Controlled trial of an elbow support ('Epitrain') in patients with acute painful conditions of the elbow: a pilot study

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Summary

A randomized, controlled, parallel-group study was undertaken to assess the clinical efficacy of a new elbow support ('Epitrain') compared with a standard elasticated tubular stockinette support ('Tubigrip') in 35 patients with acute painful elbow disorders. On entry, patients had a clinical examination, including measurement of the range of active and passive movement of the affected joint, and were allocated to one or other treatment group (19 to 'Epitrain', 16 to control). All patients were allowed to take 1g paracetamol up to 4-times daily if necessary for the control of pain. Assessments were made daily by patients, using visual analogue scales, of their pain levels at rest, at night and on activity, and of the limitation of their activity. Details were also recorded of their ability to work normally. At the end of the 14-day study period, patients were re-examined by the doctor and were asked for an overall assessment of their response to treatment.

Analysis of data from the daily diary records showed progressive, significant reductions to zero in scores for all the pain and the activity criteria in the 'Epitrain' group during the first 7 to 9 days; thereafter, this improvement was maintained. In contrast, the reductions in symptom scores in the control group were much smaller, confined to the first 3 to 5 days, with little further improvement. The median times taken for reduction of symptom scores to 10% of initial levels were at least 14 days for all four visual analogue scale assessments in the control group. In contrast, a 90% reduction occurred in the 'Epitrain' group in a median time of 6.5 days for rest pain ($p<0.01$), 7 days for night pain ($p<0.01$), 8 days for pain on activity ($p<0.01$) and 9 days for limitation of activity ($p<0.02$). The mean range of active joint movement improved from 80 degrees to 141 degrees in the 'Epitrain' group, but only from 83 degrees to 98 degrees in the control group ($p<0.0002$). Similar results were obtained for passive joint movement. Overall, 13 (68%) of the 19 patients in the 'Epitrain' group were described as 'cured' as compared with 2 (13%) of the 16 patients in the control group ($p<0.02$). At the end of the trial, 16 (89%) of 18 patients in the 'Epitrain' group were considered to have returned to normal, whilst the same was true of only 3 (19%) of 16 in the control group ($p<0.0003$). All patients who received 'Epitrain' commented positively on it. None had any difficulties or discomfort in its use.

Key words: 'Epitrain' – bandages, support – sprains and strains – athletic injuries – elbow

Introduction

Acute painful conditions of the elbow are very commonly seen in general practice and sports injury clinics. These conditions result from 'over use', e.g 'tennis elbow', falls on to the elbow itself or injuries involving twisting of the arm and/or hyper-extension of the elbow joint. In a number of cases, no direct cause of the elbow pain can be ascertained from the history, it having apparently arisen spontaneously. Whatever the cause, pain and movement limitation in the elbow joint can result in considerable disability, preventing sporting activities and sometimes even work and normal daily activities. The duration of these symptoms varies, but may range from a few days to several weeks; the average is probably about 2 weeks.

In the absence of bony injury or an inflammatory process of a type and severity likely to require local corticosteroid injection, treatment has to be essentially symptomatic. Simple analgesics are normally prescribed and the patient given some sort of simple support/bandaging to the affected joint, such as an elasticated surgical tubular stockinette. Whereas there have been numerous comparative trials of the efficacy and tolerability of different analgesics to assist the physician in his drug prescribing choice in the treatment of such conditions, it is somewhat surprising in view of their widespread use that, to the best of our knowledge, there have been few if any studies comparing the effectiveness and acceptability of different types of support commercially available.

For these reasons, it was decided to undertake a controlled trial of a sophisticated elasticated elbow support ('Epitrain'†) which has been introduced recently in the United Kingdom and to compare it with a 'standard' support ('Tubigrip', Seton) in the treatment of patients with painful elbow disorders. The 'Epitrain' elbow support differs from the standard support in that it has inbuilt silicone rubber inserts. It is claimed that these inserts are positioned so as not only to maximize the support offered but also to achieve constant massaging of the affected areas around the joint during movement; this aspect of treatment with 'Epitrain' has been described as 'active therapy'.[1,2] It has been suggested that the high quality of joint support together with the feature of 'active therapy' means that 'Epitrain' may speed resolution of symptoms and full recovery of elbow function. The present study was designed, therefore, to assess whether 'Epitrain' was superior to a 'standard' support in these respects. If so, its use should offer the advantages of reducing the amount of time spent away from work and/or sporting activities and potentially of reducing also the number of medical consultations required.

Patients and methods

Patients aged 18 years or over who presented to the participating general practitioners with acute painful conditions of the elbow were considered for inclusion in the trial. Patients were acceptable for the trial if they were suffering a current episode of a recurrent problem, or if they were suffering an acute exacerbation of

†trade mark, Bauerfeind

a longer-standing problem, but not if there was evidence of pre-existing chronic disease, e.g. arthritis, of the joint in question.

Patients were also excluded from the trial if there was any suspicion of a bony injury, confirmed by radiological examination where necessary, or of nerve compression, if they had symptoms in both elbows, if they had a history of surgery to the affected joint, if they were receiving regular analgesics, non-steroidal anti-inflammatory agents or corticosteroids or if they had an elbow and/or arm of such a size or shape that no standard size of 'Epitrain' would be suitable.

Those patients fulfilling the entry/exclusion criteria and giving their informed consent to participate were measured to determine what standard size of 'Epitrain' would be appropriate for them. If it transpired that the patient's measurements were such that none of the standard sizes of 'Epitrain' would have been suitable, the patient was excluded from the trial before the allocation of a trial number, even if the patient was destined to be randomized to the control group.

Patients entering the trial were then allocated the next available trial number. A standard history was obtained and a clinical examination undertaken, including measurement of the range of movement (both active and passive) of the affected joint.

Those patients randomized to the active treatment group commenced treatment with an 'Epitrain' elbow support of the appropriate size; those in the control group received only 'standard therapy', in the form of simple support with 'Tubigrip'. Those in the 'Epitrain' group were instructed to wear the support throughout each day; use at night was optional. All patients were permitted to take 1 g paracetamol, up to 4-times per day, for the control of pain. Apart from paracetamol, no other specific treatment for elbow pain was permitted. In particular, corticosteroids (either local or systemic) and non-steroidal anti-inflammatory agents were not permitted. Drugs for the treatment of unrelated disorders were allowed to continue but, wherever possible, at unchanging dosage throughout the trial. All medication consumption was recorded.

Patients maintained daily diary card records throughout the trial period and were then reviewed by the investigator 2 weeks later. At that time, patients were examined clinically (including repeat measurement of joint movement) and their overall improvement assessed as described below. Those patients in the active treatment group were questioned at this time regarding the acceptability and comfort of 'Epitrain'.

Assessments

The primary assessments of treatment efficacy were on the basis of daily self-assessment by patients, using 'diary cards': (i) pain self-assessment, utilizing 7 cm horizontal visual analogue scales labelled 'None' at one end and 'Worst imaginable' at the other end. These scales were applied separately to pain in three situations – at rest, during activities and at night; (ii) limitation of activity was also assessed on a 7 cm visual analogue scale, labelled 'No limitation' at one end and 'No use of arm possible' at the other end; (iii) patient's ability to work or not; and (iv) the number of doses of analgesic taken during the day.

At the end of the trial, response to treatment was assessed on a 6-point scale (0=much worse, 1=slightly worse, 2=no change, 3=slightly better, 4=much better, and 5=cured). At the start and end of the trial period the range of movement (extension/flexion) was measured, using a goniometer, in relation to both active movement and passive movement. At the end of the trial, those in the active treatment group were also questioned regarding the comfort and ease of use of 'Epitrain'.

Statistical analysis

In view of the nature of the data, most analysis was undertaken using non-parametric methods, i.e. Wilcoxon's Signed Rank Tests or Kolmogorov-Smirnov Tests for within-group changes and Mann-Whitney Tests or Kolmogorov-Smirnov Tests (applied to within-group changes) for comparison of the groups.

Two techniques were used to derive overall indices of efficacy from the diary visual analogue scale data. First, 'areas above the response-time curves' were calculated for each of the variables. These represented the reduction from baseline (Day 1) integrated with respect to time, calculated separately for each patient. Secondly, for each patient, the time was ascertained for each of the visual analogue scale scores to decrease to 10% or less of the initial (Day 1) figure for that patient. Patients with a Day 1 score $<40\%$ were excluded from these analyses. In the event that there was a secondary increase in score, the figure taken was the interval before the score first decreased to 10% of the initial score; if the score never decreased to this level, the interval was recorded as '14+' days.

A cautious approach has been taken of applying two-sided significance tests throughout, even for active-control comparisons. In all cases, the threshold of significance has been taken as $p=0.05$.

Results

A total of 35 patients (19 'Epitrain', 16 control) entered the trial. Twenty-two patients were male and 13 female. Their mean age was 40 years (range 18 to 66 years), their mean weight 76.5 kg (range 50 to 84 kg) and their mean height 169 cm (range 156 to 183 cm). The two treatment groups were well matched as regards age; in the 'Epitrain' group, patients were slightly heavier ($p<0.02$) and there was a a greater proportion of males (74%, as compared with 50% in control group; non-significant difference).

The pattern of diagnoses was similar in the two groups. Falls either directly onto the elbow or resulting in sprain/twist injuries represented the most common diagnoses (13 of 19 in the 'Epitrain' group; 10 of 16 in the control group), whilst 'tennis elbow' was the diagnosis in 7 cases (3 'Epitrain', 4 control). The median duration of symptoms at trial entry was 7 days in the 'Epitrain' group and 10 days in the control group. This difference was not statistically significant (N.S.).

The two groups were well matched with respect to arm size, with mean upper measurements of 27.1 cm (range 20 to 33 cm) and mean lower measurements of 26.4 cm (range 18 to 38 cm). The right arm was involved much more frequently than the left (82% of patients). In the active treatment group, the sizes of 'Epitrain'

required were Size 1 in 1 patient, Size 2 in 4 patients, Size 3 in 10 patients, Size 4 in 3 patients and Size 5 in 1 patient.

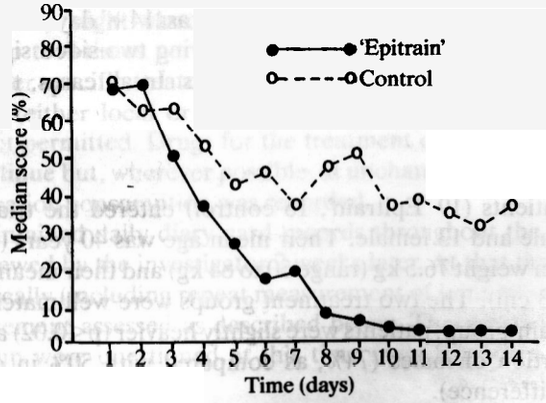
All patients completed the trial, returning for re-assessment at 2 weeks and completing daily diary cards records for at least 12 days.

Efficacy assessments – diary data

All assessments showed similar patterns of results. In the 'Epitrain' group, there were progressive improvements during the first 7 to 9 days, by the end of which period symptoms had disappeared or decreased to a very low level, with maintenance of this improvement for the remainder of the trial. In the control group, there were much smaller improvements, seen over the first 3 to 5 days, with little further improvement thereafter (Figures 1 to 4).

Pain at rest. Both groups showed significant progressive reductions in visual analogue scale scores during the trial (Figure 1). By the end of the trial, there was a median decrease of 52 units in the 'Epitrain' group ($p<0.002$) and 21 units ($p<0.05$) in the control group. The improvement was significantly greater in 'Epitrain' group from Day 10 to Day 13 ($p<0.05$). The median area above the response-time curve was 551 units with 'Epitrain' and 270 units in the control group, the difference not quite reaching statistical significance.

Figure 1. Patients' assessment of pain at rest: median visual analogue scale scores (%)



Night pain. By Day 14, the median reduction in the 'Epitrain' group was 53 units ($p<0.002$), as compared with only 7 units ($p=$N.S.) in the control group (Figure 2). The improvement was significantly greater in the 'Epitrain' group for most days from Day 4 to Day 14 ($p<0.05$). The median area above the response-time curve was 521 units with 'Epitrain' and 51 units in the control group ($p<0.05$).

Pain on activity. By Day 14, the median reduction was 50 units in the 'Epitrain' group ($p<0.002$) as compared with 19 units ($p<0.02$) in the control group (Figure 3). The improvement was significantly greater with 'Epitrain' during the period

Figure 2. Patients' assessment of night pain: median visual analogue scale scores (%)

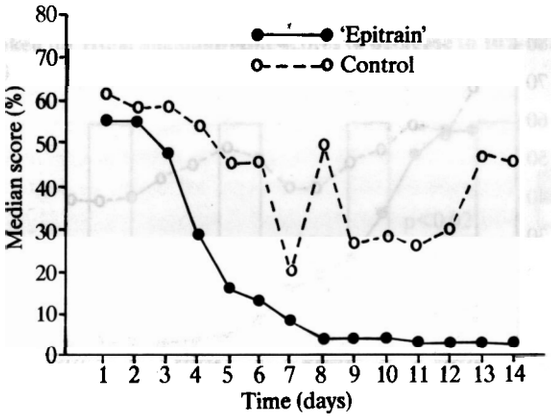
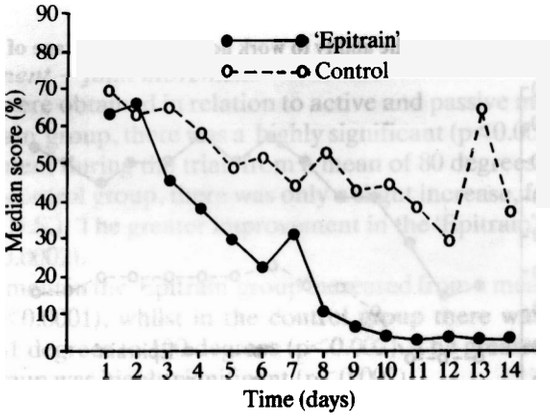


Figure 3. Patients' assessment of pain on activity: median visual analogue scale scores (%)

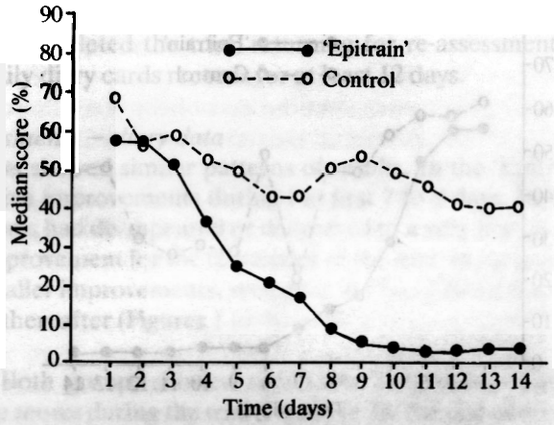


from Day 6 to Day 14 ($p<0.01$ to $p<0.05$). The median area above the response-time curve was 509 units with 'Epitrain' and 251 units in the control group ($p<0.05$).

Limitation of activity. By Day 14, the median reduction was 47 units with 'Epitrain' ($p<0.002$) and 15 units in the control group ($p<0.02$) (Figure 4). The improvement was significantly greater with 'Epitrain' during the period from Day 8 to Day 13 ($p<0.05$). The median area above the response-time curve was 498 units with 'Epitrain' and 189 units in the control group, the difference not quite reaching statistical significance with the number of patients analyzed.

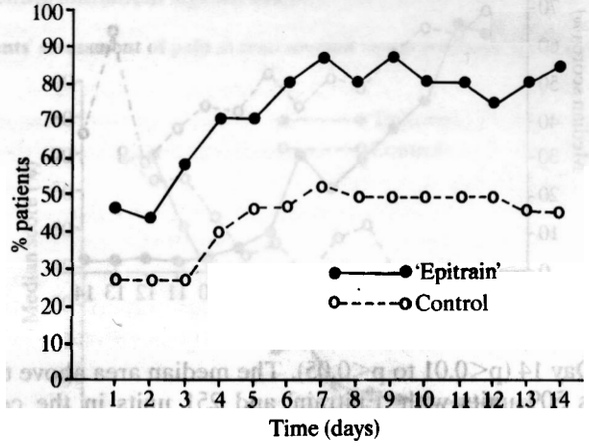
Ability to work normally. The number of patients able to work normally increased during the trial from 8 (47%) of 17 to 12 (86%) of 14 in the 'Epitrain' group, as compared with an increase from 4 (27%) of 15 to 6 (46%) of 13 in the control

Figure 4. Patients' assessment of limitation of activity: median visual analogue scale scores (%)



group; the difference between groups did not quite reach statistical significance on any day of the trial (Figure 5).

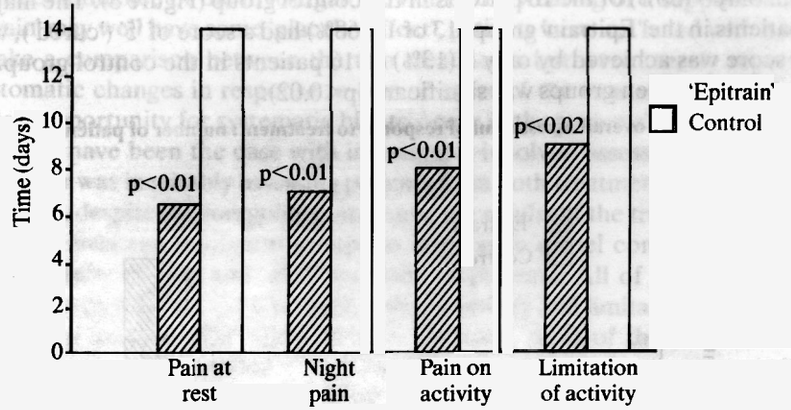
Figure 5. Patients' assessment of the ability to work normally: percentage of patients



Analgesic consumption. Too few data were recorded to allow meaningful analysis of this variable. Only about 10% of all patients recorded analgesic usage over the trial period. It was not possible, however, to determine whether this was due to a real lack of need for analgesia or to non-compliance in record keeping.

Time to respond. In the control group, the median time for scores to decrease to 10% or less of their initial value was 14 days for all four visual analogue scale assessments (Figure 6), reflecting the fact that many of the patients in this group never showed decreases to 10% at any time during the trial observation period. In contrast, the median times required for 90% reduction in scores in the 'Epitrain' group were 6.5 days for rest pain ($p<0.01$), 7 days for night pain ($p<0.01$), 8 days for pain on activity ($p<0.01$) and 9 days for limitation of activity ($p<0.02$).

Figure 6. Time taken for visual analogue scale scores to decrease to 10% of Day 1 score: median time (days)

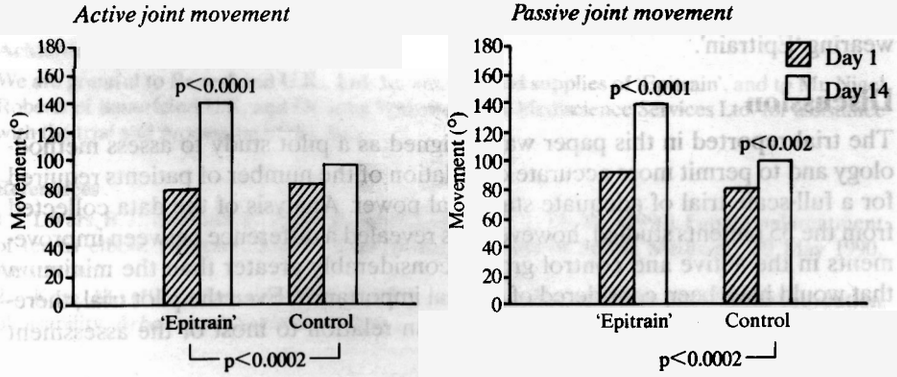


Clinical assessment – joint movement

Similar results were obtained in relation to active and passive movements (Figure 7). In the 'Epitrain' group, there was a highly significant ($p<0.0001$) improvement in active movement during the trial, from a mean of 80 degrees to a mean of 141 degrees; in the control group, there was only a slight increase, from 83 degrees to 98 degrees (p=N.S.). The greater improvement in the 'Epitrain' group was highly significant ($p<0.0002$).

Passive movement in the 'Epitrain' group increased from a mean of 92 degrees to 141 degrees ($p<0.0001$), whilst in the control group there was a much smaller increase from 81 degrees to 100 degrees ($p<0.002$). The greater improvement in the 'Epitrain' group was highly significant ($p<0.002$).

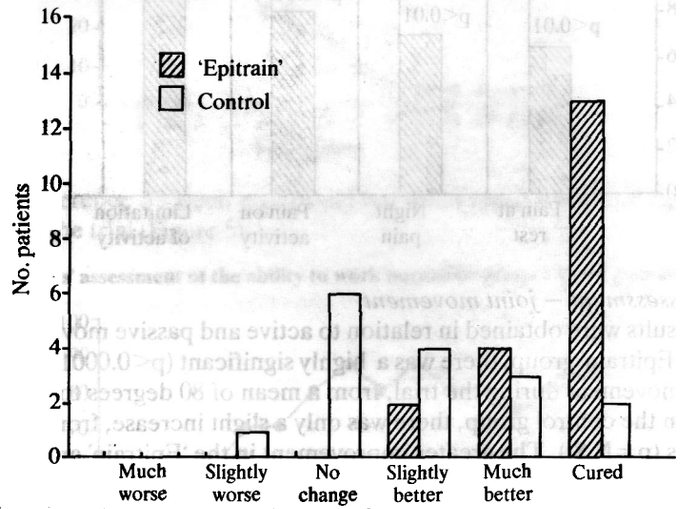
Figure 7. Physician's measurement of active and passive joint movement on entry (Day 1) and on Day 14 of the study period: mean values (°)



Overall assessment

The mean 'overall assessment' scores were 4.6 units (median 3 units) in the 'Epitrain' group and 2.9 units (median 5 units) in the control group. Some degree of improvement (score 3 or above) was seen in all 19 patients in the 'Epitrain' group, but in only 9 (56%) of the 16 patients in the control group (Figure 8). The majority of patients in the 'Epitrain' group (13 of 19, 68%) had a score of '5' ('cured'), whilst this score was achieved by only 2 (13%) of 16 patients in the control group. The difference between groups was significant ($p<0.02$).

Figure 8. Patients' overall assessment of response to treatment: number of patients



Note: $p<0.02$, significance of difference between groups

At the end of the trial, 16 (89%) of 18 patients in the 'Epitrain' group were described as 'normal', whilst this was only true of 3 (19%) of 16 in the control group ($p<0.0003$).

All 17 patients in the active group who commented on 'Epitrain' did so positively. Four patients commented that the product was comfortable, whilst 2 volunteered that it was 'supportive'. No patient experienced any problems with wearing 'Epitrain'.

Discussion

The trial reported in this paper was designed as a pilot study to assess methodology and to permit more accurate calculation of the number of patients required for a full-scale trial of adequate statistical power. Analysis of the data collected from the 35 patients studied, however, has revealed a difference between improvements in the active and control groups considerably greater than the minimum that would have been considered of clinical importance. Even the pilot trial, therefore, has proved to have adequate power in relation to most of the assessment criteria.

It has to be accepted that a trial of a product of this nature cannot be undertaken using the rigorous 'blind' methodology which would be theoretically desirable. In an attempt to minimize any resulting bias, greatest emphasis has been placed on daily self-assessments performed by patients in their own homes, away from any direct influence of the investigators. Whilst the wearing of a support such as 'Epitrain' may well have some 'placebo effect', patients were not faced with having to make a comparison between the two treatments but were merely reporting symptomatic changes in response to one or other of the treatments. There was thus less opportunity for systematic bias to occur in the patients' self-assessments than could have been the case with investigator-involved assessments, since the investigator was inevitably assessing patients from both treatment groups.

However, despite the foregoing comments, the results of the trial have revealed differences between treatment groups so large as to dispel concerns about the possible effects of bias and small numbers of patients. All of the patient self-assessments (pain at rest, pain at night, pain on activity and limitation of activities) showed very marked improvements with 'Epitrain', most of the patients being virtually symptom-free within 7 to 9 days; in the control group, about half of the patients showed little improvement at all during the full 14-day period of observation.

In addition to the self-assessment data, there were dramatic differences between the groups in relation to clinically-assessed joint movement; 'Epitrain' resulted in marked large improvements, whereas little improvement was seen in the control group. Overall, 68% of patients were classified as 'cured' by 'Epitrain', whilst this occurred with only 13% in the control group. At the end of the trial, 89% of patients in the 'Epitrain' group were regarded as having returned to 'normal', whilst this was true of only 19% of patients in the control group.

Those patients who received 'Epitrain' all commented favourably upon it. There were no reports of any difficulty or discomfort in its use.

Despite having been designed as a pilot study, this trial has demonstrated that, in patients with acute painful disorders of the elbow, the use of an 'Epitrain' elbow support results in greater and more rapid alleviation of symptoms than with a simple elasticated support. 'Epitrain' should therefore be considered as a possible valuable aid in the management of all patients with such disorders.

Acknowledgements

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References

1. Dwars, B. J., de Feiter, P., Patka, P., and Haarman, H. J. Th. M., (1990). Functional treatment of tennis elbow. Abstract; XXIV FIMS World Congress of Sports Medicine, 29 May 1990, Amsterdam.

2. Konz, M., (1984). Functional support therapy of the affected elbow joint for the prevention of disability. *Arbeitsmed. Sozialmed. Präventivmed.*, **19**, 43-44.