A Comparative Study to Determine the Efficacy
of Oral and Parenteral Traumeel® S,
in the treatment of Cervical Facet Syndrome

A research dissertation presented to the
Faculty of Health Sciences, Technikon Witwatersrand,
as partial fulfilment for the degree Magister Technologiae: Homoeopathy
by
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DECLARATION

I, Mareza Cape, declare that this dissertation is my own work. It is being submitted for the Degree of Master of Technology at the Technikon Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination in any other Technikon or University.

(Signature of Candidate)

Thirty first day of January 2005
ABSTRACT

Cervical facet syndrome is a condition characterized by neck pain and decreased mobility of the cervical spine (Bovim et al., 1994). There is a high prevalence of cervical facet syndrome in industrialized countries leading to an ever increasing loss of productivity due to time taken off from work. Cervical facet syndrome is also very costly in terms of treatment (Jordan et al., 1998).

The aim of this study was twofold: firstly, to determine whether Traumeel®S, a homoeopathic combination remedy, is useful in treating the symptoms of cervical facet syndrome; and secondly to determine which method of administration, oral or parenteral, is more effective in relieving the symptoms.

Thirty participants were recruited to participate in this six week study. The first two weeks of the trial involved treatment, followed four weeks later by a follow-up consultation. At the initial consultation the participants underwent a regional cervical spine examination (Appendix C) by a chiropractor, in order to make the diagnosis of cervical facet syndrome. Participants were excluded from the study if on the examination any fractures or subluxations of the cervical spine were detected. Participants were randomly divided into two groups of fifteen. Participants in group one were administered Traumeel®S subcutaneously into the area of pain, three times a week for a period of two weeks. Participants in group two were administered Traumeel®S ampoules; whereby one ampoule was taken orally three times a week for a period of two weeks. Each of the thirty participants were evaluated using the same tests and questionnaires, namely the Visual Analogue Scale for pain (Appendix E), and the Neck Pain Disability Index (Appendix F). Range of motion was measured using the Cervical Range of Motion Goniometer (CROM) (Appendix G). All participants underwent pre-treatment testing and evaluation which served as the baseline for that particular participant. All tests and questionnaires were repeated at the end of the first and second week as well as at the four week follow-up consultation.

The results of this study indicated that Traumeel®S is effective in decreasing pain and improving range of motion in cervical facet syndrome, regardless of oral or parenteral administration.
This research dissertation is dedicated to my mother and father, who supported me in every possible way throughout my studies.
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TABLE OF CONTENTS

DECLARATION ii
ABSTRACT iii
DEDICATION iv
ACKNOWLEDGMENTS v
TABLE OF CONTENTS vi
LIST OF APPENDICES xi
LIST OF TABLES xii
LIST OF FIGURES xiii

CHAPTER ONE

INTRODUCTION

1.1 Problem statement 1
1.2 Aim of the study 1
1.3 Benefits of the study 1

CHAPTER TWO

LITERATURE REVIEW

2.1 The Cervical Spine 2
2.1.1 Introduction
2.1.2 Anatomy of the cervical spine
   2.1.2.1 Skeletal anatomy
   2.1.2.2 Ligaments
   2.1.2.3 Neural anatomy
   2.1.2.4 Blood supply
   2.1.2.5 Muscles and movements
2.1.3 Cervical facet syndrome

2.2 Therapeutic approaches to the treatment of cervical facet syndrome
   2.2.1 Allopathic treatment for cervical facet syndrome
      2.2.1.1 Analgesics
      2.2.1.2 Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)
   2.2.2 Physical therapies in the treatment of cervical facet syndrome
      2.2.2.1 Chiropractic treatment
      2.2.2.2 Physiotherapy treatment

2.3 Routes of drug administration
   2.3.1 Introduction
   2.3.2 Bioavailability
   2.3.3 Oral route of drug administration
   2.3.4 Parenteral route of drug administration

2.4 Homoeopathy and Homotoxicology
   2.4.1 Homoeopathy
   2.4.2 Homotoxicology
   2.4.3 Traumeel®S
      2.4.3.1 Mechanisms of action of Traumeel®S
      2.4.3.2 Pharmacological and clinical notes of Traumeel®S
CHAPTER THREE

METHODOLOGY

3.1 Study sample

3.2 Research design

3.2.1 Procedure

3.2.2 Tools utilised

3.2.2.1 Cervical range of motion

3.2.2.2 Visual Analogue Scale (VAS)

3.2.2.3 The Neck Pain Disability Index

3.2.3 Medication

3.3 Data gathering

3.4 Statistical analysis

CHAPTER FOUR

RESULTS

4.1 Introduction to the results
4.2 Background variables

4.2.1 Age
4.2.2 Gender and race
4.2.3 Onset of cervical facet syndrome
4.2.4 Duration of cervical facet syndrome

4.3 Cervical range of motion results

4.3.1 Flexion results
4.3.2 Extension results
4.3.3 Right rotation results
4.3.4 Left rotation results
4.3.5 Right lateral flexion results
4.3.6 Left lateral flexion results

4.4 Visual Analogue Scale results

4.5 Neck Pain Disability Index results

CHAPTER FIVE

DISCUSSION

5.1 Background variables

5.2 Cervical range of motion results

5.2.1 Flexion and extension results
5.2.2 Right and left rotation results
5.2.3 Right and left lateral flexion results
5.3 Visual Analogue Scale results

5.4 Neck Pain Disability Index results

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

6.2 Recommendations

REFERENCES
# LIST OF APPENDICES

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix A</td>
<td>Advertisement</td>
<td>56</td>
</tr>
<tr>
<td>Appendix B</td>
<td>Case history</td>
<td>57</td>
</tr>
<tr>
<td>Appendix C</td>
<td>Regional cervical spine examination</td>
<td>62</td>
</tr>
<tr>
<td>Appendix D</td>
<td>Participant information and consent form</td>
<td>67</td>
</tr>
<tr>
<td>Appendix E</td>
<td>Visual Analogue Scale</td>
<td>69</td>
</tr>
<tr>
<td>Appendix F</td>
<td>Neck Pain Disability Index</td>
<td>70</td>
</tr>
<tr>
<td>Appendix G</td>
<td>Cervical range of motion</td>
<td>73</td>
</tr>
<tr>
<td>Appendix H</td>
<td>Cervical range of motion results</td>
<td>74</td>
</tr>
<tr>
<td>Appendix H.1</td>
<td>Detailed analysis of flexion for both groups for the duration of the study</td>
<td>74</td>
</tr>
<tr>
<td>Appendix H.2</td>
<td>Detailed analysis of extension for both groups for the duration of the study</td>
<td>74</td>
</tr>
<tr>
<td>Appendix H.3</td>
<td>Detailed analysis of right rotation for both groups for the duration of the study</td>
<td>74</td>
</tr>
<tr>
<td>Appendix H.4</td>
<td>Detailed analysis of left rotation for both groups for the duration of the study</td>
<td>75</td>
</tr>
<tr>
<td>Appendix H.5</td>
<td>Detailed analysis of right lateral flexion for both groups for the duration of the study</td>
<td>75</td>
</tr>
<tr>
<td>Appendix H.6</td>
<td>Detailed analysis of left lateral flexion for both groups for the duration of the study</td>
<td>75</td>
</tr>
<tr>
<td>Appendix I</td>
<td>Visual Analogue Scale results</td>
<td>76</td>
</tr>
</tbody>
</table>
**LIST OF TABLES**

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 2.1</td>
<td>Movements and muscles of the cervical spine</td>
<td>7</td>
</tr>
<tr>
<td>Table 2.2</td>
<td>Routes of administration and bioavailability of drugs</td>
<td>14</td>
</tr>
<tr>
<td>Table 4.1</td>
<td>Overall flexion results for the duration of the study</td>
<td>33</td>
</tr>
<tr>
<td>Table 4.2</td>
<td>Overall extension results for the duration of the study</td>
<td>35</td>
</tr>
<tr>
<td>Table 4.3</td>
<td>Overall right rotation results for the duration of the study</td>
<td>36</td>
</tr>
<tr>
<td>Table 4.4</td>
<td>Overall left rotation results for the duration of the study</td>
<td>38</td>
</tr>
<tr>
<td>Table 4.5</td>
<td>Overall right lateral flexion results for the duration of the study</td>
<td>39</td>
</tr>
<tr>
<td>Table 4.6</td>
<td>Overall left lateral flexion results for the duration of the study</td>
<td>41</td>
</tr>
<tr>
<td>Table 4.7</td>
<td>Overall results from the Visual Analogue Scale for the duration of the study</td>
<td>42</td>
</tr>
<tr>
<td>Table 4.8</td>
<td>Overall results from the Neck Pain Disability Index for the duration of the study</td>
<td>43</td>
</tr>
<tr>
<td>Table 4.9</td>
<td>Frequencies from the Neck Pain Disability Index</td>
<td>43</td>
</tr>
<tr>
<td>Figure 2.1</td>
<td>Skeletal anatomy of the cervical spine</td>
<td>3</td>
</tr>
<tr>
<td>Figure 2.2</td>
<td>Main ligaments found in the cervical spine</td>
<td>4</td>
</tr>
<tr>
<td>Figure 2.3</td>
<td>Ligaments of the upper cervical vertebrae</td>
<td>4</td>
</tr>
<tr>
<td>Figure 2.4</td>
<td>Blood supply of the cervical spine</td>
<td>5</td>
</tr>
<tr>
<td>Figure 2.5</td>
<td>Movements of the cervical spine</td>
<td>6</td>
</tr>
<tr>
<td>Figure 2.6</td>
<td>Superficial muscles of the cervical spine</td>
<td>8</td>
</tr>
<tr>
<td>Figure 2.7</td>
<td>Deep muscles of the cervical spine</td>
<td>8</td>
</tr>
<tr>
<td>Figure 4.1</td>
<td>Means of flexion of group one and group two during the study</td>
<td>33</td>
</tr>
<tr>
<td>Figure 4.2</td>
<td>Means of extension of group one and group two during the study</td>
<td>34</td>
</tr>
<tr>
<td>Figure 4.3</td>
<td>Means of right rotation of group one and group two during the study</td>
<td>36</td>
</tr>
<tr>
<td>Figure 4.4</td>
<td>Means of left rotation of group one and group two during the study</td>
<td>37</td>
</tr>
<tr>
<td>Figure 4.5</td>
<td>Means of right lateral flexion of group one and group two during the study</td>
<td>39</td>
</tr>
<tr>
<td>Figure 4.6</td>
<td>Means of left lateral flexion of group one and group two during the study</td>
<td>40</td>
</tr>
<tr>
<td>Figure 4.7</td>
<td>Means of results from VAS of group one and group two during the study</td>
<td>42</td>
</tr>
</tbody>
</table>
CHAPTER ONE

INTRODUCTION

1.1 Problem statement

Chronic or frequently recurring cervical pain affects almost one third of the adult population (Vernon and Hu, 1999), and 10-15% of the general population (Bourghouts et al., 1999). According to Stussman (1996), neck pain is one of the most common reasons for visiting the emergency department of a hospital or clinic, and one of the principal reasons for consulting a general practitioner (Schappert, 1996). It is also the second leading chief complaint reported by patients seeking chiropractic care (Stussman, 1996). Jordan et al (1998), state that neck pain is extremely common and very costly in terms of treatment, individual suffering and time lost from work.

Cervical facet syndrome is a group of similar conditions with the main symptoms being neck pain and decreased mobility of the cervical spine (Bovim et al., 1994).

1.2 Aim of the study

The aim of this comparative study was to determine the efficacy of oral and parenteral Traumeel®S, a Homoeopathic combination remedy, in the treatment of cervical facet syndrome.

1.3 Benefits of the study

It was anticipated that Traumeel®S would be an effective form of treatment for cervical facet syndrome, having the benefits of fewer side effects than allopathic treatment and being less invasive than other therapeutic approaches, in the treatment of cervical facet syndrome. It was also anticipated that Traumeel®S would alleviate pain, decrease inflammation and increase the range of motion in patients suffering from cervical facet syndrome.
CHAPTER TWO

LITERATURE REVIEW

2.1 The Cervical Spine

2.1.1 Introduction

The cervical vertebrae are located in the upper part of the vertebral column of the neck and form a stable osteo-ligamentous axis for support and movement of the head (Grant, 1998). The cervical spine is specialised for mobility and provides a wide range of movement, as well as directing gaze through a range of almost 180 degrees in the horizontal plane and 120 degrees in the vertical plane (Huelke and Nusholz, 1986). The contents of this anatomical cylinder interposed between the skull and thorax include the carotid and vertebral arteries, spinal cord, anterior and posterior nerve roots, as well as the uppermost portion of the brain stem (White and Punjabi, 1990).

The cervical spine is the most complicated articular structure of the body and the consequences of cervical injury are potentially more serious than injuries in the lower region (Porterfield and DeRosa, 1995).

2.1.2 Anatomy of the cervical spine

2.1.2.1 Skeletal anatomy

The cervical spine is made up of seven cervical vertebrae (C1-C7). C1 (atlas) and C2 (axis) are referred to as the upper cervical vertebrae and C3-C7 are the lower cervical vertebrae. C1 articulates with the occiput of the skull above and C7 with the first thoracic vertebrae (T1) below (Mc Kenzie, 1990). There are 37 separate joints that function to carry out the numerous different movements of the head and neck in relation to the trunk (Porterfield and DeRosa, 1995). The two main joints in the upper cervical spine responsible for movement of the head and neck are the atlanto-occipital joint and the atlanto-axial joint (Bland, 1994).
The connection of the cervical spine with the head leads to significant functional consequences in this area. The centre of gravity of the head lies relatively forward. This arrangement and the necessity for substantial mobility of the head, places a high demand on the stability as well as on the mobility of the cervical spine (Dos Winkel, 1996).

In the cervical spine, an intervertebral disc is present between each vertebrae, except between the occiput, C1, and C2 (Porterfield and DeRosa, 1995). The intervertebral discs function to hold the vertebral bodies together, to allow movement of the cervical spine and to absorb shock (Macaab and McCalloch, 1994).

![Skeletal anatomy of the cervical spine](image)

**Figure 2.1** Skeletal anatomy of the cervical spine (Porterfield and DeRosa, 1996)

### 2.1.2.2 Ligaments

According to Mc Kenzie (1990), it is the function of the ligaments of the cervical spine to limit movements of the head and neck and to maintain a postural equilibrium between the vertebrae. The vertebral bodies are bordered anteriorly and posteriorly by two major ligaments, namely the anterior longitudinal ligament and posterior longitudinal ligament (Borenstein et al., 1996). Certain ligaments support only the lower cervical spine; namely the interspinal ligaments, ligamentum flavum and the supraspinous ligament (Moore and Dalley, 1999). The alar ligament and cruciate ligament complex are important stabilizers of the upper cervical spine (Porterfield and DeRosa, 1995).
Figure 2.2 Main ligaments found in the cervical spine (Bornstein et al., 1996)

Figure 2.3 Ligaments of the upper cervical vertebrae (Bornstein et al., 1996)
2.1.2.3 Neural anatomy

The specific nerves involved in the innervation of pain generators of the cervical spine includes, the dorsal ramus, ventral ramus, recurrent meningeal nerve as well as the sensory nerves associated with the autonomic fibres of the cervical region (Grant, 1998).

2.1.2.4 Blood supply

The vertebral artery is the major source of blood supply for the cervical spine and the cervical portion of the spinal cord (Borenstein et al., 1996). The vertebral arteries are usually the first and largest branch of the subclavian artery (Moore and Dalley, 1999).

![Diagram of blood supply of the cervical spine]

Figure 2.4 Blood supply of the cervical spine (Borenstein et al., 1996)

2.1.2.5 Muscles and movements

Normally the neck moves over six hundred times an hour, whether the person is awake or asleep, no other part of the muscular skeletal system is in such constant motion (Bland and Boushey, 1987). The cervical spine is subject to stress and strain in ordinary everyday activities, such as speaking, gesturing, rising, sitting, walking, turning and even lying down (Kapandji, 1977).
The muscles located in the anterior part of the neck are responsible for flexion i.e. bending the head forward or nodding; the muscles in the posterior aspect of the neck are used in extension i.e. for bending the head back. The muscles on the lateral aspects of the neck are used in right and left lateral flexion or bending the head to side, and in rotating the head and neck (Giles and Singer, 1998). The atlanto-occipital joint allows movements in flexion and extension only; there is no rotation at this joint, rotation of the head and neck occurs at the atlanto-axial joints (Grant, 1998).

The normal ranges of motion of the cervical spine are:

- **Flexion** 45° - 90°
- **Extension** 55° - 70°
- **Left rotation** 70° - 90°
- **Right rotation** 70° - 90°
- **Left lateral flexion** 20° - 45°
- **Right lateral flexion** 20° - 45° (Ferlic, 1962 and Murphy, 2000).

![Figure 2.5 Movements of the cervical spine (Bernstein et al., 1996)](image-url)
The table below indicates the various movements of the cervical spine as well as the muscles responsible for each movement.

**Table 2.1 Movements and muscles of the cervical spine (Borenstein et al., 1996).**

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<thead>
<tr>
<th>Movements of flexion</th>
<th>Sternocleidomastoid</th>
</tr>
</thead>
<tbody>
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<td>Longus colli and capitis</td>
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<tr>
<td></td>
<td>Rectus capitis anterior</td>
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<td>Movements of extension</td>
<td>Splenius capitis and cervicis</td>
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<td></td>
<td>Semispinalis capitis and cervicis</td>
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<td>Longissimus capitis and cervicis</td>
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<td>Trapezius</td>
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<td>Interspinalis</td>
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<td></td>
<td>Rectus capitis posterior major and minor</td>
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<td></td>
<td>Obliquus capitis superior</td>
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<td></td>
<td>Sternocleidomastoid</td>
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| Movements of rotation and lateral bending | Sternocleidomastoid          |
|                                          | Scalene group                |
|                                          | Splenius capitis and cervicis |
|                                          | Longissimus capitis          |
|                                          | Levator scapulae             |
|                                          | Longus colli                 |
|                                          | Iliocostalis cervicis        |
|                                          | Multifidi                    |
|                                          | Intertransversarii           |
|                                          | Obliquus capitis inferior and superior |
|                                          | Rectus capitis lateralis     |
Figure 2.6 Superficial muscles of the cervical spine (Bornstein et al., 1996)

Figure 2.7 Deep muscles of the cervical spine (Bornstein et al., 1996)
2.1.3 Cervical facet syndrome

Terms such as whiplash, acute neck sprain, acute cervical sprain, cervical syndrome, hyperflexion-hyperextension neck injury, tension neck syndrome, and others are frequently used to describe what appear to be similar conditions. These different terms can be grouped together as cervical facet syndrome (Bovim et al., 1994). According to Kramer (1981), it is not possible to make a distinction of upper or lower cervical facet syndrome.

Simple, uncomplicated musculo-ligamentous neck sprains are the most common of all neck injuries (Spitzer, 1987). Most patients have a mechanical, non-inflammatory cause for their neck pain i.e. muscle strain and/or annular tear of an inter-vertebral disc. There is usually no underlying serious systemic disease (Croft and Foreman, 2002). Identifying the source of a patient’s pain to be ligamentous, muscular or articular in origin in acute circumstances does not significantly alter the therapy needed or hasten the time of recovery (Borenstein et al., 1996).

The symptoms of cervical facet syndrome may include:
- Pain in the region of the cervical spine
- Limitation of movement of the cervical spine
- Headaches, which are usually unilateral and dull in nature, with associated aching in the neck
- Occipital pain
- Pain in the shoulder, arm, forearm and hand rarely occurs (Bland, 1994).

On physical examination of a patient with cervical facet syndrome the following signs may be found:
- Limitation of movement of the cervical spine
- Active cervical spine motion will be more diminished, rather than passive motion
- Tenderness of the spinous processes
- Muscle spasms in the neck and shoulder region
- Negative signs of spinal cord involvement, subluxations, nerve root compressions, as well as any other neurological signs reflecting organic disorders (Hooper, 1996).
In cervical facet syndrome, symptoms of non-specific neck pain may appear insidiously over a period of weeks, months or even arise spontaneously overnight (McKenzie, 1990). Once cervical symptoms have developed the performance of simple movements or the adaptation of prolonged positions readily increases the intensity of symptoms. Movements previously full and free suddenly become obstructed and at times acutely painful (Giles and Singer, 1998).

The frequency of neck pain is higher among females than males and therefore suggests that gender is a risk factor. Neck pain has also been found to increase with age (Bovim et al., 1994). Makela et al (1991), found the prevalence of neck pain to be associated with a history of injury to the back, neck and shoulders, being overweight, and partly in addition to work-related mental and physical stresses.

2.2 Therapeutic approaches in cervical facet syndrome

2.2.1 Allopathic treatment for cervical facet syndrome

A number of drugs have been advocated for the treatment of cervical facet syndrome on a short-term or long-term basis, these include analgesics and nonsteroidal anti-inflammatory drugs (Bornstein et al., 1996). Analgesics, commonly known as painkillers, are drugs that relieve pain (Trounce, 1994). According to Macnab and McCulloch (1994), analgesics are usually the first line medication for pain, followed by nonsteroidal anti-inflammatory drugs (NSAID’s), which act as analgesics, anti-inflammatories and antipyretics.

After any injury, the body releases chemicals known as prostaglandins, which are responsible for pain and inflammation (Henry, 2001). Analgesics reduce pain perception by reducing the production of prostaglandins in the brain, but not in the rest of the body, and because of this, analgesics are only effective in relieving pain and not in reducing inflammation (Trounce, 1994). NSAID’s act at the site of pain by preventing the stimulation of nerve endings which are involved in the production of prostaglandins and by acting at the site will reduce both pain and inflammation (Henry, 2001).
2.2.1.1 Analgesics

Paracetamol is one of the most widely used analgesics (Beers and Berkow, 1999). It does not usually cause irritation of the stomach and allergic reactions are rare. However, an overdose can cause severe and possibly fatal liver or kidney damage (Katzung, 1998).

2.2.1.2 Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

The most common NSAID is aspirin, which is used to relieve pain, stiffness and inflammation of conditions affecting the bones, muscles and joints, although it does not alter the progression of disease (Henry, 2001). According to Murphy (2000), NSAIDs have more analgesic properties when given at low doses, and at higher sustained doses act more as an anti-inflammatory.

The metabolism of NSAIDs occurs in the liver but side effects are largely confined to the gastrointestinal tract and the kidneys (Bornstein et al., 1996). NSAIDs may cause irritation, even ulceration and bleeding of the stomach and duodenum, resulting in nausea and vomiting (Beers and Berkow, 1999). According to Macnab and McCulloch (1994), the chance of a patient on NSAIDs developing a gastric or duodenal ulcer ranges from 2-20%, and approximately 20-40% of patients admitted to hospitals with acute upper gastrointestinal bleeding are on NSAIDs. NSAIDs cause water retention and hypertensive patients therefore need careful monitoring of their blood pressure (Trounce, 1994). NSAIDs also inhibit platelet aggregation, and that is why most surgeons ask patients to stop NSAIDs at least ten days prior to surgery (Macnab and McCulloch, 1994).

Traumeel® is a Homoeopathic combination remedy produced by -Heel®. According to Reckeweg (1997), it is a safer alternative to NSAIDs, due to the fact that there is no gastrointestinal toxicity, no platelet aggravation inhibition, and no sodium or fluid retention. It is not contra-indicated in pregnancy and has no adverse renal, hepatic, cardio-vascular or central nervous system side effects.
2.2.2 Physical therapies in the treatment of cervical facet syndrome

2.2.2.1 Chiropractic treatment
Chiropractic therapy is primarily aimed at restoring proper spinal mechanics, which will in turn influence the function of the nervous system. Chiropractors therefore rely on spinal manipulation and adjustments as their primary therapeutic tool (Gatterman, 1995). Correct spinal mechanics and health of the neuromuscular system are interdependent; this explains why chiropractic management involves the analysis of all sites of spinal joint dysfunction and why chiropractic rehabilitation is driven by restoration and rehabilitation of normal structure and function, and not merely the relief of symptoms and/or pain (Troyanovich et al., 1998).

According to van Schalkwyk and Parkin-Smith (2000), spinal manipulative therapy has shown to have some value in the treatment of mechanical neck pain, both on a subjective and objective level. Research conducted on cervical facet syndrome at the Technikon Witwatersrand includes:

- A comparative study to determine the most effective treatment frequency for cervical spine facet syndrome. The conclusions to this study were that having chiropractic treatment three times a week or once a week, is equally beneficial in reducing pain and increasing range of motion of the cervical spine (de Plessis, 2001).

- The effectiveness of spinal manipulative therapy versus spinal traction in the treatment of chronic neck pain. In this study it was found that both forms of treatment are effective with good long term outcomes (Erasmus, 2002).

- A treatment protocol for the treatment of cervical facet syndrome comparing the use of cryotherapy before or after the chiropractic treatment. The conclusions to this study were that cryotherapy following chiropractic treatment provided the best results in terms of lasting benefits (Abader, 2002).

2.2.2.2 Physiotherapy treatment
Physiotherapy aims to care for patients by addressing their pain and pathology, which is manifested in local and regional movement dysfunctions in the articular, muscular and neural systems (Giles and Singer, 1998). The global aim is to alleviate the patient’s pain, reverse the dysfunction and restore optimal muscle and joint function to prevent recurrent episodes (Hooper, 1996). According to Macnab and McCulloch (1994), massage is the main tool used in a physiotherapeutic practice.
2.3 Routes of drug administration

2.3.1 Introduction

Drugs may be given to a patient in various ways; they may be injected, absorbed from the gastrointestinal tract after oral or rectal administration, or applied locally (Trounce, 1994). The method chosen to administer a drug determines the route it takes to get into the bloodstream and the speed at which it is absorbed; this will determine the speed of action as well as the efficacy of the drug (Henry, 2001). The route of administration of the drug therefore does have an influence on the clinical effectiveness of the drug prescribed (Katzung, 1998).

2.3.2 Bioavailability

The term bioavailability is used to denote the fraction of unchanged drug reaching systemic circulation following administration by any route (Katzung, 1998). According to Henry (2001), bioavailability can also be used to indicate both the extent and the rate at which the administered dose reaches general circulation.

If given intravenously the bioavailability of drugs are 100%, if taken orally then only a proportion of the drug may reach circulation (Trounce, 1994). Bioavailability may be less than 100% when taking a drug orally for two main reasons; namely incomplete extent of absorption and first pass metabolism (Beers and Berkow, 1999). Following absorption across the gut wall, the portal blood delivers the drug to the liver prior to entry into the systemic circulation. A drug can be metabolised in the gut wall or even in the portal blood, but most commonly it is in the liver, which is referred to as first pass metabolism (Katzung, 1998).
## Table 2.2 Routes of administration and bioavailability of drugs

<table>
<thead>
<tr>
<th><strong>ROUTE OF ADMINISTRATION</strong></th>
<th><strong>BIOAVAILABILITY</strong></th>
<th><strong>CHARACTERISTICS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Intravenous injection (IV)</td>
<td>100%</td>
<td>• Results in rapid absorption and action of the drug.</td>
</tr>
<tr>
<td>Intramuscular injection (IM)</td>
<td>≤ 100%</td>
<td>• Large volumes of drug can be administered.</td>
</tr>
<tr>
<td>Subcutaneous injection (Sub cut)</td>
<td>≤ 100%</td>
<td>• Useful if smaller volumes need to be administered.</td>
</tr>
</tbody>
</table>
| Oral                       | < 100%             | • Most convenient method of drug administration.  
                              • First pass metabolism may be significant. |
| Rectal                     | < 100%             | • Useful as first pass metabolism is less than via the oral route. |
| Inhalation                 | < 100%             | • Results in very rapid onset of action. |
| Transdermal                | ≤ 100%             | • Usually has a very slow absorption rate.  
                              • Is useful due to the lack of first pass metabolism.  
                              • There is prolonged duration of action. |

### 2.3.3 Oral route of drug administration

Oral administration is the commonest and easiest way to give a drug. There are many formulations for oral drug administration, namely tablets, capsules, mixtures and emulsions (Trounce, 1994). Administering a drug sublingually i.e. under the tongue, enables absorption of the drug through the oral mucosa. This method is useful when a rapid response is required (Katzung, 1998).
The oral mucosa functions primarily as a barrier and is not a highly permeable tissue and drugs absorbed from the mouth pass directly into systemic circulation without entering the portal system, thereby avoiding first pass metabolism in the liver (Florence and Attwood, 1998). A drug given orally in solution is subjected to numerous gastrointestinal secretions and to be absorbed must survive encounters with low pH and potentially degrading enzymes (Beers and Berkow, 1999).

2.3.4 Parenteral route of drug administration

Parenteral administration, via injection, is used for drugs that are poorly absorbed from the gastrointestinal tract. It is also used for treatment of unconscious patients and in circumstances that require a rapid onset of action. This method of administration provides the most control over the actual dose of drug delivered to the body (Henry, 2001). The three most common methods of injection are:

- **Intravenous** - where the drug is injected into a vein and therefore directly into the blood stream
- **Intramuscular** - where the drug is injected into the muscle, usually the thigh, upper arm or the buttock
- **Subcutaneous** – where the drug is injected directly under the surface of the skin (Tronce, 1994).

The parenteral route of drug administration, specifically via subcutaneous injection, produces a faster effect than oral administration (Rang et al., 1987). This route of absorption does however depend greatly on the site of injection and on physiological factors, such as local blood flow in the area (Tronce, 1994). Subcutaneous injections are frequently observed to take extremely rapid action when applied within the region of pain or at an acupuncture point. When applied to other areas, subcutaneous injections take effect in a manner comparable to that of an intramuscular injection (Reckeweg, 1997).
2.4 Homoeopathy and Homotoxicology

2.4.1 Homoeopathy

Homoeopathy was discovered by the German physician Samuel Hahnemann, in the late 18th century (Endacott, 1996). The term Homoeopathy is derived from two Greek words; *homoios* meaning "like" or "similar" and *pathos* meaning "suffering". It is from the understanding of the word Homoeopathy that the Law of Similars is derived i.e. "let likes be cured by likes" or *similia similibus curentur*. Homoeopathy is a therapeutic method which clinically applies the Law of Similars (Jouanny, 1993).

The law of similars states that a medicine may cure an illness in a sick person if it can cause a similar set of symptoms when given to a healthy person (Endacott, 1996). This is established by doing provings of various substances (from the animal, mineral and plant kingdoms) on healthy individuals and then recording all symptoms experienced (Hayfield, 1995).

Another principle of Homoeopathy is the principle of potentization. This involves a process of diluting the remedy in alcohol and water, and rapidly succussing or pounding the remedy on a hard surface. The vigorous process of potentization increases the therapeutic power of the substance (Foubister, 2001).

Homoeopathy emphasises the fact that diseases are not limited to the physical plane but affect the body as a whole, i.e. mentally, emotionally and physically. Therefore homoeopathic remedies are prescribed individually by the study of the whole person, according to their basic temperament and response (Hammond, 1997). Homoeopathy does not choose to combat the apparent cause of the disease or its results, but tries to correct the altered reaction by bringing harmony back to the disturbed immune system (Hayfield, 1995).

2.4.2 Homotoxicology

Homotoxicology was developed by Hans-Henrich Reckeweg, a German physician. He termed the coin ‘homotoxins’ which refers to the toxins that affect health (Reckeweg, 1997). The main principle of Homotoxicology is that “*Diseases are expressions of the battle of the organism against toxins, in its attempt to counteract and expel them*” (Bianchi, 1989).
According to Reckeweg (1997), the physiological defence mechanism of the body can be divided into 5 groups. These systems/groups must all work together to eliminate toxins.

- The reticulo-endothelial system
- The endocrine system (adenohypophysis-pituitary-suprarenal system)
- The nervous reflex system
- The detoxicating system of the liver
- The detoxicating system of the connective tissue.

Homotoxicology makes use of complex remedies in low potencies to act on clearly defined syndromes according to the strict concept of disease. The disease is always considered an inseparable part of the patient and the aim is to restore vital energy and balance to the biological flow systems (Reckeweg, 1994).

Because Homotoxicology makes reference to conventional medical indications, there is a connection between anti-homotoxic medicines and allopathy, while therapy with potentized substances unites it to homoeopathy (Reckeweg, 1997).

There are 3 main principles active in Homoeopathy and Homotoxicology:

- Similia Similibus Curentur – let likes be cured by likes.
- Arndt- Schulz Law – small excitement provoke vital activity; medium ones increase them; strong excitement inhibit them; exaggerated excitement abolish them
- Potentization – this is the process of diluting and succussing a remedy (Eizayaga, 1991).

2.4.3 Traumeel®S

Traumeel®S is a homoeopathic combination remedy. Its main indications are for acute traumatic injuries, inflammation and arthritis. It is described as an anti-inflammatory, analgesic, anti-oedematous, anti-exudative and regenerative medication (Reckeweg, 1997).

2.4.3.1 Mechanisms of action of Traumeel®S

According to Reckeweg (1997), the homoeopathic remedies found in Traumeel®S have seven main actions on the body, these are:

- *Mercurius solubilis Hahnemannii* provides an anti-inflammatory and antiviral action.
• *Aconitum napellus* and *Arnica montana* help with the improvement of vasotonia. The elimination of venous stasis and anti-thrombotic effect is provided by *Hamamelis virginiana*. *Achillea millefolium* helps with haemostasis and in the normalisation of prothrombin levels.

• There is support and improvement of cellular respiration and oxidation process by means of calcium sulphide and polysulphide, which is found in *Hepar sulphuris calcareaum*.

• All the main defence systems are stimulated.

• *Arnica montana*, *Calendula officinalis*, *Echinacea angustifolia*, *Echinacea purpurea* and *Symphytum officinale*, all contribute to the stimulation of wound healing and shock control by means of phytotherapeutic agents.

• Analgesic action is provided by *Aconitum napellus*, *Arnica montana*, *Chamomilla recutita*, *Hamamelis virginiana* and *Hypericum perforatum*.

• *Aconitum napellus*, *Arnica montana*, *Hamamelis virginiana*, *Hypericum perforatum*, *Achillea millefolium* and *Hepar sulphuris calcareaum* all function to provide haemostasis.

2.4.3.2 Pharmacological and clinical notes of Traumeel®

The mechanism of action of Traumeel® arises from a combination effect of twelve botanical substances and two mineral substances, which are characterised by the following properties:

• *Aconitum napellus D2*

*Aconitum napellus* is mostly indicated in strong, healthy individuals that fall ill suddenly. Exposure to cold, dry air while perspiring is one of the causative factors resulting in the need for *Aconitum napellus* (Allen, 1999). The characteristic symptoms experienced by a patient needing *Aconitum napellus* are hot, dry skin; intense thirst; fever; extreme restlessness and anxiety (Boericke, 1927). *Aconitum napellus* is chiefly indicated in acute conditions with rapidly developing inflammation, as well as in shock and fear that immediately follows an injury, accident or any type of trauma (Morrison, 1993). It is suitably indicated for pain, where the pain is so acute and unbearable that the patient cannot even bear to be touched (Nash, 2001).

Neck symptoms of *Aconitum napellus* include, shooting and burning pains, associated with numbness and tingling of the affected area (Boericke, 1927). Boericke (1927) also states that these pains may radiate to the right shoulder. There can be stiffness in the nape of the neck, with weariness in the neck region on movement (Vermeulen, 2001). All symptoms will be
aggravated in extremes of temperature, in the evening and by lying on the affected side. There will be amelioration of the symptoms in open air and after sleep (Allen, 1999).

- **Arnica montana D2**

*Arnica montana* is always thought of in trauma, and is frequently given for any type of injury. Allen (1999) states that *Arnica montana* is also useful for chronic effects of mechanical injury. It is used to stimulate the healing of contusions, sprains or surgical trauma where there is bruising and extravasations of blood (Morrison, 1993). *Arnica Montana* is indicated for sore bruised feelings as if suffered multiple knocks and blows, usually accompanied with exhaustion, weariness and restlessness (Nash, 2001).

Neck symptoms of *Arnica montana* include, aching, sore and bruised feelings with muscle pain and stiffness of the neck, whether at rest or in motion. The cervical vertebrae is also sensitive to pressure (Morrison, 1993). It is also indicated for weakness of the muscles of the neck (Vermeulen, 2001). The patient’s symptoms are worse for the slightest touch and movement, as well as in damp weather and in the morning. There will be amelioration of symptoms when lying down with the head lower than the rest of the body (Nash, 2001).

- **Achillea millefolium D3**

*Achillea millefolium* is often indicated for symptoms that arise after a fall (usually from a height), over-exertion and lifting (Allen, 1999). It is also well-indicated for pre-capillary arterio-venous haemorrhages (Reckeweg, 1997). According to Nash (2001), these haemorrhages are profuse, painless and bright red.

Neck symptoms of *Achillea millefolium* are stitching, drawing pains in the muscles with burning pains in the left shoulder. The pains are worse after exertion, with slow motion as well as in the evening. There is improvement of symptoms during the day (Vermeulen, 2001).

- **Atropa belladonna D2**

*Atropa belladonna* has a quick but transient action, and is therefore indicated in acute and sub acute disorders, as well as in febrile conditions (Morrison, 1993). The acute conditions start suddenly, often with high fevers, hot red face, pupils that are dilated, and pulse that is full and bounding. Often the inflamed area will have intense heat, throb with pain and have
associated redness. The pains appear suddenly and after a while disappear as suddenly as they came (Nash, 2001). *Atropa belladonna* acts upon every part of the nervous system, producing active congestion, mucosal dryness with hot sweats, fever, spasms, convulsions and pain (Boericke, 1927). Patients requiring *Atropa belladonna* usually have extreme hypersensitivity to the slightest touch accompanied with the sensation that the affected part will burst (Nash, 2001).

Neck symptoms of *Atropa belladonna* are usually stiffness at the nape, especially after exposure to cold air. A pressing burning, throbbing pain is felt externally in the neck, and is aggravated by any form of touch or jolt. The symptoms will be improved with rest and by applying warmth to the painful area (Boericke, 1927).

- **Bellis perennis D2**

  *Bellis perennis* is indicated in deep traumas, sprains, bruises, lacerations or incisions. It is also known to be useful in rheumatism and for the resorption of oedema (Morrison, 1993). According to Boericke (1927) the muscles are sore as if strained. The pains of *Bellis perennis* are aching, squeezing or throbbing.

  Neck symptoms of *Bellis perennis* include a sore and bruised sensation, aggravated by touch and cold, and improved with continued motion (Vermeulen, 2001).

- **Calendula officinalis D2**

  *Calendula officinalis* acts as an antiseptic and prevents serious infection when used topically for the treatment of wounds, abrasions and incisions. In cases of existing wound infections when taken in high potency internally its action is to promote healing. *Calendula officinalis* is also an excellent astringent (Morrison, 1993). Allen (1991) states that *Calendula officinalis* is indicated in trauma, neuritis from lacerated wounds, and exhaustion from loss of blood and in excessive pains that are out of proportion to the injury.

  Neck symptoms of *Calendula officinalis* are worse on the right hand side, and pains extend into the shoulder. Bending the neck to the right and raising the right arm aggravates these pains. The patient also often complains of a sense of feeling bruised. All symptoms will also be aggravated in damp, cloudy weather and be ameliorated when walking about or lying perfectly still (Vermeulen, 2001).
• *Chamomilla recutita D3*

*Chamomilla recutita* is an important remedy for nervous and psychological afflictions, and is indicated when pains seem to be disproportionate to the obvious cause (Nash, 2001), making *Chamomilla recutita* a good remedy for people with a low tolerance of pain (Morrison, 1993). It acts as an anti-inflammatory and analgesic, and stimulates granulation while promoting the healing of difficult wounds and ulcers (Reckeweg, 1997). According to Vermeulen (2001) mental and physical symptoms of the patient appear in paroxysms with associated irritability and restlessness.

Neck symptoms of *Chamomilla recutita* are a tense stiffness in the muscles. Pains experienced are drawing and tearing in nature and associated with numbness (Vermeulen, 2001). Pains tend to become worse at night and can become so severe that it drives the patient out of bed (Allen, 1999). Generally the symptoms will be improved in warm, wet weather (Boericke, 1927).

• *Echinacea angustifolia D2*

According to Reckeweg (1997), *Echinacea angustifolia* increases the mesenchymal defence, thereby strengthening connective tissue. It also has an anti-inflammatory action, and is therefore used in inflammations that occur in any location.

• *Echinacea purpurea D2*

According to Reckeweg (1997), *Echinacea purpurea* causes the activation of the histogenous and haematogenous defences in the inflammatory process and general infections, as well as being an effective antiseptic.

Neck symptoms of *Echinacea purpurea* is an aching in the neck, aggravated in cold air and improved with rest (Vermeulen, 2001).

• *Hamamelis virginiana D1*

In *Hamamelis virginiana* the main pathologies that are best treated are related to circulation where there is weakness of vein walls (Morrison, 1993). The veins are full, enlarged and sore to touch (Nash, 2001). *Hamamelis virginiana* is indicated for easy haemorrhaging of
profuse, very dark clotted venous blood (Allen, 1999). It also acts as an anti-inflammatory and analgesic (Reckeweg, 1997).

Neck symptoms of *Hamamelis virginiana* include a bruised soreness of the cervical vertebrae, which will be aggravated by motion. According to Vermeulen (2001) there is also a sensation of fullness in the neck, and the patient has to sleep with the neck free from any covering. The patient is better for rest and lying quietly.

- *Hepar sulphuris calcareum D6*

*Hepar sulphuris calcareum* is a remedy that has a tendency to suppuration, especially of the skin and lymph glands (Reckeweg, 1997). There is hypersensitivity with excessive splinter-like pains (Nash, 2001).

Neck symptoms of *Hepar sulphuris calcareum* include a drawing pain between the scapulae with stiffness in the nape of the neck, especially during a headache (Vermeulen, 2001). Symptoms are aggravated by cold dry winds, touch, moving about and lying on the affected side (Allen, 1999). Amelioration occurs in damp weather and with heat (Nash, 2001).

- *Hypericum perforatum D2*

*Hypericum perforatum* is a remedy for injuries to the nerve and spine (Morrison, 1993). Boericke (1927), states that excessive painfullness is a guiding symptom to its use. Pains typically radiate from the involved part, and are associated with extreme soreness and tenderness of the involved area. There may be spasms of the muscles after the injury (Vermeulen, 2001).

Neck symptoms of *Hypericum perforatum* are typically experienced in the nape of the neck with darting, shooting pains in the shoulders and down the spine; there is also great sensitiveness of the cervical vertebrae to touch (Vermeulen, 2001). Slight motion of arms or the neck extorts cries of pain (Allen, 1999). Symptoms are also aggravated in cold, damp conditions. Keeping still improves the neck symptoms (Boericke, 1927).

- *Mercurius solubilis Hahnemanni D6*

*Mercurius solubilis Hahnemanni* causes irritation which leads to ulceration and finally destruction or necrosis. It is also a remedy indicated where there is weakness and debility of
the patient (Morrison, 1993). The pains of *Mercurius solubilis Hahnemanni* are of a neuralgic nature and can therefore be described as deep prickling, shooting pains. There may also be a shivering, creeping chilliness, debilitating sweats and swollen glands confirming that *Mercurius solubilis Hahnemanni* is the indicated remedy (Boericke, 1927).

Neck symptoms of *Mercurius solubilis Hahnemanni* are drawing, burning pains in the nape of the neck and back, often accompanied by rigidity. There is often sudden pains and stiffness in the neck brought on by exposure to changes in temperature. According to Allen (1999), the pains experienced tend to be worse at night and improved with rest.

- *Symphytum officinale D6*

*Symphytum officinale* is indicated in injuries to periosteum and bone with persisting pain long after the injury. It is also the specific remedy for blunt trauma to the eye (Morrison, 1993).

Neck symptoms of *Symphytum officinale* include pains that are stitching in nature. These symptoms are usually as a result from violent motion as in wrestling (Vermeulen, 2001).

2.4.3.3 Routes of administration of Traumeel®S

Traumeel®S can be obtained in various preparations. These include drops, tablets, ointments and ampoules. The choice of preparation and hence the route of administration of Traumeel®S is based on the preference of the prescriber. The dosage of Traumeel®S is adjusted according to the disease, the clinical picture and the stage of illness. The recommendations of dosage can be found in the information insert found in Traumeel®S (Reckeweg, 1997).

2.4.3.4 Research on Traumeel®S

In a prospective study conducted by Weiser and Zemmer (1997), 1359 patients were treated with either Traumeel®S tablets or Traumeel®S drops, for injuries and inflammatory conditions. Types of injuries included bruises, sprains, haematomas, dislocations and contusions. Inflammatory conditions included arthritis, carpal tunnel syndrome, frozen shoulder and bursitis. The efficacy, tolerability, and dosage of the Traumeel®S were assessed, in order to determine if the patients experience systematic relief. Therapeutic outcome was rated by the physicians as *good* to *very good* for at least 80% of all injuries and 54-90% for all inflammatory conditions.
In a meta-analysis published by "The Lancet" three randomised, double blind, placebo controlled studies of the effectiveness of Traumeel®S in sports injuries, sports-related ankle sprains and haematomas of the knee joint were analysed. The results of the study showed results of Traumeel®S to be superior to that of the placebo groups (Linde, 1997).

Research conducted on Traumeel®S at the Technikon Witwatersrand includes:

- *The efficacy of Traumeel®S in reducing delayed onset muscle soreness.* This study involved single evaluations at twenty-four hours post inducement of delayed onset muscle soreness in order to determine the effects of the Traumeel®S. Because only a single evaluation at twenty-four hours was done the conclusions for the study were restricted to this time point only and no discernable effects were found (Saunders, 2003).

- *A study to compare the efficacy of saline versus Traumeel®S injecting in terms of pain reduction in patients suffering from myofascial pain syndrome.* Each group in the study showed significant improvement in relation to pain reduction over the treatment period; however the group on Traumeel®S performed significantly better than the group on saline (Breedveld, 1998).

CHAPTER THREE

METHODOLOGY

3.1 Study sample

Participants were recruited by means of an advertising campaign. Advertisements (Appendix A) were placed at the Technikon Witwatersrand Health Clinic, as well as in The Eastern Express, a newspaper which services the Johannesburg area, advertising free treatment for neck pain sufferers. Thirty participants were recruited to participate. Participants were required to participate in the six week study, of which the first two weeks involved treatment, followed four weeks later by a follow-up consultation.

At the initial consultation a case history (Appendix B) was taken. Each participant then underwent a regional cervical spine examination (Appendix C) by a chiropractor, in order to make the diagnosis of cervical facet syndrome. Once the diagnosis was made the participant was included into the study. Participants were excluded from the study if on the regional cervical spine examination any fractures or subluxations of the cervical spine were detected.

The Patient Information and Consent Form (Appendix D), was then read by the participant and the researcher answered any queries. The consent form was then signed.

To eliminate any possible variables, that could affect the research, each participant was required to adhere to the following criteria:

- The participant could not take any analgesics or NSAID’s during the duration of the study.
- The participant could not undergo any manipulation or traction therapy during the duration of the study.
3.2 Research design

3.2.1 Procedure

Thirty participants were used in the design of this study. Participants, who were eligible to be included in the study, were then randomly divided into two groups of fifteen. Group one was administered Traumeel®S subcutaneously in the area of pain, three times a week for a period of two weeks. Group two was administered Traumeel®S ampoules; whereby one ampoule was take orally three times a week for a period of two weeks.

Each of the thirty participants were evaluated using the same tests and questionnaires. The questionnaires that the participants were required to complete included the Visual Analogue Scale for pain (Appendix E) and the Neck Pain Disability Index (Appendix F). Range of motion was measured using the Cervical Range of Motion Goniometer (CROM) (Appendix G). All participants underwent pre-treatment testing and evaluation which served as the baseline for that particular participant. All tests and questionnaires were repeated at the end of the first and second week, as well as at the four week follow-up consultation.

3.2.2 Tools utilised

3.2.2.1 Cervical range of motion
Measurement of the cervical range of motion is considered an appropriate and objective method of assessing cervical function (Christensen and Nilsson, 1998). It is used in rating the severity of impairment, as well as in monitoring the progress and effectiveness of treatment.

The Cervical Range of Motion Goniometer (CROM) (Performance Attainment Associates, 2004), was used to measure the participant's range of motion in degrees. Degrees of flexion, extension, lateral flexion and rotation bilaterally from the neutral position of the cervical spine were measured. Cervical range of motion was measured at the initial consultation, at the end of the first and second week, as well as at the four week follow-up consultation. Measuring the cervical range of motion constituted the objective part of the study.
3.2.2.2 Visual Analogue Scale (VAS)

The Visual Analogue Scale (VAS) (Huskisson, 1974), measures the intensity of pain by visual means (Hooper, 1996). The VAS is a line 10cm in length, at one end of the line is a zero and represents no pain, and on the other end is the number ten and represents the worst pain imaginable. The participants were asked to place a mark somewhere on the line that corresponded to their level of pain.

The VAS was completed at the initial consultation, at the end of the first and second week, as well as at the four week follow-up consultation. The VAS was useful in comparing pain before the start of treatment and after treatment was completed, and was part of the subjective part of the study.

3.2.2.3 Neck Pain Disability Index

This questionnaire is designed to give information as to how neck pain has affected the participant's ability to manage in everyday life (Hooper, 1996). The Neck Pain Disability Index (Vernon and Mior, 1991), was completed at the initial consultation, at the end of the first and second weeks, as well as at the four week follow-up consultation. This questionnaire consists of 10 sections, and for each section scores fall on a 0-5 scale, with the higher values representing greater disability.

To determine the patient’s disability:

- Each of the 10 sections are scored separately (0-5 points each) and then added up. Resulting in a maximum total of 50 points.
- If all 10 sections are completed, the participants score is doubled, giving the disability index of the participant.
- If a section is omitted, the participants score is divided by the number of sections completed multiplied by 5, the total is then multiplied by 100, giving the disability index of the participant.

\[ \text{Formula: } \frac{\text{patient's score}}{(\text{Number of sections completed} \times 5) \times 100} = \% \text{ disability} \]
Example: If the patient scored 22 and only 9 out of 10 sections were completed,
Then according to the above formula \[ \frac{22}{(9 \times 5) \times 100} = 49\% \text{ disability} \]

Interpretation of disability scores are:
- 0% - 10% = no disability
- 11% - 30% = minimal disability
- 31% - 50% = moderate disability
- 51% - 70% = severe disability
- > 70% = completely disabled by pain in several areas of life

3.2.3 Medication

Each ampoule contained 2.2 ml of Traumeel®S solution, prepared by -Heel SA, Sandton, Johannesburg.

Group one received the ampoules parenterally. The injection was administered subcutaneously in the fatty layer just under the skin of the neck in the area of pain. A 2/3 ml syringe with a ½ inch needle (0.4 x 12.5mm needle) was used. The site was cleaned before and after the injection with an alcohol swab.

Group two was on a trial of Traumeel®S ampoules taken orally. The patient was instructed to place the contents of the ampoule under the tongue for a minimum of ten seconds, before swallowing the remainder of the liquid.

3.3 Data gathering

The objective data used was obtained from the readings obtained using the Cervical Range of Motion Goniometer. The subjective data was obtained from the two questionnaires, namely the Visual Analogue Scale and the Neck Pain Disability Index.
3.4 Statistical analysis

On completion of the study, all data collected from the participants was analysed. The objectives were firstly to assess whether Traumeel® was effective in treating cervical facet syndrome and secondly to assess which of the two groups, if any, had more significant results. Repeated measures ANOVA was used to test whether there was improvement of symptoms over time and if there was any significant difference between the two groups.

For each variable the Mauchly’s Test of Sphericity was conducted in order to assess the null hypothesis. If the P-values were > 0.05 then sphericity was assumed and the null hypothesis accepted. Therefore it was considered that there was no statistical difference between the two groups or improvement of symptoms over time. If the P-values were < 0.05 then sphericity could not be assumed and the null hypothesis was rejected. Therefore it was considered that there was a statistical significance between the two groups and an improvement of symptoms over time. If sphericity could not be assumed, the Huynh-Felt adjustment was then used in order to determine statistical significance (SPSS Advanced Models user’s guide 10.00, 1999).
CHAPTER FOUR

RESULTS

4.1 Introduction to results

This study was designed in order to firstly determine whether Traumeel®S was effective in treating cervical facet syndrome, and secondly which method of administration of Traumeel®S, namely parenteral or oral, was more effective. This study involved the recruitment of thirty participants diagnosed with cervical facet syndrome; they were divided into two groups of fifteen. Participants in group one were administered Traumeel®S parenterally via injection and participants in group two were administered Traumeel®S ampoules orally.

On completion of the study, all the data was collected from the participants and analysed. Cervical range of motion (Appendix G) and the Visual Analogue Scale (Appendix E) were analysed using repeated measures ANOVA, which identified trends in the overall results obtained from group one and group two. A repeated measure ANOVA was also used to determine during which week the most improvement was noted. The Neck Pain Disability Index (Appendix F) was analysed using a combination of the two groups in order to provide trends as to how the participant’s ability to manage in everyday life due to the neck pain had changed during the course of the study.

If on analysis of repeated measures ANOVA sphericity was assumed and the null hypothesis accepted, it indicated that there was no statistical significance between the two groups, meaning that in both groups the Traumeel®S was equally effective in relieving the symptoms of cervical facet syndrome. When analysing change over time, it indicated that there was no change in the symptoms over the course of the study. If sphericity was not assumed and the null hypothesis rejected, it then indicated that there was a statistical significance between the two groups, meaning that one group was more effective in treating the symptoms of cervical facet syndrome than the other. When analysing changes over time, it indicated that there was a significant change in symptoms over the course of the study.
4.2 Background variables

4.2.1 Age

The mean (average) age of the participants who participated in the study was 45 years old. On calculation, 50% of the participants were older than 50 years old and 50% were younger than 50 years old.

4.2.2 Gender and race

Twenty-five female participants participated in the study; therefore 83.3% of the total number of participants was female. Five male participants participated in the study; therefore 16.7% of the total number of participants was male. It is therefore evident that the gender distribution was disproportionate. Twenty-nine participants who participated in the study were Caucasian, and one participant was African, indicating that race distribution was also disproportionate.

4.2.3 Onset of cervical facet syndrome

The following causes for cervical facet syndrome were reported by the thirty participants who participated in the study:

- 30% of the participants reported work related injuries
- 10% of the participants reported sports injuries
- 3.3% of the participants reported motor vehicle accidents
- 56.7% of the participants had an unknown cause for their cervical facet syndrome.

4.2.4 Duration of cervical facet syndrome

Patients with symptoms of cervical facet syndrome present for three weeks or less consulted a chiropractor to determine the diagnosis of acute cervical facet syndrome. If the symptoms were present for more than three weeks, chronic cervical facet syndrome was diagnosed. It was determined that 36.7% of the participants in the study were diagnosed with acute cervical facet syndrome and 63.3% of the participants were diagnosed with chronic cervical facet syndrome.
4.3 Cervical range of motion results

The data was obtained from measuring the cervical range of motion (Appendix G). This was completed at designated times throughout the study.

- Stage 0 corresponds to measurements taken at the initial consultation
- Stage 1 corresponds to measurements taken at the end of the first week
- Stage 2 corresponds to measurements taken at the end of the second week
- Stage 3 corresponds to measurements taken at the four week follow-up consultation.

Each of the six movements of the cervical spine was independently analysed. The movements measured were flexion, extension, right rotation, left rotation, right lateral flexion and left lateral flexion.

The cervical range of motion measurements were taken in degrees, however, for the purpose of statistical analysis and ease of read the symbol (*) has not been inserted.

In order to analyse when the most improvement in symptoms took place, repeated measures ANOVA was used. Analysis took place, between the initial consultation and the end of the first week (L1 vs. L2), between the end of the first and end of the second week (L2 vs. L3), as well as between the end of the second week and the four week follow-up consultation (L3 vs. L4).

4.3.1 Flexion results

When analysing the two groups the average measurements of flexion for both groups increased from the initial to the four week follow-up consultation. The mean value of group one (Traumeel®S injection) increased from 43.93 to 54.33, and group two (Traumeel®S oral) increased from 43.27 to 48.67. Refer to Appendix H4.1 for a more detailed analysis on the differences in the mean values and standard deviations of both groups for the duration of the study.

The P-values obtained when analysing flexion results were:

- The P-value of time had a sig. of 0.000, which indicated there was a significant statistical difference over time, with the most significant improvement of symptoms occurring in week L2 vs. L3 with a P-value of 0.015.
• The P-value for method of administration of medication had a sig. of 0.517, which indicated that there was no significant statistical difference between the two groups.

![Estimated Marginal Means of MEASURE_1](image)

**Figure 4.1** Means of flexion of group one and group two during the study

**Table 4.1** indicates the results of flexion for both groups combined. The mean value increased from a measurement of 43.60 at the initial consultation to 51.50 at the four week follow-up consultation.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 0</td>
<td>43.60</td>
<td>11.440</td>
<td>30</td>
</tr>
<tr>
<td>Stage 1</td>
<td>45.80</td>
<td>9.152</td>
<td>30</td>
</tr>
<tr>
<td>Stage 2</td>
<td>50.00</td>
<td>10.422</td>
<td>30</td>
</tr>
<tr>
<td>Stage 3</td>
<td>51.50</td>
<td>7.895</td>
<td>30</td>
</tr>
</tbody>
</table>
4.3.2 Extension results

When analysing the two groups the average measurements of extension for both groups increased from the initial to the four week follow-up consultation. The mean value of group one (Traumeel®S injection) increased from 49.07 to 60.33 and group two (Traumeel®S oral) increased from 53.57 to 59.67. Refer to Appendix H4.2 for a more detailed analysis on the differences in the mean values and standard deviations of both groups for the duration of the study.

The P-values obtained when analysing extension results were:

- The P-value of time had a sig. of 0.000, which indicated there was a significant statistical difference over time, with the most significant improvement of symptoms occurring in week L2 vs. L3 with a P-value of 0.012.
- The P-value for method of administration of medication had a sig. of 0.468, which indicated that there was no significant statistical difference between the two groups.

![Estimated Marginal Means of MEASURE_1](image)

*Figure 4.2 Means of extension of group one and group two during the study*
Table 4.2 indicates the results of extension for both groups combined. The mean value increased from a measurement of 51.37 at the initial consultation to 60.00 at the four week follow-up consultation.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>51.37</td>
<td>9.905</td>
<td>30</td>
</tr>
<tr>
<td>1</td>
<td>55.27</td>
<td>10.557</td>
<td>30</td>
</tr>
<tr>
<td>2</td>
<td>59.90</td>
<td>10.810</td>
<td>30</td>
</tr>
<tr>
<td>3</td>
<td>60.00</td>
<td>7.656</td>
<td>30</td>
</tr>
</tbody>
</table>

4.3.3 Right rotation results

When analysing the two groups the average measurements of right rotation for both groups increased from the initial to the four week follow-up consultation. The mean value of group one (Traumeel® S injection) increased from 55.00 to 70.33 and group two (Traumeel® S oral) increased from 56.40 to 67.00. Refer to Appendix H4.3 for a more detailed analysis on the differences in the mean values and standard deviations of both groups for the duration of the study.

The P-values obtained when analysing right rotation results were:

- The P-value of time had a sig. of 0.000, which indicated there was a significant statistical difference over time. On analysing when the most improvement of symptoms occurred, there was a significant statistical difference between L1 vs. L2 with a P-value of 0.000, between L2 vs. L3 with a P-value of 0.012, and between L3 vs. L4 with a P-value of 0.008.
- The P-value for method of administration of medication had a sig. of 0.264, which indicated that there was no significant statistical difference between the two groups.
Figure 4.3 Means of right rotation of groups one and group two during the study

Table 4.3 indicates the results of right rotation of both groups combined. The mean value increased from a measurement of 55.70 at the initial consultation to 68.67 at the four week follow-up consultation.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 0</td>
<td>55.70</td>
<td>9.791</td>
<td>30</td>
</tr>
<tr>
<td>Stage 1</td>
<td>62.93</td>
<td>9.819</td>
<td>30</td>
</tr>
<tr>
<td>Stage 2</td>
<td>66.17</td>
<td>7.953</td>
<td>30</td>
</tr>
<tr>
<td>Stage 3</td>
<td>68.67</td>
<td>8.193</td>
<td>30</td>
</tr>
</tbody>
</table>

4.4 Left rotation results

When analysing the two groups the average measurements of left rotation for both groups of participants increased from the initial to the four week follow-up consultation. The mean value of group one (Traumeel®S injection) increased from 61.00 to 70.00 and group two
(Traumeel® S oral) increased from 59.13 to 67.00. Refer to Appendix H4.4 for a more detailed analysis on the differences in the mean values and standard deviations of both groups for the duration of the study.

The P-values obtained when analysing left rotation results were:

- The P-value of time had a sig. of 0.000, which indicated there was a significant statistical difference over time, with the most significant improvement of symptoms occurring in week L2 vs. L3 with a P-value of 0.012.
- The P-value for method of administration of medication had a sig. of 0.506, which indicated that there was no significant statistical difference between the two groups.

![Estimated Marginal Means of MEASURE_1](image)

**Figure 4.4** Means of left rotation of group one and group two during the study

Table 4.4 indicates the results of left rotation for both groups combined. The mean value increased from a measurement of 60.07 at the initial consultation to 68.50 at the four week follow-up consultation.
Table 4.4 Overall left rotation results for the duration of the study

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 0</td>
<td>60.07</td>
<td>9.421</td>
<td>30</td>
</tr>
<tr>
<td>Stage 1</td>
<td>62.83</td>
<td>10.722</td>
<td>30</td>
</tr>
<tr>
<td>Stage 2</td>
<td>67.17</td>
<td>8.477</td>
<td>30</td>
</tr>
<tr>
<td>Stage 3</td>
<td>68.50</td>
<td>7.445</td>
<td>30</td>
</tr>
</tbody>
</table>

4.5 Right lateral flexion results

When analysing the two groups the average measurement of right lateral flexion for both groups increased from the initial to the four week follow-up consultation. The mean value of group one (Traumeel® S injection) increased from 25.27 to 33.33 and group two (Traumeel® S oral) increased from 30.00 to 31.33. Refer to Appendix H4.5 for a more detailed analysis on the differences in the mean values and standard deviations of both groups for the duration of the study.

The P-values obtained when analysing right lateral flexion results were:

- The P-value of time had a sig. of 0.001, which indicated there was a significant statistical difference over time, with the most significant improvement of symptoms occurring in week L1 vs. L2 with a P-value of 0.002
- The P-value for method of administration of medication had a sig. of 0.045, which indicated there was a significant statistical difference between the two groups.
Figure 4.5 Means of right lateral flexion of group one and group two during the study

Table 4.5 indicates the results of right lateral flexion for both groups combined. The mean value increased from a measurement of 27.63 at the initial consultation to 32.33 at the four week follow-up consultation.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 0</td>
<td>27.63</td>
<td>10.864</td>
<td>30</td>
</tr>
<tr>
<td>Stage 1</td>
<td>32.17</td>
<td>9.381</td>
<td>30</td>
</tr>
<tr>
<td>Stage 2</td>
<td>32.33</td>
<td>7.512</td>
<td>30</td>
</tr>
<tr>
<td>Stage 3</td>
<td>32.33</td>
<td>7.849</td>
<td>30</td>
</tr>
</tbody>
</table>

4.6 Left lateral flexion results

When analysing the two groups the average measurements of left lateral flexion for group one (Traumeel® S injection) increased from a mean value of 31.27 at the initial to 35.00 at the four week follow-up consultation. Group two (Traumeel® S oral) increased from a mean value of
34.00 at the initial consultation to 36.33 at the end of the second week, and then decreased to 31.67 when measurements were taken at the four week follow-up consultation. Refer to Appendix H4.6 for a more detailed analysis on the differences in the mean values and standard deviations of both groups for the duration of the study.

The P-values obtained when analysing left lateral flexion results were:

- The P-value of time had a sig. of 0.098, which indicated there was no significant statistical difference over time.
- The P-value for method of administration of medication had a sig. of 0.024, which indicated that there was a significant statistically difference between the two groups.

![Estimated Marginal Means of MEASURE_1](image)

**Figure 4.6** Means of left lateral flexion of group one and group two during the study

Table 4.6 indicates the results of left lateral flexion of both groups combined. The mean value increased from a measurement of 32.63 at the initial consultation to 35.23 at the end of the second week. The mean then decreased to 33.33 at the four week follow-up consultation.
Table 4.6 Overall left lateral flexion results for the duration of the study

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 0</td>
<td>32.63</td>
<td>11.924</td>
<td>30</td>
</tr>
<tr>
<td>Stage 1</td>
<td>34.30</td>
<td>9.411</td>
<td>30</td>
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<tr>
<td>Stage 2</td>
<td>35.23</td>
<td>8.299</td>
<td>30</td>
</tr>
<tr>
<td>Stage 3</td>
<td>33.33</td>
<td>7.694</td>
<td>30</td>
</tr>
</tbody>
</table>

4.4 Visual Analogue Scale results

Results from the Visual Analogue Scale (Appendix E), which were completed at designated times throughout the study, were collected and analysed.

When analysing the two groups the average readings for both groups decreased from the initial to the four week follow-up consultation. The mean value of group one (Traumeel®S injection) decreased from 6.27 to 0.87 and group two (Traumeel®S oral) decreased from 4.47 to 1.20. Refer to Appendix I for a more detailed analysis on the differences in the mean values and standard deviations of both groups for the duration of the study.

The P-values obtained when analysing VAS results were:

- The P-value of time had a sig. of 0.000, which indicated that there was a significant statistical difference over time. On analysing when the most improvement in symptoms occurred, there was a significant statistical difference between L1 vs. L2 with a P-value of 0.000 and between L2 vs. L3 with a P-value of 0.000.
- The P-value for method of administration of medication had a sig. of 0.180, which indicated no statistical difference between the two groups.
Figure 4.7 Means of results from VAS for group one and group two during the study

Table 4.7 indicates the Visual Analogue Scale results of both groups combined. The mean value decreased from 5.37 at the initial consultation to 1.03 at the four week follow-up consultation.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 0</td>
<td>5.37</td>
<td>2.025</td>
<td>30</td>
</tr>
<tr>
<td>Stage 1</td>
<td>3.50</td>
<td>2.224</td>
<td>30</td>
</tr>
<tr>
<td>Stage 2</td>
<td>1.30</td>
<td>1.317</td>
<td>30</td>
</tr>
<tr>
<td>Stage 3</td>
<td>1.273</td>
<td>1.273</td>
<td>30</td>
</tr>
</tbody>
</table>

4.5 Neck Pain Disability Index results

A questionnaire is considered reliable if the Cronbach alpha score is > 0.7. The neck pain disability index had a Cronbach alpha score of 0.470, and therefore the questionnaire was not considered to be statistically reliable.
Results from the Neck Pain Disability Index (Appendix F), which were completed at designated times throughout the study, were collected and analysed.

Table 4.8 indicates the neck pain disability index results for both groups combined. The mean value decreased from 19.37 at the initial consultation to 3.13 at the four week follow-up consultation.

Table 4.8 Overall results from the Neck Pain Disability Index for the duration of the study

<table>
<thead>
<tr>
<th>Stage</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 0</td>
<td>19.37</td>
<td>8.544</td>
<td>30</td>
</tr>
<tr>
<td>Stage 1</td>
<td>9.97</td>
<td>5.176</td>
<td>30</td>
</tr>
<tr>
<td>Stage 2</td>
<td>4.00</td>
<td>3.017</td>
<td>30</td>
</tr>
<tr>
<td>Stage 3</td>
<td>3.13</td>
<td>4.478</td>
<td>30</td>
</tr>
</tbody>
</table>

Table 4.9 Frequencies from the Neck Pain Disability Index

| Disability | Stage 0 | | Stage 1 | | Stage 2 | | Stage 3 | |
|------------|---------|---------|---------|---------|---------|---------|---------|
|            | Count (30) | % (100) | Count (30) | % (100) | Count (30) | % (100) | Count (30) | % (100) |
| None       | 0        | 0.0     | 4        | 13.3    | 18       | 60.0    | 25       | 83.3    |
| Mild       | 12       | 40.0    | 19       | 63.3    | 12       | 40.0    | 4        | 13.3    |
| Moderate   | 13       | 43.3    | 7        | 23.3    | 0        | 0.0     | 1        | 3.3     |
| Severe     | 3        | 10.0    | 0        | 0.0     | 0        | 0.0     | 0        | 0.0     |
| Complete   | 2        | 6.7     | 0        | 0.0     | 0        | 0.0     | 0        | 0.0     |
CHAPTER FIVE

DISCUSSION

5.1 Background Variables

The average age of the participants who participated in the study was 45 years old. According to Bovim et al (1994), it has been found that neck pain increases with age. Twenty-five female and five male participants participated in the study. The frequency of neck pain has been found to be higher among females than males therefore suggesting that gender is a risk factor (Bovim et al., 1994). Makela et al (1991) found that the prevalence of neck pain is usually associated with a history of injury, in this study 43.3% of the participants reported some form of injury as a cause for their neck pain and 56.7% had an unknown cause for their neck pain. 63.3% of the participants were diagnosed with chronic cervical facet syndrome, i.e. symptoms present for more than three weeks, while 36.7% were diagnosed with acute cervical facet syndrome, i.e. symptoms present for less than three weeks.

5.2 Cervical range of motion results

5.2.1 Flexion and extension results

When analysing the results of flexion and extension, it is evident from the group statistics and graphs (Figure 4.1 and 4.2), that in both cases the two groups appear statistically similar, meaning that group one (Traumeel® S injection) and group two (Traumeel® S oral) experienced improvement in the movement of flexion (P = 0.000) and extension (P = 0.000) of the cervical spine over time and that both were equally effective in improving the respective movements. According to the mean values for both groups combined (Table 4.1 and 4.2), all the participants who participated in the study had improvement in the movement of flexion and extension of the cervical spine, regardless of method of administration of the Traumeel® S. These results prove firstly that Traumeel® S is useful in improving the movement of flexion and extension in individuals suffering from cervical facet syndrome, and secondly that either method of administration is effective to the same degree.
On analysing when the most significant improvement in flexion (\(P = 0.015\)) and extension (\(P = 0.012\)) occurred, it was noted that marked improvement occurred during the second week of treatment in both cases. By the second week of treatment significant medication i.e. repeated doses of Traumeel®S, had been administered in order to allow for maximum benefit of the medication, which is most likely the reason that marked improvement was noted. This also applies to the improvement in left rotation (\(P = 0.012\)) of the cervical spine.

5.2.2 Right and left rotation results

When analysing the results of right and left rotation, it is evident from the group statistics and the graphs (Figure 4.3 and 4.4), that in both cases the two groups appear statistically similar, meaning that group one (Traumeel®S injection) and group two (Traumeel®S oral) experienced improvement in the movement of right rotation (\(P = 0.000\)) and left rotation (\(P = 0.000\)) of the cervical spine over time and that both were equally effective in improving the respective movements. According to the mean values for both groups combined (Table 4.3 and 4.4), all the participants who participated in the study had improvement in the movement of right and left rotation of the cervical spine, regardless of method of administration of the Traumeel®S. These results prove firstly that Traumeel®S is useful in improving the movement of right and left rotation in people suffering from cervical facet syndrome, and secondly that either method of administration is effective to the same degree.

When analysing when the most improvement in right rotation occurred, it was noted that marked improvement occurred throughout the duration of the study. Therefore significant change in symptoms was found at the end of the first week of treatment (\(P = 0.000\)), at the end of the second week of treatment (\(P = 0.012\)), and at the four week follow-up consultation (\(P = 0.008\)).

5.2.3 Right and left lateral flexion results

When analysing the results of right lateral flexion, according to group statistics and the graph (Figure 4.5) it is evident that both groups experienced improvement of right lateral flexion over time (\(P = 0.001\)), with marked improvement noted during the first week (\(P = 0.002\)). The two groups appear statistically different (\(P = 0.045\)); meaning that one group (Traumeel®S injection) was more effective in improving the movement of right lateral flexion. It was found
that in both right and left lateral flexion more improvement occurred in the group administered Traumeel®S parenterally (group one) than the group administered Traumeel®S orally (group two); there is no reason evident for this fact.

When analysing the results of left lateral flexion, according to the group statistics and the graph (Figure 4.6), it was found that group one (Traumeel®S injection) experienced improvement of left lateral flexion of the cervical spine over time, with the most improvement occurring between the end of treatment and the four week follow-up consultation (P = 0.001). Group two (Traumeel®S oral) had improvement of left lateral flexion from the initial consultation to the end of the second week but then decreased at the follow-up consultation; there is no reason evident for this.

On analysing the mean values of both groups combined, it is evident from Table 4.5 that participants had improvement in the movement of right lateral flexion of the cervical spine, regardless of the method of administration of the Traumeel®S. According to Table 4.6, participants had initial improvement then a decrease in the movement of left lateral flexion of the cervical spine, regardless of mode of administration of the Traumeel®S. This indicates that Traumeel®S is useful in improving the movement of right and left lateral flexion in individuals suffering from cervical facet syndrome.

5.3 Visual Analogue Scale results

When analysing the two groups, it is evident from the group statistics and graph (Figure 4.7), that both groups appear statistically similar, meaning that the groups were equally effective in relieving pain as a result of cervical facet syndrome. According to the mean values of both groups combined (Table 4.7), all the participants who participated in the study had a decrease in the severity of pain as a result of cervical facet syndrome, from the initial to the four week follow-up consultation, regardless of which method the Traumeel®S was administered. This indicates that Traumeel®S is useful in relieving pain experienced in people suffering from cervical facet syndrome, whether administered orally or parenterally.

The VAS formed part of the subjective component of the study and the participants had a direct involvement in the scoring of their symptoms. Therefore there are a number of possible
reasons, other than medication efficacy, as to why there was a decrease in the severity of pain, these could include:

- The personal attention and time spent with each participant by the researcher, the participant could possibly just have felt better, thereby the severity of pain not seeming as bad as before.
- Each participant completed the VAS with the researcher, thereby knowing their score, so there is a possibility that on the next consultation they marked less pain than there actually was, in order to satisfy the researcher.

5.4 Neck Pain Disability Index results

Even though the questionnaire was not statistically reliable as determined by the Cronbach alpha score, certain trends were noted. As shown in Table 4.8, all participants indicated an improvement in symptoms when answering the questions on the Neck Pain Disability Index questionnaire (Appendix F), from the initial consultation to the four week follow-up consultation. The questions asked were:

- Intensity of the neck pain
- Ability of personal care due to the neck pain
- Neck pain caused on lifting
- Neck pain caused during reading
- Headaches
- Ability to concentrate due to the neck pain
- Ability to work due to the neck pain
- Neck pain caused during driving
- Ability to sleep due to the neck pain
- Ability to engage in recreation activities due to the neck pain.

At the initial consultation most of the participants reported a minimal disability. However, from the end of the first week until the four week follow-up consultation most of the participants reported no disability. As proved by the results of the cervical range of motion and VAS, Traumeel®S is useful in decreasing pain and improving range of motion, and because of this it improves the ability of the person to manage with everyday life.
CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

Thirty participants recruited for the study were randomly divided into two groups of fifteen. Group one was administered Traumeel®S parenterally and group two was administered Traumeel®S orally. Data was gathered from measuring the cervical range of motion, the Visual Analogue Scale and the Neck Pain Disability Index. It can be concluded that Traumeel®S is effective in the treatment of cervical facet syndrome, regardless of which method of administration is used i.e. either Traumeel®S parenterally or Traumeel®S orally. Both methods of administration proved to be equally effective.

Analysis of cervical range of motion indicated an increase in all movements of the cervical spine; namely flexion, extension, right and left rotation, right and left lateral flexion, from the initial to the four week follow-up consultation. The Visual Analogue Scale measuring the intensity of pain indicated a decrease in the severity of pain as a result of the cervical facet syndrome, from the initial to the four week follow-up consultation. The Neck Pain Disability Index showed a decrease in the disability index and therefore an increase in the ability to manage with everyday life due to the neck pain, from the initial to the four week follow-up consultation.

According to statistical analysis, it was determined that certain trends occurred between the end of the first week and second week, i.e. the second week of treatment. During this time marked improvement of symptoms was noted. This indicates that when administering Traumeel®S for cervical facet syndrome, repeated doses of medication are required over two weeks for maximum improvement of symptoms.

In conclusion, it can therefore be stated that according to statistical analysis and interpretation of results, that Traumeel®S is effective in increasing range of motion and decreasing pain in cervical facet syndrome, regardless of parenteral or oral administration.
6.2 Recommendations

Numerous recommendations are made for researchers considering similar further studies.

The following recommendations should be considered:

- Introduction of a placebo group would further confirm the benefits of Traumeel®S in the treatment of cervical facet syndrome.

- It would be beneficial in a future study to investigate other modes of administration of Traumeel®S e.g. topical applications, to find out whether they are also useful in treating the symptoms of cervical facet syndrome.

- The same study could be performed, focusing either on acute or chronic cervical facet syndrome.

- The onset of cervical facet syndrome may be due to a number of reasons, as determined in this study. A possibility for future studies is that a specific cause of onset be chosen, i.e. work related injuries, sports injuries, motor vehicle accidents. This will reduce the number of different variables in the study.

- In this study the gender and age distribution was disproportionate, in future studies the distribution should be more equal.

- According to Eiselen (2004), increasing the number of participants would contribute to supporting the significance of this study’s findings.

- Cervical facet syndrome is a common condition, and because of this it would be useful to determine whether simplex homoeopathic prescribing is effective in treating the symptoms.

- A future study could determine if using Traumeel®S in combination with another treatment modality i.e. physiotherapy, chiropractic, osteopathy etc, would result in a better outcome in the symptoms of cervical facet syndrome.
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APPENDIX A
Advertisement

DO YOU SUFFER FROM NECK PAIN?

IF YES, YOU CAN GET A FREE CONSULTATION AND FREE TREATMENT AT THE TECKNIKON WITWATERSRAND HEALTH CLINIC.

Contact Mareza Cape on 083 981 3426 For more information and to make appointments.
APPENDIX B

Case history

TECHNIKON WITWATERSRAND
CHIROPRACTIC DAY CLINIC

CASE HISTORY

Date: ______________

Patient: ___________________________ File No: ______
Age: _______ Sex: ___________ Occupation: ________________
Intern: _______________ Signature: ________________

FOR CLINICIANS USE ONLY

Initial visit clinician: ______________ Signature: ______________

Case History: ____________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________

Examination:
Previous:    TWR Other
Current:     TWR Other

X-ray Studies:
Previous:    TWR Other
Current:     TWR Other

Clinical Path. Lab:
Previous:    TWR Other
Current:     TWR Other

Case status:
PTT: Conditional: Signed off: Final sign out:
Intern’s case history

1. Source of history:

2. Chief complaint: (patients own words)
   
   
   
   
   

3. Present illness:

   Location

   Onset

   Duration

   Frequency

   Pain (character)

   Progression

   Aggravating factors

   Relieving factors

   Associated Sx’s and Sg’s

   Previous occurrences

   Past treatment and outcome
4. Other complaints:

5. Past history:

   General health status

   Childhood illnesses

   Adult illnesses

   Psychiatric illnesses

   Accidents/injuries

   Surgery

   Hospitalisation

6. Current health status and lifestyle:

   Allergies

   Immunizations

   Screening tests

   Environmental hazards

   Safety measures

   Exercise and leisure
Sleep patterns

Diet

Current medication

Tobacco

Alcohol

Social drugs

7. Family history:
   Immediate family:

   Cause of death
   DM
   Heart disease
   TB
   HBP
   Stroke
   Kidney disease
   CA
   Arthritis
   Anaemia
   Headaches
   Thyroid disease
   Epilepsy
   Mental illness
   Alcoholism
   Drug addiction
   Other

8. Psychosocial history:

   Home situation

   Daily life
Important experiences
Religious beliefs

9. Review of systems:

General
Skin
Head
Eyes
Ears
Nose/sinuses
Mouth/throat
Neck
Breasts
Respiratory
Cardiac
Gastro-intestinal
Urinary
Genital
Vascular
Musculoskeletal
Neurological
Haematologic
Endocrine
Psychiatric
APPENDIX C

Regional cervical spine examination

TECHNIKON WITWATERSRAND
CHIROPRACTIC DAY CLINIC

REGIONAL EXAMINATION
CERVICAL SPINE

Date: ____________

Patient: __________________________

File No: ____________

Clinician: ________________________

Signature: ____________

Intern: _________________________

Signature: ____________

OBSERVATION

• Posture
• Size
• Swellings
• Scars
• Discolouration
• Hairline
• Bony and soft tissue contours
• Shoulder level
• Muscle spasms
• Facial expressions

RANGE OF MOTION

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<tr>
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<td>45° - 90°</td>
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<tr>
<td>Extension</td>
<td>55° - 70°</td>
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<tr>
<td>L/R Rotation</td>
<td>70° - 90°</td>
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</table>
L/R Lateral flexion  20° - 45°

flexion

L. rotation  R. rotation

L. lat flexion  R. lat flexion

extension

/ = pain-free limitation  \ = painful limitation

PALPATION

- Lymph nodes
- Trachea
- Thyroid gland
- Pulses
- Tenderness
- Muscle tone
- Active MF Trigger Points
  - Trapezius
  - SCM
  - Scalenae
  - Levator Scapulae
  - Posterior Cervical musculature
ORTHOpaedic Examination

1. Doorbell Sign
2. Max. Cervical Compression
3. Spurling’s Manoeuvre
4. Lateral compression (Jackson’s Test)
5. Kemp’s Test
6. Cervical Distraction
7. Shoulder abduction Test
8. Shoulder depression Test
9. Dizziness rotation Test
10. Lhermitte’s Sign
11. O’Donognue Manoeuvre
12. Brachial Plexus Tension
13. Carpal tunnel syndrome
   • Tinel’s Sign
   • Phalen’s Test
14. TOS
   • Halsteads Test
   • Adson’s Test
   • Hyperabduction (Wright’s) Test – Pec minor

Remarks

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

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**COMMENTS:**

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**MOTION PALPATION**

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<td>Fle</td>
<td>Ext</td>
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NEUROLOGICAL EXAMINATION

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APPENDIX D

Participant information and consent form

The purpose of this study is to establish the most effective route for the administration of Traumeel®S, focusing specifically on the symptoms experienced due to cervical injury syndromes.

All participants in this research project must be experiencing some form of neck pain. Participants should not have taken any medication for their condition and are requested to refrain from using any other anti-inflammatory medication or analgesics during the duration of treatment. Participants are also requested to refrain from any other forms of treatment for their cervical injury syndrome, during the study.

The participants will randomly be placed into one of two groups of fifteen participants. One group will receive Traumeel®S ampoules, to be taken orally and the other group will receive Traumeel®S injection solution given subcutaneously. The medication will be provided free of charge.

On day one of the trial you will be required to fill out a Visual Analogue Scale, which will indicate the severity of pain you are feeling. You will also need to answer a Neck Pain Disability Index questionnaire. Your range of motions will also be tested. The same three procedures will be administered again at the end of week one, in week three after completion of treatment, and again at a four week follow up consultation, in order to record the progress made.

The potential benefits for those who receive treatment will be a decrease in pain and an increase in mobility. All participants will also be contributing to medical knowledge, resulting in a greater efficacy in the treatment of patients with cervical injuries and related conditions.
Taking part in this study is voluntary and the participant is free to refuse or withdraw their consent and can, at any time, discontinue their participation. A signed copy of this consent form will be made available to the participant.

I have fully explained the procedures and my purpose in this study. I have also asked whether any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

Date: ___________________________  Researcher: ___________________________

I have been fully informed as to the procedures to be followed in this research study. If, at any time, I have more questions about the study, I understand that they will be answered. In signing this consent form, I agree to the methods of treatment and understand that I may withdraw my participation at any time.

Date: ___________________________  Participant: ___________________________
APPENDIX E

Visual Analogue Scale (VAS)

<table>
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<tr>
<th>Name:</th>
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<tr>
<td>Telephone number:</td>
</tr>
<tr>
<td>Remedy being taken:</td>
</tr>
<tr>
<td>Date:</td>
</tr>
<tr>
<td>Week:</td>
</tr>
</tbody>
</table>

Instructions:

- Place a mark, anywhere on the line at a point that corresponds to your level of pain.
- At the one end of the line is a zero, and the words “no pain”. At the other end of the line is the number ten and the words “worst pain imaginable”.

0  NO PAIN  10  WORST PAIN IMAGINABLE
APPENDIX F

Neck Pain Disability Index

Section 1 - Pain intensity

☐ I have no pain at the moment (0)
☐ The pain is very mild at the moment (1)
☐ The pain is moderate at the moment (2)
☐ The pain is fairly severe at the moment (3)
☐ The pain is very severe at the moment (4)
☐ The pain is the worst imaginable at the moment (5)

Section 2 – Personal care (washing, dressing, etc.)

☐ I can look after myself normally without causing extra pain (0)
☐ I can look after myself normally but it causes extra pain (1)
☐ It is painful to look after myself and I am slow and careful (2)
☐ I need some help but manage most of my personal care (3)
☐ I need help every day in most aspects of my care (4)
☐ I do not get dressed; I wash with difficulty and stay in bed (5)

Section 3 – Lifting

☐ I can lift heavy weights without extra pain (0)
☐ I can lift heavy weights but it gives extra pain (1)
☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, for example on a table (2)
☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned (3)

Section 4 – Reading

☐ I can read as much as I want to with no pain in my neck (0)
☐ I can read as much as I want to with slight pain in my neck (1)
☐ I can read as much as I want with moderate pain in my neck (2)
☐ I cannot read as much as I want because of moderate pain in my neck (3)
☐ I can hardly read at all because of severe pain in my neck (4)
☐ I cannot read at all (5)

Section 5 – Headaches

☐ I have no headaches at all (0)
☐ I have slight headaches that come infrequently (1)
☐ I have moderate headaches which come infrequently (2)
☐ I have moderate headaches which come frequently (3)
☐ I have severe headaches which come frequently (4)
☐ I have headaches almost all the time (5)

Section 6 – Concentration

☐ I can concentrate fully when I want to with no difficulty (0)
☐ I can concentrate fully when I want to with slight difficulty (1)
☐ I have a fair degree of difficulty in concentrating when I want to (2)
☐ I have a lot of difficulty in concentrating when I want to (3)
☐ I have a great deal of difficulty in concentrating when I want to (4)
☐ I cannot concentrate at all (5)

Section 7 – Work

☐ I can do as much work as I want to (0)
☐ I can do my usual work but no more (1)
☐ I can do most of my usual work but no more (2)
☐ I cannot do my usual work (3)
☐ I can hardly do any work at all (4)
☐ I cannot do any work at all (5)

Section 8 – Driving

☐ I can drive my car without any neck pain (0)
☐ I can drive my car as long as I want with slight pain in my neck (1)
☐ I can drive my car as long as I want with moderate pain in my neck (2)
☐ I cannot drive my car as long as I want because of moderate pain in my neck (3)
☐ I can hardly drive at all because of severe pain in my neck (4)
☐ I cannot drive my car at all (5)

Section 9 – Sleeping

☐ I have not trouble sleeping (0)
☐ My sleep is slightly disturbed (less than 1hr sleepless) (1)
☐ My sleep is mildly disturbed (1-2hrs sleepless) (2)
☐ My sleep is moderately disturbed (2-3hrs sleepless) (3)
☐ My sleep is greatly disturbed (3-5hrs sleepless) (4)
☐ My sleep is completely disturbed (5-7hrs sleepless) (5)

Section 10 – Recreation

☐ I am able to engage in all my recreation activities with no neck pain at all (0)
☐ I am able to engage in all my recreation activities with some pain in my neck (1)
☐ I am able to engage in most, but not all of my recreation activities because of pain in my neck (2)
☐ I am able to engage in a few of my usual recreation activities because of pain in my neck (3)
☐ I can hardly do any recreation activities because of pain in my neck (4)
I cannot do any recreation activities at all (5)

APPENDIX G

Cervical Range of Motion

Patient Name: ___________ Date: ___________
Initial consultation: _____ Week one: _____ Week two: _____ Follow-up: _____

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APPENDIX H

Cervical range of motion results

Appendix H4.1 Detailed analysis of flexion for both groups for the duration of the study

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Appendix H4.2 Detailed analysis of extension for both groups for the duration of the study

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Appendix H4.3 Detailed analysis of right rotation for both groups for the duration of the study

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### Appendix H4.5  Detailed analysis of right lateral flexion for both groups for the duration of the study

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### Appendix H4.6  Detailed analysis of left lateral flexion for both groups for the duration of the study

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76
Appendix I

Visual Analogue Scale results

Detailed analysis of VAS for both groups for the duration of the study

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