

**"Efficacité de la contention lombaire souple par la ceinture de soutien *Thuasne Lomba-Cross Activity*® dans le traitement de la lombalgie subaiguë".**

**Effectiveness of flexible lumbar support provided by the *Thuasne Lomba-Cross Activity*® support belt in the treatment of subacute low back pain.**

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## **Résumé**

**Objectifs** Evaluer les effets du port d'une ceinture de contention lombaire chez le lombalgique à partir de critères d'efficacité cliniques (capacités fonctionnelles et douleur) et économiques.

**Population** 197 patients souffrant d'une lombalgie subaiguë suivis par 44 médecins généralistes pendant 90 jours.

**Méthode** Etude ouverte prospective randomisée multicentrique comportant un groupe de patients traités avec une *ceinture Lomba-Cross Activity*® (GC) et un groupe témoin (GT). Le critère clinique principal est la récupération fonctionnelle évaluée avec l'échelle EIFEL. Le critère économique principal est le coût des traitements associés.

**Résultats** Le score EIFEL a diminué de  $5,4 \pm 4,16$  pour le GC *versus*  $4,0 \pm 4,32$  pour le GT ( $p=0.022$ ) entre J0 et J30 et de  $7,6 \pm 4,48$  pour le GC *versus* de  $6,1 \pm 4,73$  pour le GT ( $p=0.023$ ) entre J0 et J90. Une évolution favorable de l'EVA a également été notée en faveur du GT aux dates correspondantes. Il existe une différence significative de l'évolution de la consommation médicamenteuse entre le GC et le GT en faveur du GC sur les périodes J0-J30 et J0-J90 avec un effet identique sur les autres traitements et sur le coût total par patient.

**Discussion** Le port d'une ceinture *Lomba-Cross Activity*® dans la lombalgie subaiguë améliore significativement l'état fonctionnel (score EIFEL) et la douleur (EVA). Il diminue la consommation médicamenteuse et les coûts médicaux à 30 et 90 jours.

Cette étude souligne l'intérêt d'une approche non pharmacologique en association à l'approche classique dans le traitement de la lombalgie.

**Mots clefs** Lombalgie. Ceinture lombaire. Douleur. Evaluation fonctionnelle. Evaluation économique.

## **Effectiveness of flexible lumbar support provided by the *Thuasne Lomba-Cross Activity* support belt in the treatment of subacute low back pain**

### **Abstract**

#### **Objective:**

To evaluate the effects of a flexible lumbar belt in low back pain treatment based on criteria of clinical effectiveness (functional capacity and pain) and economic benefit.

#### **Patients**

197 patients suffering from subacute low back pain and treated for 90 days (follow-up period) by 44 general practitioners.

#### **Methods:**

A randomized, multicentric, prospective, controlled study with two groups: one patient group treated with a *Lomba-Cross Activity*® lumbar belt (TG) and a control group (CG). The main clinical evaluation criterion is physical recovery evaluated with the EIFEL scale. The main economic criterion is the cost of associated treatment.

#### **Results:**

The EIFEL score reduced by  $5.4 \pm 4.16$  for the TG *compared with*  $4.0 \pm 4.32$  for the CG ( $p=0.022$ ) between D0 and D30 and by  $7.6 \pm 4.48$  for the TG *compared with*  $6.1 \pm 4.73$  for the CG ( $p=0.023$ ) between D0 and D90. A favourable change in the Visual Analogic Scale (VAS) was also noted for the TG over the corresponding dates. A significant difference exists, in favour of the TG, between the change in medication intake of the TG compared to the CG over the periods D0-D30 and D30-D90 and with an identical effect on other treatments and total costs per patient.

#### **Conclusion:**

Wearing a *Lomba-Cross Activity*® lumbar belt for subacute low back pain significantly improves the functional status (EIFEL score) and pain suffered (VAS). It reduces medication intake and medical costs at 30 and 90 days. This study emphasises the benefit of a non-pharmacological approach in conjunction with the classical approach to low back pain treatment.

#### **Key words:**

Low back pain. Lumbar belt. Pain. Functional evaluation. Economic evaluation.

## **I - INTRODUCTION**

Lumbago (low back pain) is the third most common cause of disability and is the most common reason for seeking medical consultation due to pain. 70 to 80% of the French suffer or have suffered from it. It has a considerable socio-economic impact on modern society: in France, "back pain" is the cause of 110 000 cases of sick leave (3.5 million days). Its annual cost is estimated to be 2.3 billion euros. Lower back pain is responsible for 13% of accidents at work with work absence: it is the main cause of sick leave and disability (1-3)

Low back pain treatment requires a combination of medication and non-medication therapies, adapted to the different stages of development (4). With or without a medical prescription, wearing a lumbar orthosis is an alternative to medical treatment. On the other hand, both physiopathological and clinical assessment remains difficult and is subject to controversies (4-5), several recently published journals (6-9) point out methodological weaknesses (insufficiently conclusive, poorly documented co-interventions, poorly measured patient compliance...).

## **II – OBJECTIVES**

The main objective is to assess the effect of a manufactured, flexible lumbar belt on the functional state and intensity of the low back pain suffered during subacute, non-specific low back pain, with follow-up monitoring over 90 days.

### Clinical effectiveness criteria

The **main** criterion is the *speed of functional recovery according to the Roland-Morris scale (10) validated in France (EIFEL scale [11-12])*, assessed after 30, 60 and 90 days.

The **secondary** criteria are:

- change in pain (measured on the Visual Analog Scale [VAS] of 100 mm).
- the number of days on which analgesics, anti-inflammatory drugs, gastroprotectants and/or muscle relaxants.
- recourse to other non-medication treatments, including consultations and hospitalizations.

### Economic efficiency criteria

The main criterion was the cost of the aforementioned medications

The secondary criterion was the average total cost of treatment for the patient during the 3 months of the study, with regard to their reimbursement by the health insurance system.

## **III - METHODOLOGY**

The method used involves an open, prospective and randomised, multicentric clinical and economic study involving 210 patients suffering from subacute low back pain with a 3-month longitudinal follow-up. This *pragmatic trial* aims to compare the effectiveness and cost of two therapeutic studies with two groups of 105 subjects, each of which received medication chosen by the investigating physicians, and subdivided as follows:

- one group of patients treated with a *Thuasne "Lomba-Cross Activity®" lumbar belt* (Test Group - TG).

- a control group (CG) of patients treated *without a lumbar belt*.

The TG patients' compliance regarding wearing of the belt was measured as well as their satisfaction. The CG patients were asked similar questions in order to confirm they followed the instruction *not* to wear the belt during the study.

The trial period, initially fixed at 3 months, was extended to 12 months to allow for the difficulties in recruiting participants. The patients were assigned to a group by randomization of blocks of six by means of a vocal server (AREMIS Consultants). The doctors were given the opportunity to include two additional patients (randomisation by block of 2).

The size of the sample was fixed at 210 patients (105 in each group) after which the estimates were carried out from the sensitivity thresholds of the EIFEL score (difference of 2 points in 24), with an alpha risk of 0.05 and a beta risk of 0.1 (statistical power of 90%), taking into account patient compliance (25% increase).

## **Population**

**Inclusion criteria:** subjects between 20 and 60 years of age, of both sexes, with an initial or recurrent episode of *subacute* non-specific low back pain, defined as having *a duration of 1 to 3 months*. The subjects were informed about the study and signed a consent form, which was explained to them first. The study was approved by the ethics committee (CCPPRB Rhône-Alpes Loire N° 2004-13).

**Non-inclusion criteria:** subjects with low back pain:

- with an inflammatory, tumoural or infectious cause  
with pain irradiating beyond the knee and/or accompanied by neurological signs (sciatica...).
- which is a side effect of an accident at work.
- with history of spinal arthrodesis or low back pain during the previous 6 months
- have worn a lumbar belt during the last 6 months.
- pregnancy.
- with contra-indications to analgesics and/or NSAID.

-associated with a chronic cardiac or respiratory complaint or cognitive disorders.

### **Type of intervention**

The investigating physician issued the persons in the TG with a *Lomba-Cross Activity belt*® (adapted to their morphology) and instructions for use (wear during the whole day for the whole period of the trial). The CG persons were not issued with the belt during the study, but could use one after the end of the study.

The remaining treatment is left to the discretion of the investigating physician.

### **Tested device**

The *Lomba-Cross Activity*® is a reinforced lumbar belt for posture support. This is a class 1 medical device, «CE» mark, in conformance with Directive 93/42/EEC and the French social security specifications, under the code LPPR 2001 E 00 022. Made from textile under the Oekotex label (certification to ISO 9001, version 2000); it comprises:

- a lumbar pad including four conformable aluminium support stays;
- an aerated elastic base strap for postural support made of patented *Combitec*® fabric (breathable, therefore enables removal of perspiration) ;
- and an over belt of the same strength, cross-wise at lower back level, enables the pressure exerted to be adjusted to the body's position;

### **Typology of the investigators**

The investigating physicians are independent general practitioners. Of the 757 practitioners approached in 2 waves, 61 of them (8%) agreed to participate in the study and 44 (5.8%) of them became active centres. They were able to consult an information centre throughout the whole study.

### **Assessment procedures**

Patients joined the study over a period of 12 months, from January to December 2005. Following a detailed initial visit (D 0), each patient returned for a consultation on D30 (+/-3 days) and D90 (+/-3 days). An intermediate assessment by means of a telephone interview took place on D 60. The data was made anonymous and was regularly sent to an analysis centre (AREMIS Consultants).

The assessment parameters applied were:

- on D 0, the socio-professional data (age, sex, weight, height, occupational and marital status, level of education), way of life (tobacco, alcohol), physical and occupational activities, general

state of health, comorbidities and personal medical history, particularly concerning lumbar problems.

-the following was carried out on each visit (D 30 and D 90):

-measurement of the score on the EIFEL scale (self-assessment questionnaire on the functional impact of the back ache – 24 questions) (10-11-12) and of the VAS pain score (13)

-an assessment of the wearing of the belt (patient compliance; an evaluation of the discomfort /comfort/convenience and satisfaction index) and use of treatments since the last visit.

-During the phone interview on D 60, a questionnaire enabled assessment of wearing of the belt and the use of treatments since the last visit.

**Valuation of the costs:** this involves the medical costs incurred during the 3 months since joining the study, as well as the non-medical costs (lost work days).

### **Statistical analysis**

The analysis was performed on two populations:

- the "intention to treat" (ITT) population: all patients included in the study, regardless of whether they followed the recommendations to wear the belt or not.

- the "per-protocol" (PP) population: all patients from the ITT population who wore the belt at least once a week for the duration of the follow-up monitoring (TG) or who never wore the belt (CG).

The analysis covers both clinical and economic data: descriptive analysis of the population in the two groups; variance analysis of repeat measurements to compare the efficacy criteria (EIFFEL et VAS, days on which analgesics were taken); descriptive analysis of the costs per category: medical expenditure (consultations, supplementary examinations, other treatments, medication, non-medication treatments) and non-medical expenditure (sick days). A comparative test was carried out between the two groups (t-test for the quantitative variables and chi-square test (CST) for the qualitative variables). The missing data was taken into account by applying the imputation method to the average data.

## **IV - RESULTS**

### **Population**

Of the 207 initially included in the trial, 10 had to be removed (failure to comply with the inclusion criteria: n=6; questionnaires not received on D0 n=4) so that 197 were included in the ITT population (TG n=102; CG n=95). The PP population was made up of 171 patients (TG n=90; CG n=81). Within the 2 groups, the majority of the population was male (54.8%), the average age was  $43 \pm 10.7$  years, the average weight was  $73 \pm 15.4$  kg and the average height

was  $170 \pm 8.7$  cm.

At the start of the trial, perfect homogeneity was noted between the groups (no significant differences) with respect to:

- the socio-demographic and clinical characteristics: Duration of the low back pain (49.6 days), eliciting factors (carrying a heavy load [39.6%], incorrect movements [33.5%], other physical effort [27.9%]).

- efficacy criteria: EIFEL score:  $10.2 \pm 4.34$  for the set (CG:  $10.3 \pm 4.35$ ; TG:  $10.1 \pm 4.35$ ); VAS score:  $60.3 \pm 17.9$  for the set (CG:  $60.9 \pm 17.7$ ; TG:  $59.7 \pm 18.1$ ); medication intake: 33% of the patients took at least one analgesic medication, NSAID and/or muscle relaxants.

### **Change in functional state (EIFEL score) and pain intensity (VAS)**

There is a significant difference between the change in EIFEL score and VAS in the TG and CG in favour of the CG during periods D0-D30 and D0-D90.

The EIFEL score reduced:

-by  $5.4 \pm 4.16$  for the TG *compared with* by  $4.0 \pm 4.32$  for the CG ( $p=0.022$ ) between D0 and D30

-by  $7.6 \pm 4.48$  for the TG *compared with* by  $6.1 \pm 4.73$  for the CG ( $p=0.023$ ) between D 0 and D 90 (Figure 1).

The pain intensity (VAS) reduced:

-by  $26.8 \pm 18.26$  for the TG *compared with* by  $21.3 \pm 18.70$  for the CG ( $p=0.038$ ) between D 0 and D 30.

-by  $41.5 \pm 21.49$  for the TG *compared with* by  $32.0 \pm 20.07$  for the CG ( $p=0.002$ ) between D 0 and D 90 (Figure 2).

### **Medication intake**

A significant difference between the TG and the CG in favour of the CG was noted during the periods D0-D30 and D0-D90, with a reduction in the number of subjects taking at least one medication (Table 1), as well as a reduction in all medication intake on D90 ( $p = 0.029$ ), and in the number of days on which medication was taken by D60 ( $p = 0.01$ ) and D90 ( $p = 0.001$ ).

### **Medical expenditure and recourse to non-medication treatments other than lumbar support**

The CG patients had consulted their GPs more often at D30 ( $p = 0.015$ ) and D90 ( $p = 0.014$ ). Few patients received additional examinations during the follow-up monitoring, with no significant difference between the two groups. None of the patients were hospitalised.

On the other hand, there is a significant difference in the use of non-medication treatments between the TG and CG in favour of the CG (Table 2). This difference notably involves kinesitherapy (Table 3).

### **Patient compliance and overall satisfaction of the patients**

The TG patients had worn the belt, on average and per week, 5 days at D 30, 4 days at D 60 and 3 days and 5 days respectively at D 90. In addition, the number of daily hours on which the belt was worn was 8 hours at D 30, 6 hours at D 60 and 5 hours at D 90.

The overall satisfaction with wearing the belt was judged by 90% of the patients as very good, very satisfied or fairly satisfied.

### **Total average costs**

The medication costs were much lower in the TG in all periods ( $p < 0.012$ ), as were other medical costs (consultations and additional examinations) ( $p < 0.006$ ). Sick days were rare (no difference between the two groups). Total cost per patient was significantly much lower for the TG in each of the periods ( $p < 0.024$ ) with a *difference in total average costs of 205.72 €* over the three months of the follow-up monitoring (value of the belt 36.31 €) (Table 4).

## **V - DISCUSSION**

We did not find any randomised study with at least 3 months of follow-up monitoring, which simultaneously assess the clinical and socio-economic benefits of wearing a lumbar belt on low back pain. However, three studies merit recalling.

Penrose et al. (14) assessed the benefit of a pneumatic lumbar belt in a randomised study of low back pain patients, without details of the supplementary treatment and without any study of patient compliance, with follow-up monitoring after 1 hour, then 3 and 6 weeks. The pain (algo-functional index score) reduced significantly compared to the control group; by 18% after 1 hour, by 46% after 3 weeks and by 73% after 6 weeks. The same applied to muscular strength and overall suppleness of the spine.

Valle-Jones et al. (15) report on the benefit of wearing a flexible corset in 216 patients suffering from acute low back pain in a comparative and randomised study (111 persons wearing the corset and 105 control persons), all of whom received paracetamol (1 to 4 g/day) if necessary. Whereas all the patients had improved on D 21, the clinical progress was more marked in the "corset group" compared with the "control group" ( $p < 0.002$ ), with a lower analgesic intake ( $p < 0.0001$ ). In addition, at J 21, 85% of the persons wearing the corset were able to work normally compared with 67% of the control group ( $p < 0.02$ ).

Finally, Calmels et al. (16), in a randomised, multicentric study of 36 persons with acute low back pain who wore an orthosis determined that wearing a flexible orthosis made of elastic fabric resulted in a significant reduction in pain (VAS) ( $p = 0.029$ ), in the hand-floor distance on D8 ( $p = 0.05$ ), and functional capacity ( $0.028 < p < 0.032$ ) as well as a much higher frequency of cessation of medical treatment on D 21 ( $p = 0.028$ ).

With regard to our study, the results show that wearing a *Lomba-Cross Activity*® belt by sufferers of subacute low back pain:

- significantly improved their functional state determined by means of the EIFEL score and the pain experienced determined by means of the VAS at 30 days and 90 days;
- experienced good patient compliance
- significantly reduced all medical costs after 30, 60 and 90 days.

They confirm the fact that a quality lumbar support should become an available option in the treatment of sub-acute low back pain, as already proposed following other studies concerning low back pain itself (6, 16-17), spinal mobility (18-19), intra-abdominal and intervertebral disc pressure (20), muscular activity (21-24) as well as postural and proprioceptive activity (25-26).

Other medical-economic studies must be carried out in order to better define the position of lumbar support in the treatment of sufferers of subacute low back pain, and equally chronic low back pain, for which the sometimes considerable therapeutic difficulties and main direct and indirect costs incurred are already known (in particular sick leave and disability).

## **VI – CONCLUSION**

This study provides significant results, both clinical and economic, in favour of the wearing of the *Lomba-Cross Activity*® belt in the treatment of subacute low back pain. They show an improvement in the functional state and pain compared to treatment with medication only. This treatment results in an overall reduction in medication intake and use of non-medication treatments.

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**Table 1:**

**Percentage of patients who received at least 1 analgesic drug, NSAID or spasmolytic drug, per period and per group**

<b>Periods</b>	<b>Treated group (n=102)</b>	<b>Control group (n=95)</b>	<b>p</b>
<b>D0</b>	33.0	32.6	0.917
<b>D0-D30</b>	66.7%	78.9%	<b>0.039</b>
<b>D30-D60</b>	49.0%	65.3%	<b>0.020</b>
<b>D60-D90</b>	34.3%	56.8%	<b>0.002</b>

**Table 2:**

**Percentage of patients who received at least one non-medication treatment other than wearing a lumbar belt, per visit and per group**

<b>Visits</b>	<b>Total (n = 196)</b>	<b>Belt group (n = 102)</b>	<b>Control group (n=95)</b>	<b>P</b>
<b>D30</b>	32.1%	22.5%	42.6%	<b>0.003</b>
<b>D60</b>	26.2%	16.8%	36.2%	<b>0.002</b>
<b>D90</b>	17.8%	9.2%	27.2%	<b>0.001</b>

**Table 3:**

**Percentage of patients who had at least one kinesitherapy session, per visit and per group**

<b>Visits</b>	<b>Total (n = 196)</b>	<b>Belt group (n = 102)</b>	<b>Control group (n=95)</b>	<b>P</b>
<b>D30</b>	28.1%	19.6%	37.2%	<b>0.006</b>
<b>D60</b>	23.1%	15.8%	30.9%	<b>0.013</b>
<b>D90</b>	16.2%	8.2%	25.0%	<b>0.002</b>

**Table 4:**

**Total costs during the 3 months of the follow-up monitoring (in €): Health insurance perspective**

<b>Variable</b>	<b>Total Population (n=197)</b>	<b>Treated group (n=102)</b>	<b>Control group (n=95)</b>	<b>p</b>
<b>Total costs</b>	179.99 ± 522.63	80.79 ± 158.52	286.51 ± 721.38	<b>0.005</b>