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Effectiveness and cost of the lumbar support
Lomba-Cross Activity®

Thuasne

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Effectiveness and cost of the lumbar support

Summary

The "effectiveness and costs of the lumbar support – Lomba-Cross Activity®" study is an open, multi-centric, prospective and randomised clinical and economic study of the Lomba-Cross Activity® lumbar belt and a control group in the treatment of subacute low back plain with longitudinal follow-up monitoring lasting 3 months.
The population studied was made up of patients aged 20 to 60 years suffering from subacute low back pain who consulted a general practitioner about their complaint.

The main objective of the study was to assess the effectiveness of the Lomba-Cross Activity® lumbar belt in the treatment of patients suffering from subacute low back pain as well as measuring the impact of the lumbar support on low back pain patients' use of treatments and in particular treatment with analgesics, anti-inflammatory agents and myorelaxants. Therefore, this study aimed to compare the effectiveness and costs of two therapeutic strategies in the treatment of subacute low back pain over a period of 3 months, i.e.:

- One group of patients treated by means of the Lomba-Cross Activity® lumbar belt, the other treatments were left to the discretion of the investigating physician.
- The second group of patients were given the usual treatments for low back pain as judged appropriate by the investigating physician (with the exception of a lumbar belt).

Three efficacy criteria were used:

- Comparison of the two treatment groups in terms of the speed of functional recovery measured over three months using the Roland-Morris scale validated in France (Eifel scale) – which constitutes the main efficacy criteria
- Comparison of the two treatment groups in terms of change in pain measured with the help of a visual analog scale (VAS) of 10 cm
- Comparison of the two treatment groups in terms of the number of days on which they took an analgesic, anti-inflammatory agent and/or a myorelaxant

The main economic criteria was based on assessment of the cost of medication (analgesic, anti-inflammatory agent and/or myorelaxant). Comparison of the two groups of patients in terms of the total average costs per patient was the secondary economic criteria.

In order to take into account any possible "dose" effect on the clinical and economic results obtained, the patients in the group with lumbar belt were asked questions concerning patient compliance in wearing the lumbar belt as well as questions regarding their satisfaction. The control group was asked the same type of questions to confirm their compliance with the instruction not to purchase or wear a lumbar belt for the whole duration of the study.

Each practitioner had to consecutively enrol the first 6 patients who satisfied the inclusion and non-inclusion criteria during the set inclusion period. Initially 3 months, this was extended to compensate for the difficulties in recruiting patients encountered during the study and in total lasted 12 months. The patients were assigned to one group or another by means of randomisation of a block of 6 by providing a vocal server. The physicians who had enrolled their 6 patients in the study, were able to enrol two additional patients. These latter patients were randomised in a block of two.

Apart from the inclusion visit (D0), the patients had to be seen in consultations on three occasions: after 1 month ± 3 days (D30) and after 3 months ± 3 days (D90). An intermediate contact was realised after 2 months ± 3 days (D60).

The analyses were carried out on the "intention to treat" population as allowed for in the protocol.

Forty four general practitioners of the 61 who agreed to participate enrolled at least 1 patient in the study.

In total, 207 patients were randomised: 106 belonged to the "belt wearing" group and 101 to the (experimental) control group.
However, 10 patients (4 in the belt group and 6 in the control group) were withdrawn from the study because they failed to adhere to the inclusion criteria (breach of protocol)
So the remaining 197 patients correspond to the intention to treat population (ITT), which is defined as "all randomised patients fulfilling the inclusion and non-inclusion criteria regardless of whether they complied with the recommendations relating to wearing or not wearing the lumbar belt".

The majority of the population of both groups was male (55%) and the average age was 43 years.

Analysis of the clinical and socio-demographic characteristics on inclusion showed perfect homogeneity of both groups of patients (the patients in the belt wearing group and the patients in the control group):

- **Intergroup homogeneity of the characteristics**:
  - socio-demographic, way of life (consumption of alcohol and tobacco, physical activities)
  - occupational activities
  - general state of health,
  - associated pathologies,
  - personal history of low back pain

- **Intergroup homogeneity of the characteristics of the current case of low back pain**
  - Duration of the episode (49.6 days)
  - Responsible factors: carrying a heavy load (39.6%), incorrect movements (33.5%) and physical effort other than carrying a heavy load (27.9%).

- **Intergroup homogeneity of all effectiveness criteria on inclusion**
  - Eifel score: 10.2 ± 3.4
  - VAS score: 60.3 ± 17.9
  - Medication intake: at the time of inclusion in the study, 33% of the patients were currently being treated with at least one of the listed medications (analgesics, NSAID, and/or myorelaxant).

From the first month of the follow-up monitoring, but also during the whole observation period, significant differences were nevertheless observed between the group of patients with a belt and the patients in the control group, all in favour of the patients wearing the lumbar belt.

- **Change in EIFEL score**

A significant different was observed between the Eifel score of the two treatment groups, in favour of the group with belt. Indeed, more of the patients in the belt wearing group patients got better and recovered (functional recovery) more quickly than the patients in the control group. The patients essentially improved from the first month of treatment (i.e. between DO and D30) in both groups, but to a far greater extent in the group wearing the belt. This difference in functional recovery observed between the two groups at D30 continued throughout the whole follow-up monitoring of the study.

The patients more severely affected at the start benefited the most from their treatment in general, but also from wearing the lumbar belt:

- Change D0-D30: Reduction in the average EIFEL score by 5.4 (±4.16) for the group of patients with lumbar belt *compared with* 4.0 (±4.32) for the group of patients without lumbar belt (p=0.022)
- Change D0-D90: Reduction in the average EIFEL score by 7.6 (±4.48) for the group of patients with lumbar belt *compared with* 6.1 (±4.73) for the group of patients without lumbar belt (p=0.023)

- **VAS score**

The patients in the "belt wearing" group experienced a faster and more significant reduction in pain intensity than the patients in the "control" group. This difference observed between D0 and D30 remained throughout the whole duration of the study. Thus, the patients in the "belt wearing" group improved more quickly and in a more significant way with regard to the pain linked with their backache than the patients in the "control" group.

- Change D0-D30: Reduction in the average VAS score by 26.8 (±18.26) for the group of patients with lumbar belt *compared with* 21.3 (±18.70) for the group of patients without lumbar belt (p=0.038)
- Change D0-D90: Reduction in the average VAS score by 41.5 (±21.49) for the group of patients with lumbar belt *compared with* 32.0 (±20.07) for the group of patients without lumbar belt (p=0.002)

- **Medication intake**

From the first month of the follow-up monitoring, the number of patients with at least one treatment with medication from the list increased for both groups and then reduced throughout the whole of the follow-up monitoring thereafter. However, whichever period is considered, the patients with belt who took at least one product from the list was significantly lower and they took significantly fewer of them than the patients in the control group; this difference increased with time.

- **Recourse to treatment**

– More non-medication treatments over the 3 periods in the control group (without belt)
– No hospitalisation observed
– No significant difference between the groups as regards consultations and examinations & tests, whatever the visit

- **Cost estimation**

– The average costs of medication intake were significantly lower in the experimental group (with belt) over all periods
– A similar trend occurred for the average total medical costs and the average total costs.
– A different in total average costs (from the perspective of the health insurance - AM) per patient between the two groups accumulated over the three months of 2O5.72 €
    - Comparable with the unit cost of a Lomba-Cross Activity® lumbar belt (from perspective of AM) = 36.31 €

In addition, apart from these favourable results associated with wearing the lumbar belt, we noted:

– Good patient compliance (wearing the belt) which was reduced over time parallel with the improvement in the patient's condition
– Overall satisfaction with wearing the belt is very good
    ↳ ~ 90% of the patients were very satisfied or fairly satisfied with their belt. Satisfaction tended to increase during the follow-up maintenance.

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1. Introduction

Low back pain is a very frequent symptom in industrialised countries. French studies estimate that 70% of adults suffer or have suffered from low back pain during their life (1), this proportion varies between 60 and 90% in industrialised countries (2-3). Moreover, the frequency of low back pain has increased constantly and quickly for the past 40-50 years; in France it tripled between 1982 and 1992 (4).
In 1998, back complaints accounted for 6.9% (5-6) of consultations with physicians in cities; the second highest reason for seeking consultation (3). In 1990, low back pain also accounted for 13% of sick leave (110 000) and was thus the main cause of sick leave and the main cause of complaints limiting activity in under 45 year olds (3,7).

Low back pain is a symptom and not a sickness. It can be defined as a pain in the lumbar region which does not radiate beyond the gluteal fold A distinction is made between symptomatic low back pain, which indicates spinal complaints (less than 1% of low back pain) and non-specific low back pain, i.e. all low-back pain which is not an indication of a secondary lesion caused by an infectious, traumatic inflammatory or tumoural complaint.
Non-specific low back pain accounts for a very large majority of low back pain. A distinction is made between acute non-specific low back pain (less than 4 weeks progression), subacute (between 4 weeks and 3 months progression) which accounts for most cases and chronic non-specific low back pain (longer than 3 months progression) (8).
More often than not, low back pain progression is quickly favourable within a few days, with or without treatment. Indeed, 50% of episode last less than one week and 90% less than two weeks (9). However, there is frequently a risk of recurrence (10). The recurrence rate is estimated to be between 60 and 85% (3).

All studies carried out show a considerable impact of low back pain, both in terms of direct costs (consultations, medical prescriptions) and in terms of indirect costs (repercussion on occupational activity). Indeed, in 1990, the direct cost of low back pain in France was estimated to be 1.2 billion euros (3, 11). Furthermore, in 1980 the United States of America estimated the total costs of low back pain to be 120 billion dollars of which 80% was attributable for indirect costs and 20% for direct costs (12).

There are many treatment options available for low back pain:

- medication: analgesics, non-steroid anti-inflammatory agents, muscular relaxants (Spasmolytic drugs) and antidepressants,

- "physical" treatments: traction, manipulations, back "school" (exercises and advice on posture) and kinesitherapy.

Thus, low back pain treatment tries to make the pain phase more comfortable and to sufficiently control the pain to enable fast resumption of occupational and personal activities.

The lumbar belt is part of the wide range of therapeutic (13-15) and prevention (16-18) options widely used in practice by physicians in the treatment of low back pain.
Lumbar belts act on three levels. The first level of action is biomechanical, the second is muscular and the third is subjective (Appendix 1). The expected effects of these three levels of action are of several natures: correcting malformation, reducing lumbar mobility, immobilising part of the lumbar spine, and promoting subjective effects such as the sensation of heat, massage, and placebo effect (19).

These effects are currently still the subject of debate (15-18). Indeed, recent literature was reviewed by the "Cochrane Review" (20), about the efficacy of lumbar belts in the prevention and treatment of low back pain. In the conclusion of this analysis is was reported that use of a lumbar belt as a means of preventing low back pain is not proven, current knowledge does not allow a judgement to be given on the therapeutic interest of lumbar belts in the treatment of low back pain.
Thus, we have scientific information which emphasises the therapeutic potential of lumbar belts for low back pain (20). Nevertheless, few studies have been carried out on the therapeutic efficacy of lumbar belts and, those that have been carried out are now outdated, contain contradictory results and/or are often not comparable. Furthermore, the methodological weakness of most of these studies reported in the Cochrane Review (20) (low number of subjects included, co-intervention not documented…) does not allow robust interpretation of their results and therefore does not allow assessment.

Therefore, a controlled study is necessary. This study must satisfy certain methodological requirements, in particular, according to the "Cochrane" recommendations (20): randomisation of the patients, exclusion of acute low back pain, and use of instruments for measuring efficacy which are valid, reliable and sensitive and above all, must be done in such a way to ensure patient compliance is maximised and measured.

Thuasne, which has long years of experience in the field of lumbar support, wanted to carry out such a study in order to provide convincing arguments for the clinical benefit and economic impact of using a lumbar belt in the treatment of patients suffering from subacute low back pain.

2. Objectives

2.1. Main objective

The main objective of the study was to assess the effectiveness of the Lomba-Cross Activity® lumbar belt in the treatment of patients suffering from subacute low back pain as well as measuring the impact of the lumbar support on low back pain patients' use of treatments and in particular treatment with analgesics, anti-inflammatory agents and gastroprotectants. Therefore, this study aimed to compare the effectiveness and costs of two therapeutic strategies in the treatment of subacute low back pain over a period of 3 months, i.e.:

- One group of patients treated by means of the Lomba-Cross Activity® lumbar belt, the other treatments were left to the discretion of the investigating physician.
- The second group of patients were given the usual treatments for low back pain as judged appropriate by the investigating physician (with the exception of a lumbar belt).

The characteristics and properties of the tested devices are described in detail in Appendix 2.

2.2. Research hypothesis

The Lomba-Cross Activity® lumbar belt significantly improves the symptomatic conditions of patients with subacute low back pain and significantly reduces costs incurred by the social security system for its patients' treatment and in particular the cost of medication

3. Efficacy criteria

3.1. Clinical effectiveness criterion

Two clinical effectiveness criteria were defined.

The main efficacy criteria is based on comparison of the two treatment groups in terms of the speed of functional recovery measured over three months using the Roland-Morris scale (21) validated in France (Eifel scale) (2).

This is a survey scale in the form of a self-questionnaire completed by the patient during the inclusion visit, at D30 and at D90. The speed of recuperation was evaluated based on the combination of the total difference in Eifel score over the whole follow-up monitoring period

and the distribution of this difference over the three measurement intervals between D0 and D90.

The secondary efficacy criteria were based both on the change in pain measured with the help of a visual analogic scale (VAS) of 10 cm assessed at D0, D30 and D90 as well as on the number of days on which an analgesic, anti-inflammatory agent and/or a myorelaxant was taken recorded at D0, D30, D60 and D90.

3.2. Economic efficiency criterion

The main economic criterion is based on assessment of the cost of pharmacological treatment (analgesic, anti-inflammatory agent or myorelaxant) taken by the patient.
The secondary economic criterion is based on estimate of the total average cost of treatment for the patient over the three months of the study from the perspective of the "Assurance Maladie" (health insurance company).
The cost comprises the following components: consultations and visits, additional examinations and tests, pharmaceutical intake, possible hospitalisation, other non-medication treatments (kinesitherapy, vertebral traction, etc…), as well as sick leave.

4. Patient compliance and satisfaction

The instruction given to the patients assigned to the "wearing the lumbar belt" group was to wear the belt all day during the whole duration of the study (3 months). However, in order to take into account any possible "dose" effect on the clinical and economic results obtained, on each visit the patients were asked how frequently they had worn the belt during the past weeks.
The control group was asked the same type of questions to confirm their compliance with the instruction not to purchase or wear a lumbar belt for the whole duration of the study.

The patient compliance involves assessing any dose effect. This effect was measured on the one hand by means of the frequency of wearing the belt (for the "belt wearing" group) and on the other hand by means of the personal assessment of the patients wearing the lumbar belt in terms of:

- Comfort/discomfort
- Wearing the belt and movement
- Analgesic effect
- Overall satisfaction.

5. Type of trial

The trial involves a multicentric, open, prospective and randomised clinical and economic study of the Lomba-Cross Activity® lumbar belt and control group in the treatment of low back pain with follow-up monitoring lasting 3 months

6. Methods

6.1. Studied population

The studied population was made up of patients suffering from subacute low back pain treated by a general physician.

The inclusion and non-inclusion criteria were as follows:

Inclusion criteria:

- Men or women between 20 and 60 years of age
- Treatment for an initial episode or recurring non-specific low back pain
- Episode lasting 1 to 3 months
- No contraindications to step I or step II analgesics, NSAID, benzodiazepines and thiocolchicoside
- Signing the consent form, which was explained to them first

Exclusion criteria

- Patients who have used a lumbar belt during the last 6 months,
- Patients who have low back pain irradiating beyond the knee and/or accompanied by neurological signs, including sciatica,
- Patients who have suffered from a low back pain episode during the 6 months preceding inclusion,
- Patients who had had a spinal operation during the 5 years preceding inclusion,
- Patients who have secondary low back pain due to an accident at work,
- Patients who have a history of spinal arthrodesis,
- Patients who have an unstabilised or symptomatic, chronic cardiac or respiratory complaint,
- Patients who suffer from low back pain with an inflammatory, tumoural or infectious cause
- Patients with a contraindication to step I or step II analgesics, NSAID, benzodiazepines and thiocolchicoside
- Patients who are pregnant

- Patients whose higher functions do not enable them to properly comprehend the protocol or to reliably record the data.

Exclusion of patients with a chronic cardiac or respiratory complaint was justified by the theoretical warning of the potential effect of wearing a lumbar belt on the increase in cardio-respiratory load.

6.2. Sample size

The sample size had an estimated total of 210 patients, of which 105 patients in each of the two groups.

Indeed, the number of necessary subjects was estimated in such a way to highlight a significant difference in the level of score on the functional Eifel scale between the two groups analysed.

French experience shows the natural change in score on the functional Eifel scale in patients affected by subacute low back pain is between 4 and 5 points over a period of 90 days (3 months), including a standard deviation between 3 and 4.

A difference of 2 points on the Eifel scale out of a maximum score of 24 is considered to be clinically significant.

Under these hypotheses and based on a comparison of the average changes in Eifel score between the two groups, with an alpha risk of 0.05 and a beta risk of 0.1 (statistical power of 90%) the number of patients required to show a statistically significant difference of 2 points on the scale is 84 per group, or 168 patients in total.

However, in order to take into account patient compliance issues regarding wearing of the lumbar belt reported in the literature, a 25% increase in the number of persons involved was allowed for, i.e. 105 patients per group with a total of 210 patients.

6.3. Recruitment of the patients

Recruitment of the patients was competitive and had to stop after the planned 210 patients had been recruited.

6.4. Type of intervention

The study was defined as prospective follow-up monitoring of 210 patients (105 in the "belt wearing" group and 105 in the "control" group) suffering from subacute low back pain and treated by general practitioners. Assignment to one group or the other was randomised.

6.4.1. THE TRIAL GROUP

The investigating general practitioners gave the Lomba-Cross Activity® lumbar belt to the eligible randomised patients in the intervention group. The instructions for use (wear during the whole day and over the whole duration of the trial, advice on how to adjust the belt) were issued with the belt.
A call centre was set up by Thuasne to answer all the questions asked by the patients regarding the belt. The other treatments were left to the discretion of the investigating physician.

6.4.2. THE CONTROL GROUP

The patients in the control group did not receive the belt or the associated advice. The investigating physician asked them not to purchase the belt with their own means and not to wear a lumbar belt for the whole duration of the study. Their treatment was left to the discretion of the investigating physician.
At the end of the three months of the study, if the physician considered it to be necessary, prescription of a lumbar support could be suggested to the patient. In this case it was also provided free of charge by Thuasne (at the request of the CCPPRB of Saint Etienne).

6.4.3. RANDOMISED ASSIGNMENT

Initial randomisation was carried out with a block of 6 patients, each investigating physician had to include 6 patients in the study. Later, during the course of the study, to compensate for the insufficient number of patients recruited by certain investigating physicians, the number of patients to be included by the investigating physician was increased from 6 to 8 (modification approved by the CCPPRB of Saint Etienne in March 2005 and applied from this date). Thus, all the investigating physicians who had already recruited their 6 patients were able to include an additional two patients.

On the inclusion of each patient (satisfying the eligibility criteria and after they had signed the consent form, previously explained to them), the investigating physician had to dial a green (freephone) number which connected them with a vocal server, to find out which group the patients were in.

Each investigating physician had their own access code in order to identify them to the vocal server.

6.4.4. PROVISION OF THE TESTED DEVICE

The tested device, the Lomba-Cross Activity® lumbar belt (see Appendix 2), was provided and directly delivered to the practitioners taking part in the study by Thuasne after notification had been given of fulfilment of all the necessary regulations and after the protocol had been signed as well as the agreement with the physician.

Thuasne supplied each investigating physician, before the start of the inclusions, with a complete set of the 6 available sizes of Lomba-Cross Activity® lumbar belt, as well as the instructions for use and recommendations for use. The lumbar belt had to be adjusted to each patient's waist measurement.

At each inclusion of a patient assigned to the treatment group "wearing the lumbar belt", the physician had to notify Thuasne of the reference and size issued to the patient (either by fax or by phone). In return, Thuasne then arranged for delivery of an identical belt (of the same size) to the physician in the shortest possible time by courier so that the physician could then top up their stocks and had the full range of belts ready for inclusion of the next patient.

For reasons of traceability, Thuasne was responsible for managing identification of the lumbar belts delivered and the identification of the researching physician to whom they were delivered.

At the end of the study, all unused devices were returned to Thuasne.

6.5. Recruitment of the investigating physicians

The trial was carried out by general physicians who were drawn randomly from the TVF database of CEGEDIM.

At first, CEGEDIM gave us an initial list of 300 randomly selected general practitioners from which it was planned to recruit 35 investigating physicians. To achieve this objective, all the physicians on this initial list were written to.

In order to remove difficulties encountered and to achieve our objective regarding the number of patients to be included, several actions were undertaken during the study (approved by CCPPRB of Saint Etienne), in particular writing to and recruiting new investigating physicians (to replace inactive investigating physicians) and several additional centres in order to correct the deficits in recruitment of certain centres,

Thus, during a subsequent period, a second list of 500 randomly drawn investigating physicians was applied for from CEGEDIM.

The physicians were thus written to in two sequential waves:

- September - December 2004: 300 physicians written to and recruitment of 35 general practitioners
- May 2005: 457 physicians written to and recruitment of 25 general practitioners

The physicians were written to by AREMIS Consultants who sent a fax or letter stating:

- The objectives of the study
- The criteria which had to be satisfied in order to be an investigating physician
- The tasks of the investigating physicians
- The proposed remuneration
- An acceptance or rejection slip to be returned to AREMIS Consultants

Recruitment was stopped as the number of general practitioners agreeing to participate reached 35 during the first recruitment and 25 in the second recruitment.

Participation of the investigating physician in the study required that they:

- Accept the protocol

- Agree to the remuneration
- Be capable of fulfilling the recruitment objective
- Agree to reply to the persons responsible for data management at AREMIS Consultants in order to clarify certain items and/or for completion of any missing data
- Agree to possible quality control carried out by employees of AREMIS Consultants.

In addition, each general practitioner had to send their curriculum vitae to CCPPRB in order to participate in the study.

6.6. Outline of the study

6.6.1. SEQUENCE

Over an inclusion period initially planned for 3 months (January 2005 to March 2005), the investigating physician had to include / recruit 6 patients, who consulted them during this period (irrespective of the reason), satisfied the inclusion and non-inclusion criteria and agreed to participate in the study.
In order to correct inadequacies in the number of patients included at the end of the initial inclusion period, this inclusion period was extended to 9 months during the course of the study, i.e. to a total inclusion period of 12 months (from January to December 2005), with each investigating physician given the possibility of recruiting 8 patients instead of the initially planned 6. These modifications were approved by CCPPRB of Saint Etienne on 27 May 2005.

The patients had to be seen in consultations on three occasions:

- On D0 inclusion
- On D30 +/- 3 days
- On D90 +/- 3 days

An intermediate contact was realised after 2 months ± 3 days (D60) by means of phone survey.

The investigating physician had to complete the following for each patient included in the study:

- Inform them about the trial using the information sheet and to issue them with this sheet
- Have the consent form dated and signed (with initials on all pages including the information sheet)
- Contact the dedicated vocal server to find out which group the patient belonged to

- Issue patients in the treated group with their belt and the explanatory notes and instructions for use
- Complete the questionnaires starting with the patient's medical file and by directly asking the patient during the consultation or during the telephone questioning
- Issue the Eifel questionnaire and satisfaction questionnaire to the patient during the consultation so that they could complete them directly
- Collect the questionnaires from the patients once they had been completed
- After each visit or phone questioning, return the completed observation notebooks to AREMIS Consultants in the stamped addressed envelopes provided for this purpose
- Inform Thuasne by fax using the dedicated form or by phone after each inclusion of a un patient assigned to the "wearing the belt" treatment group, the reference and size of the belt used, so that Thuasne could deliver an equivalent belt to the physician to refill their stock of belts

The number of consultations planned within the scope of this research corresponds to the rhythm of usual treatment of patients with low back pain. However, if the patient's state of health allowed and the number of necessary consultations should have been less, the additional consultations required for the study had to be paid for by Thuasne.

6.6.2. DURATION OF THE STUDY

The total duration of the study was 24 months (September 2004 - September 2006), including recruitment of the physicians, recruitment of the patients by the physicians, data management, statistical analysis and preparing the report.

6.6.3. DATA COLLECTED

The data collected during the study at D0, D30, D60 and D90, was made anonymous using a two digit centre number for the investigating physician and a ordinal number for the patients defined by the investigating physician in the chronological order in which the patients were included. The analysis was carried out in an anonymous way thanks to these codes.

During the follow-up monitoring the following information was collected:

- **An inclusion questionnaire (D0)**
  - Complete sociodemography of the patient (age, sex, height, weight, SOC, residence, etc.)
  - Way of life (physical activity, smoking, etc.)
  - General clinical state
  - Clinical condition of the low back pain
  - History of illness, previous treatments
  - Measurement of the Eifel and VAS pain scores
  - Current treatment
  - Prescribed treatment

- **A follow-up questionnaire during the visits (D30, D90)**
  - Assessment of wearing the belt since the last visit:
    - Patient compliance,
    - Assessment of discomfort, comfort etc. (satisfaction) (treated group),
  - Measurement of the Eifel and VAS pain scores
  - Use of treatments since the last visit (consultations and visits, pharmaceutical intake, additional examinations and tests, paramedical treatments, hospitalisation, sick leave)
  - Treatments prescribed resulting from the visit.

- **A follow-up questionnaire during the phone questioning (D60)**

  - Assessment of wearing the belt since the last visit:
    - Patient compliance,
    - Assessment of discomfort, comfort etc. (satisfaction) (treated group).
  - Use of treatments since the last visit (consultations and visits, pharmaceutical intake, additional examinations and tests, paramedical treatments, hospitalisation, etc)
  - Sick leave

The questionnaires are included in Appendix 3[1].

[1] Appendix 3 only contains the inclusion questionnaire and the questionnaire at D30 because the questionnaires at D90 and D60 are identical with the one used on D30, with the exception for D60, the VAS score and EIFEL questionnaire, which were not assessed as the questionnaire was completed during a phone call.

6.6.4. RECORDING INSTRUMENT – EIFEL SCALE

The EIFEL questionnaire is a questionnaire for assessing functional capacity of sufferers of low back pain. This questionnaire enables assessment of the repercussions of the low back pain on the patient's capacity to carry out activities in their daily life (21-22).
It consists of 24 questions. The patient must answer each of these questions by ticking a box which corresponds to a difficulty which is applicable to them on the day the questionnaire is completed. If on the other hand the situation described is not applicable to them, they must leave the corresponding box empty.
Each situation (question) described and ticked by the patient equals 1 point. The total Eifel score corresponds to the sum of the points obtained (i.e. number of boxes ticked). Thus, a score of 24 corresponds to the most unfavourable situation (i.e. where the patient has ticked all the boxes, this means total functional incapacity associated with their low back pain). Indeed, the higher the score the greater the repercussions of the patient's low back pain on their capacity to carry out everyday acts and vice versa. The Eifel questionnaire is included in Appendix 4.

6.7. Setting up, study follow-up monitoring and data quality

The setting up, follow-up monitoring and logistics of the study were carried out by AREMIS Consultants, a specialised service company under contract with Thuasne.
This company ensured centralised management of the different documents of the participating physicians as well as the follow-up monitoring, quality control of the data, sending correction enquiries, and data analysis.
A specific management database was developed for the follow-up monitoring of the study. This database enables the development status regularly sent to the Laboratoire Thuasne to be edited.
Randomisation by the vocal server and recording of the data was carried out by ClinInfo, a specialist firm under contract with AREMIS Consultants.

6.7.1. SETTING UP

The study was set up by an employee of AREMIS Consultants with each investigating physician recruited. This setting up was carried out by phone conference in which several investigating physicians took part or by individual phone conference if not possible otherwise.

Before these phone conferences, each physician was sent the documents (investigator kit) necessary for presenting the study so that they could find out about the study and the different documents.

The "investigator kit" contained the following

- Synopsis
- Research protocol
- Information sheet for the patients
- Consent form
- Observation book
- Sheet for identification of the patients included in the study, to be stored by the investigating physicians
- Schema of the information cycle and document flow
- General instructions on the tasks to be completed and the sequence/procedure for the follow-up monitoring
- Instructions for completing the observation books
- An administrative part containing
    - Agreement to participate
    - Confidentiality agreement
    - Financial agreement
    - Stamped addressed envelope for returning the administrative documents to AREMIS Consultants
    - Copy of the CPPRB certificate
    - Copy of the CNOM certificate

During these phone meetings a complete presentation of the study was given:

- The introduction to the study, the protocol, the observation book
- The key points for inclusion of the patients (subacute low back pain, etc.)
- Introduction to the information cycle
- Reminder of the deadlines
- Reminder of the formalities for billing fees

If the physician had taken part in the setup phone conference and still agreed to participate in the study, after their financial agreement had been received by AREMIS Consultants, they were sent 6 patient kits. These contained:

- Detachable information sheet for the patients

- Consent form
- The questionnaires
- Stamped addressed envelopes for returning each of the questionnaires (each visit)

6.7.2. DATA MANAGEMENT AND QUALITY

A quality control was carried out on the data at different levels and during the whole study. A specific database was created for the study, was tested and validated before the start of the data capture. A plan was drawn up for validating the data. This describes in detail the checks to be carried out for each variable as well as the list of approved marked corrections.

The questionnaires were checked on receipt by AREMIS Consultants. Omissions, incoherent answers or other errors were noted on the forms for requesting corrections which were sent to the physicians for correction, and were then the subject of double data capture. The data was checked during the follow-up monitoring by the team responsible for managing the data using error messages issued by the validation program. The database was frozen after the final quality control.

The investigating physicians retained the documents, source of all the clinical data, mentioned in the observation book.

6.7.3. STEERING COMMITTEE AND ETHICAL AND ADMINISTRATIVE ASPECTS

This study was carried out under the control and validation of a steering committee whose members are listed in Appendix 5.

This study falls within the scope of the "Huriet" law (on the task and responsibility of the ethics commission) was registered with AFSSAPS and was approved by CCPPRB of Saint-Etienne as well as receiving authorisation from the CNIL (see Appendix 6 notifications set).

7. Data Processing

7.1. Statistical analysis

7.1.1. ANALYSIS POPULATIONS

The statistical analyses presented in this report have been carried out on the "intention to treat" population (ITT), as planned in the research protocol, i.e.:

- **The Intention to Treat (ITT) population** corresponds to all randomised patients fulfilling the inclusion and non-inclusion criteria regardless of whether they complied with the recommendations relating to wearing or not wearing the lumbar belt.

However, analyses of the efficacy criteria were also carried out on the Per Protocol (PP) population in accordance with the following definition:

- **The Per Protocol (PP) population** contains all the patients in the ITT population whose efficacy criteria (EIFEL and VAS) were measured at D0 and D90 and who wore a lumbar belt at least once a week during the whole duration of the follow-up monitoring for the group with belt and who those who never work the belt for the group without belt

The main results of this PP analysis are included in the appendices to the report – Appendix 15.

7.1.2. ANALYSES OF THE CLINICAL STATISTICS

A descriptive analysis of the population was carried out on the two groups (frequency, average, standard deviation-type) at DO in order to compare the two populations and to identify any differences. This analysis enabled the description and comparison of the two populations and ensured their comparability at the time of their inclusion.

An assessment of wearing the belt over the three months of the follow-up monitoring with respect to patient compliance and satisfaction (in the treated group) of patients was carried out in order, in particular, to evaluate the frequency of carrying the belt and the patient's personal experience of wearing the belt. Patient compliance, evaluated in the treated group, formed the subject of a classification on several levels taking into account the daily duration during which the belt was worn and the number of day on which the belt was worn.

In addition, the efficacy analyses were carried out on the various treatment groups by means of a variance analysis with recurring measurements for comparing the main and secondary efficacy criteria.
The main and secondary efficacy criteria were as follows:

- variations in the Eifel and VAS scores
- Days of analgesic intake

In addition, a comparison was carried out on the rate of patients responding (i.e. showing an improvement in Eifel score of at least 2 points from 24).

7.1.3. ANALYSES OF ECONOMIC STATISTICS

A descriptive analysis was carried out of the costs per category for the two groups and for each of the periods (monthly).
The economic results, depending on the cost items, are also given in cumulative form for the whole of the observation period of the study, i.e. 3 months.

7.1.3.1. Economic evaluation of the medical expenditure

The economic evaluation of the items of medical expenditure was carried out with reimbursement rate (from the perspective of the health insurance ("Assurance Maladie")) and without reimbursement rate (from the perspective of the payer).
The medical costs of the treatment were calculated using the data entered in the observation book regarding the use of resources. Utilisation of the resources was evaluated from the perspective of the payer (paying body) in a broad sense, but also according to the perspective of the health insurance (taking into account the different reimbursement rates).

- **Consultations**
- **Consultations**

The economic evaluation of the consultations is based on the contractual tariffs in force in June 2006 : 20€ for consultation with a general practitioner and 25€ for a consultation with a medical specialist (rheumatologist or other)[2].
The cost of the consultation were obtained by multiplying the number of consultations by the common tariff and this for the different periods considered.

[2] http://www.ameli.fr/

The reimbursement rate paid by the health insurance is 70%.

- **Biological tests and/or investigations and auxiliary treatment**

The evaluation was carried out individually in accordance with the classification of these biological and/investigation and auxiliary treatment based on the national contractual tariffs in force in June 2006 for "lettres-clés" coefficients (Nomenclature des Actes de Biologie Médicale et Classification Commune des Actes Médicaux - nomenclature of biomedical treatments and common medical classification).

- **Medication**

The cost of medication was determined based on their commercial name, dosage, form, date on which treatment started and ended, recommended public price published in Vidal and/or Offisemp 2006.

If no information was available for the dosage, we referred to the relevant data given in Vidal. If several dosages were feasible, an average dosage was used.

A differentiation was made between several therapeutic classes in our analyses: Analgesics, NSAID or muscular relaxants and the other medications.

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- **Non-medication treatments** (acupuncture, kinesitherapy, mesotherapy, vertebral manipulation, osteopathy, physiotherapy)

Only kinesitherapy treatments are paid by the social security system. Thus, the kinesitherapy treatments were valued as follows based on the contractual tariffs in force in June 2006:

- The "lettre-clé" AMS corresponding to the "rehabilitation of orthopaedic and rheumatological disorders carried out by a masseur-kinesitherapist"
- based on the classification of an orthopaedic and rheumatological session for rehabilitation of the spine, i.e. AMS 7.

On the applicable national contractual tariff in force of the "lettre clé" (general nomenclature for professional treatment and rehabilitation and functional readaptation and general nomenclature for medical treatments UCANSS), "lettre clé" AMS = 2.04€.

7.1.3.2. Economic evaluation of the non-medical expenditure

The non-medical costs include the possible loss of work days, evaluated only from the perspective of the health insurance.

- **Sick leave**

For patients with an occupational activity, i.e. in employment, the number of days sick leave were valued based on the maximum amount of sick pay paid by the health insurance "Assurance Maladie"[3] (i.e. 43.15€ per day) and extending beyond the recommended period from which 3 days were deducted, corresponding to the waiting period not paid for by social security.

7.1.4. STATISTICAL METHODS

- Presentation of the analyses and significance test

The qualitative variables are presented with the persons involved and frequency of representation for each modality. The quantitative variables are presented with their average, standard deviation, median and extreme values.

All the descriptive analyses were carried out according to the randomisation group (wearing the lumbar belt or not) and for the whole population.

For each variable, a comparison test was carried out between the two groups studied and was presented in the table of results:

- t-test for the quantitative variables
- Chi-2 for the qualitative variables.

- Missing data

For the main criteria, the missing data (no answer) for the main clinical criteria (Eifel score and VAS score) was taken into account by applying the imputation method to the average data. For an individual, the missing data of a variable were replaced with the average of the calculated values based on the individuals in the same sub-population.

[3] http://www.ameli.fr/82/DOC/33/fiche.html?page=2

- ANOVA with repeated data

Analysis of the variance of the repeated data enables the existing correlation between different measurements (over time) for the same individual to be taken into account.
ANOVA, with repeated data was carried out using the MIXED procedure of SAS, with retention of the REPEATED option for the individuals.

The statistical analyses were carried out using the SAS software V8.02 in the Windows™ environment.

8. Results

8.1. The investigating physicians

In total, 757 general practitioners were approached in 2 waves. Of these physicians, 61 agreed to participate in the "effectiveness and cost of lumbar support" study, i.e. 8% of the centres approached.

Of the 61 centres which agreed to participate, 44 were active, that is to say they had at least 1 patient (i.e. 5.8% of all physicians initially approached to participate and 72% of all centres recruited, which agreed to participate).

The active centres were made up of 5 women (11.4%) and 39 men (88.6%).
The geographical distribution of the centres which agreed to participate and that of those who finally enrolled at least one patient are shown in Appendix 7 in comparison with the national distribution (metropolitan France without Corsica) of the general practitioners.

8.2. The populations

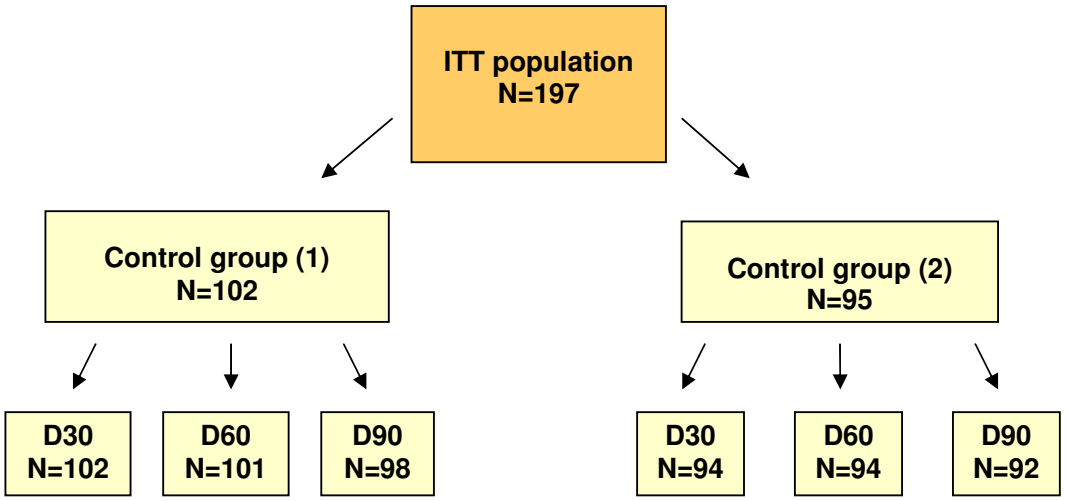
In total, 207 patients were randomised in the "effectiveness and costs of lumbar support" study. Of these 207 patients, 106 belonged to the "belt wearing" group and 101 to the (experimental) control group.
The number of patients withdrawn from the study is described as follows:

- 6 patients did not observe the inclusion criteria (breach of protocol) (2 in the belt group and 4 in the control group)
- 4 patients for whom we never received the inclusion questionnaires (2 in the belt group and 2 in the control group).

After checking with the investigating physicians that all questionnaires had been sent, then checking and validating the data, the final analysis was able to be carried out for 197 patients (102 in the belt group and 95 in the control group).

These 197 patients correspond to the intention to treat population (ITT), which is defined as "all patients fulfilling the inclusion and non-inclusion criteria regardless of whether they complied with the recommendations relating to wearing or not wearing the lumbar belt".

The diagram below shows the breakdown of this population and the number of persons in each group for each of the visits or telephone contact (on D60).



The per protocol population, according to the given definition, contained 171 persons: 90 in the group with belt and 81 in the control group, being in total 26 persons (13%) less than the ITT population.

The characteristics of this population are no different to those of the ITT population (see Appendix 8).

8.3. Characteristics of the ITT population

8.3.1. SOCIO-DEMOGRAPHIC DATA

All the socio-demographic data is summarised in Table 1.

54.8% of the study population were men (n=108). The average age of the whole population was 43 ± 10.7 years.

Regarding the marital status of the patients, a large majority of them were married or cohabitating/living together with someone (73.6% ; n=145).

Table 1: Socio-demographic characteristics

Socio-demographic data		***Belt group***	***Control group***		
Variables		**N=197**	**n1=102**	**n2=95**	**P**
Age	Average (ET)	43 (10.7)	43 (11.0)	43 (10.5)	0.910
	Median	45	47	45	
Sex	Male	108 (54.8%)	56 (54.9%)	52 (54.7%)	0.981
	Female	89 (45.2%)	46 (45.1%)	43 (45.3%)	

Table 2 shows the education, occupational status and SOC (socio-occupational category) data.

More than 50% of the patients' level of education corresponds to CAP-BEP level (CAP = vocational training certificate, BEP = vocational studies certificate) (50.8%, n=100). The majority of the patients are salaried employees (white collar staff) (31.7%, n=58) or are workers (blue collar employees) (20.2%, n=37) and are in full-time employment (68.5%, n=135).

There are no significant differences between the socio-demographic characteristics of the two groups (belt group and control group) with respect to their level of education, occupational status and SOC.

Table 2: Level of education, occupational status and SOC

Level of education, occupational status and SOC		***Belt group***	***Control group***	
Variables	**N=197**	**n1=102**	**n2=95**	**P**
Level of education				
Primary school	13 (6,6%)	8 (7,8%)	5 (5,3%)	0,761
CAP-BEP	100 (50.8%)	52 (51.0%)	48 (50.5%)	
Bac or final year of sec.ed	27 (13.7%)	15 (14.7%)	12 (12.6%)	
BAC+2	24 (12.2%)	13 (12.7%)	11 (11.6%)	
Higher than BAC+2	33 (16.8%)	14 (13.7%)	19 (20.0%)	
Occupational status				
In full-time employment	135 (68.5%)	64 (62.7%)	71 (74.7%)	0.235
In part-time employment	20 (10.2%)	12 (11.8%)	8 (8.4%)	
Retired (due to ill health)	3 (1.5%)	3 (2.9%)	0 (0.0%)	
Retired (due to age)	10 (5.1%)	6 (5.9%)	4 (4.2%)	
Unemployed	13 (6.6%)	10 (9.8%)	3 (3.2%)	
No occupational activity	11 (5.6%)	4 (3.9%)	7 (7.4%)	
School pupil/Student	2 (1.0%)	1 (1.0%)	1 (1.1%)	
Other	3 (1.5%)	2 (2.0%)	1 (1.1%)	
SOC (socio-occupational category)				
Missing/no answer	14	6	8	0.674
Farmer	5 (2.7%)	4 (4.2%)	1 (1.1%)	
Craftsmen, businessmen, comp	18 (9.8%)	8 (8.3%)	10 (11.5%)	
Executives, professionals	26 (14.2%)	12 (12.5%)	14 (16.1%)	
Managers, senior staff	29 (15.8%)	16 (16.7%)	13 (14.9%)	
(Salaried) employees	58 (31.7%)	34 (35.4%)	24 (27.6%)	
Workers	37 (20.2%)	17 (17.7%)	20 (23.0%)	

Finally, the majority of the patients (83.8% ; n=165) have general social security treatment cover and supplementary mutual insurance cover. Table 3 summarises the patients' medical costs cover.

As already noted, there are no significant differences between the two treatment groups regarding their social security cover situation.

Table 3: Patients' medical costs cover

Social security cover		***Belt group***	***Control group***	
Variables	**N=197**		**n1=102**	**n2=95**
P				
Social security cover				
Social security only	8 (4.1%)	4 (3.9%)	4 (4.2%)	0.704
Social security & mutual ins	165 (83.8%)	84 (82.4%)	81 (85.3%)	
Social security & private ins	14 (7.1%)	7 (6.9%)	7 (7.4%)	
CMU	10 (5.1%)	7 (6.9%)	3 (3.2%)	

Finally, it is important to note that there are no significant differences between the two groups, the belt wearing group and the control group, regarding their socio-demographic characteristics. ***Thus, the two groups are completely identical and comparable regarding their socio-demographic characteristics***.

8.3.2. WAY OF LIFE

No significant differences occurred between the two groups for any of the analysed variables relating to their way of life.

8.3.2.1. Consumption of alcohol/tobacco

As Table 4 shows, the majority of the patients in the study stated they were non-smokers (53.3% ; n=105).

Table 4: Tobacco consumption

Smoking		***Belt group***	***Control group***	
Variables	**N=197**	**n1=102**	**n2=95**	**P**
Smoker status				
Has never smoked	105 (53.3%)	52 (51.0%)	53 (55.8%)	0.794
Former smoker	42 (21.3%)	23 (22.5%)	19 (20.0%)	
Smoker	50 (25.4%)	27 (26.5%)	23 (24.2%)	
No. of years as smoker				
Average (ET)	15.1 (8.25)	15.6 (9.07)	14.4 (7.18)	0.463
Median 15.0	15.0	15.0		
Range	[0.0 - 38.0]	[0.0 - 38.0]	[2.0 - 30.0]	
Average number of cigarettes smoked per day				
Average (ET)	14.9 (8.72)	15.2 (9.22)	14.6 (8.15)	0.769
Median	15.0	15.0	12.0	
Range	[0.0 - 40.0]	[0.0 - 40.0]	[4.0 - 40.0]	

Almost half the patients stated they drink alcohol occasionally (47.2% ; n=93)

Table 5: Alcohol consumption

Alcohol consumption		***Belt group***	***Control group***	
Variables	**N=197**	**n1=102**	**n2=95**	**P**
Alcohol consumption status				
Has never drunk alcohol	73 (37.1%)	43 (42.2%)	30 (31.6%)	0.496
No longer drinks alcohol	10 (5.1%)	5 (4.9%)	5 (5.3%)	
Drinks occasionally	93 (47.2%)	44 (43.1%)	49 (51.6%)	
Drinks regularly	21 (10.7%)	10 (9.8%)	11 (11.6%)	
Number of years of alcohol consumption				
Missing (no answer)	6	3	3	
Average (ET)	19.3 (10.20)	19.5 (10.75)	19.1 (9.75)	0.844
Median	20.0	20.0	20.0	
Range	[0.0 - 45.0]	[0.0 - 45.0]	[3.0 - 40.0]	
Number of units of alcohol consumed per day*				
Missing/no answer		12	6	6
Average (ET)	1.7 (1.41)	1.7 (1.66)	1.6 (1.15)	0.811
Median	1.0	1.0	1.0	
Range	[0.0 - 10.0]	[0.0 - 10.0]	[0.0 - 5.0]	

** 1 unit of alcohol is about equal to a half a pint (280ml) of ordinary strength beer or cider, 1 glass of wine (125ml), 1 measure (70ml) of fortified wine (port) or 1 measure (25ml) of gin or vodka, whisky or other spirits.*

8.3.2.2. Occupational activities

A large number of the patients' occupational activity (43.7% ; n=86) is characterised by carrying heavy loads. In addition, 10.2 % (n=20) of the patients work in an environment with strong vibrations.

Table 6 shows the data concerning the patients' occupational activity.

A significant difference was observed between the two groups at the level of the "environment with strong vibrations" variable. However, this difference must be taken cautiously because in both groups it only applies to a small number of patients.

Table 6: Occupational activities

Occupational activities		***Belt group***	***Control group***	
Variables	**N=197**	**n1=102**	**n2=95**	**P**
Occupational activities				
Do they carry heavy loads?				
Yes	86 (43.7%)	48 (47.1%)	38 (40.0%)	0.097
Not applicable	28 (14.2%)	18 (17.6%)	10 (10.5%)	
Environment with strong vibrations?				
Yes	20 (10.2%)	16 (15.7%)	4 (4.2%)	**0.008 ***
Not applicable	29 (14.7%)	18 (17.6%)	11 (11.6%)	

8.3.2.3. Physical activity

Regarding physical activity, 32.5% (n=64) of all patients stated they regularly take part in one sporting activity, on average for 4.1 hours per week (standard deviation 3.1), with no significant difference observed between the two groups

Table 7: Physical activities

Physical activities		***Belt group***	***Control group***	
Variables	**N=197**	**n1=102**	**n2=95**	**P**
Regular sporting activities				
Yes	64 (32.5%)	34 (33.3%)	30 (31.6%)	0.793
No. of hours taking part in sporting activities				
Average	4.1 (3.10)	4.2 (3.41)	3.9 (2.76)	0.670
Median	4.0	4.0	3.0	
Range	[1.0 - 21.0]	[2.0 - 21.0]	[1.0 - 15.0]	

On the whole, no significant difference was observed between the two groups of patients in terms of physical activities and in the context of their occupation, with the exception of the working environment with strong vibrations which seems to occur more frequently in the group of patients with lumbar belt.

8.3.3. PATIENTS' STATE OF HEALTH

On the day they joined the study, 91.8 % (n=181) of the patients assessed their health as being good, very good or excellent.

There is no significant difference between the two treatment groups regarding the assessment of their state of health at the time of joining the study.

Table 8: General state of health

General state of health	*Belt group*	*Control group*	
Variables	**N=197**	**n1=102**	**n2=95**
P			
General state of health			
Excellent	30 (15.2%)	15 (14.7%)	15 (15.8%)	0.663
Very good	58 (29.4%)	27 (26.5%)	31 (32.6%)	
Good	93 (47.2%)	52 (51.0%)	41 (43.2%)	
Below average	15 (7.6%)	8 (7.8%)	7 (7.4%)	
Poor	1 (0.5%)	0 (0.0%)	1 (1.1%)	

As far as associated pathologies are concerned, 36.2% (n=71) of the patients have at least one associated pathology. The two most frequent associated pathologies were "metabolic disorders" for 13.7% (n=27) of the patients and "cardio-vascular system" for 11.2% (n=22). Table 9 shows the associated pathologies data in the studied population.

Il addition, there is no significant difference between the two groups at the level of presence and type of associated pathologies.

Table 9: Associated pathologies

Associated pathologies		***Belt group***	***Control group***	
Variables		**N=197**	**n1=102**	**n2=95**
P				
Associated pathology?	71 (36.2%)	38 (37.6%)	33 (34.7%)	
Missing/no answer	1	1	0	0.674
Cardio vascular system	22 (11.2%)	13 (12.7%)	9 (9.5%)	0.466
Psychiatry	9 (4.6%)	5 (4.9%)	4 (4.2%)	0.816
Respiratory system	5 (2.5%)	4 (3.9%)	1 (1.1%)	0.201
Skeleton and muscles	4 (2.0%)	2 (2.0%)	2 (2.1%)	0.943
Urinary and genital system	2 (1.0%)	1 (1.0%)	1 (1.1%)	0.960
Digestive system	11 (5.6%)	7 (6.9%)	4 (4.2%)	0.418
Cancer	0	0	0	NS
Immune system	0	0	0	NS
ENT	3 (1.5%)	1 (1.0%)	2 (2.1%)	0.519
Central nervous system	4 (2.0%)	1 (1.0%)	3 (3.2%)	0.279
Skin and appendages	4 (2.0%)	1 (1.0%)	3 (3.2%)	0.279
Metabolic disorders	27 (13.7%)	17 (16.7%)	10 (10.5%)	0.210
Other(s)	2 (1.0%)	2 (2.0%)	0 (0.0%)	0.170

28.4% of all the patients (n=56), had previously suffered from sciatica and a very small proportion, 1.5% (n=3) had already had surgical intervention on their spine.

There was no apparent significant difference between the patients regarding their personal medical histories.

Table 10: Personal medical history

Personal medical history		***Belt group***	***Control group***	
Variables	**N=197**	**n1=102**	**n2=95**	**P**
History of sciatica	56 (28.4%)	29 (28.4%)	27 (28.4%)	0.999
History of spinal surgery	3 (1.5%)	0 (0.0%)	3 (3.2%)	0.071
How long since the intervention (years)				
Average (ET)	11.7 (3.60)		11.7 (3.60)	
Median	13.4		13.4	
Range	[7.6 - 14.2]		[7.6 - 14.2]	

No significant difference was observed between the two groups of patients in terms of their general state of health, comorbidities, history of sciatica and surgical intervention on the spine.

8.3.4. PATHOLOGY DATA: ANAMNESIS AND CURRENT EPISODE

8.3.4.1. Anamnesis

A large majority of the patients (82.7% ; n=163) had already had low back pain in the past. On average, this medical history is characterised by an initial attack 8.8 years ago and an average 7 attacks in total. The previous attacks lasted an average of 1 to 3 months for 63.6% (n=105) of the patients.

Table 11: Personal history of non-specific low back pain

Personal history of non-specific low back		***Belt group***	***Control group***	
Variables	**N=197**	**n1=102**	**n2=95**	**P**
History of low back pain	163 (82.7%)	80 (78.4%)	83 (87.4%)	0.097
Years since the 1st attack				
Average (ET)	8.8 (8.62)	9.2 (9.68)	8.4 (7.43)	0.519
Median 5.7	5.7	5.7		
Range	[0.1 - 39.8]	[0.1 - 39.8]	[0.2 - 38.2]	
Years since the last attack				
Missing/no answer	4	3	1	
Average (ET)	2.0 (2.27)	1.9 (2.11)	2.1 (2.42)	0.672
Median 1.2	1.2	1.2		
Range	[0.1 - 14.2]	[0.1 - 10.3]	[0.1 - 14.2]	
Total number of attacks				
Average (ET)	7 (8.8)	7 (8.6)	6 (9.0)	0.521
Median	4	4	3	
Range	[0 - 56]	[0 - 50]	[1 - 56]	
Average duration of the attack				0.926
Less than one month	54 (32.7%)	28 (34.1%)	26 (31.3%)	
Between 1 and 3 months	105 (63.6%)	51 (62.2%)	54 (65.1%)	
More than 3 months	6 (3.6%)	3 (3.7%)	3 (3.6%)	
Attack longer than 3 months	27 (15.7%)	14 (16.1%)	13 (15.3%)	0.886

The two factors considered to be responsible for previous episodes of low back pain by the majority of the patients who had previously suffered from at least one attack were mainly "carrying a heavy load" and "incorrect movements" by 63.2 % (n=103) and 61.3% (n=100) of the patients respectively.

There is no significant difference between the two groups regarding the factor generally responsible for their low back pain.

Table 12: Factors generally responsible for these previous attacks (among the 163 patients with previous episodes)

Factors generally responsible		*Belt group*	*Control group*	
Variables	**N=163**	**n1=80**	**n2=83**	**P**
Carrying a heavy load	1 03 (63.2%)	53 (66.3%)	50 (60.2%)	0.426
Any physical effort	37 (22.7%)	18 (22.5%)	19 (22.9%)	0.952
Stress and/or anxiety	68 (41.7%)	32 (40.0%)	36 (43.4%)	0.662
Incorrect movements	1 00 (61.3%)	45 (56.3%)	55 (66.3%)	0.189
Accident	15 (9.2%)	10 (12.5%)	5 (6.0%)	0.153
Nothing in particular	28 (17.2%)	12 (15.0%)	16 (19.3%)	0.469
Other(s)	21 (12.9%)	10 (12.5%)	11 (13.3%)	0.886

78.1% (n=153) of the patients with at least one previous case of low back pain received medical treatment for their previous attacks. A slightly higher number of patients in the control group had received medical treatment for their previous episodes (72.3% in the belt group *compared with* 84.2% in the control group, p=0.044). This treatment was characterised by:

- Consultation with a physician by 74.6% of patients
- X-ray of the spine for 59.4% of the patients
- Medication intake for 72.1% of the patients
  - Analgesics I and II for 75.1% (n=148)
  - NSAID 67% (n=132)
  - Spasmolytic drugs 64% (n=126).
- Kinesitherapy for 50.8% (n=100) of the patients
- Vertebral manipulation and physiotherapy each respectively for 20.3% of the patients

No significant difference was observed between the two groups regarding the practical details of the previous medical treatment, with the exception of certain non-medication treatments which occurred more frequently in the group without the lumbar belt (control group) compared with the group of patients with lumbar belt (belt group), i.e.: vertebral manipulations (11.8% in the belt group *compared with* 29.5% in the control group, p=0,004), physiotherapy (12.7% in the belt group *compared with* 28.4% in the control group, p=0.010) and wearing a lumbar belt (4.9% in the belt group *compared with* 12.6% in the control group, p=0.037).

The details of this previous treatment of the patients according to the group of which they are a member (with lumbar belt and without lumbar belt) are shown in Appendix 9.

In addition, only 3.6% (n=7) of the patients had been hospitalised for a previous case of low back pain. These hospital stays for low back pain lasted 11 days on average.

Table 13: Other medical treatment received for previous episodes

		Belt group	***Control group***
Variables	**N=197**	**n1=102**	**n2=95** **P**
Has the patient already been hospitalised due to low back pain?			
Missing/no answer	1	1	0 0.640
Yes	7 (3.6%)	3 (3.0%)	4 (4.2%)
No	189 (96.4%)	98 (97.0%)	91 (95.8%)
Duration of hospital stay (number of nights)			
Missing/no answer	190	99	91 0.466
Average (ET)	11 (4.7)	13 (6.7)	10 (3.1)
Median	10	11	9
Range	[7 - 20]	[7 - 20]	[7 - 14]
N present	7	3	4

Finally, for 32.1% (n=63) of the patients, these previous episodes of back pain had been accompanied by an average 4 periods of sick leave with average duration 19 days. There is

no significant difference between the two groups regarding the number of periods of sick leave prescribed for their previous episodes of low back pain.

Table 14: Sick leave

Sick leave	*Belt group*	*Control group*	
Variables		**N=197**	**n1=102**
n2=95	**P**		
Has the patient already had sick leave for low back pain?			
Missing/no answer	1	1	0	0.148
Yes	63 (32.1%)	31 (30.7%)	32 (33.7%)	
Non	119 (60.7%)	66 (65.3%)	53 (55.8%)	
Not applicable	14 (7.1%)	4 (4.0%)	10 (10.5%)	
If yes, how many times?				
Average	4 (5.1)	5 (6.8)	3 (2.1)	0.183
Median	2	2	2	
Range	[1 - 34]	[1 - 34]	[1 - 10]	
Average duration of these periods of sick leave				
Average (ET)	19 (19.6)	21 (22.0)	17 (17.0)	0.389
Median	15	15	13	
Range	[5 - 120]	[5 - 120]	[5 - 90]	

There is no significant difference between the two groups regarding their previous cases of non-specific low back pain. Thus, our two groups (the group treated with the lumbar belt and the control group) are identical regarding their low back pain history.

8.3.4.2. Episode currently under treatment

The average duration of the low back pain episode for which the patients were included in the study was 49.58 days (±17.6), with no significant difference between the two groups.

The main factors responsible for this episode were: "carrying a heavy load" (39.6% ; n=78), "incorrect movements" (33.5% ; n=66) and finally "physical effort other than carrying a heavy load" (27.9% ; n=55).

No significant difference was observed between the two study groups regarding the factors responsible for the episode of low back pain for which the patients had been included in the study.

The episode of low back pain due to which the patients had been included did not differ from one group to the other.

Table 15: Characteristics of the current low back pain - responsible factor

		Belt group	*Control group*	
Variables	**N=197**	**n1=102**	**n2=95**	**P**
Duration since episode started				
Missing/no answer	1	0	1	0.990
Average (ET)	49.85 (17.627)	49.86 (18.392)	49.83 (16.857)	
Median	46.00	45.50	46.50	
Carrying a heavy load	78 (39.6%)	46 (45.1%)	32(33.7%)	0.102
Physical effort other than carrying a load	55 (27.9%)	30 (29.4%)	25 (26.3%)	0.628
Stress and/or anxiety	39 (19.8%)	20 (19.6%)	19 (20.0%)	0.945
Incorrect movements 0.338	66 (33.5%)	31 (30.4%)	35 (36.8%)	
Nothing in particular 0.308	28 (14.2%)	12 (11.8%)	16 (16.8%)	

8.4. Change in the patients' clinical condition: main and secondary clinical efficacy criteria.

8.4.1. CHANGE IN EIFEL AND VAS SCORES

8.4.1.1. Change in Eifel score

First of all, we established that on D0 the Eifel scores of the "belt wearing" group and of the "control" group were identical: 10.3 for the "belt wearing" group and 10.1 for the "control" group. During the follow-up monitoring, the functional condition of the patients in both groups improved. However, it became apparent that the differences in change in Eifel score between the two groups between D0-D30 as well as between D0-D90 are significant; both in favour of the group of patients with lumbar belt:

- Change D0-D30: Reduction in the average EIFEL score by 5.4 (±4.16) for the group of patients with lumbar belt *compared with* 4.0 (±4.32) for the group of patients without lumbar belt (p=0.022)

- Change D0-D90: Reduction in the average EIFEL score by 7.6 (±4.48) for the group of patients with lumbar belt *compared with* 6.1 (±4.73) for the group of patients without lumbar belt (p=0.023)

In addition, there was a large reduction in Eifel score between D0 and D30 for both groups of patients and this continued between D30 and D90 but to a lesser extent.
Thus, since a difference of 2 points on the Eifel scale out of a maximum score of 24 is considered to be clinically significant, the difference observed with the results of our study is therefore not only clinically significant for the two treatment groups but also between the two treatments (see Figure 1 and Table 16 on the next page).

Figure 1: Change in EIFEL score between D0 and D90

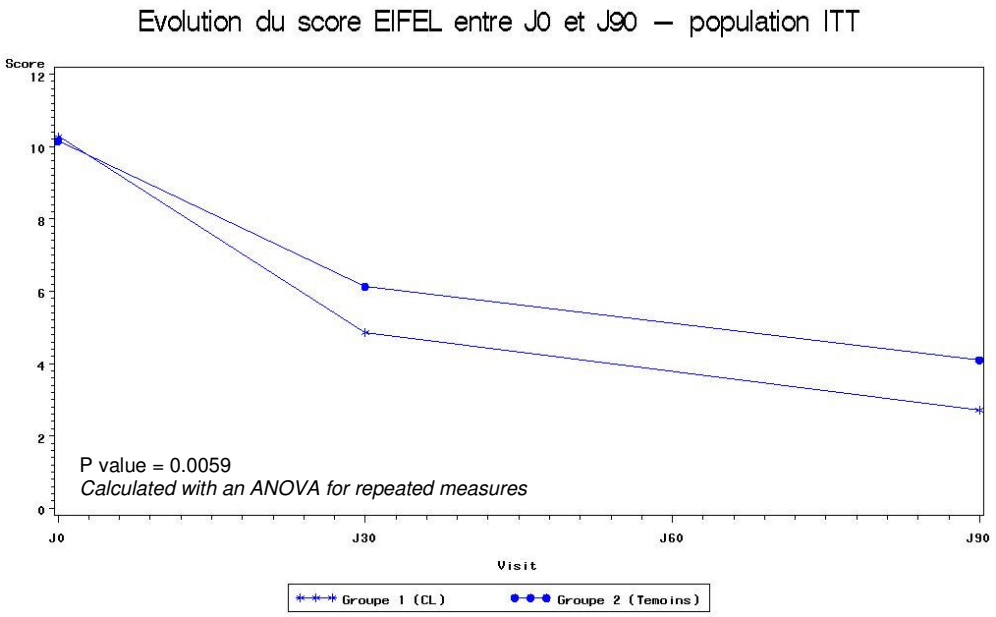


Table 16: Change in EIFEL score

Change in EIFEL score		***Belt group***	***Control group***	
Variables		**N=197**	**n1=102**	**n2=95**
P				
D0 score				
Average (ET)	**10.2 (4.34)**	**10.3 (4.35)**	**10.1 (4.35)**	0.826
Median	10.0	10.0	10.0	
Range	[0.0 - 24.0]	[1.0 - 21.0]	[0.0 - 24.0]	
Change D0-D30				
Average (ET)	**4.7 (4.29)**	**5.4 (4.16)**	**4.0 (4.32)**	**0.022 ***
Median	5.0	5.0	4.0	
Range	[-8.0 - 17.0]	[-4.0 - 17.0]	[-8.0 - 16.0]	
Change D0-D90				
Average (ET)	**6.8 (4.65)**	**7.6 (4.48)**	**6.1 (4.73)**	**0.023***
Median	8.0	8.0	6.0	
Range	[-8.0 - 18.0]	[-3.0 - 18.0]	[-8.0 - 17.0]	
Proportion responding	160 (81.2%)	89 (87.3%)	71 (74.7%)	**0.025 ***

There is a significant difference between the 2 treatment groups as far as the proportion of persons responding to the treatment is concerned, which corresponds to the patients with an improvement in Eifel score of at least 2 points out of 24 (see Table 16). The "belt wearing" group improved more quickly and over a larger number of patients than the patients in the "control" group.

In order to complete this analysis based on the EIFEL score, we carried out an analysis per class of the EIFEL score in order to examine whether there is a threshold from which patients benefit most from their treatment and in particular the lumbar belt. The classes were defined based on the distribution of the EIFEL scores of our ITT population on inclusion, taking into account the terciles. Thus, the three classes of Eifel scores defined in this way are as follows:

- EIFEL score <= at 8
- EIFEL score]8;11]
- EIFEL score > 11

Table 17, next page, shows the results of the analysis of the EIFEL score per class for each of the periods and the change between each period of the whole ITT population. Tables 18 to 20 then show the results of this analysis for each of the classes considered according to the group in which the population is a member (patients with belt and patients without a lumbar belt).

The results obtained confirm the previous results. For all the patients, regardless of the EIFEL score and group of which they are a member, the improvement was mainly achieved during the first month of treatment. This continued afterwards, but to a lesser extent.

From the separate analysis of the classes of EIFEL score it appears that the patients with a changed level or highly changed (EIFEL>8) who mainly benefit from the effect of wearing the lumbar belt. The patients making up the first class (EIFEL ≤ 8) did not show any significantly different change between the two groups.

On the other hand, as far as the two other classes are concerned from the first month a significant difference is achieved between the members of the two groups of patients in favour of the patients with belt.

The proportion of patients responding to treatment is all the more higher the higher the EIFEL score is on inclusion.

Table 17: Change in EIFEL score for the whole ITT population – analysis per class (3 classes of EIFEL scores)

	All	*Eifel<=8*	*Eifel]8 ;11]*	*Eifel >11*	
Variables	**N=197**	**n=65**	**n=65**	**n=67**	**P**
D0 score					
Average (ET)	**10.2 (4.34)**	**5.6 (2.17)**	**9.9 (0.63)**	**15.0 (2.53)**	**<0.001***
Median	10.0	6.0	10.0	14.0	
Range	[0.0 - 24.0]	[0.0 - 8.0]	[9.0 - 11.0]	[12.0 - 24.0]	
D 30 score					
Average (ET)	**5.5 (3.31)**	**4.1 (2.92)**	**5.6 (2.5)**	**6.6 (3.87)**	**<0.001***
Median	5.0	3.0	5.0	6.0	
Range	[0.0 - 17.0]	[0.0 - 14.0]	[1.0 - 14.0]	[0.0 - 17.0]	
D 90 score					
Average (ET)	**3.4 (3.30)**	**2.4 (2.52)**	**3.2 (2.98)**	**4.4 (3.93)**	**0.002***
Median	2.0	2.0	2.0	3.0	
Range	[0.0 - 16.0]	[0.0 - 16.0]	[0.0 - 13.0]	[0.0 - 15.0]	
Change D0-D30					
Average (ET)	**4.7 (4.29)**	**1.5 (2.85)**	**4.3 (2.59)**	**8.4 (4.01)**	**<0.001***
Median	5.0	2.0	5.0	9.0	
Range	[-8.0 - 17.0]	[-8.0 - 8.0]	[-4.0 - 9.0]	[-2.0 - 17.0]	
Change D0-D90					
Average (ET)	**6.8 (4.65)**	**3.1 (2.80)**	**6.7 (3.19)**	**10.6 (4.38)**	**<0.001***
Median	8.0	4.0	8.0	11.0	
Range	[-8.0 - 18.0]	[-8.0 - 8.0]	[-3.0 - 10.0]	[-1.0 - 18.0]	
Change D30-D90					
Average (ET)	**2.1 (3.02)**	**1.7 (3.25)**	**2.4 (2.54)**	**2.2 (3.2)**	0.356
Median	2.0	2.0	3.0	2.0	
Range	[-12.0 - 13.0]	[-12.0 - 13.0]	[-9.0 - 9.0]	[-6.0 - 11.0]	
Proportion responding	160 (81.2%)	41 (63.1%)	57 (87.7%)	62 (92.5%)	**<0.001***

Table 18: Change in EIFEL score according to the group in which the patients are a member among patients with an Eifel score <=8 on inclusion

	All	*Belt group*	*Control group*	
Variables	**N=65**	**n1=37**	**n2=28**	**P**
D0 score				
Average (ET)	5.6 (2.17)	5.9 (2.09)	5.1 (2.23)	0.137
Median	6.0	7.0	5.0	
Range	[0.0 - 8.0]	[1.0 - 8.0]	[0.0 - 8.0]	
D 30 score				
Average (ET)	4.1 (2.92)	4.2 (2.84)	4.0 (3.06)	0.864
Median	3.0	4.0	3.0	
Range	[0.0 - 14.0]	[0.0 - 12.0]	[0.0 - 14.0]	
D 90 score				
Average (ET)	2.4 (2.52)	2.4 (1.80)	2.6 (3.27)	0.730
Median	2.0	2.0	1.0	
Range	[0.0 - 16.0]	[0.0 - 8.0]	[0.0 - 16.0]	
Change D0-D30				
Average (ET)	1.5 (2.85)	1.8 (2.81)	1.1 (2.91)	0.341
Median	2.0	2.0	1.0	
Range	[-8.0 - 8.0]	[-4.0 - 8.0]	[-8.0 - 8.0]	
Change D0-D90				
Average (ET)	3.1 (2.80)	3.6 (2.52)	2.5 (3.07)	0.142
Median	4.0	4.0	3.0	
Range	[-8.0 - 8.0]	[-2.0 - 8.0]	[-8.0 - 8.0]	
Change D30-D90				
Average (ET)	1.7 (3.25)	1.8 (2.41)	1.5 (4.15)	0.674
Median	2.0	1.0	2.0	
Range	[-12.0 - 13.0]	[-2.0 - 9.0]	[-12.0 - 13.0]	
Proportion responding	41 (63.1%)	26 (70.3%)	15 (53.6%)	0.167

Table 19: Change in EIFEL score according to the group in which the patients are a member among patients with an Eifel score]8 ;11] on inclusion

	All	*Belt group*	*Control group*	
Variables	**N=65**	**n1=29**	**n2=36**	**P**
D0 score				
Average (ET)	9.9 (0.63)	10.0 (0.63)	9.9 (0.65)	0.760
Median	10.0	10.0	10.0	
Range	[9.0 - 11.0]	[9.0 - 11.0]	[9.0 - 11.0]	
D 30 score				
Average (ET)	5.6 (2.50)	4.7 (1.61)	6.4 (2.81)	**0.004** *
Median	5.0	5.0	5.0	
Range	[1.0 - 14.0]	[1.0 - 9.0]	[2.0 - 14.0]	
D 90 score				
Average (ET)	3.2 (2.98)	2.2 (2.32)	4.0 (3.23)	**0.015** *
Median	2.0	2.0	2.0	
Range	[0.0 - 13.0]	[0.0 - 12.0]	[0.0 - 13.0]	
Change D0-D30				
Average (ET)	4.3 (2.59)	5.3 (1.87)	3.5 (2.82)	**0.004** *
Median	5.0	5.0	5.0	
Range	[-4.0 - 9.0]	[0.0 - 9.0]	[-4.0 - 7.0]	
Change D0-D90				
Average (ET)	6.7 (3.19)	7.7 (2.60)	5.9 (3.40)	**0.020** *
Median	8.0	8.0	8.0	
Range	[-3.0 - 10.0]	[-3.0 - 10.0]	[-3.0 - 9.0]	
Change D30-D90				
Average (ET)	2.4 (2.54)	2.4 (2.68)	2.4 (2.46)	0.969
Median	3.0	3.0	3.0	
Range	[-9.0 - 9.0]	[-9.0 - 9.0]	[-3.0 - 7.0]	
Proportion responding	57 (87.7%)	28 (96.6%)	29 (80.6%)	0.051

Table 20: Change in EIFEL score according to the group in which the patients are a member among patients with an Eifel score > 11 on inclusion

	All	*Belt group*	*Control group*	
Variables	**N=67**	**n1=36**	**n2=31**	**P**
D0 score				
Average (ET)	15.0 (2.53)	15.0 (2.54)	15.0 (2.56)	0.924
Median	14.0	14.0	14.0	
Range	[12.0 - 24.0]	[12.0 - 21.0]	[12.0 - 24.0]	
D 30 score				
Average (ET)	6.6 (3.87)	5.8 (2.79)	7.7 (4.67)	**0.041** *
Median	6.0	5.0	7.0	
Range	[0.0 - 17.0]	[0.0 - 11.0]	[0.0 - 17.0]	
D 90 score				
Average (ET)	4.4 (3.93)	3.5 (3.10)	5.5 (4.52)	**0.032** *
Median	3.0	2.0	5.0	
Range	[0.0 - 15.0]	[0.0 - 13.0]	[1.0 - 15.0]	
Change D0-D30				
Average (ET)	8.4 (4.01)	9.3 (3.09)	7.3 (4.71)	**0.042** *
Median	9.0	9.0	7.0	
Range	[-2.0 - 17.0]	[2.0 - 17.0]	[-2.0 - 16.0]	
Change D0-D90				
Average (ET)	10.6 (4.38)	11.5 (3.59)	9.4 (4.98)	**0.049** *
Median	11.0	12.0	10.0	
Range	[-1.0 - 18.0]	[2.0 - 18.0]	[-1.0 - 17.0]	
Change D30-D90				
Average (ET)	2.2 (3.20)	2.3 (3.03)	2.1 (3.43)	0.879
Median	2.0	3.0	2.0	
Range	[-6.0 - 11.0]	[-6.0 - 8.0]	[-5.0 - 11.0]	
Proportion responding	62 (92.5%)	35 (97.2%)	27 (87.1%)	0.116

Thus, our study's data shows a significant difference in Eifel score between the two treatment groups in favour of the group with belt. Indeed, more of the patients in the belt wearing group patients got better and recovered (functional recovery) more quickly than the patients in the control group. The patients essentially improved from the first month of treatment (i.e. between DO and D30) in both groups, but to a far greater extent in the group wearing the belt. This difference in functional recovery observed between the two groups at D30 continued throughout the whole follow-up monitoring of the study.

The patients more severely affected at the start benefited the most from their treatment in general, but also from wearing the lumbar belt.

8.4.1.2. Change in pain intensity

First of all we were able to observe that the initial characteristics in terms of pain intensity measured using the VAS score were identical between the two treatment groups. On D30 the average VAS score was 60.9 for the "belt wearing" group compared with 59.7 for the "control" group.

As shown in Table 21, the patients' pain intensity reduced throughout the follow-up monitoring in both the groups. The change is significant among both treatment groups between D0 and D30 as well as between D0 and D90. The differences in change in average VAS score between the two treatment groups "wearing the belt" and the "control" group are significant. Thus, the patients in the "belt wearing" group experienced a faster and more significant reduction in pain intensity than the patients in the "control" group. This difference observed between D0 and D30 remained throughout the whole duration of the study. Thus, the patients in the "belt wearing" group improved more quickly and in a more significant way with regard to the pain linked with their backache than the patients in the "control" group.

- Change D0-D30: Reduction in the average VAS score by 26.8 (±18.26) for the group of patients with lumbar belt *compared with* 21.3 (±18.70) for the group of patients without lumbar belt (p=0.038)
- Change D0-D90: Reduction in the average VAS score by 41.5 (±21.49) for the group of patients with lumbar belt *compared with* 32.0 (±20.07) for the group of patients without lumbar belt (p=0.002)

These results are shown in Table 21 as well as in Figure 2.

Figure 2: Change in VAS score between D0 and D90

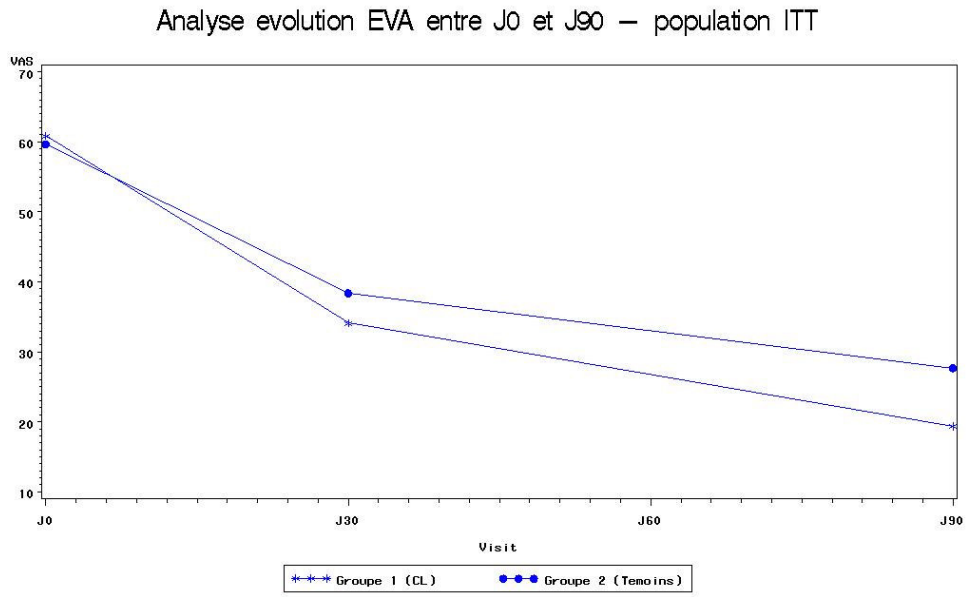


Table 21: Change in pain intensity measured with the help of a visual analogue scale (VAS)

Change in VAS score		***Belt group***	***Control group***	
Variables		**N=197**	**n1=102**	**n2=95**
P				
VAS score (D0)				
Average (ET)	60.3 (17.86)	60.9 (17.70)	59.7 (18.10)	0.633
Median	60.0	60.0	60.0	
Range	[8.0 - 100.0]	[10.0 - 100.0]	[8.0 - 95.0]	
Change D0-D30				
Missing/no answer		1	0	1
Average (ET)	**24.1 (18.63)**	**26.8 (18.26)**	**21.3 (18.70)**	**0.038 ***
Median	24.0	24.0	24.0	
Range	[-37.0 - 70.0]	[-20.0 - 70.0]	[-37.0 - 70.0]	
Change D0-D90				
Missing/no answer		1	0	1
Average (ET)	**36.9 (21.31)**	**41.5 (21.49)**	**32.0 (20.07)**	**0.002 ***
Median	40.0	40.0	38.5	
Range	[-20.0 - 89.0]	[-18.0 - 89.0]	[-20.0 - 80.0]	

Thus, the patients' pain intensity measured with the help of a visual analogue scale reduced sharply for both groups of patients during the course of the observation period. This improvement was nevertheless more marked among the patients in the group with belt (faster and more significant improvement). There difference observed between the two groups was significant.

8.4.2. CHANGE IN MEDICATION INTAKE

At the time of inclusion, the medication intake was identical between both groups. 66.0% of the whole population did not take any medication. Just over a quarter of the patients only were taking analgesics (26.9%) and around 11% of the patients were on NSAID and the same proportion of patients used spasmolytic drugs.

The general trend during the whole follow-up monitoring period of the study was towards a reduction in medication intake for both treatment groups (all classes of medication taken together) and an even greater increase in patients not taking any medication. This proportion reached 26.9% by D30 and 51.3% by D90 (Table 22).

In addition, on D90, the medication intake was significantly different between the two treatment groups. Thus, at D90, the proportion of patients treated with the lumbar belt and who did not take any medication is 60.8% versus 40% in the control group (p=0.029) (Table 22).

Table 22: Medication intake

group		*Belt group*	*Control*
Variables	**N=197**	**n1=102**	**n2=95**
P			
D0 No medication	130 (66.0%)	66 (64.7%)	64 (67.4%) 0.693
Analgesics	53 (26.9%)	29 (28.4%)	24 (25.3%)
NSAID	23 (11.7%)	12 (11.8%)	11 (11.6%)
Spasmolytic drugs	22 (11.2%)	12 (11.8%)	11 (11.6%)
Others	6 (3.0%)	4 (3.9%)	2 (2.1%)
D30 No medication	53 (26.9%)	34 (33.3%)	19 (20.0%) 0.572
Analgesics	129 (65.5%)	61 (59.8%)	68 (71.6%)
NSAID	87 (44.2%)	35 (34.3%)	52 (54.7%)
Spasmolytic drugs	72 (36.5%)	29 (28.4%)	43 (45.3%)
Others	45 (22.8%)	12 (11.8%)	33 (34.7%)
D60 No medication	82 (41.6%)	50 (49.0%)	32 (33.7%) 0.204
Analgesics	102 (51.8%)	47 (46.1%)	55 (57.9%)
NSAID	29 (14.7%)	8 (7.8%)	21 (22.1%)
Spasmolytic drugs	35 (17.8%)	13 (12.7%)	22 (23.2%)
Others	17 (8.6%)	5 (4.9%)	12 (12.6%)
D90 No medication	101 (51.3%)	62 (60.8%)	38 (40.0%) **0.029 ***
Analgesics	79 (40.1%)	30 (29.4%)	49 (51.6%)
NSAID	23 (11.7%)	4 (3.9%)	19 (20.0%)
Spasmolytic drugs	22 (11.2%)	6 (5.9%)	16 (16.8%)
Others	6 (3.0%)	2 (2.0%)	4 (4.2%)

In addition, the proportion of patients who took at least one medication on the list (i.e. "patients taking at least one analgesic, NSAID or spasmolytic drug") at the time of inclusion

was identical for both groups (33% of the whole population). During the course of the observation period, this proportion increased sharply (particularly during the first month of follow-up monitoring in both groups, only to fall afterwards). But throughout the whole follow-up monitoring, this proportion increased significantly less in the group of patients with lumbar belt compared to the control group without lumbar belt, and this during each of the periods (at D30, D60 and D90) (see table below). Thus, the group of patients with belt consumed far fewer medication treatments than the patients in the control group without belt.

Table 23: Percentage of patients with at least 1 treatment in the list (analgesics, NSAID or spasmolytic drugs)

	Belt group (n=102)	*Control group (n=95)*	**p**
D0	33,0%	32,6%	**0,917**
D30	66,7%	78,9%	**0,039***
D60	49,0%	65,3%	**0,020***
D90	34,3%	56,8%	**0,002***

* p<0.05 - significant

This result is in accordance with the analysis of the number of days of intake of these treatments. Indeed, these reduced with time and were significantly lower in the group with belt (Tables 24 and 25).

Table 24: Medication intake: number of days of <u>intake among the patients who</u> at least took analgesics, NSAID or spasmolytic drugs during the period under consideration

Variables	**Total**	***Belt group***	***Control group***	**P**
D30	*(n=143)*	*(n=68)*	*(n=75)*	
Average (ET)	**37 (25.0)**	**32 (23.9)**	**40 (25.6)**	0.062
Median	30	25	35	
Range	[2 - 105]	[2 - 103]	[3 - 105]	
D60	*(n=112)*	*(n=50)*	*(n=62)*	
Average (ET)	**27 (22.0)**	**21 (14.9)**	**32 (25.5)**	**0.010***
Median	20	16	30	
Range	[1 - 90]	[1 - 60]	[1 - 90]	
D90	*(n=89)*	*(n=35)*	*(n=54)*	
Average (ET)	**23 (18.4)**	**15 (11.8)**	**28 (20.2)**	**0.001***
Median	20	10	30	
Range	[1 - 90]	[2 - 42]	[1 - 90]	

In addition, when we look at the intake of analgesics, NSAID and spasmolytic drugs in number of days <u>among all patients</u> from the D30 visit, a significant difference is observed between the two groups, which continued throughout the follow-up monitoring up to D60 and D90.

Thus, the number of days of intake of at least one medication from the therapeutic classes of interest was significantly lower in the "belt wearing" group over all periods. This difference became more marked with time.

Table 25: Average number of days (standard deviation) of analgesic, NSAID and/or spasmolytic drugs intake among all patients

Variables	Total	*Belt group*	*Control group*	P
D30	*(n=196)*	*(n=102)*	*(n=94)*	
Average (ET)	32 (34.6)	24 (27.6)	40 (39.1)	**<0.001***
Median	21	15	29	
Range	[0 - 197]	[0 - 124]	[0 - 197]	
D60	*(n=195)*	*(n=101)*	*(n=94)*	
Average (ET)	17 (24.8)	12 (17.7)	23 (29.6)	**<0.001***
Median	6	1	10	
Range	[0 - 120]	[0 - 90]	[0 - 120]	
D90	*(n=191)*	*(n=98)*	*(n=92)*	
Average (ET)	12 (19.2)	6 (11.5)	18 (23.4)	**<0.001***
Median	0	0	7	
Range	[0 - 90]	[0 - 50]	[0 - 90]	

The details of the number of days of intake for each of the classes of interest (NSAID, analgesics and/or spasmolytic drugs) as well as the intake of other therapeutic classes are shown in Appendix 10.

On inclusion, the medication intake of the patients in both groups was identical (33% of the patients took at least one medication in the list of interest). From the first month of the follow-up monitoring, the number of patients with at least one treatment with medication from the list increased for both groups and then reduced throughout the whole of the follow-up monitoring thereafter. However, whichever period is considered, the patients with belt who took at least one product from the list was significantly lower and they took significantly fewer of them than the patients in the control group.

8.5. Patient compliance and satisfaction

8.5.1. PATIENT COMPLIANCE

The instruction to wear the belt issued for the study was that patients in the "belt wearing" group had to wear the belt on every day for the whole of the study, i.e. for the three months of the follow-up monitoring.

Thus, the patients in the "belt wearing" group wore the belt, on average and per week, 5 days at D30, 4 days at D60 and 3 days at D90. In addition, the number of daily hours on which the belt was worn was 8 hours at D30, 6 hours at D60 and finally 5 hours at D90.

With respect to this data, the fact that the patient wore their belt less often as the study progressed is an indication of the patients' clinical improvement.

Table 26: Patient compliance with wearing the belt: number of days and daily number of hours of belt wearing

Belt group	**D30 (N=102)**	**D60 (N=101)**	**D90 (N=98)**
No.. of days per week on which belt worn			
Missing/no answer	0	1	6
Average (ET)	**5 (1.6)**	**4 (1.9)**	**3 (1.8)**
Median	5	5	3
Range	[0 - 7]	[0 - 7]	[0 – 7]
No. of hours per day belt worn			
Missing/no answer		1	1 6
Average (ET)	**8 (30.1)**	**6 (3.3)**	**5 (2.8)**
Median	8	6	5

As seen in the previous table, the number of days on which the belt was worn reduced during the course of the follow-up monitoring.

Table 27: No. of days per week belt worn

Belt group	D30 (N=102)	D60 (N=101)	D90 (N=98)
0	1 (1.0%)	1 (1.0%)	1 (1.0%)
1	1 (1.0%	7 (7.0%)	14 (15.2%)
2	4 (3.9%)	11 (11.0%)	19 (20.7%)
3	12 (11.8%)	11 (11.0%)	14 (15.2%)
4	15 (14.7%)	17 (17.0%)	17 (18.5%)
5	24 (23.5%)	22 (22.0%)	16 (17.4%)
6	16 (15.7%)	15 (15.0%)	3 (3.3%)
7	29 (28.4%)	16 (16.0%)	8 (8.7%)
Missing/no answer	0	1	6

As far as the "patient compliance" of the group without belt is concerned, among the 95 patients in the control group, 7 (7.4%) wore a lumbar belt at least once during the period of the follow-up monitoring:

- 4 patients wore it at least once during the 3 periods (D30, D60 and D90)
- 2 patients wore it at least once during 2 of the 3 periods (D60 and D90)
- 1 patient wore it during one period only (D30)

→ Among the 17 "patient visits", the average number of days on which the belt was worn was 6.64±5.1 [2-20]

8.5.2. COMFORT AND DISCOMFORT: DISCOMFORT CAUSED BY WEARING THE BELT

The three main discomforts caused by wearing the belt, as shown in table 28, are "realisation of certain daily activities", "at the end of the day" and "only during certain movements" and at D30, D60 and D90. The "constant discomfort" of the belt reduced during the course of the follow-up monitoring (10.8% at D30, 4.3% at J90), as did the "discomfort at the end of the day" as well as the "in realising certain activities".

Table 28: Does wearing the belt cause discomfort?

Belt group	D30	D60	D90
Constantly	11 (10.8%) *(n = 102)*	8 (8.1%) *(n = 99)*	4 (4.3%) *(n= 93)*
At the end of the day	**27 (26.5%)** *(n= 102)*	**26 (26.3%)** *(n= 99)*	**21 (22.6%)** *(n= 93)*
At work	17 (16.8%) *(n=101)*	11 (11.1%) *(n= 99)*	16 (17.2%) *(n= 93)*
When realising certain daily activities	**37 (36.3%)** *(n = 100)*	**29 (29.3%)** *(n= 99)*	**23 (24.7%)** *(n= 93)*
Only during certain movements	**25 (24.5%)** *(n = 100)*	**19 (19.2%)** *(n= 99)*	**24 (25.8%)** *(n= 93)*
Other circumstance(s)	9 (8.9%)	10 (10.2%)	5 (5.4%)

The main effects engendered by wearing the belt and felt by around 90% of the patients were:

- Analgesic: very small reduction during the course of the follow-up monitoring (94.1% at D30 ; 92.4% at D90)
- Feeling of safety: increase during the course of the follow-up monitoring (88.2% at D30; 93.5% at D90)
- Stability of the spine: increase during the course of the follow-up monitoring (87.1% at D30; 92.5% at D90)

Table 29: Effect(s) engendered by wearing the belt

Belt group	D30	D60	D90
Analgesic	96 (94.1%) *(n= 102)*	93 (93.9%) *(n= 99)*	85 (92.4%) *(n= 92)*
Stability of the spine	88 (87.1%) *(n= 101)*	91 (92.9%) *(n= 98)*	86 (92.5%) *(n= 93)*
Feeling of safety	90 (88.2%) *(n=102)*	89 (89.9%) *(n= 99)*	87 (93.5%) *(n= 93)*
Limitation of movements	59 (57.8%) *(n=102)*	60 (60.6%) *(n= 99)*	53 (57.0%) *(n= 93)*
Relaxation/ease	64 (62.7%) *(n=102)*	66 (66.7%) *(n= 99)*	75 (80.6%) *(n= 93)*

The impression of heat, brought about by wearing the belt was felt by more than 70% of the patients wearing the belt. This feeling was pleasant for more than 80% of them.

Table 30: Impression of heat

Belt group	D30	D60	D90
Impression of heat	74 (72.5%) *(n= 102)*	79(79.0%) *(n= 100)*	72(76.6%) *(n= 94)*
Was this impression?	***(n= 73)***	***(n= 79)***	***(n= 72)***
Pleasant	61 (83.6%)	64 (81.0%)	60 (83.3%)
Unpleasant	12 (16.4%)	15 (19.0%)	12 (16.7%)

In addition, wearing the belt caused disadvantages for certain patients (Table 31). Thus, the main disadvantages felt by the patients as far as wearing their belt is concerned were as follows:

- Belt slides upwards: around 30% during the follow-up monitoring
- Unsightly/unaesthetic: reduction in this disadvantage during the study, 32.4% at D30 and 24.7% at D90
- Discomfort during work: Reduction in the discomfort during the follow-up monitoring, 28.4% at D30; 17.2% at D90.

The longer the follow-up monitoring lasted, the fewer the number of patients expressing disadvantages associated with wearing their belt.

Table 31: Disadvantages associated with wearing the belt

Belt group	D30 (N=102)	D60 (N=99)	D90 (N=93)
Belt slides up	35 (34.3%)	25 (25.3%)	31 (33.3%)
Difficult to put on	6 (5.9%)	4 (4.0%)	4 (4.3%)
Discomfort at work	29(28.4%)	20 (20.2%)	16 (17.2%)
Unsightly/unaesthetic	33 (32.4%)	28 (28.3%)	23 (24.7%)
Other(s)	13 (12.7%)	6 (6.1%)	5 (5.4%)

During the follow-up monitoring, a large majority of the patients (70 to 80%) expressed the fact that the belt **greatly** enabled them:

- To move correctly
- To maintain a good position
- To avoid painful movements
- To carry out handling work
- Physical activity

As regards "car driving" as well as "taking part in sports", wearing the lumbar belt was less appreciated. Indeed, around 30% of the patients did not appreciate wearing the belt at all during the follow-up period when driving a car; around 50% did not at all appreciate wearing the belt while taking part in sports.

Table 32: Belt and movements

Belt group	**D30 (N=102)**	**D60 (N=101)**	**D90 (N=98)**
To move correctly			
A lot	**73 (71.6%)**	**66 (66.7%)**	**75 (80.6%)**
A little	28 (27.5%)	30 (30.3%)	17 (18.3%)
Not at all	1 (1.0%)	3 (3.0%)	1 (1.1%)
To maintain a good position			
A lot	**84 (82.4%)**	**78 (78.8%)**	**80 (86.0%)**
A little	17 (16.7%)	20 (20.2%)	12 (12.9%)
Not at all	1 (1.0%)	1 (1.0%)	1 (1.1%)
To avoid painful movements			
A lot	**71 (69.6%)**	**76 (76.8%)**	**67 (72.0%)**
A little	26 (25.5%)	22 (22.2%)	24 (25.8%)
Not at all	5 (4.9%)	1 (1.0%)	2 (2.2%)
Handling work			
A lot	**71 (69.6%)**	**75 (75.8%)**	**71 (76.3%)**
A little	24 (23.5%)	17 (17.2%)	19 (20.4%)
Not at all	7 (6.9%)	7 (7.1%)	3 (3.2%)
Physical activities			
A lot	**67 (65.7%)**	**66 (66.7%)**	**67 (72.0%)**
A little	22 (21.6%)	20 (20.2%)	17 (18.3%)
Not at all	13 (12.7%)	13 (13.1%)	9 (9.7%)
While driving a car			
A lot	**34 (33.3%)**	**26 (26.3%)**	**26 (28.0%)**
A little	42 (41.2%)	37 (37.4%)	37 (39.8%)
Not at all	22 (21.6%)	32 (32.3%)	27 (29.0%)
Not applicable	4 (3.9%)	4 (4.0%)	3 (3.2%)
While taking part in sports			
A lot	**14 (13.7%)**	**10 (10.1%)**	**14 (15.1%)**
A little	27 (26.5%)	27 (27.3%)	23 (24.7%)
Not at all	52 (51.0%)	52 (52.5%)	47 (50.5%)
Not applicable	9 (8.8%)	10 (10.1%)	9 (9.7%)

Thus, with regard to data concerning comfort and discomfort associated with wearing the lumbar belt, we were able to observe that on the whole the patients were satisfied with wearing the belt. This is confirmed by the data in Table 33 since 94.7% of the patients are "fairly satisfied" or "very satisfied" at D90. This satisfaction improved during the follow-up maintenance (89.2% at D30, 93.1% at D60 and 94.7% at D90).

Thus, what is noted is a qualitative effect (the patient adapts better to wearing the belt) as well as a quantitative effect of wearing the belt.

Table 33: Overall satisfaction

Belt group	**D30 (N=102)**	**D60 (N=101)**	**D90 (N=95)**
Very satisfied	41 (40.2%)	51 (50.5%)	50 (52.6%)
Fairly satisfied	50 (49.0%)	43 (42.6%)	40 (42.1%)
Fairly dissatisfied	9 (8.8%)	5 (5.0%)	4 (4.2%)
Not at all satisfied	2 (2.0%)	2 (2.0%)	1 (1.1%)

8.6. Use of medical treatment/medical expenditure

8.6.1. CONSULTATIONS D30, D60, D90

Consultations during the study were predominantly general practitioner consultations. In total, only 4 consultations with a rheumatologist were observed at D30 and D60 and 3 at D90.

A significantly larger number of patients in the group without belt consulted their general practitioners during the course of the first month and during the third month than the patients in the group with belt (see Table 34).

On average, patients consulted a general practitioner once between each visit and in both treatment groups (see Appendix 11 for details).

Table 34: Patients with at least 1 consultation with a general practitioner at D30, D60 and D90 according to group membership

Consultation General practitioner	**Total (n= 197)**	*Belt group (n1=102)*	*Control group (n2= 95)*	P
D30	**55 (*27.9%*)**	21 (*20.5%*)	34 (*35.8%*)	0,015*
D60	**32 (16.2%)**	13 (*12.7%*)	19 (*20.0%*)	0,167
D90	**27 (*13.7%*)**	8 (*7.8%*)	19 (*20.0%*)	0,014*

* significant, p< 0.05

8.6.2. EXAMINATIONS D30, D60, D90

First of all, in general few patients were examined during the follow-up monitoring. The examinations carried out mainly tool place during the first month of follow-up monitoring (at D30). Very few of the examinations were carried out afterwards at D60 and D90.

No significant difference was observed between the two groups of patients.

Table 35: Patients with at least 1 examination at D30, D60 and D90 according to group membership

Visits	Total (n= 197)	*Belt group (n1= 102)*	*Control group (n2=95)*	*p*
D30	25 (*12.7%*)	9 (*8.8%*)	16 (*16.8%*)	0.086
D60	6 (3.1%)	3 (*2.9%*)	3 (*3.2%*)	0.929
D90	6 (3.1%)	2 (2.0%)	4 (*4.2%*)	0.363

In addition, the main examinations carried out during the study are shown in Table 36. Thus, X-rays of the spine and CBCs (complete blood count) were the main examinations made, particularly during the first month. No significant difference was observed between the two groups. Details of the average number for each of the prescribed examinations and the periods considered are given in Appendix 12.

Table 36: Distribution of examinations/tests carried out at D30, D60 and D90

	All	***Belt group***	***Control group***	**P**
D30	***(N=25)***	***(N=9)***	***(N=16)***	
X-ray of the spine	18 (72.0%)	6 (66.7%)	12 (75.0%)	0.656
Lumbar MRI	2 (8.0%)	2 (22.2%)	0 (0.0%)	**0.049** *
Computer tomography	4 (16.0%)	1 (11.1%)	3 (18.8%)	0.617
CBC	11 (44.0%)	4 (44.4%)	7 (43.8%)	0.973
Ethrocyte sedimentation rate	8 (32.0%)	3 (33.3%)	5 (31.3%)	0.915
Inflammatory protein profile	8 (32.0%)	4 (44.4%)	4 (25.0%)	0.317
D60	***(N=6)***	***(N=3)***	***(N=3)***	
X-ray of the spine	3 (50.0%)	2 (66.7%)	1 (33.3%)	0.414
Lumbar MRI	1 (16.7%)	0 (0.0%)	1 (33.3%)	0.273
Computer tomography	1 (16.7%)	1 (33.3%)	0 (0.0%)	0.273
CBC	1 (16.7%)	0 (0.0%)	1 (33.3%)	0.273
Ethrocyte sedimentation rate	1 (16.7%)	0 (33.3%)	1 (0.0%)	0.273
Inflammatory protein profile	1 (16.7%)	0 (0.0%)	1 (33.3%)	0.273
D90	***(N=6)***	***(N=2)***	***(N=4)***	
X-ray of the spine	3 (50.0%)	1 (50.0%)	2 (50.0%)	1.000
CBC	3 (50.0%)	1 (50.0%)	2 (50.0%)	1.000
Ethrocyte sedimentation rate	3 (50.0%)	1 (50.0%)	2 (50.0%)	1.000
Inflammatory protein profile	2 (33.3%)	1 (50.0%)	1 (25.0%)	0.540

8.6.3. HOSPITALISATION

None of the patients were hospitalised during the study.

8.6.4. NON-MEDICATION TREATMENTS

The proportion of patients receiving non-medication treatments reduced during the follow-up monitoring. Indeed, this proportion changed from 32% at D30 to 18% at D90.

In addition, it is important to note that from D30 and up to D60 and D90, a significant difference appeared between the "belt wearing" group and the "control group" with respect to patients' non-medication treatments. This difference became more marked as the study progressed. This means that from D30, the patients in the "belt wearing" group used less non-medication treatments and that this difference between the two treatment groups increased during the study at D60 and D90.

Table 37: Patients with at least one non-medication treatment per visit and per group.

Visits	Total (n= 196)	Belt group (n1= 102)	Control group (n2=94)	P
D 30	63 (32.1%)	23 (22.5%)	40 (42.6%)	**0.003***
D 60	51 (26.2%)	17 (16.8%)	34 (36.2%)	**0.002***
D 90	34 (17.8%)	9 (9.2%)	25 (27.2%)	**0.001***

For all patients, the most frequent non-medication treatment received throughout the study was kinesitherapy. Indeed, 28% had had at least one kinesitherapy session during the first month (at D30), 23% at D60 and 16% at D90. In each of these periods, the number of patients in the control group (without belt) who had recourse to kinesitherapy sessions was significantly higher (Table 38)

Table 38: Patients with at least one kinesitherapy session per visit and per group.

Visits	Total (n= 196)	Belt group (n1= 102)	Control group (n2=94)	P
D 30	55 (28.1%)	20 (19.6%)	35 (37.2%)	**0.006***
D 60	45 (23.1%)	16 (15.8%)	29 (30.9%)	**0.013***
D 90	31 (16.2%)	8 (8.2%)	23 (25.0%)	**0.002***

No significant difference was observed between the two groups of patients with regard to the distribution of non-medication treatments.

Table 39: Distribution of non-medication treatments at D30, D60 and D90

P	*All*	*Belt group*	*Control group*	
D30	***(N=63)***	***(N=23)***	***(N=40)***	
Vertebral manipulations	6 (9.5%)	1 (4.3%)	5 (12.5%)	0.289
Kinesitherapy	55 (87.3%)	20 (87.0%)	35 (87.5%)	0.950
Physiotherapy	2 (3.2%)	1 (4.3%)	1 (2.5%)	0.687
Infiltrations	1 (1.6%)	0 (0.0%)	1 (2.5%)	0.445
Other(s)	3 (4.8%)	2 (8.7%)	1 (2.5%)	0.266
D60	***(N=51)***	***(N=17)***	***(N=34)***	
Vertebral manipulations	1 (2.0%)	0 (0.0%)	1 (2.9%)	0.475
Kinesitherapy	45 (88.2%)	16 (94.1%)	29 (85.3%)	0.357
Physiotherapy	4 (7.8%)	2 (11.8%)	2 (5.9%)	0.461
Infiltrations	2 (3.9%)	0 (0.0%)	2 (5.9%)	0.308
Other(s)	3 (5.9%)	1 (5.9%)	2 (5.9%)	1.000
D90	***(N=34)***	***(N=9)***	***(N=25)***	
Vertebral manipulations	4 (11.8%)	2 (22.2%)	2 (8.0%)	0.256
Vertebral traction	1 (2.9%)	1 (11.1%)	0 (0.0%)	0.091
Kinesitherapy	31 (91.2%)	8 (88.9%)	23 (92.0%)	0.778
Physiotherapy	2 (5.9%)	1 (11.1%)	1 (4.0%)	0.437
Other(s)	1 (2.9%)	0 (0.0%)	1 (4.0%)	0.543

In addition, on average the patients in both groups had 6 to 7 kinesitherapy sessions between each of the visits (each month). During the follow-up monitoring, between each visit, on average the patients had 2 to 3 vertebral manipulation sessions and 5 to 8 physiotherapy sessions. No significant difference was observed between the two groups of patients at this level. (Details of the results are given in Appendix 13)

8.7. Use of non-medical treatment/non-medical expenditure Sick leave

In total, 31 periods of sick leave were prescribed for both groups during the three months of the follow-up monitoring. These 31 periods of sick leave involved 23 patients, 8 in group 1 (wearing lumbar belt) and 15 in group 2 (control group). Thus, in total 65% of the periods of sick leave prescribed were for patients in the control group. However, no significant difference was observed between the two groups of patients.

The periods of sick leave were essentially prescribed during the first month of the follow-up monitoring.

Table 40: Sick leave

Visits	*Belt group (n1=102)*	*Control group (n2=95)*	Total (N=197)	P
D 30	8	13	**21**	**NS**
D 60	0	6	**6**	**NS**
D 90	0	4	**4**	**NS**
Total	**8**	**23**	**31**	

8.8. Costs: Health insurance perspective

8.8.1. COSTS ASSOCIATED WITH MEDICAL TREATMENT

The average medical treatment cost was 11.57 € at D30. This reduced with time and reached 3.54 € at D90; indicating an improvement in the patients' state of health. This average cost was significantly lower in the "belt wearing" group and in all periods compared with the control group. This significant difference became more marked at D60 and at D90.

Table 41: Costs of medication intake in €: Health insurance perspective

	All	*Belt group*	*Control group*	
Variables		**N=197**	**n1=102**	**n2=95**
P				
D30				
Avge. (ET)	**11.57 (15.109)**	**8.96 (11.274)**	**14.36 (18.005)**	**0.012 ***
Median	9.96	6.96		4.94
Range	[0.00 - 127.36]	[0.00 - 44.90]	[0.00 - 127.36]	
D60				
Avge. (ET)	**5.21 (8.063)**	**3.43 (6.009)**	**7.13 (9.466)**	**0.001 ***
Median	2.59	1.42		0.12
Range	[0.00 - 34.92]	[0.00 - 28.42]	[0.00 - 34.92]	
D90				
Avge. (ET)	**3.54 (6.624)**	**1.87 (4.765)**	**5.33 (7.798)**	**<0.001 ***
Median	1.33	0.00		0.00
Range	[0.00 - 46.04]	[0.00 - 26.55]	[0.00 - 46.04]	

The same situation occurs for the other medical costs (consultations, additional examinations and tests and non-medication treatments) as shown in Table 42.

Table 42: Other medical costs in €

	All	*Belt group*	*Control group*	
Variables		**N=197**	**n1=102**	**n2=95** **P**
D30				
Avge. (ET)	**27.52 (40.578)**	**19.79 (36.796)**	**35.82 (42.944)**	**0.005 ***
Median	16.50	0.00	0.00	
Range	[0.00 – 217.85]	[0.00 – 152.13]	[0.00 – 217.85]	
D60				
Avge. (ET)	**15.58 (27.669)**	**10.40 (22.000)**	**21.15 (31.870)**	**0.006 ***
Median	0.00	0.00	0.00	
Range	[0.00 – 115.82]	[0.00 – 85.68]	[0.00 – 115.82]	

In total, when considering all average medical costs, the difference observed between the two treatment groups is very significant from the first month of treatment. Thus, the treatment of patients suffering from subacute low back pain differs in terms of costs for the two treatment groups. Indeed, the patients in the "belt wearing" group had less treatment and therefore their treatment is less costly than the patients in the "control" group.

Table 43: Total medical costs in €

	All	*Belt group*	*Control group*	
Variables		**N=197**	**n1=102**	**n2=95** **P**
D30				
Avge. (ET)	**39.09 (45.819)**	**28.76 (42.137)**	**50.18 (47.219)**	**<0.001 ***
Median	32.93	20.44	7.99	
Range	[0.00 – 224.77]	[0.00 – 190.40]	[0.00 – 224.77]	
D60				
Avge. (ET)	**20.80 (30.968)**	**13.83 (24.763)**	**28.28 (35.094)**	**<0.001 ***
Median	13.0	4.41	1.57	
Range	[0.00 – 125.97]	[0.00 – 100.84]	[0.00 – 125.97]	
D90				

Added up over the 3 months of the follow-up monitoring, the average total medical costs were twice as high for the patients in the group without lumbar belt (104 € compared with 50 €, p<0.001).

Table 44: Total medical costs during the 3 months of the follow-up monitoring in €: Health insurance perspective

	All	*Belt group*	*Control group*	
Variables		**N=197**	**n1=102**	**n2=95**
P				
Avge. (ET)	**76.39 (82.43)**	**50.33 (66.11)**	**104.37 (89.11)**	**<1 ***
Median	43.60			22.10
85.68				
Range	[0.00 – 327.73]	[0.00 – 293.56]	[0.00 – 327.73]	

8.8.2. COSTS ASSOCIATED WITH NON-MEDICAL TREATMENT

The average cost of sick leave of 64.18 € at D30 reduced to 14.02 € at D90 during the follow-up monitoring. The number of sick leave periods became fewer; no significant difference was observed between the two groups of patients.

Table 45: Costs of sick leave in €: Health insurance perspective

	All	*Belt group*	*Control group*	
Variables		**N=197**	**n1=102**	**n2=95**
P				
D30				
Avge. (ET)	64.18 (279.03)	**30.46 (135.85)**	**100.38 (364.78)**	0.072
Median	0.00			0.00
0.00				
Range	[0.00 – 2459.6]	[0.00 – 819.85]	[0.00 – 2459.6]	
D60				
Avge. (ET)	**25.41 (196.24)**	**0.00 (0.000)**	**52.69 (280.79)**	0.060
Median	0.00			0.00
0.00				
Range	[0,00 – 2200,7]	[0,00 – 0,00]	[0,00 – 2200,7]	
D90				
Avge. (ET)	**14.02 (119.74)**	**0.00 (0.000)**	**29.7 (171.62)**	0.089
Median	0.00			0.00
0.00				

8.8.3. TOTAL COSTS

The average total costs per patient in each of the periods were significantly lower for the belt group compared with the group without belt.

Table 46: Total costs per period in €: Health insurance perspective

	All	*Belt group*	*Control group*	
Variables		**N=197**	**n1=102**	**n2=95**
P				
D30				
Avge. (ET)	**103.26 (284.32)**	**59.22 (149.10)**	**150.56 (374.57)**	**0.024***
Median		20.49		7.99
38.70				
Range	[0.00 – 2531.2]	[0.00 – 920.59]	[0.00 – 2531.2]	
D60				
Avge. (ET)	**46.21 (204.99)**	**13.83 (24.763)**	**80.97 (290.86)**	**0.021***
Median		4.42		1.57
13.36				
Range	[0.00 – 2255.5]	[0.00 – 100.84]	[0.00 – 2255.5]	
D90				
Avge. (ET)	**30.52 (124.07)**	**7.74 (19.732)**	**54.98 (174.68)**	**0.007 ***
Median		1.13		0.00
8.74				
Range	[0.00 – 1221.5]	[0.00 – 107.69]	[0.00 – 1221.5]	

Accumulated over the three months of the follow-up monitoring, the difference in total average costs observed between the two groups of patients was 205.72 €. Taking into account the cost of the Lomba-Cross Activity® lumbar belt of 36.31€ based on the applicable health charges scale, the saving achieved by using the lumbar belt over the 3 months is around 170 euros.

Table 47: Total costs over the 3 months of the follow-up monitoring in €: Health insurance perspective

		Belt group	*Control group*
Variables		**N=197**	**n1=102**	**n2=95**
P				
Avge. (ET)	**179.99 (522.63)**	**80.79 (158.52)**	**286.51 (721.38)**	**0.005 ***
Median		45.93		22.10
89.37				
Range	[0.00 – 4733.30]	[0.00 – 976.90]	[0.00 – 4733.30]	

8.9. Costs: Perspective of paying bodies in a broad sense

The same conclusions can be made for the analysis of costs from the perspective of paying bodies in a broad sense.

Indeed, the average medical costs per patient were significantly less higher for the patients in the belt group compared with the patients in the group without belt, and in each of the periods[4].

Table 48: Total medical costs in €: Perspective of paying bodies in a broad sense

	All	*Belt group*	*Control group*	
Variables		**N=197**	**n1=102**	**n2=95**
P				
D30				
Avge. (ET)	**63.80 (73.48)**	**46.88 (68.33)**	**81.97 (74.81)**	<**0.001***
Median	33.60			15.20
57.59				
Range	[0.00 – 321.86]	[0.00 – 313.64]	[0.00 – 321.86]	
D60				
Avge. (ET)	**34.23 (51.11)**	**22.80 (41.30)**	**46.50 (57.62)**	**0.001 ***
Median	6.92			3.16
23.05				
Range	[0.00 – 212.92]	[0.00 – 170.58]	[0.00 – 212.92]	
D90				
Avge. (ET)	**27.20 (51.32)**	**12.75 (33.16)**	**42.71 (61.98)**	<**0.001***
Median	1.74			0.00
13.44				
Range	[0.00 – 260.28]	[0.00 – 185.37]	[0.00 – 260.28]	
D30+D60+D90				
Avge. (ET)	**125.23 (134.16)**	**82.43 (108.56)**	**171.19 (144.02)**	
<**0.001***				
Median	71.59			35.05
142.80				
Range	[0.00 – 513.02]	[0.00 – 487.77]	[0.00 – 513.02]	

For more details of the costs from the perspective of paying bodies in a broad sense, please refer to Appendix 14.

In addition, the main results of the analysis of the PP population are given in Appendix 15.

[4] We would like to reiterate that the periods of sick leave were not taken into account in the analysis from the perspective of paying bodies in a broad sense. The medical costs only were taken into account.

9. Conclusion

This study was carried out according to a robust methodology, that is to say:

- Randomisation of the patients
- Significant sample size
- Patient compliance is taken into account
- Free choice of other treatments by the physician: documented co-interventions and no restriction at this level

In addition, as far as we are aware, it is the only study to show the effect of the lumbar support on overall treatment of the patients.

This robust study also enables confirmation of the research hypotheses, i.e. that the Lomba-Cross Activity® lumbar belt significantly improves the symptomatic state of patients with subacute low back pain and significantly reduces the costs incurred by the social security system for the treatment of its patients and in particular the costs of medication.

All lumbar belts are not the same, it would be interesting to carry out this type of study on the other types of belt in order to demonstrate their specific benefits.

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