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# Lumbar supports in the management of non-specific low back pain: a literature review and meta-analysis

Paul Gignoux

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UNIVERSITÉ CLERMONT AUVERGNE  
UFR DE MÉDECINE ET DES PROFESSIONS PARAMÉDICALES

THÈSE D'EXERCICE

pour le

DIPLÔME D'ÉTAT DE DOCTEUR EN MÉDECINE

par

GIGNOUX, Paul

Présentée et soutenue publiquement le 30 juin 2021

LUMBAR SUPPORTS IN THE MANAGEMENT OF NON-SPECIFIC LOW BACK PAIN:  
A LITERATURE REVIEW AND META-ANALYSIS

Directeur de thèse et président de jury : Monsieur COUDEYRE Emmanuel, Professeur, UFR de Médecine et des Professions paramédicales de Clermont-Ferrand, Médecine Physique et de Réadaptation

Membres du jury :

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- Madame LANHERS Charlotte, Docteur, Centre de rééducation Notre Dame, Chamalières, Médecine Physique et de Réadaptation
- Monsieur PEREIRA Bruno, Biostatisticien, Direction de la Recherche Clinique et de l'Innovation, CHU Clermont Ferrand







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Table 2 - Characteristics of trials included in the qualitative synthesis: population, intervention, measurements.

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Figure 4 - Forest plot of effect of lumbar orthoses on pain.

## **LISTE D'ABBREVIATIONS**

**LBP** : Low Back Pain

**NSLBP** : Non Specific Low Back Pain

**NRLS** : Non Rigid Lumbar Supports

**PRISMA** : Preferred Reporting Items for Systematic Reviews and Meta-Analyses

**PEDro** : Physiotherapy Evidence Database

**BMI** : Body Mass Index

**RCT** : Randomized Control Trial

**PROMs** : Patient Reported Outcome Measured

**ODI** : Oswestry Disability Questionnaire

**RMDQ** : Roland-Morris Disability Questionnaire

## **1 Introduction**

Low back pain (LBP) is a worldwide frequent health symptom [1]. Sixty to ninety percent of the populations in developing countries have already experienced an episode of acute low back pain. Low back pain is the leading cause of activity limitation and sick leave throughout the world [2,3].

Non-specific low back pain (NSLBP) is the most frequent cause of low back pain. NSLBP is most often classified according to its duration and whether it is acute (less than four weeks of progression), subacute (between 4 weeks and 3 months) and chronic (more than 3 months of progression) [4]. First episodes of low back pain are frequently without consequences and complete recovery at 1 year ranges from 54% to 90% of cases [5]. However, non-recovering patients represent the largest part of the overall cost of low back pain [6].

Management of NSLBP varies according to the duration of the symptoms. For acute and subacute LBP, the aim is mainly to decrease and control the pain in order to recover and go back to occupational activities. For chronic low back pain, management is more complex due to psychosocial factors linked to chronic pain development [4,7].

Whatever the duration of the LBP, the management must associate pharmacological and non-pharmacological approaches. Pharmacological management is based on paracetamol, non-steroidal anti-inflammatory drugs, muscle relaxants (as second-line drugs only, due to the side effects), and weak opioids [8]. There is a wide range of non-pharmacological treatments, including multidisciplinary management, physical exercises, and psychological support [9].

Lumbar supports can be proposed for the treatment and prevention of NSLBP but despite frequent prescription, there is currently no consensus [10,11].

There are multiple names to designate lumbar support as orthosis, belt or corset. To clarify the definition, a non-rigid lumbar support (NRLS) is an adjustable elastic belt with back reinforcement in order to sustain or maintain the lumbar segment. Those supports are serial

manufactured with standard sizes. This definition eliminates fully rigid corsets or abdominal belts. The mechanism of action of lumbar support depends on its stiffness and we will only discuss non-rigid lumbar supports, which is our interest for this study.

About biomechanical aspect, it increases abdominal pressure and reduces intervertebral disc compression [12,13]. Lumbar mobility is reduced for rotation and inclination movements but not for sagittal movements. It improves postural control [14] but not proprioception [15]. There is a limited impact on trunk muscles with no action on energetic expenditure reduction and no local muscular activity reduction associated with a lack of trunk muscles strength loss [16]. Some effects on cardiorespiratory and digestive function are found and could be considered before prescription especially for high and rigid lumbar supports. Compression of the abdominal cavity might raise blood pressure and reduce venous return [17]. Moreover, modifications of ventilatory mechanics were reported when lifting loads, for example an increase in the respiratory rate or a decrease in vital capacity [18]. It is possible to consider that no contraindications have been highlighted. These effects are still investigated and still debatable [19].

Prescription of NRLS is not systematic for all physicians and physiotherapists due to the lack of practice guidelines or specific education on this topic. Management variations from one country to another and prescription of lumbar supports still vary greatly [20].

There are many articles in the literature concerning treatment and prevention of NSLBP which highlight the importance of non-pharmacologic therapy as first choice, but overall there is a moderate level of evidence that argue the non-recommendation of NRLS. The latest European recommendations [10] do not suggest lumbar supports in the treatment of chronic low back pain. The 2016 NICE recommendations are clear and do not advise the use of belts or corsets in the management of low back pain with or without sciatica [21]. For French recommendation, lumbar supports can be used shortly but with no evidence [22].

The literature is controversial concerning the prescription of NRLS. The 2008 Cochrane review, updated in 2011, included 15 studies (7 for preventive interventions and 8 for treatment interventions) on the efficacy of lumbar supports in NSLBP [23]. According to the results, NRLS are considered no more effective than no intervention in the treatment or prevention in patients with NSLBP. According to the authors, it remains unclear whether NRLS are more effective than no or other interventions in treating low back pain. Moreover, this Cochrane review did not focus on low back pain duration regarding the effect of lumbar support, despite management differ between acute, subacute and chronic low back pain.

Thus, we aimed to conduct a systematic review with meta-analysis to evaluate the effectiveness of non-rigid lumbar supports (NRLS) on disability and pain in the treatment and prevention of NSLBP. A secondary aim was to describe the differences according to NSLBP duration and to characterize the clinical and psychosocial phenotypes of good responding patients to lumbar support wearing.



## 2 Methods

Our methodological strategy follows the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [24].

The literature review and meta-analysis are registered on the “Centre for Reviews and Dissemination” PROSPERO with the number CRD42018109855 (**Erreur ! Source du renvoi introuvable.**).

### 2.1 Literature search

We conducted a systematic review in the following databases: Pubmed, Cochrane library, EMBASE, Science Direct and Pedro. The search strategy used the keywords “low back pain”; “lumbar orthosis”; “lumbar belt”; “back support”; “lumbar support”; “lumbar brace”. Research was performed from January 2017 to March 2020. We focused on studies that explored the efficiency of NRLS in the treatment and prevention of NSLBP, with disability and pain as main outcomes and with no time limit.

The search strategy is presented in the APPENDIX. We first selected articles by reading the titles. All articles that contained at least one keyword in the title were selected. Duplicates were removed after all databases were searched. We then read all the titles and abstracts to screen articles according to the following criteria and assessed the eligibility of the remaining articles by reading the full text.

### 2.2 Selection Criteria

Only articles with the following criteria were retained: written in English or French; recommendations from learned societies related to low back pain; trials about efficiency of NRLS assessed with disability and pain as the outcomes in adult populations (from 18 to 65

years old). Patients with acute, subacute or chronic low back pain were included in treatment studies. Patients with no pain or recurrent pain were included in prevention studies.

For prevention trials, lumbar supports had to be compared to the usual prevention. For treatment trials, NRLS had to be compared to the usual care. We excluded articles that didn't consider disability assessment and studies that assessed rigid lumbar belts, corsets or all other supports, except for NRLS. Also, secondary forms of low back pain, such as inflammatory disease, infection, cancer, osteoporosis or post-operative management were excluded.

### *2.3 Data extraction*

Whole research was performed independently with the help of a specialized documentarian to limit bias. One author (PG) conducted all literature searches and collated the abstracts. Two authors (PG and CL) separately reviewed the abstracts and, based on the selection criteria, decided on the suitability of the articles for inclusion. A third author (EC) was asked to review the article where consensus on suitability was debated. All the authors then reviewed the eligible articles.

Only articles on randomized controlled trials in which wearing a NRLS was compared to conventional management and which measured disability and pain outcomes were retained for the meta-analysis. For all studies where data were available, we extracted sample size, mean, and standard deviations for each treatment group, at each time point reported.

When the data were not available, we contacted the authors to obtain the missing data.

### *2.4 Quality of assessment*

The analysis of the methodological quality was performed by two independent readers using the Physiotherapy Evidence Database (PEDro) scale [25] (Annex 2). This scale has eleven indicators to identify major risks of bias. Each point was scored. If mentioned and included, the

point was given and noted as YES (Y), if not included the point was not given and noted as No (N), if not mentioned, the item was noted Non-Attributed (NA)

According to the PEDro guidelines, the first point was not considered in the final score. A score out of 10 was given for each trial.

### *2.5 Statistical considerations*

After extraction, the data were compiled into software designed specifically for meta-analyses (Comprehensive Meta-Analysis, version 2; Biostat, Englewood, NJ). For descriptive analyses, data were presented as means and standard deviations or a median with interquartile range, depending on the statistical distribution. The pooled standardized mean difference (SMD) was then calculated using a random-effects model (DerSimonian and Laird approach) that accounted for the true variation in effects occurring from study to study and for random errors within a single study. In other words, to address the non-independence of data due to study effect, random-effects models that assumed between and within study variability were performed rather than fixed-effect ones as certain experimental parameters had wide variations. When necessary, odds ratios reported in individual studies were converted into SMD [26]. The type I-error was fixed at 5%. Statistical heterogeneity between results was assessed by examining forest plots, confidence intervals and using  $I^2$ .  $I^2$  values range between 0% and 100% and are typically considered low for <25%, modest for 25–50%, and high for >50%.

### 3 Results

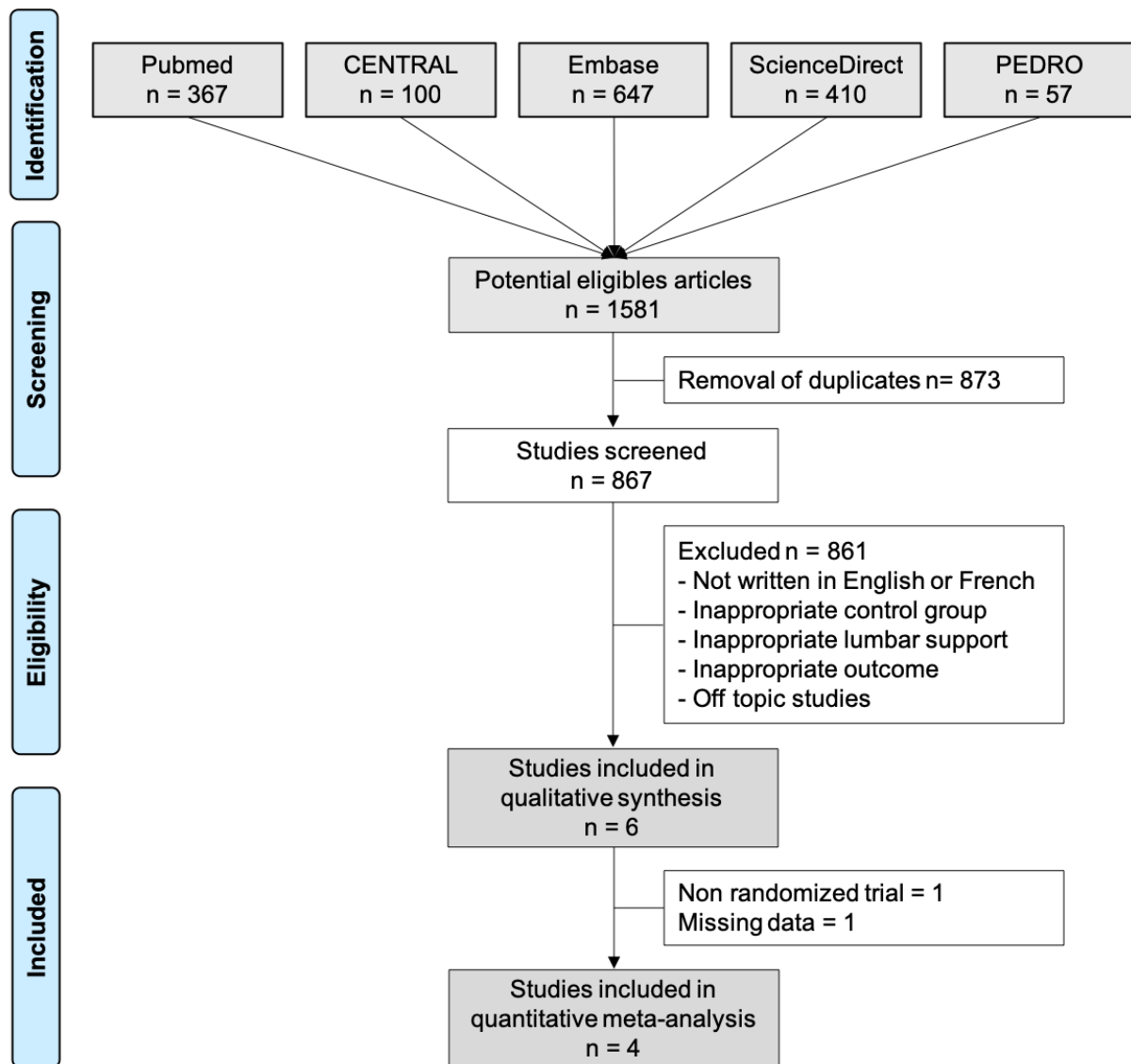
#### 3.1 Overview of included studies

The database search resulted in 1581 articles (*Erreur ! Source du renvoi introuvable.*).

Ultimately, 11 original articles were eligible for full-text review for the efficiency of non-rigid lumbar support in NSLBP [27–37].

Among these articles, 4 [27,28,33,36] were eventually selected for the meta-analysis. Trials were excluded because of improper study design (cohort study) [32], inappropriate lumbar support (“spinal underwear”) [37], and inappropriate study methodology [30]. For this last study, using non-randomized clinical trial design, 3 groups were compared (no LBP/no orthoses; no LBP/orthoses; LBP/orthoses), but the only interesting data to extract was for the low back pain with lumbar orthoses group. Some data were missing for two articles [33,34]. For the first [33], the authors couldn’t provide the data because they no longer had access to the database, but we succeeded in extracting sufficient data to include it in the final analysis. We received no answer from the authors of the second article [34].

Figure 1 - Flow diagram of the PRISMA 2009 guidelines.



### 3.2 *Quality of articles*

We used the 11 items of the PEDro scale but, as stated in the PEDro guide, the first criterion (specified eligibility criteria) was not considered for the final score. Quality assessment was homogeneous (*Figure 2*). The mean score was 6.5 out of 10, including two trials with a score of 6 and two trials with a score of 7. Patients, therapists and outcome assessors could not be blinded because the lumbar support was worn. One study didn't have similar population characteristics at baseline for the intention to treat population [27], and one didn't have measurements for at least 85% of the subjects [33]. All studies mentioned their randomization method except one, which did not mention if the allocations were concealed [30].

**Figure 2 - Methodological quality of the studies according to the PEDro scale.**

	Random allocation	Concealed allocation	Groups similar at baseline	Participant blinding	Therapist blinding	Assessor blinding	Adequate follow up	Intention to treat analysis	Between-group difference reported	Point estimate and variability reported	<b>General level of evidence (/10)</b>
Calmels 1999	+	+	+	-	-	NA	+	+	+	+	<b>7</b>
Calmels 2009	+	+	-	-	-	-	+	+	+	+	<b>6</b>
Oleske 2007	+	+	+	-	-	-	-	+	+	+	<b>6</b>
Morrisette 2014	+	+	+	-	-	-	+	+	+	+	<b>7</b>
Kawchuk 2015	+	?	+	-	-	?	+	+	+	+	<b>6</b>
Roelofs 2007	+	+	+	-	-	-	+	+	+	+	<b>7</b>

Yes = + (1 point), No = - (0 points), Can't say = ? (0 points), Not applicable: NA.

### 3.3 Characteristics of participant

*Sample size:* In these four studies, population sizes ranged from 36 to 433 individuals (*Table 1*). Seven hundred and seventy-seven patients were included, 378 individuals in the lumbar support group and 348 individuals in the control group.

*Gender:* The proportion of males was higher (61.5%). The proportion of females was superior in one study [37] and inferior in three studies.

*Age:* Studies reported participants' mean age range between 38.4 and 48.4 years old.

*BMI:* The mean BMI, reported in two studies, is over 29 kg/m<sup>2</sup> [33,36].

*Physical activity:* Only one study reported physical activity [27]. Two hundred and fifty participants (57.7%) practiced regular exercise outside of work.

*Type of LBP:* 36 subjects had acute LBP, 210 subjects had subacute LBP, 24 subjects had chronic low back pain, and 175 had recurrent LBP. Thirty-five subjects had acute or subacute LBP.

*Professional categories:* Two studies detailed professional categories. One study consisted of manual workers with 433 participants [33]. Another study enrolled 36 participants with 17 sedentary workers and 19 manual workers [28].

*Use of medication:* Three studies revealed the use of medication [27,33,36], with a total of 456 individuals consuming medication among 741 (48%) participants. The medication could be an association of analgesics (paracetamol or aspirin) and a muscle relaxant possibly prescribed to all participants for 8 days. Also, patients could take narcotics, NSAID, corticosteroids or antidepressants.



**Table 1 - Characteristics of the trials of low back pain (LBP) and non-rigid lumbar supports (LSs) included in the qualitative synthesis: population, intervention, measurements.**

Study	Population					Intervention		Measurement			
	n	Age (mean±SD)	Sex (%Male)	Mean BMI (kg/m <sup>2</sup> ±SD)	Professional Catégory (n)	Type of LBP	Type	Duration	time (weeks)		
									T1	T2	T3
Calmels 1999	36	38.35 ± 10.2	72.2		Sedentary(17) Manual(19)	Acute	Gr 1: LBP + LS Gr 2: LBP + usual care	3 weeks	1	3	-
Kawchuk 2015	54	36.1 ± 13.5	51.8			Acute	Gr 1: LBP + LS Gr 2: healthy controls Gr 3: healthy controls + LS	2 weeks	2	-	-
Calmels 2009	210	43 ± 10.7	54.8			Subacute	Gr 1: LBP + LS Gr 2: LBP + usual care	12 weeks	4	8	12
Oleske 2007	433	46.1 ± 7.6	79.8	29.9±5.4	Manual(433)	Recurrent	Gr 1: LS + education Gr 2: education	48 weeks	48	-	-
Roelofs 2007	360					Recurrent	Gr 1: LS Gr 2: usual care + education	48 weeks	48	-	-
Morrisette 2014	98	48 ± 15.3	39	29.0±7.2		Mixed	Gr 1: iLS + usual care Gr 2: eLS + usual care Gr 3: usual care	2 weeks	2	-	-

BMI : Body Mass Index; iLS: inextensible Lumbar Support; eLS: extensible Lumbar Support

### 3.4 *Characteristics of intervention*

The four studies used serial manufactured produced lumbar supports. The main characteristics were a soft elastic lumbar belt with back reinforcements. One study [36] used two different lumbar supports, one elastic and one inelastic with posterior reinforcements. The length of time the lumbar supports were worn varied from 2 weeks [36] to 48 weeks [33].

### 3.5 *Outcomes*

Disability assessment used different scores, including the Patient Reported Outcome Measures (PROMs) (*Table 2*). Two different scores were used in the selected studies: Oswestry Disability Index [38] for 2 studies [33,36], Roland Morris Disability Questionnaire [39] for one study [27]. One study used functional tests assessed by a yes or no answer [28]. To be compared, PROMs were normalized to a base of hundreds.

Pain assessment was performed using a visual analog scale (VAS) [27,33,36] or Verbal Scale (EVS) [28]. Details of the characteristics of selected RCTs are shown in **Erreur ! Source du renvoi introuvable.** and

. Pain scores were normalized to a base of hundreds.

No adherence assessment was performed in the selected studies.

Study	Primary outcome	Secondary outcome	Results		
			T1	T2	T3
Calmels 1999	Pain (VAS, VRS)	-	Gr1>Gr2	NS	-
	Pain attitude	-	NS	NS	-
	Lumbar stiffness	-	Gr1>Gr2	NS	-
	Muscle contraction	-	Gr1>Gr2	NS	-
	Disability (clinical test)	-	NS	Gr1>GR2	-
Kawchuk 2015	Disability (ODI)	-	Decrease	-	-
	-	Spinal stiffness	NS	-	-
	-	Muscle endurance	Increase	-	-
Calmels 2009	Disability (RMDQ)	-	Gr1>Gr2	-	Gr1>Gr2
	Pain (VAS)	-	Gr1>Gr2	-	Gr1>Gr2
	Drugs consumption	-	Gr1>Gr2	-	Gr1>Gr2
Oleske 2007	Pain (VAS)	-	NS	-	-
	Disability (ODI)	-	NS	-	-
	Recurrence	-	Gr1>Gr2	-	-
	Physical health	-	NS	-	-
	Mental health	-	NS	-	-
Roelofs 2007	Number of days of LBP	-	Gr1>Gr2	-	-
	Sick leave	-	NS	-	-
	-	Disability (Quebec*)	Gr1>Gr2	-	-
Morrisette 2014	Disability (ODI)	-	Gr1>Gr3	-	-
	-	Pain (VAS)	NS	-	-
	-	PSAS	Gr1>Gr3	-	-
	-	FABQ	NS	-	-

FABQ= Fear and Avoidance Beliefs Questionnaire; NS: Non-Significant; ODI = Oswestry Disability Index; PSAS= Patient Specific Activity Score; RMDQ= Roland Morris Disability Questionnaire; VAS= visual analogic scale; VRS= verbal rating scale;

\*Quebec Disability Scale

**Table 2 - Characteristics of trials included in the qualitative synthesis: population, intervention, measurements.**

Study	Primary outcome	Secondary outcome	Results		
			T1	T2	T3
Calmels 1999	Pain (VAS, VRS)	-	Gr1>Gr2	NS	-
	Pain attitude	-	NS	NS	-
	Lumbar stiffness	-	Gr1>Gr2	NS	-
	Muscle contraction	-	Gr1>Gr2	NS	-
	Disability (clinical test)	-	NS	Gr1>GR2	-
Kawchuk 2015	Disability (ODI)	-	Decrease	-	-
	-	Spinal stiffness	NS	-	-
	-	Muscle endurance	Increase	-	-
Calmels 2009	Disability (RMDQ)	-	Gr1>Gr2	-	Gr1>Gr2
	Pain (VAS)	-	Gr1>Gr2	-	Gr1>Gr2
	Drugs consumption	-	Gr1>Gr2	-	Gr1>Gr2
Oleske 2007	Pain (VAS)	-	NS	-	-
	Disability (ODI)	-	NS	-	-
	Recurrence	-	Gr1>Gr2	-	-
	Physical health	-	NS	-	-
	Mental health	-	NS	-	-
Roelofs 2007	Number of days of LBP	-	Gr1>Gr2	-	-
	Sick leave	-	NS	-	-
	-	Disability (Quebec*)	Gr1>Gr2	-	-
Morrisette 2014	Disability (ODI)	-	Gr1>Gr3	-	-
	-	Pain (VAS)	NS	-	-
	-	PSAS	Gr1>Gr3	-	-
	-	FABQ	NS	-	-

FABQ= Fear and Avoidance Beliefs Questionnaire; NS: Non-Significant; ODI = Oswestry Disability Index; PSAS= Patient Specific Activity Score; RMDQ= Roland Morris Disability Questionnaire; VAS= visual analogic scale; VRS= verbal rating scale;

\*Quebec Disability Scale

### 3.6 *Study design*

Three were multi-center studies [27,28,33]. Two studies were situated in France [27,28] and two were in the USA [33,36]. All studies were RCTs. Randomizations were computer generated in two cases [27,36] and were manually performed with opaque envelopes in the two remaining studies [28,33].

### 3.7 *Selection of patients in the included articles*

Inclusion criteria were male or female adult subjects with an acute low back pain with a maximum of ten days of pain [28]; with treatment for an initial episode or recurring non-specific low back pain; with episodes lasting 1 to 3 months [27] or a primary report of an acute, subacute, or chronic LBP [36]; or having a non-traumatic work-related low back disorder within 8 weeks of the date of diagnosis of an injury/illness [33].

Exclusion criteria included secondary forms of low back pain, neurological signs, spinal surgery, current pregnancy (in two studies [27,36]), and contra indication to non-rigid lumbar supports.

### 3.8 *Evaluation of the therapeutic effect*

The systematic review did not find any recommendations for the prescription of NRLS for non-specific low back pain. NRLS was effective for disability, pain, and pain killer consumption for subacute low back pain (increases of time intervals for dispensing medication). It was also effective in secondary prevention on the probability of a recurrence of low back pain. Benefits of lumbar supports were not highlighted, possibly due to a lack of adherence.

There were no adverse effects reported in the studies.

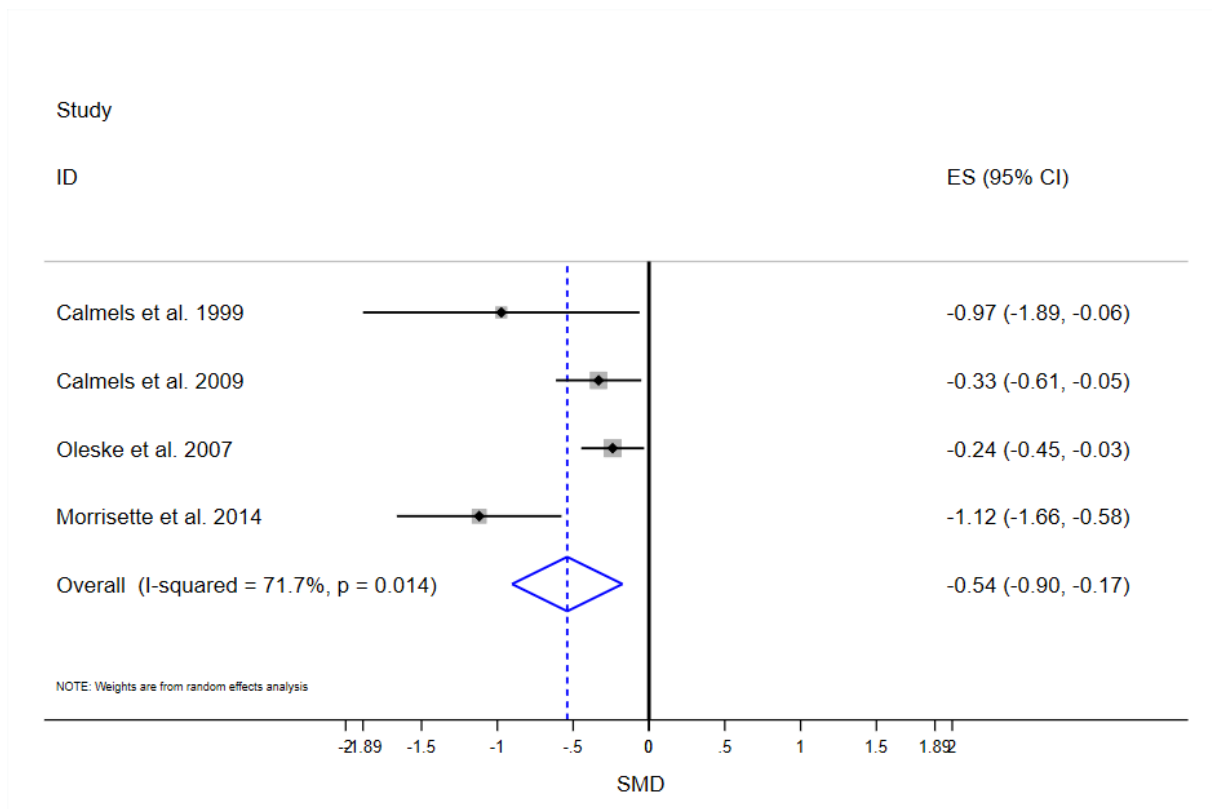
The four studies included in the meta-analysis showed a reduction in disability (*Erreur !*

*Source du renvoi introuvable.*). The pooled standard mean difference showed a statistically

significant reduction of disability with NRLS compared to standard management: ES -0,54 (95% CI - 0,90; -0,17) with a substantial heterogeneity (I-squared = 71.7%, p=0.014). Results were stratified by the duration of low back pain and were statistically significant for all studies with regard to acute -0.97 (-1.89; -0.06), subacute -0.33 (-0.61; -0.05) and recurrent low back pain -0.24 (-0.45; -0.03).

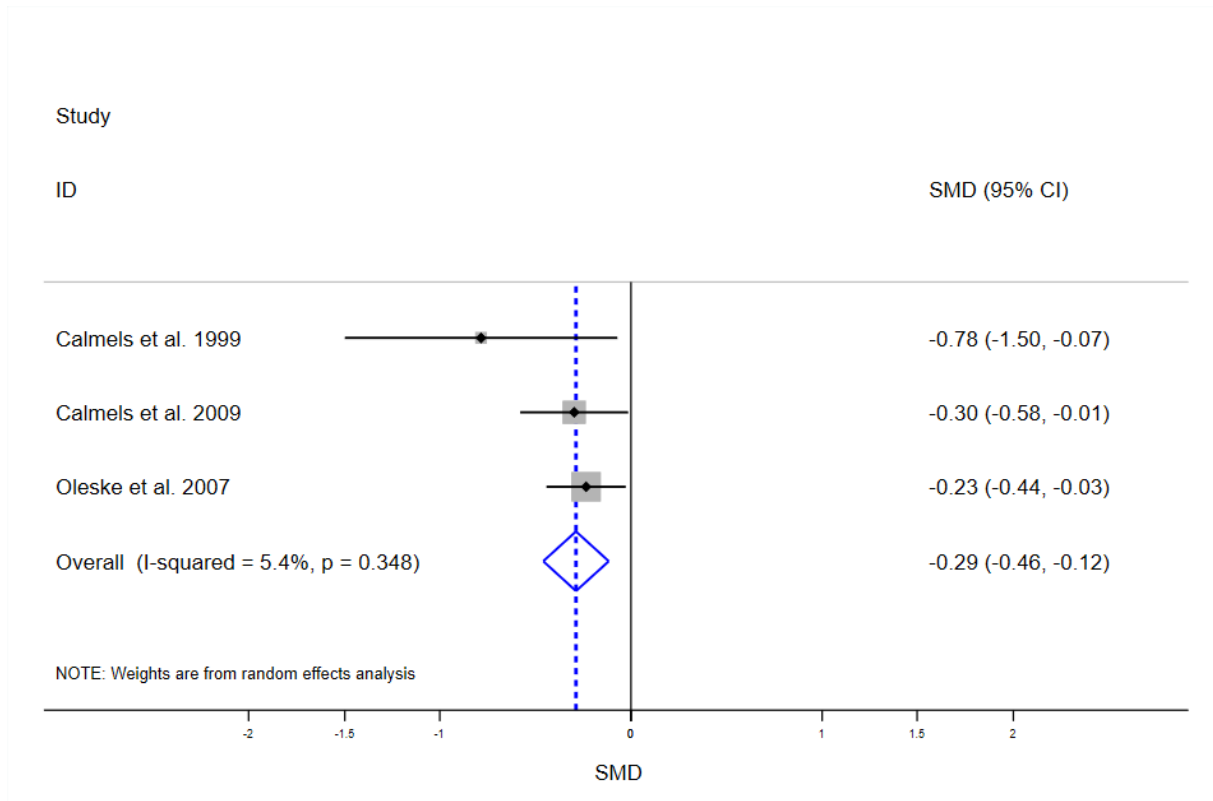
Concerning pain criteria, three of the included studies showed a reduction in pain of -0,29 (95% CI -0,46; -0,12), with a homogeneity of I-squared = 5.4% (p= 0,348) (*Figure 4*).

**Figure 3 - Forest plot of effect of lumbar orthoses on function.**



SMD, standardized mean difference; 95% CI: 95% confidence interval.

**Figure 4 - Forest plot of effect of lumbar orthoses on pain.**



SMD, standardized mean difference; 95% CI, 95% confidence interval.



## 4 Discussion

The main findings were that non-rigid lumbar supports demonstrated significant improvements in disability (effect size = -0.54, 95 CI -0.90 to -0.17) and in pain (-0.29, -0.46 to -0.12). Insufficient data prevented the efficiency between acute, subacute and recurrent low back pain from being compared. Nor did it allow meta-regressions to be computed on the sociodemographic and other characteristics of the patients who could benefit the most from NRLS.

To our knowledge, this is the first systematic review that has highlighted the effects of NRLS through meta-analysis. Other systematic reviews, such as the one of the Cochrane Library, did not carry out a meta-analysis due to the heterogeneity of the study populations and the outcomes [23]. They drew conclusions concerning NRLS used in prevention or in treatment with no improvement for prevention and limited evidence of improvement in disability when treating LBP. These results can be explained by the fact that the methodology score was quite low, with nine of the fifteen studies included being published before 1995 and by the fact that the outcomes were sometimes not accurate enough to show a difference as being an overall improvement. Though, a few high quality randomized controlled studies succeeded in demonstrating the efficacy of NRLS [27]. We noticed that only a few studies are of good methodological quality due to a low number of subjects, no blinding, and the lack of assessments of co-interventions. Moreover, the heterogeneity in the choice of outcome variables and measurement instruments hinder comparisons between studies and systematic reviews [40]. Disability, is considered by researchers, clinicians and patients to be the most important outcome domain to be assessed in LBP clinical trials [41]. NSLBP concerns very heterogeneous patient phenotypes that could lead to a major risk of bias, particularly when comparing interventions with limited samples.

To overcome this, we focused on only the most pertinent primary outcomes, such as disability and pain, to evaluate the effectiveness of NRLS. The stratification by duration of LBP is a way of reflecting the clinical reality and avoiding any bias linked to differences in management. But this classification has some limitations. Chronic low back pain is a particular entity and is part of chronic pain, which has psychosocial consequences and needs a more general management. Some acute low back pains, which are not managed as well as possible, can last more than three months without being considered as chronic pain. Moreover, subacute LBP cannot be individualized. It is considered as a longer acute low back pain or a “pre-chronical” phase in which more intensive care needed. So, this classification is insufficient for classifying different physiopathological mechanisms of different diseases.

Concerning the selection of the articles, three different PROM’s for disability were used in the selected studies: ODI [38] and RMDQ [39] and close-ended questions. We had to convert scores to a base of hundreds to compare them to each other. For one study, disability assessment was performed with clinical functional tests because, at the time of publication (1999), the use of questionnaires was not common place and authors lacked validated questionnaires for low back pain. We decided to keep this study in the quantitative analysis because of the good methodological quality and the very limited number of studies that included acute LBP patients.

To our knowledge, comparability between disability questionnaires was not represented in the available literature, but it is well known that disability is one of the most important outcome for low back pain rather than pain intensity itself [41].

#### *4.1 The benefits of lumbar supports in disability and pain*

Non-rigid lumbar supports are easily prescribed medical advices with no serious adverse effects. The only side effects could be an increase in localized heat or sweating, which may be uncomfortable, particularly for overweight people.

Low back pain, mainly chronic low back pain, leads to a fear of movement and results in patients reducing their activity to avoid pain. We know that sedentarity is a worsening factor and leads to chronicization through global deconditioning.

The main purpose of the treatment of low back pain is to reduce disability and pain.

All included studies showed an improvement in disability except for Oleske et al. [33], whose results were not significant for pain and disability, and showed only a decrease over the 12-month follow-up period with a significant reduction of low back pain recurrence.

Due to its biomechanical properties, NRLS increased spine stability and were used to relieve the impaired lumbar proprioception in people with low back pain [42]. Morissette et al. [36] showed a greater improvement in the pain and disability scores (ODI) with inextensible lumbar support and linked it with the increase in trunk stiffness and motion limitation that it provides. In fact, spinal muscles are over activated to provide a compensatory stiffness to the spine [43].

Moreover, NRLS may have a psychological impact that can help restore confidence in the back, reduce the fear of movement and facilitate a gradual return to activities [44].

It has been shown that increasing abdominal pressure can lead to increased spine stability by increasing the stiffness of trunk muscles and favoring muscle contraction [45].

The local increase in heat could also help to reduce pain, even if this effect has not been definitively demonstrated.

As previous reviews have mentioned, the heterogeneity of the NSLBP population and the outcomes were major difficulties to a meta-analysis. However, we found that some good methodological studies exist and show the efficacy of lumbar supports.

#### *4.2 Limitations*

This work has some limitations. First, the limited number of trials included, in our case four. Numerous published studies concerned the biomechanical action of lumbar supports, with lots of studies focusing on muscular effects, posture effects, and proprioception but only a limited number of clinical randomized studies carried out a disability assessment. In addition to the lack of RCTs, published studies did not use the same outcomes or the same orthoses. Moreover, the prescription of orthoses is cultural, with some countries prescribing them more than others. We chose to select only French and English articles and we may have missed some results from studies published in other languages.

Secondly, most trials were of low methodological quality. Prevalent methodological flaws among the selected RCTs were no concealment of treatment allocation (item 2), no assessment of co-interventions (item 4) and adherence (item 5), and no blinding of patients (item 6) and outcome assessors (item 7) due to the impossibility to deliver a placebo.

With regard to the selection bias, we could have missed some articles despite the large search on several major search databases. We made the choice to select only articles in French and English.

Adherence assessment was not mentioned in any study. It is a confounding factor when studying effectiveness and is a potential bias as the length of time the support is worn might be a predictive factor of efficacy [46]. Adherence assessment should be part of these studies and measured by the length of time the support is worn. This is lacking in the majority of publications about NRLS and there is a need for further study in this domain. Some studies

have already developed methods to quantified adherence, such as temperature recording sensors [47].

#### *4.3 Phenotypes of patients who can benefit the most from lumbar supports*

The next step is to identify risk factors of non-adherence and patients with an adherent profile. Roelofs et al. [48] analyzed the determinants of intention to use a lumbar support among home care workers. For these workers, the perceived benefit has to be superior to the discomfort, which is why they are unlikely to experience benefits from its usage in primary intention. A positive attitude was found to be the strongest predictor for intention, followed by good self-efficacy. Conversely, obesity or poor self-efficacy correlated with low intention to use. Some studies investigated the factors affecting adherence and found that these could be categorized into patient-centered factors, therapy-related factors, social and economic factors, healthcare system factors, and disease factors [49]. So, the physician has to consider these different factors before prescribing and there is a need to inform patient on factors affecting adherence before prescription. There is proof that adherence and persistence is related with treatment satisfaction and that treatment satisfaction is explained by compliance or persistence [50].

Systematic or collective prescription of lumbar orthoses has no sense. Patients with adherent profiles, with a positive vision of the treatment, recurrent pain or with a positive expectation could be more capable of receiving lumbar support.

With regard to cost effectiveness, there is a lack of studies concerning lumbar supports. Roelofs et al. [51] showed that wearing a NRLS as secondary prevention, in addition to the usual care, correlates with a reduction of sick leave.

## **5 Conclusion**

Among non-pharmacologic treatments for NSLBP, non-rigid lumbar supports are a non-negligible option. The large population described as NSLBP is problematic to the generation of good quality evidence about the effectiveness of NRLS.

It is clear that patient profiles with a potential good response might exist and further studies should explore the effectiveness of NRLS regarding patients' phenotypes. Further studies should include patients from a homogeneous population, classified by the duration of the pain. Precise and validated outcomes, such as disability and pain scores, should be standardized and used in investigations. An evaluation of the compliance and adherence should also be carried out. Other studies concerning the cost effectiveness in the whole NSLBP population are still needed.

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## **ANNEXES**

### **Annexe I - SEARCH STRATEGIES**

#### **Search strategy for CENTRAL:**

1. ("low back pain\*" OR "lumbago" OR "low back ache" OR "lower back pain\*" OR "pain, low back" OR "low backache" OR "back pain, low" OR "back pain, lower" OR "Low back syndrome" OR "Lumbalgia" OR "Lumbar pain" OR "LBP")

2.("orthotic device\*" OR "orthoses" OR "orthosis" OR "lumbar support\*" OR "lumbar belt" OR "back support\*" OR "lumbar orthosis" OR "lumbar brace\*" OR "brace\*")

3.("Foot Orthoses" OR "athletic tape" OR "athletic tape" OR "orthotic tape" )

4. 1 AND 2

5. 4 NOT 3

#### **Search strategy for Pubmed:**

1. ("low back pain"[MH] OR "low back pain\*"[TW] OR "lumbago"[TW] OR "low back ache"[TW] OR "lower back pain\*"[TW] OR "pain, low back"[TW] OR "low backache"[TW] OR "back pain, low"[TW] OR "back pain, lower"[TW] OR "Low back syndrome"[TW] OR "Lumbalgia"[TW] OR "Lumbar pain"[TW] OR "LBP"[TW])

2.("orthotic devices"[MH] OR "orthotic devices"[TW] OR "orthotic device"[TW] OR "orthoses"[TW] OR "orthosis"[TW] OR "lumbar support\*"[TW] OR "lumbar belt"[TW] OR "back support\*"[TW] OR "lumbar orthosis"[TW] OR "lumbar brace\*"[TW] OR "brace\*"[TW])

3.("Foot Orthoses"[Mesh] OR "Foot orthoses"[TW] OR "athletic tape"[MH] OR "athletic tape"[TW] OR "orthotic tape"[TW])

4. 1 AND 2

5. 4 NOT 3

### **Search strategy for EMBASE:**

1. 'low back pain'/exp
2. 'low back ache'
3. 'low back syndrome'
4. Lumbalgia
5. Lumbago
6. 'lower back pain'
7. 'low backache'
8. 'ibp'
9. 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8
10. 'orthosis'/exp
11. 'orthotic devices'
12. 'orthoses'/exp
13. 'lumbar support'
14. 'lumbar belt'
15. 'lumbar orthosis'
16. 'lumbar brace'
17. 'brace'/exp
18. #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17
19. #9 AND #18
20. 'foot orthosis'/exp
21. 'foot orthoses'
22. 'athletic tape'/exp
23. 'orthotic tape'
24. #20 OR #21 OR #22 OR #23
25. #19 NOT #24

### **Search strategy for PEDro:**

Advanced search:

1. Abstract & title: low back pain\*

Therapy: orthoses, taping, splinting

Body part: lumbar spine, sacro-iliac joint or pelvis

Method: clinical trial

**Search strategy for Science Direct:**

Basic search : ("low back pain") AND ("lumbar orthosis" OR "lumbar belt" OR "back support" OR "lumbar support" OR "lumbar brace")

## Annexe II - PEDro Scale

### PEDro scale

- 
- |   |   |
|---|---|
| 1. eligibility criteria were specified  | no <input type="checkbox"/> yes <input type="checkbox"/> where: |
| 2. subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)   | no <input type="checkbox"/> yes <input type="checkbox"/> where: |
| 3. allocation was concealed   | no <input type="checkbox"/> yes <input type="checkbox"/> where: |
| 4. the groups were similar at baseline regarding the most important prognostic indicators   | no <input type="checkbox"/> yes <input type="checkbox"/> where: |
| 5. there was blinding of all subjects   | no <input type="checkbox"/> yes <input type="checkbox"/> where: |
| 6. there was blinding of all therapists who administered the therapy  | no <input type="checkbox"/> yes <input type="checkbox"/> where: |
| 7. there was blinding of all assessors who measured at least one key outcome  | no <input type="checkbox"/> yes <input type="checkbox"/> where: |
| 8. measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups  | no <input type="checkbox"/> yes <input type="checkbox"/> where: |
| 9. all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat" | no <input type="checkbox"/> yes <input type="checkbox"/> where: |
| 10. the results of between-group statistical comparisons are reported for at least one key outcome  | no <input type="checkbox"/> yes <input type="checkbox"/> where: |
| 11. the study provides both point measures and measures of variability for at least one key outcome   | no <input type="checkbox"/> yes <input type="checkbox"/> where: |
- 

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (*Verhagen AP et al (1998). The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41*). The list is based on "expert consensus" not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to "weight" scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (ie RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or "generalisability" or "applicability" of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the "validity" of a study's conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the "quality" of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Last amended June 21st, 1999

### **Annexe III - PROSPERO REGISTRATION**

Objet : PROSPERO acknowledgement of receipt [109855]

Dear Registrant,

Thank you for submitting details of your systematic review for registration in PROSPERO.

We will check the information supplied to :

- make sure that your systematic review is within scope
- ensure that the fields have been completed appropriately.

PLEASE NOTE THAT THESE CHECKS DO NOT CONSTITUTE PEER REVIEW OR IMPLY APPROVAL OF YOUR SYSTEMATIC REVIEW METHODS.

We will let you know when your record has been published on PROSPERO, or alternatively ask for further information or clarification. If your application is rejected we will advise you of the reasons for non-publication (usually this will be if your review is out of scope).

With the current very high demand for registration, we aim to respond within 10 working days for UK submissions and 20 working days for submissions outside the UK.

We will process your application as soon as possible. During this time the record will be locked and you will not be able to access it.

Please note that this does not stop you working on your review.

Yours sincerely,

PROSPERO Administrator  
Centre for Reviews and Dissemination  
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[www.york.ac.uk/inst/crd](http://www.york.ac.uk/inst/crd)

## Annexe IV - REVIEWER'S COMMENTS

**Reviewer #1:** Titre: Lumbar supports in the management of non-specific low back pain: a literature review and meta-analysis

Avis général: Intéressant travail de revue de la littérature sur un sujet qui fait toujours débat à savoir le bénéfice thérapeutique des orthèses de rachis dans la lombalgie commune ou non spécifique.

Il faut cependant envisager une révision importante de la rédaction compte tenu en premier d'erreurs dans les références qui « perturbent » nettement la lecture et la cohérence des résultats et de la discussion, et dès l'introduction, la nécessité de bien identifier que l'étude porte sur les orthèses souples par rapport aux rigides, avec des effets biomécaniques ou physiologiques qui peuvent être différents, des objectifs thérapeutiques aussi. Il faut peut-être aussi que les auteurs soient plus attentifs à la terminologie entre « belts » ou « orthosis » ou « corset » en terme de conséquence sur la typologie de dispositifs et de ce fait de la rigidité, de produits manufacturés ou sur mesure, de taille, de hauteur au niveau antérieur ou postérieur, d'effet thérapeutique ou d'effet préventif recherché.

Text :

En premier, il y a des erreurs de références et en particulier les références des articles retenues pour la méta-analyses puisque ces références sont citées 2 fois souvent (voir même 3 fois) avec des numéros de référence différents.

Cas : 22 et 43

[22] Calmels P, Queneau P, Hamonet C, Le Pen C, Maurel F, Lerouvreur C, et al. Effectiveness of a lumbar belt in subacute low back pain: an open, multicentric, and randomized clinical study. *Spine* 2009;34:215-20. doi:10.1097/BRS.0b013e31819577dc.

[43] Calmels P, Queneau P, Hamonet C, Le Pen C, Maurel F, Lerouvreur C, et al. Effectiveness of a lumbar belt in subacute low back pain: an open, multicentric, and randomized clinical study. *Spine* 2009;34:215-220. doi:10.1097/BRS.0b013e31819577dc.

Cas : 37 et 41

[37] Morrisette DC, Cholewicki J, Logan S, Seif G, McGowan S. A randomized clinical trial comparing extensible and inextensible lumbosacral orthoses and standard care alone in the management of lower back pain. *Spine* 2014;39:1733-42.

doi:10.1097/BRS.0000000000000521.

[41] Morrisette D, Cholewicki J, Logan S, Seif G, McGowan S. A randomized clinical trial comparing extensible and inextensible lumbosacral orthoses and standard care alone in the management of lower back pain. *Spine* 2014;39:1733-1742.

doi:10.1097/BRS.0000000000000521.

Cas : 34, 42 et 44

[34] Oleske DM, Lavender SA, Andersson GBJ, Kwasny MM. Are back supports plus education more effective than education alone in promoting recovery from low back pain?: Results from a randomized clinical trial. *Spine* 2007;32:2050-7.

doi:10.1097/BRS.0b013e3181453fcc.

[42] Oleske D, Lavender S, Andersson G, Kwasny M. Are back supports plus education more effective than education alone in promoting recovery from low back pain?: results from a randomized clinical trial. *Spine* 2007;32:2050-2057. doi:10.1097/BRS.0b013e3181453fcc.

[44] Oleske D, Lavender S, Andersson G, Kwasny M. Are back supports plus education more effective than education alone in promoting recovery from low back pain?: results from a randomized clinical trial. *Spine* 2007;32:2050-7.

Cas : 39 et 53



- [39] Roelofs PDDM, van Poppel MNM, Bierma-Zeinstra SMA, van Mechelen W. Determinants of the intention for using a lumbar support among home care workers with recurrent low back pain. Eur Spine J 2010;19:1502-7. doi:10.1007/s00586-010-1399-5.
- [53] Roelofs P, van Poppel M, Bierma-Zeinstra S, van Mechelen W. Determinants of the intention for using a lumbar support among home care workers with recurrent low back pain. European Spine Journal 2010;19:1502-1507.

Cette révision est majeure et essentielle pour une bonne lecture du contenu et des résultats.

Text:

Introduction

« Low back pain (LBP) is a frequent health symptom both in developed and in developing countries [1] ».

- Ne pourrait-il pas être dit partout dans le monde - as everywhere? Ou alors spécifier si différence entre pays développées et pays en voie de développement.

« The mechanism of action of lumbar support is initially biomechanical by increasing the abdominal pressure and reducing intervertebral disc compression [12] [13]. Lumbar mobility is reduced for rotation and inclination movements but not for sagittal movements. It improves postural control [14] but not proprioception [15]. There is a limited impact on trunk muscles with no action on energetic expenditure reduction and no local muscular activity reduction associated with a lack of trunk muscles strength loss [16] »

- Cette partie doit mieux prendre en considération le type de support ou orthèses lombaires, souples ou rigides, manufacturés ou sur mesure et la taille. Ou bien il faut d'emblée dire que le travail se limite aux supports ou orthèses souples.

« The mechanism of action of lumbar support is initially...»

- Pourquoi initially... - Il y a des effets biomécaniques et des effets cliniques, comme pour les médicaments des effets pharmacologiques et cliniques - cela n'est pas dissocié - c'est un mode d'action physiologique puisqu'il s'agit d'un dispositif médical ayant pour but d'obtenir un effet thérapeutique.

« There are also effects on cardiorespiratory and digestive function that must be considered before prescription. Compression of the abdominal cavity might raise blood pressure and reduce venous return [17]. Moreover, modifications of ventilatory mechanics were found when lifting loads, for example an increase in the respiratory rate or a decrease in vital capacity [18]. »

- Ce sont des effets souvent rapportés, plutôt historiquement, peu rencontrés en pratique clinique. Il me semble que ces effets un peu théoriques sont souvent rapportés, mais ces études sont anciennes, donc peut-être à nuancer, sans doute selon le type d'orthèse (en particulier rigide et de haut niveau), et il est aussi rapporté des effets bénéfiques de certaines orthèses sur la dynamique diaphragmatique par exemple et respiratoire dans certaines situations.

« There are many articles in the literature concerning the treatment and prevention of NSLBP which highlight the importance of non-pharmacologic therapy as first choice, but overall there is a moderate level of evidence that supports the non-recommendation of back supports. »

- Revoir la phrase sans doute car "supports" and "supports". Peut-être aussi spécifier que si les orthèses sont un traitement non-pharmacologique, on peut aussi les identifier comme un traitement physique et comme l'usage d'un dispositif médical pour dissocier aussi des

nombreux autres et divers traitements non-pharmacologiques dans la lombalgie.

« The latest European recommendations [10] do not recommend lumbar supports in the treatment of chronic low back pain. The 2016 NICE recommendations are clear and do not advise the use of belts or corsets in the management of low back pain with or without sciatica [21]. »

- Peut-être mettre en référence aussi les dernières recommandations HAS en France ? 2019

« Thus, we aimed to conduct a systematic review with meta-analysis to evaluate the effectiveness of lumbar supports on disability and pain in the treatment and prevention of NSLBP. »

- Peut-être spécifier à ce stade de quel type de supports il s'agit vu les critères par la suite, à savoir des ceintures ou orthèses souples.

« .....secondary aim was to describe the differences in NSLBP duration and to characterize the phenotypes of patients with a good response.»

- Peut-être mettre plutôt "to characterize the clinical and psychosocial phenotypes of good responding patients to lumbar support (or lumbar belt) wearing".

#### Methods

« The search strategy used the keywords "low back pain"; "lumbar orthosis"; "lumbar belt"; "back support"; "lumbar support"; "lumbar brace". Research was performed from January 2017 to June 2018 ».

- Il serait bien, d'envisager d'actualiser la recherche jusqu'en fin 2019 vu la date de soumission. En regardant rapidement il ne semble pas il y avoir beaucoup d'étude nouvelle pouvant modifier la méta-analyse mais ceci permet d'éliminer cette période de Juin 2018 à 2020 il me semble.

« We focused on studies that explored the efficiency of lumbar supports, with function and pain as main outcomes and with no time limit. »

- Il y a sans doute à préciser ou modifier les notions de traitement et prévention évoqués dans l'introduction comme effet des supports lombaires et dans cette phrase l'analyse de la fonction et de la douleur.

- Peut-être aussi harmoniser le terme de « disability » et de « function » indépendamment utilisés selon les paragraphes dans la méthode et qui peuvent être sources de confusion.

« Patients with acute, subacute or chronic low back pain were included in treatment studies. We excluded articles that didn't consider functional assessments and studies that assessed rigid lumbar belts, corsets or all other supports, except for soft lumbar belts. »

- Dans cette partie avec les critères d'inclusion sont exclus les corsets, les ceintures rigides et autres divers supports. Il serait bien que cette restriction apparaisse dans l'abstract, peut-être dans le titre et que dans l'introduction soit fait état de cette diversité de support, de l'hétérogénéité des études sur le type d'orthèses comme sur les effets recherchés dans l'ensemble de la littérature - fusion ou stabilisation / correction / en particulier pour des orthèses rigides, et souples à des fins fonctionnelles ou antalgiques. Ainsi la recherche serait mieux identifiée et peut être plus en cohérence avec les résultats obtenus.

#### Results

« Ultimately, 12 original articles were eligible for full-text review for the efficiency of lumbar support in NSLBP [29]-[30]-[31]-[32]-[22]-[33]-[34]-[35]-[36]-[37]-[38]-[39] ».

- Compte tenu de la remarque initiale, il faut bien revoir les références et de ce fait l'ordre aussi dans les textes - par exemple déjà pourquoi 22 après 32 ?

« Among these articles, 4 [30]-[22]-[37]-[34] were eventually selected for the meta-analysis.»  
- A revoir aussi suite à la remarque initiale concernant les références.

« Trials were excluded because of improper study design (cohort study) [33], inappropriate lumbar support ("spinal underwear") [40], and inappropriate study methodology [31] ».  
- La référence 40 n'est pas dans les 12 articles retenus ?

« The length of time the lumbar supports were worn varied from 2 weeks [37] to 48 weeks [44]. »  
- Revoir les références dont 44 qui n'est pas dans les 12 et doit être en fait la 34

« Some data were missing for two articles [34], [35] »  
- Mettre : [34, 35].

« For the first, the authors couldn't provide the data because they no longer had access to the database, but we succeeded in extracting sufficient data to include it in the final analysis. We received no answer from the authors of the second article. » Mettre : à la suite de « first » la référence du premier et idem pour à la suite de "second"

« 3.4 Characteristics of intervention

The four studies used commercially produced back supports.. »

- Mettre plutôt : « serial manufactured » que commercial car ils sont tous des productions commerciales, de série ou sur mesure.

« Two different scores were used in the selected studies: Oswestry Disability Index [45] for 2 studies [34,37], Roland Morris Disability Questionnaire [46] for one study. One study used functional tests assessed by a yes or no answer [30]. »  
- Revoir les références et mettre la référence après "for one study "

« Pain assessment was performed using a visual analog scale (VAS) (3 studies) or Verbal Scale (EVS) (1 study). »  
- Mettre plutôt les références des études concernées que 3 studies et 1 study

« Three were multi-center studies [30,42,43]. Two studies were situated in France [43,30] and two were in the USA [41,42]. »  
- Revoir les références

Discussion

« To our knowledge, comparability between functional questionnaires was not represented in the available literature, but it is well known that disability is one of the most important outcome for low back pain rather than the pain itself [24]. »  
- Mettre peut-être plutôt "pain intensity itself"

«Lumbar supports are easily prescribed non-pharmacological tools with no serious adverse effects. »  
- Mettre plutôt : "medical devices " que "non pharmacological tools"

« The only side effects are an increase in localized heat or sweating, which may be uncomfortable, particularly for overweight people. »

- Cet effet "chaleur" est parfois évoqué dans la littérature, souvent un peu ancienne, mais jamais bien analysé, en particulier en profondeur, et l'effet thérapeutique de la chaleur en superficie n'est pas non plus bien documenté il me semble.

« Low back pain, mainly chronic low back pain, leads to a fear of movement and results in patients reducing their activity to avoid pain. We know that sedentary is a worsening factor and leads to chronification through muscular deconditioning. »

- Le terme "chronification" est-il bien anglo-saxon ? - Plutôt « global deconditioning than muscular deconditioning »

« Morissette [41] showed a greater improvement in the pain and disability scores »

- Mettre : « Morissette et al. ...." »

« The local increase in heat also helps to reduce pain, even if this effect has not been demonstrated. »

- Cf Remarque précédemment sur chaleur

#### Abstract

Il doit être revu en tenant compte des remarques pour le texte concernant le type d'orthèse finalement étudié, les objectifs thérapeutiques, etc, ...

**Reviewer #2:** Thank you for giving me the opportunity to criticize this very interesting meta analysis on back supports. The back supports are widely used in clinical practice but efficacy remains a belief for clinicians. Strong guidelines are still lacking.

Even I support the publication in the Annals, I wish to make some comments before decision:

C1 Overall the paper is clear and well written. I commend the authors for their work

C2 Introduction : I suggest to move the paragraph 'to our knowledge ...limited samples' in the discussion as the previous and the following paragraphs already give the basis for this work.

C3 Introduction : last paragraph line 34: I suggest 'A secondary aim was to describe the differences «according to» NSLBP duration'

C4 Method: please check the references for all the document

C5 Method: P2.5 Line 4: I suggest to delete the sentence 'The authors were contacted when data were missing' previously written (last line P 2.3)

C6 Results: Chp 3.1 last paragraph: difficult to read. I suggest to report each commentary with its reference. A commentary for the second reference before the first at the end of the paragraph is confusing. Please add the reference for each comment.

C7 Results: the characteristic of the population may be reported in a table.

C8 Results chap 3.5 ; why 'aim' in the title of the chapter?

C9 Results ; the chapter 'Evaluation of the therapeutic effect' is the the 3.8 and not 3.5

C10 Results chap 3.8 first line: why the authors are seeking for the systematic prescription of lumbar support? why not only prescription?

C11 Results: Please check the following sentence Chap 3.5 Lines 24-27: 'Orthosis benefits were not highlighted, probably due to a lack of adherence, which was a limiting factor' is not clear for the reviewer

C12 Results last paragraph ; when the authors say 'The pooled standard mean difference of

disability at -0.54' it means a decrease of 54% of disability ?

C13 Results: the authors stated in the introduction that they will analyze the use of lumbar support in prevention as primary outcome and two other secondary outcomes. However specific results related to these criteria are missing, please check,

C14 Discussion: The sentence line 34 to 36 p12 needs to be linked to the previous paragraph.

C15 Discussion: I do not think that the discussion related to duration between line 36 and 56 brings additionnal knowledge.

C16 Discussion: I suggest to move the sentence P13 line 19 to 24 'To our knowledge, comparability between functional questionnaires was not represented in the available literature, but it is well known that disability is one of the most important outcome for low back pain rather than the pain itself [24].' to the method section to justify the criteria's choice.

C17 Discussion: P13 line 53-54 please consider: '...Oleske [42], whose results were not significant for pain and disability, and showed «only» a decrease over...'

C18 Discussion P14 line 5 to 7: The authors mean that the lumbar support is supposed to avoid paraspinal muscle over activation?

C19 Discussion: I suggest to delete the sentence P14 Line 19 to 21 (supposed link between heat and pain relief).

C20 Discussion P14 lines 24 to 34: already stated, to delete.

C21 Discussion : please move the paragraph limitations at the end of the discussion

C22 Discussion : part of the discussion related to adherence needs to be supported by results and thus move the results reported to the appropriated section. The authors cannot discuss such outcome without result to my opinion.

C23 Conclusion: recall the strong messages of this work in the conclusion and move the second part to the perspective section if any.

C23 Please add the  $I^2$  on the figures



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## Review

## Non-rigid lumbar supports for the management of non-specific low back pain: A literature review and meta-analysis

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## ABSTRACT

**Background:** Clinical practice guidelines for non-specific low back pain do not recommend the use of non-rigid lumbar supports (NRLSs) despite the publication of several positive randomized controlled studies. **Objective:** We conducted a systematic review with meta-analysis to assess the efficacy of NRLSs in the treatment and prevention of non-specific low back pain.

**Methods:** We searched for reports of randomized controlled trials in PubMed, Cochrane Library, EMBASE, Science Direct and Pedro databases. Data were analyzed by disease stage (acute, subacute, and chronic) and type of prevention (primary and secondary). The analysis of methodological quality involved the Physiotherapy Evidence Database (PEDro) scale.

**Results:** Of the 1581 records retrieved, only 4 full-text articles were included, with 777 patients: 378 in the NRLS group, and 348 in the control group. NRLSs conferred greater amelioration of disability (effect size  $-0.54$ , 95% CI  $-0.90$ ;  $-0.17$ ) and pain ( $-0.29$ ,  $-0.46$ ;  $-0.12$ ) than standard management. Insufficient data prevented a comparison of the efficiency for acute, subacute and recurrent low back pain as well as meta-regression of responder phenotypes (sociodemographic and other patient characteristics).

**Conclusion:** We demonstrated the overall efficacy of NRLSs for both disability and pain. However, further studies are needed to assess which patients can benefit the most from lumbar supports based on patient phenotype and the characteristics of low back pain.

PROSPERO (CRD42018109855).

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## 1. Introduction

Low back pain (LBP) is a worldwide frequent health symptom [1]. Overall, 60% to 90% of the populations in developing countries have already experienced an episode of acute LBP. LBP is the leading cause of activity limitation and sick leave throughout the world [2,3].

Non-specific LBP (NSLBP) is the most frequent cause of LBP. NSLBP is most often classified according to duration and whether it is acute (< 4 weeks of progression), subacute (4 weeks to 3 months)

and chronic (> 3 months of progression) [4]. First episodes of LBP are frequently without consequences, and complete recovery at 1-year ranges from 54% to 90% of cases [5]. However, non-recovering patients represent the largest part of the overall cost of LBP [6].

Management of NSLBP varies by duration of symptoms. For acute and subacute LBP, the aim is mainly to decrease and control the pain in order to recover and return to occupational activities. For chronic LBP, management is more complex due to psychosocial factors linked to chronic pain development [4,7].

Whatever the duration of the LBP, the management must associate pharmacological and non-pharmacological approaches. Pharmacological management is based on paracetamol, non-steroidal anti-inflammatory drugs, muscle relaxants (as second-line drugs only because of the side effects), and weak opioids [8]. The wide range of non-pharmacological treatments includes

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multidisciplinary management, physical exercises, and psychological support [9]. Lumbar supports can be proposed for treating and preventing NSLBP, but despite frequent prescription, consensus is lacking on the supports [10,11].

Lumbar supports are designated as orthoses, belts or corsets. To clarify the definition, we choose the term non-rigid lumbar support (NRLS), an adjustable elastic belt with back reinforcement that sustains or maintains the lumbar segment. These supports are serial manufactured with standard sizes. This definition eliminates fully rigid corsets or simple abdominal belts.

The mechanism of action of lumbar supports depends on its stiffness, and we only discuss NRLSs here. For the biomechanical aspect, the NRLS acts by stiffening the lumbar spine as it increases abdominal pressure and reduces intervertebral disc compression [12,13]. Lumbar mobility is reduced for rotation and inclination movements but not sagittal movements. It improves postural control [14] but not proprioception [15]. The supports have limited impact on trunk muscles, with no action on reducing energetic expenditure and no reduction in local muscular activity associated with a lack of trunk muscle strength loss [16]. Some effects on cardiorespiratory and digestive functions are reported and could be considered before prescription, especially for the highest and more rigid lumbar supports. Compression of the abdominal cavity might raise blood pressure and reduce venous return [17]. Moreover, modifications of ventilatory mechanics such as an increase in respiratory rate or a decrease in vital capacity were reported when lifting loads [18]. No contraindications have been highlighted. These effects are still investigated and still debatable [19].

Prescription of an NRLS is not systematic by all physicians and physiotherapists because of the lack of practice guidelines or specific education on this topic. Management variations among countries and prescription of lumbar supports still vary greatly [20].

The literature contains many articles concerning treatment and prevention of NSLBP; the articles highlight the importance of non-pharmacologic therapy as a first choice, but overall we have only a moderate level of evidence for the non-recommendation of NRLSs [21–23]. The European recommendations [10] do not suggest lumbar supports for treating chronic LBP. The 2016 NICE recommendations do not advise the use of belts or corsets for managing LBP with or without sciatica [21]. For French recommendations, lumbar supports can be used for a short time without any evidence [22].

The literature is controversial concerning the prescription of NRLSs. The 2008 Cochrane review, updated in 2011, included 15 studies (7 for preventive interventions and 8 for treatment interventions) on the efficacy of lumbar supports in NSLBP [23]. According to the results, NRLSs are considered no more effective than no intervention for treating or preventing NSLBP. According to the authors, whether NRLSs are more effective than no or other interventions in treating LBP is unclear. Moreover, this Cochrane review did not focus on LBP duration regarding the effect of lumbar supports, despite difference in management of acute, subacute and chronic LBP.

Thus, we conducted a systematic review with meta-analysis to evaluate the effectiveness of NRLSs on disability and pain in treating and preventing NSLBP. A secondary aim was to describe the differences by NSLBP duration and to characterize the clinical and psychosocial phenotypes of patients who respond well to wearing lumbar supports.

## 2. Methods

Our methodological strategy followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [24]. The literature review and meta-analysis were registered at PROSPERO (CRD42018109855).

### 2.1. Literature search

We conducted a systematic review of articles in the databases PubMed, Cochrane library, EMBASE, Science Direct and Pedro from January 2017 to March 2020. The search strategy included the keywords “low back pain”; “lumbar orthosis”; “lumbar belt”; “back support”; “lumbar support”; “lumbar brace”. We focused on studies that explored the efficiency of NRLSs in treating and preventing NSLBP, with disability and pain as main outcomes and with no time limit.

The search strategy is presented in the Appendix. We first selected articles by reading the titles. Duplicates were removed. We then read all titles and abstracts to screen articles according to the following criteria and assessed the eligibility of the remaining articles by reading the full text.

### 2.2. Selection criteria

We retained articles with the following criteria: written in English or French; recommendations from learned societies related to LBP; and trials about the efficiency of NRLS assessed with disability and pain as the outcomes in adult populations (age 18 to 65 years) for treatment and prevention. Participants with acute, subacute or chronic LBP were included in treatment studies. Participants without pain or recurrent pain were included in prevention studies. For prevention trials, lumbar supports had to be compared to the usual prevention. For treatment trials, NRLS had to be compared to usual care. We excluded articles that did not consider disability assessment and studies that assessed rigid lumbar belts, corsets or all other supports, except for NRLSs. Also, data on secondary forms of LBP, such as inflammatory disease, infection, cancer, osteoporosis or post-operative management were excluded.

### 2.3. Data extraction

The research was performed independently with the help of a specialized documentarian (NPD) to limit bias. One author (PG) conducted all literature searches and collated abstracts. Two authors (PG and CL) independently reviewed the abstracts and decided on the suitability of the articles for inclusion, with discussion with a third author (EC) if needed to achieve consensus. All authors then reviewed the eligible articles.

Only articles of randomized controlled trials (RCTs) in which wearing a NRLS was compared to conventional management and that measured disability and pain outcomes were retained for the meta-analysis. For all studies with available data, we extracted sample size, means, and standard deviations for each treatment group, at each time point reported. If data were not available, we contacted the authors to obtain missing data.

### 2.4. Assessment of methodological quality

The assessment of methodological quality was performed by 2 independent readers (PG, CL) by using the Physiotherapy Evidence Database (PEDro) scale [25]. This scale has 11 indicators to identify major risks of bias. Each point is scored. If mentioned and included, the point is given and noted as yes. According to the PEDro guidelines, the first point is not considered in the final score. A score out of 10 is given for each trial.

### 2.5. Statistical considerations

After extraction, data were compiled by software designed specifically for meta-analyses (Comprehensive Meta-Analysis v2; Biostat, Englewood, NJ). For descriptive analyses, data are presented as means (SD) or median (interquartile range), depending on the

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statistical distribution. Because outcomes were continuous (i.e., disability evaluated by Oswestry Disability Index and Roland Morris Disability Questionnaire and pain by a visual analog scale), the pooled standardized mean difference (SMD) was calculated with a random-effects model (DerSimonian and Laird approach) that accounted for the true variation in effects occurring among studies and for random errors within a single study. In other words, to address the non-independence of data due to study effect, random-effects models that assumed between- and within-study variability were used rather than fixed-effect ones because certain experimental parameters had wide variations. When necessary (i.e., when the outcome was not continuous, such as functional tests assessed by a dichotomous yes/no answer), odds ratios reported in individual studies were converted to SMDs [26]. The SMD can be seen as an effect size (ES) calculated as the difference between 2 means divided by the standard deviation and was interpreted according to Cohen's recommendations (*Statistical Power Analysis for the Behavioral Sciences*, 2nd ed., New Jersey: Lawrence Erlbaum, 1988), defining ES bounds as small (0.2), medium (0.5) and large (0.8). The type I error was fixed at 5%. Statistical heterogeneity between results was assessed by examining forest plots, confidence intervals and the  $I^2$  statistic.  $I^2$  values range from 0% 100% and are typically considered low at < 25%, modest 25–50%, and high > 50%.  $P < 0.05$  was considered statistically significant.

### 3. Results

#### 3.1. Overview of included studies

The database search resulted in 1581 articles. Ultimately, 11 original articles were eligible for full-text review for the

efficiency of non-rigid lumbar support in NSLBP [27–37]. Among these articles, 4 [27,28,33,36] were eventually selected for the meta-analysis (Fig. 1). Trials were excluded because of improper study design (cohort study) [32], inappropriate lumbar support (“spinal underwear”) [37], and inappropriate study methodology [30]. For this last study, using a non-randomized clinical trial design, 3 groups were compared (no LBP/no orthoses; no LBP/orthoses; LBP/orthoses), but the only interesting data to extract was for LBP with lumbar orthoses. Some data were missing for 2 articles [33,34]. For the first [33], the authors could not provide the data, but we succeeded in extracting sufficient data to include it in the final analysis. We received no answer from the authors of the second article [34].

#### 3.2. Assessment of methodological quality

We used the 11 items of the PEDro scale but as stated in the PEDro guide, Quality assessment was homogeneous (Fig. 2). The mean score was 6.5 out of 10, including 2 reports with a score of 6 and 2 with a score of 7. Patients, therapists and outcome assessors could not be blinded because the lumbar support was worn. One study did not have similar population characteristics at baseline for the intention-to-treat population [27], and one did not have measurements for at least 85% of the participants [33]. All studies mentioned their randomization method except one, which did not mention whether the allocations were concealed [30].

#### 3.3. Characteristics of participants

In the 4 studies, 777 participants were included, 378 in the lumbar support group and 348 in the control group; population

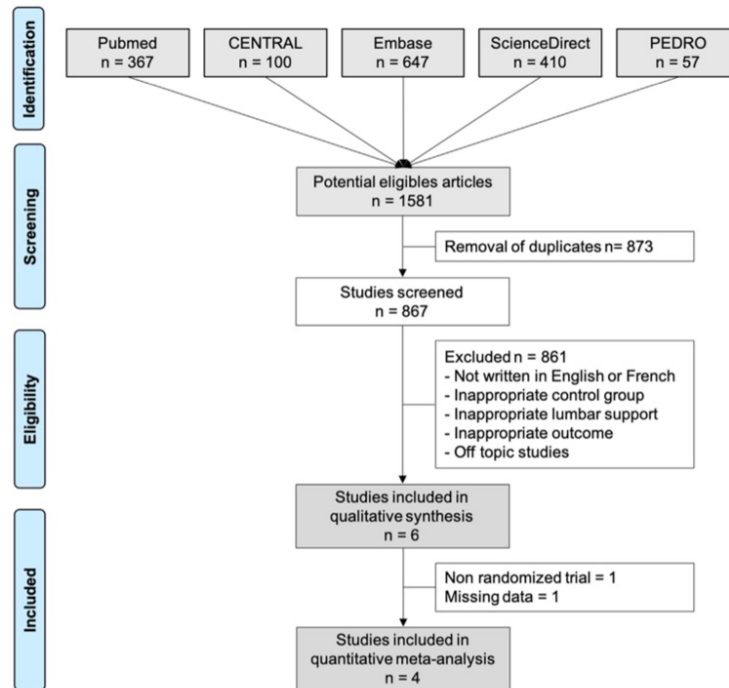


Fig. 1. Flow diagram of the articles in the study.

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	Random allocation	Concealed allocation	Groups similar at baseline	Participant blinding	Therapist blinding	Assessor blinding	Adequate follow up	Intention to treat analysis	Between-group difference reported	Point estimate and variability reported	General level of evidence (/10)
Calmels 1999	+	+	+	-	-	NA	+	+	+	+	7
Calmels 2009	+	+	-	-	-	-	+	+	+	+	6
Oleske 2007	+	+	+	-	-	-	+	+	+	+	6
Morrisette 2014	+	+	+	-	-	-	+	+	+	+	7
Kawchuk 2015	+	?	+	-	-	?	+	+	+	+	6
Roelofs 2007	+	+	+	-	-	-	+	+	+	+	7

Fig. 2. Methodological quality of the studies according to the PEDro scale. Yes = + (1 point), No = - (0 points), Can't say = ? (0 points), Not applicable: NA.

sizes ranged from 36 to 433 individuals (Table 1). The proportion was higher for males (61.5%) than females. The proportion of females was superior in one study [37] and inferior in 3 studies. The mean age was from 38 to 48 years. The mean body mass index, reported in 2 studies, was > 29 kg/m<sup>2</sup> [33,36]. Only one study reported physical activity [27]: 250 (57.7%) participants practiced regular exercise outside of work. Overall, 36 participants had acute LBP, 210 had subacute LBP, 24 had chronic LBP, and 175 had recurrent LBP; 35 had acute or subacute LBP. Two studies detailed professional categories. One study was of manual workers, with 433 participants [33]. Another study enrolled 36 participants: 17 sedentary workers and 19 manual workers [28]. Three studies revealed the use of medication [27,33,36]: 456 of 741 (48%) participants took medication. The medication could be an association of analgesics (paracetamol or aspirin) and a muscle relaxant possibly prescribed to all participants for 8 days. Also,

patients could take narcotics, non-steroidal anti-inflammatory drugs, corticosteroids or antidepressants.

3.4. Characteristics of the intervention

The 4 studies used serial manufactured lumbar supports. The main characteristics were a soft elastic lumbar belt with back reinforcements. One study [36] used 2 different lumbar supports: one elastic and one inelastic with posterior reinforcements. The length of time the lumbar supports were worn ranged from 2 weeks [36] to 48 weeks [33].

3.5. Outcomes

Disability assessment involved different scores, including patient-reported outcome measures (PROMs) (Table 2). Two

Table 1 Characteristics of the trials of low back pain (LBP) and non-rigid lumbar supports (LSs) included in the qualitative synthesis: population, intervention, measurements.

Study	Population				Intervention			Measurement time (weeks)			
	n	Age mean (SD)	Sex % male	Mean BMI (kg/m <sup>2</sup> ) mean (SD)	Professional work (n)	Type of LBP	Type	Duration	T1	T2	T3
Calmels 1999	36	38.3 (10.2)	72.2	Unknown	Sedentary (17) Manual (19)	Acute	Gr 1: LBP+LS Gr 2: LBP+usual care	3 weeks	1	3	-
Kawchuk 2015	54	36.1 (13.5)	51.8	Unknown	Unknown	Acute	Gr 1: LBP+LS Gr 2: healthy controls Gr 3: healthy controls+LS	2 weeks	2	-	-
Calmels 2009	210	43 (10.7)	54.8	Unknown	Unknown	Subacute	Gr 1: LBP+LS Gr 2: LBP+usual care	12 weeks	4	8	12
Oleske 2007	433	46.1 (7.6)	79.8	29.9 (5.4)	Manual (433)	Recurrent	Gr 1: LS+education Gr 2: education	48 weeks	48	-	-
Roelofs 2007	360			Unknown	Manual	Recurrent	Gr 1: LS Gr 2: usual care+education	48 weeks	48	-	-
Morrisette 2014	98	48 (15.3)	39	29.0 (7.2)	Unknown	Mixed	Gr 1: iLS+usual care Gr 2: eLS+usual care Gr 3: usual care	2 weeks	2	-	-

BMI: body mass index.

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**Table 2**  
Characteristics of the trials included in the qualitative synthesis: outcomes, results.

Study	Primary outcome	Secondary outcome	Results		
			T1	T2	T3
Calmels 1999	Pain (VAS, VRS)	-	Gr1>Gr2	NS	-
	Pain attitude	-	NS	NS	-
	Lumbar stiffness	-	Gr1>Gr2	NS	-
	Muscle contraction	-	Gr1>Gr2	NS	-
	Disability (clinical test)	-	NS	Gr1>Gr2	-
Kawchuk 2015	Disability (ODI)	-	Decrease	-	-
	-	Spinal stiffness	NS	-	-
	-	Muscle endurance	Increase	-	-
Calmels 2009	Disability (RMDQ)	-	Gr1>Gr2	-	Gr1>Gr2
	Pain (VAS)	-	Gr1>Gr2	-	Gr1>Gr2
Oleske 2007	Drug consumption	-	Gr1>Gr2	-	Gr1>Gr2
	Pain (VAS)	-	NS	-	-
	Disability (ODI)	-	NS	-	-
	Recurrence	-	Gr1>Gr2	-	-
	Physical health	-	NS	-	-
Roelofs 2007	Mental health	-	NS	-	-
	Number of days of LBP	-	Gr1>Gr2	-	-
	Sick leave	-	NS	-	-
Morrisette 2014	-	Disability (Quebec*)	Gr1>Gr2	-	-
	Disability (ODI)	-	Gr1>Gr3	-	-
	-	Pain (VAS)	NS	-	-
	-	PSAS	Gr1>Gr3	-	-
-	FABQ	NS	-	-	

FABQ: Fear and Avoidance Beliefs Questionnaire; NS: non-significant; ODI: Oswestry Disability Index; PSAS: Patient Specific Activity Score; RMDQ: Roland Morris Disability Questionnaire; VAS: visual analog scale; VRS: verbal rating scale. Quebec Disability Scale.

different scores were used: Oswestry Disability Index [38] for 2 studies [33,36] and Roland Morris Disability Questionnaire [39] for 1 study [27]. One study used functional tests assessed by a yes/no answer [28]. To be compared, PROMs were normalized to a base of hundreds. Pain assessment was assessed with a visual analog scale [27,33,36] or verbal rating scale (VRS) [28]. Pain scores were normalized to a base of hundreds. No adherence assessment was performed in the selected studies.

### 3.6. Study design

Three studies were multicentre [27,28,33]; 2 were conducted in France [27,28] and 2 in the United States [33,36]. All studies were RCTs. Randomization was computer-generated in 2 studies [27,36] and was manually performed with opaque envelopes in the 2 remaining studies [28,33].

### 3.7. Selection of participants in the included articles

Inclusion criteria were male or female adults with acute LBP for a maximum of 10 days [28], with treatment for an initial episode or recurring non-specific LBP, episodes lasting 1 to 3 months [27] or the primary report indicating acute, subacute, or chronic LBP [36] or having a non-traumatic work-related low-back disorder within 8 weeks of the date of diagnosis of an injury/illness [33]. Exclusion criteria included secondary forms of LBP, neurological signs, spinal surgery, current pregnancy (in 2 studies [27,36]), and contraindication to NRLSs.

### 3.8. Evaluation of the therapeutic effect

The systematic review did not find any recommendations for the prescription of NRLS for non-specific LBP. NRLS was effective for disability, pain, and pain-killer consumption for subacute LBP (increases of time intervals for dispensing medication). It was also effective for secondary prevention of LBP recurrence. Benefits of lumbar supports were not highlighted, possibly because of lack of adherence.

No adverse effects were reported for the studies.

For the 4 studies included in the meta-analysis, the pooled standard mean difference showed statistically significant reduced disability with NRLSs compared to standard management: ES -0.54 (95% CI -0.90; -0.17) with substantial heterogeneity ( $I^2 = 71.7\%$ ,  $P = 0.014$ ) (Fig. 3). Results were stratified by duration of LBP and were statistically significant for all studies for acute (-0.97, -1.89; -0.06), subacute (-0.33, -0.61; -0.05) and recurrent LBP (-0.24, -0.45; -0.03). Concerning pain criteria, 3 of the included studies showed reduced pain (ES -0.29, 95% CI -0.46; -0.12), with  $I^2 = 5.4\%$  ( $P = 0.348$ ) (Fig. 4).

## 4. Discussion

The main findings were that NRLSs demonstrated significant improvements in disability and pain. Insufficient data prevented the comparison of the efficiency among acute, subacute and recurrent LBP, nor did it allow for meta-regression of the sociodemographic and other characteristics of individuals who could benefit the most from NRLSs.

To our knowledge, this is the first systematic review to highlight the effects of NRLSs through meta-analysis. Other systematic reviews, such as the Cochrane Library review, did not conduct a meta-analysis because of the heterogeneity of the study populations and the outcomes [23]. The review drew conclusions concerning NRLSs used for prevention or treatment with no improvement for prevention and limited evidence of alleviation of disability when treating LBP. These results can be explained by the low methodology score, with 9 of the 15 studies included published before 1995 and the outcomes sometimes not accurate enough to show a difference as being an overall improvement. However, a few high-quality RCTs demonstrated the efficacy of NRLSs [27]. Only a few studies were of good methodological quality because of the low number of participants, absence of real blinding, and lack of assessment of co-interventions. Moreover, the heterogeneity in choice of outcome variables and measurement instruments hinder comparisons between studies and systematic

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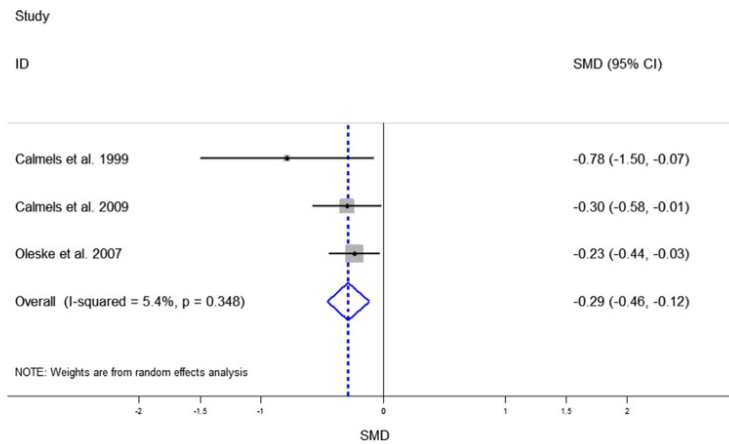


Fig. 3. Forest plot of effect of lumbar orthoses on pain. SMD, standardized mean difference; 95% CI: 95% confidence interval.

reviews [40]. Disability is considered by researchers, clinicians and patients to be the most important outcome domain to be assessed in LBP clinical trials [41]. NSLBP concerns very heterogeneous patient phenotypes that could lead to a major risk of bias, particularly when comparing interventions with limited samples.

To overcome this situation, we focused on only the most pertinent primary outcomes, such as disability and pain, to evaluate the effectiveness of NRLSs. The stratification by duration of LBP can reflect the clinical reality and avoid any bias linked to differences in management. However, this classification has some limitations. Chronic LBP is a particular entity and is part of chronic pain, which has psychosocial consequences and needs a more general management. Some acute LBP, which is not managed as well as possible, can last > 3 months without being considered chronic pain. Moreover, subacute LBP cannot be individualized. It is considered a longer acute LBP or a “pre-chronic” phase for which

more intensive care is needed. So, this classification is insufficient for classifying different pathophysiological mechanisms of different diseases.

Concerning the selection of the articles, 3 different PROMs for disability were used in the selected studies: Oswestry Disability Index [38], Roland Morris Disability Questionnaire [39] and close-ended questions. We had to convert scores to a base of hundreds to compare data. For one study, disability was assessed with clinical functional tests because at the time of publication (1999), the use of questionnaires was not common-place and authors lacked validated questionnaires for LBP. We decided to keep this study in the quantitative analysis because of its good methodological quality and the very limited number of studies of acute LBP. To our knowledge, comparability between disability questionnaires was not represented in the literature, but disability is one of the most important outcomes for LBP rather than pain intensity itself [41].

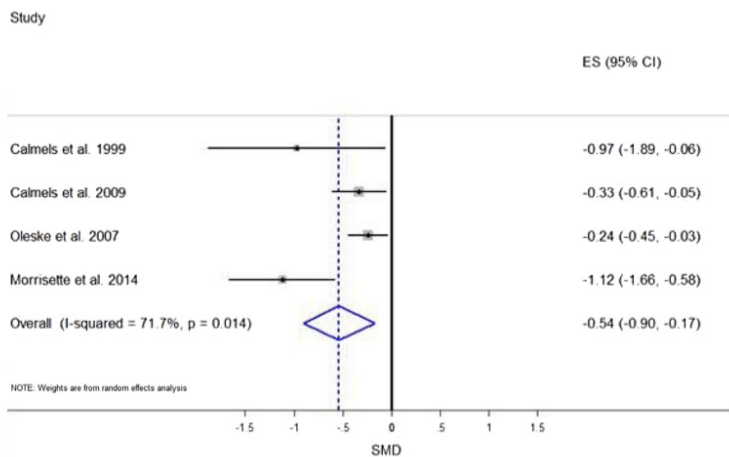


Fig. 4. Forest plot of effect of lumbar orthoses on pain. SMD, standardized mean difference; 95% CI, 95% confidence interval.

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## 5. The benefits of lumbar supports in disability and pain

NRLSs are easily prescribed medical advices with no serious adverse effects. The only side effects could be an increase in localized heat or sweating, which may be uncomfortable, particularly for overweight people.

LBP, mainly chronic LBP, leads to a fear of movement and results in patients reducing their activity to avoid pain. Sedentarism is a worsening factor and leads to chronicization through global deconditioning.

The main purpose of treatment of LBP is to reduce disability and pain. All included studies showed an amelioration of disability except for Oleske et al. [33], whose results were not significant for pain and disability and showed only a decrease over the 12-month follow-up with a significant reduction in LBP recurrence.

Because of their biomechanical properties, NRLSs increase spine stability and are used to relieve the impaired lumbar proprioception in people with LBP [42]. Morisette et al. [36] showed greater improvement in the pain and disability scores (Oswestry Disability Index) with inextensible lumbar support and linked it to the increase in trunk stiffness and motion limitation that it provides. In fact, spinal muscles are over-activated to provide a compensatory stiffness to the spine [43].

Moreover, NRLSs may have a psychological impact that can help restore confidence in the back, reduce the fear of movement and facilitate a gradual return to activities [44].

Increasing abdominal pressure can lead to increased spine stability by increasing the stiffness of trunk muscles and favouring muscle contraction [45]. The local increase in heat could also help reduce pain, even if this effect has not been definitively demonstrated.

As previous reviews have mentioned, the heterogeneity of the NSLBP population and the outcomes were major difficulties in a meta-analysis of this topic. However, we found that some good methodological studies exist and show the efficacy of lumbar supports.

## 6. Limitations

The first limitation is the limited number of trials included. 4. Numerous published studies concerned the biomechanical action of lumbar supports, with many studies focusing on muscular effects, posture effects, and proprioception, but only a limited number of randomized clinical studies assessed disability. In addition to the lack of RCTs, published studies did not use the same outcomes or the same orthoses. Moreover, the prescription of orthoses is cultural, with some countries prescribing them more than others. We selected only French and English articles and may have missed studies published in other languages.

Second, most trials were of low methodological quality. Prevalent methodological flaws among the selected RCTs were no concealment of treatment allocation (item 2), no assessment of co-interventions (item 4) and adherence (item 5), and no blinding of patients (item 6) and outcome assessors (item 7) owing to the impossibility to deliver a placebo.

Assessment of adherence was not mentioned in any report. It is a confounding factor when studying effectiveness and is a potential bias because the length of time the support is worn might be a predictor of efficacy [46]. Assessment of adherence should be part of these studies and measured by the length of time the support is worn. This assessment was lacking in most publications of NRLSs and there is a need for further study of this domain. Some studies have developed methods to quantify adherence, such as temperature recording sensors [47].

## 7. Phenotypes of patients who can benefit the most from lumbar supports

The next step is to identify risk factors of non-adherence and individuals with an adherent profile. Roelofs et al. [48] analyzed the determinants of intention to use a lumbar support among home care workers. For these workers, the perceived benefit must be superior to the discomfort, which is why they are unlikely to experience benefits from its use in primary intention. A positive attitude was found the strongest predictor for intention, followed by good self-efficacy. Conversely, obesity or poor self-efficacy was correlated with low intention to use.

Some studies investigated the factors affecting adherence and found that these could be categorized into patient-centred, therapy-related, social and economic, healthcare system, and disease factors [49]. So, the physician has to consider these different factors before prescribing, and the patient must be informed about factors affecting adherence before prescription. Adherence and persistence are related to treatment satisfaction and treatment satisfaction is explained by compliance or persistence [50].

Systematic or collective prescription of lumbar orthoses cannot be recommended. Patients with adherent profiles, with a positive vision of the treatment, recurrent pain or with a positive expectation could be more capable of receiving lumbar support.

We lack studies concerning the cost-effectiveness of lumbar supports. Roelofs et al. [51] showed that wearing an NRLS as a secondary prevention, in addition to usual care, was correlated with reduced sick leave.

## 8. Conclusions

Among non-pharmacologic treatments for NSLBP, NRLSs are a non-negligible option. The large population described as having NSLBP is problematic for generating good-quality evidence about the effectiveness of NRLSs. Patient profiles with a potential good response might exist, and further studies should explore the effectiveness of NRLSs regarding patient phenotypes. Further studies should include patients from a homogeneous population, classified by the duration of the pain. Precise and validated patient-reported outcomes, such as disability and pain scores, should be standardized and used in investigations. Adherence should be assessed. Other studies concerning cost-effectiveness in the whole NSLBP population are needed.

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### Authors' contribution

Conception and design of the study. P.G., C.L., F.D., L.B., B.P., E.C.: drafting of the original protocol. C.L., L.B., B.P., E.C.: acquisition of data. P.G., C.L., L.B., E.C.: coordination of the study. B.P., E.C.: design of the statistical analysis plan. F.D., B.P., E.C.: data analysis and interpretation. P.G., F.D., B.P., E.C.: drafting of the present manuscript. P.G., F.D., B.P., E.C.: final approval. P.G., C.L., F.D., L.B., B.P., E.C.

### Disclosure of interest

E.C. has regular consulting activities for Thuasne, which was not involved in the study design; collection, management, analysis, and interpretation of data; writing of the report; or decision to publish the results. The other authors declare that they have no competing interest.

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### Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.rehab.2020.05.010>.

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## SERMENT D'HIPPOCRATE

Au moment d'être admis(e) à exercer la médecine, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité.

Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux.

Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions. J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité.

J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences.

Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.

Je donnerai mes soins à l'indigent et à quiconque me les demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

Admis(e) dans l'intimité des personnes, je tairai les secrets qui me seront confiés. Reçu(e) à l'intérieur des maisons, je respecterai les secrets des foyers et ma conduite ne servira pas à corrompre les mœurs.

Je ferai tout pour soulager les souffrances. Je ne prolongerai pas abusivement les agonies. Je ne provoquerai jamais la mort délibérément.

Je préserverai l'indépendance nécessaire à l'accomplissement de ma mission. Je n'entreprendrai rien qui dépasse mes compétences. Je les entretiendrai et les perfectionnerai pour assurer au mieux les services qui me seront demandés.

J'apporterai mon aide à mes confrères ainsi qu'à leurs familles dans l'adversité.

Que les hommes et mes confrères m'accordent leur estime si je suis fidèle à mes promesses ; que je sois déshonoré(e) et méprisé(e) si j'y manque.

## SERMENT D'HIPPOCRATE

En présence des Maîtres de cette FACULTE et de mes chers CONDISEIPLES, je promets et je jure d'être fidèle aux lois de l'Honneur et de la Probité dans l'exercice de la Médecine.

Je donnerai mes soins gratuits à l'indigent et je n'exigerai jamais un salaire au-dessus de mon travail. Admis dans l'intérieur des maisons, mes yeux ne verront pas ce qui s'y passe, ma langue taira les secrets qui me seront confiés et mon état ne servira pas à corrompre les mœurs ni à favoriser le crime.

Respectueux et reconnaissant envers mes MAÎTRES, je rendrai à leurs enfants l'instruction que j'ai reçue de leurs pères.

Que les HOMMES m'accordent leur estime si je suis fidèle à mes promesses. Que je sois couvert d'OPPROBRE et méprisé de mes confrères si j'y manque.



## LUMBAR SUPPORTS IN THE MANAGEMENT OF NON-SPECIFIC LOW BACK PAIN: A LITERATURE REVIEW AND META-ANALYSIS

### **Abstract :**

**Objective:** Clinical practice guidelines for non-specific low back pain do not recommend the use of non-rigid lumbar supports (NRLS) despite the publication of several positive randomized controlled studies. We aimed to assess the efficacy of NRLS in the treatment and prevention of non-specific low back pain by conducting a systematic review with meta-analysis.

**Methods:** We searched for randomized controlled trials referenced in the PubMed, Cochrane Library, EMBASE, Science Direct and Pedro databases with the following keywords: “low back pain”, “lumbar orthosis”, “lumbar belt”, “back support”, “lumbar support”, and “lumbar brace”. Data were analyzed according to the stages of the disease (acute, subacute, and chronic) and type of prevention (primary and secondary). The analysis of the methodological quality was performed using the Physiotherapy Evidence Database (PEDro) scale.

**Results:** Of the 1581 records retrieved, we included only 4 full-text articles, for a total of 777 patients: 378 in the NRLS group, and 348 in the control group. Non-rigid lumbar supports showed greater improvements in disability (effect size = -0.54, 95 CI -0.90 to -0.17) and in pain (-0.29, -0.46 to -0.12). Insufficient data prevented a comparison of the efficiency for acute, subacute and recurrent low back pain, as well as the computation of meta-regressions on responder phenotypes (sociodemographic and other patient characteristics).

**Conclusion:** We demonstrated the overall efficacy of NRLS on both disability and pain. However, further studies are necessary to assess which patients can benefit the most from lumbar supports based on patient phenotypes and the characteristics of low back pain.

*Keywords:* low back pain, acute, chronic, subacute, lumbar orthosis, meta-analysis, prevention.