Surgical treatment of lateral epicondylitis: a prospective, randomised, blinded, placebo controlled pilot study

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Surgical treatment of lateral epicondylitis:

A prospective, randomised, blinded, placebo controlled pilot study

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Background: Tennis elbow (lateral epicondylitis) is a common condition with a community prevalence of 1-3%, resulting in pain at the elbow and weakness extending the wrist. It is associated with overuse and if it progresses to a chronic stage, it shows degeneration at the insertion of extensor carpi radialis brevis (ECRB) macroscopically and microscopically. While there is no universally effective management for chronic tennis elbow, a common surgical technique as described by Nirschl & Pettrone (Nirschl, RP & Pettrone, FA (1979). "Tennis elbow. The surgical treatment of lateral epicondylitis." J Bone Joint Surg Am, 61(6A): 832-839) involves cutting out the degenerated portion of ECRB. Although the results of this procedure have been reported as excellent, no surgical procedure for tennis elbow has been compared with placebo surgery.

Methods: This study was a prospective, randomised, double-blinded, placebo controlled clinical trial investigating the Nirschl technique (surgical excision of the macroscopically degenerated portion of ECRB; n=11) compared with a sham operation (skin incision and exposure of ECRB alone; n=11) to treat chronic tennis elbow. The primary outcome was defined as patient rated elbow pain with activity at 6 months. Secondary outcome measures included patient rated pain and functional outcomes, elbow stiffness and range of motion, epicondyle tenderness and strength.

Results: The two groups were matched for age, sex and duration of symptoms. Both the Nirschl and sham procedures improved patient rated pain frequency and magnitude, elbow stiffness, difficulty with picking up objects and twisting motions and grip strength over 6 months ($p<0.01$). There was, however, no difference between the Nirschl and sham procedure in all outcomes, with the exception of patient ranked pain with activity at 2 weeks. Patients who underwent the Nirschl procedure for tennis elbow had more pain with activity at 2 weeks when compared with sham surgery alone ($p<0.05$). No side effects or complications were reported.

Conclusion: This pilot study demonstrates that, in the short term, surgical excision of the degenerative portion of ECRB confers no additional benefits to patients with chronic tennis elbow over and above a skin incision alone.

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Martin Kroslak

Abstract

Background: Tennis elbow (lateral epicondylitis) is a common condition with a community prevalence of 1-3%, resulting in pain at the elbow and weakness extending the wrist. It is associated with overuse and if it progresses to a chronic stage, tennis elbow shows both macroscopic and microscopic degeneration at the origin of the extensor carpi radialis brevis (ECRB). While there is no universally effective management for chronic tennis elbow, a common surgical technique (Nirschl & Pettrone. *J Bone Joint Surg Am,* 61(6A): 832-839) involves cutting out the degenerated portion of the ECRB. The results of this technique have been reported as excellent, yet no surgical procedure for tennis elbow has been compared with placebo surgery.

Methods: This study was a prospective, randomised, double-blinded, placebo controlled clinical trial investigating the Nirschl technique (surgical excision of the macroscopically degenerated portion of ECRB; n=11) compared with a sham operation (skin incision and exposure of ECRB alone; n=11) to treat chronic tennis elbow. The primary outcome measure was defined as patient rated elbow pain with activity at 6 months post-surgery. Secondary outcome measures included other patient rated pain and functional outcomes, elbow stiffness and range of motion, epicondyle tenderness and strength measurements.

Results: The two groups were matched for age, gender and duration of symptoms. Both the Nirschl and sham procedures improved patient rated pain frequency and severity, elbow stiffness, difficulty with picking up objects and twisting motions and grip strength over 6 months ($p<0.01$). The only difference observed between the groups was that patients who underwent the Nirschl procedure for tennis elbow had significantly more pain with activity at 2 weeks, when compared with sham surgery alone ($p<0.05$). No side effects or complications were reported.

Conclusion: This pilot study indicates that, in the short term, surgical excision of the degenerative portion of ECRB confers no additional benefits to patients with chronic tennis elbow over and above a skin incision alone.

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Introduction

1. Tennis Elbow

Lateral epicondylitis of the elbow, more commonly known as tennis elbow, was first described in the late 19th century by Runge[1] as a consequence of the growing popularity of lawn tennis. As equipment and training methods improved, lateral epicondylitis became less associated with tennis and now only 5% of all cases are due to racket sports.[2] The condition is currently more commonly seen in manual workers whose tasks involve repetitive movement at the wrist and elbow, including supination and extension of the wrist.[3] The community prevalence of tennis elbow is 1-3% and it causes significant morbidity, mainly through lateral elbow pain and weakness of extension at the wrist.[4] It can occur at any age, but has a peak incidence between 35 and 55 years, with an even gender distribution.[5]

Various theories have been proposed regarding the cause of tennis elbow. These have included posterior interosseous nerve entrapment at the elbow,[6,7] tension of the origin of the extensor carpi radialis brevis (ECRB) on the lateral epicondylar periosteum,[1] chondromalacia of the radial head,[8] annular ligament or synovial trapping in the radio-humeral joint[9] and degeneration of the ECRB tendon origin.[10]

Most authors now agree that the structure responsible for symptoms in lateral epicondylitis is the origin of the extensor carpi radialis brevis (ECRB), although in 35-50% of patients, the origin of the extensor digiti communis (EDC) is also thought to contribute.[11] Biomechanically, the ECRB is under most strain during forceful gripping with the wrist flexed, ulnar deviated and the forearm pronated.[12] This is because the ECRB acts as a stabiliser during wrist flexion, contracting eccentrically, but also as flexor of the elbow, contracting concentrically. Its bony attachment at the lateral epicondyle is also smaller than the other wrist extensors, leaving a very small area to dissipate the forces transmitted through the muscle.[6]

One of the most commonly accepted concepts is that the basic lesion of tennis elbow is a degeneration of the origin of the extensor carpi radialis brevis, brought on by repetitive overuse.[13] Macroscopically, the affected portion of the ECRB consists of greyish, immature scar tissue, which appears shiny, friable and oedematous.[10] Histopathologically, the main features of lateral epicondylitis are seen at the enthesis of the ECRB and include angiofibroblastic tendinosis with neovascularisation, disordered collagen alignment and increased mucoid ground substance.[3,10,14] These features are consistent with tendinopathies at other sites and have been speculated to indicate a pattern of repeated micro-injury and unsuccessful attempts at healing.[15,16] It has been proposed that the healing is unsuccessful due to the poor vascularity of the tendon origin, as well as the normal anatomical absence of periosteal lining over the epicondyles.[11,17] While the histopathology of tennis elbow appears consistent across different studies, its severity has not correlated well with surgical outcome.[15] The condition has also been termed lateral epicondylosis of the elbow, as histopathologically, few inflammatory cells have been observed beyond the acute phase.[18]

Clinically, tennis elbow usually presents insidiously with point tenderness over the lateral epicondyle, with pain frequently radiating into the proximal forearm. The symptoms can usually be reproduced with resisted wrist extension, while the elbow is extended;[1] or with resisted extension of the middle finger at the metacarpophalangeal joint, while the elbow is extended and forearm pronated (Maudsley's test).[19] A very specific test is the back of the chair pick up test, which involves gripping and lifting an object (such as the back rest of a chair), with the wrist flexed and ulnar deviated, the forearm pronated and the elbow flexed.[12,20] Grip strength has also often been found to be decreased on the affected side.[21,22]

Imaging is usually not required for diagnosis, but when performed, plain radiographs occasionally show calcifications within the extensor mechanism origin[10] and ultrasound often shows focal hypoechoic areas, intrasubstance microtears or thickening of the common extensor origin.[23,24] Although MRI is not commonly used for the imaging of lateral epicondylitis, the usual findings are oedema and thickening of the extensor origin in 90% of symptomatic patients.[25]

2. Non Surgical Management

In the majority of cases, acute lateral epicondylitis responds well to activity modification, with a wait and see approach successful in 83% of cases at 12 months.[26] Although lateral epicondylitis is considered a non-inflammatory condition, short term non-steroidal anti-inflammatory medications may help relieve the pain and inflammation in the surrounding tissues in the acute phase.[11,27] Those patients that do not respond to relative rest have been offered various other modalities to help with their recovery, however, only a few of these have been studied to support their efficacy.

A rehabilitation program is one of the proven mainstays of tennis elbow treatment.[28,29] The aim of rehabilitation is to load the ECRB both concentrically and eccentrically,[30] a period of at least three months required to form structurally and biomechanically mature collagen.[31] It is speculated that the strengthening program allows the tendon fibres to realign, re-vascularise and promote an increase in the collagen content and cross-sectional area.[32] Stretching is normally considered a part of the rehabilitation and in addition to maintaining a normal range of motion in the joints, it is thought to enhance the longitudinal alignment of collagen fibers in the healing tissue.[33]

A recent placebo controlled study has shown that another effective treatment modality is glyceryl trinitrate (GTN) patches, applied over the affected elbow. These are in much lower concentration than those required for cardiac problems and are thought to work by supplying nitric oxide to the healing tissue. Nitric oxide dilates blood vessels locally, hence increasing blood flow and promoting healing at the site. The improvement in patients' symptoms with these patches was 20% more than with placebo at 6 months[34] and the GTN patches have also been successfully applied to other degenerative tendinopathies.

Tennis elbow bracing is also a popular option, however, strong evidence for its usefulness is lacking.[35] While some authors think bracing may work by aiding proprioception around the elbow and hence correcting any biomechanical stresses,[36] most believe that compression of the extensor carpi radialis brevis distal

to the affected portion unloads the enthesis and allows it to heal.[37-39] Unfortunately, biomechanical research suggests that in order to achieve significant unloading at the enthesis, the pressure developed at the forearm would be sufficient to occlude venous return. Thus it would appear that bracing offers at best a 13-15% reduction in the forces at the lateral epicondyle, before circulation is affected.[40]

Corticosteroid injection into the affected area has been a common treatment for tennis elbow for many years, though histopathological studies confirm there is minimal inflammatory component to tennis elbow beyond the first few weeks.[16] Recent studies have confirmed that patients who have had a steroid injection for lateral epicondylitis have a reduction in symptoms at 6 weeks. However, they may have worse outcomes at six to twelve months compared to those who have had rehabilitation or physiotherapy only.[29,41]

Recently, studies have been performed evaluating botulinum toxin as a possible treatment for lateral epicondylitis. The aim is to relax the ECRB muscle for the duration of the toxin effect, allowing the muscle time to repair. Results have thus far been mixed, with some studies showing lower pain scores compared to placebo at 12 weeks,[42] while other studies have shown no difference.[43] Neither study has shown any difference in grip strength, however some patients reported mild paresis of the fingers and weakness of wrist and finger extension, with symptoms persisting for up to 12 weeks.

Of interest in the last few years have been studies looking at the use of prolotherapy in the treatment of tennis elbow. Prolotherapy involves injecting an irritant around the affected area and is thought to stimulate an inflammatory response and, subsequently, a healing process. In support of this, *in vitro* studies on human renal fibroblasts have shown significant up-regulation of connective tissue growth factors after exposure to hyperosmolar glucose, compared to an inactive medium.[44,45] Prolotherapy has initially been used more for lax ligaments and joint pain, but a recent blinded, randomised, placebo controlled trial has shown a decrease in pain and increase in grip strength at 16 weeks in patients whose tennis elbow was injected with dextrose injections, versus normal saline.[46]

Similarly, research has been conducted into injected autologous growth factors, either as autologous whole blood, or platelet rich plasma (PRP). The theory is that the body's natural healing response will be stimulated by injecting the patient's own growth factors into areas of hypovascular degenerative tendinopathy. Platelets are considered to be a more concentrated source of growth factors than whole blood, hence platelet rich plasma has been gaining in popularity for injection therapy. Although no placebo controlled trials have been done, recent studies compared the outcome of PRP injection with corticosteroid injection, with more than 75% of patients improving over 6 months after PRP injection and maintaining the improvement at 2 year follow up, compared with 48% after steroid injection.[47,48] A smaller study compared PRP injection with bupivacaine and found a 60% improvement in pain scores in the PRP group at 8 weeks, compared to only 16% improvement in the bupivacaine group.[49] A review of whole autologous blood injections, however, has failed to show any significant improvement in outcomes over control groups.[50]

3. Surgical Management

Lateral epicondylitis generally responds well to non-surgical treatment, but there are recalcitrant cases, with 4-11% of patients requiring surgery.[51] There are many theories about the causes of tennis elbow, and many surgical techniques described for its management. They can be broadly grouped into four categories – (1) extensor origin release, (2) nerve releases, (3) radio-humeral joint debridement and (4) excision/debridement of a defect in the extensor carpi radialis brevis.

In the 1970s and 1980s several surgeons proposed that the symptoms of tennis elbow were caused by an imbalance between the tension in the common extensor origin at the lateral epicondyle, and its ability to resist the tension.[1,12] Many alternatives have been trialled to release this tension, including complete detachment of the extensor origin[52-55] and extensor fasciotomy.[56] By detaching the common origin and letting it heal in a shortened position, some authors found

over 75% of patients had minimal or no pain at one year post-operatively, with minimal complications. Others felt that a better way to address the increased tension was by either lengthening the extensor carpi radialis brevis tendon[1] or by reconstructing the common extensor tendon.[12] Again, both of these approaches described a success rate in excess of 75% at one year after surgery. One study evaluated whether any benefit could be gained by drilling the lateral epicondyle after an extensor release, aiming to stimulate bleeding and the healing response, but found no significant differences between the groups.[57]

A less popular approach to the management of tennis elbow dealt with the suggestion that entrapment of the posterior interosseous nerve was responsible for the symptoms. Different authors attempted releases of the nerve at the epicondyle,[58] some going as far as complete sensory denervation of the lateral epicondyle.[59] The reported success for this group of procedures was also in excess of 80%, although there have been suggestions that releasing the nerve invariably also released some of the extensor mechanism. Leppilahti compared the release of the posterior interosseous nerve with lengthening of the extensor carpi radialis brevis, but the success rate in both groups was below 50%.[60]

The third group of surgeons believe that symptoms of tennis elbow are caused by the radio-humeral joint, including irritation of the orbicular (annular) ligament,[61] inflammation of the synovium,[9] radiocapitellar capsule degeneration[62] or radial head chondromalacia.[8] Their treatment favours the intra-articular debridement of these structures and also claims success rates of over 85%. This approach has been disputed by other authors, who routinely inspect the radio-humeral joint as part of their debridement of the extensor mechanism. In their practice, they have only observed intra-articular pathology in 5% of patients with long-standing tennis elbow.[11]

The procedure that addresses the overuse tendinopathy of the extensor carpi radialis brevis with degeneration of its origin was initially described by Coonrad,[14] but later refined and popularised by Nirschl and Pettrone.[10] During their operation, the origin of the ECRB is exposed, the degenerated portion of ECRB excised and any defect sutured. The initial study reported a return to full

activity in over 85% of patients and further modifications have improved on these results. The operation is now routinely performed faster and through a mini-incision.[11] A study in which the debrided ECRB was attached back to the epicondyle with a suture anchor reported good results, although no comparison was made with the original procedure.[63] Drilling or decorticating the lateral condyle to promote the natural healing process was described in the original paper as a key component of the procedure. However, a recent randomised, double blinded study has shown that drilling offers no benefit, rather it increases the pain, stiffness and wound bleeding post-operatively.[64]

Because of the varying nature of the different types of surgery, various complications have been described. One of the most common problems associated with the extensor mechanism release has been excessive debridement and subsequent lateral elbow instability.[51] The nerve releases have the potential for persistent paraesthesia and neuroma of the posterior interosseous nerve,[65] and all procedures for lateral epicondylitis carry the risk of infection, bleeding and reactive bone formation.[66]

In an attempt to reduce the morbidity associated with tennis elbow surgery, minimally invasive versions of the described procedures have been developed. Percutaneous releases are being utilised with good effect,[67,68] as are arthroscopic releases and debridement,[62,69-71] or even a radiofrequency microtenotomy.[72] The success rate with these minimally invasive operations has been reported as over 90% improvement in patient outcomes, similar to the open surgeries. Dunkow compared the open Nirschl procedure to a percutaneous tenotomy in a prospective study and found that even though both groups had significant improvements in all parameters at 12 months post-operatively, patients in the percutaneous group were able to return to work earlier and were generally more satisfied with their outcomes.[73] A review comparing open releases to arthroscopic procedures found no significant differences in outcomes between groups at six months post-operatively, but again, patients with arthroscopic procedures were able to return to work earlier.[74] A study by Szabo et al. retrospectively compared the outcomes of the Nirschl open procedure, percutaneous tenotomy and arthroscopic release over

two years, all performed by the same surgeon. They found significant improvements within all three groups, but no differences in outcomes between any of the groups at any single time point.[75]

With the number of surgical options available, each surgeon will believe the procedure they are most familiar with is the "best". Indeed, with most studies reporting patient satisfaction rates in excess of 80%,[52] some authors have suggested surgical management at an earlier stage, rather than persisting with conservative management.[76] Despite the various surgical methods available for the management of chronic tennis elbow, the procedure described by Nirschl and Pettrone remains the "gold standard". It is one of the most common surgeries performed therapeutically for, and it best addresses the currently agreed pathology of, chronic lateral epicondylitis. Much of our understanding of its efficacy, however, is only at evidence level III and level IV and as with many surgical procedures, level II and level I evidence is lacking. Thus whether the excision of the degenerate part of the ECRB is necessary for the treatment of tennis elbow remains to be confirmed.

Hypothesis

Excision of the degenerative portion of the extensor carpi radialis brevis is a key/essential component in the surgical management of chronic tennis elbow.

Aim

This randomised, double-blinded, placebo controlled pilot study aims to determine whether an open debridement of the extensor carpi radialis brevis origin (as described by Nirschl and Pettrone) improves the outcomes of pain, strength and function in patients with symptoms of lateral epicondylitis, over and above that of placebo surgery.

Methods

4.1 Study Design

The study is a prospective, randomised, double blinded, placebo controlled clinical trial.

4.2 Ethics Approval

Ethics approval for the tennis elbow surgery trial was obtained through the South Eastern Sydney Area Health Service Research Ethics Committee (Southern Section) prior to patient recruitment (approval number 04/117 Murrell).

4.3 Sample Size and Power Analysis

A pre-study power analysis, with r=0.8, determined that to have a 90% chance of finding a 40% difference between the standard and sham surgery groups in the frequency of elbow pain with activity at 6 months post surgery (the primary outcome measure), the trial would require 80 symptomatic patients to be recruited and treated. The frequency of elbow pain with activity was chosen as it is a primary feature of chronic lateral epicondylitis.[11]

4.4 Standard Surgery and Sham Surgery Selection

Although various surgical options are available for the treatment of lateral epicondylitis, the procedure as described by Nirschl and Pettrone was deemed to be the most appropriate as the standard surgery. This technique has been used for

more than 30 years with excellent follow-up,[77] was the most quoted in scientific and surgical literature and is one of the most commonly performed operations for chronic lateral epicondylitis.[30,78]

The cause of lateral epicondylitis is still under debate, and correspondingly, many surgical approaches have been proposed, including division of the orbicular ligament,[9] radial nerve releases,[58] tendon lengthening[1] and complete tendon detachment.[52,55] Nirschl and Pettrone's theory is that lateral epicondylitis symptoms are caused by a degenerative region within the origin of the extensor carpi radialis brevis (ECRB) and they have confirmed this hypothesis with histopathological studies.[11]

Their operation aims to address this pathology by making a small incision over the lateral epicondyle, identifying the affected portion of the ECRB, excising it and suturing the resulting longitudinal defect. The skin is then closed over the wound and the patient begins rehabilitation. In the original paper, the incision made over the lateral epicondyle was described as 7.6cm long and to improve the blood supply, Nirschl and Pettrone decorticated a small area of the lateral condyle with either an osteotome or multiple small drill holes.[10] Since the original description, Nirschl has further refined the technique by recommending a smaller, 2.5cm long incision.[11] Also, Khashaba's work has shown that the decortication as originally described causes more pain and complications post-operatively.[64] For this reason, we chose not to decorticate the lateral condyle in our study.

We have used Nirschl and Pettrone's technique through the smaller incision and without decortication of the condyle as our control study. The sham surgery involved the same incision, non-traumatic examination of tissues and skin closure.

4.5 Inclusion and Exclusion Criteria

Inclusion criteria for the clinical trial required that the patients are adult (over 18 years of age), with a clinical diagnosis of lateral epicondylitis, still

persisting after at least 6 months of medical therapy. Medical therapy was defined as a course of physiotherapy or rehabilitation, massage, acupuncture, non-steroidal anti-inflammatories, splinting/bracing or any elbow injections. Patients were required to have tried at least two of the modalities to qualify for the trial.

Patients were excluded from the trial if:

1. Symptoms appeared to be referred from another area
2. They had previous surgery to the affected elbow
3. They had a corticosteroid injection into the affected elbow in the last 3 months
4. They had a previous dislocation of the affected elbow
5. There was inadequate skin coverage over the affected elbow
6. There were sensory or motor changes distal to the affected elbow
7. The patient was pregnant
8. The patient was unwilling or unable to attend the required follow ups
9. The patient was unwilling or unable to enter either treatment branch

4.6 Patient recruitment

Patients with symptomatic elbows were recruited through advertising in local newspapers, mail-outs to general practitioners in the area and direct promotion at conferences and presentations. Potential patients had the opportunity to either speak to the author on the telephone or book an appointment directly at the surgeon's rooms.

During the initial interview, patients were screened for eligibility criteria and provided with background information about the study. This information was provided both verbally and as a printed handout (Appendix 1). If the patient had any further questions, these were answered. Once the patients had met all the inclusion criteria and were willing to participate in the trial, the author examined them to confirm clinical signs and upon confirmation, enrolled them in the study.

If a patient failed to meet the required criteria and/or was unable to participate in the trial, the author provided them with the best practice advice and management, with follow up referral to their GP.

4.7 Information and Consent

Further to the information provided verbally and in handout form, eligible patients were then seen by the surgeon (GM) and provided with a more detailed explanation of the operation and the surgery process (admission, anaesthesia, recovery etc.). Potential complications of surgery were explained and discussed, along with the follow up protocol, including the number of post-operative visits required for follow up. The adjunctive rehabilitation protocol (same for both groups) was explained to each patient. A final opportunity was provided for any further questions or problems to be addressed.

Once the patients were satisfied, they were provided with a standard consent form (Appendix 2), that informed that the consent form did not constitute a legal obligation to complete the trial. They were then asked to sign as an indication of informed consent to enrol in the clinical trial. The patients' signature was witnessed and countersigned.

4.8 Randomisation

Patient randomisation was done in two stages. Initially, a computer generated code allocated a number to one of the two surgical protocols. This allocation matrix was then securely stored and not accessed until the conclusion of the trial. After the computer allocation, randomisation slips were printed and sealed in unmarked envelopes. These were randomly chosen on the day of the surgery and the surgeon had the envelope opened by an assistant in theatres after the patient was sedated and the ECRB exposed. The patient's name was then

written on the randomisation slip, the slip placed back in the envelope and the envelope stored in the Orthopaedic Research Institute rooms until the conclusion of the trial.

4.9 Outcome Measures

An accurate assessment of each patient's symptoms can be difficult, so it was decided to use a questionnaire containing a series of verbal descriptor pain scales. These have been validated as a reliable and accurate measure of clinical change in musculoskeletal conditions.[79,80] The symptoms rated included the frequency of pain with activity and rest, the severity of pain with activity and rest, the frequency of extreme pain, the severity of pain during sleep, as well as difficulty with picking up objects and twisting motions. To gain an insight into the functional effect lateral epicondylitis had on their lives, the patients were also asked to rate the level of activity at work, the level of sport they played, if any, and an overall impression of their elbow stiffness and function. The questions are attached as Appendix 3.

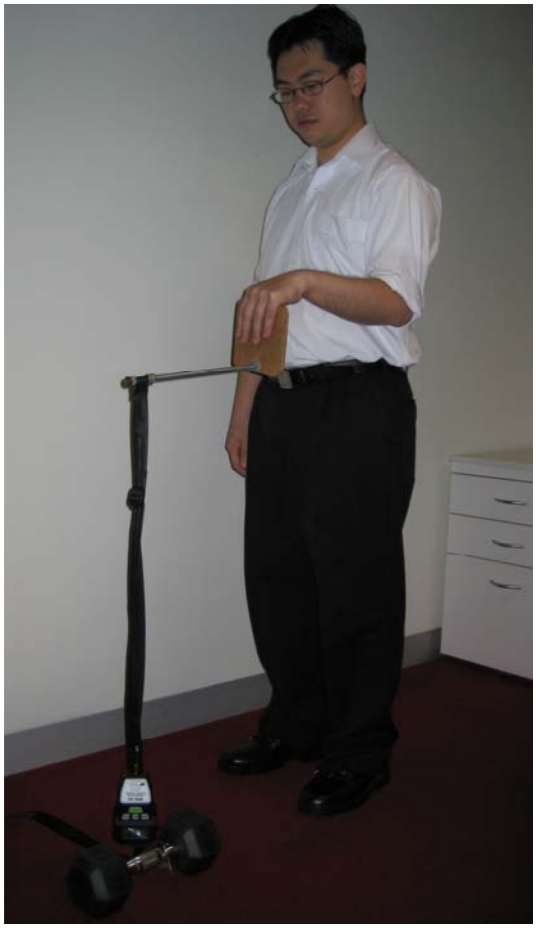

Figure 1. Orthopaedic Research Institute - Tennis Elbow Testing System (ORI-TETS)

The clinical tests chosen to assess the patients' signs were point tenderness over the lateral epicondyle, active range of motion, ORI-TETS maximal strength and maximal grip strength. As tenderness over the lateral epicondyle is a subjective assessment, a verbal descriptor pain scale was used. Elbow stiffness is

not considered an intrinsic feature of tennis elbow, however some studies have suggested that, infrequently, patients have lost a few degrees of motion post-operatively.[52] To monitor this, an 8 inch 360 degree goniometer (Sportstek, Oakleigh, Australia) was used to measure the patients' active extension, flexion, pronation and supination of the elbow at each visit.

Another clinical test that has been accepted as a suitable measure for extensor carpi radialis brevis (ECRB) function is the chair pick up test.[12] By keeping the wrist in pronation and neutral extension and the elbow at 90 degree of flexion, it dynamically stresses the muscle as it crosses both the wrist and elbow joints. In order to measure the function of the ECRB, the Orthopaedic Research Institute – Tennis Elbow Testing System (ORI-TETS)[20] handle was used with a Mecmesin force gauge (Mecmesin Compact Force Gauge CFG+ 200N, West Sussex, UK) (Fig. 1). The maximal force of wrist extension was used as an outcome measure. The last clinical outcome measure was performed with a hand grip dynamometer (SAEHAN Hydraulic Hand Dynamometer SH5001, Changwon, Korea) (Fig. 2) assessing maximal grip strength, given that forceful gripping is one of the activities that causes patients the most discomfort[81] and is frequently reduced in lateral epicondylitis.[22]


Figure 2. SAEHAN Hand Dynamometer

The frequency of elbow pain during activity at 26 weeks post-surgery was selected as the primary outcome measure, and all the remaining parameters were considered as secondary outcome measures.

5. Trial Protocol

5.1 Pre-operative Procedure

At the initial assessment, patients were asked to complete a background questionnaire, recording their age, gender, occupation, handedness, date of initial problem, any causative injury and any associated workers' compensation claim. Their previous medical treatment was also explored in detail, to make sure they complied with the inclusion criteria (Appendix 4).

After the initial interview and explanation, patients were randomly allocated to either the standard surgery group (as per Nirschl & Pettrone) or to the sham surgery group. This was done in a double blind manner, with the operation details only revealed when the patient was anaesthetised on the operating table.

At the pre-operative visit, patients were required to complete the symptom assessment questionnaire and were then examined by the author. Finally, their epicondyle pain, active range of motion, grip strength and ORI-TETS maximal effort were recorded.

5.2 Operative Procedure

On the day of the surgery, patients were admitted to the National Day Surgery – Sydney (Kogarah, NSW) as day stay patients. After routine admission and anaesthetic pre-operative checks, they were taken to the operating theatre and given intravenous sedation (midazolam, fentanyl and propofol infusion).

The patient's arm was prepped and draped in a standard sterile fashion after local anaesthetic (bupivacaine 0.5% with adrenaline 1 in 200,000) was infiltrated around the lateral epicondyle. An incision approximately 3cm long was made over the lateral epicondyle and the extensor carpi radialis brevis (ECRB) origin was exposed. Once the ECRB origin was visible, the randomisation envelope was opened and the procedure read out to the surgeon.

If the patient was randomised to the Nirschl procedure group, the degenerated portion of the ECRB was identified and excised. Any defect in the ECRB was closed with 2-0 Vicryl sutures and the wound was closed with a running subcuticular Monocryl suture. If the patient was randomised to the sham surgery group, the ECRB was inspected and the skin was closed with Monocryl subcuticular running suture without any further intervention.

Both groups of patients were transferred to the recovery area where a sling was applied to the operated elbow, as well as an ice pack. They were discharged following the routine observation period, with simple analgesia and the post-operative rehabilitation protocol (Appendix 5). The post-operative rehabilitation protocol included initial rest post surgery with appropriate analgesia, ice application, gentle regular stretching and a strengthening rehabilitation program that commenced at 2 weeks post-operatively. The rehabilitation program was reinforced and reviewed at each follow up visit.

5.3 Post-operative procedure

All patients attended a post-operative follow up with the surgeon at 8 days post surgery for review and wound check. No data was collected at this visit and all subsequent follow-ups were with the author.

At the initial pre-operative visit and at all subsequent follow ups, patients were required to complete a symptom assessment questionnaire using a verbal descriptor scale (0-4) to rate the severity or frequency of their symptoms. The patients were asked how often their elbow was painful during activity, painful at rest and extremely painful. They were asked what level their pain was at rest, with activity and during sleep. They were also asked to rate how stiff they felt their elbow was, how much difficulty they had picking up things and with twisting/turning motions. They were then asked to rate their current level of activity at work and the highest level of sport, as well as the overall feel of their elbow (Appendix 3).

Once the symptom questionnaire was completed and checked, a single examiner assessed each patient and recorded the maximal level of pain at the lateral epicondyle using a verbal descriptor scale (0-4). The active range of extension, flexion, pronation and supination at the elbow was then measured with a goniometer. Patients were asked to produce a maximal effort gripping a hand dynamometer (measured in pound.force), with the highest reading out of three attempts recorded. Finally, the maximal peak force using the ORI-TETS (measured in kilogram.force) was recorded, likewise determined from the best of three attempts. The grip strength and ORI-TETS tests were omitted at the 2 week follow up, on account of post-operative pain and healing.

All clinical assessments were repeated pre-operatively and at weeks 2, 6, 12 and 26 with an identical format, except for the two tests at week 2 as described above. Non attendance at any two visits disqualified the patient from the clinical trial.

6. Statistical analysis

The outcome measures were analysed with Sigmaplot 11 (Systat Software Inc. San Jose, USA) software using an intention to treat analysis. The parametric data (active range of motion, grip strength and ORI-TETS maximal force) were analysed using Student's paired t-test for differences over time within each group and the non-parametric data (the remaining measures) were analysed using Wilcoxon sign rank tests to compare for differences over time within each group. The differences between groups were compared using un-paired Student's t-tests for the parametric data and Mann Whitney rank sum tests for the non-parametric data. The level of significance was defined as $p<0.05$. Sigmaplot 11 was also used to calculate the post hoc sample size.

Results

7.1 Demographics

Twenty two patients with a clinical diagnosis of lateral epicondylitis were recruited through newspaper advertisements, doctor mailouts and referrals from other health professionals. There were 15 females and 7 males, with a median age of 51 (range 41 to 77 years) (Table 1.). Two patients were ambidextrous, four were left hand dominant and 16 were right hand dominant. Thirteen patients had an operation on their dominant side, seven on their non dominant side and both ambidextrous patients were operated on their right side. The condition was due to an initiating event or injury in nine patients, five of which involved workers' compensation claims. The average duration of symptoms was four years and eleven months, with a range of 9.5 months to 27 years.

The 22 patients were divided evenly between the two operative groups, with 11 patients in the sham surgery group and 11 patients in the Nirschl surgery group. All patients completed the full 6 month follow up without any complications. There were no significant differences in the patient demographics between the sham and Nirschl surgery groups. All statistical analyses were made on an intention to treat basis.

	Sham	Nirschl
Age (years)	41-77 (median 47, mean 51)	42-66 (median 50, mean 52)
Male	3/11	4/11
Female	8/11	7/11
Injury related	5/11	4/11
Right handed	8/11	9/11
Left handed	3/11	2/11
Dominant side affected	8/11	7/11
Symptom duration (years)	0.8-10.8 (median 2.6)	0.8-26.8 (median 2.4)
Steroid injections	6/11	5/11
Brace	1/11	4/11

Table 1. Demographic data

7.2 Primary Outcome Measure

Both groups experienced a significant improvement in the frequency of their pain with activity at 12 weeks ($p<0.05$) and 26 weeks ($p<0.01$), with the average frequency of pain reducing from always/daily to weekly/monthly in both groups. There was no significant difference in the frequency of pain between the groups at 12 or 26 weeks, however, the placebo group had significantly less frequent pain at two weeks ($p<0.05$), on average rating their frequency just above weekly, while the Nirschl group still rated their frequency as between always and daily (Fig. 3). A post hoc sample size power analysis showed that to see a significant difference between the groups at 26 weeks, 1119 patients would need to be enrolled in each group.

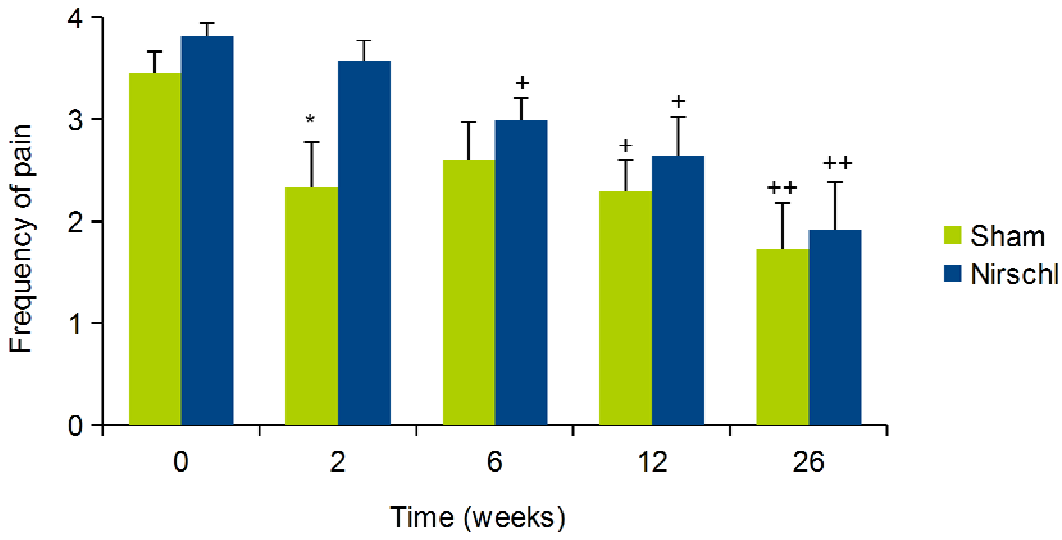

Figure 3. Patient rated frequency of pain with activity. *Mean (SEM), n=11 for each group, * = $p<0.05$ between group comparison using Mann Whitney rank sum tests, + = $p<0.05$, ++ = $p<0.01$ compared with time 0 using Wilcoxon signed rank sum tests.*

7.3 Secondary Outcome Measures

Frequency of pain

The frequency of pain at rest was significantly improved in both groups at 26 weeks post-operatively ($p<0.01$ sham, $p<0.05$ Nirschl), with the patients rating their mean frequency of pain at rest as daily before surgery and monthly at 26 weeks after surgery. No difference was detected between the groups at any time point (Fig. 4).

After surgery, both trial groups showed a significant decrease in the frequency of extreme pain as early as 12 weeks ($p<0.01$), and the improvement persisted at 26 weeks ($p<0.01$ sham, $p<0.05$ Nirschl). The mean patient rated frequency of extreme pain was reduced from daily/weekly to less than monthly over the 26 week period. No significant difference between the two groups was observed (Fig. 5).

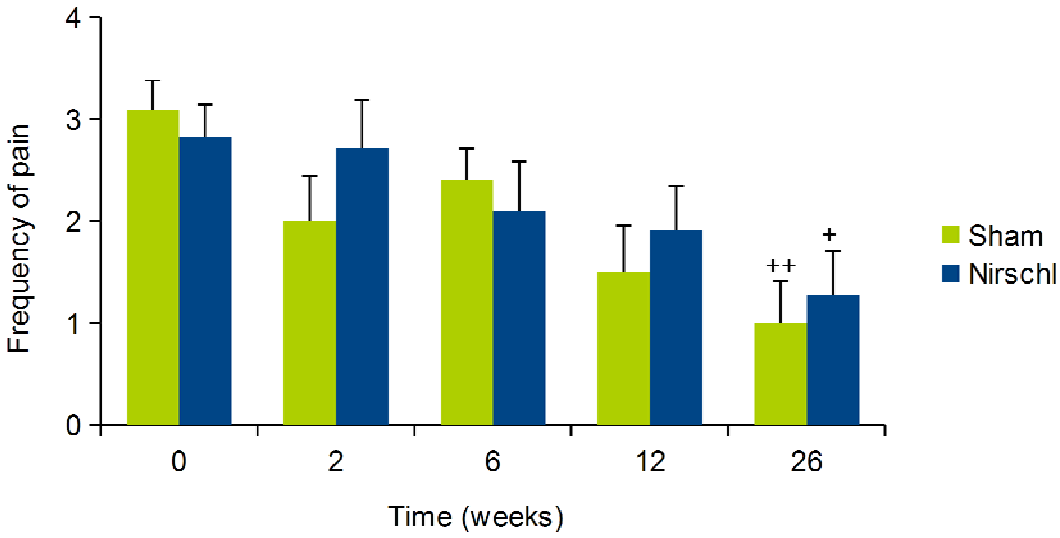

Figure 4. Patient rated frequency of pain at rest. *Mean (SEM), n=11 for each group, + = p<0.05, ++ = p<0.01 compared with time 0 using Wilcoxon signed rank sum tests.*

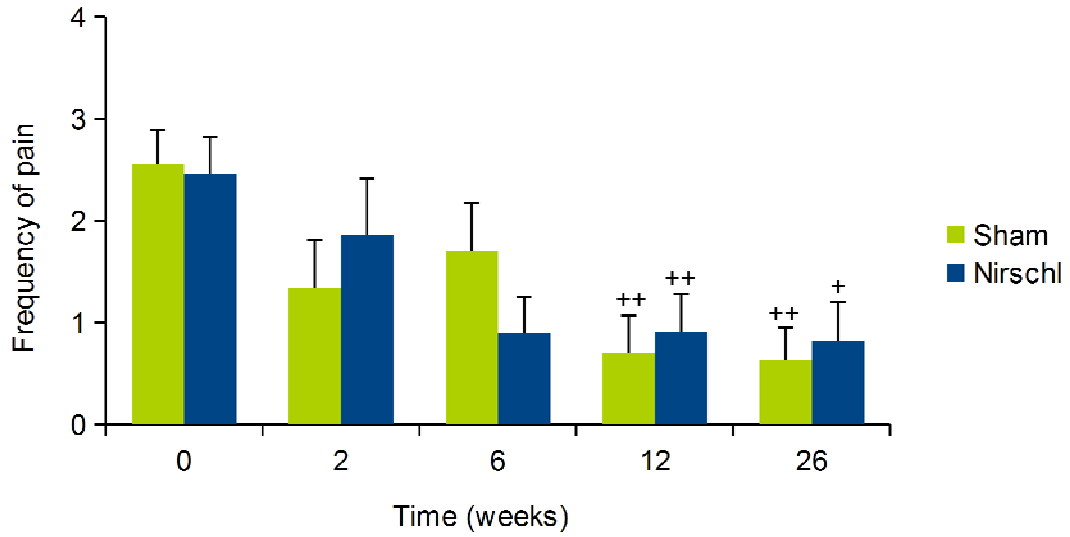

Figure 5. Patient rated frequency of extreme pain. *Mean (SEM), n=11 for each group, + = p<0.05, ++ = p<0.01 compared with time 0 using Wilcoxon signed rank sum tests.*

Severity of pain

Both the sham and Nirschl groups showed significant improvement in their level of pain with activity after their surgery, starting at six weeks ($p<0.05$) and continuing at 12 weeks ($p<0.01$) and 26 weeks ($p<0.001$ sham, $p<0.01$ Nirschl). The average level of pain decreased from severe to mild in the sham group and from severe to mild/moderate in the Nirschl group, over 26 weeks. No significant difference was observed between the groups (Fig. 6).

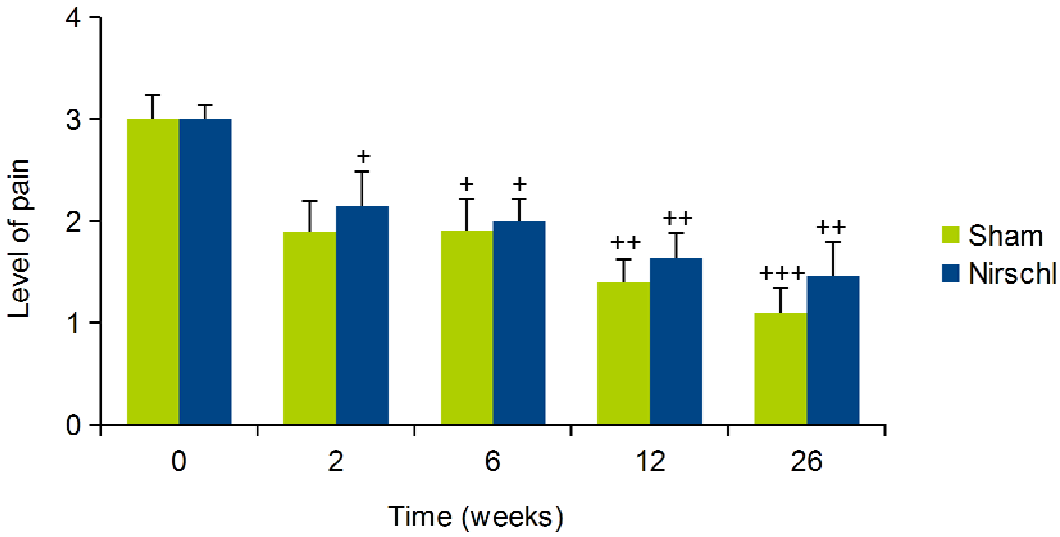

Figure 6. Patient rated level of pain with activity. *Mean (SEM), n=11 for each group, + = p<0.05, ++ = p<0.01, +++ = p<0.001 compared with time 0 using Wilcoxon signed rank sum tests.*

The level of pain at rest decreased in both groups by 26 weeks post-operatively ($p<0.001$ sham, $p<0.05$ Nirschl), with significant improvement observed in the sham group at six weeks ($p<0.05$) and 12 weeks ($p<0.01$) as well. The average improvement over 26 weeks decreased from moderate/severe to mild/none in the sham group, and from just under moderate to mild in the Nirschl group. A between group analysis showed no significant difference (Fig. 7).

The patient rated level of pain during sleep improved significantly in both groups at 12 weeks ($p<0.01$ sham, $p<0.05$ Nirschl) and 26 weeks ($p<0.001$ sham, $p<0.01$ Nirschl) post-surgery. On average, patients in the sham group rated their level of pain during sleep as moderate/severe before surgery and mild/none at 26 weeks. The Nirschl group on average rated their level of night pain as moderate pre-operatively and less than mild at 26 weeks post-operatively. No significant difference was detected between the groups (Fig. 8).

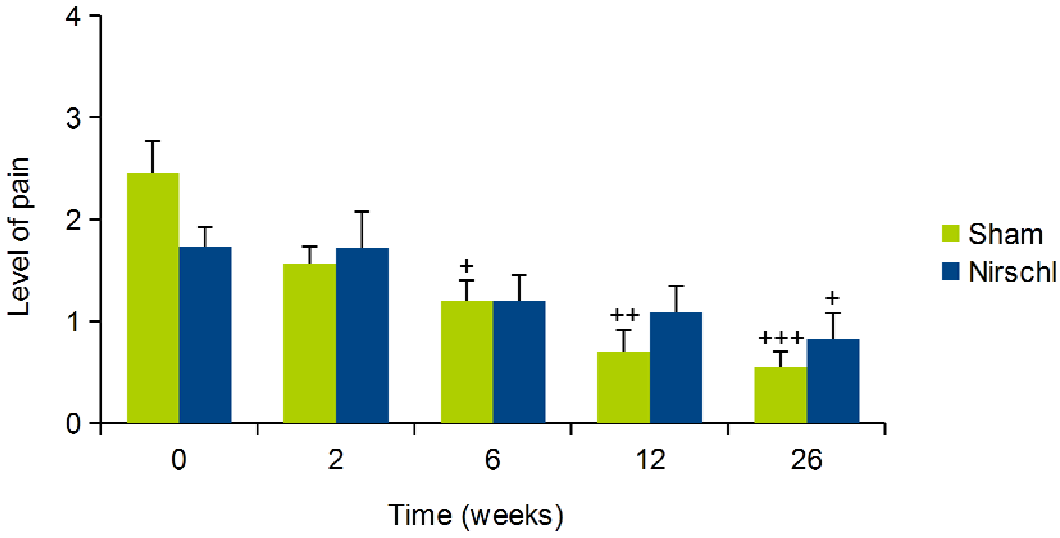

Figure 7. Patient rated level of pain with rest. *Mean (SEM), n=11 for each group, + = p<0.05, ++ = p<0.01, +++ = p<0.001 compared with time 0 using Wilcoxon signed rank sum tests.*

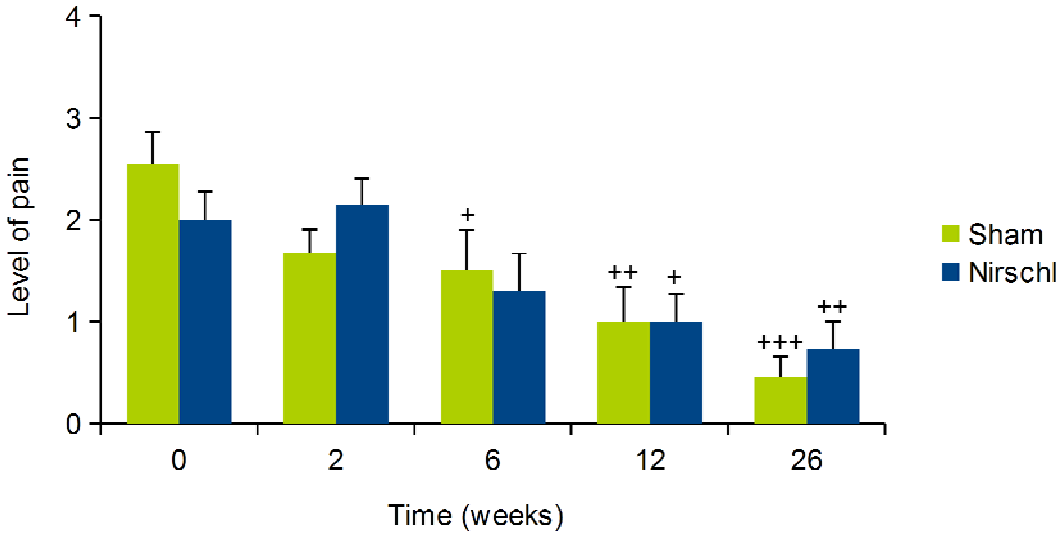

Figure 8. Patient rated level of pain during sleep. *Mean (SEM), n=11 for each group, + = p<0.05, ++ = p<0.01, +++ = p<0.001 compared with time 0 using Wilcoxon signed rank sum tests.*

Functional measures

After surgery, both groups reported less difficulty with picking up objects at 12 weeks ($p<0.01$) and 26 weeks ($p<0.01$ sham, $p<0.05$ Nirschl). On average, both patient groups rated their difficulty with picking up objects as moderate/severe pre-operatively, improving to mild at 26 weeks post-operatively. No significant difference was detected between the groups (Fig. 9).

Patients' difficulty with forearm twisting motions also improved post-operatively, at 12 weeks ($p<0.05$ sham, $p<0.01$ Nirschl) and 26 weeks ($p<0.01$). The average improvement in both groups over 26 weeks was from moderate/severe to mild. There was no difference observed between the groups (Fig. 10).

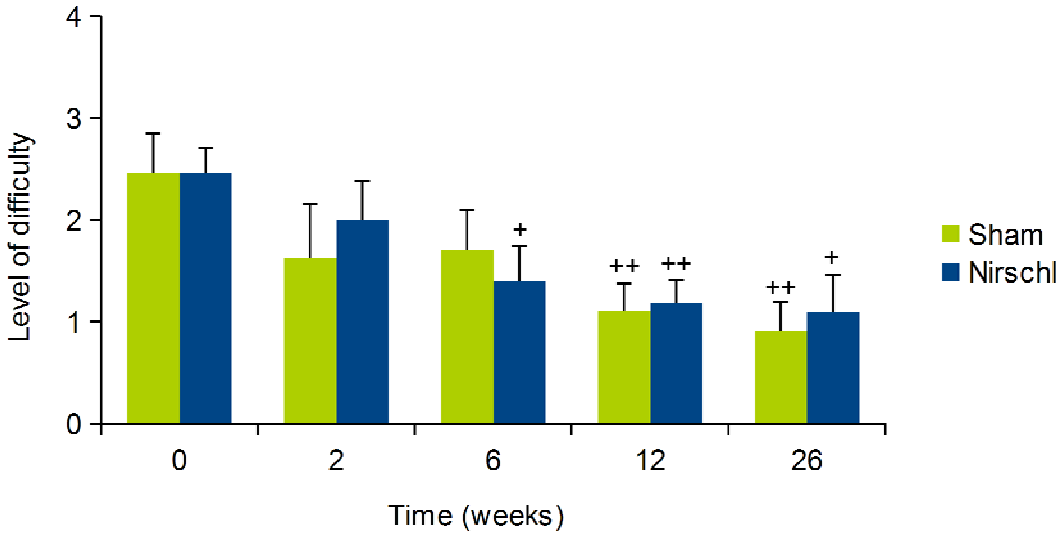

Figure 9. Patient rated difficulty picking up objects. *Mean (SEM), n=11 for each group, + = p<0.05, ++ = p<0.01 compared with time 0 using Wilcoxon signed rank sum tests.*

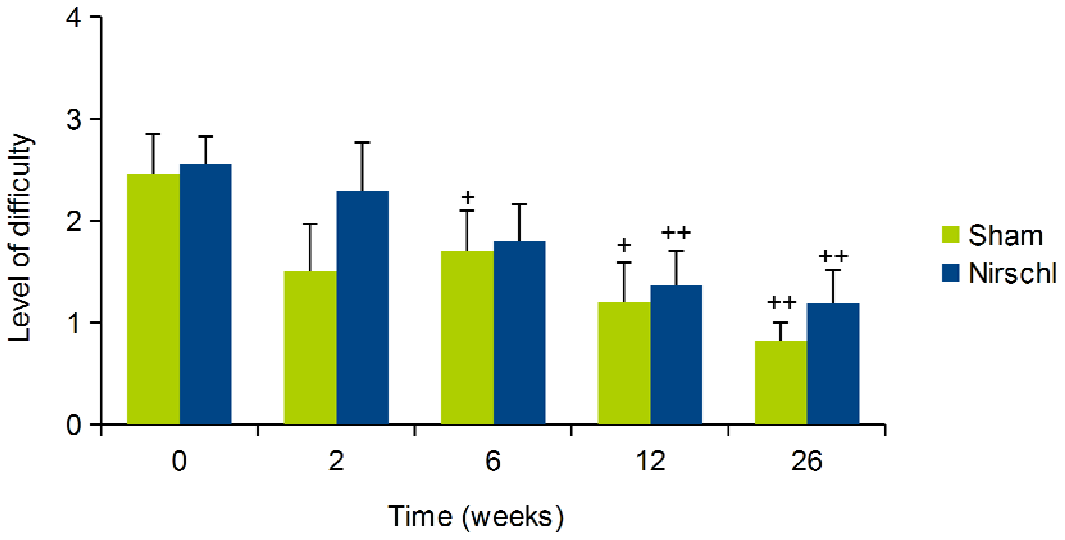

Figure 10. Patient rated difficulty with twisting motions. *Mean (SEM), n=11 for each group, + = p<0.05, ++ = p<0.01 compared with time 0 using Wilcoxon signed rank sum tests.*

Overall ratings

Although a non-significant increase in patient rated stiffness was observed at two and six weeks post-operatively, this reversed and a significant improvement in patient rated elbow stiffness was observed at 26 weeks post-surgery ($p<0.05$ sham, $p<0.01$ Nirschl). Patients rated their elbows mildly to moderately stiff before their operation and improved to less than mildly stiff at 26 weeks post-operatively. No significant difference was observed between the groups at any time point (Fig. 11).

When patients were asked to rate the condition of their elbow overall, both groups on average considered their elbow as poor before surgery, improving to between good and fair by 26 weeks. There was a significant improvement in the overall elbow rating in both groups at 12 weeks ($p<0.05$ sham, $p<0.001$ Nirschl) and at 26 weeks ($p<0.01$) post-operatively. In addition, patients that had the Nirschl procedure reported a significant improvement at two weeks ($p<0.05$) and six weeks ($p<0.01$). Statistical analysis showed no difference between the groups (Fig. 12).

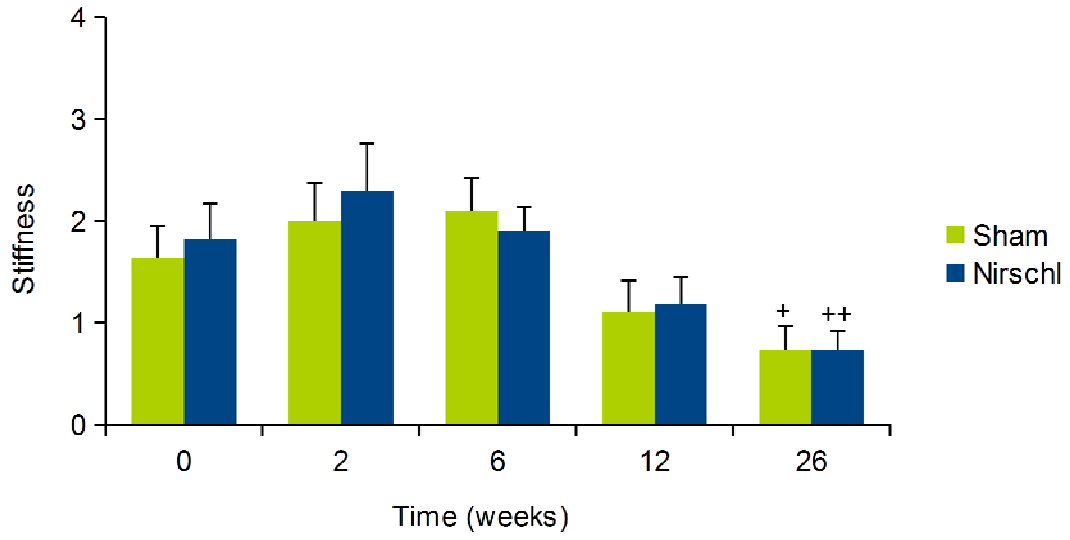

Figure 11. Patient rated elbow stiffness. *Mean (SEM), n=11 for each group, + = p<0.05, ++ = p<0.01 compared with time 0 using Wilcoxon signed rank sum tests.*

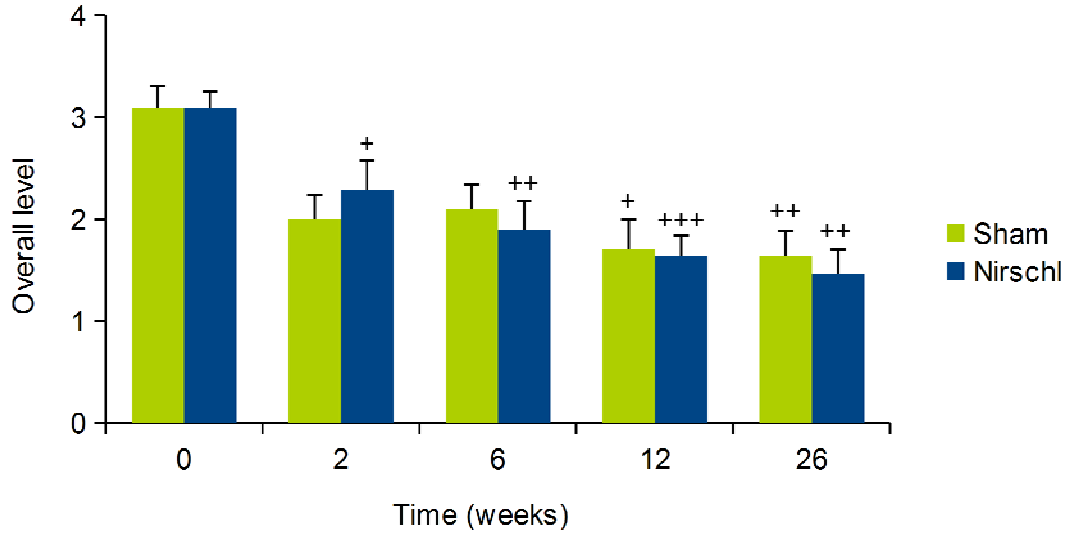

Figure 12. Patient rated overall elbow rating. *Mean (SEM), n=11 for each group, + = p<0.05, ++ = p<0.01, +++ = p<0.001 compared with time 0 using Wilcoxon signed rank sum tests.*

Work and sport

The patients' highest level of manual work decreased at two weeks after their surgery, reaching significance in the sham group ($p<0.05$), however both groups recovered and showed no significant difference compared to their pre-operative highest level of manual work at 26 weeks. There was no significant difference between the groups at any time point (Fig. 13).

After surgery, there was a transient non-significant decrease in the highest level of sport in both groups at two weeks, but both groups returned to pre-operative levels of sport by 12 weeks, with no significant difference detected within either group or between the groups (Fig. 14).

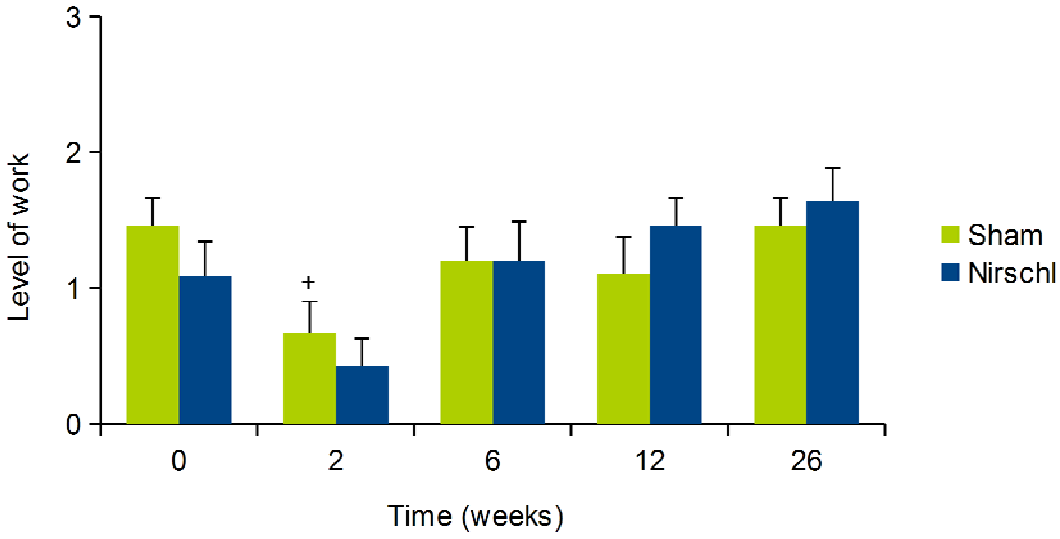

Figure 13. Patient rated highest level of work. *Mean (SEM), n=11 for each group, + = p<0.05 compared with time 0 using Wilcoxon signed rank sum tests.*

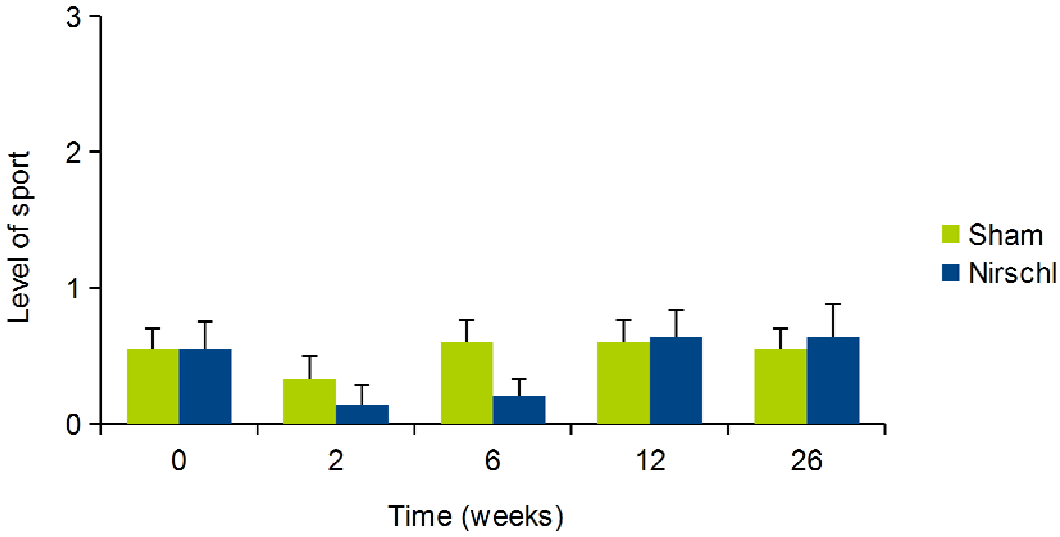

Figure 14. Patient rated highest level of sport. *Mean (SEM), n=11 for each group.*

Epicondyle tenderness

Both groups showed significant improvement in the level of pain on palpating the lateral epicondyle at 12 weeks ($p<0.01$ sham, $p<0.001$ Nirschl) and 26 weeks ($p<0.001$) post-operatively. In addition, the sham group showed an improvement at two weeks ($p<0.05$) and the Nirschl group at six weeks ($p<0.01$). Patients rated their epicondyle pain on average as between moderate to severe before the operations, which improved to less than mild by 26 weeks after their operations. No significant difference was detected between the groups (Fig. 15).

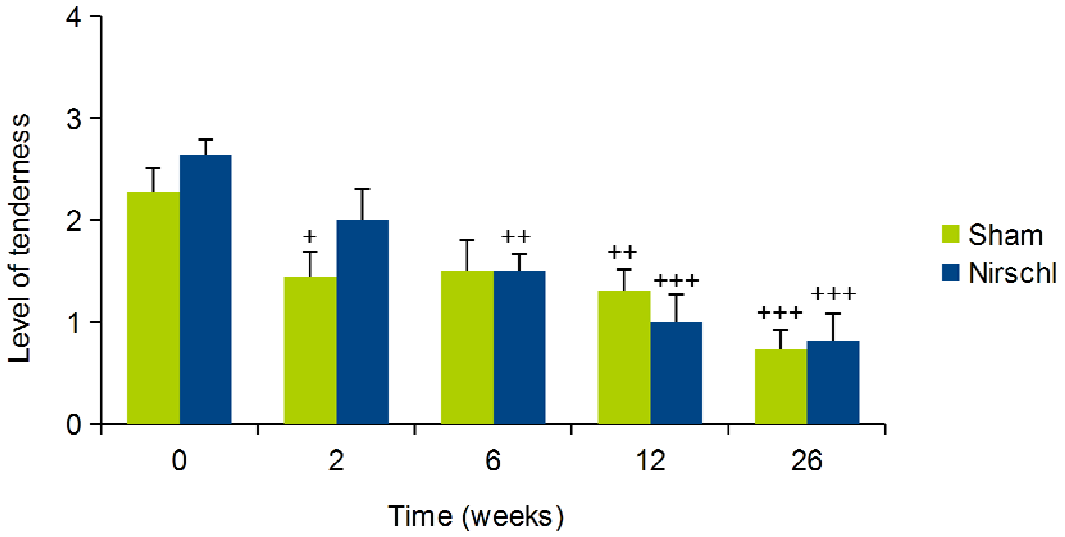

Figure 15. Patient rated lateral epicondyle tenderness on palpation. *Mean (SEM), n=11 for each group, + = p<0.05, ++ = p<0.01, +++ = p<0.001 compared with time 0 using Wilcoxon signed rank sum tests.*

Active range of motion

At two weeks after the operation, both groups showed a significant decrease in their active extension-flexion at the elbow (p<0.05 sham, p<0.01 Nirschl), however, both groups regained their full range of extension-flexion by 26 weeks, with no significant difference compared to their pre-operative range. No difference between the two groups was observed (Fig. 16).

Active pronation-supination of the forearm was significantly improved by week 12 in both groups (p<0.05), but only the sham group maintained the improvement at 26 weeks post-operatively (p<0.05). On average, the sham group improved their active pronation-supination by 13 degrees at 26 weeks, while the Nirschl group improved it by 8 degrees. There was a significant difference between the groups pre-operatively, but no difference was observed at any time point after the surgery (Fig. 17).

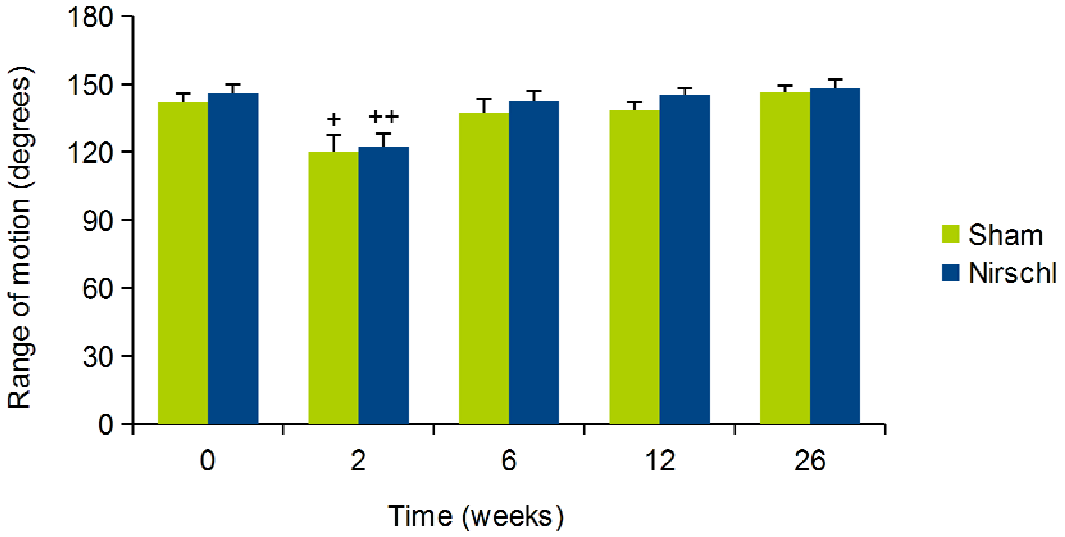

Figure 16. Active range of motion (extension-flexion). *Mean (SEM), n=11 for each group, + = p<0.05, ++ = p<0.01 compared with time 0 using Student's paired t-tests.*

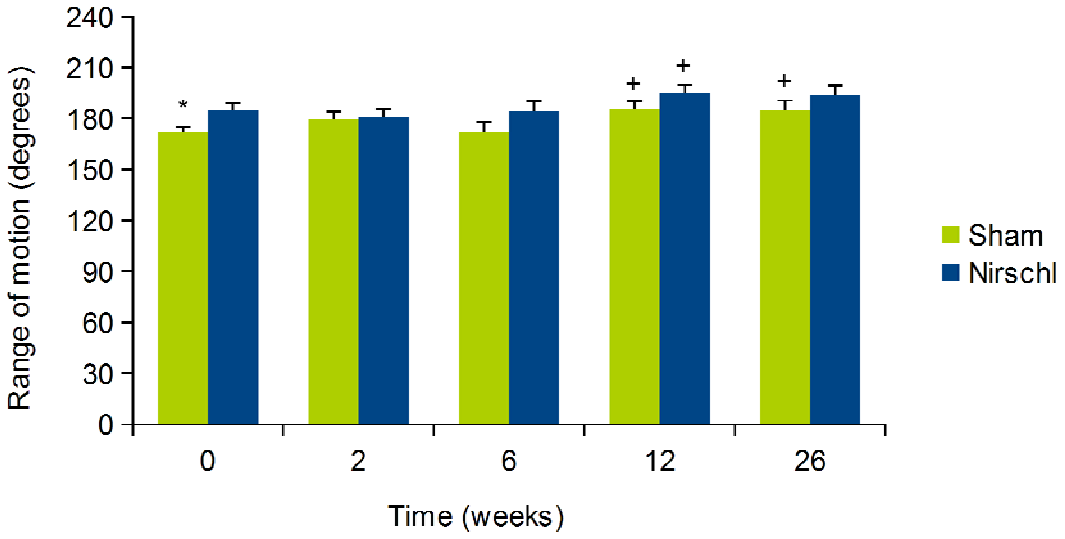

Figure 17. Active range of motion (pronation-supination). *Mean (SEM), n=11 for each group, * = p<0.05 between group comparison using Student's unpaired t-tests, + = p<0.05 compared with time 0 using Student's paired t-tests.*

Strength testing

Both groups showed significant improvement in maximal grip strength at 26 weeks ($p<0.01$ sham, $p<0.05$ Nirschl), with the average increase in maximal grip for the sham group of 17 pounds of force and 15 pounds of force in the Nirschl group by 26 weeks post-operatively. No significant difference was detected between the groups (Fig. 18).

Although there was an improvement in the maximal force using the ORI-TETS in both groups, this was not statistically significant. No difference between the groups was observed at any time point (Fig. 19).

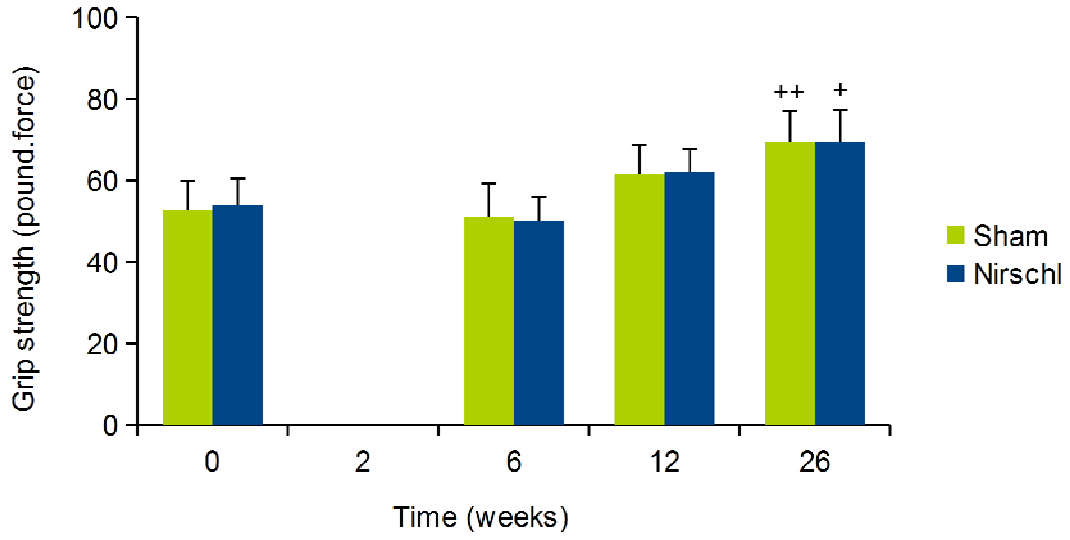

Figure 18. Maximal grip strength. *Mean (SEM), n=11 for each group, + = p<0.05, ++ = p<0.01 compared with time 0 using Student's paired t-tests.*

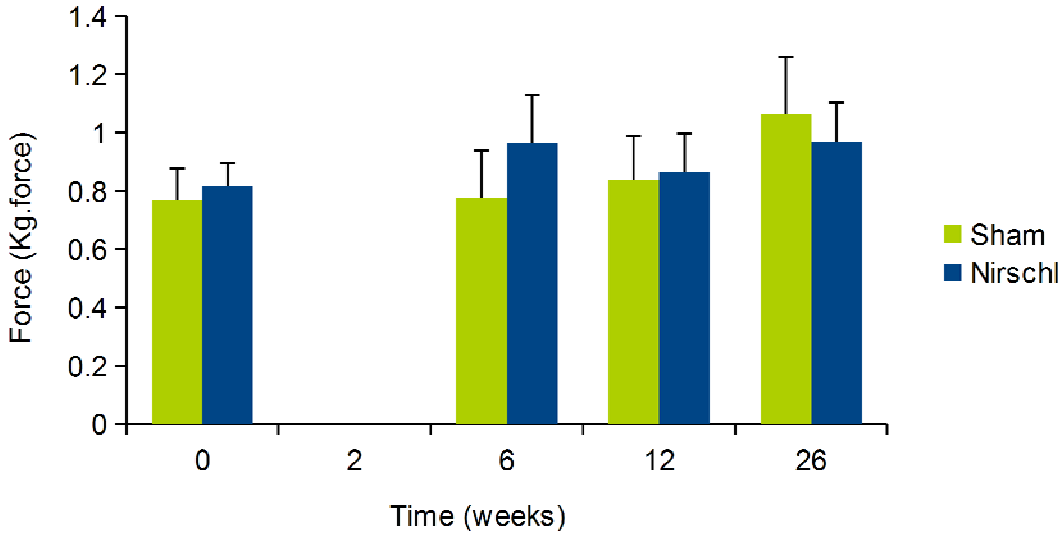

Figure 19. Maximal ORI-TETS force. *Mean (SEM), n=11 for each group.*

7.4 Power analysis

No significant differences were observed in the outcome measures between the surgical and sham groups, except for the frequency of pain with activity at two weeks post-operatively. It is possible that this may be due to the study being underpowered, i.e. due to a type II error. In order to evaluate for this possibility, a post hoc power analysis was performed, using the difference of means at 26 weeks, the average of standard deviations of the sham group and the Nirschl group, a power of 0.8 and alpha of 0.05. The group sizes required to show a statistically significant difference for each outcome measure are summarised in Table 2 below.

Outcome measure	Group size to see difference
Frequency of pain with activity	1119
Frequency of pain at rest	404
Frequency of extreme pain	617
Level of pain at rest	104
Level of pain with activity	115
Level of pain during sleep	135
Elbow stiffness	infinite
Difficulty picking up objects	558
Difficulty with twisting motions	85
Overall elbow	317
Maximum level of work	267
Maximum level of sport	843
Epicondyle tenderness	1100
Extension – flexion at the elbow	646
Pronation – supination at the elbow	76
Hand grip stregth (pound.force)	322686
ORITETS maximal force (kilogram.force)	497

Table 2. Post hoc power analysis for group size requirements.

Discussion

This trial was a prospective, randomised, double blinded, placebo-controlled pilot study which aimed to determine whether the current gold standard surgery for chronic tennis elbow offered any benefits over and above sham surgery. The results show that patients in both groups had significant improvements in all pain measures by 26 weeks post-operatively, including pain with activity, the primary outcome measure of this study. In fact, the results of those who underwent the sham surgery only differed significantly from those repaired by the Nirschl technique by having less frequent pain with activity at 2 weeks post-surgery ($p<0.05$), which might be expected from the less invasive procedure. Both groups demonstrated significantly decreased frequency of pain at rest and extreme pain, and significantly less severe pain with activity, at rest and during sleep, with reduction in elbow stiffness. Both groups had significantly less difficulty with twisting motions and picking up objects, less epicondyle tenderness on palpation, significantly greater grip strength and greater satisfaction with their overall elbow condition. There was no difference in the highest level of work and sport in either group, and no significant change in the patients' active range of motion or maximal ORI-TETS force at 26 weeks post-operatively. No deterioration in any parameters was detected.

These results are consistent with the hypothesis that the placebo surgery produces comparable outcomes to the Nirschl procedure for surgical management of chronic tennis elbow at 26 weeks post-operatively. In fact, the results would indicate that in the immediate post-operative period, the Nirschl procedure shows slower improvement than placebo surgery at a comparable time.

Considering the chronic nature of the patients' lateral epicondylitis, it was reassuring to see a significant improvement in nine of the 17 outcome measures at 12 weeks and in 12 of the 17 outcome measures at 26 weeks post-operatively. Murtagh estimated that the average duration of lateral epicondylitis is between 6 months and 2 years if untreated[82] and more than 80% of patients are markedly better or completely recovered at 12 months with a “wait and see” approach.[26] The

average duration of symptoms in our groups was close to five years at enrolment, with a conservative approach and most medical therapies failing. This makes the significant improvement at both the 12 week and 26 week time point very encouraging. The finding that most outcome measures started to improve after 12 weeks is consistent with animal models, which show it takes over 100 days to synthesise structurally and biomechanically sound collagen after injury.[31] The question remains whether patients should be offered surgery at an earlier stage, with multiple studies suggesting better outcomes are being achieved with shorter duration of symptoms before surgery.[55,83] Indeed, in at least one study, patients that underwent a surgical release for their tennis elbow retrospectively indicated a preference for earlier surgical intervention.[76]

Earlier surgical studies have suggested that a small proportion of patients who undergo surgery for chronic tennis elbow suffer from a measurable reduction in their active range of motion, usually in terminal extension.[11,52] Our results have shown that although there was a significant decrease in the active extension-flexion of the elbow at two weeks post-operatively, both groups subsequently improved and showed no significant difference in their active extension-flexion at 26 weeks, compared to their pre-operative findings. Their pronation-supination had, in fact, significantly improved by week 12, but became non-significant in the Nirschl group by week 26. Also, both groups rated their elbow stiffness as significantly improved at 26 weeks on the symptom questionnaire.

A question many patients had at enrolment was when they would be able to return to their pre-operative levels of sport and work activities. Both groups experienced a temporary decrease in their activity levels at work and sport at two weeks post-operatively, which was in keeping with the post-operative instructions to refrain from manual labour and sport until at least the two week follow up. Depending on the patients' work and chosen sport, they were then given specific advice, for example to avoid racquet sports until week 6 post-operatively. Most patients still avoided sport at week 6, but both groups reached their pre-operative level by week 12. Patients in both groups matched or exceeded their previous level of manual work by 26 weeks post-operatively.

Although the ORI-TETS was developed specifically to test for lateral epicondylitis and has shown good reliability and sensitivity,[20] in this study no significant improvements in maximal ORI-TETS force were detected at any time points. Grip strength testing using a hand dynamometer showed virtually identical values between the two groups at each time point and showed significant improvement in strength at 26 weeks for both groups.

When reviewing Nirschl's original paper, many similarities were noted with the current study. Their patients had the operated elbow immobilised in a slab post-operatively, commenced rehabilitation on day 17 after the operation and racquet sports were gradually restarted at week 6.[10] This is very similar to our protocol, although our patients did not have their elbow immobilised in a cast. Our patients were instructed to rest for two weeks post-operatively, start their home exercise program after their two week review and commence light sport as tolerated from six weeks. In Nirschl's study, patients' generally returned to full power within four months, mirroring the improvement of most outcome measures between 12 and 26 weeks in our groups. Nirschl's patients were instructed to wear a forearm brace during any vigorous activities in the first four months after surgery. Conclusive evidence that elbow bracing adds to the treatment of lateral epicondylitis is still lacking,[35] as such we did not utilise it in our study. In Nirschl's grading system, full return to activity with no pain was rated as excellent and full return to activity with occasional mild pain was rated as good. On the basis of that system, 75 of 88 patients (85%) were rated as either excellent or good, with complete resolution obtained on average at 2.6 months post-operatively. This is difficult to compare directly to our results, however, on average, both our groups were able to return to at least pre-surgery levels of work and sport by week 26, with seven out of eleven (64%) patients in the sham group rating their level of pain with activity as none or mild, and five out of eleven (45%) patients in the Nirschl group rating it as none or mild 26 weeks after their surgery. Fisher exact testing showed that this difference between the two groups was not significant ($p=0.67$).

In a non-randomised prospective study of 63 patients with tennis elbow, Verhaar's group performed a release of the extensor mechanism at the lateral

epicondyle, with a similar peri-operative and post-operative protocol to our study.[52] Their results showed 76% of patients had either no pain or only mild pain at 12 months post-operatively, which compares well with our findings, with all patients in our sham group and eight patients (73%) in the Nirschl group rating their pain at rest as mild or none, at 26 weeks post-operatively. When Verhaar reviewed grip strength of patients at different time points, he found a significant increase in strength only between six weeks and one year, the results plateaued thereafter. Our study also confirms significant increase in grip strength at 26 weeks, but needs longer follow up to determine any further increases.

Another prospective randomised controlled trial compared the Nirschl procedure to a percutaneous tenotomy,[73] following 47 patients over one year. This study used the American Academy of Orthopedic Surgeons Disability of Arm, Shoulder and Hand (DASH) score and both groups were shown to have significantly improved over the course of the study. However, patients in the percutaneous group were able to return to work and sport at two weeks, which was significantly earlier than the Nirschl group, who did so at five weeks. This is consistent with our findings that although Nirschl's procedure is an effective treatment for recalcitrant tennis elbow, it may delay the early post-operative recovery.

Meknas and his colleagues compared Nirschl's open technique with radiofrequency microtenotomy and also found a significant decrease in the microtenotomy patients' pain rating at three weeks post-operatively.[72] In contrast, the three week pain scores were virtually unchanged in the Nirschl group, compared to their pre-operative levels. Both groups achieved significant improvements in pain scores by six weeks and maintained them for the duration of the follow up. In their study, hand grip strength improved in both groups by 12 weeks, but only reached significance in the microtenotomy group. Meknas also reported that the difference in pain scores at three weeks was likely due to the more invasive nature of the Nirschl procedure, in keeping with our findings.

A large randomised, placebo controlled trial investigating the effect of glyceryl trinitrate (GTN) patches on lateral epicondylitis found a significant

improvement in patient rated elbow pain with activity in both the active treatment and placebo groups over 24 weeks.[34] Because the median duration of symptoms in their study was 17 months, and the patient questionnaire and rehabilitation protocol was very similar to our study, direct comparisons can be made. In Paoloni's trial, the placebo group ranked their level of pain pre-operatively as moderate/severe, decreasing to mild/moderate by 24 weeks, compared to the GTN group whose pain levels improved from moderate to mild in the same time. In our study, both groups rated their pain with activity as severe preoperatively, and improved to mild in the sham group and mild/moderate in the Nirschl group. Apart from the placebo patch and the sham cut, the placebo groups in these studies were virtually identical. Considering the significant improvement in patient rated level of pain with activity, this would suggest that the rehabilitation protocol or some other factor(s) associated with participating in a clinical trial may play a large role in the treatment of chronic tennis elbow.

The main limitations of our study were the duration of follow up and the number of patients in the treatment groups. Longer follow up will allow us to determine whether the improvements in symptoms have been maintained, or indeed, improved further. Higher patient numbers would allow for a more accurate statistical analysis and increase the likelihood that the patients were representative of the tennis elbow population in general. Nevertheless, the large number of measures that showed significant improvement between the pre-operative appointment and the 26 week follow up suggest that the null hypothesis is correct, i.e. that the excision of the degenerative portion of the extensor carpi radialis brevis is not an essential component to the management of chronic tennis elbow.

Conclusion

In conclusion, despite the small patient group sizes, significant improvements were seen in both the Nirschl and sham surgery groups in all the major outcome measures, without any patient drop-outs or complications. Patients were able to return to their previous levels of work and sport and the frequency and severity of their pain significantly improved over the course of the study. The sham surgery group compared favourably with the Nirschl surgery group, with no differences detected between the groups at 26 weeks post-operatively. In the two week post-operative period, the sham group demonstrated significantly decreased frequency of pain with activity, compared to the Nirschl group at the same time point. The results of this study suggest that there is no benefit to be gained from the gold standard tennis elbow surgery over placebo surgery in the management of chronic lateral epicondylitis. In fact, the Nirschl procedure may increase the morbidity of the condition in the immediate post-operative period.

Publications/Presentations Arising from Thesis

Kroslak, M., Murrell GAC. *Tennis Elbow Counterforce Bracing.* Techniques in Shoulder and Elbow Surgery. 8(2): 75-79, 2007

Tendinopathy bracing. Presentation at 'New Horizons in Sports Medicine'. Orthopaedic Research Institute, Kogarah, Australia. 20-22 May 2010

Elbow. Presentation at 'What's New, What Works and What Does Not'. Kirk Place, Kogarah, Australia. 14 August 2010

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Appendix 1. Patient information sheet

PREMIER ORTHOPAEDICS
AND
SPORTS MEDICINE

Lateral Epicondylosis (Tennis Elbow) Study

Thank you for participating in this tennis elbow study, conducted at the Orthopaedic Research Institute, St George Hospital, Sydney.

Tennis elbow is a relatively common condition, affecting up to 5% of people during their lifetime, and despite its name, the majority of patients are not tennis players. Tennis elbow is an overuse injury, usually resulting from repetitive, often forceful, twisting and gripping movement at the wrist and elbow.

Over the years, many theories have been proposed as to the exact mechanism of this injury, and even now, it is not completely clear. The most popular theory at the moment proposes that one of the forearm muscles is the main cause of the pain. Because this muscle starts just above the elbow and ends just below the wrist, it crosses both joints and is therefore exposed to stresses from movements at both joints. It is the attachment just above the elbow that is thought to result in the pain and weakness of tennis elbow. As the muscle and its tendon get overused, small tears start appearing and in some cases the body is unable to repair the damage on its own and surgery may be required.

As there are many theories on the cause of tennis elbow, there have been many different suggested surgical solutions. These range from complicated tendon lengthening procedures to simple "nicks" in the tendon through tiny incisions. Again, the best supported surgery at present involves cutting out the damaged part of the tendon, which is usually only a small part of the whole and does not affected movement or strength. Interestingly, all the operations described in the various studies have had success rates reported well over 80%.

We are conducting this trial, because all the operations around the elbow appear to have a high success rate, regardless of which part of the problem they address and because one theory is that any type of operation will increase blood flow to the area and therefore increase healing. Our control will be the operation where a small part of the diseased tendon is cut out and we will compare it to an identical procedure, but without cutting out the tendon. We will then compare any difference in the healing and symptoms.

The surgery is a day-only procedure, carried out under local anaesthetic at the elbow, and short acting sedation. A small, 3cm cut is made on the outside of the elbow and the muscles and tendons of the elbow are examined. If you are randomly allocated to one group, we will cut out the diseased part of the tendon, if you are randomly allocated to the other group, the tendon will be examined, but not cut into. The tissues are then repaired and the skin is closed with a dissolvable, cosmetic stitch.

There are some potential risks associated with this study. Anaesthesia always carries some risk, but you will be fully monitored throughout the procedure by our anaesthetic consultant. Because tissues are being cut, there is a possibility of bleeding, infection and some loss of skin sensation around the incision site. One study found that a few people lost a few degrees of movement at the elbow, but it did not affect the patients functionally. The risks could be compared to having a skin lesion removed.

You will need to wear a sling for a week, although you can and should exercise your wrist and shoulder. Your first review will be at nine days to check the wound and remove the stitches. If everything is going well, we will show you some exercises to do over the next few weeks. You should be able to return to light duties within three weeks and gentle sport within six weeks. Based on previous experience, most people are able to function fully at four to six months after their operation.

We will continue to monitor your progress, with follow up visits at six weeks, then three, six and twelve months. Obviously, if you have any concerns in the meantime, you should contact us earlier.

Appendix 2. Patient consent form

PREMIER ORTHOPAEDICS AND SPORTS MEDICINE

ST GEORGE HOSPITAL AND THE UNIVERSITY OF NEW SOUTH WALES

SUBJECT INFORMATION STATEMENT AND CONSENT FORM

Title of Project: Surgical treatment of tennis elbow trial

You are invited to participate in a study comparing the benefits of surgical treatment of tennis elbow. There are no studies to conclusively show which type of operation may help tennis elbow. Recent studies have shown that "sham" operations have benefited patients as much as the "real" operation. Our study hopes to determine whether the recommended operation for tennis elbow is more useful than a placebo ("sham") operation. You were selected as a possible participant in the study because you have suffered from tennis elbow for at least six months and have not responded to maximal medical treatment.

If you decide to participate, we will offer you an operation on your affected elbow, to be performed at St George Public Hospital. You will have 50% chance of having the operation where we remove the affected part of one of the tendons at the elbow and 50% chance of having the "sham" operation, where we make a small cut over the elbow and then close the skin again. Both operations would be carried out under local anaesthetic. In addition to the local anaesthetic, a "conscious" sedation would be administered, which involves short acting sedatives being administered intravenously, to reduce the discomfort of the procedure. There is a small risk of infection, bleeding and pain with both operations, comparable with having a skin lesion cut out. If you have any problems after the operation, please let us know. You will not be able to do heavy labour or play racquet sports for three weeks. The operation as described in medical literature has a success rate of over 80% of relieving patients' symptoms. However, we cannot and do not guarantee or promise that you will receive any benefits from this study. We will review you at regular intervals after your surgery to test your arm and get you to fill in progress forms.

Any information that is obtained in connection with this study and that can be identified with you will be kept strictly confidential. It will only be disclosed with your permission or except as required by law. If you give us your permission by signing this document, we plan to use this information as the basis for a research thesis at the University of NSW and discuss/publish the results in scientific meetings and literature. In any publications, information will be provided in such a way that you cannot be identified.

Complaints may be directed to the Ethics Secretariat, South Eastern Sydney Area Health Service Research Ethics Committee (Southern Section), St George Hospital, Gray Street, Kogarah 2217, ph: 02 9350 2481, fax: 02 9350 3968.

Your decision whether or not to participate will not prejudice your future relations with Prof Murrell or St George Hospital. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice.

If you have any questions, we would like you to ask us. If you have any further questions later, Professor Murrell will be happy to answer them for you on 02 9350 2827.

You will be given a copy of this form to keep.

Signature of Patient

ST GEORGE HOSPITAL AND THE UNIVERSITY OF NEW SOUTH WALES

SUBJECT INFORMATION STATEMENT AND CONSENT FORM (Continued)

Title of Project: Surgical treatment of tennis elbow trial

You are making a decision whether or not to participate. Your signature indicates that you have decided to participate having read the information provided above.

Signature of patient

Signature of witness

Please PRINT name

Please PRINT name

Date

Nature of witness

Signature of Investigator

Please PRINT name

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the St George Hospital or my medical attendants.

Signature

Date

Please PRINT name

The section for Revocation of Consent should be forwarded to A/Prof Murrell at the Department of Orthopaedics, St George Hospital, Kogarah 2217 NSW.

Appendix 3. Patient symptom questionnaire

ELBOW FORM

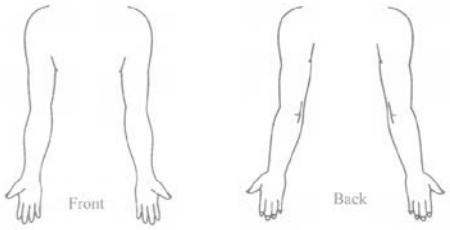
Today's Date

Medical Record Number

Please answer all questions on this side of the form.

1. Which of your elbows is affected? Right ☐ Left ☐

2. Mark X where the pain is and an arrow where it goes



	Always	Daily	Weekly	Monthly	Never
3. *How often* is your elbow					
a. painful during activity?	☐	☐	☐	☐	☐
b. painful at rest?	☐	☐	☐	☐	☐
c. extremely painful?	☐	☐	☐	☐	☐

	Very Severe	Severe	Moderate	Mild	None
4. What is the level of your elbow pain					
a. when you are resting?	☐	☐	☐	☐	☐
b. with activities?	☐	☐	☐	☐	☐
c. when you sleep?	☐	☐	☐	☐	☐

	Very	Quite	Moderately	A Little	Not at all
5. How "stiff" is your elbow?	☐	☐	☐	☐	☐

	Very Severe	Severe	Moderate	Mild	None
6. How much difficulty do you have					
a. picking up things?	☐	☐	☐	☐	☐
b. with twisting/turning motions?	☐	☐	☐	☐	☐

	Very Bad	Poor	Fair	Good	Excellent
7. How is your elbow over-all?	☐	☐	☐	☐	☐

	None	Light Activity	Moderate Activity	Strenuous Labour
8. What is your current level of activity at work?	☐	☐	☐	☐

	None	Hobby Sport	Club Sport	National Sport
9. What is your highest level of sport now?	☐	☐	☐	☐

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For your first visit, please also fill out the reverse side

Appendix 4. Patient initial visit questionnaire

FIRST VISIT ONLY
ADDITIONAL INFORMATION

Date Stamp

Medical Record Number

1. Gender: ☐ Female ☐ Male
2. Age
3. Birth Date - -
4. What is your occupation?
5. Which elbow is affected? ☐ Right ☐ Left ☐ Both
6. Are you right handed, left handed or ambidextrous? ☐ Right ☐ Left ☐ Both
7. Date your elbow problem began - -
8. Was this related to a specific injury? ☐ Yes ☐ No
9. If yes, how did you injure your elbow?
10. Does this injury involve an insurance claim? ☐ Yes ☐ No
11. What was your level of activity at work *before* your elbow problem? ☐ None ☐ Light activity ☐ Moderate activity ☐ Strenuous labour
12. What was your highest exercise level *before* your elbow problem? ☐ None ☐ Hobby sport ☐ Club sport ☐ National sport

13. Have you any allergies? ☐ Yes ☐ No If so, to what? _____

14. Do you take medications regularly? ☐ Yes ☐ No If so, list their names _____

15. Please indicate if you have ever suffered from any of the following:

Heart trouble, chest pain or palpitations	☐	Rheumatoid arthritis	☐
High blood pressure	☐	Indigestion, heart burn or ulcers	☐
Bleeding disorder	☐	Hepatitis or jaundice	☐
Shortness of breath	☐	Kidney trouble	☐
Asthma	☐	Stroke	☐
Thrombosis or clots	☐	Fits or funny turns	☐
Diabetes	☐		

17. Have you had any of these treatments for your elbow?

		How many?	Mark if treatment helped
Physiotherapy	☐		☐
Acupuncture	☐		☐
Injections	☐		☐
Splints, braces	☐		☐
			☐

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Appendix 5. Post-operative rehabilitation protocol

Lateral Epicondylosis

19 February 2008

PROFESSOR GEORGE MURRELL

Lateral Epicondylosis

Rehabilitation Guidelines

National Day Surgery Sydney

The following is a detailed outline of the rehabilitation regime for patients who have had surgery for lateral epicondylosis (tennis elbow) by Prof Murrell.

Day 0 — 2

You will have a sling until the first follow up. You need to keep your sling on at all times in the first 48 hours, except for sleep.

Ice your elbow and continue every 2 hours for 20 minutes regularly for the first 48 hours. You can either use a commercial ice pack or frozen peas.

12 to 16 Hours

Local anaesthetic

The anaesthetic affecting your elbow will begin to wear off, so it is advisable to begin taking the pain killers prescribed for you (eg panadeine forte).

Day 2 — 14

Continue resting your arm in the sling as required. You can gently start moving your elbow, wrist and shoulder as pain permits. NO weight or force is to be used with the operated arm. Keep the dressings intact and try to keep them clean and dry. Continue taking pain killers as required.

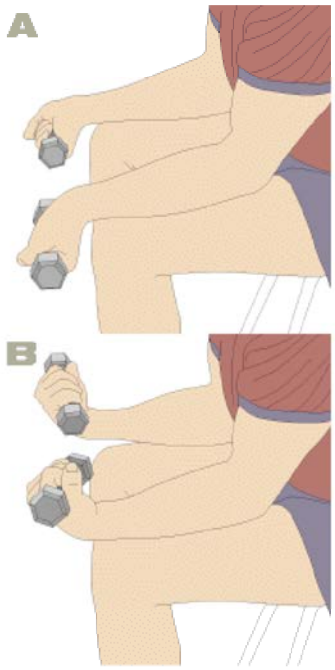
We recommend that you don't drive until your review.

Day 14 — 3 weeks

You will be reviewed in the clinic and your wound checked.

You can now start active range of motion exercises (as detailed below), within your pain limits. Do not use any weight at this stage, although you can use a coin or a pen as a focus. Each of the four exercises needs to be done 10 times, repeated three times a day.

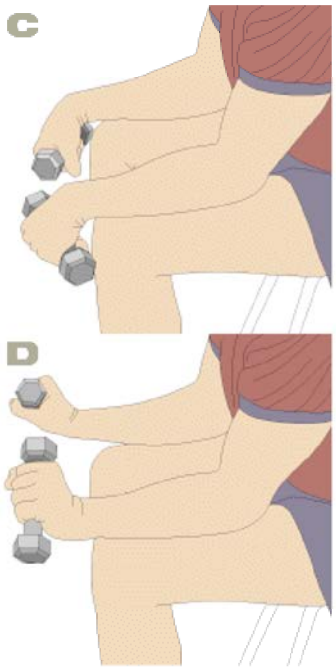
Wrist Curls



Bend your elbow to a right angle and rest your forearm on your thigh or table, with the wrist hanging over the edge. Hold the weight with the palm up and the wrist stretched down.

Lift your wrist and hand up as far as possible, hold at the top for 2 seconds and slowly lower to the starting position.

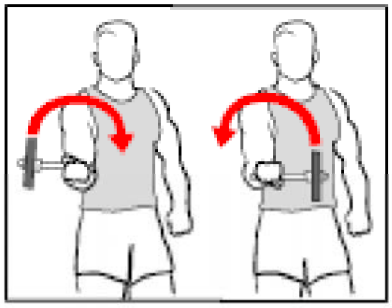
Reverse Wrist Curls



Bend your elbow to a right angle and rest your forearm on your thigh or table, with the wrist hanging over the edge. Hold the weight with the palm down and the wrist stretched down.

Cock your wrist and hand up as far as possible, hold at the top for 2 seconds and slowly lower to the starting position.

Forearm rotation



Sit or stand with the elbow bent to a right angle and your forearm free in the air. Keep your wrist and hand in line with the forearm. Hold the weight with the palm up.

Roll your forearm to reach the full palm down position, hold for 2 seconds and slowly return to the starting position.

Elbow curls

Sit or stand with your elbow by your side. Hold the weight with your palm facing away from your body.

Bend your elbow up as far as it will go, aiming to touch your shoulder. Hold the position for 2 seconds and then slowly return to the starting position.

Week 3 — Week 6

Continue with the exercises, but start using light weights, if pain permits. Start with 0.5kg, using either commercial dumbbells or a can of soft drink / drink bottle. Repeat each exercise ten time, 3x each day, careful not to "push through" the pain. We will review your progress in the clinic at 6 weeks.

Week 6 — Month 3

Continue the exercises with gradually increasing weights, as pain permits. If you reach 2.5kg, do not go any heavier. You can now gradually return to your normal activities.

We will again review your progress in the clinic at 3 months.

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Other milestones

ACTIVITIES	6 Months and 12 Months	6 Months
• *You should be able to do your full activities between 3-6 months*	• *Post operative check up with Dr Kroslak.*	• *Final visit with Prof Murrell.*

Surgeon	SAL	19 February 2008
Nurse	.....	19 February 2008
Carer	.....	19 February 2008