

Report on a case series investigating a neurostimulation device for the treatment of pain and improvement of mobility and function following elbow surgery



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ABSTRACT

A group of seven patients received neurostimulation (Stimpod) post-tennis or golfer's elbow surgery as their sole treatment to relieve acute post-operative pain, improve mobility and function. Patients undergoing the above-mentioned surgery have had chronic pain with and without neuropathic symptoms for a prolonged period. There is usually severe injury with active inflammatory processes due to the surgery. It was thought that treating these patients aggressively early post-operatively may expedite pain relief and the healing process.

Method: After their surgery, seven patients were given neurostimulation for three treatments of 20 min each on the brachial plexus during the 10 days before the splint was removed. This was followed by 6 treatments, twice weekly of 20 min each after the splint was removed. At each of these treatments 5-min stimulation were administered to four areas: the nerve supply (1) superior and (2) inferior to the elbow and (3 and 4) on either end of the wound. Patients were evaluated for pain with the visual analogue scale, movements of flexion and extension measured with a goniometer, strength and flexibility with a 12-movement activity scale, status of the wound and satisfaction with treatment, mobility and function. These measures were re-evaluated telephonically at one, three and six months after the last treatment.

Results: Significant pain relief was achieved by all of the seven patients before the splint was removed at the 4th treatment. Pain relief, range of movement and function was greatly improved at the final (9th) treatment by six of the seven patients and this was maintained with nearly full improvement of the above parameters for most of the participants at one month after the last treatment. Two patients had to have re-operation due to requiring more extensive surgery in the one patient and falling and injuring the original surgical site in the other patient. At three and six months after the last treatment full improvement in all the parameters above was maintained in the remaining five patients who also had excellent wound healing and satisfaction with their treatment, mobility and function.

Conclusion: It appears that the neurostimulation (Stimpod) has the capacity to improve acute post-surgical pain and reduce pain, improve mobility, function and stimulate wound healing once the splint was removed. This treatment is relatively cost effective, is non-invasive and of short duration. Positive effects were all maintained at 6 months.

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1. Background

Patients undergoing epicondylitis surgery whether medial or lateral have had chronic elbow pain for a prolonged period often of many months to a year in some cases that has been unresponsive to conservative measures.

Although epicondylitis is a common condition in the arm due to physical overload, the prevalence of definitive lateral epicondylitis was 1.3% and that of medial epicondylitis was 0.4% according to a study in Finland (between 2000 and 2001). The prevalence did not differ between men and women and was highest in subjects aged 45–54 years [1,5]. Prior to surgery these patients have usually had non-surgical treatment and conservative care that includes decreased activity, ice, non-steroidal anti-inflammatory medications, muscle strengthening [2] and these modalities usually help most people. Recalcitrant cases may require cortisone injections that demonstrate the best conservative treatment for lateral

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epicondylitis [3] but provides only short-term benefits in medial epicondylitis [4].

Lateral epicondylitis, also known as “tennis elbow,” is an overuse syndrome of the common extensor tendon, predominantly affecting the extensor carpi radialis brevis. Patients complain of poorly defined pain located over the lateral elbow that is typically exacerbated by activities requiring wrist extension and/or wrist supination against resistance. There will often be pain in the morning as well as after any period of time that the elbow has been held in a flexed position [5].

Medial epicondylitis is a clinical entity characterized by pain in the medial aspect of the elbow and dysfunction induced by degenerative changes in the origin of the flexor-pronator muscle mass. The accumulated pathological evidence suggests that the process is associated with fibrillary degeneration of collagen and angiofibroblastic hyperplasia at the origin of the flexor-pronator muscle mass, microfragmentation or tears of the tendon, accumulation of vascular granulation tissue and tendinous necrosis, all of which are also accompanied by a secondary inflammatory reaction [6].

Non-operative treatment has been deemed highly successful, yet the few prospective reports available suggest that symptoms frequently persist or recur. Operative treatment is indicated for debilitating pain that is diagnosed after the exclusion of other pathologic causes for pain and that persists in spite of a well-managed non-operative regimen spanning a minimum of 6 months. The surgical technique involves excision of the pathologic portion of the tendon, repair of the resulting defect, and reattachment of the origin to the lateral or medial epicondyle. Surgical treatment results in a high degree of subjective relief, although objective strength deficits may persist [7].

During the last decade, increased attention has been paid to persistent pain complaints after almost any surgical operation with reported incidences ranging between 5% and 50% [8]. The International Association for the Study of Pain defines post-surgical pain as persistent pain after surgery of greater than three months duration [9].

Persistent post-surgical pain syndromes (PPSP) have been considered neuropathic [8] and a strong association is reported between PPSP and sensory abnormalities [10]; however, there is evidence that mechanisms other than nerve injury such as inflammation, central sensitization or a combination of these may play a role. It is important to elucidate whether persistent pain is due to surgical injury of the nerves, ongoing inflammatory processes, injury to the somatic or visceral structures or other causes [11].

Most of those patients that elected to have the surgery for the elbow in these case reports had chronic pain before surgery with or without neuropathic symptoms. It was thought that treating the acute post-operative pain aggressively early by blocking pain, improving wound healing and improving strength may have some impact on post-surgical pain.

If the patients in this case series elect to have the elbow surgery after 3–6 months of conservative care they are operated on the medial or lateral epicondyle. The procedures enumerated herein were given to the author by the orthopaedic surgeon performing the surgery.

The tendon of the extensor carpi radialis brevis is incised on the lateral aspect for tennis elbow and on the medial side, the common flexor origin is incised and any necrotic tendon is removed. A debridement of the epicondyle is performed on each side if necessary depending whether it is a tennis or a golfer's elbow. The patients are then placed into a back slab for 1 week or 10 days. This procedure will involve a certain amount of trauma to both soft tissue and bone and usually there is considerable pain from the intra-operative procedure that is usually ameliorated with anti-inflammatory and analgesic medication. Different types of these medications may be recommended as more suitable for different

individuals. Some of these patients may continue to have post-operative pain that could develop into a persistent post-operative pain syndrome with neuropathic elements. These symptoms may include burning, shooting and or sharp pain, hyperaesthesia on the wound site and may also produce electric shocks, tingling and paraesthesia [9] along the radial or ulna nerve distribution with prolonged limitation of movement and decreased strength in the forearm.

Recently a newly developed non-invasive pulsed radio frequency device (NI-PRF known as Stimpod or NMS 460) has been used to relieve neuropathic symptoms, improve nociceptive pain and increase mobility by decreasing muscle spasm, improving nerve conduction and thereby improving muscle control. It has also been observed that wound healing improves.

This device has been used in Europe and the United Kingdom with rapid effects occurring within 3–6 treatments even in intractable pain states for many patients since 2009. It has been investigated and used clinically in South Africa for the past 5 years and it has indeed relieved neuropathic symptoms and improved mobility and strength in many patients with varied conditions including intractable pain states [12].

The purpose of this study was to test this device as the only treatment provided for these patients receiving elbow surgery. It was thought that a population of patients requiring tennis or golfer's elbow surgical repair may be investigated to determine if a non-interventional pulsed radio frequency device alone could provide: (i) relief for the acute post-operative stage, (ii) assist with wound healing, (iii) improve range of motion and strength and have an effect on post-operative pain.

2. Literature review

Many attempts have been made to prevent post-operative pain with preemptive analgesia that may include intra-articular opioid injections or adjuvant pharmacological approaches without consistent clinical research findings [13].

The highest prevalence of PPSP was found after thoracic and breast surgery (34.5% and 31.0%), followed by THA/TKR and iliac crest bone harvest (19.8% and 18.7%); similar PPSP prevalences were found after prostatectomy (14%), gynaecologic surgery (13.7%), abdominal surgery (11%), mandibular osteotomy (10%), and donor nephrectomy (9.6%); the lowest PPSP was reported with groin hernia repair (7%) and varicose vein surgery (4.7%) [14].

The pathogenic mechanisms are multiple and can be grouped into preoperative, intra-operative and post-operative factors. This type of persistent post-operative pain (PPSP) is understood to be iatrogenic and could be prevented by identification of the mechanisms and risk factors although the underlying aetiology still remains unclear [15].

In evaluating electrical currents for post-surgical pain, according to a meta-analysis of transcutaneous electrical nerve stimulation (TENS) there was a reduction of post-operative analgesic consumption with assessment of the optimal treatment parameters [16].

Johnson reported some good quality systematic reviews on TENS that suggest that TENS is effective for musculoskeletal and post-operative pain [17].

TENS treatment was shown to be ineffective when used alone in severe post-thoracotomy pain (i.e. posterolateral thoracotomy incision), but useful as an adjunct to other medications in moderate post-thoracotomy pain (i.e. muscle sparing thoracotomy incision) and very effective as the sole pain-control treatment in patients experiencing mild post-thoracotomy pain (i.e. video-assisted thoracoscopy incision) but not in severe pain post-thoracotomy pain [18]. Hence, current evidence shows TENS associated with post-operative medications to be safe and effective in alleviating

post-operative pain and in improving patient recovery, thus enhancing the choice of available medical care and bettering outcome after thoracic surgery [19].

It appears however that there is a paucity of studies evaluating electrical currents (except for TENS) that includes non-interventional pulsed radio frequency and direct current for post-operative acute and persistent post-operative pain syndromes.

The non-invasive pulsed radio frequency device that was used in the pilot study is a current that consists of three types of current: a low frequency pulse varying between 1 and 10 Hz, a square wave direct current of 0.1–0.2 ms width with a superimposed radio frequency of 133 kHz. The low frequency component mimics the TENS current (alternating current) and the combination of direct current and pulsed radio frequency wave has elements of the direct current and magnetic field effects.

Studies have demonstrated that other non-interventional radio frequency devices that are applied with electrodes either in contact with the skin or not have been known to improve wound healing [20,21].

3. Method

Seven patients who had elbow surgery either for golfers or tennis elbow were sent for neurostimulation within a day post-surgery. The University of the Witwatersrand Human Ethics Committee approval was received for the study. An information and consent form was presented to patients and duly signed.

The treatment protocol was divided into two sections.

The first three treatments with non-invasive pulsed radio frequency:

- 20 min in total
- brachial plexus region for 10 min superior to the clavicle
- brachial plexus region for 10 min inferior to the clavicle

This treatment was given on alternate days over 1 week before the splint was removed and the aim was to reduce pain immediately and to have a possible influence on post-operative pain syndromes that may occur, to prime the nerve supply to the elbow to increase mobility and to improve muscle strength (this could be visualized by fasciculation of the muscles under the splint) to enable better function after the splint was removed.

Once the splint was removed all measures and evaluations were taken before the second section of treatment was implemented.

Measurements were taken of:

- flexion and extension measurements with a goniometer
- status of the wound was assessed
- amount of medication required – this was non-specific due to different medications required by the individuals.
- VAS (visual analogue scale – worst pain imaginable 10/10 and least pain 0/10)
- scores of active function were recorded (on a five-point scale) – functional movements are assessed out of 5 with 0/5 indicating poor movement and 5/5 if full range is achieved
- satisfaction with the treatment, pain control and mobility out of 5 with 0/5 indicating poor and 5/5 indicating good results

The treatment protocol that then followed was:

- 5 min treatment each on the ulna or radial nerve (depending whether lateral or medial epicondylitis surgery was performed) superior and inferior to the elbow
- 5 min each end of the scar after the dressing was removed
- six treatments were then given twice a week for 3 weeks to complete the study.

The aim of this treatment was to reduce pain that had then increased due to active functioning of the arm, impact on increasing the range of movement, strength and function, improve healing in the scar tissue as the scar itself is also known to influence post-operative pain conditions.

A simple exercise list was given to each patient to practice active exercises at home within their level of strength and competence and date post-surgery.

Treatment nos. 1–3: make a fist 3–5 times twice daily.

Treatment no. 4:

Make a fist five times for three sets

Bend and straighten the arm in supination supporting with the other hand – three times

Pushing palms together – three times or

Lifting wrist with fist clenched or fingers extended three times

Treatment nos. 5–9:

Practice exercises three times per day

Make a fist five times for three sets

Bend and straighten the arm with support from the other arm or not depending on pain and strength available, in supination three times for five sets

Pushing palms together three times for five sets or

Lifting wrist with fist clenched or fingers extended depending on the epicondylitis surgery.

Assessment of the ability to function as in the movements listed below:

Functional movements:

Activity – making fist (/5)

Activity – washing face (/5)

Activity – writing (/5)

Activity – brushing hair (/5)

Activity – push palms together (/5)

Activity – extend wrist fingers closed (/5)

Activity – extend wrist fingers straight (/5)

Driving (/5)

Pull clothes on (/5)

Pick up weight (/5)

Pull on weight (/5)

Typing (/5)

Patients were evaluated for their satisfaction with the treatment, their level of pain and mobility on a scale of 5 with 0/5 being poor and excellent being 5/5.

Satisfied with treatment

Satisfied with pain control

Satisfied with mobility

All patients were re-evaluated telephonically at one month, three months and six months after the last (9th) treatment for pain, medication, flexion, extension, functional ability, satisfaction with the treatment, pain control and mobility.

4. Results

List of patients in study group.

No	Age	Gender	Type of surgery	Re-operated
102	39	Female	Tennis elbow	
103	38	Male	Tennis elbow	Yes
104	47	Female	Tennis elbow	
105	60	Male	Golfer's elbow	
106	52	Male	Tennis elbow	
107	39	Female	Tennis elbow	Yes
108	50	Female	Tennis elbow + shoulder surgery for impingement	

In the patient study group there were four females and three males and the ages ranged from 38 to 60 years. Only one patient had a golfer's elbow repair the remainder had a tennis elbow repair. Five patients recovered well and two patients had to have the surgery redone due in the first patient to a complication within the arm due to a previous knife wound and a more extensive approach being required than as in the initial surgery and in the other patient re-operation was required after a fall that had occurred during the recovery period damaging the original site of the surgery.

1–3 treatments before the splint was removed.

Minimum and maximum VAS from Treatments 1 to 3.

Patient	Rx1	Rx2	Rx3
102	4–8	2–3	0–3
103	Missed	3–10	2–3
104	4–8.5	8–11	0–6
105	Missed	Missed	Missed
106	5.5–8	0–5	0–4.5
107	7–9	8–10	6–7
108	5–5	3–3	2–2

Patient 103 missed the first treatment and recording of data and patient 105 was unable to attend the first three treatments and recording of the data.

When patients recorded their pain some commented that pain would reach a peak but only for a short period and did not persist.

4th treatment, the first treatment after the brace was removed.

Patient	VAS	Flexion	Extension	Mvt scores for 2 mvts only (%)
102	0–5	132	5	0.15
103	5–6	110	26	0.06
104	3–4	112	50	0.13
105	0–6	112	10	0.13
106	0–0	110	20	0.15
107	3–7	145	25	0.15
108	0–2	125	10	0.11

Percentage was evaluated on 2 movements out of 10 points.

Flexion and extension are measured in degrees, full flexion is between 130° and 150° and full extension is 0° – these ranges are dependent on muscle bulk.

There was significant pain post-surgery but the movements of flexion and extension were already quite advanced immediately after the splint was removed and this may have been expedited by the electrical stimulation. There were only two movements such as making a fist and washing the face that were evaluated on the fourth treatment as all others were not attainable and there were 12 movements that were attainable and evaluated from the sixth to ninth treatment.

Patient 107 had a good range of movement of flexion and patient 102 had a good range of extension before the 4th treatment.

9th and last treatment.

Patient	VAS	Flexion	Extension	Mvt scores for 12 mvts (%)
102	0–0.5	142	0	100
103	0–5	120	9	76
104	0–4	135	0	90
105	0–3	136	0	95
106	0–2.5	136	0	95
107	2–2	140	2	91
108	2–2	145	2	90

Percentage was evaluated from 12 movements (×5/5) out of 60 points in total.

On the last treatment, pain levels were greatly reduced except for the patient that had to be re-operated. Range of movements and activities were achieved or almost full.

Medications required on as needed basis by patients.

Patient	Rx1	Rx2	Rx3	Rx4	Rx5	Rx6	Rx7	Rx8	Rx9
102	+, ++	+	–	–	–	–	–	–	–
103	0	+, ++	++	+	–	+	+	–	–
104	+, ++	+, ++	++	–	–	–	–	–	–
105	0	0	0	–	–	–	–	–	–
106	+, ++	+, ++	–	–	+, ++	++	–	–	+
107	+, ++	+, ++	+, ++	++	–	–	–	++	–
108	+, ++	–	–	–	–	–	–	++	–

Medication: analgesics and anti-inflammatories required by patients from treatment 1–9.

Rx=treatments; 0=missed treatment (did not attend); +=non steroidal anti-inflammatories; ++=analgesics.

Most of the patients required nil non-steroidal anti-inflammatories and no analgesics on evaluation on the last treatment except for one patient.

One month follow up.

Patient	VAS	Flexion	Extension	Mvt scores for 12 mvts (%)
102	0–0	FROM	FROM	100
103	No data			
104	0–3	FROM	FROM	100
105	0–2	FROM	95%	93
106	0–2	FROM	FROM	97.5
107	0–3	FROM	FROM	58
108	0–0	FROM	FROM	96

FROM – full range of movement on the 12-point scale as assessed by the patient on telephonic communication.

It was evident that there was even further improvement in the one-month follow up.

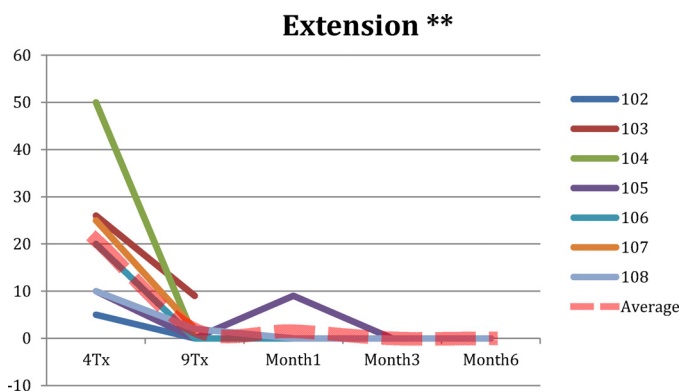
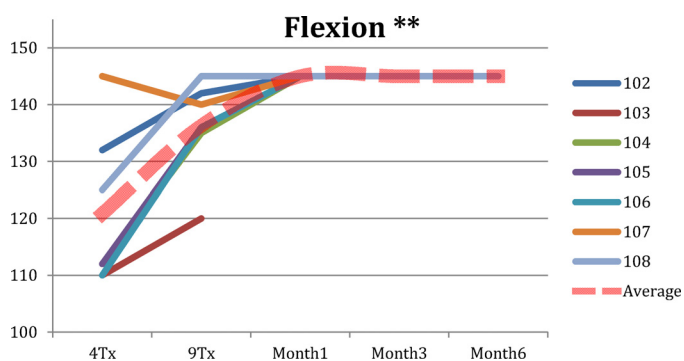
Three month follow up.

Patient	VAS	Flexion	Extension	Mvt scores for 12 mvts (%)
102	0–0	FROM	FROM	100
103	4–4	FROM	FROM	74
104	0–3.5	FROM	FROM	100
105	0–1	FROM	FROM	100
106	0–0	FROM	FROM	100
107	Re-operated after a fall			
108	0–0	FROM	FROM	100

FROM – full range of movement assessed by the patient on telephonic communication.

The parameters were all achieved except for the patient that was re-operated and patient 103 that would ultimately have further surgery.

The Averages for Flexion and Extension are also demonstrated in the slides below. The dotted line indicates the averages for the different periods evaluated.



5. Discussion

Prior to this case series of patients undergoing epicondylitis surgery the author had evaluated a random group of eight patients from 2006 to 2011 from the patient records that had also had the above mentioned surgery and had been referred by their orthopaedic surgeons for pain control and improved mobility.

On evaluation of this group of patients there was consistency with other studies in the comparison of their ages, gender and type of surgery with lateral epicondylitis surgery performed more frequently than medial epicondylitis surgery [1,5]. Unfortunately there was limited information in VAS and wound status in some of the patients but there was evidence of some patients requiring treatment many weeks after surgery, 16 weeks in one patient with the minimum referral being 10 days after surgery. There were a minimum number of treatments provided in one patient of two treatments and a maximum number of 12 treatments in another patient, with varying numbers of treatments in the others. Some of the wounds were oedematous and inflamed, most of the patients had limitation of extension of the elbow and there was only 50% resolution of the condition in these elbows according to the notes scrutinized. The treatments that were offered to these patients were usually multiple modalities that included ultrasound, electro-acupuncture, infrared laser, functional electrical stimulation, stretching, mobilization of the joint and exercises depending on the condition. These treatments would extend for longer than 20 min duration.

Random group of eight patients post-elbow surgery.

Patient	VN	FM	RP	AS	JC	MHP	MG	MG
Sex	F	F	M	F	M	M	F	F
Age	48	59	49	50	54	47	61	48
Surgery	T	T	T	T	T	G	T	T
Post-op (/52)	7	4	8	2	6	16	10d	2
1st appt	7/08	3/08	1/11	2/10	5/07	10/08	6/08	6/06
Wound	O	K	nil	R/O	nil	nil	I	TT
VAS 0/10	nil	nil	3–9	4–5	1–10	0	4–5	nil
Flexion	L	F	S	S	L	L	F	F
Extension	L	L	S	L	L	F	L	L
No of treatments	2	6	12	9	6	5	6	5
Full resolution	Y	N	Y	Y	Y	N	N	N

Surgery: T – tennis elbow; G – golfer's elbow; post-op in weeks or in d = days.
1st appt – date of first appointment: month, year; wound: O – oedema, K – keyloidal, nil – indicates no information available, R – red, I – indurated, TT – tender; flexion and extension: L – limited, F – full range, S – stiff; full resolution or complete healing: Y – Yes, N – No.

Although the incidence of neuropathic pain and or PPSP in elbow surgery is minimal yet chronic pain may be more common than realized. The condition could elicit chronic pain that may be due to pathogenic mechanisms that can be ascribed to preoperative, intra-operative and post-operative factors and that may produce ongoing complications for the patient and even neuropathic symptoms. It was then decided to use this example of post-operative elbow surgery for treatment with a neurostimulator (Stimpod) that is minimal, non-invasive, of short duration and cost-effective and may prevent PPSP and relieve neuropathic symptoms.

In the results achieved the patients in the pilot study had some relief of severe and uncomfortable pain before the splint was removed and they required less medication than prescribed as it was given on an as needed basis. After the splint was removed pain levels increased as mobility improved but the pain increase was due to stretching of injured tissues with active movements and did not produce chronic and or spontaneous pain.

The most surprising effect was the movement that was already available immediately after the splint was removed and that continued to improve to full range without the usual treatment requiring mobilization, stretching and strengthening during rehabilitation.

The wounds also demonstrated minimal oedema and inflammation that is not usually expected with recent surgery and continued to improve in some cases to an imperceptible scar. Scarring and sensitivity in the wound may augur chronic pain conditions and it is imperative to block pain and improve wound healing to prevent persistent pain and dysfunction.

By the last treatment patients had significantly improved and at one month after the last treatment the patients had almost all attained their goals of pain relief, range of movement and strength in their functional activities.

Patients were generally content with their progress in pain, movement and the type of treatment that was offered as it was of short duration, with a limited number of treatments required to achieve these results with minimal discomfort.

The neurostimulation device stimulated the brachial plexus in the first three treatments that then activates the specific nerve supply affected by the operation, e.g. radial nerve superior and inferior to the elbow if a lateral epicondylitis surgery was performed. Initially this stimulation produced minimal fasciculation in the nerve but as the nerve conduction improved then activity within the nerve supply became more evident with strong fasciculations occurring. This current could also translate in the opposite direction to the dorsal root ganglion of the cervical nerve roots.

When the splint was removed and the wound was exposed the neurostimulation was then applied to the radial nerve (in lateral epicondylitis surgery) superior and inferior to the elbow and to

either end of the wound. The effect of this was increased fasciculations in the radial nerve and this even occurred with stimulation on the wound. Again the current would translate in the opposite direction to the brachial plexus and the dorsal root ganglion of the nerve involved.

The neurostimulation device that has been used in this case series appears to have effects on nerve conduction e.g. found in Bell's palsy patients and relieves neuropathic pain from different aetiologies in many clinical situations since 2009 [12,20].

This type of neurostimulation was originally developed from a nerve-mapping device used by anaesthetists (2003) to detect a nerve before injecting and creating a nerve block prior to surgery. It was thought that to apply a magnetic field of 133 kHz to the square wave component of the nerve mapping current, a treatment would be developed that may be similar to that used in conventional pulsed radiofrequency (PRF) and that also included nerve mapping detection. In effect the current can target the nerve supply to an injury or damaged region. It is possible that nerve stimulation of the affected nerve may become a seminal treatment for blocking pain, normalizing nerve conduction with improvement in strength and range of movements. This treatment would therefore be non-invasive and of short duration to create these healing effects.

In conventional PRF there is no destruction of the tissue involved (this could be at the dorsal root ganglion, among others) and it is the presence of the high frequency (pulsed 500 kHz) that improves nerve pain and dysfunction, albeit during an invasive procedure. It is also known that pulsed and continuous radio frequency adjacent to the dorsal root ganglion in a rat model induces latent cellular activity [22]. Neuroscientists measure expression of c-fos as an indirect marker of neuronal activity as c-fos is often expressed when neurons fire action potentials. Up-regulation of c-fos mRNA in a neuron indicates recent activity [23].

The neurostimulation provided to these patients demonstrated a capacity to decrease acute post-surgical pain, improve mobility and wound healing with treatment of short duration and minimal intervention by the physiotherapist. There was no sign of neuropathic symptoms in these patients 6 months post-surgery and any pain that was experienced could be attributed to a normal post-operative healing process and improvement in strength with functional activities. All patients were able to resume their normal function and sporting activities.

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