

## **Research for Mmed Neurosurgery 2018**

### **Title:**

*The comparison of pain relief between fluoroscopic guided and free hand lumbar facet infiltration for lumbar facet syndrome.*

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## **Abstract**

**Background:** Lumbar facet syndrome has become a commonly accepted term for lower back pain caused primarily by the facet joints of the lumbar spine. Listed as one of the most common causes for patients to seek medical counsel, lumbar facet syndrome is a frequent diagnostic and treatment conundrum for medical practitioners. Lumbar facet infiltration techniques have been used for over half a century in an attempt to alleviate symptoms of the disease process. This study has attempted to discern whether the standard lumbar facet infiltration with the use of fluoroscopy is superior in terms of pain relief to a technique using no fluoroscopy, but rather a free handed technique guided on sound anatomical landmarks.

**Method:** A total of 40 patients, eligible for the study according to the inclusion criteria, were recruited for the study. All patients participated and were randomised into 2 groups of 20 patients each. Group 1 patients received a lumbar facet infiltration procedure with fluoroscopic guidance, Group 2 patients received a lumbar facet infiltration procedure with the free hand technique. Randomisation separated male and female (10:10 group 1 and 11:9 group 2). All 40 patients were included to the results with age ranging 24-73 years of age. Patients would score their pain experienced due to lumbar facet syndrome on the Visual analogue Scale (VAS)(0-10) as well as completing the Oswestry Low Back Pain Disability Questionnaire which would score their disability secondary to lower back pain as a percentage namely the Oswestry Low Back Pain Disability Score (OLBPDS). Data was collected over a period of 12 months with patients providing information pre-lumbar facet infiltration, 1 hour post infiltration, 24 hours post infiltration, 1 week post infiltration and 4 weeks post infiltration.

**Results:** Results showed a suggestion of improvement in disability secondary to pain and in lower back pain in both techniques, particularly after 1 week (Group 1- OLBPDS 57%-49.5%, VAS 8-6) (Group 2 – OLBPDS 58%-43%, VAS 8-7), however, all p-values are above 0.05 and thus there is no statistical significance, this was reproduced at 1 hour, 24 hours, 1 week and 4 weeks procedure.

**Conclusion:** symptomatic treatment of lumbar facet syndrome by facet infiltration is effective in temporary pain relief. Both fluoroscopic guided and free hand techniques show improvement in lower back pain and disability secondary to pain without a statistically significant difference in the amount of pain relief experienced or a difference in the change in the disability index between the 2 procedures. One can thus suspect that the free handed anatomic technique of lumbar facet infiltration may provide a faster, cheaper procedure to treat symptomatic lumbar facet syndrome in comparison with the standard fluoroscopic technique as results in pain relief and improvement in disability are comparable. Future studies with larger study populations will be needed to confirm this study.

## Introduction

Since its first use in 1933 by Ghormly, “lumbar facet syndrome” (LFS) has now become a widely used term to describe the facet joint as a common cause of chronic lower back pain<sup>1, 2</sup>. LFS is reported to account for around 15% of chronic lower back pain, with some reports indicating as high as 45%<sup>3,4,5</sup>. Modern day treatment of LFS includes a range of therapies including physical therapy, oral anti-inflammatory drugs, peri-facet infiltrations, intra-articular facet injections, radiofrequency ablation of the medial branch of the dorsal rami, open denervation and fixation procedures<sup>2,5,6</sup>.

Various facet infiltration techniques are used as diagnostic measures as well as for symptomatic relief of the pain generated by the facet joint. Reports on efficacy are inconsistent and especially so when being used as a diagnostic tool<sup>1</sup>, but most of the literature suggests an overall reduction in pain and improvement in general disability secondary to pain after facet infiltration procedures, provided the correct diagnosis is made<sup>2,4,7,8</sup>. There seems to be no consensus on the duration of pain relief that can be expected from facet infiltrations, if relief is experienced at all, with reviews reporting pain relief experienced between 1 week to 6 months and some patients reporting long term, sustained relief<sup>2,3,9,10</sup>.

Furthermore, there has been very little evidence to suggest that intra-articular infiltration is superior to peri-facet infiltration, the latter implying blockade of the nervus medialis of the dorsal ramus<sup>10,11,12,13</sup>.

Whether ablation or infiltration is done for LFS, most techniques make use of a portable X-Ray device to identify the facet joint and thus accurate placement of the needle used during the procedure<sup>5,6,8</sup>. Despite the use of fluoroscopy in facet infiltration, there are numerous reports of high failure rates, inadequate pain reduction, false negative and false positive diagnostic values (up to 38%) as well as a high placebo effect of 32%<sup>4,7,10,13</sup>. The reasons for the variability are multiple, ranging from operator interdependency to the different drugs used in the infiltration<sup>6</sup>. Another cause for variation is likely to be that pain relief will be experienced from both intra-articular infiltration, medial branch nerve block and blockade of the structures surrounding the facet, and the patient will interpret the relief as the same despite exact location of the block<sup>13</sup>.

With this in mind, one must consider the risks involved in the use of fluoroscopy including that of radiation dose which can be between 10-50mGy/min for normal fluoroscopy and 100-200mGy/min in high dose fluoroscopy. Fluoroscopic procedures account for up to 10% of all medical related exposure to ionising radiation. Together with the high prevalence of lower back pain, and specifically, lumbar facet syndrome, the exposure risk to both patients and surgeons has become a concern to say the least<sup>6</sup>.

With improvement in technology, new techniques using spinal navigational systems have been implemented with comparable results, however, this equipment is costly and takes time to implement correctly<sup>6,8</sup>.

In current practice, the fluoroscopic assisted technique is done in an operating theater. The procedure then requires theater time, staff, equipment and admission into hospital. The procedure is thus costly and time consuming.

This study sought to identify if using standard fluoroscopic guidance to infiltrate the lumbar facet region would be any different in terms of pain relief than to relying on sound anatomical landmarks and infiltrating without fluoroscopy.

### **Methods and materials:**

The study was a randomised controlled study conducted over a period of 12 months. After the study protocol was approved by the Health Sciences Research Ethics Committee (ethics approval number: HSREC 08/2017 UFS-HSD2017/0068) patients were recruited for the study as per the inclusion criteria. All patients who were recruited signed informed consent to participate in the study and receive treatment, a clear indication of intent to treat was relayed to the patients. Information regarding the disease process, the details of the procedure and the details of the study were given to the patients in either English, Afrikaans or Sesotho as per their preference.

A total 40 patients qualified for the study and were randomised into 2 groups of 20. Randomisation occurred by gender. The patients allocated to group one received a fluoroscopic guided lumbar facet infiltration and those in group two received a free-handed technique.

The number of males to females allocated to group 1 and 2 were 10:10 (50%:50%) and 11:9 (55%:45%).

The inclusion criteria included <sup>(8,14,15)</sup>:

- lower back pain worse in the mornings
- pseudoradicular pains around the buttock, groin or thigh, not extending past the knee
- pain worsened by lumbar extension, rotation, prolonged standing and/or prolonged sitting
- pain relieved with lumbar flexion
- mild pain on palpation of the lumbar region
- exclusion of other causes of lower back pain
- radiological signs of facet pathology including plain film X-Rays (2 views or more) and/or CT lumbar spine, and/or MRI lumbar spine.

The exclusion from the study were:

- age less than 18 years old
- patients refusing to partake in the study
- lower back pain secondary to lumbar disc herniation or stenosis
- gross deformity on examination or radiological investigation
- any "Red Flag" for lower back pain (table 1)
- intolerance or allergy to local anaesthetics
- intolerance or allergy to corticosteroids
- patients where Xray exposure is contra-indicated (eg:pregnancy)

**(Table 1 – Red Flags)**

<b>On History:</b> *Previous history malignancy (however long ago) *Weight loss (unexplained) *Previous longstanding steroid use *Recent serious illness *Recent significant infection	<b>Signs:</b> *Saddle anaesthesia *Reduced anal tone *Hip or knee weakness *Generalised neurological deficit *Progressive spinal deformity *Urinary retention	<b>Symptoms:</b> *Non-mechanical pain (worse at rest) *Thoracic pain *Fever/rigor *General malaise *Urinary retention
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A questionnaire was given to each patient which included the *Oswestry Low Back Pain Disability Questionnaire*<sup>16</sup> (appendix A) and a *Visual Analog Scale*(appendix B) which assessed their grade of disability due to pain and severity of pain caused by the lumbar facet syndrome that was diagnosed. Each patient completed the questionnaire (provided in English, Afrikaans and Sesotho), at intervals including before the procedure, 1 hour post procedure, 24 hours post procedure, 1 week post procedure and 1 month post procedure. The results were then collected from the patients roughly 4 weeks after the procedure was performed.

All patients complied with a 100% follow up rate.

The Oswestry Low Back Pain Disability score<sup>16</sup> was then calculated according to each of the patients scores either out of a possible 45 or 50 (depending if the patient was sexually active or not). This score was then converted into a percentage. Interpretation of this index can be seen below:

**(OLBDS summary)**

<b>0% to 20%: minimal disability:</b>	The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting sitting and exercise.
<b>21%-40%: moderate disability:</b>	The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means.
<b>41%-60%: severe disability:</b>	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation.
<b>61%-80%: crippled:</b>	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
<b>81%-100%:</b>	These patients are either bed-bound or exaggerating their symptoms.

### **Procedure techniques:**

The techniques used for both procedures were standard described techniques<sup>6,8,12,14</sup> and were performed as follows:

#### **The fluoroscopic guided procedure:**

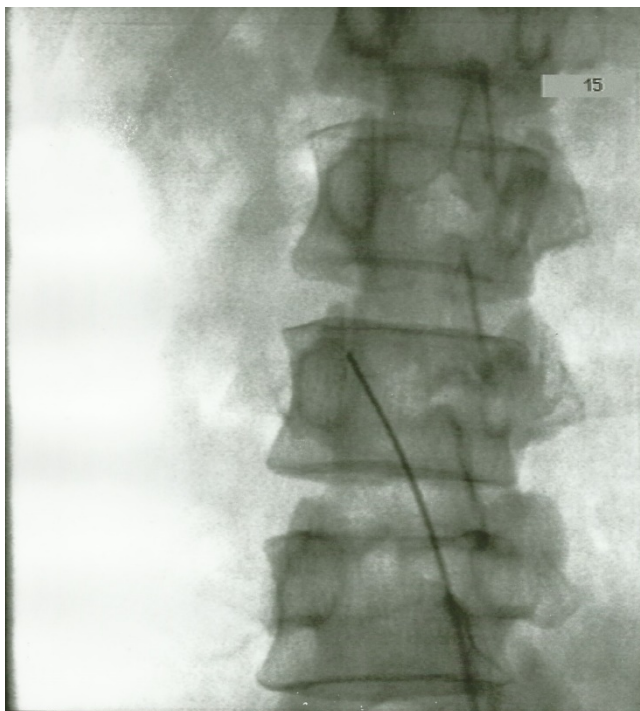
The patient was placed on a theater list, and taken to an operative theater for the procedure where he/she would be placed prone on a standard spinal operative table with care of the potential bony pressure points. A cushion was placed under the abdomen to flatten out the lordotic curvature of the lumbar spine.

The lumbar region was then cleaned with hibitane in alcohol skin cleaner, or equivalent antiseptic skin cleaner if the patient reported to have a skin sensitivity. The clean field was then be draped in a sterile manner.

The lumbar vertebrae were identified initially with the fluoroscopy device in an antero-postero view and then the facets were further identified with an oblique view at 30 degrees from the verticle line.

The Lumbar peri-facet space L1-L5 was then infiltrated under fluoroscopic vision bilaterally using a 20G spinal needle with 2ml of a Bupivacaine-methylprednisolone mix.

After the procedure, an occlusive dressing was applied to the infiltration sites.



The infiltrate described above included:

-50mg Bupivacaine (Macaine 0,5% - 10ml)

-80mg methylprednisolone (Solumedrol 2ml)

-28ml normal saline dilutant

The above made up a 40 ml solution with each ml containing:

-1.25mg of Bupivocaine, 2mg of methylprednisolone

This will equated to each facet being infiltrated with

-2.5mg Bupivacaine and 4mg methylprednisolone.

***(Image 2: fluoroscopic guided facet infiltration)***

The maximum dose for Bupivacaine is 3mg/kg and the maximum dose for methylprednisolone is 10mg peri-articular for each joint with a maximum of 120mg per 24 hours, therefore since all patients included in this study were over the age of 18 and above 20kg, the dose given is was below maximum dose.

### The free hand procedure:

The patient was placed in a treatment room in the outpatient department and positioned prone with a cushion under the abdomen to reduce the lordotic curvature of the lumbar spine, care of the potential boney pressure points was taken.

The skin was cleaned with hibitane in alcohol or similar antiseptic skin cleaning agent if the patient reported having a skin sensitivity. The clean field was then draped in a sterile manner.

Landmarks were marked out on the patients skin surface using a technique described by Theodoridis, T Ludwig J and Kramer J. ie:



-The iliac crests were palpated bilaterally and the index fingers would rest on the superior border of the iliac crests.

-The thumbs then palpate the posterior-superior-iliac-spine in a infero-medial plain.

-The L4 spinous process would be expected to lie on the line and in the center of the two superior borders of the iliac crests.

-The L5 spinous process would be expected to lie midway between the PSIS and the L4 spinous process. Once the L5 and L4 spinous processes were marked, the L3, L2, and L1 process were palpated in ascending succession and marked.

*(Photograph of skin marking for group 2 patients)*

The entry points for infiltration would then lie 2-2.5 cm lateral to and between the spinous processes. The variation in distance was checked with the radiological investigation.

A 20G spinal needle was then used to inject 2ml of a Bupivacaine\methylprednisolone mix from L1-L5 in the peri-facet joint region bilaterally.

After the procedure, an occlusive dressing was applied to the infiltration sites.

## Pilot study

The first 2 patients randomised into each group were utilised as a pilot study over the first four weeks of the study. During this time, there were no complaints from the patients regarding the ease of the questionnaire or the procedure itself. All patients followed up and no complications were encountered that would cause cessation of the trial. Thus the trial continued and the data from all four of the patients from the pilot study were included in final results.

## Results

Both groups were evenly represented with 20 patients per group and male to female representation as mentioned above (group 1 50:50, group 2 45:55).

Data was calculated to the median as there was a skewed distribution of results (see table 1)

**(Table 1)**  
**Group 1 (fluoroscopic guided technique)**

<u>Variable</u>	<u>N</u>	<u>Median</u>	<u>Lower Quart (25%)</u>	<u>Upper Quart (75%)</u>	<u>Range</u>	
<b>Oswestry Lower Back Pain Disability Score (OLBPDS) (% 0-100)</b>						
	Pre procedure	20	57.0	48.0	60.0	26.0-78.0
	1h post	20	53.0	40.0	59.0	20.0-72.0
	24h post	20	49.5	36.5	55.5	56.0-72.0
	1 week post	20	48.0	36.5	56.0	20.0-72.0
	4 weeks post	20	49.5	36.5	57.0	20.0-72.0
<b>Visual Analog Scale (VAS) for pain (0-10)</b>						
	Pre procedure	20	8.0	7.0	8.0	6.0-9.0
	1h post	20	6.0	5.0	7.0	1.0-9.0
	24h post	20	5.0	4.0	7.0	1.0-9.0
	1 week post	20	5.0	3.5	7.0	1.0-9.0
	4 weeks post	20	6.0	4.0	7.5	2.0-9.0
<b>Change in OLBPDS over time (%)</b>						
	Pre to 1h	20	-4.5	-13.0	0	-22.0 – 6.0
	Pre to 24h	20	-8.0	-16.5	0	-75.44 – 16.0
	Pre to 1 week	20	-10.0	-18.0	0	-31.0 – 4.0
	Pre to 4 weeks	20	-6.0	-16.0	0	-31.0 – 4.0
<b>Change in VAS over time</b>						
	Pre to 1h	20	-2.0	-2.5	0	-6.0 – 1.0
	Pre to 24h	20	-2.5	-4.0	0	-6.0 – 0.0
	Pre to 1 week	20	-2.5	-4.5	0	-6.0 – 0.0
	Pre to 4 weeks	20	-1.0	-4.0	0	-5.0 – 0.0

### Group 2 (free hand technique)

Variable		N	Median	Lower Quart (25%)	Upper Quart (75%)	Range
<b>Oswestry Low Back Pain Disability Score (OLBPDS) (% 0-100)</b>						
	Pre procedure	20	58.0	48.5	63.0	26.0-78.0
	1h post	20	49.5	41.0	58.0	20.0-72.0
	24h post	20	43.0	39.0	50.0	56.0-72.0
	1 week post	20	42.0	29.0	49.5	20.0-72.0
	4 weeks post	20	43.0	29.5	53.5	20.0-72.0
<b>Visual Analog Scale (VAS) for pain (0-10)</b>						
	Pre procedure	20	8.0	7.0	8.5	6.0-9.0
	1h post	20	6.0	5.0	7.0	1.0-9.0
	24h post	20	5.0	4.0	6.5	1.0-9.0
	1 week post	20	4.5	3.5	7.5	1.0-9.0
	4 weeks post	20	7.0	4.0	7.5	2.0-9.0
<b>Change in OLBPDS over time (%)</b>						
	Pre to 1h	20	-4.5	-10.0	-1.0	-22.0 – 6.0
	Pre to 24h	20	-11.5	-18.0	-2.0	-75.44 – 16.0
	Pre to 1 week	20	-12.5	-20.0	-6.0	-31.0 – 4.0
	Pre to 4 weeks	20	-10.0	-18.0	-2.0	-31.0 – 4.0
<b>Change in VAS over time</b>						
	Pre to 1h	20	-1.5	-2.0	-1.0	-6.0 – 1.0
	Pre to 24h	20	-3.0	-4.0	-1.0	-6.0 – 0.0
	Pre to 1 week	20	-3.0	-4.0	-1.5	-6.0 – 0.0
	Pre to 4 weeks	20	-1.0	-4.0	0	-5.0 – 0.0

Age was evenly distributed with the median age being 49.5 and 51 years of age in groups 1 and 2 respectively (range 24-73)

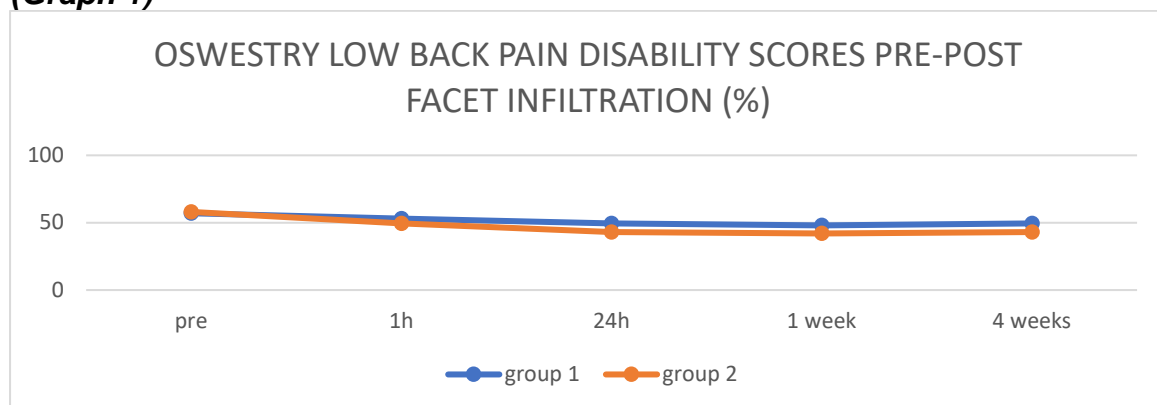
The results were processed to identify a difference with a 95% confidence interval between groups 1 and 2 at the various times as stipulated on the questionnaire. (see table 2)

**(Table 2)**

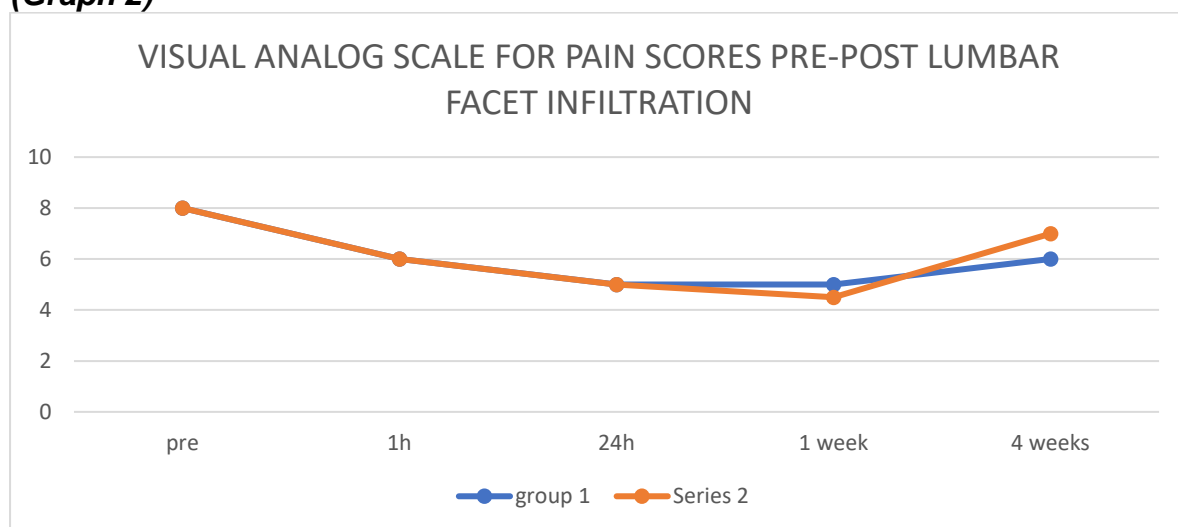
Variable	95% C.I	p-value
<b>OLBPDS</b>		
Pre procedure	-8;7	0.81
1h post	-10;9	0.96
24h post	-8;10	0.35
1 week post	-5;14	0.35
4 weeks post	-6;14	0.43
<b>VAS</b>		
Pre procedure	-1;0	0.50
1h post	-1;1	0.83
24h post	-1;2	0.73
1 week post	-1;2	0.83
4 weeks post	-2;1	0.67

In both groups, there appeared to be a trend toward improvement in both disability due to pain and severity of pain after the procedure with the greatest relief seen after 1 week (group 1- OLBPDS 57%-49.5%, VAS 8-6) (group 2 – OLBPDS 58%-43%, VAS 8-7). However, the interpretation of the Oswestry Low Back Pain Disability Score showed that the median distribution did not see the majority of patients improving their disability from severe to moderate, but rather remained in the severe group. The amount of pain relief at the various stages between the two groups differed minimally and showed no statistical significance after the completion of 4 weeks, although the median 4 week visual analogue scale for pain score was 1 point higher in the free hand group. (OLBPDS -6;14 95%C.I (p=0.43)) (VAS -2;1 95%C.I (p=0.67)).

**(Graph 1)**



**(Graph 2)**



14 out of the 20 patients in group 1 (70%) reported some improvement at any given stage of the trial in both disability due to pain and the severity of pain, while 6 (30%) reported no improvement. No patients (0%) reported to have deteriorated. There were no complications due to the procedure reported in group 1.

17 out of the 20 patients in group 2 (85%) reported some improvement at any given stage of the trial in both disability due to pain and the severity of pain, while 3 (15%) reported no improvement. As in group 1, no patients (0%) reported to have deteriorated. There were no complications due to the procedure reported in group 2.

## **Discussion**

The controversy surrounding facet infiltrations and the various techniques is partly due to the fact that no high-powered study has been able to demonstrate convincingly superiority of one technique over the other<sup>1,13</sup>. Various reports show a tendency to favour intra-articular infiltrations while as many report no difference between intra-articular injections and blocking of the medial branch of the dorsal rami.

This study was designed to identify if using accurate visual aid when placing the needle for a facet infiltration, using fluoroscopy, would result in a greater amount of pain relief for the patient which would inevitably improve their disability. Although the population studied was small with only 20 patients per group, it appeared to show a general trend towards improvement in both the fluoroscopic guided and free hand groups. Furthermore, more patients reported improvement in both pain and disability due to pain in the free hand group (17 vs 14 ( $p>0.05$ )). Although not statistically significant, one can at the very least suggest that the two procedures produced similar results.

To understand why this result would be possible one should revise the anatomical basis.

The facet joint is a diarthrodial joint. The subchondral bone which makes up the facet is surrounded by cartilage and a synovial membrane. The cartilage is thickest at the center. A fibrous joint capsule surrounds the synovial membrane and encloses the joint from superior to inferior<sup>8,9,17</sup>. The capsule can accommodate 0.5 to 1.5ml of fluid<sup>6,14</sup>.

Each facet joint is innervated by the medial branch of the dorsal ramus<sup>2,3,7,9</sup>. The medial branch also supplies the multifidus, interspinales and intertransversarii mediales muscles and the interspinal ligament<sup>7</sup>. Important to note is that the facet joint of each lumbar segment is supplied by the medial branches of 2 dorsal rami. For example, the L4-5 facet will be supplied by the L3 above and L4 medial branches. This makes it important when using selective segmental blocks for diagnostic purposes, to include the segment above the desired level<sup>2,4,14</sup>.

Chronic low back pain is a major health problem with a lifetime prevalence ranging from 11 to 84% and the lumbar facets are the main pain generators in as much as 15%-45% of the cases<sup>2</sup>. It is the leading cause for all visits to neurosurgeons and orthopaedic surgeons and the second leading symptom making all patients visit a physician<sup>2</sup>. Stressed lumbar facet (zygapophysial) joints, muscular imbalances, and degenerative changes of lumbar facet joints are often involved in the clinical picture of the lumbar facet syndrome<sup>2</sup>. Studies by Shealy showed that 82% of patients with chronic low back pain had one or more facet joints involved.

One must then consider the pain generators of the lumbar facet syndrome not only to involve the multiple facet joints themselves, being the primary affected structures, but also to be the muscles and ligaments supplied by the medial branch of the dorsal ramus as described above<sup>17</sup>.

The free hand technique used in this study is designed to infiltrate and block the region supplied by the medial branch of the dorsal ramus. If the pre-procedural images are studied, as was done in this study, then the anatomical landmarks are very reliable and rarely differ if the patient has no gross deformities<sup>14</sup>. One can therefore deduce that a reliable peri-facet block will be achieved and that the patients will experience a

measure of pain relief for a period of time, comparable to that of more accurately placed infiltrations. This was seen in the results (see graph 1).

The idea of a free hand technique may be currently discouraged due to patient risk, medico-legal risk and procedure failure risk. Although there were no complications in either of the two groups, the study population was small and thus no difference in safety between the two procedures can be deduced, though one would argue that direct visualisation of the needle would theoretically be safer.

The counter argument would be that the free hand technique, when done with adequate knowledge and skill, is reliable and safe<sup>14</sup> with a comparable efficacy to the guided technique and at the same time will reduce the amount of exposure to ionising radiation to both the patient and the surgeon performing the procedure. Ionising radiation has both stochastic and non-stochastic effects. Stochastic effect is where the probability of complications increases with the dose and lacks a threshold dose, meaning all patients and surgeons are at risk to develop a complication of ionising radiation during fluoroscopic procedures. In recent reports, up to 1.3-3.2% of all newly diagnosed cancers, can be attributable to diagnostic exposure to X-rays<sup>5</sup>.

The utilisation of the free-hand technique would also provide an opportunity to improve the cost efficacy of the procedure and at the same time use less resources in an already burdened health care system. As mentioned prior, lumbar facet syndrome is a very common entity and thus forms part of the burden of disease. In the current setting in the South African health system, many of the patients suffering from lower back pain are not given priority due to the lack of resources and burden of disease focusing on more life-threatening illnesses. In our setting, patients would wait for extended periods awaiting symptomatic relief by a facet infiltration procedure as there is a constraint on available hospital beds and space on a surgical list. With the ability to give the patient the option to perform the procedure without having to be in a theatre with fluoroscopic equipment, one could reduce all the above obstacles and help the patient earlier, while at the same time offering comparable efficacy.

#### *A note regarding the scoring system*

The use of the Oswestry Low Back Pain Disability Questionnaire<sup>16</sup>, score and index gives a clear indication as to how the pain the patient experiences, affects their daily activities. The interpretation of such a score is challenging, and in a study such as this with a small study population and minor numerical changes reported, the scale's grading system proved too broad to be able to accurately consider if the patient had improved or not. When using the scale, it appears, according to the median distribution, that no patients in either of the groups improved their disability due to back pain after the procedures, while the subjective interpretation of the visual analogue scale, with its smaller numerical scale, relayed a different account with more dramatic displays of improvement. It would thus be advisable to use one scale for future reference with a smaller numerical range.

## **Conclusion**

Lumbar facet syndrome is a common cause of lower back pain. Consistent studies and reviews have shown that lumbar facet infiltration techniques can improve symptoms and pain while allowing greater functionality by reducing disability secondary to pain. While the current standard is use fluoroscopic guidance to infiltrate within the facet joint using a local anaesthetic with or without a long acting corticosteroid, this randomised control trial has shown that a free handed peri-articular technique may offer a suitable alternative. By showing no statistically significant difference in the patient response to the procedure, and perhaps an inclination towards a peri-articular free handed response in improvement, one could consider this technique as an option for those patients who would consent to such. The population of the study was indeed small, for that reason, a definite conclusion cannot be made and a similar study of a larger population group would be necessary to back the suggestive results of this trial.

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## **Appendix A**

### **Section 1 – pain intensity**

- I have no pain at the moment
- The pain is very mild at the moment
- The pain is moderate at the moment
- The pain is fairly severe at the moment
- The pain is very severe at the moment
- The pain is the worst imaginable at the moment

### **Section 2 – Personal care (washing, dressing etc)**

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

### **Section 3 – Lifting**

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

### **Section 4 – Walking**

- Pain does not prevent me walking any distance
- Pain prevents me from walking more than 1km
- Pain prevents me from walking more than 500m
- Pain prevents me from walking more than 100m
- I can only walk using a stick or crutches
- I am in bed most of the time

**Section 5 – Sitting**

- I can sit in any chair as long as I like
- I can only sit in my favourite chair as long as I like
- Pain prevents me sitting more than 1 hour
- Pain prevents me sitting more than 30 minutes
- Pain prevents me sitting more than 10 minutes
- Pain prevents me from sitting at all

**Section 6 – Standing**

- I can stand as long as I want without extra pain
- I can stand as long as I want but it gives me extra pain
- Pain prevents me from standing for more than 1 hour
- Pain prevents me from standing for more than 30 minutes
- Pain prevents me from standing for more than 10 minutes
- Pain prevents me from standing at all

**Section 7 – Sleeping**

- My sleep is never disturbed by pain
- My sleep is occasionally disturbed by pain
- Because of pain I have less than 6 hours sleep
- Because of pain I have less than 4 hours sleep
- Because of pain I have less than 2 hours sleep
- Pain prevents me from sleeping at all

**Section 8 – Sex life (if applicable)**

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

### **Section 9 – Social life**

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

### **Section 10 – Travelling**

- I can travel anywhere without pain
- I can travel anywhere but it gives me extra pain
- Pain is bad but I manage journeys over 2 hours
- Pain restricts me to journeys of less than 1 hour
- Pain restricts me to short necessary journeys under 30 minutes
- Pain prevents me from travelling except to receive treatment

**Reference:** Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine 2000 Nov 15;25(22):2940-52;discussion 52

**Appendix B**

**Visual Analog Scale (VAS)**

