Chapter 1

1.0 INTRODUCTION

The presence of significant back pain including cervical, thoracic and lumbar pain is reported to occur in 30-70% of cyclists (Salai et al 1999). Cycling is a popular recreational sport, in both indoor and outdoor training facilities. Spinning® is becoming an increasingly popular indoor training alternative in fitness facilities worldwide.

Cycling in a position of lumbar and hip flexion allows the cyclist's body weight to be evenly distributed between the saddle and the handlebars(Harrison et al 1999), so that the skeletal system bears the weight instead of the muscular system, minimising the risk of injury to the passive and active movement systems (Burke 1994).

Christianns and Bremner (1998) reinforced the finding of Kolehmainen et al (1989), that a high handlebar position on a bicycle reduces the load on the lower cervical spine and decreases the risk of prolonged periods of cervical extension. Incorrect positioning of the handlebar may predispose a cyclist to overuse injuries and damage to joints, tendons and ligaments (Burke 1994).

Low back pain (LBP) experienced by cyclists may be due to an inappropriate position of the handlebar of the bicycle (Mellion 1994). This may cause an increase in intradiscal pressure (Alexander 1985).

The lumbar spine is highly susceptible to injury due to the large forces acting on it. These forces include body weight, external forces such as a dumbbell weight as in weightlifting, a medicine ball in gymnastics as well as vector forces on the lumbar spine caused by static and dynamic postures (Alexander 1985).

There may be an increase in compressive and shearing forces on the spine during lumbar flexion (Alexander 1985), as well as an increase in inertial forces on spinal structures causing muscle strains, ligament sprains, lumbar vertebral fractures, disc injuries and neural arch fractures, during dynamic movement (Alexander 1985).

Cyclists who have reduced mobility of the lumbo - pelvic region may be affected by an inappropriate saddle adjustment of the bicycle resulting in low back pain (Salai et al 1999). Low back pain may cause recreational cyclists to abandon the sport (Salai et al 1999).

1.1 Aim of the study:

The aim of this study was to measure the effect of three different handlebar heights of the Johnny G.Spinner® bicycle on cyclists' perception of low back pain. The three handlebar heights analysed in the study with respect to the perception of low back pain experienced by the cyclist included the low handlebar, normal handlebar and high handlebar height.
The subjects' pain perception was measured using a visual analogue scale (Melzack 1987), the Lickert scale (Melzack 1987) and the McGill pain questionnaire (Melzack 1975; Melzack 1987).

1.2 Significance of the study:

The Spinning® programme has a relatively new existence, and little research has been conducted on the programme. Spinning® is a unique indoor cycling "workout". It brings the element of athletic training to people of all fitness levels, from beginners to elite athletes. Spinning® is a high-energy group exercise

programme, integrating music, camaraderie and visualisation in a complete mind/body exercise programme.
This programme is individualised for participants of any age or ability.

This study was conducted to provide relevant information to cyclists as to the most appropriate handle bar height of the Johnny G Spinner® bicycle for cyclists who experience low back pain during a Spinning® class. The prevention of low back pain would enable them to participate in this form of cardiovascular exercise without discomfort (Salai et al 1999).
The significance of this study is that it will enable people who would otherwise not be able to participate in a Spinning® class due to LBP to train optimally indoors, whether training for a cycling race or purely to increase their cardiovascular fitness.

- <u>1.3 Null hypotheses:</u>

The height of the handlebars does not influence low back pain in cyclists.

- <u>1.4 Alternative hypotheses:</u>

A change in handlebar height does affect low back pain in cyclists.

In conclusion, a study is required to determine the optimal handlebar height on the Johnny G. Spinner bicycle®. It is hypothesized that this will enable the cyclist to maintain a neutral spine position during a Spinning® class, thereby facilitating the optimal biomechanical function of the lumbar spine to prevent LBP.

The relevance of this study is that physiotherapists will be able to convey recent and relevant information to cyclists on how to adjust their Spinning® bicycle to maintain a neutral spine position, thereby facilitating optimal biomechanical function of the lumbar spine, so as to prevent or alleviate low back pain during Spinning®. Information from this study will provide physiotherapists with a better understanding of the biomechanics of Spinning®.

Chapter 2

2.0 LITERATURE REVIEW

2.1 Introduction

In this literature review, a similarity has been drawn between the biomechanical aspects of cycling with that of Spinning® due to the limited research available on Spinning®. The Spinning® programme has only been in existence since 1992, and current research available on this programme is mainly on the cardiovascular benefits of this form of exercise.

The purpose of this literature review is to place the study, **The effect of handlebar height on low back pain in cyclists during Spinning®,** into context in the available evidence of the subject of low back pain experienced by cyclists. The literature review will provide support for the study, the use of the Visual Analogue Scale, Lickert Scale and McGill pain Questionnaire measuring instruments. The review will provide a synthesis and critique of the recent literature available on the topic being researched.

The search engines used in this literature review include: Pubmed, Medline, Google.

Keywords used to conduct the study: neutral spine, low back pain in cycling, pelvic tilt, loaded seated position, saddle angle, lumbo-sacral angle.

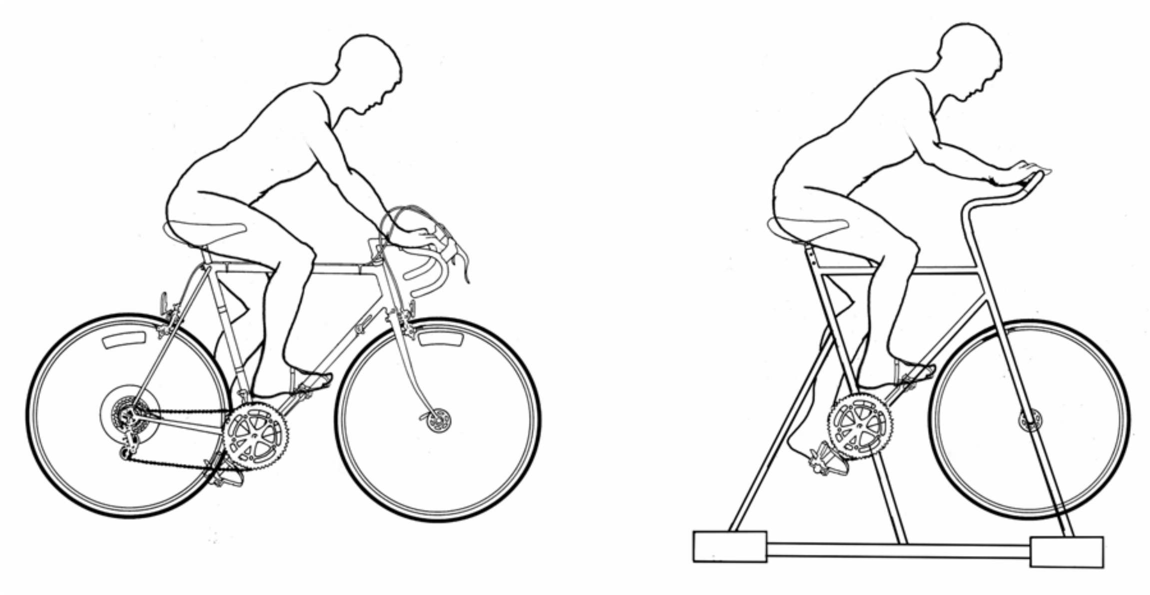
The articles researched were between the years 1975-2002.

2.2 Definition of Spinning®

Spinning® is an athletic training programme, which incorporates the simulation of an outdoor ride, brought indoors. The programme incorporates the use of different terrains, which the participant simulates via a fixed gear, working on the strength and endurance aspects of the programme. The Spinning® programme requires the participant to cycle on a stationary bicycle, the Johnny G. Spinner® made by Schwinn® (Appendix A).

2.3 The causes of low back pain experienced by cyclists

The primary cause of low back pain in cycling would appear to be due to abnormal stresses on the cyclist’s spine due to the inclined postural position during the seated position (Salai et al1999), which is maintained for a prolonged period of time (Pope et al 2002). This biomechanical position is the same as that of the subject on the Spinning® bicycle. (Figure 2.1) Thus it can be hypothesised that the forces acting on the spine in Spinning® are similar to those in cycling.



A cyclist on a road bicycle — A cyclist on a Spinning® bicycle

Figure 2.1

(Original illustration by C. Kaminski. Permission obtained.)

Adaptation of the lumbar spine to different positions in cycle racing was researched by Usabiaga et al (1997), in which three professional cyclists were observed to evaluate changes in the lumbar spine. Radiographs were obtained of the different positions adopted by the cyclists during competition, and changes in the the lumbar spine were measured. An electromyographic study was also conducted on the abdominal, lumbar and thoracic paravertebral muscles. Results of the study concluded that a cyclist's position involved a change from discal lordosis to kyphosis during cycling. To maintain a more aerodynamic position, each cyclist flexed their hips and made the angle of their pelvis more horizontal without changing lumbar disc angles.

Contraction of paravertebral lumbar muscles was proportional to pedalling intensity and decreased with a more aerodynamic position of the cyclists on their bicycles. The tone of the paravertebral thoracic muscles depended on the extent of cervical hyperextension. Abdominal muscles remained relaxed in all bicycle positions (Usabiago et al 2002).

Three subjects were involved in this study. All subjects were professional cyclists so the reliability and applicability of these results to the general cycling population needs to be further investigated. No clear inclusion or exclusion criteria were given, so it is unclear whether any of the three cyclists had any lumbar spine abnormalities or pain or biomechanical adaptations. The cycles used in this study were not adequately described so it is unclear as to whether the cyclists were all compared using the same cycle or three different cycles. This could influence the radiographic and electromyographic outcomes. The use of radiographs was not adequately described as to whether a series of radiographs were used and as to whether the radiographs were taken during the dynamic phase of cycling or the static position of the cyclist on the cycle.

Further description of the abdominal muscles is needed as the abdominal muscles may have been the superficial layers of muscles or the muscles involved in core stabilisation, i.e. transversus abdominis muscles. It is unlikely to be the transversus abdominis muscle as a deep needle electrode is required to measure activity in this muscle.

2.3.1 Definition of spinal stability and contributing factors resulting in low back pain

Panjabi (1992) suggested that stability of the spine depends on three subsystems (figure 2.2), namely the passive, active and control systems. The passive system is the spinal column, made up of the vertebrae, discs, facet joints, ligaments and joint capsules. The active system consists of the muscles and tendons that surround the spinal column. The control system or neurological system monitors the position, loading and demands on the spinal column. The control system directs the active system to provide the required stability and functions (Panjabi 1992).

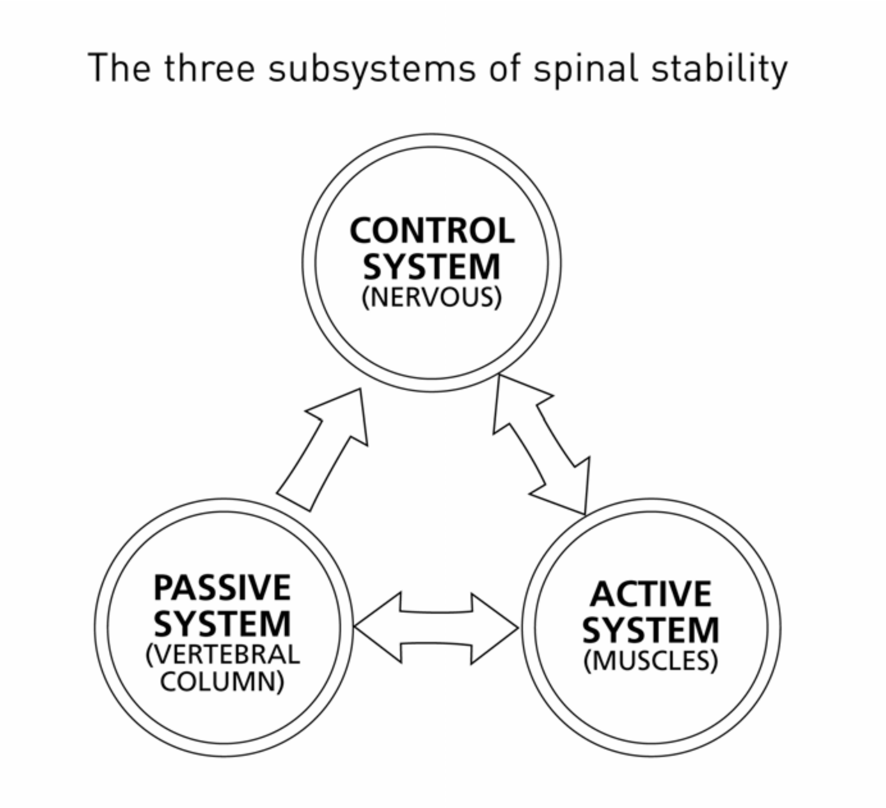


Figure 2.2

(Adapted from original Panjabi 1992)

LBP may frequently arise when there is functional overloading of active and passive systems. Damage and injury to the active and passive systems surrounding the spinal cord may predispose the athlete/participant in sport to complaints related to their specific sport (Jacchia et al 1994).

Dysfunction in the passive, active or control systems (Waddell 1998), (figure 2.2) would result in a compensation in one or both of the other systems, which may or may not compensate, or lead to long-term adaptation or failure in that system.

Low back pain may be acute or chronic. Spontaneous healing follows a single injury to the active and passive structures of the spinal column. However during repetitive or sustained loading, continued damage and incomplete healing may occur simultaneously (Waddell 1998).

LBP experienced by participants in a Spinning® class may cause facilitation of mobilising/phasic muscles and inhibition of stabilising/tonic muscles. (Waddell 1998).The resultant muscle imbalance around the vertebral joint may cause altered biomechanical function i.e. malalignment of the joints and faulty movement patterns, resulting in joint strain and degeneration as well as myofascial strain. (Waddell 1998)

2.3.2 Definition of the neutral zone

The neutral zone is defined as the amount of vertebral displacement, which occurs early in range, without a significant increase in load (Panjabi 1992). The neutral zone represents the vertebral movement, which is free or unrestrained (Panjabi 1992).

2.3.3 Definition of spinal instability

Panjabi (1992) defines spinal instability as a significant decrease in the capacity of the stabilising system to maintain the intervertebral neutral zone within physiological limits which results in pain and disability. This results in a region of laxity around the neutral position of a spinal segment.
Alteration of the neutral zone of the spine, results in an excessive range of abnormal movement for which there is no protective muscular control (Richardson and Sims 1991). The muscles involved in controlling the range of the neutral zone are the transversus abdominus and lumbar multifidi muscles (Panjabi 1992).

Clinical diagnoses of LBP are based on reports of pain and observation of movement dysfunction within the neutral zone, and the associated finding of excessive intervertebral motion at the symptomatic level (O'Sullivan et al 1997).

2.3.4 The adverse effect of an altered neutral zone

In a pilot study conducted by Richardson et al (1992), participants who experienced chronic LBP, had significantly lower muscle control in the region of the lumbar spine, in comparison to participants who experienced no LBP (Richardson et al 1992). A subsequent finding was evaluated, that a neutral spinal position was found to be more favourable, resulting in more efficient core muscle activation (Richardson and Sims 1991). Panjabi (1992) considers the lumbar segment’s neutral zone as a sensitive region. The small range of displacement around the lumbar segment’s neutral position is described as the position where minimal resistance is offered by passive spinal restraints.

In a study conducted by O’Sullivan et al (1997), chronic LBP sufferers reflected the presence of a neuromuscular dysfunction of abdominal muscle recruitment patterns (O’Sullivan et al 1997).

These studies suggest, that sportsmen who experience chronic LBP, are more likely to have reduced spinal stability, making them more susceptible to injury of the lumbar spine. Linking this result to the position of a participant on a Spinning® bicycle, the optimal postural position of the participant on the bicycle needs to be determined, so as to facilitate the efficient biomechanical function of the participant’s core stabilisers of their spine. This may result in a marked reduction of pain and discomfort in Spinning® participants who experience LBP.

Back and neck problems in cyclists can be reduced by a combination of bicycle adjustment and modification (Mellion 1994). He stated that it is often necessary to relieve a cyclist’s extended position by using handlebars which have not been lowered excessively, using a stem with a shorter extension, raising the stem of the handlebars or moving the saddle forward.

Dynamic muscular stabilisation (e.g. abdominal bracing) involves establishing range of motion, finding and stabilising the neutral position and adapting the neutral position to exercise (Mellion 1994). Farwood (1995) suggests that optimal biomechanical function of the lumbar spine can be facilitated by maintaining a neutral spine position that is, maintaining a neutral position via abdominal bracing, hip hinging and pivoting, an appropriate base of support and efficient weight transference over the base of support.

2.3.5 Loading of the lumbar spine with alterations in spinal positions

Nachemson (1975) stated that loading of the spine is higher in the sitting position compared with erect standing and greatest in the loaded sitting position, leaning forward. This early study was of great relevance; however the study was conducted on a small sample size. In a more recent study conducted by Wilke et al (1999) to complement this earlier study, Wilke et al (1999) confirmed some earlier data, however contradicted others. The new data did not confirm that the load on the spine is higher in sitting compared to standing and did not find distinct differences between positions in which the subjects were lying down. Rohlmannt et al (2001) compiled a paper to compare results from two independent in vivo studies to provide information on spinal loading. Rohlmannt et al (2001) supported the findings of the study conducted by Wilke (1999), in that the loads placed on the internal spinal fixation devices (an implant for stabilising unstable spines) were determined in ten patients. The absolute values from these studies were normalised and compared for many body positions and movements.
Wilke (1999) conducted his study to measure intradiscal pressure on one volunteer in different postures and exercises. A study involving one subject needs further investigation where the results can be compared to a larger population group to ascertain the validity of the results produced.

The results of the study of the relative differences in intradiscal pressure and flexion movements in the fixators are stated to have corresponded in most cases, however the exact correlation is not stated and therefore it is questionable as to whether one or more subject's results correlated. This would affect the validity of the study.

Differences between trends for intradiscal pressure and for flexion movements in the fixators were found when the load was predominately carried by the anterior spinal column i.e. the vertebral bodies and intervertebral discs, during flexion of the torso or when lifting and carrying weights (Rohlmannt et al 2001; Waddell et al 1998). The combination of the results, for the differences between the trends for intradiscal pressure and for flexion movements as carried by the anterior spinal column, as found in the studies conducted by Wilke (1999) and Rohlmannt et al (2001) may improve the understanding of the biomechanical behaviour of the lumbar spine and spinal loading, thereby illustrating the biomechanics of the lumbar spine during flexion.

Usabiago et al (2002), showed in their study that a decrease in lumbar lordosis resulted in an increase in intradiscal pressure as the anterior spinal column carried an increased spinal load, due to the altered gravitational force on the cyclist's body weight. (Figure 2.3)

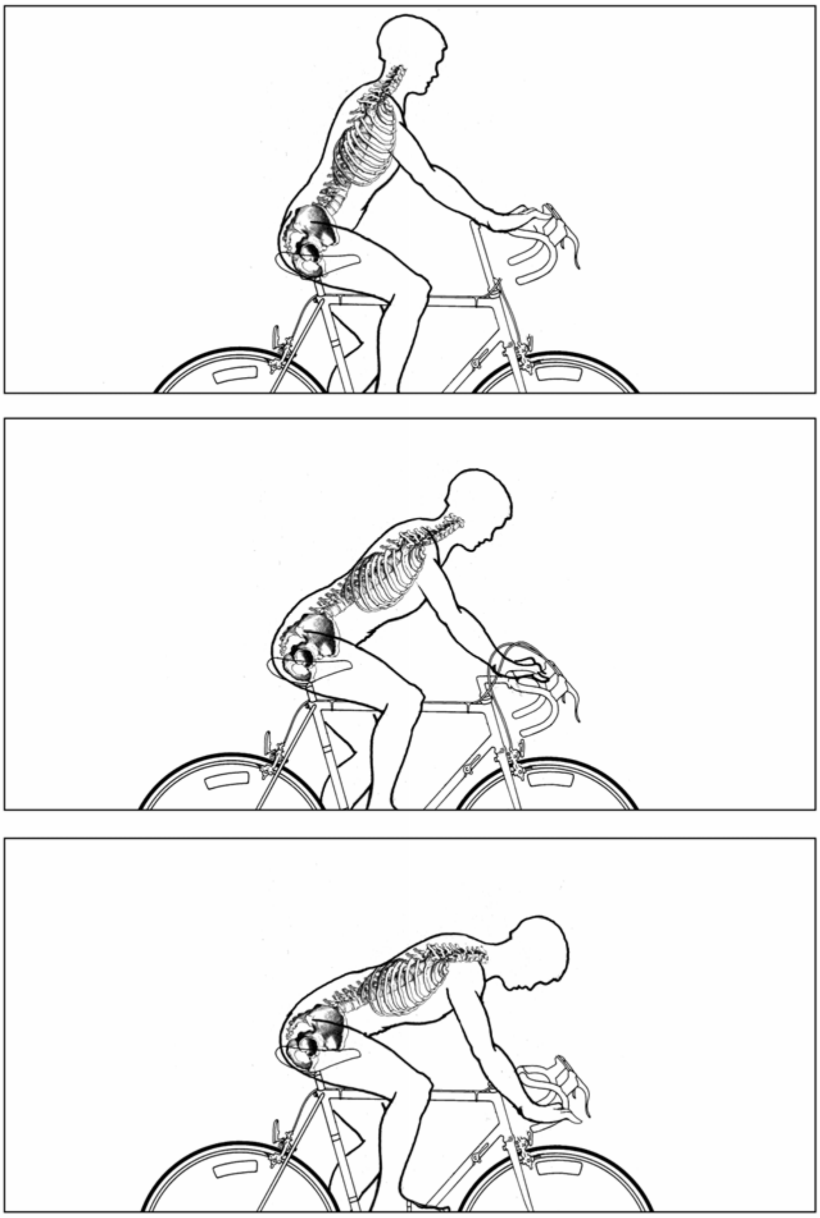


Figure 2.3

The alteration in lumbar lordosis due to a handlebar height adjustment- high, normal and low handlebar height

(Original illustration by C. Kaminski. Permission obtained.)

As it is seen in figure 2.3, a higher handlebar height will indirectly create a shorter lever on the lumbar spine, thereby encouraging a change from lumbar kyphosis to a lumbar lordosis. This will decrease the intradiscal pressure and decrease the shear force on the lumbar spine.

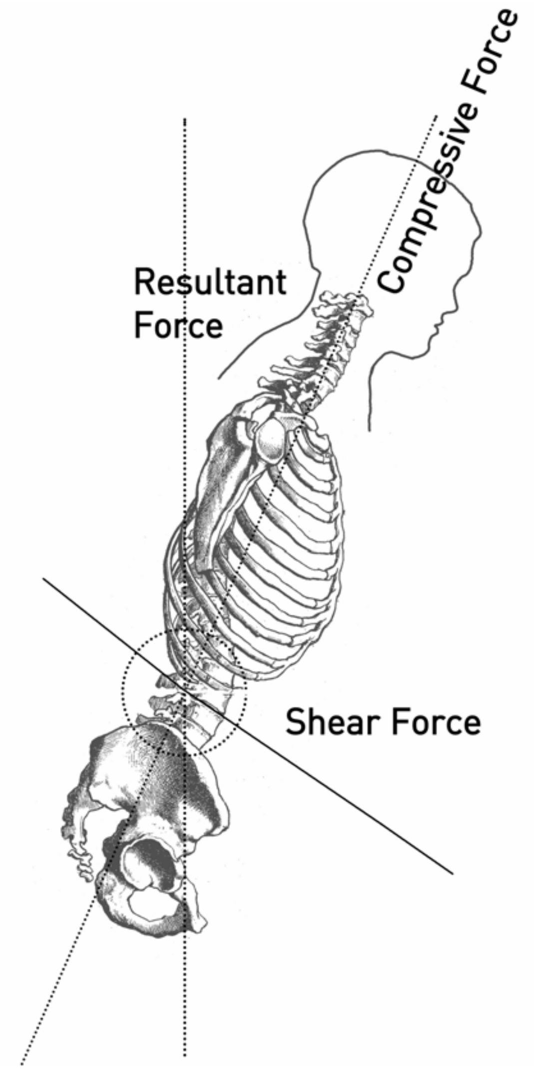


Figure 2.4

Forces occurring around the lumbar spine during cycling

(Original illustration by C. Kaminski. Permission obtained.)

As forward flexion of the lumbar spine increases, the compressive forces on the discs decrease, and the shear forces on the discs increase.

With the high handlebar height position, the body is more upright i.e. compressive forces are greatest and shear forces decreased. With the low handlebar height position, lumbar flexion is increased i.e. compressive forces decrease, shear forces increase, making the lumbar discs more vulnerable to damage (Sahrmann 2002).

2.4 Bicycle configuration

2.4.1 Spinal angle related to crossbar

Salai et al (1999) suggested that the preferred spinal angle of 40-50 degrees would decrease the risk of developing LBP in cyclists. Van Heerden, (2002), agrees that a preferred spinal angle of 40-50 degrees, lumbar spine to cross bar, should be maintained to attain the benefits of even weight distribution. The even distribution of the cyclist's body weight allows the cyclist's skeletal system to bear the weight, instead of the muscular system (Harrison et al 1999). (Figure 2.5)

2.4.2 Spinal angle related to saddle angle

Salai et al (1999) suggested that the seat angle should be angled horizontally or angled slightly upward, 10-15 degrees of anterior inclination of the seat angle from horizontal. (Figure 2.5) The incidence and magnitude of LBP in cyclists can be reduced by the appropriate adjustment of the angle of the saddle (Salai et al 1999). This well conducted study by Salai et al (1999), consisting of forty subjects, a fluoroscopic serial study was performed while cyclists sat on sports, city and mountain bicycles. The pelvic/spine angles were measured at different saddle angles, and then the related vector force analysed. The description of the subjects was however inadequate, as one can not ascertain as to whether the subjects did experience LBP or were asymptomatic, as subjects were described as healthy with no further elaboration. The age range of the subjects was extremely diverse in that subjects between the ages of 17- 72 years old were included.

The results of the study clearly indicated that they were statistically valid when using the existence of low back pain as a variable, however no statistically valid correlation was drawn with regard to the type of bicycle, gender, age, distance cycled per week or the angle of inclination of the saddle.

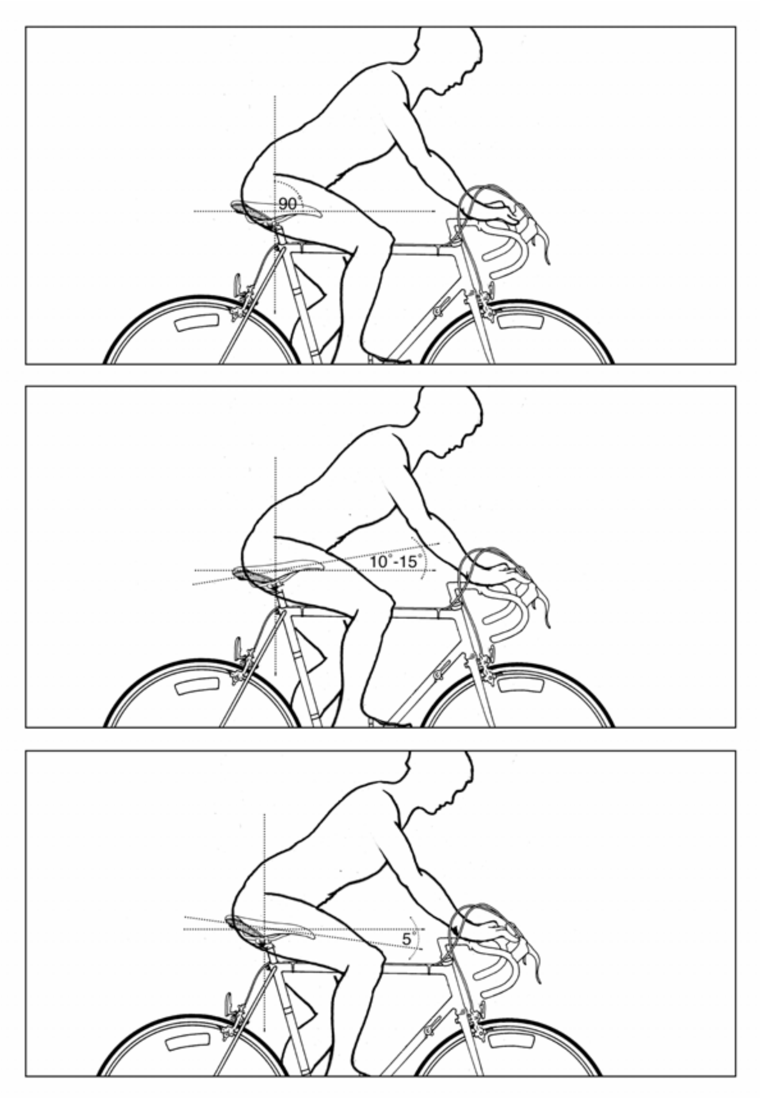


Figure 2.5
Spinal angle related to saddle angle

(Original illustration by C. Kaminski. Permission obtained.)

2.4.3 LBP and pedal unit positions

Fanucci et al (2002), conducted a further study based on the fact that LBP reported by cyclists is a frequent pathology, probably related to an inappropriate saddle position. A radiographic study was conducted to evaluate dorso-lumbar angular values in two different pedal unit positions. The dorso-lumbar angles were measured in the seated position. The results concluded that the incidence of LBP in cyclists can be reduced with the appropriate pedal unit position. The position of the pedals behind the saddle axis permits a greater variety of physiological spine angles in comparison with the classic position of the pedals in front of the axis. This fact is due to the different pelvic positions which coincide with lumbar angles (Fanucci et al 2002).

This well conducted study was performed on non competitive cyclists, however the description of "healthy" volunteers is inadequate as healthy may indicate lack of cardiovascular problems but needs to clarify the presence or absence of musculo-skeletal problems in the subjects as this will affect the results of the study.

The fluoroscopic studies were conducted in a series; however one needs to conclude whether the study was done in the static or dynamic position of the cyclist on the bicycle that is whether to establish if the cyclist was stationary on the bicycle or whether the study was conducted while the cyclist was actually cycling.

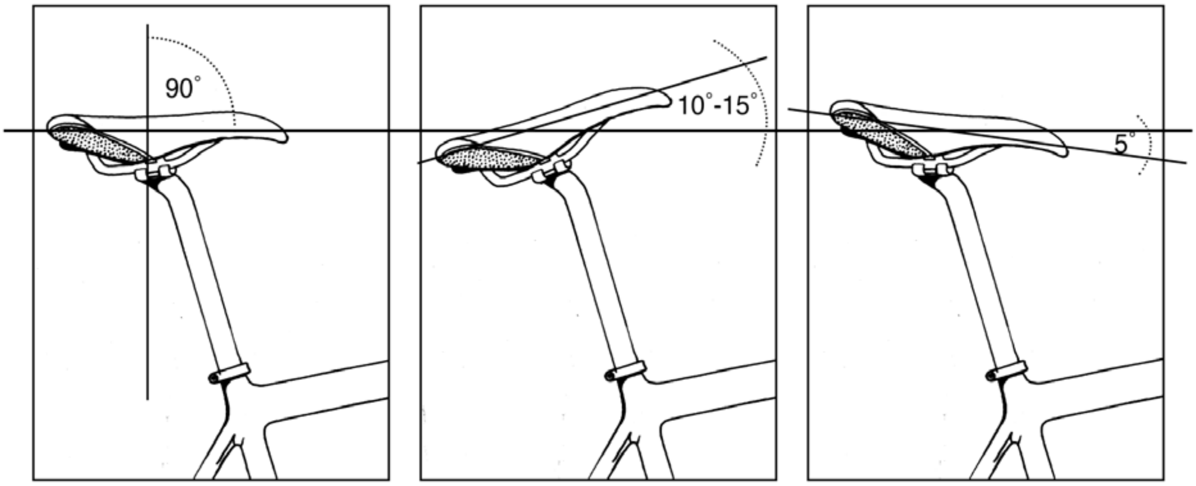


Figure 2.6

The optimal saddle angle on a bicycle

(Adapted from original by Salai et al 1999)

During the study conducted by Salai et al (1999) the lumbo-pelvic angle was measured at different seat angles and the vector forces analysed in the population whose saddle was angled slightly upwards. A tendency towards hyperextension of the lumbo-pelvic angle was noted. The resultant LBP experienced by cyclists, was probably due to an increased tensile force on the lumbosacral junction (Salai et al 1999).

Salai et al (1999) may have overlooked the fact that the symptomatic population of cyclists, who have a history of lumbar pain, may have a reduced lumbo–pelvic flexibility i.e. an inability to extend the lumbosacral region. Inclining the saddle angle downwards encourages flexion of the lumbar spine therefore increasing the risk of lumbar pain and injury, as the vector force on the cyclist’s lumbar – pelvic angle increases (Figure 2.5).

The even weight distribution in the neutral spine position on the cyclist’s osteo-ligamentous structures may reduce weight bearing on the buttocks, thereby reducing pressure on the piriformis and gluteal muscles as the cyclist is able to distribute his body weight evenly between the handlebars and the saddle. This weight distribution is only attainable if cyclists have had their bicycles correctly adjusted to assist in the optimal biomechanical functioning of their neuro-muscular-skeletal systems and osteo-ligamentous systems (Salai et al 1999).

Decreased pressure on the buttock muscles prevents early fatigue on these muscles as the innervation and vascularisation of the buttock area is sustained for a prolonged period of time (Christian 2002). This reference is not ranked highly with regard to a source of research, as the article has no reference list and therefore the quality of the article is questionable.

If the hamstrings, which are a two-joint muscle over the hip and knee joint, are placed in their optimal mid range position, a higher speed cadence is able to be maintained (Van Heerden 2002). This is a lay reference and therefore its credibility can be questioned. Richardson and Sims (1991) showed that competitive road cyclists, who habitually use their gluteus maximus muscles in a lengthened position, have a reduced ability to control inner range contraction of gluteus maximus. The mean holding time in the normal population was 5.085 seconds as compared to the competitive road cyclist, whose mean holding time was 3.7065 seconds. The results indicated a marked functional loss in gluteus maximus ability in its lengthened position.

The study conducted by Richardson and Sims (1991) supports the necessity of attaining a participant's optimal bicycle configuration i.e. the saddle post height, saddle angle, fore/aft of the saddle and the handlebar height on the Spinning® bicycle, to allow optimal functioning of the participant's gluteus maximus muscle.

Van Heerden (2002) suggested that the correct fore/aft seat position requires the saddle to be positioned in the middle of the saddle post. (Figure 2.7)

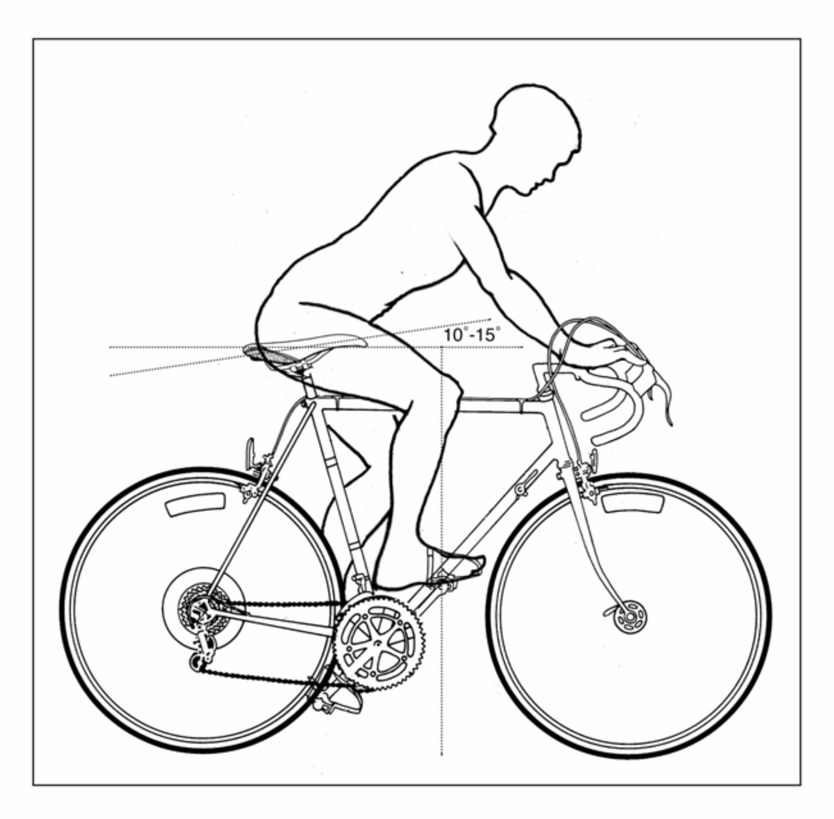


Figure 2.7

Optimal bicycle configuration

(Adapted from original Van Heerden 2002)

The correct fore/aft position can be confirmed when a vertical plumb –line runs through the tibial tuberosity, and the front pedal's axle, when the cranks are positioned horizontally at the quarter to three o'clock position.

2.5 The alteration in bicycle configuration to compensate for anatomical variations of the cyclist

If a cyclist presents with an anatomical variation, that is they do not present with a normal upper limb to lower limb ratio, or torso/arm to lower limb ratio, the seat fore/aft will need to be adjusted to compensate for this biomechanical disadvantage (Fanucci et al 2002). (Figure2.8)

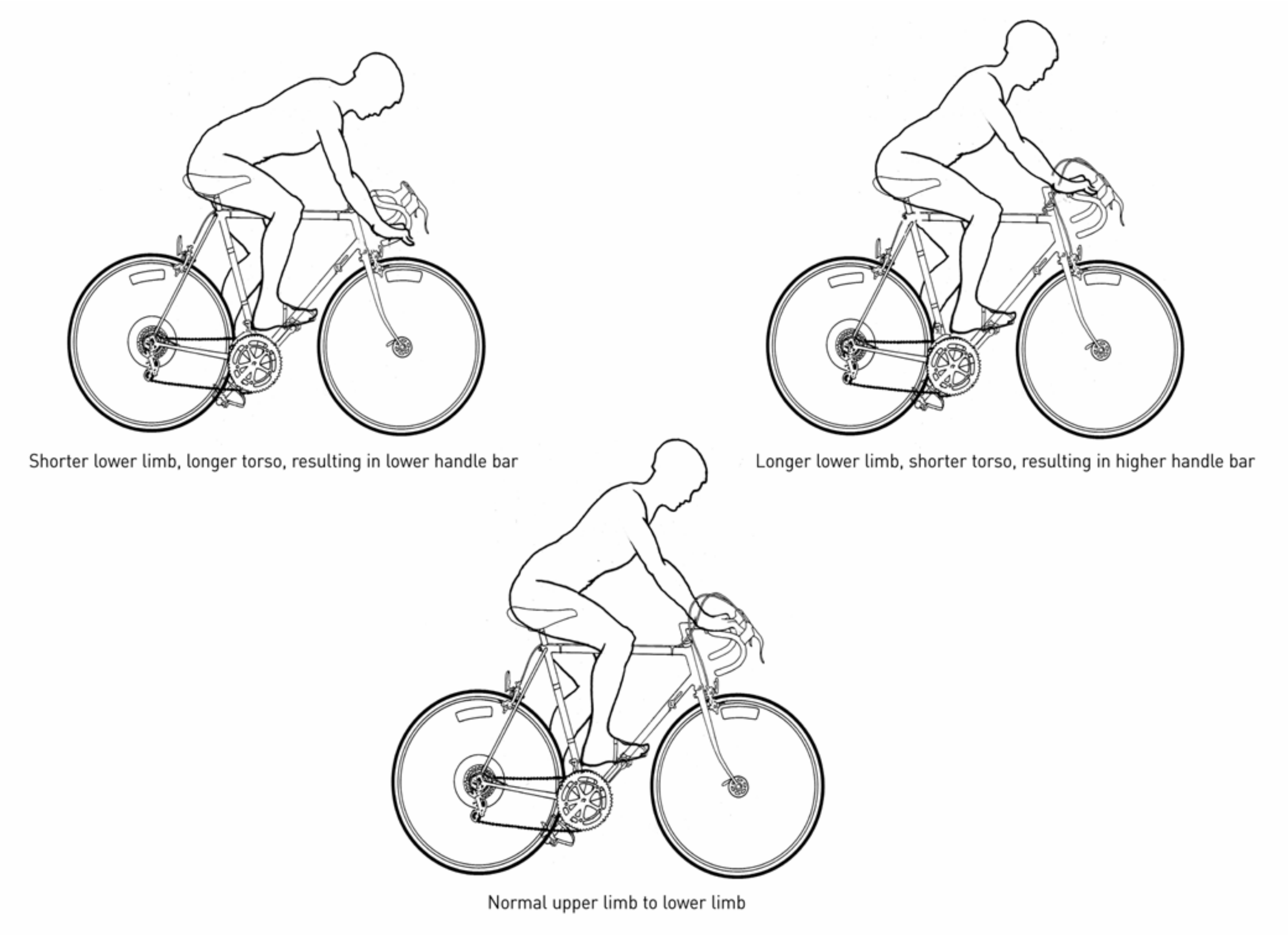


Figure 2.8

Possible alterations in bicycle configuration due to an alteration in a cyclist's biomechanics

(Original illustration by C. Kaminski. Permission obtained.)

The biomechanical disadvantage of having an altered torso/arm to lower limb ratio, results in a change in the available range of movement of the glutei and hamstring muscles due to the fact that the neuro-musculo-skeletal, and osteo-ligamentous systems have an altered biomechanical position. This may result in the cyclist sustaining a hyper-flexed position of the lumbar spine (Salai et al 1999). The cyclist will reach the end-point of hamstring/glutei flexibility with maximum flexion of the lumbar spine, when the cyclist is seated on the saddle, resulting in the pelvis being posteriorly tilted and the lumbar spine being pulled out of the neutral spine position. This ultimately results in biomechanical LBP (Salai et al 1999).

According to McConnell (1995), clinical observation has showed a large number of low back pain sufferers to have internally rotated femurs. It is postulated that internal femoral rotation reduces the hip range of movement into extension and external rotation. This results in an increase in lateral flexion and rotation movement required in the lumbar spine (McConnell 1995). The internal rotation of the hip may result from iliotibial band tightness and diminished activity in the posterior fibres of gluteus medius muscle (Sahrmann 2002; McConnell 1995).
The increase in movement around the lumbar spine due to the limited range of hip movement and control, in combination with poor abdominal support, seems to be a precipitating factor in the development of low back pain (McConnell 1995).
An alteration in the neutral spinal position will ultimately affect the core stability of the lumbar spine, the transversus abdominus and lumbar multifidis muscles, altering their recruitment and timing, thereby producing LBP (O'Sullivan et al 1997).

McConnell (1995) describes a clinical trial conducted on twenty one chronic back and leg pain patients. No description of what type of pain experienced by these patients is given. Conservative management previously given to these patients is mentioned; however the researcher does not explain the type of management. All subjects were reported to have tightness of the anterior hip structures, thoracic spine tightness, and poor pelvic and abdominal control. How the researcher obtained these results is not described and therefore one can conclude a poor study was conducted and further description or analysis is needed in this study (McConnell 1995).

Furthermore if one looks at the relative flexibility of cyclist's hip range of movement, that is the ability of the muscles involved in hip range of movement to adequately lengthen or shorten to provide sufficient range of movement around the hip joint, a relative lack of movement may occur in one joint hip flexor muscles, i.e.

Iliopsoas muscle due to the seated posture. This will result in an increased risk of lumbar pain and injury (Salai et al 1999).

A factor to consider is that a cyclist in the position where the cyclist is seated and the hip range of movement is limited, the cyclist will need to compensate for this altered biomechanical position, i.e. shortened/lengthened one joint and two joint muscles of the lower limb by externally rotating the femur, to compensate for a posteriorly rotated pelvis (McConnell 1995). This allows cyclists to continue cycling, however they may develop early onset muscle fatigue and subsequently predispose themselves to injury. It is extremely difficult to maintain an efficient pedal stroke, until the optimal biomechanics of the lower limb have been adjusted (Christian 2002).

In the position of forward flexion, which the cyclist adopts, the osteo-ligamentous structures may become overstretched, thereby increasing the neutral zone of the lumbar spine, causing LBP (Roy et al 1989). As lumbar flexion increases or if the spine is angled forward on the hip, the surface of the vertebral body will face more vertically therefore increasing the shearing force due to gravity. (Figure 2.4) Sustained lumbar flexion posture will increase spinal creep thereby increasing the deformation on the lumbar discs resulting in LBP (Waddell 1998).
This biomechanical factor occurs in cycling.

Lumbo - pelvic rhythm during cycling occurs as a combination of movements of the hip on the pelvis and the lumbar spine on the pelvis due to a fixed position of the pelvis on the saddle.

For lumbo - pelvic rhythm to function correctly, Norris (1995) suggested that hip flexion greater than lumbar flexion should occur first during functional activities.
In subjects with a history of LBP, the reverse situation occurs (O'Sullivan et al 1997) leading to stress on anatomical structures resulting in an altered biomechanical function due to a repeated motion of flexion of the lumbar spine.

2.6 Associated injuries seen in cyclists with low back pain

Handlebar problems are common among cyclists. Compression neuropathy, more commonly of the ulnar than median nerve is frequent, but seldom produces permanent injury of deficit if diagnosed early, allowing the cyclist to adjust their handlebar to the appropriate height. Overuse symptoms may be due to repetitive motion of the wrist resulting in the aggravation of wrist tendons and connective tissue of the neck and shoulders (Richmond 1994).

Poor biomechanical function could result in the cyclist complaining of neurological symptoms e.g. intermittent pins and needles and/or numbness in either their upper limb or lower limb extremities (Jacchia et al 1994). Incorrect bicycle configuration can result in compromised blood flow and neural innervation. Adverse neural tension can also result from poor posture adopted by the cyclist, thereby compromising the cyclist's biomechanical function (Christiaans et al 1998).

2.7 Measuring instruments

The Visual Analogue Scale (Melzack 1987) and a Lickert Scale (Melzack 1987) are ordinal ranked scales frequently used in questionnaires. The Visual Analogue Scale is measured on a ten centimetre ruler (Melzack 1987). The start of the line is ranked as no pain, and the end is ranked the worst intensity of pain experienced. The subject is required to mark their rating of the amount of pain they perceive on this scale. The Lickert scale is a series of "opinion" statements about a specific issue being studied and the subject is required to choose one statement that relates to his pain. The Lickert scale is in the form of a six-point scale and ranks the subject's perception of pain from 0=no pain to 5=excruciating pain.

The McGill Pain Questionnaire consists primarily of three major classes of adjectives - sensory, affective and evaluative - that are evaluated by patients to specify their subjective pain experience (Melzack 1975).

The value of the pain questionnaire lies in the ability to provide useful research data. The questionnaire provides a useful tool for examining the dimensions of pain. It provides quantitative information that can be treated statistically, it is sufficiently sensitive to detect differences among different methods to relieve pain and it provides information about the relative effects of a given manipulation on the sensory, affective, and evaluative dimensions of pain (Melzack 1975).

The measuring instruments used in this study are easy for the participant to understand. The adjectives that the patients use to describe their pain, assesses the quality of their pain very accurately (Melzack 1987). According to Liebenson and Yeomans (1997), the most valuable pain assessment tools include the VAS and the McGill Pain Questionnaire (Liebenson and Yeomans 1997).
Outcome measures including the VAS and McGill Pain Questionnaire are reported by Liebenson and Yeomans (1997), to have excellent reliability. They are easy to administer and score, and are not time consuming for the provider and their validity is highly ranked. The McGill Pain Questionnaire was designed to measure pain perception according to sensory discrimination, motivational evaluation, and cognitive evaluation (Melzack 1975).

Chapter 3

3.0 MATERIALS AND METHODS

3.1 Study Design:

A three period open label cross over design, consisting of thirty six subjects, randomised into three groups was performed. Each group underwent three handle bar height adjustments i.e.

N= Normal handlebar height, L = Low handlebar height, H = High handlebar height.

These were defined for the purposes of the study as:

Normal handlebar height: handlebar height was equivalent to saddle post height.

Low handlebar height: handlebar adjusted to first notch on Johnny G. Spinner bicycle (3 centimetres from base of stem of the handlebar) i.e. handlebar lower than saddle post height.

High handlebar height: handlebar adjusted to sixth notch on Johnny G. Spinner bicycle (15.5 centimetres from base of stem of the handlebar) i.e. handlebar higher than saddle post height.

- #### 3.1.1 Sample size:

Sample size calculations were based on the VAS (Liebenson and Yeomans 1997; Melzack 1987). The VAS is usually denoted by values of 0-10. In this study these numerical values were multiplied by 10 to obtain a percentage value.

The planned sample size of twelve subjects in each of the three groups of this study ensured power in excess of 90% to detect the expected change of 30 points on the visual analogue scale (VAS), when testing at the 0.05 level of significance.

The power calculation was performed by Dr P Becker, the statistician involved in the study from the biostatistics unit at the Medical Research Council, making use of the nQuery Advisor Release 5.0 software.

The primary efficacy variable was pain measured on the VAS, Lickert scale and the McGill Pain Questionnaire (shortened form).

3.1.2 Subjects:

Ethical clearance was obtained from the Committee on Human Subjects (Medical), University of the Witwatersrand, Johannesburg. The Certificate Clearance Protocol Number was M01-06-18 (Appendix G).

A total of 36 subjects participated in the study, randomly assigned to one of three groups. Each group had 12 subjects.

Subjects were recruited by the researcher from Core Health Fitness Centre in Morningside, Sandton. A Subject Information sheet (Appendix B) was handed out to participants prior to the week in which the study was to be conducted. After completion of the Subject Details questionnaire (Appendix D) and the informed consent form (Appendix C), 36 subjects were recruited based on the inclusion criteria as described below. Subjects were recruited from the questions answered in the Subject details Questionnaire (Appendix D). 43 subjects completed the Subject Details Questionnaire (Appendix D), and therefore 7 subjects were rejected on the basis of having unilateral LBP and one of the subjects had previous lumbar surgery.

Each subject participated in 3 Spinning® sessions. The handlebar height for each subject was adjusted at each session. Each subject completed a Spinning® session with a low handlebar height, a session with a normal handlebar height, and a session with a high handlebar height.

- 3.1.3 Inclusion criteria:

- Male and female subjects aged 30 - 50 years of age. The specific age parameters were chosen as intervertebral disc deformation occurs due to a decrease in water content and increased collagen formation as age increases (Rohlmannt et al 2001). The lower age parameter was chosen as degenerative changes in subjects younger than 30 years differ with respect to degenerative changes in a more mature spine.
- All subjects must have experienced LBP during an interval Spinning® class prior to commencement of the study (Appendix A).
- All subjects were required to be asymptomatic during activities of daily living, with regards to LBP; however Spinning® provoked the subjects' LBP during a Spinning® class.
- LBP was defined as pain in the region between lumbar vertebra 1 up to and including the sacroiliac joint.
- A history of central and/or bilateral LBP for longer than three months, provoked by the participation in Spinning® classes.
- The level of pain experienced by the cyclists during Spinning® was required to be categorised as mild or discomforting on the VAS (Appendix F) or mild or moderate on the McGill Pain Questionnaire (Appendix E).
- The type of pain described by the participant experienced during the Spinning® class was musculo- skeletal type discomfort with no neurological involvement. From the Subject Details Questionnaire (Appendix D), the question of "What type of LBP do you have?" the response of "aching pain, as opposed to "shooting pain" would indicate musculo-skeletal type pain.
- Subjects were to be between 1,23metres –1,8 metres in height. The specific height parameters were stated due to the fact the Spinning® bicycle cannot adjust to accommodate a subject of less than 1.23 meters.
  The upper limit height parameter of 1.8 metres was chosen, as subjects greater than 1.8metres in height need to extend their torso forward, placing strain on the shoulder joint and scapula. This position compromises the efficiency of the accessory muscles of respiration, and the diaphragm

muscle (Christian 2002).

- Minimum requirement of three months participation in Interval spinning® classes prior to the period of the study so that the participants understood the principles of Spinning® and were familiar with the Spinning® programme.
- Subjects were required to attend Interval spinning® classes three times per week (Appendix A) so that no additional stresses were placed on the participants.

- <u>3.1.4 Exclusion criteria:</u>

- History of heart or lung diseases.
- Unilateral low back pain.
- Radiculopathy i.e. subjects with a history of nerve root compression, nerve root irritation and referral patterns.
- Subjects with a spondylolisthesis and/or spondylolysis.
- Subjects who were taking non steroidal anti-inflammatory drugs (NSAIDS) on a daily basis as this would mask the musculo-skeletal symptoms experienced by the participant. The symptoms of subjects taking NSAIDS on days of the study sessions would be masked by the pain inhibitory effects of the NSAIDS. Participants taking NSAIDS on days when they are not participating in the study sessions were not excluded as the NSAIDS, which have a half-life of 12 hours, would not be present in their systems on days of study sessions.
- Subject Details Questionnaire (Appendix D) positive answers to the special questions such as “Do you experience any of these symptoms related to your LBP?” Numbness, pins and needles, sensation changes and muscle weakness would eliminate the subject from the study, due to the fact that pain experienced has neurological involvement.
- Night pain
- Constant LBP

3.1.5 Withdrawal criteria:

- Cervical or thoracic pain during participation in the class
- An increase in intensity of the subject's lumbar pain during the period of the study (LBP lasting more than 30 minutes after completion of a Spinning® class).
- Participants who experienced severe lumbar pain, with increasing intensity during the Spinning® class, could withdraw from further study sessions.
- If these symptoms did not abate within 24 hours of each study session, the participant would be entitled to physiotherapy treatment at no extra cost as stated in the Subject Information Sheet (Appendix B).

3.2 Procedures:

The study took place over a three week period. Each of the three groups (12 subjects) participated in three study Spinning® sessions. This conformed to a three period open label cross-over design study.

A three period cross over design study was used as the cyclists been studied were placed into three groups each undergoing three different handlebar height adjustments. The three period cross-over design allowed the study to be conducted by eliminating any carry-over effect that the handlebar height adjustment may have had from a previous study session. The design also allowed the researcher to establish whether the order in which the handlebar heights were adjusted was of any relevance to the low back pain experienced by the cyclists during the Spinning® sessions.

Subjects were randomly placed into three groups, each consisting of twelve subjects. Randomisation took place in that subjects were allocated on a first come, first serve basis. Three piles of completed questionnaires were made. On completion of the questionnaires, the subjects' placed their completed questionnaires on one of the respective piles in sequence.

Groups were stratified according to height and activity level. Twenty female and sixteen male subjects were involved in the study. All three groups had male and female participants. Seventeen of the subjects had taken part in Spinning® classes for a period of twelve months or longer. Only one subject had been Spinning® for four months and the rest for longer then six months. All subjects were moderately active, participating in cardiovascular activities at Core Health Fitness Centre three to six times per week. The average mass of the female subjects was 63.88kg and height 1.65m and of the male subjects 82kg and height 1.77m.The average age of the female subjects was 38 years old and of the male subjects 46 years old. Thirty-three of the subjects were professionals, and three were housewives.

Exclusion criteria:
Some of the questions in the Subject Details Questionnaire were designed to elicit responses for exclusion criteria. On the basis of these answers, 36 subjects were included in the study, while 7 respondents were excluded from the sample.

Each subject participated in 3 Spinning® sessions during the period of observation of one week. Each Spinning® session was conducted by the same Spinning® instructor. The same twelve Spinning® bicycles were used. A prior arrangement was made with the manager of Core Health Fitness Centre, to ensure that the saddle angle position of the bicycles used in the study sessions were not tampered with. The prescribed saddle angle was set at a 10 degree upward inclination that is the saddle tip was angled 10 degrees upward from the horizontal position.

Each group's study sessions were conducted on three separate days, with a rest day in between. At each Spinning® session the handlebars were adjusted to a different height. Each group of subjects underwent three Spinning® sessions at three different handlebar heights: the high handlebar height, normal handlebar height and the low handlebar height, not in the same sequence.

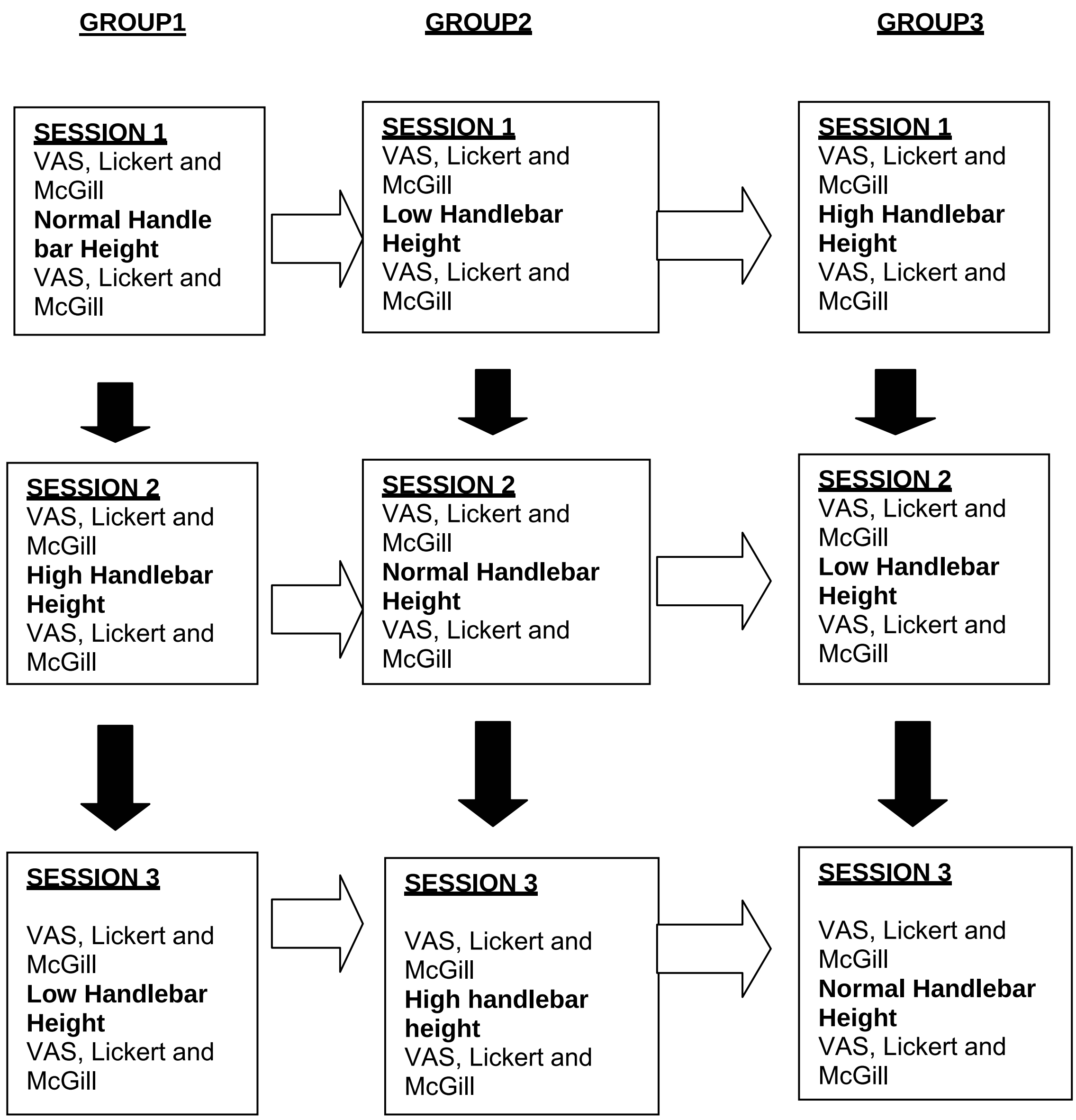
Each Spinning® session was equivalent to one spinning® class, which took place between 5:30-6:10pm. The same instructor conducted all the sessions.

The subjects attended three separate sessions during the period of the study, in place of their normal scheduled Spinning® classes. No additional sessions were attended during the period of study.

3.2.1 Pilot study:

A pilot study was conducted prior to commencement of the study to establish whether the study would be viable, as to whether an adjustment made to the handlebar height on the Spinning® bicycle would alter low back pain experienced by the cyclist during Spinning®. The handlebar height was adjusted to the three different heights, low handlebar height, normal handlebar height and high handlebar height and a verbal score was noted on the cyclist's pain perception.

3.2.2 FLOW CHART



- Session one: Subjects completed the VAS scale, Lickert scale and the McGill Pain Questionnaire prior to commencement of the class. Collection of relevant personal details via questionnaire (Appendix D) was completed.
    - The current set-up of each subject was assessed and a modified set-up was implemented, if required. A corrected saddle post height was set and measured, fore and aft of the saddle and saddle angle of a ten degree inclination of the tip of the saddle was set to eliminate variability.
    - Group one: Handlebar height was adjusted to normal position, i.e. handlebar height was equivalent to saddle post height.
    - Group two: Handlebar height was adjusted to low position, i.e. handlebar adjusted to first notch on Johnny G. Spinner bicycle®, 15.5 centimetres from base of stem of the handlebar.
    - Group three: Handlebar height was adjusted to high position, i.e. handlebar adjusted to sixth notch on Johnny G. Spinner® bicycle, 3 centimetres from base of stem of the handlebar.

Subjects completed the VAS scale, Lickert scale and McGill Pain questionnaire, within fifteen minutes of completion of the class.

- Session two: Subjects completed the VAS scale, Lickert scale and the McGill Pain questionnaire prior to commencement of the class.
    - Adjust handlebar height for each of the three groups.
    - Group one: Adjusted to high handlebar height.
    - Group two: Adjusted to normal handlebar height.
    - Group three: Adjusted to low handlebar height.

Subjects completed the VAS scale, Lickert scale and McGill Pain questionnaire at completion of the Spinning® class within fifteen minutes of completion of the class.

- Session three: Subjects completed the VAS scale, Lickert scale and McGill pain questionnaire prior to commencement of the class.
    - Re-adjusted handlebar height.
    - Group one: Adjusted to low handlebar height.

- Group two: Adjusted to high handlebar height.
- Group three: Adjust to normal handlebar height.

Subjects completed VAS, Lickert scale and McGill Pain questionnaire at completion of the Spinning® class within fifteen minutes of completion of the class.

3.3 Instrumentation:

- Visual analogue scale (VAS) – Appendix F

The Visual Analogue Scale is measured on a ten centimetre ruler (Melzack 1987). The start of the line is ranked as no pain, and the end is ranked the worst intensity of pain experienced. The subject is required to mark their rating of the amount pain they perceive on this scale.

- Lickert scale – Appendix F

The Lickert scale is a series of “opinion” statements about a specific issue being studied and the subject is required to choose one statement that relates to his pain. The Lickert scale is in the form of a six-point scale and ranks the subject’s perception of pain from 0=no pain to 5=excruciating pain (Melzack 1987).

- McGill Pain Questionnaire – Appendix E

The McGill Pain Questionnaire consists primarily of three major classes of adjectives - sensory, affective and evaluative - that are evaluated by patients to specify their subjective pain experience (Melzack 1975).

- Subject Details Questionnaires - Appendix D
- A body chart has been included in the Subject Details Questionnaire (Appendix D). The use of the body chart was used to ensure the area of pain the subject was experiencing during the study was congruent with the area described as the region between lumbar vertebra 1 up to and including the sacroiliac joint and that the pain experienced was bilateral.

3.4 Equipment:

- Johnny G. Spinner bicycle® – Appendix A

3.5 Variables:

- Independent variable: Handlebar height
- Dependant variable: The subjects' perception of pain as measured on the VAS, Lickert scale and the McGill Pain Questionnaire.
- Controlled variable: Standardised positioning of subject on Johnny G. Spinner bicycle® i.e. Saddle angle position, saddle post height and fore and aft of the saddle. The saddle angle was measured at a ten degree inclination. The tip of the saddle was inclined five degrees upwards as indicated by Salai et al (1999) as the optimal saddle inclination for the prevention of LBP. The angle was measured using a protractor and fixed in this position.

3.6 Special ethical issues:

An application was submitted to the Committee For Research on Human Subjects (Medical) at the University of The Witwatersrand Johannesburg, for ethical clearance of research involving human subjects.
Clearance Certificate Protocol Number M01-06-18

Potential risk of injury was reduced by ensuring:

- Education of participants was given prior to the commencement of each Spinning® session about the safety features of the Spinning® bicycle and the relevance of the study. A two minute talk and demonstration was given by a qualified physiotherapist.

- Participants' postures were observed by a qualified physiotherapist and an observation was noted that due to cyclist's anatomical pelvic differences, some cyclists adopt a lumbar lordotic posture, while others adopt a more kyphotic posture.
- Instruction of spinning classes by a qualified spinning instructor.

(Appendix G)

Pain was measured within fifteen minutes of completion of each Spinning® session so that other activities of daily living did not influence it.

3.7 Data analysis:

The data from this study were analysed using an Anova (analysis of variance) appropriate for dealing with a three period cross-over study design. The significance of the study was set at the 0.05 level. Analysis was done using a random effects Generalised Least Squares (GLS) regression.

Due to the fact that no pain was experienced when cycling with the handlebars in the high position, as seen on completion of the VAS, Lickert-type VAS and McGill Pain Questionnaire, this study was then considered a two-period cross-over study design and was analysed as such on the advice of the statistician Dr P Becker. Analysis was done in three ways (i) groups 1 & 2, (ii) groups 1 & 3, (iii) all three groups.

The two period cross-over study design is a subject design. As the subjects were randomly allocated to each group, a random-effects model was used to compare treatments with respect to pain on the visual analogue scale (VAS), the Lickert scale and the McGill pain Questionnaire.

Chapter 4

4.0 RESULTS

4.1 Introduction

The study was conducted to establish if the handlebar height of a spinning bicycle had an effect on low back pain in cyclists. The handlebar height was adjusted to three different levels on the Spinning® bicycle to determine which handlebar height is the most favourable position in preventing low back pain.

The study was conducted over a period of three weeks. A three period open label cross-over design was used and analysed with respect to the visual analogue scale (VAS), the Lickert scale and the McGill pain score.

The results of the study were analysed and interpreted using the mean, standard deviation and p-values. The significance of the study was set at the 0.05 level. The results are shown in the form of figures and tables.

To enable statistical analysis these groups were sorted into groups 1, 2 and 3. The sequence of handlebar height adjustment for Group one (12 subjects) was normal handlebar height, high handlebar height, low handlebar height.
The sequence of handlebar height adjustment for Group two (12 subjects) was low handlebar height, normal handlebar height, high handlebar height.
The sequence of handlebar height adjustment for Group three (12 subjects) was high handlebar height, low handlebar height, normal handlebar height.

The three period cross-over design study is a study powered for difference testing and therefore similarity between the groups cannot be shown. This design is used for difference testing and not for equivalence testing. The three period cross-over design was used for this study as three different analysis sessions were used within the study design and the decision to work within groups allowed for the use of this study design. The three period cross over design also allowed for a change in direction of the testing within the groups, taking into consideration any carry-over effect and adjusting for it.

4.2 Justification for the alteration of the study design

A three period cross-over design study was originally used. After the study was concluded it was ascertained that at a high handlebar height the pain perceived by the cyclists had a zero value on the visual analogue scale, the Lickert scale and the McGill pain score. This enabled the use of a two period cross-over design study as the sequencing for groups two and three was thus the same ie initially a low handlebar height followed by the normal handlebar height position, once the pain score of the high handlebar height equated to a zero value.

Group 1 Normal handlebar height→High handlebar height→Low handlebar height

Group 2 Low handlebar height→Normal handlebar height→High handlebar height

Group 3 High handlebar height→Low handlebar height→Normal handlebar height

At the conclusion of the study it was determined that each participant began each session with a pain score of zero. There was thus no carry-over of pain between the study sessions. Therefore the order of testing made no difference on the pain reported by the cyclists during each study session. It was concluded that there was no difference between the groups and that therefore the data could be combined for analysis.

The two period cross-over design took into account the randomisation of the groups and allowed for no carry-over between the groups.

In the tables below, the raw data from the study has been combined and represented graphically.
Thirty six subjects (n=36) were analysed in the study. Three groups of twelve subjects were formed. The mean scores of the data collected via the VAS, Lickert scale and McGill Pain Questionnaire were calculated at the commencement of each Spinning® sessions and at completion of each session.
The standard deviation was calculated for the data scores, thereby measuring the average amount that the set of scores deviated from the mean scores and represented graphically via error bars on the figures below.

Table 4.1
The mean VAS at the start and end of the Spinning® class

n=36	Mean starting VAS	Mean VAS at end of class	Difference	Standard deviation
Low handlebar position	zero	45.47	45.47	±20.19
Normal	zero	17.38	17.38	±13.34
High	zero	zero	zero	zero

From the table it can be seen that the mean VAS before the class was zero.
The mean VAS score at the end of the class was 45.47 for the low handlebar position, 17.38 for the normal and zero for the high handlebar position.
For easier manipulation of the scores recorded via the VAS scale, the scores were converted to a percentage and tabulated.

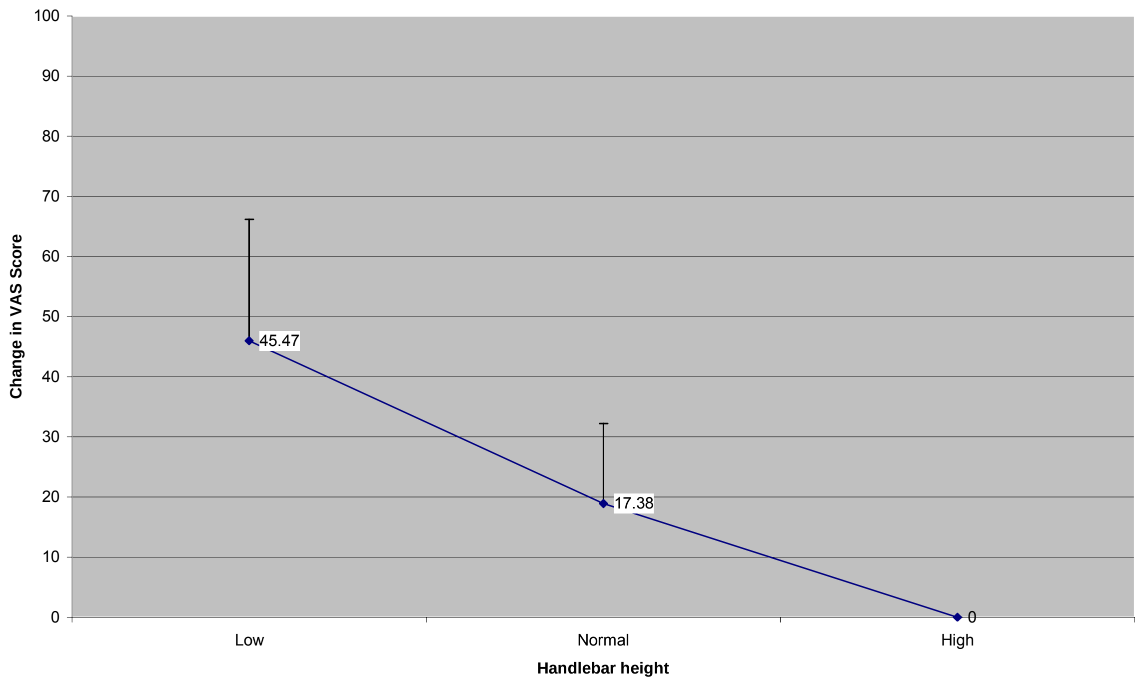


Figure 4.3.1

Comparison between groups with respect to the change in mean of the VAS scores for low, normal and high handlebar heights on completion of the Spinning® class

Table 4.2

The mean Lickert scale at the start and end of the Spinning® class

N=36	Mean starting Lickert scale	Mean Lickert scale at end of class	Difference	Standard deviation
Low handlebar position	zero	2.64 (2=discomforting)	2.64	±0.99
Normal	zero	1.33 (1=mild)	1.33	±0.82
High	zero	zero	zero	zero

From the table it can be seen that the mean Lickert scale before the class was zero. The Lickert scale at the end of the class was 2.64 for the low handlebar position, 1.33 for the normal and zero for the high handlebar position.

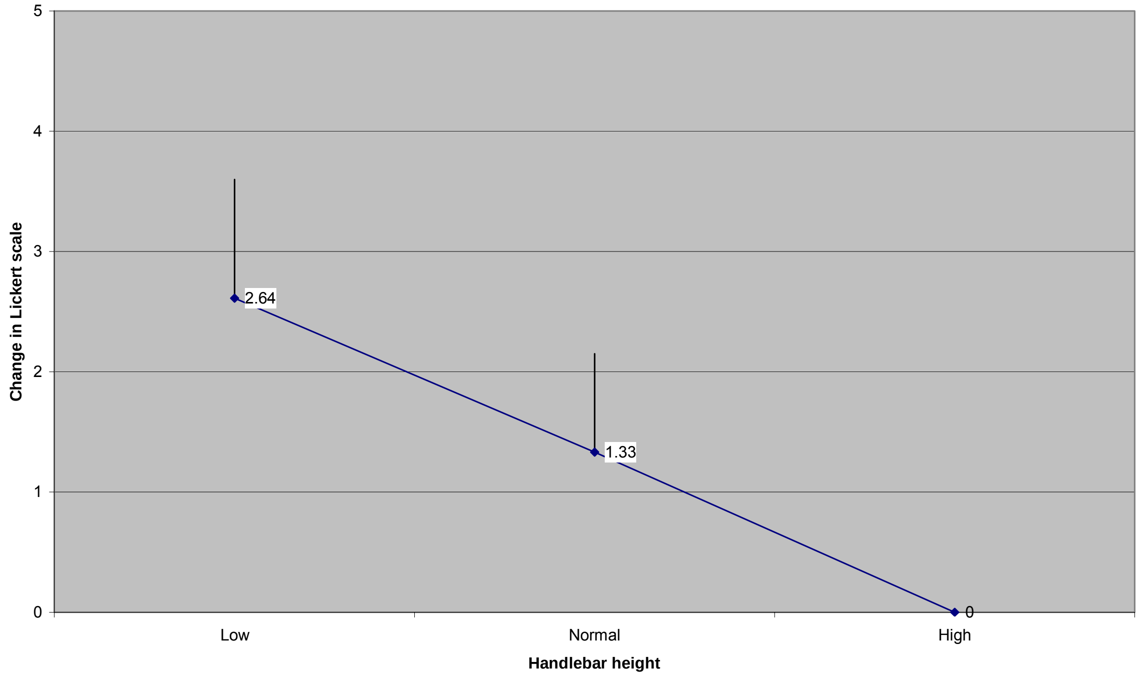


Figure 4.3.2

Comparison between groups with respect to the change in mean of the Lickert scale for low, normal and high handlebar heights on completion of the Spinning® class

Table 4.3

The mean McGill Pain score at the start and end of the Spinning® class

n=36	Mean starting McGill Pain	Mean McGill Pain at end of class	Difference	Standard deviation
Low handlebar position	zero	1.92	1.92	±0.50
normal	zero	1.16	1.16	±0.65
High	zero	zero	zero	zero

From the table it can be seen that the mean McGill Pain scale before the class was zero. The McGill Pain scale at the end of the class was 1.92 for the low handlebar position, 1.16 for the normal and zero for the high handlebar position.

Due to the fact that the McGill pain questionnaire is a score of verbal adjectives, none, mild, moderate and severe, for the purpose of interpretation, numerical values have been given. That is, none=0; mild=1; moderate=2; severe= 3.

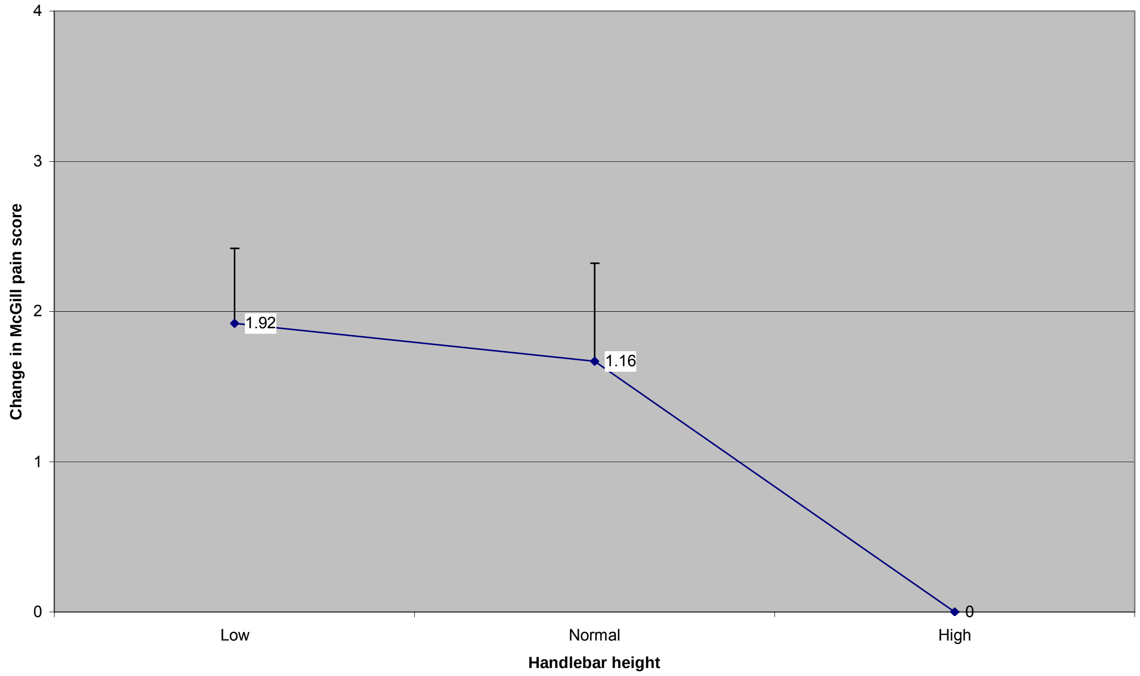


Figure 4.3.3
Comparison between groups with respect to the change in mean of McGill pain scores for low, normal and high handlebar heights on completion of the Spinning® class

As seen in figure 4.3.3, a slight drop in value of the change in McGill pain score is noted between the low and normal handlebar position. However a steep drop is noted in the change in value of the McGill pain score between the normal and high handlebar position. The pain recorded when the handlebars were placed in the high handlebar position was of zero value therefore the cyclists experienced no pain when the handlebars were placed in the high handlebar position.

In the above figures, because all starting values for the VAS, Lickert scale and McGill pain questionnaire were zero, change in value as noted in the graphs, equalled the value of the final score.

The analysis of the mean scores of the VAS, Lickert scale and McGill Pain Questionnaire and p-value between the groups was tabulated to indicate whether random error produced the results in the study.

Table 4.4

Analysis of groups 1 and 2

Group 1 and 2 n=24	Mean VAS	Mean Lickert	Mean McGill	p-value
Normal handlebar position	18.91	1.38	1.21	p<0.001
Low handlebar position	45.96	2.71	1.92	p<0.001
High	zero	zero	zero	

When the results of group 1 were combined with the results of group 2 the statistical analysis (Appendix H), showed pain resulting from the low handlebar height (mean VAS = 45.96) differed significantly (p< 0.001) from the pain value of the normal handlebar height position (mean VAS = 18.91), This shows that there is a 99.9% probability that the pain was as a result of the handlebar height variation. For easier manipulation of the scores recorded via the VAS scale, the scores were converted to a percentage and tabulated.

Pain measured on the Lickert scale differed significantly (p<0.001).The mean Lickert score for normal handlebar was 1.38 versus 2.71 for low handlebar height.

Similarly for the pain Questionnaire pain resulting from the normal handlebar height differed significantly (p<0.001), from low handlebar height. The mean McGill pain score for normal handlebar heights was 1.21 versus 1.92 for low handlebar height.

Table 4.5

Analysis of groups 1 and 3

Group 1 and 3 n=24	Mean VAS	Mean Lickert	Mean McGill	p-value
Normal handlebar position	16.08	1.33	1.16	p<0.001
Low handlebar position	44.29	2.46	1.92	p<0.001
High	zero	zero	zero	

When the results of group 1 (Normal handlebar height→ low handlebar height) were combined with group 3 (low handlebar height→ normal handlebar height) pain resulting from the low handlebar position (VAS= 44.29) and normal handlebar height positions (VAS=16.08), differed significantly (p<0.001).
Pain measured on the Lickert scale for groups 1 and 3 differed significantly (p<0.001), in particular the mean Lickert score for normal handlebar was 1.33 versus 2.46 for low handlebar height.

Similarly for McGill Pain Questionnaire pain inflicted differed significantly (p<0.001), in particular for the mean McGill pain score for normal handlebar heights was 1.16 versus 1.92 for low handlebar height.
Groups 2 and three cannot be shown to be equivalent do to the fact that the study design is powered to show difference testing, however the sequence of handlebar height adjustments that groups two and three underwent, equated to low handlebar height followed by normal handlebar height adjustment. The study design provided for the carry-over effect and adjusted for it, thereby allowing the analysis between the groups' one and two/three as the sequence of handlebar adjustments were the same for groups two and three.

Table 4.6

Analysis of groups 1 and 2/3

Group 1 and 2/3 n=36	Mean VAS	Mean Lickert	Mean McGill	p-value
Normal handlebar position	17.38	1.33	1.16	p<0.001
Low handlebar position	45.47	2.64	1.91	p<0.001
High	zero	zero	zero	

Analysis of groups 1 and groups 2/3 was done as the sequence of handlebar adjustments in group 2 and 3 followed the same sequence. Group 1 (Normal handlebar height→ low handlebar height) and group 2/3 (low handlebar height→ normal handlebar height) pain resulting from the low handlebar and normal handlebar height positions, measured on the VAS, differed significantly (p<0.001). The mean VAS score for normal handlebar height position was 17.38 versus 45.47 for the low handlebar height.

Pain as measured on the Lickert scale for groups 1 and 2/3 differed significantly (p<0.001). The mean Lickert score for normal handlebar was 1.33 versus 2.64 for low handlebar height. Similarly for McGill Pain Questionnaire pain differed significantly (p<0.001).The mean McGill pain score for normal handlebar heights was 1.16 versus 1.91 for low handlebar height.

This study shows that the mean pain scores reported by cyclists during a Spinning® class are significantly different (p<0.001) when the handlebar positions are adjusted to different heights. Cyclists report lower pain scores with the handlebars at the normal handlebar height position compared to the low handlebar height position.

The standard deviation remains fairly constant between the pain scores, indicating that the pain scores deviated by a constant amount, when comparing the normal and low handlebar height adjustments made to the Spinning® bicycle, indicating that the pain experienced by the cyclists during a Spinning® class with their handlebars placed in the low and normal handlebar positions was of significance ($p<0.001$) as compared with a zero pain score when the handlebars were placed in the high handlebar position.

In this study, pain experienced by cyclists with their handlebar height placed in the low handlebar height position, as measured on the McGill Pain Questionnaire, was noted as ”Mild” to “Moderate”, indicating that the majority of LBP experienced by the cyclists was not of a serious nature.

In conclusion, there is a statistically meaningful difference ($p<0.001$) between the mean values of pain recorded by participants of the low handlebar height compared to the normal handlebar height, with the normal handlebar height being the better position. The standard deviation remains relatively constant. No pain was recorded on the VAS, Lickert scale and on the McGill Pain scale when the handlebars were placed in the high handlebar height position on the Spinning® bicycle. The results of the study allow one to conclude that the high handlebar height position is best position for participants in a Spinning® class.

Chapter 5

5.0 DISCUSSION

The results of this study, **The effect of handlebar height on low back pain in cyclists during Spinning®,** indicated that no low back pain was experienced by the cyclist who participated in a Spinning® class with the handlebars placed in the high handlebar height position, as measured on the VAS and McGill Pain Questionnaire. The cyclists commenced the Spinning® class with no low back pain and completed the session without elicitation of low back pain when the handlebars were placed in the high handlebar position. These results support the experimental hypothesis.

The result of the study concluded that optimal handle bar height is the high handlebar height position. This position allowed the cyclist to participate in a Spinning® class without LBP being provoked. This is probably due to the fact the participant was able to maintain a neutral spine position, thereby facilitating the optimal biomechanical function of the lumbar spine during a Spinning® class. This supports Mellion (1994), who stated that it is often necessary to relieve a cyclist's extended position by using handlebars which have not been lowered excessively, using a stem with a shorter extension, raising the stem of the handlebars or moving the saddle forward. His research related to cyclists is shown to be relevant to the Spinning® participants in this study. Back and neck problems in cyclists should be alleviated by a combination of bicycle adjustment or modification (Mellion 1994).

The study conducted by Richardson and Sims (1991) supports the necessity of attaining a participants' optimal bicycle configuration i.e. the saddle post height, saddle angle, fore/aft of the saddle and the handlebar height on the Spinning® bicycle, to allow optimal functioning of the participants' gluteus maximus muscle. The subjects who participated in the study reported musculo-skeletal type LBP when the handlebar height was lowered to a low handlebar height. The altered handlebar position would result in an altered lumbar position from lumbar lordosis to a lumbar kyphosis, thereby increasing the intradiscal pressure as the anterior spinal column would carry an increased spinal load due to the altered gravitational force on the cyclist's body weight (Usabiago et al 2002).

The results are similar to those of Richmond (1994) in that he found that handlebar problems are common among cyclists. From this study conducted on Spinning®, it is possible that LBP encountered by cyclists who experience LBP while Spinning® are due to an incorrect handlebar height position.

Christiaans et al (1999) suggested that the incorrect bicycle configuration will result in compromised blood flow, neural innervation and impulse, thereby compromising the cyclist's biomechanical function (Christiaans et al 1998). When the low handlebar height position was studied, LBP was elicited due to an incorrect bicycle configuration, compromising the cyclist's biomechanical function.

Handlebar problems are common among cyclists. Compression neuropathy, more commonly of the ulnar than median nerve is frequent. This is seldom a permanent injury or deficit if diagnosed early, and may be prevented by advising the cyclist to adjust their handlebar height to the appropriate height. Overuse symptoms may be due to repetitive motion of the wrist resulting in the aggravation of wrist tendons and connective tissue of the neck and shoulders (Richmond 1994). In the results of the study, a low handlebar height position was noted by one cyclist to have produced a triceps brachii heaviness and low cervical pain. In two separate cases, hand numbness was reported when the handlebars were adjusted to the low position. These symptoms were not elicited when the high handlebar position was adopted. This would also support the use of a high handlebar position on the Spinning® bicycle.

An observation was made in that a higher handlebar height will indirectly create a shorter lever on the lumbar spine, thereby encouraging a change from lumbar kyphosis to a lumbar lordosis. This will decrease the intradiscal pressure and decrease the shear force on the lumbar spine (Mellion 1994).

A limitation of the study is that one may not be able to adapt the results of this study to the cycling population who do not have a normal upper limb/torso to lower limb ratio. A reduced upper limb/torso to lower limb ratio may need a lower handlebar height on a Spinning® bicycle. A cyclist with an increased upper limb/torso to lower limb ratio may require a higher handlebar height on the Spinning® bicycle.

5.1 Suggestions for further research

While the study has demonstrated that the effect of adjusting the handlebar height on the Spinning® bicycle to the high position prevented low back pain in cyclists during Spinning®, it would be interesting to ascertain whether an adjusted saddle position on the Spinning® bicycle would alter the low back pain experienced by cyclists during a Spinning® class. The saddle position needs to encompass the optimal seat angle to cross bar of the bicycle, the fore/aft of the saddle and saddle post height.

This suggestion is supported by the research conducted by Fanucci et al (2002), that LBP reported by cyclists is a frequent pathology, probably related to an inappropriate saddle position (Fanucci et al 2002).

Chapter 6

6.0 CONCLUSION

The results of this study indicate that the pain score as measured on the VAS, Lickert scale and McGill Pain Questionnaires was significantly ($p<0.001$) less in cyclists, who participated in a Spinning® class with their handlebars placed in the high handlebar height position.

It is hypothesized that the high handlebar position allows the cyclist to maintain a neutral spine position, thereby facilitating the optimal biomechanical function of the lumbar spine, while participating in a Spinning® class.

The low handlebar height and normal handlebar height were shown too significantly ($p<0.001$) increase the subjects' perception of LBP experienced during a spinning class. However no pain was recorded on the VAS, Lickert scale and on the McGill Pain scale when the handlebars were placed in the high handlebar height position on the Spinning® bicycle. The results of the study indicate that the high handlebar height position is the best position for cyclists participating in a Spinning® class.

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APPENDIX A

The origin of Spinning®:

Spinning®, is a registered trademark of Mad Dogg Athletics, Inc., a Santa Monica, California based company established in 1992 by Johnny Goldberg and John Baudhuin.
Spinning®, the original indoor stationary cycling program, was developed in 1987 by endurance cyclist Johnny Goldberg.

This athletic training program has been offered to fitness facilities and consumers worldwide since 1992.

What is Spinning®?

The Spinning® program is the simulation of an outdoor ride brought indoors, over different terrains, incorporating strength and endurance. Spinning® is a unique indoor cycling workout. It brings the element of athletic training to people of all fitness levels, from beginners to elite athletes. Spinning® is a high- energy group exercise program, integrating music, camaraderie and visualisation in a complete mind/body exercise programme.

This program is individualised for participants of any age or ability.
The Spinning® program uses the specially designed Johnny G. Spinner® stationary bicycle made by Schwinn®.

A spinning® session consists of a 40 minute workout. Participants use heart rate monitors during participation to optimise the cardiovascular benefits of the workout.

A simple set of movements i.e. flat road cycling, hill climbing, jumping and sprints, hand positions, and heart rate training, deliver personal empowerment and unparalleled fitness results.

Hand positions on the handlebars can be categorised as hand position one (cyclist's hands are placed at the base of the semi-circle of the handlebar); hand position two (the cyclist's hands are placed approximately twenty centimetres apart on either side of the semi-circle of the handlebar); hand position three (the cyclist only performs this hand position when hill climbing out of the saddle, the cyclist places their hands at the end of the straight portion of the handlebar).

A Spinning® class may be described as Interval Spinning® class, where the participant moves in and out of the saddle, incorporates all hand positions, and performs flat road cycling (seated on the saddle, hand position one), hill climbing (increased resistance on the fly wheel, seated or standing, hand position two or three), jumps (increased resistance on the fly wheel, movement of the cyclist from seated to standing, maintaining hand position two) and sprints (increased resistance on the fly wheel, seated in the saddle, hand position two).
Instructors undergo specific training including heart rate training principles.
They motivate and guide a class through a 40 minute workout, coaching each participant with motivational, athletic and visualisation techniques which help them achieve their training goals within the workout.

The participant can select:

- The seat post height position
- The fore and aft of the saddle
- Saddle angle
- The handle bar height.

The cyclist has complete control over the bicycle, due to fixed gear and adjustable resistance settings.

The Johnny G. Spinning® bicycle

Subject information sheet

THE EFFECT OF HANDLEBAR HEIGHT ON LOW BACK PAIN IN CYCLISTS DURING SPINNING®.

Dear Participant

I am a registered physiotherapist, currently completing my Master of Science in Physiotherapy at the University of the Witwatersrand. As part of the requirement for the degree, I will be conducting a research study. I will be assessing the effect of handle bar positions on low back pain in cyclists during Spinning® by changing the position of the handlebars on the Spinning® bicycle.

Little research has been conducted on changing handlebar positions. The aim of my research will be to determine whether adjusting handlebar height reduces lumbar pain in cyclists during Spinning®, and to optimise the handlebar height for cyclists with low back pain.

Participation in this study is voluntary, and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
The benefit of participating in this study will be to provide participants with an optimal handlebar position, thereby reducing their low back pain during Spinning®.

The participant may discontinue participation at any time during the period of the study. During the study participants may experience an increase in intensity of their symptoms. Should these symptoms not abate within 24 hours of each study session; the participant will be entitled to physiotherapy at no extra cost.

Each participant will be required to attend 3 Spinning® classes during one week on alternate days. The classes will be held between 5:30-7:30pm, and will be conducted by the same instructor.

During the first session participants will be required to complete the subject details sheet. Two questionnaires will be completed at each session, before and after the class. All your details will remain anonymous.
Approximately 10 minutes in total will be required for completion of the questionnaires at each session.

At the completion of the research study, all the results will be made available to participants via a written information sheet, as well as verbal feedback.

Thanking you for your assistance
Kim Modlin
Registered Physiotherapist – BSc Physiotherapist

APPENDIX C

Consent form for research

A study is currently been conducted on assessing the effect of handle bar positions on low back pain in cyclists during Spinning® by changing the position of the handlebars on the Spinning® bicycle. As a potential participant I require your written consent before you participate in the research study.

I agree to participate in this study, aiming at measuring the effects of handle bar height adjustments made to the Johnny G. Spinner bicycle on a cyclist's low back pain.

I understand the procedure in which the study sessions will be conducted and I understand that I may withdraw from the study at any stage in the research without prejudice. I understand that I may feel an increase in intensity of my symptoms during the period of the study. Should my symptoms not abate within 24 hours of each study session, I will be entitled to physiotherapy at no extra cost.

Signed at…………………………..on…………………………………………………

Signature of participant:………………………………………………………………..

Signature of researcher:………………………………………………………………

Subject Details Questionnaire

Subject Name: Mr/Mrs/Miss………………………… Date:…………………………

Male/Female:……………… Age:…………………………

Height:……………………… Weight:……………………...

Main occupation…………………………………………………………

Sports/Hobbies:………………………………………………………………

Please colour in the blocks on the body chart , where you experience your low back pain.

What type of low back pain do you have?

(Please mark with an “x” in the appropriate box)

Pain:

Sharp pain	☐	Stabbing pain	☐
Shooting pain	☐	Cramping pain	☐
Gnawing pain	☐	Hot/burning pain	☐
Aching pain	☐	Heavy pain	☐
Splitting pain	☐	Tenderness	☐

Weakness in low back ☐

Uncontrolled movement of your low back ☐

Stiffness in your low back ☐

Have you had low back pain for longer than three months?

Yes ☐ No ☐

Behaviour of symptoms

What makes your low back pain worse?……………………….

What makes your low back pain better?…………………….

Do you experience night pain? Yes ☐ No ☐

Do you experience low back pain when:

Coughing?	Yes	No	☐	☐
Resting?	Yes	No	☐	☐
Standing?	Yes	No	☐	☐
Sitting?	Yes	No	☐	☐
Spinning®?	Yes	No	☐	☐
Stair climbing?	Yes	No	☐	☐
Walking?	Yes	No	☐	☐

When is your low back pain most prominent?

Morning ☐

Evening ☐

Constant ☐

During spinning® ☐

After spinning® ☐ Duration ☐

Frequency of episodes

How long have you had low back pain?

1 month ☐

2 months ☐

3 months ☐

3-6 months ☐

6-12 month ☐

greater than I year ☐

Hospitalisations related to low back pain: Yes ☐ No ☐

If yes, please specify……………………………………………………………

Do you know the cause of your low back pain? Yes ☐ No ☐

If yes, please mention diagnosis if known……………………………………

Have you received physiotherapy treatment for your low back pain?

Yes ☐ No ☐

If no, have you received any other treatment, and if so please mention treatment……………………………………………………

Are you currently receiving physiotherapy treatment for your low back pain?

Yes ☐ No ☐

Do you have a family history of joint problems?

Yes ☐ No ☐

Special questions

Do you experience any of these symptoms related to your low back pain?

Numbness	Yes	☐	No	☐
Pins and needles	Yes	☐	No	☐
Sensation changes	Yes	☐	No	☐
Muscle weakness	Yes	☐	No	☐

How is your general health? Good ☐ Fair ☐ Poor ☐

Do you have any heart or lung diseases? Yes ☐ No ☐

If yes, please specify………………………………………

Are you taking any medication on a daily basis? Yes ☐ No ☐

If yes, please specify………………………………………….

Activities

Level of activity: Low ☐ Moderate ☐ High ☐

Type of activity:
- Cycling ☐
- Circuit/weights ☐
- Running ☐
- Spinning® ☐
- Walking ☐
- Other………………………………………..

How often do you attend Core Health Fitness Centre per week?

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐

The number of months you have been participating in spinning® classes?

< 3 months ☐ 3-6 months ☐ 6-9 months ☐

9-12 months ☐ > 12months ☐

Appendix E

McGill Pain Questionnaire

Please tick only those adjectives that describe your pain and score them as **none, mild, moderate or severe.**

Appendix F

Visual Analogue Scale and Lickert scale

Appendix G

Ethical Clearance

Appendix H

Statistical Analysis

On all three scales it was found that low handlebars inflict significantly more pain than high handlebars for each of the three analyses (i), (ii) & (iii).

(i) Group 1 has sequence Normal/Low and Group 2 has sequence Low/Normal the three outcomes were (VAS: $p<0.001$, 45.5 for Low vs 17.4 for Normal), (Lickert scale: $p<0.001$, 1.4 vs 2.7),(Mcgill: $p<0.001$, 1.2 vs 1.9).

(ii) Group 1 has sequence Normal/Low and Group 3 has sequence Low/Normal the three outcomes were (VAS: $p<0.001$, 16.1 for Normal vs 44.3 for Low), (Lickert scale: $p<0.001$, 1.3 vs 2.5),(McGill VAS: $p<0.001$, 1.2 vs 1.9).

(iii) Group 1 has sequence Normal/Low and Group 2 & 3 has sequence Low/Normal the three outcomes were (VAS: $p<0.001$, 17.4 for Normal vs 45.5 for Low), (Lickert scale: $p<0.001$, 1.3 vs 2.6),(McGill VAS: $p<0.001$, 1.2 vs 1.9).

```
. for var  vas vas_l mcgill: xi: xtreg  X  i.group i.treat i.period if group ~= 3, i
> ( id ) \ table  treat if group ~= 3, c(N X mean X sd X)  \ xi: xtreg  X  i.group i
> .treat i.period if group ~= 2, i( id ) \ table  treat if group ~= 2, c(N X mean X
> sd X)  \ xi: xtreg  X  i.group2 i.treat i.period , i( id ) \ table  treat, c(N X m
> ean X sd X)
```

-> xi: xtreg vas i.group i.treat i.period if group ~= 3, i(id)

```
i.group           _Igroup_1-3        (naturally coded; _Igroup_1 omitted)
i.treat           _Itreat_0-1        (naturally coded; _Itreat_0 omitted)
i.period          _Iperiod_1-2       (naturally coded; _Iperiod_1 omitted)

Random-effects GLS regression                   Number of obs      =        48
Group variable (i) : id                         Number of groups   =        24

R-sq:  within  = 0.8262                         Obs per group: min =         2
       between = 0.0090                                        avg =       2.0
       overall = 0.3994                                        max =         2

Random effects u_i ~ Gaussian                   Wald chi2(3)       =    104.81
corr(u_i, X)       = 0 (assumed)                Prob > chi2        =    0.0000

------------------------------------------------------------------------------
         vas |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
   _Igroup_2 |   2.958333   6.604433     0.45   0.654    -9.986117    15.90278
   _Igroup_3 |  (dropped)
   _Itreat_1 |   27.04167   2.645006    10.22   0.000     21.85755    32.22578
  _Iperiod_2 |  -.7916667   2.645006    -0.30   0.765    -5.975782    4.392449
       _cons |   17.83333   5.030635     3.54   0.000     7.973469     27.6932
-------------+----------------------------------------------------------------
     sigma_u |  14.823456
     sigma_e |   9.162568
         rho |  .72355579   (fraction of variance due to u_i)
------------------------------------------------------------------------------
```

-> table treat if group ~= 3, c(N vas mean vas sd vas)

```
----------------------------------------------
    treat |     N(vas)   mean(vas)     sd(vas)
----------+-----------------------------------
   Normal |         24     18.9167    13.34465
      Low |         24     45.9583    20.19358
----------------------------------------------
```

```
->  xi: xtreg vas i.group i.treat i.period if group ~= 2, i( id )
i.group           _Igroup_1-3         (naturally coded; _Igroup_1 omitted)
i.treat           _Itreat_0-1         (naturally coded; _Itreat_0 omitted)
i.period          _Iperiod_1-2        (naturally coded; _Iperiod_1 omitted)

Random-effects GLS regression                   Number of obs      =        48
Group variable (i) : id                         Number of groups   =        24

R-sq:  within  = 0.8267                         Obs per group: min =         2
       between = 0.0029                                        avg =       2.0
       overall = 0.4467                                        max =         2

Random effects u_i ~ Gaussian                   Wald chi2(3)       =    105.03
corr(u_i, X)       = 0 (assumed)                Prob > chi2        =    0.0000

------------------------------------------------------------------------------
         vas |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
   _Igroup_2 |  (dropped)
   _Igroup_3 |  -1.541667   6.126597    -0.25   0.801    -13.54958    10.46624
    _Itreat_1 |   28.20833    2.75994    10.22   0.000     22.79895    33.61772
  _Iperiod_2 |  -1.958333    2.75994    -0.71   0.478    -7.367715    3.451049
       _cons |   17.83333   4.751445     3.75   0.000     8.520672    27.14599
-------------+----------------------------------------------------------------
     sigma_u |  13.398044
     sigma_e |  9.5607111
         rho |  .66259796   (fraction of variance due to u_i)
------------------------------------------------------------------------------
```

```
->  table treat if group ~= 2, c(N vas mean vas sd vas)

----------------------------------------------
    treat |     N(vas)   mean(vas)     sd(vas)
----------+-----------------------------------
   Normal |         24     16.0833    13.39992
      Low |         24     44.2917    18.49202
----------------------------------------------
```

```
->  xi: xtreg vas i.group i.treat i.period , i( id )
i.group2          _Igroup2_1-2        (naturally coded; _Igroup2_1 omitted)
i.treat           _Itreat_0-1         (naturally coded; _Itreat_0 omitted)
i.period          _Iperiod_1-2        (naturally coded; _Iperiod_1 omitted)

Random-effects GLS regression                   Number of obs      =        72
Group variable (i) : id                         Number of groups   =        36

R-sq:  within  = 0.8483                         Obs per group: min =         2
       between = 0.0005                                        avg =       2.0
       overall = 0.4465                                        max =         2

Random effects u_i ~ Gaussian                   Wald chi2(3)       =    190.22
corr(u_i, X)       = 0 (assumed)                Prob > chi2        =    0.0000

------------------------------------------------------------------------------
         vas |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
  _Igroup2_2 |   .7083333   5.268895     0.13   0.893    -9.618512    11.03518
   _Itreat_1 |     27.625   2.162143    12.78   0.000     23.38728    31.86272
  _Iperiod_2 |     -1.375   2.162143    -0.64   0.525    -5.612722    2.862722
       _cons |   17.83333    4.65017     3.83   0.000     8.719168     26.9475
-------------+----------------------------------------------------------------
     sigma_u |  13.590113
     sigma_e |  8.6485718
         rho |  .71174962   (fraction of variance due to u_i)
------------------------------------------------------------------------------

->  table treat, c(N vas mean vas sd vas)

----------------------------------------------
    treat |     N(vas)   mean(vas)     sd(vas)
----------+-----------------------------------
   Normal |         36     17.3889    13.01269
      Low |         36     45.4722    18.32794
----------------------------------------------
```

-> xi: xtreg vas_l i.group i.treat i.period if group ~= 3, i(id)

```
i.group           _Igroup_1-3        (naturally coded; _Igroup_1 omitted)
i.treat           _Itreat_0-1        (naturally coded; _Itreat_0 omitted)
i.period          _Iperiod_1-2       (naturally coded; _Iperiod_1 omitted)

Random-effects GLS regression                   Number of obs      =        48
Group variable (i) : id                         Number of groups   =        24

R-sq:  within  = 0.8395                         Obs per group: min =         2
       between = 0.0228                                        avg =       2.0
       overall = 0.3908                                        max =         2

Random effects u_i ~ Gaussian                   Wald chi2(3)       =    115.59
corr(u_i, X)       = 0 (assumed)                Prob > chi2        =    0.0000

------------------------------------------------------------------------------
       vas_l |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
   _Igroup_2 |        .25   .3490608     0.72   0.474    -.4341466    .9341466
   _Igroup_3 |  (dropped)
   _Itreat_1 |   1.333333   .1281177    10.41   0.000     1.082227    1.584439
  _Iperiod_2 |  -.3333333   .1281177    -2.60   0.009    -.5844394   -.0822273
       _cons |   1.416667   .2629235     5.39   0.000      .901346    1.931987
-------------+----------------------------------------------------------------
     sigma_u |  .79534631
     sigma_e |  .44381268
         rho |  .76255708   (fraction of variance due to u_i)
------------------------------------------------------------------------------
```

-> table treat if group ~= 3, c(N vas_l mean vas_l sd vas_l)

```
-------------------------------------------------
    treat |    N(vas_l)  mean(vas_l)    sd(vas_l)
----------+--------------------------------------
   Normal |          24        1.375     .8242256
      Low |          24      2.70833     .9990938
-------------------------------------------------
```

```
->  xi: xtreg vas_l i.group i.treat i.period if group ~= 2, i( id )
i.group           _Igroup_1-3        (naturally coded; _Igroup_1 omitted)
i.treat           _Itreat_0-1        (naturally coded; _Itreat_0 omitted)
i.period          _Iperiod_1-2       (naturally coded; _Iperiod_1 omitted)

Random-effects GLS regression                   Number of obs      =        48
Group variable (i) : id                         Number of groups   =        24

R-sq:  within  = 0.7885                         Obs per group: min =         2
       between = 0.0008                                        avg =       2.0
       overall = 0.3312                                        max =         2

Random effects u_i ~ Gaussian                   Wald chi2(3)       =     82.02
corr(u_i, X)       = 0 (assumed)                Prob > chi2        =    0.0000

------------------------------------------------------------------------------
       vas_l |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
   _Igroup_2 |  (dropped)
   _Igroup_3 |  -.0416667   .3195542    -0.13   0.896    -.6679814    .5846481
    _Itreat_1 |      1.125       .125     9.00   0.000     .8800045    1.369995
  _Iperiod_2 |      -.125       .125    -1.00   0.317    -.3699955    .1199955
       _cons |   1.416667   .2426313     5.84   0.000     .9411181    1.892215
-------------+----------------------------------------------------------------
     sigma_u |  .72037448
     sigma_e |   .4330127
         rho |  .73458445   (fraction of variance due to u_i)
------------------------------------------------------------------------------

->  table treat if group ~= 2, c(N vas_l mean vas_l sd vas_l)

-------------------------------------------------
    treat |    N(vas_l)  mean(vas_l)    sd(vas_l)
----------+--------------------------------------
   Normal |          24      1.33333     .7019641
      Low |          24      2.45833     .9315329
-------------------------------------------------
```

```
->  xi: xtreg vas_l i.group i.treat i.period , i( id )
i.group2          _Igroup2_1-2        (naturally coded; _Igroup2_1 omitted)
i.treat           _Itreat_0-1         (naturally coded; _Itreat_0 omitted)
i.period          _Iperiod_1-2        (naturally coded; _Iperiod_1 omitted)

Random-effects GLS regression                   Number of obs      =        72
Group variable (i) : id                         Number of groups   =        36

R-sq:  within  = 0.8406                         Obs per group: min =         2
       between = 0.0040                                        avg =       2.0
       overall = 0.3914                                        max =         2

Random effects u_i ~ Gaussian                   Wald chi2(3)       =    179.38
corr(u_i, X)       = 0 (assumed)                Prob > chi2        =    0.0000

------------------------------------------------------------------------------
       vas_l |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
  _Igroup2_2 |   .1041667   .2821676     0.37   0.712    -.4488717     .657205
   _Itreat_1 |   1.229167   .1048385    11.72   0.000     1.023687    1.434646
  _Iperiod_2 |  -.2291667   .1048385    -2.19   0.029    -.4346464   -.0236869
       _cons |   1.416667   .2457772     5.76   0.000     .9349521    1.898381
-------------+----------------------------------------------------------------
     sigma_u |  .74095857
     sigma_e |  .41935408
         rho |  .75739645   (fraction of variance due to u_i)
------------------------------------------------------------------------------

->  table treat, c(N vas_l mean vas_l sd vas_l)

-------------------------------------------------
    treat |    N(vas_l)  mean(vas_l)    sd(vas_l)
----------+--------------------------------------
   Normal |          36      1.33333     .7559289
      Low |          36      2.63889      .930523
-------------------------------------------------
```

```
->  xi: xtreg mcgill i.group i.treat i.period if group ~= 3, i( id )
i.group           _Igroup_1-3         (naturally coded; _Igroup_1 omitted)
i.treat           _Itreat_0-1         (naturally coded; _Itreat_0 omitted)
i.period          _Iperiod_1-2        (naturally coded; _Iperiod_1 omitted)

Random-effects GLS regression                   Number of obs      =        48
Group variable (i) : id                         Number of groups   =        24

R-sq:  within  = 0.6360                         Obs per group: min =         2
       between = 0.0017                                        avg =       2.0
       overall = 0.2779                                        max =         2

Random effects u_i ~ Gaussian                   Wald chi2(3)       =     38.47
corr(u_i, X)       = 0 (assumed)                Prob > chi2        =    0.0000

------------------------------------------------------------------------------
      mcgill |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
   _Igroup_2 |  -.0416667   .2157761    -0.19   0.847    -.4645801    .3812468
   _Igroup_3 |  (dropped)
    _Itreat_1 |   .7083333   .1144541     6.19   0.000     .4840074    .9326593
  _Iperiod_2 |  -.0416667   .1144541    -0.36   0.716    -.2659926    .1826593
       _cons |       1.25   .1727123     7.24   0.000     .9114901     1.58851
-------------+----------------------------------------------------------------
     sigma_u |  .44805979
     sigma_e |  .39648073
         rho |  .56084656   (fraction of variance due to u_i)
------------------------------------------------------------------------------

->  table treat if group ~= 3, c(N mcgill mean mcgill sd mcgill)

----------------------------------------------------
    treat |    N(mcgill)  mean(mcgill)    sd(mcgill)
----------+-----------------------------------------
   Normal |           24       1.20833      .6580054
      Low |           24       1.91667      .5036101
----------------------------------------------------
```

```
->  xi: xtreg mcgill i.group i.treat i.period if group ~= 2, i( id )
i.group           _Igroup_1-3         (naturally coded; _Igroup_1 omitted)
i.treat           _Itreat_0-1         (naturally coded; _Itreat_0 omitted)
i.period          _Iperiod_1-2        (naturally coded; _Iperiod_1 omitted)

Random-effects GLS regression                   Number of obs      =        48
Group variable (i) : id                         Number of groups   =        24

R-sq:  within  = 0.7593                         Obs per group: min =         2
       between = 0.0076                                        avg =       2.0
       overall = 0.3473                                        max =         2

Random effects u_i ~ Gaussian                   Wald chi2(3)       =     69.55
corr(u_i, X)       = 0 (assumed)                Prob > chi2        =    0.0000

------------------------------------------------------------------------------
      mcgill |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
   _Igroup_2 |  (dropped)
   _Igroup_3 |  -.0833333   .2025718    -0.41   0.681    -.4803669    .3137002
   _Itreat_1 |        .75   .0905929     8.28   0.000     .5724412    .9275588
  _Iperiod_2 |  -.0833333   .0905929    -0.92   0.358    -.2608921    .0942255
       _cons |       1.25   .1569115     7.97   0.000     .9424592    1.557541
-------------+----------------------------------------------------------------
     sigma_u |  .44381268
     sigma_e |  .31382296
         rho |  .66666667   (fraction of variance due to u_i)
------------------------------------------------------------------------------

->  table treat if group ~= 2, c(N mcgill mean mcgill sd mcgill)

----------------------------------------------------
    treat |    N(mcgill)  mean(mcgill)    sd(mcgill)
----------+-----------------------------------------
   Normal |           24       1.16667      .4815434
      Low |           24       1.91667      .5835921
----------------------------------------------------
```

```
->  xi: xtreg mcgill i.group i.treat i.period , i( id )
i.group2          _Igroup2_1-2        (naturally coded; _Igroup2_1 omitted)
i.treat           _Itreat_0-1         (naturally coded; _Itreat_0 omitted)
i.period          _Iperiod_1-2        (naturally coded; _Iperiod_1 omitted)

Random-effects GLS regression                   Number of obs      =        72
Group variable (i) : id                         Number of groups   =        36

R-sq:  within  = 0.7026                         Obs per group: min =         2
       between = 0.0041                                        avg =       2.0
       overall = 0.3431                                        max =         2

Random effects u_i ~ Gaussian                   Wald chi2(3)       =     80.46
corr(u_i, X)       = 0 (assumed)                Prob > chi2        =    0.0000

------------------------------------------------------------------------------
      mcgill |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
  _Igroup2_2 |     -.0625   .1677736    -0.37   0.710    -.3913302    .2663302
   _Itreat_1 |   .7291667   .0890359     8.19   0.000     .5546595    .9036738
  _Iperiod_2 |     -.0625   .0890359    -0.70   0.483    -.2370071    .1120071
       _cons |       1.25   .1550814     8.06   0.000      .946046    1.553954
-------------+----------------------------------------------------------------
     sigma_u |  .40219983
     sigma_e |  .35614356
         rho |  .56050955   (fraction of variance due to u_i)
------------------------------------------------------------------------------

->  table treat, c(N mcgill mean mcgill sd mcgill)

----------------------------------------------------
    treat |    N(mcgill)  mean(mcgill)    sd(mcgill)
----------+-----------------------------------------
   Normal |           36       1.16667      .5606119
      Low |           36       1.91667            .5
----------------------------------------------------
```