Only the ruptured portion of the disc is removed to decompress the spinal nerve root. The entire disc is not removed. Bone

spurs or a synovial cyst that may press on the nerve root are also removed. The retractor holding the muscles is removed. The muscle and skin incisions are sewn together with sutures or staples. Steri-Strips are placed across the incision.

2.2 Outcome

2.2.1 Introduction

Patient's outcome score post discectomy is one of the important tools for measuring the quality of health care in spinal procedures. Patient's expectation post-operative may not correlate with functional outcomes and it is important to document this in the post-operative period. Patients with higher expectations seem to have better outcome in the post operation period (Yee, Adjei, Do, Ford, and Finkelstein, 2008).

The outcome scores measure the improvements in symptomatology as per patients own perspective. This is achieved by asking the patients to compare their health before surgery to their current status (Lloyd, Jenkinson, Hadi, Gibbons, and Fitzpatrick, 2014). Patient's own assessments of the treatment they receive greatly reflect the outcome that is important to them and by asking patients to assess the outcome of their treatment has face validity. Patient's report of their own health in the pre-operative period maybe an important factor in the post-operative period predictor of symptom severity, walking capacity and the ability to resume work (Yee et al., 2008).

Sedighi and Haghnegahdar, (2014) in their study evaluated patients' subjective satisfaction post discectomy and reported a satisfaction rate of 94% irrespective of "age, sex, level of education, preoperative VAS for back, preoperative VAS for radicular pain, return to previous job, or level of herniation". There was a reduction in radicular pain of up to 93.3% using the VAS score in the post-surgical period. In the same study, it was observed that patients with upper lumbar disc herniation (L1-

L2, L2-L3) had better outcomes than those with lower lumbar disc herniation (L3-L4). In comparison, Lurie et al., (2014) observed a significant improvement in patients managed conservatively with 73% of the patients reporting satisfaction with their care after eight years. In other studies, pre-operative disability and female gender were found to have a higher negative correlation with surgical outcome (Saberi & Isfahani, 2008).

Females have higher levels of disability and back pain in the pre-operative period compared to males patients but this difference was not observed in the post-operative period in both genders (Häkkinen, Kautiainen, Järvenpää, Arkela-Kautiainen, and Ylinen, 2006). There was also a significant drop in the ODI level in the post-operative levels compared to the pre-operative levels in both genders. This change was more significant in the initial 6 weeks' post-operative compared to the change in the period between 6 weeks and one-year post-operative. The early post-operative outcome therefore appears to be a reliable indicator of the overall post-operative outcome at subsequent follow ups (Häkkinen et al., 2006).

2.2.2 Oswestry Disability Index

The Oswestry Disability Index (ODI) also known as the Oswestry Low Back Pain Disability Questionnaire is a crucial tool that is used by clinicians to evaluate a patient's functional disability. The ODI is a condition-specific measure of disability which is used extensively in studies of low back pain, and has demonstrated validity and reliability in this context (Fairbank and Pynsent, 2000).

The measurement of disability is an important part of low back pain's assessment and management. In low back pain patients, Oswestry disability index (ODI) is widely used and has been found to be a reliable and valid method for assessment of disability (Fairbank & Pynsent, 2000). Vianin, (2008) observes that "the ODI is a valid,

reliable, and responsive condition-specific assessment tool that has withstood the test of time and scrutiny". It is also very sensitive to small changes in the parameters (Kim, Oh, Yoon, Park, and Park, 2012).

ODI has been found to be the best for those patients with persistent disability as compared to the Roland-Morris Disability Questionnaire (Fairbank and Pynsent, 2000).

While comparing between the ODI and Quebec back pain disability scale (QUE), ODI was found to be preferable, reliable and more responsive to changes in scores compared to the QUE (Fritz and Irrgang, 2001).

The ODI is divided into ten sections to assess the level of pain and level of interference with several physical activities including sleeping, self-care, sex life, social life and travelling (Maughan & Lewis, 2010). Scores are associated with degree of disability ranging from minimal to bed bound. The scoring system includes a description of degrees of disability relating to scores on the ODI (Fairbank and Pynsent, 2000).

The Oswestry Disability index, as a self-administered tool requires as little as 15 minutes to complete and a relatively short time to score is designed to assess limitations of various activities of daily living. Each section is scored on a 0–5 scale, with 0 representing normal function and 5 representing the greatest disability. The index is then expressed as a percentage by calculating sum scores divided by the total possible score and multiplied by 100. A higher score indicates a higher level of physical disability (Mehra et al., 2008). When the participant fails to answer any section of the questionnaire the total score is reduced by 5. If a participant marks more than one statement in one section, the highest scoring statement would be recorded as a true indication of disability (Mehra et al., 2008).

Table 1: Interpretation of the ODI scores

Scores	Interpretation
0 – 20	Minimal disability
21 – 40	Moderate disability
41 – 60	Severe Disability
61 – 80	Crippled
81 – 100	Bed Bound or Exaggerated

Adapted from (Fairbank and Pynsent, 2000).

In the post-surgical duration following discectomy, there was a significant change in the ODI levels in the first 6 weeks hence the ODI at 6 weeks post-operative is seen as a reliable indicator of the outcome even at one year follow up (Häkkinen et al., 2006).

In the study by (Azimi et al., 2016), the baseline ODI score was 38.3 ±9.2. At two year follow up, the score had dropped to 16.8 ±11.9. The change in mean ODI score of 21.4 ±12.8 was statistically significant ($p < 0.001$) at two years of follow up after the surgery. There were no significant differences observed in post-surgical success between the level of herniation. Another study had a baseline ODI score of 56.7 ±21.1 with a range of 16-92 (Omidi-Kashani, Hasankhani, Moghadam, and Esfandiari, 2013). In this study, which made findings on single level discectomy, there was no significant relationship between level of disc herniation and sex of the patient ($p = 0.570$). Most of their patients were in the severe disability and crippled stage when scored using ODI at the per-operative period. The study by Aichmair et al., (2014) did find that patients in the post-operative period had a score of 15.4 ±20.7, with a range

of 0-80 at 11 years of follow up. This classified their patients at minimal disability stage at the follow up period but the study failed to collect a baseline ODI and hence could not compare the outcome of the score. In the study, there was no statistically significant difference on the ODI score with age at surgery (p= 0.752), gender (p>0.999) or discectomy level (p=0.090).

2.2.3 VAS

Visual analogue scale is a rating scale first described by Hayes and Patterson, (1921) that uses fine gradations to measure other than using discrete scales. Participants would mark on the line indicating a spot that corresponds to the amount of pain they feel hence giving them a greater degree of freedom to choose the point of their pain's intensity.

VAS is one way in which pain can be measured subjectively in a scale rated 0-10, and it is usually used in the clinical practice for assessment of pain after surgical and non-surgical interventions.

Patients score the intensity of low back pain and leg pain using the visual analogue scale (Benzakour et al.). The relevance, validity, and reliability of the VAS has been published widely and as a tool it is used in the assessment of low back and leg pain (De Boer et al., 2004; Price, McGrath, Rafii, and Buckingham, 1983; Toyone et al., 2004). The intensity of leg pain and low-back pain is recorded with use of a 100-mm visual analog scale, with a score of 0 indicating no pain and a score of 100 indicating the worst conceivable pain. The following cut points on the pain VAS that have been recommended: no pain (0–0.4), mild pain (0.5–4.4), moderate pain (4.5–7.4), and severe pain (7.5–10) (Hawker, Mian, Kendzerska, and French, 2011) .

In the study by Peul et al., (2007), patients were followed up, comparing operative versus non-operative techniques in the management of sciatica. It was observed, in

the operative arm, the patients' VAS score for back and leg pain were 33.8 ±29.6 and 67.2 ±27.7. At two weeks of follow up, the VAS score for back had not dropped a lot but the VAS score for leg had significantly reduced to 33.3 ±2.1 and 28.5 ±1.9. but at 8 weeks post operatively, these scores had reduced to 14.4 ±2.1 and 10.2 ±1.9 for VAS score back and leg pain respectively.

The VAS score back and leg pain as noted by Azimi et al., (2016) was 5.7 ±1.8 (range of 1.5-10) and 5.3 ±2.4 (range 1.9-10) respectively. In the study by Sedighi & Haghnegahdar, (2014) they found a preoperative VAS score of 6.69 ±4.31 while Porchet et al., (2009) study noted that the patients had a VAS score of 4.4 ±2.7 and 7.6 ±1.7 for back and leg pain respectively at the pre-operative period. At 12 weeks, the VAS score had dropped to 2.3 ±2.1 and 2.9 ±2.5 respectively. The change of VAS score at 2.1 ±2.8 from 0 to 12 weeks was significant. At one year of follow up, the VAS score back was 2.4 ±2.1, which was slightly higher compared to the VAS score at 12 weeks post-operatively. But the VAS score for leg had dropped to 2.1 ±2.6 at one year of follow up.

In the retrospective study by Aichmair et al., (2014), they found a preoperative VAS score for back and leg of 4.8 ±3.2 and 6.5 ±2.1 respectively while at 11 years of follow up, this had significantly lowered to 2.1 ±1.9 and 1.6 ±1.6 respectively. The change in the pre- to postoperative VAS score was -2.7 ±3.7 (-9-5) and -4.9 ±2.6 (-9-1) for back and leg pain respectively, the difference being statistically significant ($p < 0.001$ and $p < 0.001$ respectively).

CHAPTER THREE

3.0 Methodology

3.1 Study sites

The study was carried out at the Moi Teaching and Referral Hospital (MTRH), St Luke's Orthopaedic and Trauma Hospital and Reale Hospital of Eldoret town, Uasin Gishu County in Kenya.

The study sites included both the Neurosurgical and Orthopaedic clinics, in the above hospitals. Patients at these clinics are attended to by orthopaedic and neurosurgery consultants and registrars.

Eldoret town is located in the North west of Nairobi City, the capital city of Kenya. It is located approximately 310 kilometres from Nairobi.

MTRH is the second largest National Teaching and Referral hospital in Kenya, is located along Nandi road in Eldoret town, Uasin Gishu county. It has a bed capacity of 991. On average 1500 patients are seen each day as outpatients from a catchment area of about 24 million people (MTRH. 2019, April 11) retrieved from *www.mtrh.go.ke/?page_id=598*)

St Luke's Orthopaedic and Trauma Hospital is a private hospital, located along Nandi road opposite Moi University school of Dentistry. It has a bed capacity of 90 beds and 4 ICU beds (St. Luke's Orthopaedic and Trauma Hospital. 2019, April 11. Retrieved from *www.stlukesorthopaedics.com/aboutus.html*). Reale Hospital is private hospital in Eldoret town, located along Nyerere road. It serves patients in its in-patient and out-patient wings (Reale Hospital. 2019, April 11. Retrieved from *https://realehospital.com*). Both these hospitals treat patients in their orthopaedic and neurosurgical departments.

3.2 Study population

The study population included all those patients whose main complaints were low back pain and/or radicular pains, had an MRI one to confirm lumbar disc herniation and the attending surgeon scheduled them to managed for lumbar disc herniation by standard open discectomy.

3.3.1 Inclusion criteria:

All patients admitted with a confirmed diagnosis of disc herniation on MRI and who had been scheduled for discectomy for the first time.

3.3.2 Exclusion criteria:

1. All repeat or revision surgeries.
2. Patients with disc prolapse but had other spinal conditions such as fractures.
3. Children up to the age of 18 years with disc prolapse.

3.4 Study design

The study used a prospective descriptive design. The patient data was collected and recorded during patients' regular presentation and care at the above hospitals in the orthopaedic and neurosurgical departments after consent had been sought.

3.5 Sample size determination

The objective of the study was to describe patient outcome scores following discectomy for lumbar disc prolapsed using the VAS and ODI tools. For reasons of sample size estimation, the researcher used VAS as the measure of the outcome of back pain and the leg pain. According to Häkkinen, Kautiainen et al., (2006) the mean VAS measure for the back pain 6 weeks post surgery was 18 ± 25 (n=60) for male and 13 ± 17 (n=18) for female subjects. However, the differences was not statistically significant (p=0.24). Pooling these averages give an overall back pain VAS score of 16.1 ± 21.9. The overall (pooled) leg pain VAS score was 22.8 ±17.9

(Male: 24 ± 28, Female: 21 ±26). The researcher assumed a margin of error of 5 unit scores on a VAS scale and a standard deviaton of 25 unit scores on the same scale. The researcher used the formula (Hulley, Cummings, Browner, Grady, & Newman, 2009) to estimate the sample size.

$$n = \left(\frac{Z_{1-\alpha/2}}{\Delta} \right)^2 \times \sigma^2$$
$$= \left(\frac{1.96}{5} \right)^2 \times 25^2$$
$$= 97$$

Where σ is the standard deviation, Δ is the margin of error, and $Z_{1-\alpha/2}$ is the $\left(1-\alpha/2\right)\times 100\%$ quantile of the standard normal distribution.

At Moi Teaching and Referral Hospital (MTRH) an average of 10 patients, with lumbar disc herniation get operated per month, giving a total of 120 patients per annum. Thus adjusting our sample size for a finite population of 120 cases that are seen per year in the hospital resulted in $\left(\frac{n}{1+\frac{n}{N}} \right) = \left(\frac{97}{1+\frac{97}{120}} \right) = 54$ valid number of patients to be studied. The notation N is the population size per year in the MTRH.

3.6 Sampling techniques

Consecutive sampling was used to recruit the participants into the study. All patient who consented were included in the study consecutively.

3.7 Data collection

Patient's data was collected once consent had been granted by the patients or their guardian, during their routine presentation and care at these hospitals' orthopaedic and neurosurgical clinics in the data collection tool that had been developed.

Data was collected by the principal investigator aided by a research assistant. The data was collected over a period of 12 months beginning from January 2016 until March 2017.

Preoperative questionnaires were used to collect baseline data (gender, age, level of surgery, analgesics consumption and employment status).

The patients were then requested to fill in the VAS leg and VAS low back forms and the ODI form at the pre-operative stage. The patients were followed up at 6 and 12 weeks and they were asked to fill these forms.

3.8 Data Management

Collected data was entered into a database. The data was de-identified and the databases encrypted to ensure confidentiality was maintained. Data was accessed by the principal investigator only. The data collection forms and questionnaires were kept in safe cabinets under lock and key kept by the principal investigator to ensure safety and confidentiality. The databases were also backed up to avoid loss of data.

3.9 Study Variables

The study variables were recordings of:

1. ODI scores,
2. VAS leg pain and
3. VAS back pain scores.

These variables were scored at 0, 6 and 12 weeks' post-surgery. A comparison of these scores was done using the 0 week scores as the baseline.

3.10 Data Analysis

The categorical variables were analyzed as frequencies and percentages. Test of associations between such variables was conducted using the Pearson's Chi-square test. The continuous variables were summarized as mean and standard deviation for

the normally distributed variables and as median and quartiles for the skewed variables. Analysis of covariance (ANCOVA) method of analysis was used to determine the association between the outcome variable and the main exposure adjusting for the other explanatory. The outcome variable was treated as the change in the score from the previous measures. The researcher used graphical presentations to illustrate the change in the outcome variables from that of one visit to the other.

3.11 Ethical considerations, clearance and informed consent

- For this study Institutional Research Ethics Committee (IREC) of MTRH / Moi University (FANC 1501) was requested to give ethical permission.
- Permission was also sought from the management of the hospitals where the study was carried out.
- The autonomy of the patient was highly respected and taken into consideration and confidentiality was highly maintained. Patients were not compelled to enrol in this study.
- An informed written consent was used for each patient. The purpose of the study was fully explained to the patients in either English or Kiswahili or if by use of an interpreter so that patients fully understood the purpose of the study. None of the participating patient was exposed to harm of any nature during the study. The participating patients were free to withdraw from the study any time they changed their minds. Only after obtaining informed consent were the patient's data recorded in the data collection sheet.
- While compiling the research report no misconduct (for example fabrication, falsification, plagiarism and other deviant practices) took

place. The disposal of the patient's particulars after the completion of the MMed programme has been as per IREC guidelines.

- The medium of communication was in a language and terms that the patient clearly understood.
- The collected data was locked in a secure cabinet that was only accessible to the principal investigator. Electronic data were stored in a password protected laptop. Backup copies were stored in a password protected external hard drive kept by the principal investigator. To further ensure and guarantee patients confidentiality and privacy, all reported data was de-identified and de-sensitized in any reports or presentation.

3.12 Data Dissemination

Data dissemination via:

1. Oral defense.
2. Thesis publication.

3.13 Limitations of the study

The duration of the study was limited to the duration of the masters' programme thus unable to follow patients for a long duration of time.

Patients misunderstanding of the various components of the tool. This was mitigated by giving practical examples to the patients that they could relate to.

Loss to follow up for patients. This was mitigated by recording patients and/relatives phone numbers to remind them of their revisits.

CHAPTER FOUR

4.0 RESULTS.

4.1 INTRODUCTION

A total of 58 patients were recruited into this study over a period of one year, between the months of January 2016 and December 2016. The recruited patients were those who had low back pains and/or leg pains who had been scheduled for discectomy. They come from different backgrounds and were mainly from the North Rift Valley and Western part of the Republic of Kenya. These patients were admitted to the surgical wards, either the orthopedic or neurosurgical wards in the participating hospitals.

The patients recruited into the study were from a wide spectrum of age group ranging from 18 years to 58 years, with them either having a one level or two level discectomy done. The commonest disc level operated on was L4/L5 and L5/S1 disc.

4.2 Patient Demographics

4.2.1: Age and Gender

The study recruited 30 males and 28 females, giving a ratio of M: F of approximately 1.1:1.

This study population had a mean age of 42 years with a standard deviation of 8.6 and a range of 18 – 58 years.

4.2.2: Education Level

The majority of the participating patients were mainly drawn from the persons who had obtained a tertiary level of education with only one patient having only gone to school to the primary school level. The table below shows the distribution of the patients according to their level of education.

Table 2: Education Level

	Frequency	Percentage(%)
Primary	1	1.7
Secondary	15	25.9
Tertiary	42	72.4
Total	**58**	**100**

4.2.3: Pain location

The complaints by these patients recruited into the study was low back pain and/or leg pains. Majority (62.1%) of the patients presented with both low back pain and leg pains. Only 9 (15.5%) had a complaint of leg pain alone. No patient was diagnosed with cauda equina symptoms.

Table 3: Pain Location

Category	Frequency	Percentage (%)
Back	13	22.4
Leg	9	15.5
Both	36	62.1
Total	**58**	**100**

4.2.4: Co-morbidities

Of all the 58 patients recruited into the study, a total of 8 had co-morbidities. These were mainly hypertensive and diabetic patients.

Table 4: Co-morbidities

	Frequency	Percentage (%)
Present	8	13.8
None	50	86.2
Total	**58**	**100**

The table below shows the co- morbidities the 8 patients had.

Table 5: Type of Co-morbidities

Conditions	**Frequency**	**Percentage (%)**
Diabetes Mellitus	1	12.5
Heart Disease (VSD)	1	12.5
Hypertensive	5	62.5
Rheumatic Heart disease	1	12.5
Total	**8**	**100**

4.3: Imaging

All the 58 (100%) patients had MRI prior to being admitted to the wards for the scheduled surgery.

The patients had 3 main types of disc herniation position as described in the MRI scans with the paracentral type being the frequently reported type.

Table 6: Disc herniation positions

Type	Frequency	Percentage (%)
Paracentral	50	86.2
Central	6	10.3
Foraminal	2	3.5
Total	**58**	**100**

In terms of the type of herniation, about 48.3% (n=28) of the patients had extruded type of disc herniation and 17.2% (n=10) has sequestered type of disc herniation.

Table 7: Types of herniation

Type	Frequency	Percentage (%)
Protruded	20	34.5
Extruded	28	48.3
Sequestered	10	17.2
Total	**58**	**100**

4:4 Spine Level Operated On

The recruited patients were either operated on one level or two level or three level spine. The most common level operated on was L4/L5 for those who had one level surgery while those who had a two level surgery the most common operated sites was L4/L5, L5/S1.

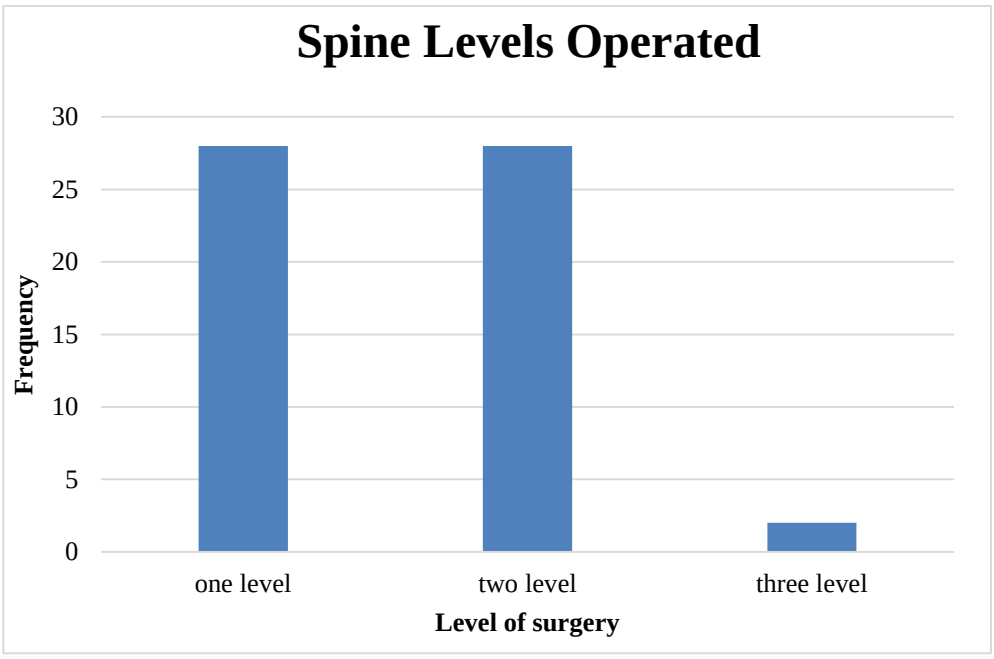

Figure 6: Spine Levels Operated

The table below shows the levels that were operated on for the patients participating in the study with the most number of patients operated being a two level surgery at levels L4/L5 and L5/S1. No patients were operated on the L1/L2 or L2/L3 level discs.

Tables 8: Spine disc level operated on

Spine disc level	Frequency	Percentage (%)
L3/L4	1	1.7
L4/L5	15	25.9
L5/S1	12	20.7
L3/L4, L4/L5	2	3.4
L4/L5, L5/S1	26	44.8
L3/L4, L4/L5, L5/S1	2	3.4
Total	**58**	**100**

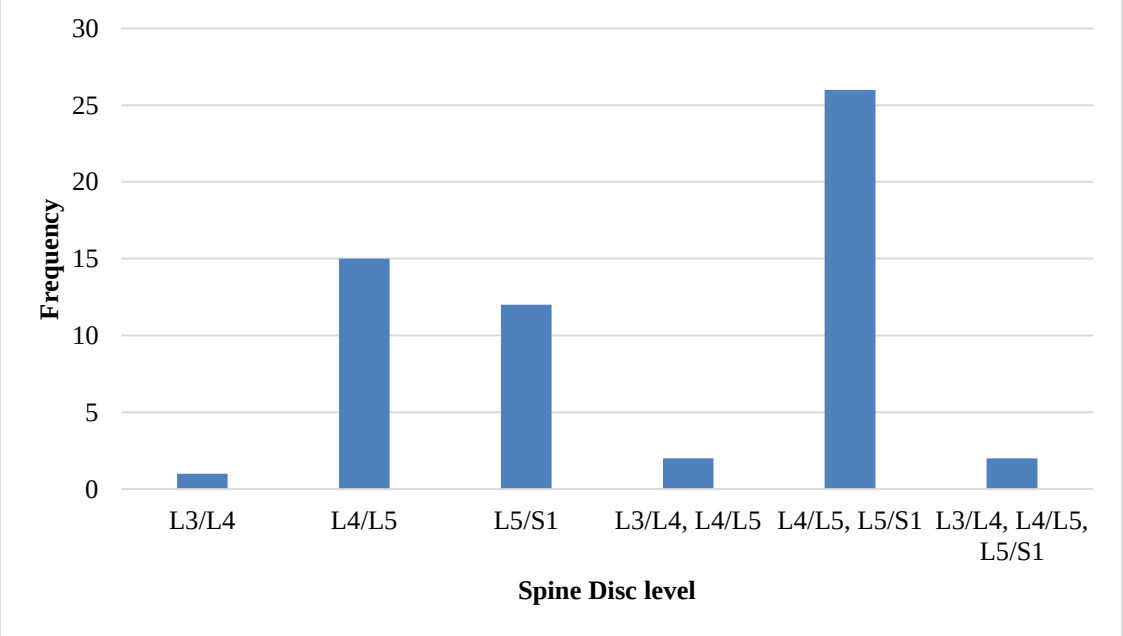

Figure 7: Spine level operated on

4.5.1 ODI scores

Patients ODI scores were recorded at 0, 6 and 12 weeks. In the pre-operative period, majority of the patients had a ODI score in the crippling stage. The preoperative ODI score had a mean of 69.2 ±11.1.

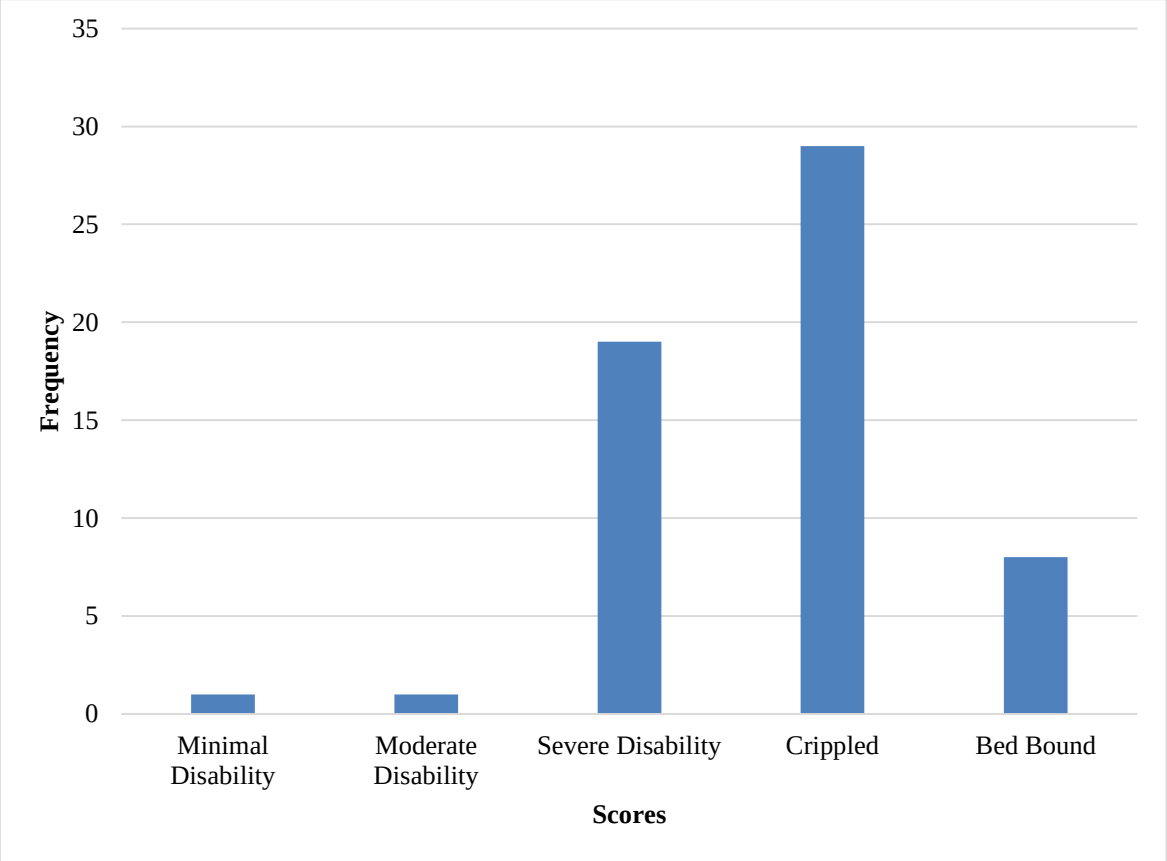

Figure 8: Baseline ODI scores

The mean ODI at 6 weeks post operatively was 39.4 ±13.1. These patients had reduced to the moderate and severe disability at 6 weeks post operatively.

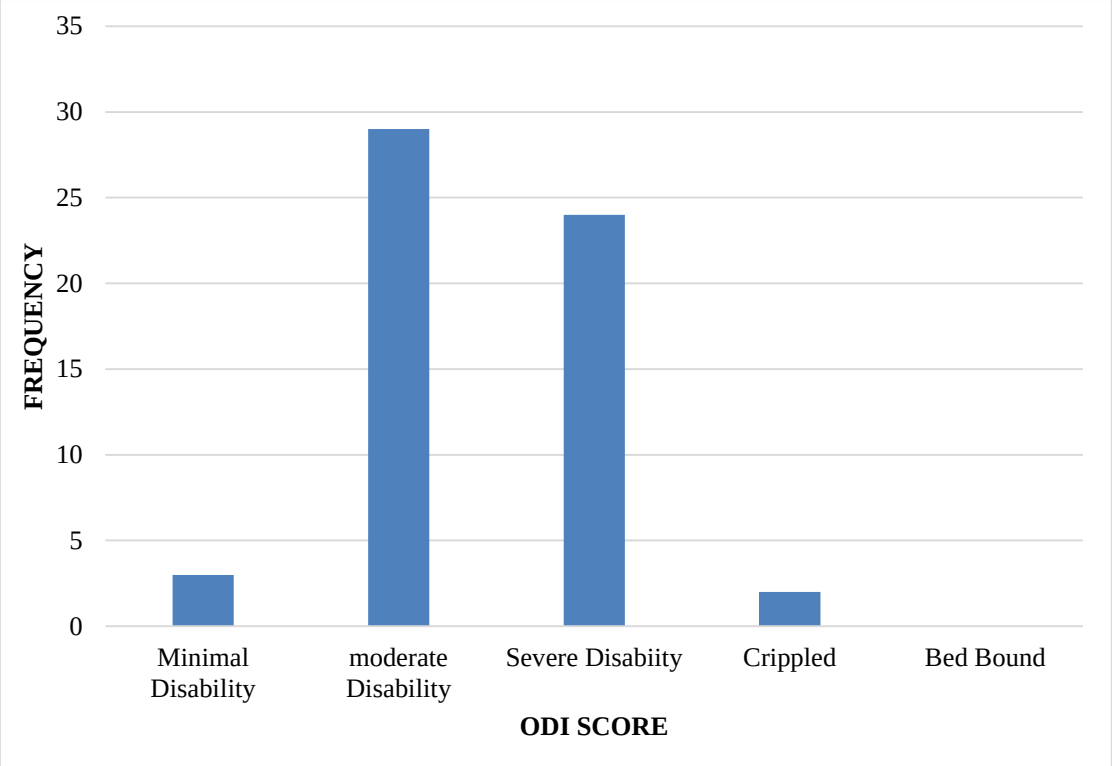

Figure 9: ODI Score at 6 weeks' post-operative

The ODI score at 12 weeks had a mean score of 23.9 ± 10.4.

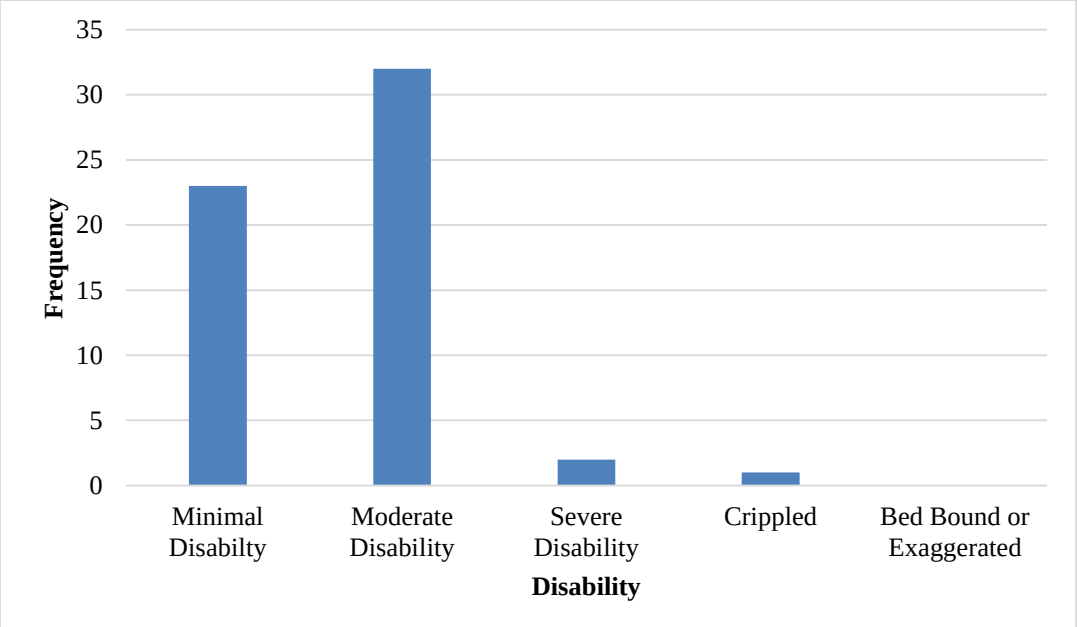

Figure 10: ODI score 12 weeks post-operative

The below bar graph represent the change through the pre- operative to 12 weeks' post- operative.

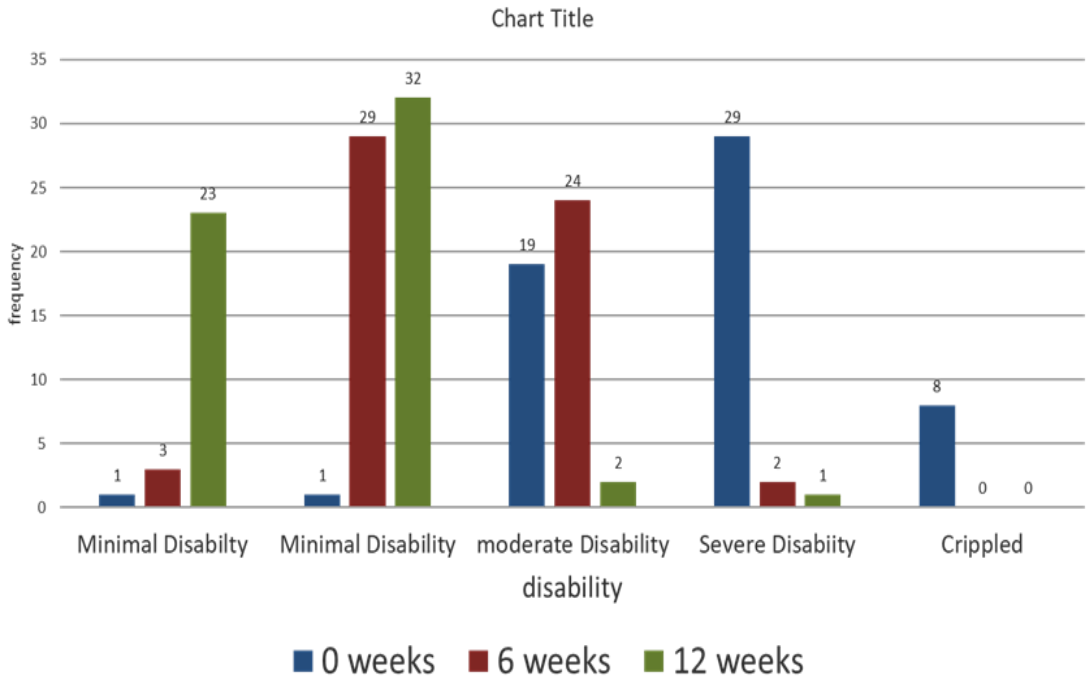

Figure 11: ODI score bar chart at 0, 6, 12 weeks.

There was a statistically significant change in the mean ODI over the follow up period, p <0.001. There was no statistically significant difference on mean ODI score between males and females (p= 0.918). There was also no statistically significant difference between the mean ODI score and the type of herniation (p=0.360). While comparing the level of surgery to the mean ODI score, there was no statistically significant difference on the mean ODI score (p=0.543).

4.5.2: VAS Scores back pain

The mean scores of the VAS score for back pain at the pre-operative and at 6 and 12 weeks is presented in the table below.

Table 9: VAS score back pain

	Pre- operative	6 weeks Post-Op	12 weeks Post-Op
Mean	7.3	3.8	2.2
Variance	2.3	1.6	1.3
Minimum	3	0	0
Maximum	9	6	4

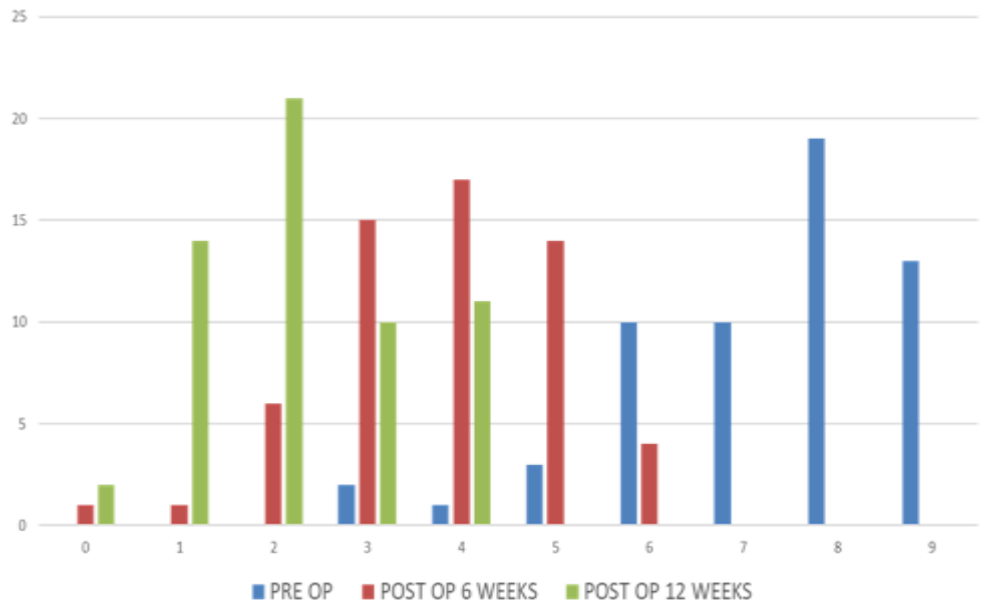

Figure 12: VAS scores back pain

There was no statistical significance difference on the mean VAS score for back pain between males and females (p=0.864) and the type of herniation (p=0.176). Also

there was no significant difference on mean VAS score for back pain and the level of surgery (p=0.387).

4.5.3: VAS Score Leg

The mean VAS score for leg pain is presented in the below table at the pre-operative period and at 6 and 12 weeks

Table 10: VAS score leg pain

	Pre- operative	6 weeks Post-Op	12 weeks Post-Op
Mean	5.5	2.6	1.3
Variance	4.2	2.8	0.97
Minimum	0	0	0
Maximum	9	9	4

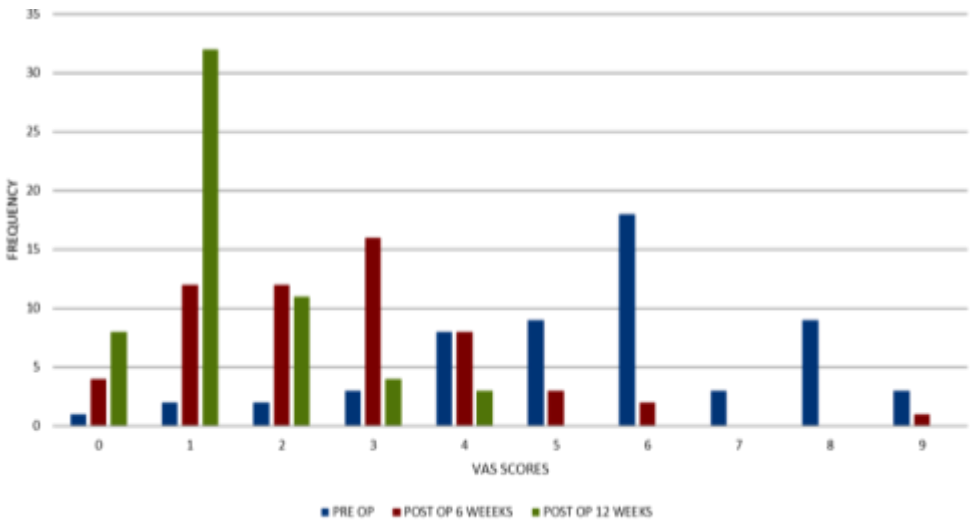

Figure 13: VAS scores leg pain

There was no statistical significance difference on the mean VAS score for leg pain between the males and the females (p=0.998) or the herniation type (p=0.635). There was no difference between the VAS score leg pain and the level of surgery (p=0.862)

4.6: Satisfaction

Patients satisfaction post-surgery was classified as uncertain for 8 patients (13.8%) while the rest, 50 patients (86.2%) their satisfaction was rated as satisfactory.

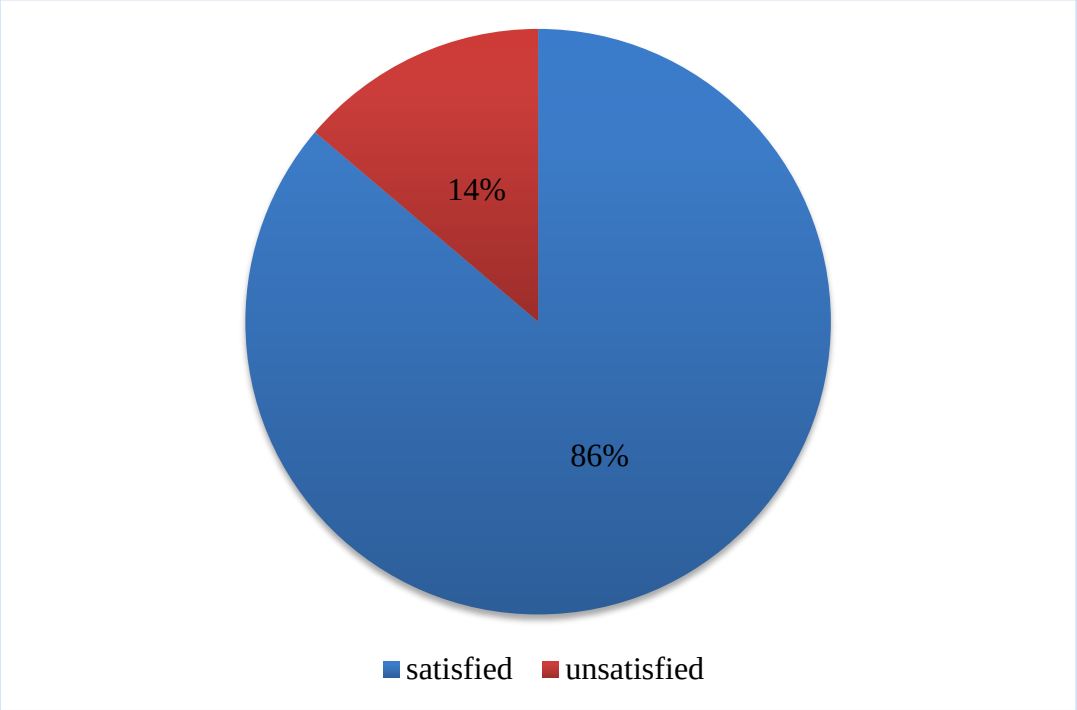

Figure 14: Satisfaction

CHAPTER FIVE

5.0 DISCUSSION

5.1:1 Sociodemographic Data

In this study, it was noted that the mean age for the patients recruited was 42 ±8.6 years. The age range for these patients was 18 to 58 years. This is the time at which the risk of having a disc herniation is higher as compared to other causes of low back pain (Schoenfeld et al., 2010; Sedighi and Haghnegahdar, 2014). In comparison to other studies, this finding concurs with a study that was done by Lurie et al., (2014) in the SPORT study, which noted that the mean age for those who were operated on to be 42.2 years as at 8 years of follow up period. In the study by Almeida et al., (2007), the mean age was 43.1 years with a range of 14-77 years which also concurred with findings in this study. In the prospective cohort study by Aichmair et al., (2014) who followed up a total of 40 patients for an average of 11 years, had a mean age of their patients was 39.9 years with a range of 18-80 years.

The study by Porchet et al., (2009), for patients who had standard discectomy had a mean age of 48 ±14.1 years while the study by Azimi et al., (2016) reported a mean age of 49.6 ±9.3 years. These studies had older patients in their study series compared to this study, a finding which contrasted the mean age found in this study.

In this study, the male to female ratio was found to be 1.1:1. This was in contrast to the study done by several authors (Jordan et al., 2011; Peul et al., 2007; Weinstein et al., 2008) which showed that males had a slightly higher incidence than females. The study by Aichmair et al., (2014) reported a male to female ratio of 3:2, showing a higher male preponderance This contrasted the SPORT study, which showed a slightly higher females preponderance. In the study by Porchet et al., (2009) for

patients who had standard discectomy, their male to female ratio was 2:1, which also contrasted the findings in this study.

The majority of the patients recruited into this study had attained at least a tertiary level of education. This was also observed in the SPORT study whereby, of the patients recruited into the study and underwent surgery, at least 77% of them had obtained at least college level of education. In the study by Sedighi and Haghnegadar, (2014), the study population had attained a Bachelor's Degree (25.2%) and high school graduates (34.4%).

5.2.1: Pain location

In this study, it was observed that a majority of the patients complained of both low back pain and radicular pains as opposed to either low back pains or radicular pains alone. This concurred with the findings in the studies by Aichmair et al., (2014) and Azimi et al., (2016). In the SPORT study, all their patients had radiculopathy symptoms, a finding that concurs to the findings in this study (Weinstein et al., 2008).

However, this contrasted an observation by Sedighi and Haghnegahdar, (2014) who had most of their patients (97.4%) in their study complain of radicular pains.

In this study, no patient was diagnosed with cauda equina syndrome, a finding that contrasted the Sidiq et al., (2011) who reported 3 cases of patients with cauda equina syndrome.

5.2.2: Co Morbidities

In this study only 8 out of the total number of number of patients recruited in the study were noted to have other comorbidities. Majority of the patients were reported to have hypertension.

5.3: Diagnosis

All the patients who participated in the study had a MRI of the lumbar spine done preoperatively to aid in diagnosis of the disc herniation as well as to locate the spine level and the type of disc herniation. This concurs with other similar studies Azimi, et al., (2016); Weinstein et al., (2008) which have noted that the use of MRI aids in making a conclusive diagnosis of lumbar disc herniation.

The commonest diagnosed site for disc herniation was posterolateral site at 86.2%. This was in agreement with the SPORT study which had the paracentral group at 78% of the total number of patients who were operated on at 8 years of the study (Weinstein et al., 2008).

The commonest type was the extruded type at 48.3% in this study. In the SPORT study, they too noted that the extruded type (67%) of herniation was the commonest followed by the protruding type (25%). The study by Azimi et al., (2016) also had extruded type as the frequently diagnosed type at 38% followed by sequestered type at 29%.

5.4: Level of Disc Herniation

In this study, a similar number of patients either had a single level or a two level surgery.

The commonest site for those who had a single level surgery was L4/L5 (25.4%) followed by level L5/S1 disc (20.3%) of the total number of surgeries done. While for those who had two level spine surgery, the highest number of patients had surgery at levels L4/L5 and L5/S1 discs (44%). No patient was operated on at the disc levels L1/L2 and L2/L3 in this study.

In the study by Sedighi and Haghnegahdar, (2014) noted that in a single level surgery, the commonest level that was operated on was disc at level L4/L5 (51.3%) while the patients operated on at level L5/S1 were the second commonest at 33.5% of the total number of patients followed, which was in concurrence to this study. In that study, only patients who had single disc level surgeries were recruited. This was also in concurrence to the findings in the study by Dohrmann and Mansour, (2015) which had 49% operated on at L4/L5 and 46% operated on at L5/S1 discs.

In contrast, the retrospective study by Almeida et al., (2007) showed the commonest operated level for a single level surgery to be L5/S1 (47.7%) followed by L4/L5 (37.7%). In the SPORT study that followed up two cohorts of group, in the group assigned to operative management, the commonest operated disc level was L5/S1 (53%) followed by L4/L5 (38%) disc level as at 8 year follow up period. In the study by Aichmair et al., (2014) at 11 years of follow up for single level surgery, the commonest level of disc level operated on was L5/S1 (70%) followed by L4/L5 (22.5%). In their study there was no patient who was operated on at the disc level L2/L3 but had 5% of their patients operated on at disc level L1/L2.

For patients who had surgery at more than one level, Almeida et al., (2007) in their study had only 10.3% having had surgery at more than one disc level, a finding that contrasted this study findings.

In the study by Junaid et al., (2016), of all the patients studied, for single level disc prolapse L5/S1 (34.6%) had the highest number followed by L4/L5 (33.4%) a finding that contrasted with this study. But a majority of patients had disc herniation at the disc levels L4/L5 and L5/S1 combined a finding that concurs with this study. For patients who had two level disc herniation in the study by Junaid et al., (2016),

majority of the patients had disc prolapse at L4/L5 and L5/S1 (19.5%) followed by L3/L4 and L4/L5 (4.7%), a finding that concurred with this study. Those patients that had a three level disc prolapse, had a disc herniation at level L3/L4, L4/L5 and L5/S1 (2.7%), a finding that concurs to this study.

5.5: ODI Scores

The baseline ODI score had a mean of 69.2 which represents crippled grading but this improved to record a grading of severe and moderate disability at 6 and 12 weeks respectively. Majority of the patients who were operated on were in the severe disability or crippled stage. This was in concurrence to the study by (Omidi-Kashani et al., 2013) which was done in Iran that reported a baseline ODI score of 56.7 ± 21.1 with a range of 16-92.

The study by Aichmair et al., (2014) reported ODI score of 15.4 ± 20.7 at 11 years of follow up, contrasted with this study by being lower compared to the mean ODI score in this study at 12 weeks post-operatively. But their study did not collet pre-operative ODI score that can be used for comparison. The study by Azimi et al., (2016) also had a lower baseline ODI mean scores of 38.3 ±9.2. This score had dropped to a score of 16.8 ±11.9 at two years of follow up. The difference in the baseline score could be explained by fear of seeking early treatment for patients in this study while the difference in the lower follow up score may be explained to their study reporting on single level surgery only and the long period of follow up in these studies.

There was only significant difference in the mean change to ODI score over time but no difference between mean ODI score and gender, type of herniation and level of

surgery. Omidi-Kashani et al., (2013) also showed no significant relationship between mean change to the ODI score and level of disc herniation or gender of the patient.

5.6.1: Outcome VAS scores

In this study, it was observed that a majority of the patients had both lower and back pains that were severe as compared to those patients who either have low back pain or radiculopathy. The patients recruited in this study reported higher back pains as compared to leg pains.

The VAS scores contrasted the study by Aichmair et al., (2014) which noted that there was a higher pain score in the radiculopathy than the low back pain unlike in this study which reported a higher back pain.

In both studies the improvement of leg symptoms was greater than the back pain.

5.6.2: Outcome VAS Score back pain

In this study, the preoperative mean VAS score was 7.31 $\pm$2.25 with a range of 3-9. While the post-operative mean VAS score was 3.7 ±1.61 and 2.24 ±1.27 with ranges of 0-6 and 0-4 post-operatively at 6 and 12 weeks respectively.

In the study by Sedighi and Haghnegahdar, (2014) they found a preoperative mean VAS score of 6.7 ±4.31 which concurred to the findings in this study while Porchet et al., (2009) noted that their patients had a mean VAS score of 4.4 ±2.7 at the pre-operative period which contrasted with the findings in this study. At 12 weeks, the VAS score had dropped to 2.3 ±2.1 which was in concurrence to this study. The change of VAS score at 2.1 ±2.8 from 0 to 12 weeks was statistically significant ($p < 0.001$) At one year of follow up, the VAS score was 2.4 ±2.1, which was slightly higher compared to the VAS score at 12 weeks post-operatively. The change was not

statistically significant. Azimi et al., (2016) had a mean VAS score for back pain of 5.7 ±1.8 pre- operatively, a finding which was in concurrence to this study.

In the retrospective study by Aichmair et al., (2014), they found a preoperative VAS score for back of 4.8 ±3.2 which contrasted the findings in this study while at 11 years of follow up, this had significantly lowered to 2.1 ±1.9 ($p < 0.001$). The change in the VAS score for back from the pre-operative period to the post- operative period was – 2.7 ±3.7. The study by Peul et al., (2007) observed a pre-operative VAS score for back of 3.4 ±2.9, a lower mean, which contrasted this study. At 8 weeks post-operatively the score had dropped to 1.4 ±0.2, the reduction of the score was statistically significant. The difference in both of these findings could be explained by higher tolerance to pain in our study population, or fear of surgery hence delay in seeking operative management.

5.6.3: Outcome VAS score leg pain

For VAS score leg, the pre- operative mean score was found to be 5.5 ±4.2 with a range of 0-9. At 6 and 12 weeks post-operatively, the mean scores had dropped to 2.6 ±2.8 and 1.3 ±0.97 respectively.

The Porchet et al., (2009) study concurred with this study, reported a pre-operative VAS score for back pain of 4.4 ±2.7 while at 12 weeks post-operatively, the score was 2.9 ±2.55. The reduction in the VAS score at 12 weeks was 5.0 ±3.1. The VAS score at one year of follow up had dropped to 2.1 ±2.6, denoting a statistically significant reduction of 5.8 ±2.5 as compared to the reduction at 12 weeks of follow up. In the study by Aichmair et al., (2014), they found a preoperative mean VAS score for back of 6.5 ±2.1 while at 11 years of follow up, this had significantly lowered to 1.6 ±1.6 ($p < 0.001$). The change in the VAS score for back from the pre-

operative period to the post- operative period was – 4.9 ±2.6. The change was clinically significant in these patients. Azimi et al., (2016), had pre-operative VAS sore for leg pain of 5.3 ±2.4, which concurred to the findings in this study.

In contrast the study by Peul et al., (2007), had a higher pre-operative score of 6.7 ±2.7 which dropped significantly to 1.4 ± 0.2 at 8 weeks post- operatively. This was much lower than what was observed in this study. This was much lower than what was observed in this study. This could be explained maybe due to higher pain endurance in patients recruited into this study.

5.7: Satisfaction.

Majority of the patients were satisfied with the outcome of their surgery despite residual pain. This was in agreement to findings in most studies which reported very high satisfaction among patients managed by discectomy.

Porchet et al., (2009) reported that a total of 91.2% of their patients who had discectomy as either very satisfied or somewhat satisfied with the outcome of their surgeries, a finding which concurs with this study's findings. Sedighi and Haghnegahdar (2014) also reported a similar higher satisfaction rate of 94%, while Aichmair et al. (2014) recorded similar higher satisfaction rate of 95%, a finding that concurs to the findings in this study.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

The baseline pre-operative ODI score was in the severe disability and crippled stage for patients in this study but had dropped to minimal and moderate disability postoperative. There was a significant reduction of the ODI score post discectomy.

There was a significant reduction in the VAS score for both the back pain and leg pain post-discectomy despite residual pain.

These reductions in ODI score and VAS scores have no correlation with gender or level of disc herniation.

6.2 Recommendations

1. Discectomy should be encouraged since it is effective in reduction of pain in patients with disc prolapse despite residual pain.

2. Further studies with longer duration of follow up for these patients need be done.

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APPENDICES

Appendix 1: Introductory letter

INTRODUCTORY LETTER

DR CHARLES KIPCHUMBA KURGAT,

P.O BOX 713-20300,

ELDAMA RAVINE, KENYA

Dear respondent,

I would like to inform you that I am conducting a study on patient's reported outcome post discectomy. This study would be conducted on all patients who willingly give consent to participate. In the study, we will be measuring parameters pain and level of usual activities at both pre- and post-operative periods. Patients would be required to fill a questionnaire in the pre-operative period and at 6 and 12 weeks post operatively.

The results of this study are aimed at providing more information on the post-operative patient's perspective on the outcome of the surgery with the procedure and therefore may assist in improving provision of care.

In this study, the principles of medical ethics will be carefully exercised.

Yours faithfully,

DR. CHARLES KIPCHUMBA KURGAT

Appendix 2: Consent Form

STUDY TITLE: PATIENT-REPORTED OUTCOME POST-DISCECTOMY FOR LUMBAR DISC HERNIATION AT HOSPITALS IN ELDORET TOWN.

INVESTIGATOR - DR CHARLES KIPCHUMBA KURGAT,

P.O BOX 713-20300,

ELDAMA RAVINE, KENYA.

I _____of P.O. BOX
_____, Telephone _____

Hereby willingly give agree to participate in the study mentioned above regarding lumbar discectomy at Moi Referral and Teaching Hospital, St. Luke Orthopedic and Trauma hospital and Reale hospital. The study has been clearly explained to me by Dr. Charles Kurgat (or his assistant) in a language and terms that I understand. I understand that I am not forced to take part in this study. I have been assured that no injury will come to me as a result of taking part in this study and my personal information will be kept private. It has also been explained to me that I may withdraw from the study when I wish to and that I will not be treated any differently or mistreated if I withdraw from the study.

Name of participant_____

Signature_____

Date_____

Name of witness_____

Signature_____

Date_____

Appendix 3: Fomu ya Idhini

KICHWA CHA UTAFITI: MGONJWA KURIDHIKA NA UPASUAJI WA DISC KUSONGA KATIKA HOSPITALI KADHA, ELDORET MJINI.

Mpelelezi Mkuu- DR. CHARLES KIPCHUMBA KURGAT
SLP 713-20300,
Eldama Ravine, KENYA.

Mshiriki _____ Wa Anwani
_____, Numbari ya Simu _____

Katika hili kwa hiari yangu natoa kibali kushiriki katika utafiti kuhusu upasuaji wa disc kusonga katika Hospitali ya Mafunzo na rufa la Moi, Hospitali ya Mifupa na dhiki St Luke na Hospitali ya Reale. Nimeelezwa lengo la utafiti na Dk Charles Kurgat (au msaidizi wake) katika lugha na maneno ambayo mimi naelewa vyema. Naelewa kwamba mimi si lazimishwi kushiriki katika utafiti huu. Nimepewa uhakika kwamba hakuna madhara yoyote au kuumia kwangu kutokana na kushiriki katika utafiti huu na habari yanguya kibinafsi yatawekwa binafsi. Ni pia alinielezea kwamba ninaweza kuondoka kutoka utafiti wakati wowote na kwamba mimi sitatibiwa tofauti au vibaya kwa sababu ya mimi kutoka utafiti.

Jina la Mshiriki
_____
Sahihi_____
_
Tarehe_____
_

Jina la
Mshaidi_____
Sahihi_____
Tarehe_____
_

Appendix 4: Data collection sheet (Questionnaire)

STUDY ON PATIENT-REPORTED OUTCOME POST-DISCECTOMY

Code: _____

Hospital/ Clinic: _____ Date: _____

Patient's Name _____

IP NO. _____

Address_____

Phone NO. _____

D.O.B _____ _____

Sex: Male Female Weight _____ kg

Occupation_____

Education Level: Primary Secondary Tertiary None

Total number of days off duty/activity: _____ days.

Diagnosis/cause of LBP:

_____

_____

Onset of LBP:

_____

Location pain: Back Leg Both

Duration of symptoms prior to surgery: Years Weeks Days.

Number of previous hospital visits related to LBP

_____

Co-morbid illness (es) Yes ☐ No ☐

If yes, specify

_____

_

Radiological investigations performed

Spine X-rays: Yes NO

Spine CT scan: Yes NO

Spine MRI: Yes NO

If yes, give findings positive findings:

_____

_____

_____

Spine level (s) affected

_____

Type of disc herniation: Protrusion Sub Ligamentous Extruded Sequestered

Reason for referral for surgery

_____

_____

__

Need for analgesia post operatively Yes NO

If yes state, the duration _____ Days

State the frequency of medication

_____

Any other comments:

_____

_____

__

Pre – operative ODI score /50

Pre-operative VAS for low back pain /10

Pre-operative VAS for leg pain /10

Post-operative

ODI score	6 weeks	/50	12 weeks	/50
VAS (Back)	6 Weeks	/10	12 Weeks	/10
VAS (Korse et al.)	6 Weeks	/10	12 Weeks	/10

Appendix 5: Oswestry Disability index form

Dr. Charles Kurgat,

P.O. Box 713,

Eldama Ravine, Kenya.

Instructions

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life.

Please answer by checking ONE box in each section for the statement which best applies to you. We realize you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes your problem.

Section 1 – Pain intensity
I have no pain at the moment
The pain is very mild at the moment
The pain is moderate at the moment
The pain is fairly severe at the moment
The pain is very severe at the moment
The pain is the worst imaginable at the moment
Section 2 – Personal care (washing, dressing etc.)
I can look after myself normally without causing extra pain
I can look after myself normally but it causes extra pain
It is painful to look after myself and I am slow and careful
I need some help but manage most of my personal care
I need help every day in most aspects of self-care
I do not get dressed, I wash with difficulty and stay in bed
Section 3 – Lifting
I can lift heavy weights without extra pain
I can lift heavy weights but it gives extra pain
Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed e.g. on a table
Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
I can lift very light weights
I cannot lift or carry anything at all
Section 4 – Walking
Pain does not prevent me walking any distance
Pain prevents me from walking more than 2 kilometers
Pain prevents me from walking more than 1 kilometer
Pain prevents me from walking more than 500 meters
I can only walk using a stick or crutches
I am in bed most of the time
Section 5 – Sitting

I can sit in any chair as long as I like
I can only sit in my favorite chair as long as I like
Pain prevents me sitting more than one hour
Pain prevents me from sitting more than 30 minutes
Pain prevents me from sitting more than 10 minutes
Pain prevents me from sitting at all
Section 6 – Standing
I can stand as long as I want without extra pain
I can stand as long as I want but it gives me extra pain
Pain prevents me from standing for more than 1 hour
Pain prevents me from standing for more than 3 minutes
Pain prevents me from standing for more than 10 minutes
Pain prevents me from standing at all
Section 7 – Sleeping
My sleep is never disturbed by pain
My sleep is occasionally disturbed by pain
Because of pain I have less than 6 hours sleep
Because of pain I have less than 4 hours sleep
Because of pain I have less than 2 hours sleep
Pain prevents me from sleeping at all
Section 8 – Sex life (if applicable)
My sex life is normal and causes no extra pain
My sex life is normal but causes some extra pain
My sex life is nearly normal but is very painful
My sex life is severely restricted by pain
My sex life is nearly absent because of pain
Pain prevents any sex life at all
Section 9 – Social life
My social life is normal and gives me no extra pain
My social life is normal but increases the degree of pain
Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sport
Pain has restricted my social life and I do not go out as often
Pain has restricted my social life to my home
I have no social life because of pain
Section 10 – Travelling
I can travel anywhere without pain
I can travel anywhere but it gives me extra pain
Pain is bad but I manage journeys over two hours
Pain restricts me to journeys of less than one hour
Pain restricts me to short necessary journeys under 30 minutes
Pain prevents me from travelling except to receive treatment

The Oswestry Disability Index. Source: Fairbank and Pynsent, 2000.

Interpretation:

Simply add up your points for each section and plug it in to the following formula in order to calculate your level of disability:

Point total / 50 X 100 = % disability

(‘point total' divided by '50' multiply by ' 100 = percent disability) Example: on my last ODI I scored an 18. So, 18/50 x 100 = 36% disability:

ODI Scoring:

Minimal disability (0% to 20%): Patients can cope with most activities of daily living. No treatment may be indicated except for suggestions on lifting, posture, physical fitness and diet. Patients with sedentary occupations (ex. secretaries) may experience more problems than others.

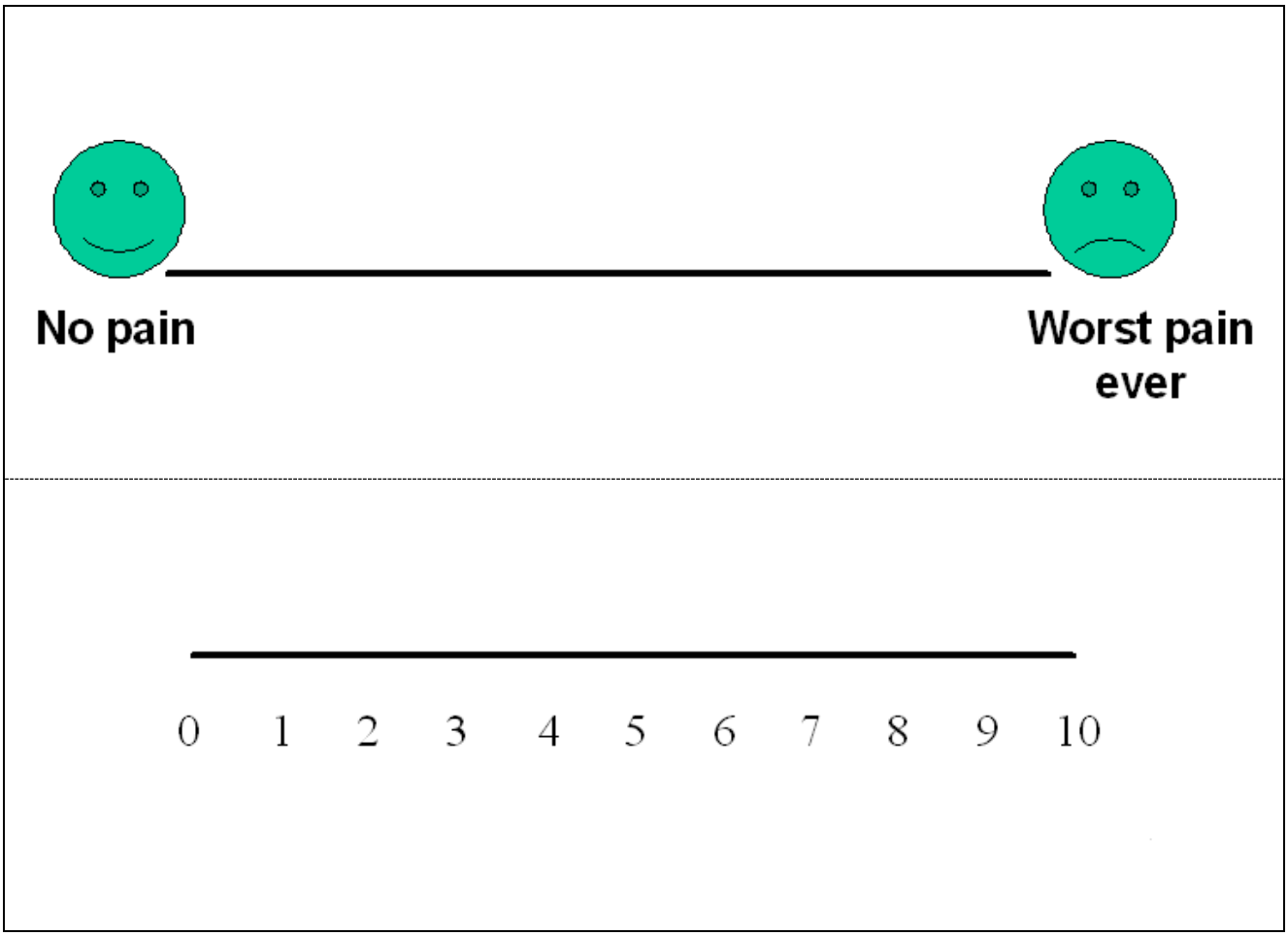
Moderate disability (21%-40%): Patients may experience more pain and problems with sitting, lifting and standing. Travel and social life are more difficult. Patients may be off work. Personal care, sleeping and sexual activity may not be grossly affected. Conservative treatment may be sufficient.

S**evere disability (41%-60%)**: Pain is a primary problem for these patients, but they may also be experiencing significant problems in travel, personal care, social life, sexual activity and sleep. A detailed evaluation is appropriate.

Crippled (61%-80%): Back pain has an impact on all aspects of daily living and work. Active treatment is required.

Bed bound/Exaggerated (81%-100%): These patients may be bed bound or exaggerating their symptoms. Careful evaluation is recommended

Appendix 6: Visual Analogue Scale form



Instructions:

- Print or photocopy the next two diagrams on an A4 sheet ensuring that the lines are exactly 10cm in length
- Fold at the dotted line
- Do not show the patient the numbered scale
- Instruct the patient to point to the position on the line between the faces to indicate how much pain they are currently feeling. The far left end indicates 'No pain' and the far right end indicates 'Worst pain ever'

Appendix 7: Work Plan

January 2015 to June 2017	January 2015 to April 2015	May 2015	June 2015	July 2015 to August 2015	November 2015 to October 2016	November 2016 to January 2017	February 2017 to February 2019	June 2017	September 2019
Developing a Proposal									
Proposal presentation									
Submission of the proposal to IREC for review									
Making corrections if any from IREC									
Data collection									
Data entry, coding, cleaning and Analysis									
Thesis Write up and submission									
Thesis defense									
Submission of Thesis									

Appendix 8: Budget

Items	**Quantity**	**Unit Price (Kshs.)**	**Total (Kshs.)**
Stationery & Equipment			
Printing Papers	6 reams	600.00	3,600.00
CD-ROMs	4	50.00	200.00
Writing Pens	1 packet	500.00	500.00
Flash Discs	1	2,000.00	2,000.00
Box Files	2	200.00	400.00
Document Wallets	4	50.00	200.00
Sub total			**6,900.00**
Research Proposal Development			
Printing drafts & final proposal	6 copies	1,000.00	6000.00
Photocopies of final proposal	6 copies	200.00	1200.00
Binding of copies of Proposal	6 copies	250.00	900.00
Sub total			**8,100.00**
Personnel			
Data analyst	1	15,000.00	15,000.00
Research assistants	3	10,000.00	30,000.00
Sub total			**45,000.00**
Communication (bundles and airtime)			**30,000.00**
Thesis Development			
Printing of drafts and final thesis	6 copies	1200.00	7,200.00
Photocopy of final thesis	6 copies	500.00	3000.00
Binding of thesis	6 copies	500.00	3000.00
Sub total			**13,200.00**
IREC approval fees			**1,000.00**
Total			**104,200.00**
Miscellaneous Expenditure (10% of Total)			10,420.00
Grand Total			**114,620.00**

Appendix 9:IREC Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2015/150
Approval Number: 0001501

11th September, 2015

Dr. Charles Kipchumba Kurgat,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
11 SEP 2015
APPROVED

Dear Dr. Kurgat,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Patient Satisfaction Post Microdiscectomy for Disc Herniation in Hospitals in Eldoret Town."

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1501*** on 11th September, 2015. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 10th September, 2016. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Authorized

Sincerely,

ST. LUKE'S ORTHOPAEDIC AND TRAUMA HOSPITAL
ADMINISTRATION
07 JUN 2016
P. O. Box 3705-30100, ELDORET.

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc Director - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
FACULTY OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2015/150
Approval Number: 0001501

2nd February, 2016

Dr. Charles Kipchumba Kurgat,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Kurgat,

RE: RATIFICATION OF THE DECISION TO GRANT FORMAL APPROVAL

Please note that in the IREC meeting of 28th October, 2015 the full Committee did not ratify your Formal Approval for study titled; ***"Patient Reported Outcome Post Microdiscectomy for Disc Herniaton in Hospitals in Eldoret Town*** However, after addressing the concerns raised by the Committee your Formal Approval is now ratified. You may continue with your study.

Sincerely,

MS. CATHERINE OKWIRI
HUMAN SUBJECT'S ADMINISTRATOR
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

Appendix 10:Hospital Approval

MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke
P. O. Box 3
ELDORET

Ref: ELD/MTRH/R.6/VOL.II/2008

9th February, 2016

Dr. Charles Kipchumba,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"Patient Reported Outcome Post Microdiscrectomy for Disc Herniation in Hospitals in Eldoret Town".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

09/02/2016

DR. WILSON ARUASA
AG. DIRECTOR
MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
- Chief Nurse
- HOD, HRISM

Apppendix 11:Reale Hospital Approval

Reale Hospital
Quality Healthcare made affordable

Services
24 Hours Out patient | Casualty Services | Inpatient Services | Maternity & Child Health | Theatre | ICU - Neonatal, Pediatric & Adult | Radiology - Ultrasound & X-ray | Pharmacy | Laboratory Services

Thursday, April 28, 2016
Our ref. RHL /adm/16/29

Dr. Charles Kipchumba,
Moi University,
School of Medicine,
P.O.Box 460-30100
Eldoret - Kenya

Dear Sir,

RE: PERMISSION TO CONDUCT RESEARCH AT REALE HOSPITAL.

Dr. Charles Kipchumba has obtained permission from the Administration to carry out his research at the Institution.

"Patient Reported outcome post Microdisectomy Disc Herniation in Hospitals in Eldoret town"

Please accord him the necessary support as he conducts his research.

Thank you.

ASUMANI Abdillahi
Administrator

Cc

1. Hospital Matron
2. Nurse Manager

Located at Elgon View - Nyerere Road | Next to Potters academy 500 metres from Eldoret C.B.D
Hospital Emergency Line: 0705 671 057 | Mobile no: 0720 738 740 | **Email:** info@realehospital.com | www.realehospital.com