Acknowledgements

It is deeply regretted that the co-author Dr. J. O'Hara died shortly after this paper was submitted for publication.

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References

1. Krause, W., (1983). Eine Bandage die stützt, aber nicht drückt. In: "Ärztliche Praxis". Werk Verlag Dr. Edmund Banaschewski GmbH, Munich.
2. Yücel, M., Breitenfelder, J. Liebscher, F., and Nicol, K., (1984). Untersuchungen zum Wirkungsprinzip der Lumbotrainbandage: eine klinische und experimentelle Untersuchung. *Z. Orthop.*, **122,** 287-289.

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Summary

A randomized, controlled, parallel-group clinical trial was carried out in general practice to assess the clinical efficacy of a new back support ('Lumbotrain') compared with 'standard therapy' of advice on rest and lifestyle in the treatment of patients with non-specific low back pain. A total of 216 patients entered this study (111 'Lumbotrain' group, 105 control group). All patients were allowed to take 1 g paracetamol up to 4-times daily if necessary for control of pain. Self-assessments were made daily by patients, over a period of 21 days, of pain levels at rest, on activity, at night, and limitation of activity using visual analogue scales. Details were also recorded of their ability to work or not, and the number of doses of paracetamol taken. At the end of the study period, patients assessed their overall response to treatment and those in the 'Lumbotrain' group were questioned on the comfort and ease of use of the back support. A clinical examination was carried out by the doctor at the start and end of the study period and an assessment made of the total range of active and passive back movement. Analysis of the daily diary records showed there were progressive, significant reductions in mean scores for all the pain and activity criteria in both groups and these were significantly greater in the 'Lumbotrain' group from Day 7 onwards. The times taken for reduction of symptom scores to 10% of initial values were significantly less in the 'Lumbotrain' group, such a degree of recovery occurring 2 to 4 days more rapidly than in the control group. A significantly higher proportion of patients in the 'Lumbotrain' group became able to work normally. After 3 weeks, 85% of patients in the 'Lumbotrain' group could work normally, as compared with 67% in the control group ($p<0.02$). Total analgesic consumption during the trial was significantly lower ($p<0.0001$) in the 'Lumbotrain' group (median 24.5 doses) than in the control group (median 51 doses). Overall clinical assessment scores were significantly superior in the 'Lumbotrain' group ($p<0.002$). Improvement was seen

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in 106 (95%) of 111 patients in the 'Lumbotrain' group, as compared with 79 (77%) of 103 of those in the control group ($p<0.0002$). At the end of the trial, 92 (89%) of 103 patients in the 'Lumbotrain' group were considered to have returned to normal, whilst the same was true of 63 (68%) of 92 in the control group ($p<0.002$). Of those patients who wore 'Lumbotrain', 103 (94%) of 109 commented positively on it. The remaining 6 patients reported minor discomfort or skin irritation, not severe enough to require discontinuing the use of the support. It is suggested, therefore, that because of its patient acceptability and the significantly greater and more rapid alleviation of symptoms than with conventional measures, the use of 'Lumbotrain' should be considered as a possible valuable aid in the management of patients with non-specific low back pain.

Key words: 'Lumbotrain' — bandages, support — backache

Introduction

Low back pain is an extremely common disorder which results in considerable suffering and widespread economic consequences; in the United Kingdom alone, several million working days are lost every year because of this condition. It is often possible to relate symptoms to a specific injury, frequently associated with lifting heavy objects or twisting of the back, e.g. as a result of a fall. However, in many cases no traumatic cause of the back pain can be ascertained from the history. Whilst many such cases of low back pain are associated with demonstrable pathological lesions (particularly prolapsed intervertebral discs), there remains a large group of cases in which no such causative pain can be found. When low back pain occurs in the absence of bony injury or disc pathology it is usually termed 'non-specific' low back pain.

The natural history of low back pain is very variable. Whether due to identifiable injury or not, symptoms may resolve spontaneously within a few days or weeks, or alternatively may persist for months or years. The treatment of low back pain unassociated with bony injury or intervertebral disc prolapse is unsatisfactory and essentially symptomatic. It relies mainly upon analgesics, drugs with some muscle relaxant activity, e.g. diazepam, and advice to the patient to rest, to sleep on hard surfaces, etc. Various types of mechanical back supports are also sometimes offered. In our experience, their usefulness is limited, however, because many are so uncomfortable to wear that patients soon discard them.

Whilst there has been a number of reports in the literature of controlled studies assessing the usefulness of pharmacotherapy in such conditions, to the best of our knowledge there have been few if any controlled or comparative trials carried out in general practice to evaluate the effectiveness and acceptability of commercially available supports for patients with painful back disorders.

Recently, a sophisticated elasticated back support with an attached silicone rubber pad of special shape ('Lumbotrain'†) has been developed and introduced.

†trade mark, Bauerfeind

It is claimed that this pad is positioned so as not only to maximize the support offered but also to achieve constant massaging of the lumbo-sacral area during movement; this aspect of treatment with 'Lumbotrain' has been described as 'active therapy'. The support has been designed to be of particular value during the ambulatory recovery phase when its comfort and failure to immobilize the back are of importance. It has also been suggested that the high quality of back support, together with the feature of 'active therapy' means that 'Lumbotrain' may speed resolution of symptoms and full recovery of back function, particularly since it is comfortable to wear and thus likely to continue to be worn by patients.[1,2]

If these claims can be confirmed, 'Lumbotrain' would represent a form of treatment for this large group of patients which was superior to the standard therapy available, reducing the amount of time spent away from work and/or sporting activities and potentially reducing the number of medical consultations required. For these reasons, a controlled trial was undertaken to compare 'Lumbotrain' with standard treatment for patients with painful back disorders.

Patients and methods

All patients who presented to the participating general practitioners with low back pain, unassociated with bony injury or intervertebral disc pathology, were considered for inclusion in the trial. Patients were acceptable for the trial if they were suffering the first episode of low back pain, chronic low back pain or an acute exacerbation of a longer-standing problem. Patients were excluded from the trial if there was any suspicion of a bony injury (where necessary confirmed by radiology), if there was any other demonstrable specific pathological cause for the low back pain (particularly prolapse of an intervertebral disc, evidenced by nerve root pain or neurological signs) or any history of spinal injury. Patients were not allowed to enter the trial if they were receiving regular analgesics, non-steroidal anti-inflammatory agents or corticosteroids which could not be stopped for the period of the trial or if the size of the patient and/or shape was such that no standard size of 'Lumbotrain' would be suitable.

When patients were considered for inclusion in the trial, clinical and, where necessary, radiological examination was performed in order to confirm the absence of bony injury or any other demonstrable causative pathology.

Those patients fulfilling the entry criteria and giving their informed consent to participate were measured to determine what standard size of 'Lumbotrain' would be appropriate for them. If it transpired that the patient's shape and/or girth measurement was such that none of the standard sizes of 'Lumbotrain' 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 total range of back movement (both active and passive).

Those patients randomized to the active treatment group then commenced

treatment with a 'Lumbotrain' back support of the appropriate size; they were instructed to wear it throughout the day-time, use whilst in bed being optional. Those in the control group received only 'standard therapy', consisting of advice on rest and lifestyle.

All patients were permitted to take analgesics, if required, in the form of paracetamol, 1 g up to 4-times per day, and the consumption of paracetamol was used as one of the indices of efficacy. Drugs for the treatment of unrelated disorders were allowed to continue but, wherever possible, at unchanging dosage throughout the trial.

Patients maintained daily diary card records throughout the trial period and were then reviewed by the investigator 3 weeks later. At that time, patients were examined clinically (including repeat measurement of back 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 'Lumbotrain'.

All patients who gave informed consent to participate in the trial were aware that they were free to withdraw from the trial at any time without prejudice to their subsequent clinical management.

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 scale, 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 activity, and during the night; (ii) limitation of activity was also assessed on a 7 cm visual analogue scale, labelled 'No limitation' at one end and 'No activity 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 start and end of the trial period, the total range of back movement was assessed by the physician in relation to both active movement and passive movement. At the end of the trial, patients assessed their response to treatment on a 6-point scale (0=much worse, 1=slightly worse, 2=no change, 3=slightly better, 4=much better, and 5=cured) and were questioned regarding their current activity/work status. Those in the active treatment group were also questioned regarding the comfort and ease of use of 'Lumbotrain'.

Statistical analysis

The significance of within-patient changes within groups was assessed using Wilcoxon's Signed Ranks tests, Kolmogorov-Smirnov tests or paired t-tests. The two groups were compared using Mann-Whitney tests, Kolmogorov-Smirnov tests, χ^2-tests and unpaired t-tests, applied to the within-group changes during the trial.

The visual analogue scale diary data were analyzed in terms of areas under the response-time curves and also the time taken for each of the visual analogue scale

scores to decrease to 10% or less of the initial score; patients with a Day 1 score <40% were excluded from these calculations.

All significance tests were 2-tailed and the threshold of significance has been taken as $p=0.05$.

Results

A total of 216 patients (111 'Lumbotrain', 105 control) entered the trial. One hundred and thirteen patients were male and 97 female (sex not stated in 6 cases). Their mean age was 43 years (range 14 to 76 years), their mean weight 68.1 kg (range 51 to 110 kg) and their mean height 169 cm (range 150 to 190 cm). The two treatment groups were well matched as regards sex, weight and height; in the 'Lumbotrain' group, patients were slightly older (mean 45.9 years, as compared with 40.5 years in the control group, $p<0.02$).

In the majority of patients (83%), symptoms were attributable to a specific injury (commonly lifting or falling); the median duration of symptoms was 12 days in the 'Lumbotrain' group and 10 days in the control group. This difference was not statistically significant. Prior to the trial, a similar number of patients in both treatment groups had been receiving analgesics and/or anti-inflammatory agents.

In the active treatment group, the sizes of 'Lumbotrain' required were Size 1 in 14 (13%) patients, Size 2 in 32 (29%), Size 3 in 42 (38%), Size 4 in 18 (16%) and Size 5 in 5 (5%).

All patients completed the trial, returning for re-assessment at 3 weeks.

Efficacy assessments – diary data

Visual analogue scales. All assessments showed similar patterns of results (Figure 1). Both groups showed progressive highly significant improvements during the 21 days of observation, in all cases the improvement being greater in the 'Lumbotrain' group. In general, the differences between groups became statistically significant within about 7 days and remained so for the rest of the observation period.

The percentages of patients showing improvements in visual analogue scale scores relative to Day 1 showed results which mirror those seen for the mean scores. In terms of rest pain, for example, by Day 21 over 90% showed improvement in the 'Lumbotrain' group as compared with approximately 70% of patients in the control group.

A summary of results and analyzes of areas under the visual analogue scale response-time curves are given in Table I, whilst the intervals required for scores to decrease to 10% are given in Table II.

Ability to work normally. The number of patients able to work normally increased during the trial from 36 (32%) to 92 (83%) of 111 patients in the 'Lumbotrain' group, as compared with an increase from 29 (28%) to 77 (73%) of the 105 patients in the control group (Figure 2). The percentage able to work normally was, in fact, anomalously high on Day 21; the Day 20 figures are more typical of the trend, the

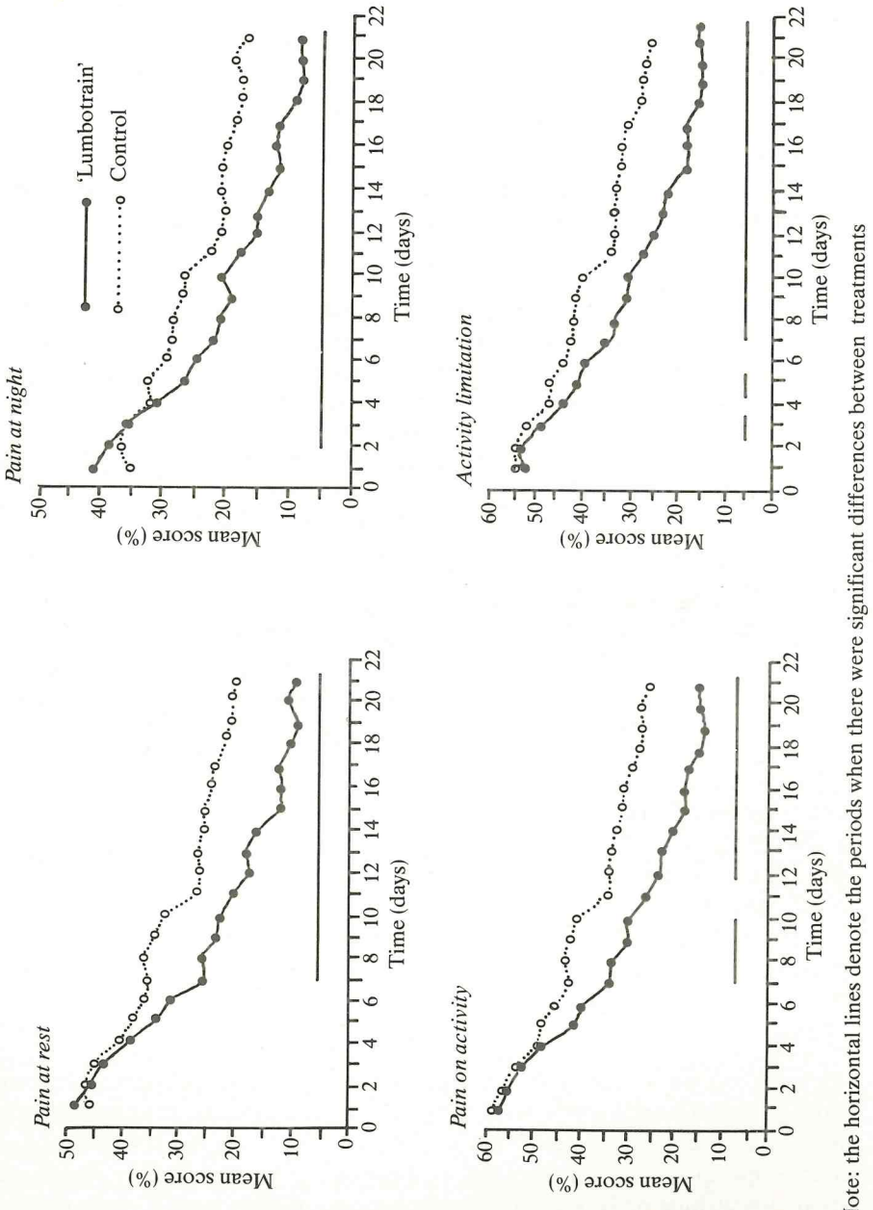


Figure 1. Patients' assessments of pain at rest, on activity and at night, and limitation of activity on entry and during the study period: mean visual analogue scale scores (%)

Note: the horizontal lines denote the periods when there were significant differences between treatments

Table I. Areas under the visual analogue scale score-time curves in the two treatment group: mean area (units)

Patient self-assessment	'Lumbotrain' group (n=111)	Control group (n=105)	Significance of difference between groups
Pain at rest	456.6	627.7	$p<0.004$
Pain on activity	581.1	769.2	$p<0.001$
Pain at night	382.8	507.0	$p<0.03$
Activity limitation	587.1	763.8	$p<0.003$

Table II. Time for visual analogue scale scores to decrease to 10% of the initial values: mean time (days)

Patient self-assessment	'Lumbotrain' group (n=111)	Control group (n=105)	Significance of difference between groups
Pain at rest	10.76	14.15	$p<0.0001$
Pain on activity	12.83	15.56	$p<0.002$
Pain at night	10.30	12.54	$p<0.03$
Activity limitation	13.46	15.32	$p<0.04$

proportion able to work normally being 85% in the 'Lumbotrain' group and 67% in the control group. Significantly greater proportions of patients in the 'Lumbotrain' group were able to work during the period from Day 5 to Day 20.

Doses of analgesics. Analgesic consumption decreased progressively during the trial in both treatment groups (Figure 3). The decrease was significantly greater with 'Lumbotrain' patients during the first 15 days. Thereafter, although average consumption continued to decrease in both groups, the absolute level became so low (with the majority of patients taking no analgesic at all) that statistical significance was lost.

The median total number of doses of analgesic taken during the 21-day trial period was 24.5 in the 'Lumbotrain' group, as compared with 51.0 in the control group ($p<0.0001$).

Speed of response. A reduction in visual analogue scores to 10% occurred significantly more rapidly in the 'Lumbotrain' group for all four visual analogue scale assessments, the improvement with 'Lumbotrain' being seen 2 to 4 days earlier than in the control group (Table II).

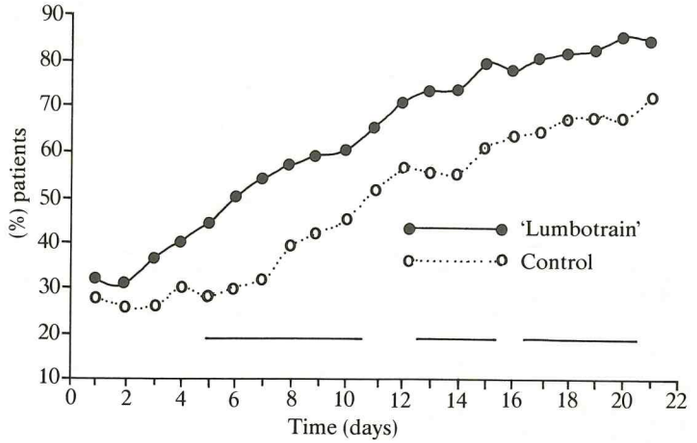
Clinical assessment

There were highly significant ($p<0.0001$) improvements in mean ranges of both active and passive back movement during the trial in both treatment groups, but no appreciable or significant differences between the groups (data on file).

Overall assessment

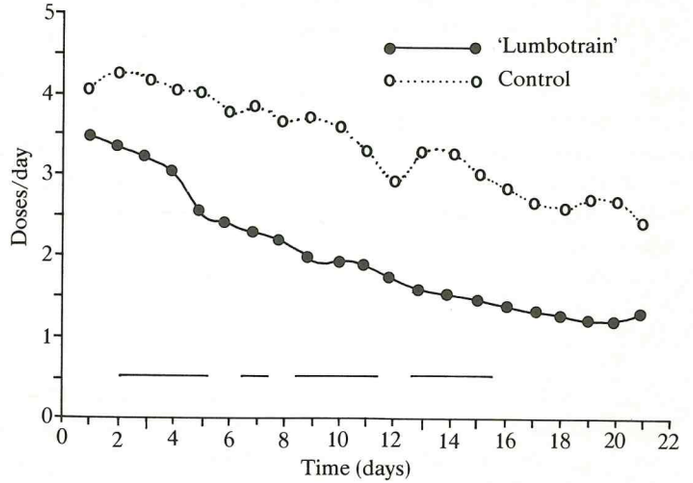
The mean 'overall assessment' scores were 4.17 units in the 'Lumbotrain' group

Figure 2. Percentage of patients able to work normally on entry and during the study period



Note: the horizontal lines denote the periods when there were significant differences between treatments

Figure 3. Analgesic consumption during the study period: mean number of doses per day



Note: the horizontal lines denote the periods when there were significant differences between treatments

and 3.56 units in the control group ($p<0.002$). Some degree of improvement (score 3 or above) was seen in 106 (95%) of the 111 patients in the 'Lumbotrain' group, as compared with 79 (77%) of the 103 in the control group ($p<0.0002$).

At the end of the trial, 92 (89%) of 103 patients in the 'Lumbotrain' group were described as 'normal' or 'near normal', whilst this was only true of 63 (68%) of 92 in the control group ($p<0.002$).

Patients' comments on 'Lumbotrain'

A total of 103 (94%) of the 109 patients in the 'Lumbotrain' group who commented did so positively. Four (4%) patients considered that the back support was uncomfortable in some way, whilst 2 (2%) said that it caused itching; in none of these 6 cases did the use of 'Lumbotrain' have to be discontinued. No patient experienced any other problems with wearing 'Lumbotrain'.

Discussion

It would be unrealistic to expect that a rigorous 'blind' methodology, theoretically desirable, could be used for a trial involving a product of the nature of the back support studied. An attempt was made, therefore, to minimize any resulting bias by carrying out a study with a large patient population and by placing the greatest emphasis on daily self-assessments by patients in their own houses away from any direct influence of the participating investigators. Whilst it must be accepted that the wearing of a support such as 'Lumbotrain' 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 less opportunity, therefore, for systematic bias to occur in the patients' self-assessments than could have been the case with investigator-involved assessments because inevitably the investigator was assessing patients from both treatment groups.

Bearing these comments in mind, it is interesting to note that the results of this trial involving 216 patients with non-specific low back pain have demonstrated a very clear difference between treatment groups in relation to virtually all of the indices of disease considered. In fact, the only assessment variable which failed to show a significant difference in favour of 'Lumbotrain' was the measurement of back movement; this is an assessment which is notoriously difficult and inaccurate and one which was only undertaken in approximately half of the patients. In terms of all other indices of efficacy, 'Lumbotrain' resulted in significantly greater improvement, significantly more rapid improvement and improvement in significantly more patients. Significantly more patients in the 'Lumbotrain' group became able to work normally, and this return to normal working occurred more rapidly than in the control group. Nearly all of those patients who wore the 'Lumbotrain' support commented favourably upon it, with a minimal number of reports of mild discomfort or irritation – in no case such as to prevent the continued use of the product.

In conclusion, this trial has demonstrated that, in patients with 'non-specific' low back pain, the use of a 'Lumbotrain' back support increases the speed and extent of alleviation of symptoms compared with conventional management, increases the speed at which patients can return to normal work and is very acceptable to patients. 'Lumbotrain', therefore, should be considered as a possibly valuable aid in the management of all patients with such disorders.

Acknowledgements

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