Steroid injection therapy is the best conservative treatment for lateral epicondylitis: a prospective randomised controlled trial

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Introduction
First described as a clinical entity by Runge in 1873 (1), ‘tennis elbow’ also known as lateral epicondylitis or lateral epicondylalgia, are terms used to describe a myriad of symptoms about the lateral aspect of the elbow. Tennis elbow is the most commonly diagnosed elbow condition (2) and has an incidence of four new cases per thousand annually (3). Peak incidence is at 40–50 years of age, and for women of 42–46 years of age the incidence increases to 10% (4,5). The colloquial term ‘tennis elbow’ persists despite the fact that fewer than 10% of all patients with the condition are tennis players (6). Whilst randomised controlled trials (RCTs) comparing conservative treatments for this common condition have been performed previously (7–9), to our knowledge none of the previous studies have combined the modalities of physiotherapy and steroid injection as one of the treatment groups, as we have done in this study. Patients who received steroid injection were statistically significantly better for all outcome measures at follow up. No statistically significant effect of physiotherapy nor interaction between physiotherapy and injection was found. On the basis of the results of this study, the authors advocate steroid injection alone as the first line of treatment for patients presenting with tennis elbow demanding a quick return to daily activities.

Methods
Study design
The study was a prospective RCT of a factorial design performed in the orthopaedic outpatient department. Patients deemed by their general practitioners to have a diagnosis of tennis elbow and referred to the outpatient department for further management were assessed for their suitability for inclusion in the study. Criteria for inclusion in the study were patients with symptoms of tennis elbow who had not had treatment for this complaint in the preceding 6 months, pain reproduced on palpation of the common extensor origin, pain reproduced on resisted extension of the wrist with the elbow extended and age over 18 years. Exclusion criteria are detailed in Table 1.

The trial was explained to the patient by a research physiotherapist who also provided the prospective patients with an information sheet outlining the aims and the proposed conduct of the study. In each case, if the patient wished to participate, written informed consent was obtained confirming this. Subsequent demographic and baseline assessments were then carried out by the research physiotherapist for each patient participating in the

SUMMARY
The relative merits of a watch and wait policy, physiotherapy alone, steroid injection therapy alone, and physiotherapy and steroid injection therapy combined, for the treatment of tennis elbow, were assessed using a prospective randomised controlled trial (RCT) of factorial design. Although RCTs comparing different treatment strategies for tennis elbow have previously been published, to our knowledge none of the previous studies have combined the modalities of physiotherapy and steroid injection as one of the treatment groups, as we have done in this study. Patients who received steroid injection were statistically significantly better for all outcome measures at follow up. No statistically significant effect of physiotherapy nor interaction between physiotherapy and injection was found. On the basis of the results of this study, the authors advocate steroid injection alone as the first line of treatment for patients presenting with tennis elbow demanding a quick return to daily activities.

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### Randomisation schedule

Patients were randomised to one of four treatment groups according to the study number given to the patient at their baseline assessment:

- **Group 1**: no treatment/observation only.
- **Group 2**: injection therapy only.
- **Group 3**: physiotherapy.
- **Group 4**: injection plus physiotherapy.

The numbers were issued in a predetermined random sequence using a block size of 24 and generated by the use of a random numbers table, in such a way that each block consisted of the four treatment groups in equal proportions. The treatment group details were then sealed in a series of opaque numbered envelopes.

### Treatment protocols

Injection therapy consisted of a single injection of 10 mg of triamcinolone acetonide and of 2% lignocaine hydrochloride made up to a volume of 1 ml injected into the symptomatically tender region of the common extensor origin.

Physiotherapy consisted of the exercise programme devised by Pienimaki et al. (10) and comprised progressive slow, repetitive wrist and forearm stretching and muscle conditioning, intensified into four steps.

### Outcome measures utilised

The outcome measures used to assess response to the different treatment regimens are outlined in Table 2. Outcome assessments were performed by the research physiotherapist before randomisation and 7 weeks after the actual start of the treatment. The primary outcome measure, pain free grip strength (PFGS), was measured in kilograms. A baseline hydraulic hand dynamometer (Fabrication Enterprises Inc, Irvington, NY, USA) which had been calibrated by the manufacturer before its use in this study was used. The testing procedure consisted of the patient standing with the shoulder adducted and in a neutral position, the elbow extended and the forearm in neutral. The concept of PFGS was explained to the patient. They were instructed to slowly squeeze the dynamometer and to stop the instant any discomfort was first felt. Three attempts with twenty second intervals in between were recorded, and the mean value in kilograms was calculated.

The secondary outcome measure, extensor weight strength was measured with the patient’s forearm supported on a table, the wrist was taken from full flexion into full extension. The maximum weight lifted using a floor mounted spring weight balance, without pain was recorded in kilograms. The Patient Related Forearm Evaluation Questionnaire (PRFEQ) is a validated tennis elbow disability questionnaire developed by Overend et al. (11). This questionnaire consists of two sections:

1. **(i)** five questions assessing the degree of pain brought on in the affected elbow by various activities of daily living (PRFEQ – Pain).
2. **(ii)** ten questions assessing the actual ability to carry out certain activities of daily living in the arm affected by tennis elbow (PRFEQ – Function).

For each question, a score of zero (no pain) to 10 (worst pain imaginable/unable to do task) is awarded by the patient. The scores are totalled at the end to produce a 'PRFEQ – Total' score, the higher the

### Table 1 Criteria resulting in exclusion from the study

| Exclusion Criteria |
|--------------------|
| 1. Trauma to the affected elbow in the preceding 6 weeks |
| 2. Patients with a past history of elbow instability |
| 3. Previous elbow surgery |
| 4. Bilateral symptoms |
| 5. Any other pathology involving the affected upper limb |
| 6. Coexisting cervical spine pathology |
| 7. Physiotherapy or steroid injection for the presenting condition within the previous 6 months |
| 8. Patients already on oral/systemic steroids |
| 9. Patients with contraindications to injection therapy: |
| (i) Patients with bleeding diatheses or on anticoagulant therapy |
| (ii) Local or systemic infection |
| (iii) Past history of hypersensitivity to local anaesthetics |
| (iv) Poorly controlled diabetics and other immunosuppressed individuals |
| (v) Pregnant or breast feeding patients |
| (vi) Uncooperative patients with an underlying psychiatric diagnosis |
| (vii) Prosthetic elbow joint |

### Table 2 Outcome measures used to assess response to the different treatment regimens

| Outcome Measure |
|-----------------|
| Primary outcome measure: |
| 1. Pain free grip strength (PFGS) |
| Secondary outcome measures: |
| 2. Extensor weight strength |
| 3. Pain score component of the Patient Related Forearm Evaluation Questionnaire (PRFEQ) – see text for details |
| 4. Function score component of the PRFEQ |
| 5. Total score obtained on the PRFEQ |
| 6. Complications of treatment |
score indicating the greater the pain severity and degree of disability.

**Statistical analysis**

Statistical analysis was performed using SPSS (v. 13; LEAD Tech, Chicago, IL, USA). For all of the outcome measures studied, we subtracted baseline values from the values obtained at 7 weeks for each patient. The mean change from baseline for each of the treatment groups at 7-week follow up was calculated for each of the outcome measures studied. The differences in the mean changes between treatment groups at 7-week follow up for all the outcome measures was then analysed using a two-factor analysis of variance (with interaction). The assumptions of equality of variances and normality of errors were checked. A p-value of <0.05 was taken as representing a statistically significant difference for the various primary and secondary outcome measures under consideration.

**Results**

A total of 142 patients were referred to the outpatient department by their general practitioners with a working diagnosis of tennis elbow for further treatment. Of these 14 (10%) declined to take part in the study. Eighty patients (56%) possessed one or more of the exclusion criteria and were therefore not allowed to enter the study. A breakdown of the reasons why patients were excluded from the study is shown in Table 3. As a result of the above exclusions, we were able to successfully recruit 48 patients between May 2003 and February 2005 with history and examination findings consistent with a diagnosis of lateral epicondylitis, who satisfied the eligibility criteria of the study. Twelve patients were randomised to each of the four treatment groups.

Baseline characteristics for patients in each of the four groups are shown in Table 4. The recruitment of patients for the study, their randomisation and the subsequent flow of patients through the study are shown in Figure 1. Comparisons between the results seen at 7 weeks for patients in the four different treatment groups for each of the five outcome measures under study are shown in Table 5.

**Pain free grip strength**

A statistically significant result (p = 0.045) in favour of steroid injection therapy was found at 7-week follow up (improvement of 6.24 points, 95% CI 0.15–12.33). There was no significant effect of physiotherapy (p = 0.73), nor was there an interaction between physiotherapy and injection (p = 0.42) (Table 6).

**PRFEQ – total**

A statistically significant result (p < 0.001) in favour of steroid injection therapy was found at 7-week follow up (improvement of 2.73 points, 95% CI 1.44–4.03). There was no significant effect of physiotherapy (p = 0.99), nor was there an interaction between physiotherapy and injection (p = 0.68).

**PRFEQ – pain**

A statistically significant result (p < 0.001) in favour of steroid injection therapy was found at 7-week follow up (improvement of 2.92 points, 95% CI 1.59–4.25). There was no significant effect of physiotherapy (p = 0.27), nor was there an interaction between physiotherapy and injection (p = 0.65).

**PRFEQ – function**

A statistically significant result (p = 0.001) in favour of steroid injection therapy was found at 7-week follow up (improvement of 2.65 points, 95% CI 1.25–4.05). There was no significant effect of physiotherapy (p = 0.60), nor was there an interaction between physiotherapy and injection (p = 0.73).

**Extensor weight strength**

A statistically significant result (p = 0.001) in favour of steroid injection therapy was found at 7-week follow up (improvement of 1.849 points, 95% CI 0.77–2.93). There was no significant effect of physiotherapy (p = 0.91), nor was there an interaction between physiotherapy and injection (p = 0.20).

**Complications**

There was only one complication noted during the conduct of the study, that of one instance of skin depigmentation and atrophy in a patient in the injection only group.

**Discussion**

We found that those patients who received steroid injection were statistically significantly better for all

Table 3 Breakdown of the primary reason for exclusion of the 80 patients excluded from participation in the study

| Reason for Exclusion | Number (Percentage) |
|----------------------|---------------------|
| 1. Coexisting cervical spine or other upper limb pathology | 35/80 (44%) |
| 2. Incorrect diagnosis | 12/80 (15%) |
| 3. Elbow injection therapy in the preceding six months | 12/80 (15%) |
| 4. Contraindication to injection therapy | 4/80 (5%) |
| 5. Elbow physiotherapy in the preceding six months | 2/80 (2%) |
| 6. Treatment no longer required/did not attend | 15/80 (19%) |
outcome measures at the 7-week follow up. There was no statistically significant effect of physiotherapy treatment for any of the outcome measures at the 7-week follow up. Furthermore, no significant interaction was found between physiotherapy and injection for any of the outcome measures. The three outcome measures utilised in this study were chosen because they have been proven to be inexpensive, reliable and sensitive to change: Stratford et al. (12) evaluated the usefulness of several outcome measures for tennis elbow, and found that PFGS was the most useful measure of change over time in patients with tennis elbow. Furthermore, the same author concluded that PFGS correlated significantly with a patient’s global impression of change ($r = 0.59$) whilst maximum grip strength did not ($r = 0.07$). Smidt et al. (7) also recommended using PFGS as an outcome measure in studies on tennis elbow.

### Table 4 Baseline characteristics of patients in the four treatment groups

| Observation | Physio alone | Injection alone | Physio plus injection |
|-------------|--------------|-----------------|-----------------------|
| Age (years) | 43.4 (7.1)   | 43.8 (7.5)      | 48.2 (6.5)            | 41.9 (7.4)            |
| PFGS (kg)   | 22.3 (10.8)  | 19.4 (11.4)     | 14.5 (7.5)            | 17.6 (7.2)            |
| EWS (kg)    | 4.9 (2.3)    | 3.9 (1.9)       | 2.6 (1.1)             | 4.5 (1.9)             |
| PRFEQ – pain| 5.1 (1.2)    | 4.6 (1.8)       | 5.0 (1.4)             | 4.7 (2.3)             |
| PRFEQ – function | 4.9 (1.3) | 3.7 (2.0)       | 5.0 (2.7)             | 3.6 (2.3)             |
| PRFEQ – total| 5.0 (1.1)   | 4.0 (1.1)       | 5.0 (2.2)             | 4.0 (2.2)             |

Results are given as mean (SD).
PFGS, pain free grip strength; EWS, extensor weight strength; PRFEQ, Patient Related Forearm Evaluation Questionnaire.

![Figure 1](https://example.com/figure1.png)
The PRFEQ devised by Overend et al. (11) was produced based on the work of a previous precursor study: one by Stratford et al. (13) which used a similar scale incorporating visual analogue scores of both pain and function and also a series of pain free function questions. The authors found it to be sensitive to change, possess high reliability ($r = 0.93$) and moderately high validity. We the authors of current study presented here acknowledge that the PRFEQ has now been superseded by the Patient Related Tennis Elbow Evaluation (PRTEE) (14); however, at the time when our RCT was designed the PRTEE had not been published in the literature and to our knowledge was not in common use at the time. This newer scale differs from its predecessor in a few minor respects in terms of wording of the questionnaire, and is so similar to the PRFEQ in fact, that it is envisaged that previously published reliability and validity data pertaining to the PRFEQ should also apply to the newer version of the questionnaire (14); however, MacDermaid (14) in an article outlining the new changes to the scale stated that re-testing of this revised tool in the author’s own institution’s tennis elbow studies was in progress to ensure that this was the case.

Although extensor weight strength has not been formally validated as an outcome measure, Kochar and Dogra (15) assessed the weight a patient could lift with wrist extension in supported elbow extension and forearm pronation without pain. This measure was used alongside grip strength and VAS to assess intervention effectiveness. They concluded that these outcome measures demonstrated close conformity and thus justified their use. It was felt that a direct measure of extensor grip strength was needed, as pain on resisted wrist extension is one the most common diagnostic tests used in the diagnosis of tennis elbow.

The natural history of tennis elbow is that of a benign self-limiting condition which improves with or without treatment within 12 months [Cyriax (16)], this statement being true in between 70% and 80% of patients [Bowyer et al. (17)]. Whilst there is wide consensus on these two facts, a year is a long time for a patient to wait not only in terms of pain and disability, but also loss of economic productivity. What patients often require is a safe minimally invasive procedure that will enable them to return to their daily activities as soon as possible.

The design of our study is similar to that of Smidt et al. (7). However, in addition to the three groups in this study (observation, physiotherapy and steroid injection), our study had a fourth group combining the modalities of steroid injection and physiotherapy, to see if these two treatments when combined had a synergistic effect that would outstrip any of the other conservative options used in previous studies in terms of efficacy. We agree with the findings of Smidt et al. (7) that steroid injections are the best option in the short term for patients with tennis elbow. When placed head to head with observation and physiotherapy respectively, the results were statistically significant in favour of injection. Despite large numbers of patients in each group however ($n = 60$), Smidt et al. (7) were still unable to demonstrate statistically significant treatment effects between groups at 12-month follow up. This echoed the findings of Cyriax (16) mentioned above that patients with tennis elbow improve at 12 months whether or not they have had treatment. Hay et al.

### Table 5

|               | Injection | Physiotherapy | Injection plus physiotherapy | Observation |
|---------------|-----------|---------------|------------------------------|-------------|
| PFGS (kg)     | 10.14 (8.64) | 4.96 (12.22) | 8.76 (6.13)                  | 1.47 (7.70) |
| EWS (kg)      | 2.87 (2.08)  | 0.96 (1.05)   | 2.11 (1.66)                  | 0.32 (1.12) |
| PRFEQ – pain  | −2.88 (1.80) | −0.70 (1.85)  | −3.31 (2.81)                 | 0.34 (1.43) |
| PRFEQ – function | −3.42 (2.58) | −0.40 (0.81)  | −2.81 (2.43)                 | −0.53 (1.66) |
| PRFEQ – total | −3.24 (2.19) | −0.50 (1.09)  | −2.97 (2.49)                 | −0.24 (1.49) |

Positive values indicate an increase from baseline.

### Table 6

|               | Physiotherapy alone | Injection plus physiotherapy interaction | Injection alone |
|---------------|---------------------|-----------------------------------------|----------------|
| PFGS (kg)     | 0.73                | 0.42                                    | 0.045          |
| EWS (kg)      | 0.91                | 0.20                                    | 0.001          |
| PRFEQ – pain  | 0.27                | 0.65                                    | 0.001          |
| PRFEQ – function | 0.60                | 0.73                                    | 0.001          |
| PRFEQ – total | 0.99                | 0.68                                    | 0.001          |

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(8) who compared steroid injection with oral naproxen for the treatment of tennis elbow found that injection therapy had a clear clinical advantage over oral NSAID at 4 weeks, but that by 12 months patients had improved irrespective of their initial treatment, again reflecting the underlying natural history of the disease.

Similarly, Verhaar et al. (9) who compared steroid injection with Cyriax-type physiotherapy for the treatment of tennis elbow, despite having large numbers of patients (53) available for follow up in each arm at 12 months were unable to demonstrate a statistically significant difference between the groups using an intention to treat analysis.

Iontophoresis, or ion transfer, uses a continuous direct current of a low amperage to introduce topically applied physiologically active ions through the body’s surface (18). The principle behind this therapy is that an electrically charged electrode will repel a similarly charged ion (19) (across the surface of the skin in this instance). It has been shown that the corticosteroid dexamethasone can be transferred iontophoretically into all tissue layers down to and including tendinous structures. Furthermore, iontophoresis requires local tissue concentrations of corticosteroid that are lower than those achieved with injection, and is therefore considered to be both safe and effective (18). In comparison with local injection, the therapy is non-invasive and painless, increasing its acceptability to patients.

The authors of the current study acknowledged the perceived benefits of iontophoresis as a potential method of delivering steroid to the patients randomised to receive this drug in the current trial; however, its efficacy over that of placebo in a RCT has been called into question (18). In view of this, it was decided that during the design stage of this trial to stick with the more traditional approach of local targeted delivery of corticosteroid by means of injection therapy.

We like the other studies (even though our study was smaller than the others mentioned here, which the authors acknowledge) were able to demonstrate statistically significant differences between steroid injection and other forms of therapy at the 7-week follow-up stage. In addition, this study found no interaction between injection and physiotherapy and subsequently no additional benefit was derived when steroid injection and physiotherapy were combined. Another limitation of our study was the relatively small sample size, which is comparable to the numbers employed in our control group. It is therefore believed that our study may be unable to detect any statistically significant differences between the treatment groups who had physiotherapy as a part of their treatment and the other treatment groups in this study.

In conclusion, based on the findings in this study, we would advocate steroid injection as the first line treatment for patients presenting with acute tennis elbow. Injections alone are effective not only in terms of their pain relieving and function improving effect, but are much more time and cost efficient than physiotherapy, which in some cases can involve the patient attending the out patient physiotherapy department up to six times for treatment, with the consequent loss of time and/or earnings also for the patient. Furthermore, as has been demonstrated in this study and others, steroid injection has a low level of relatively minor and well tolerated side effects.

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