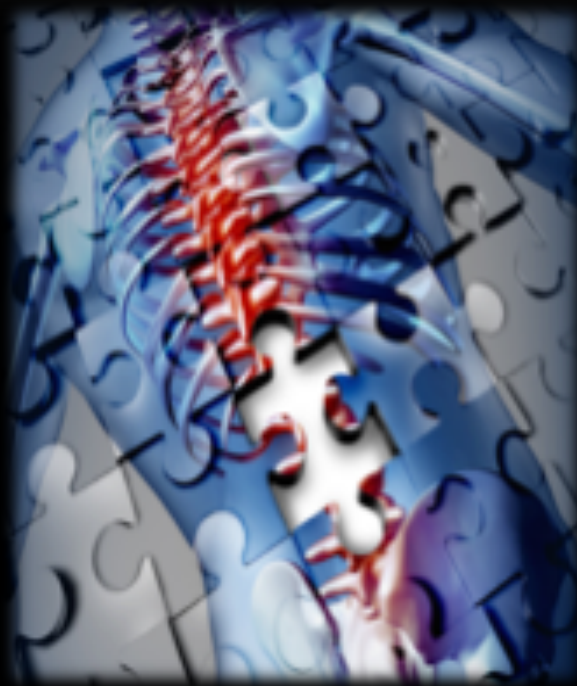


EVIDENCE-BASED ORTHOPAEDIC MANUAL THERAPY FOR PATIENTS WITH NONSPECIFIC LOW BACK PAIN

ANALYSIS OF A KINEMATIC MODEL OF THE SPINE



Benjamin Hidalgo

Thesis submitted in fulfillment of the requirements for the degree of

« Docteur en Sciences de la Motricité »

Supervisors: Professors Christine Detrembleur and Henri Nielens



Faculté des Sciences de la Motricité
Institute of Neuroscience

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**Université Catholique de
Louvain**

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**Supervisors: Professor Christine Detrembleur and Professor Henri Nielens
(UCL)**

Committee members:

Chair: Prof. Schepens Bénédicte (UCL)

Prof. Berquin Anne (UCL)

Prof. Feipel Véronique (ULB)

Prof. Vanderthommen Marc (ULG)

Prof. Thonnard Jean-Louis (UCL)

Prof. Bragard Dominique (UCL)

Benjamin Hidalgo



Pictured as speaker in 2012 during the World Musculoskeletal Congress of the International Federation of Orthopaedic Manipulative Physical Therapists (IFOMPT), Québec, Canada

Benjamin was born in December 1975 in Belgium. He completed his master's degrees in Physical Education, supplemented with a pedagogical degree for teaching, in 2000 and in Physical Therapy and Rehabilitation in 2002 at the Faculty of Motor Sciences (FSM) of the Université Catholique de Louvain (UCL), Louvain-La-Neuve, Belgium. He completed a degree in Osteopathy in 2007 after 5 years of continuing education (160 ECTS) at the Sutherland College of Osteopathic Medicine, Belgium. Benjamin was certified in Orthopaedic Manual Therapy (OMT) by the Manual Concepts Program (25 ECTS) of Curtin University, Australia in 2011, and by UCL in 2014 after 2 years of continuing education (60 ECTS). He has fulfilled the requirements for certificates in sport physiotherapy, trigger points therapy and dry needling, mobilisation with movement (Mulligan concept), spinal manipulative therapy, functional movement assessment, classification-based cognitive functional therapy for low back pain, and specific osteopathic care. He continues to learn through continuing education courses in his field of interest, and is the co-founder and co-head of the Certificate Program in Orthopaedic Manual Therapy (75 ECTS) at UCL.

Since 2002, Benjamin has specialised in the evaluation and treatment of neuromusculoskeletal disorders of the whole body for elite sportsmen and the public in his private clinical practice. In the last 6 years, he has focused his clinical and research expertise on the spine, particularly the lumbopelvic region. He is an accomplished practitioner, teacher and researcher in the neuromusculoskeletal field. These three areas of expertise and skills are complementary and interrelated, providing Benjamin with a broad

view of OMT, great satisfaction in his work, and, he hopes, a good quality of care and education for his patients and students.

As the historic context of this thesis, in 2008 Prof. Jean-Louis Thonnard contacted Benjamin and encouraged him to begin a PhD in the field of OMT for patients with low back pain. Benjamin accepted this challenge, motivated by curiosity and a desire for intellectual development in this very interesting and complex topic of research. In the beginning, the research was difficult because there was no background in manual therapy at UCL. Fortunately, the advice of Benjamin's thesis supervisors, Profs. Christine Detrembleur and Henri Nielens (FSM-UCL), and a great meeting with an external international expert in OMT, Dr. Toby Hall (Curtin University, Australia), combined to enable on-time completion of this ambitious project. Regarding the picture on the cover, with this thesis, Benjamin hopes to contribute insight to understanding the complex puzzle of low back pain, thereby improving the management of patients with this debilitating disorder.

benjamin.hidalgo@uclouvain.be

Remerciements

Entreprendre une thèse, un « PhD », n'est vraiment pas une épreuve de vie anodine... Cela représente un défi important et même un combat qui a comme conséquence, qu'une longue période de vie y soit entièrement dévouée. Cette quête de soi-même en ce qui me concerne, implique que la vie privée ainsi que parfois la santé, en subissent certaines conséquences.

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« Last but not least », je remercie ma famille sans qui je n'aurai pas eu la force de terminer ce doctorat. Grâce à eux j'ai pu trouver des ressources inattendues lors des nombreux

passages difficiles tout au long de ce projet professionnel et de ma vie, je remercie donc chaleureusement et avec amour : ma mère Elyane Clesse, mon frère Pierre Hidalgo et sa compagne Mélanie Glenda-Gillis, ma sœur Adèlanne Hidalgo, ainsi que ma petite chienne Lana. Enfin, j'aimerais remercier ma compagne Concetta Crimi qui a su me donner le sourire et la volonté à travers son amour et son humour, ainsi que les innombrables fous rires dont j'avais besoin parfois pour m'échapper temporairement afin de finaliser ce travail que vous allez j'espère lire attentivement...

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Summary of the thesis

This thesis on the study of the efficacy of **orthopaedic manual therapy** (OMT) for patients with **nonspecific low back pain** (LBP) was developed by following the steps of an evidence-based practice process through three major sections.

The Introduction defines the debilitating disorder of LBP and OMT, and describes an integrative approach for the stratification of care in LBP patients.

Section 1 presents a **systematic review** that updates the best evidence of OMT efficacy in terms of pain, functions, activities and participation. The findings allow us: (I) to establish different levels of evidence for this form of therapy, (II) to understand the complexity of LBP and (III) to affirm the importance of the study design quality in OMT trials (e.g. splitting design, complexity of the placebo procedure and integration of clinical reasoning).

Section 2, which is composed of three studies, investigates **a kinematic model of the spine** to help in the diagnosis of LBP patients, as well as outcome measures for future investigations of OMT in LBP patients. This kinematic tool permits a valid assessment of body structures (lumbopelvic and thoracic vertebral column, muscles of the trunk and pelvic regions), body functions (mobility in a vertebral segment, control of complex voluntary movements, proprioceptive function) and activities (bending, maintaining a body position).

Finally, Section 3 presents two clinical studies. The first is a reliability study on a standardised and original pain provocation examination of the lumbar spine in a **combined movement** fashion. This examination provides the direction and vertebral level(s) of treatment. On the basis of this reliable objective examination and evidence described throughout this thesis, a randomised controlled trial was conducted. This last study questions the short-term efficacy of a novel form of OMT, namely **mobilisation with movement**, on primary kinematic outcome measures (kinematic algorithms for range of motion and speed) and secondary self-reported outcome measures (pain, function, activities and participation) in LBP patients with a mechanical pain pattern in flexion. The results of this investigation raise the overall level of evidence from limited to moderate in favour of using central sustained natural apophyseal glides in LBP patients.

In conclusion, the different points and perspectives developed along this thesis contribute towards solving the complex puzzle of LBP within a patient-centred approach. Manual therapy is an art developed through clinical practice, as well as a science developed through fundamental and clinical research. **Clinical research** is of major importance because it directly drives clinical practice and education towards an **evidence-based OMT practice** within the biopsychosocial framework, thereby aiding many patients, students and health professionals.

Cette thèse étudie l'efficacité de la thérapie manuelle orthopédique (TMO) auprès de patients présentant une lombalgie commune (LBP). Elle s'articule selon les différentes étapes d'un processus de pratique fondée sur les preuves scientifiques à travers trois sections principales. Au préalable, nous définissons la LBP ainsi que la TMO selon une vision contemporaine. La présentation d'une approche intégrative a également été abordée pour mieux comprendre la stratification des soins chez les patients LBP avec une TMO adaptée à chaque sous-groupe.

Dans la section 1, qui compose la première étape de notre travail, une revue systématique met à jour les meilleures preuves existantes sur l'efficacité de la TMO (techniques passives et actives) sur la LBP (de la phase aiguë à chronique) pour la douleur et la fonction, ainsi que pour les activités et la participation. Ce qui nous a permis : (I) d'établir différents niveaux de preuve pour cette forme de thérapie avec une fluctuation assez large du niveau de preuves (de faible à forte), (II) de mieux comprendre la complexité de la LBP, (III) de mettre en avant l'importance de la qualité de conception des études cliniques en TMO comme par exemple : le fractionnement en sous-groupes, la complexité de la procédure placebo, ainsi que de l'intégration du raisonnement clinique dans les études sur la TMO et la LBP.

La section 2, représentant la deuxième étape, se compose de trois études pour évaluer l'intérêt d'un modèle cinématique de la colonne vertébrale pour aider dans le diagnostic des patients LBP, ainsi que comme outil de mesure pour les futures études cliniques sur la TMO et la colonne vertébrale. Cet outil cinématique a démontré une bonne reproductibilité et validité pour l'analyse des mouvements du tronc, c'est-à-dire: des structures du corps (colonne vertébrale lombo-pelvienne et thoracique, des muscles du tronc et de la région du bassin), des fonctions du corps (les fonctions de mobilité articulaire: spécifié comme la mobilité dans un segment vertébral, le contrôle volontaire de mouvements complexes, ainsi que la fonction proprioceptive) et des activités (flexion du tronc et le maintien d'une position du corps).

Enfin la section 3 de cette thèse présente deux études cliniques originales. La première est une étude sur la fiabilité de l'examen physique en TMO par provocation de la douleur sur le rachis lombaire selon le principe des mouvements combinés. Sur base de cet examen qui a démontré une fiabilité suffisante nous donnant la direction et les niveaux vertébraux de traitement, ainsi que sur base des éléments de preuve décrits le long de cette thèse, une étude placebo-contrôlée et randomisée a été menée. Cette dernière étude interroge l'efficacité à court terme d'une nouvelle forme de TMO très peu étudiée au niveau du rachis lombaire, à savoir la mobilisation avec mouvement. Celle-ci a été étudiée sur des mesures principales cinématiques (algorithmes cinématiques pour l'amplitude et la vitesse) déterminées dans la section 2 et sur des mesures secondaires à l'aide d'échelles /

questionnaires (douleur, la fonction, activités et participation) chez des patients LBP avec présence d'une douleur à comportement mécanique lors de la flexion du tronc (sous-groupe de LBP). Les résultats de cette enquête ont élevé le niveau global de preuve qui était faible auparavant à modéré en faveur de l'utilisation des "glissements naturels soutenus des apophyses articulaires" (mobilisation avec mouvement au niveau du rachis) chez un sous-groupe de patients LBP.

En conclusion, les différents points et perspectives développés tout au long de cette thèse devraient probablement contribuer à résoudre le puzzle complexe de la LBP dans une optique d'approche centrée sur le patient. La thérapie manuelle est un art développé par la pratique clinique ainsi qu'une science développée par la recherche fondamentale et clinique. Nous croyons que la recherche clinique est d'une importance capitale car elle détermine directement la qualité de la pratique clinique, ainsi que l'éducation et l'enseignement. Une pratique clinique qui s'appuie sur des preuves issues de la recherche tout en s'inscrivant dans une approche biopsychosociale devrait, d'une manière générale, aider de nombreux patients, étudiants et professionnels de la santé.

Index of abbreviations

CB-CFT	Classification Based Cognitive Functional Therapy
CCBRG	Cochrane collaboration back review group
CCR	clinical classification rule
CLBP	chronic low back pain
CM	combined movements
CPR	clinical predictive rule
CS	classification system
EBP	evidence-based practice
HLS	high lumbar spine
ICF	International Classification of Functioning, Disability and Health
KA-R	kinematic algorithm for range of motion
KA-S	kinematic algorithm for speed
LLS	low lumbar spine
LS	logit score
LTS	low thoracic spine
MD	means of difference
MICS	Movement Impairments Classification System
MT	manual therapy
MT1	spinal manipulation
MT2	spinal mobilisation and soft-tissue-techniques
MT3	MT1 combined with MT2
MWM	mobilisation with movement
NSLBP	nonspecific low back pain
NS-CLBP	nonspecific chronic low back pain
OMT	orthopaedic manual therapy
PAIVM	passive accessory intervertebral movement

PPIVM	passive physiological intervertebral movement
QTF	Quebec task force
RCTs	randomised controlled trials
RE	repositioning error
ROM	range of motion
SBT	Start Back Tool
SMD	standardised means of difference
SNAGs	sustained natural apophyseal glides
SR	systematic review
SS	shoulder segment
TLS	total lumbar spine

INTRODUCTION

The topic of this thesis regards the efficacy of **orthopaedic manual therapy** (OMT) for patients with **low back pain** (LBP). This thesis is organised with the presentation of different ideas following a continuum. First, the concept of **evidence-based practice** (EBP) will be described (1) in the contexts of OMT and the complex disorder of LBP (2). Second, OMT will be defined (3), potential mechanisms of action for OMT will be described (3.1) and an integrative approach of using validated classification systems in the care of patients with LBP will be presented (3.2). An objective examination (4) with a clinical physical examination of the lumbar spine will be described (4.1), together with the role of kinematic measures in diagnosis and as primary outcome measures of the body structures, functions and activities for patients with **nonspecific low back pain** (NSLBP) (4.2). Finally, the context, objectives and organisation (5) of this thesis according to an EBP process will be presented through three major sections:

Section 1: Evidence for the use of OMT for patients with LBP

Section 2: Development of a kinematic model of the spine

Section 3: Clinical physical examination and evaluation of the efficacy of OMT for patients with LBP

1. EVIDENCE-BASED PRACTICE

EBP is a philosophical approach that is in opposition to medical ‘folklore’, tradition and the random treatment of patients. An interdisciplinary approach to clinical practice, EBP originally began as **evidence-based medicine** (EBM) and spread to other fields with complex intervention, such as psychology and physical therapy. EBP recognises that care is individualised, ever changing and sometimes involves doubts as well as probabilities.¹

In OMT, EBP involves complex and conscientious decision making in applying high-quality therapy that is based not only on the best available clinical evidence, but also on the patient’s values (biopsychosocial and lifestyle influences) and the clinician’s clinical expertise (basic education, experience and continuing education) and reasoning (Figure 1).¹⁻⁴ EBP constitutes a **dynamic integrative approach** that must be adapted during treatment according to the severity and sensitivity of the disorder, as well as the improvements gained. Also important are the influences of the manual therapist’s practical skills across the range of commonly used OMT techniques to manage people with LBP, as well as the therapist’s level of clinical reasoning skills in dealing with the complexity of LBP.⁴⁻⁵

Figure 1. EBP concept³



2. DEFINITION OF NONSPECIFIC LOW BACK PAIN

LBP is the leading cause of disability and absence from work, and its increasing prevalence has had major socioeconomic impacts.⁵⁻⁶ LBP has reached epidemic proportions, with about 80% of the population experiencing LBP at some point in their lives. Of these sufferers, 75% are in their most productive years, between the ages of 30 and 59.⁷⁻⁸

In 1987, the biopsychosocial model was suggested as a theoretical framework for LBP treatment.⁹ Most LBP cases are described as 'nonspecific', as a precisely identified cause for pain can only be determined in a small minority of cases. Indeed, there is a poor correlation between findings on medical images and symptoms, with a radiologic diagnosis being clearly identified in only 15% of cases.¹⁰⁻¹¹ Hence, based on imaging, **NSLBP** is defined by the lack of a recognisable, specific pathology, and is usually multifactorial/multidimensional and of unknown origin and etiology.¹¹ In the absence of specific diagnoses, profiling LBP patients on the basis of biological, psychological and social prognostic factors appears relevant.¹²

Among the biological influences, **nociceptive factors** play a major role in acute and subacute NSLBP. Various structures in the lumbar spine are recognised as possible origins of LBP due to their innervations. In particular, the zygapophyseal joints, intervertebral discs and sacroiliac joints, with up to 75% of involvement, have been determined as nociceptive sources for NSLBP.^{11,13-14} However, an important distinction in terms of pain stages needs to be made, as nociceptive 'sources' can only be clearly determined in approximately half of subjects with chronic LBP.¹⁵

The topography of pain in NSLBP is generally defined as pain in the lower back between the lowest ribs and inferior gluteal folds.^{5,16-17} The duration or stage of the pain disorder is typically categorised as **acute** (0–6 weeks), **subacute** (6–12 weeks) or **chronic** (>12 weeks).^{5,16-18}

It is becoming increasingly clear that the clinical evaluation of patients with LBP, particularly in the chronic stage, should not focus solely on the **pathoanatomical** examination (structural nociceptive sources).^{5,10-11,15} Indeed, **psychological and social factors**^a, **lifestyle influences**^b and **pain mechanisms**^c have important roles in explaining the development of chronic LBP.^{11,19-20} This assumption is particularly important when conceiving a comprehensive management strategy. Instead, it would be better to classify patients with LBP into distinct subgroups by developing **classification systems** based on clusters of signs and symptoms relevant to physical therapy.¹⁹⁻²³

Use of the **International Classification of Functioning, Disability and Health** (ICF) is of potential interest for improving clinical practice and stimulating research. The ICF comprises four components: body functions, body structures, activities and participation, and environmental factors. Short and comprehensive, the **ICF Core Set for LBP** was developed with ICF codes and category titles for each of the four components, to aid in defining the multidimensional aspects of LBP.^{5,8} In this Core Set, body structures has 5 categories^d, body functions has 19 categories^e, activities and participation has 29 categories^f and environmental factors has 25 categories^g.^{5,8}

3. MODERN ORTHOPAEDIC MANUAL THERAPY OF NONSPECIFIC LOW BACK PAIN

A consensus definition of OMT was determined at a general meeting in Cape Town in March 2004 (www.ifompt.com^h):

^a Fears, beliefs/attitudes, coping strategies, education, anxiety, depression, work satisfaction

^b Sedentary lifestyle, poor sleep, stress, nutrition, smoking, alcoholism

^c Peripheral/functional or central sensitisation

^d Such as: s7401/joints of pelvic region, s76001/thoracic vertebral column, S76002/lumbar vertebral column, s7601/muscles of trunk region, and s7402/muscles of pelvic region

^e Such as: b28013/pain in back, b7101/mobility of several joints, b7108/mobility of joint functions, specified as mobility in a vertebral segment, b7601/control of complex voluntary movements, b260/proprioceptive function

^f Such as: d4108/bending, d415/maintaining a body position, d430/lifting and carrying objects

^g Such as: e410/individual attitudes of immediate family members, e450/individual attitudes of health professionals

^h Organised in 1974, the International Federation of Orthopaedic Manipulative Physical Therapists (IFOMPT) is a subgroup of the World Confederation of Physical Therapy recognised by World Health Organisation. IFOMPT represents groups of manipulative physical therapists around the world who have completed stringent specialisation programs in the field of neuromusculoskeletal disorders. IFOMPT sets educational and clinical standards in this area of physical therapy. IFOMPT actively encourages improved patient management by its standards and by endorsing EBP.

'Orthopaedic Manual Therapy is a specialized area of physiotherapy/physical therapy for the management of neuromusculoskeletal conditions, based on clinical reasoning, using highly specific treatment approaches including manual techniques and therapeutic exercises. Orthopaedic Manual Therapy also encompasses, and is driven by, the available scientific and clinical evidence and the biopsychosocial framework of each individual patient.'

In physical therapy, various forms of OMT are currently used to manage LBP, and there is growing evidence in favour of this kind of treatment.^{4-5,21} Manual therapists use a range of treatment approaches, including various 'hands-on' **passive techniques** (e.g. lumbopelvic spinal mobilisation/manipulation, neurodynamic mobilisation of sciatic and femoral nerves and soft tissue techniques)ⁱ and **active-passive techniques** (e.g. mobilisation with movement or muscle energy techniques of the lumbopelvic region). Use of OMT involves 'hands-off' **active techniques**, such as motor control, directional preference, core stability of the lumbar spine and communication skills.^{j 4,5,21}

In some OMT approaches, the frequency, intensity and, particularly, direction of treatment are driven by the patient's **pain severity and irritability**. In the presence of **high irritability** (i.e. easily provoked pain that lingers at a high level), OMT in a single or combined movement, in the direction away from the most pain-provoking movement, is recommended. The opposite is true for a **low irritability** disorder (i.e. hard to provoke pain that abates quickly).²⁴ Use of these collective OMT approaches, along with **clinical reasoning based on the biopsychosocial model**, represents the fundamentals of OMT.^{4-5,25}

3.1. Hypothetical mechanisms of action of orthopaedic manual therapy

When managing **neuromusculoskeletal disorders**, the aims of OMT are to reduce pain and improve movement and function. Potential mechanisms of action for OMT in this context have been described.²⁶⁻⁴⁵ To illustrate these mechanisms, hands-on techniques of OMT are thought to cause mechanical, neurophysiological and placebo effects, as described below.

Mechanical effects. The key mechanism of OMT, which may underlie all others, is the administration of objective biomechanical segmental vertebral movement²⁶⁻³¹ from the initial mechanical action of the therapist's hands. (I) A slight component of the load and peak forces is absorbed by the paraspinal soft tissues, (II) while the main component is absorbed by the spine.³¹ Spinal manipulative therapy of the lower back may generate motion of the

ⁱ Facilitated positional release (strain-counterstrain), myofascial release, neuromuscular technique, muscle energy technique and trigger points therapy

^j Empathy, listening, motivational interview, education, positivism and reassurance

vertebral bodies that will, from a cavitation phenomenon, separate the articular facet joints and increase the lumbar zygapophyseal joints space separation over several days.²⁶⁻³² Separation of the joint surface may release entrapped synovial meniscus, facilitate transsynovial fluid fluctuation in the zygapophyseal joints and stretch the intra-articular capsular adhesions that limit movement.^{26,29,31} Although research in human cadavers showed that OMT decreases the intervertebral disc pressure, one study in a living human subject did not support this mechanism of action.³³ A recent study demonstrated that spinal manipulative therapy facilitates water diffusion in the nucleus pulposus of the lumbar intervertebral discs.³⁴

Neurophysiological effects. OMT can stimulate responses from mechanoreceptors of the joints, among others, and normalise neurogenic reflex activity.³⁵⁻⁴³ OMT has been reported to 1) reduce paraspinal muscle spasms and the gastrocnemius H-reflex, 2) increase the central motor excitability and the isometric strength of the paraspinal or quadriceps muscles, and 3) influence motor control and proprioception.³⁵⁻⁴³ OMT can induce hypoalgesia through peripherally inducing pain inhibition at the spinal cord (gate control theory) and centrally activating descending inhibitory pathways from the dorsal periaqueductal gray area, while concurrently activating the sympathetic nervous system.^{35,37,42-43}

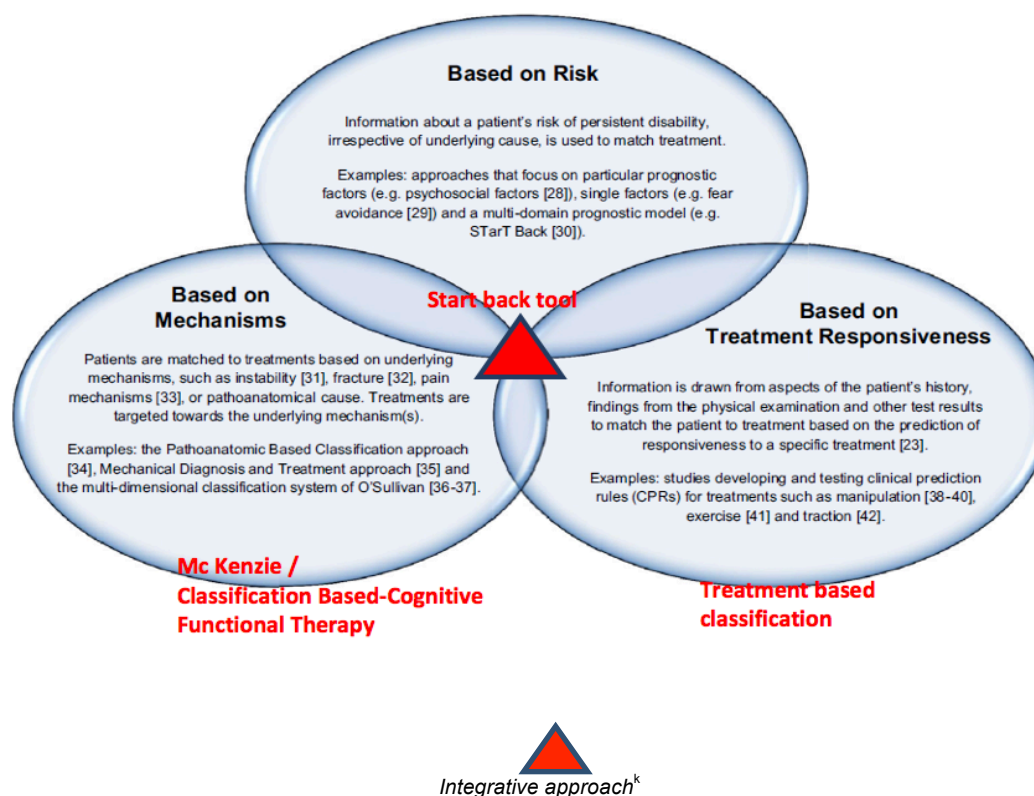
Placebo effects. As in any therapeutic intervention, OMT probably generates a placebo effect through various psychological mechanisms. Such an effect may be explained by the patient's and therapist's interests, beliefs, concerns and interactions.^{44,45} The fact that the OMT therapist physically interacts with the patient ('therapeutic touch') may reinforce this phenomenon.

3.2. Integrative stratified care in orthopaedic manual therapy for patients with low back pain

Stratification of treatment represents a method to apply targeted OMT to LBP patients, with the potential for greater effectiveness and efficiency of physical therapy. LBP is an ideal clinical condition for stratified care research, as LBP patients comprise a **heterogeneous** population⁴⁻⁵ with variations in prognosis and treatment options. Thus, stratified care is becoming a dominant topic in research and clinical practice for LBP.⁴⁶ However, most randomised controlled trials (RCTs) addressing the effectiveness of OMT have treated LBP patients as a homogeneous group. Consequently, the concept of **subgrouping people with LBP** is more and more common in the OMT literature and in research. Classifying patients into subgroups and applying specific OMT interventions for each subgroup is thought to be effective approach.^{5,46}

In physical therapy, stratified care comprises three main approaches of classification systems, with overlaps between them. These approaches are based on the patients' treatment responsiveness, prognosis and underlying causal pain mechanisms (Figure 2).⁴⁶

Figure 2. Stratified care approaches, adapted from Foster et al.⁴⁶



The **Treatment-Based Classification** (TBC) system to identify targeted OMT interventions for people with LBP is an example of a treatment responsiveness-based stratification scheme.⁴⁷ The main principle of the TBC system is to group patients who are likely to respond to a well-defined OMT technique (e.g. lumbopelvic manipulation, stabilisation, directional preference exercise and traction), rather than trying to classify patients on the basis of their hypothesised pain mechanisms and/or prognosis. The challenge of this approach is providing evidence of patient features that consistently identify those who will respond to a specific treatment.⁴⁶

The **Start Back Tool** (SBT) is a prognosis-based classification system that aims to subclassify patients according to physical and psychosocial factors. SBT is more effective than a non-subgrouping approach, especially when patients are fast-tracked to an

^k Targeted OMT for specific subgroups using an integrative approach merging classification systems and OMT interventions should be useful for patients. This integrative approach will be discussed in detail in the General Discussion section.

appropriate treatment course, and is particularly designed to support care decision making in the primary/first-contact context.^{46,48-49}

Classification-Based Cognitive Functional Therapy (CB-CFT) is a classification system based on the causal pain mechanism. This multidimensional approach integrates evidence from pathoanatomical, neurophysiological, psychosocial, physical and lifestyle domains.^{19,49} Modifiable beliefs^l and behaviours^m considered to contribute to pain and disability are identified and become targets of treatment.^{19,46,49}

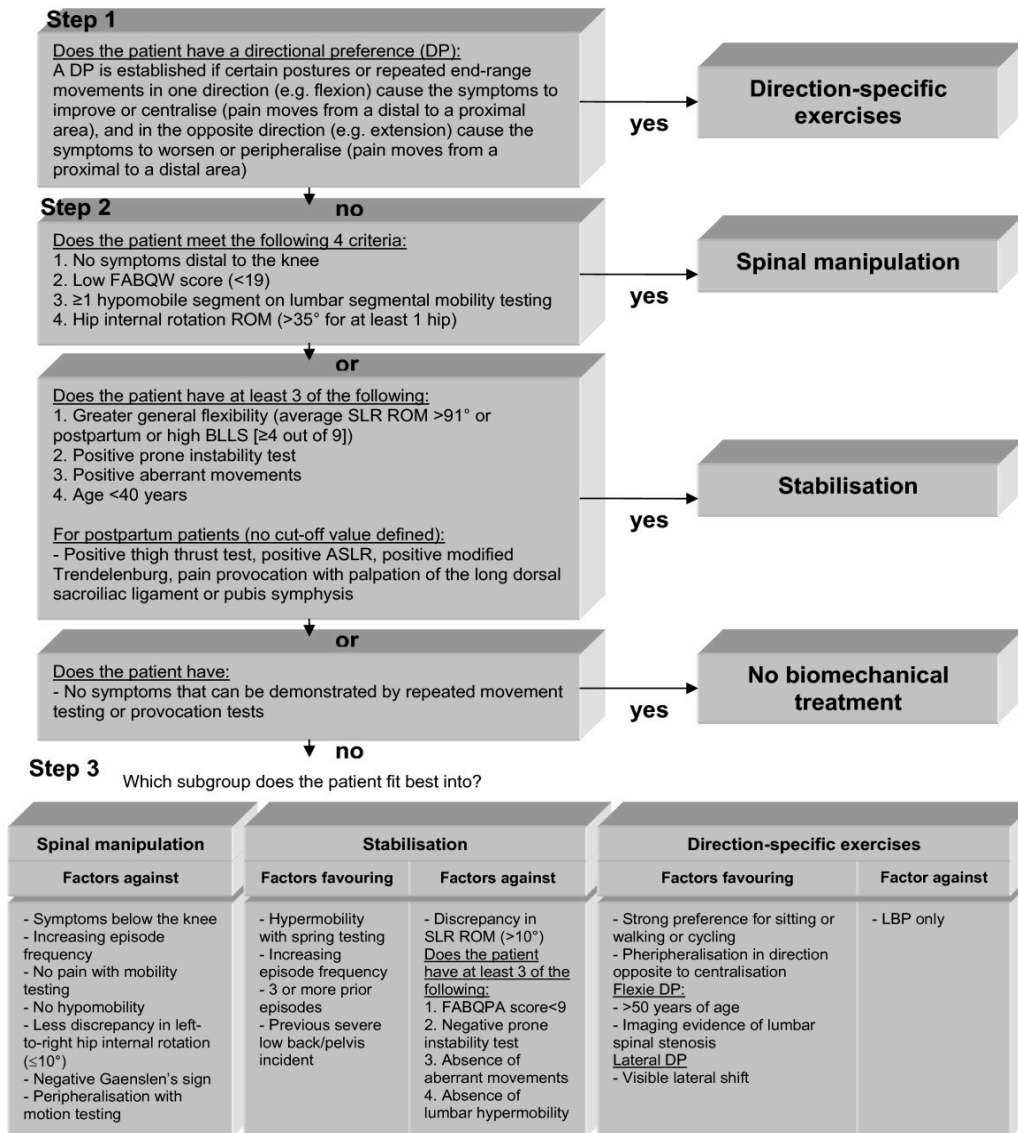
The TBC and CB-CFT systems have moderate to good reliability, with some evidence of validity.⁵⁰ It has been recommended that these classification systems be implemented in clinical practice.⁵⁰ Moreover, the patients' beliefs and expectations regarding treatment effects of OMT interventions have been shown to be important predictors of treatment outcomes and should be integrated into classification systems.⁵¹

In the specific field of physical therapy, several classification systems for LBP have been proposed. However, only four of them directly tailor OMT management to the patient and have been evaluated scientifically: the McKenzie LBP classification system, the TBC system (Figure 3), the Movement-System Impairment Classification for LBP, and the CB-CFT approach.^{19,52-53}

^l Fear of movement and pain-related anxiety

^m Pain-provoking postures and movement patterns

Figure 3. Treatment-based classification algorithm⁵⁷



Abbreviations: LBP=low back pain, FABQW=Fear-Avoidance Beliefs Questionnaire Work, FABQPA=Fear-Avoidance Beliefs Questionnaire Physical Activity, ROM=Range Of Motion, SLR=Straight Leg Raise, BLLS=Beighton Ligamentous Laxity Scale, ASLR=Active Straight Leg Raise, DP=directional preference

Nevertheless, the best way to subgroup patients with LBP has not been determined.⁴⁶ For example, in the TBC system, after an objective examination based on the assumption of mechanical NSLBP, patients may be classified in the spinal manipulation subgroup and matched to a directional preference exercise. Some patients classified into one treatment category may meet criteria for another treatment subgroup and benefit from either or both treatments.⁵⁴ Different stratified care approaches may not necessarily be mutually exclusive, and could be integrated in the management of LBP patients.^{46,54}

The McKenzie and TBC systems interpret the patient's symptoms and behaviour through a series of single standardised and repeated spinal movements and sustained postures performed during clinical examination. The goal of the assessment is to identify the directional patterns that worsen or improve the patient's symptoms.⁵⁴⁻⁵⁶ The following modalities of physical examination provide a basis for the patient's classification and treatment: repeated spinal movements and sustained positions in a directional preference (Figure 4A), passive spinal mobilisation/manipulation (Figure 4B), stabilisation exercises (Figure 4C) and traction.^{5,46,47} In all of these classification systems, the sagittal plane is of major importance to determine specific patterns.⁵⁵⁻⁵⁸

Figure 4. Illustration of interventions in the TBC System

- A. Example of repeated spinal movements and/or sustained positions in a directional preference of extension, which centraliseⁿ symptoms



ⁿ Centralisation is a clinical phenomenon that can be reliably detected and is associated with a good prognosis. Centralisation was first recognised by McKenzie in the 1950s and, after much experimentation and verification, was described in the literature (McKenzie, 1981). It is the process by which pain radiating from the spine is sequentially abolished, distally to proximally, in response to therapeutic positions or movements, and includes reduction and abolition of spinal pain.

- B. Example of passive spinal mobilisation/manipulation in a combined movement position (flexion/left lateral side bending and left rotation)



- C. Example of a stabilisation exercise for transversus abdominis muscle strengthening



Long-term chronic LBP is a complex multidimensional condition that represents a management challenge. A recent review of clinical classification systems for chronic LBP patients concluded that most systems do not consider the underlying pain mechanisms and focus largely on biomedical (pathoanatomical and pathophysiological) assessments.⁵⁹ A multidimensional classification system for LBP has been proposed (i.e. CB-CFT)¹⁹ and will be discussed in detail in the General Discussion of this thesis.

4. OBJECTIVE EXAMINATION IN ORTHOPAEDIC MANUAL THERAPY

4.1. Clinical physical examination of the lumbar spine

To be evidence-based, the objective evaluation of patients with LBP, as part of the clinical reasoning implemented in OMT, should be based on valid and reliable tests. During physical examination, several testing manoeuvres may be implemented, including reproduction or abolition of movement-induced symptoms, as well as palpation to detect hypo- or hypermobility. The most reproducible tests in clinical examination of the lumbar spine are based on **mechanically induced symptom reproduction**.⁵⁵ Specifically, examination of the mechanical pain response during repeated lumbar spinal movements in the sagittal plane (flexion/extension) is the only procedure to show moderate evidence of high reliability (based on inter-raters agreement).⁵⁵ Reliability is good when the physical examination is based on the response to symptoms, but generally low when the examination is based on palpation to detect mobility.⁵⁵

One mechanical pain provocation test that is commonly used in OMT during objective examination is an active movement test in single or combined planes (Figure 5A). The concept of **combined movements** testing was originally developed by Edwards and is an expansion of the routine clinical examination.²⁴ Another form of pain provocation testing is passive accessory intervertebral movement (PAIVM) testing (Figure 5B). In the concept proposed by Edwards, data obtained from the single- and combined-plane active movement examinations (Figure 5A), together with the results of the PAIVM tests (Figure 5B) performed in different lumbar spine positions (Figure 5C), are used to determine a pain-provoking direction that is specific to the patient's condition.²⁴

In OMT, LBP management is based on the identification of the pain-provoking direction. For cases of high irritability, some authors recommend treating by a single or combined movements in a direction away from the most pain-provoking movement. The opposite approach is recommended for low irritability disorders, as the goal is to reduce pain by restoring pain-free range of motion (ROM) in the specific direction.²⁴

The presence of a painful pattern of flexion or extension, coupled with pain on PAIVM tests, comprises a **clinical classification rule** (CCR), developed to identify the presence of mechanical NSLBP. This CCR consists of three criteria (Figures 5A-C), all of which are all required for the rule to be positive⁶⁰:

Figure 5. Illustrations of the clinical classification rule

- A. Example of a Criteria 1 manoeuvre^o; combined movement assessment in flexion with left lateral flexion



- B. Example of a Criteria 2 manoeuvre^p; PAIVM tests at L3 in neutral position



^o Active movement tests with a predominant pain-provoking movement direction (flexion or extension) during single, repeated, sustained or overpressure tests or, if required, in a combined direction (i.e. flexion or extension combined with lateral flexion right or left). The examiner should establish the most painful pattern of spinal movement direction.

^p Passive movement tests with at least two adjacent vertebral levels provoking pain on PAIVM tests

C. Example of a Criteria 3 manoeuvre⁹; PAIVM tests at L3 in a flexed position



There are various concepts for the management of LBP by OMT, including McKenzie,⁵⁶ Maitland,⁶¹ and Mulligan,⁶² as well as several forms of spinal mobilisation/manipulation and exercises with different putative mechanisms of action. One of the strongest paradigms in OMT is that localised techniques may reduce pain and improve global ROM. Even if the principles of treatment vary from one method to another, the underlying goal of OMT is to reduce pain. It is essential that the treatment, regardless of the concept, be performed on the basis of a reliable and valid physical clinical examination, such as the CCR. Pain provocation tests within the CCR might be confidently used in clinical practice to direct the treatment of NSLBP patients with various OMT concepts.

4.2. Analysis of a kinematic model of the spine

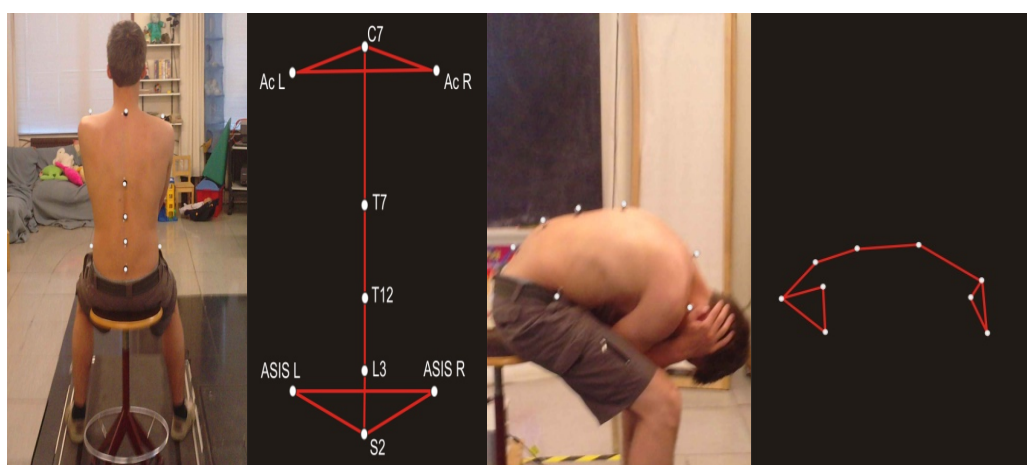
A diagnosis of NSLBP resulting from clinical reasoning is based on subjective and objective examination criteria. In the context of objective examination, kinematic variables of lumbopelvic and trunk motion/coordination are useful for identifying impairments in LBP patients, both quantitatively (ROM, speed and acceleration, repositioning error [RE] accuracy) and qualitatively (smoothness of speed curves, 'motion signatures'), when single or combined planes of trunk movement are investigated. Some of these features may enable differentiation into treatment-specific subgroups.⁶³⁻⁶⁶

⁹ Pain provoked by PAIVM made worse at the specific vertebral level, by flexing or extending the spine, with the direction in concordance with the direction of the active pain-provoking movement identified in Criteria 1

Studies have demonstrated the validity of movement tests to discriminate people with NSLBP from healthy controls by using **kinematic analyses** of active spinal movement during objective examination.⁶³⁻⁶⁶ For example, in the ICF model, kinematic analyses of the back represent assessments of (I) body structures (e.g. s7401/joints of the pelvic region, s76001/thoracic vertebral column, S76002/lumbar vertebral column, s7601/muscles of the trunk region, and s7402/muscles of the pelvic region), (II) body functions (e.g. b7101/mobility of several joints, b7108/mobility of joint functions, specified as mobility in a vertebral segment, b7601/control of complex voluntary movements, b260/proprioceptive function), and (III) activities (e.g. d4108/bending, d415/maintaining a body position).

Using an optoelectronic measurement system, our team developed a kinematic model of the spine to measure, in two dimensions, trunk movements of people with NSLBP from a sitting position in various directions (flexion, extension, rotation, side bending and combined movements). Passive markers were placed on body landmarks to measure the displacement of the spine, which was modelled in seven segments: shoulder and pelvic girdles, high and low thoracic spine, high and low lumbar spine, and total lumbar spine (Figure 6). Speed and ROM were evaluated during movement in all planes.⁶³⁻⁶⁵

Figure 6. Kinematic model of the spine in a trunk flexion task

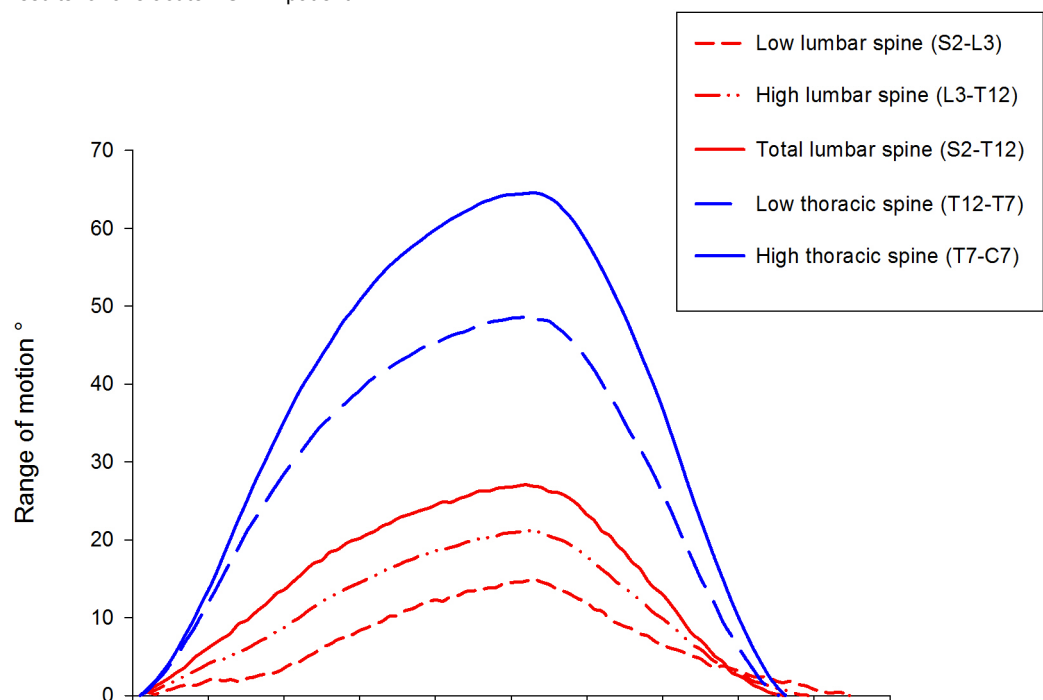


Placement of markers in the sitting position, and model representation. Girdles are represented by two triangles. The pelvis is delimited by S2 and the anterior-superior-iliac-spinous (ASIS). Shoulders are delimited by C7 and both acromio-clavicular (Ac) joints. Low lumbar spine (LLS: S2-L3), high lumbar spine (HLS: L3-T12), total lumbar spine (TLS: S2-T12), low thoracic spine (LTS: T12-T7), and high thoracic spine (HTS: T7-C7). Illustration of the flexion task from the sitting position to the end of the ROM.

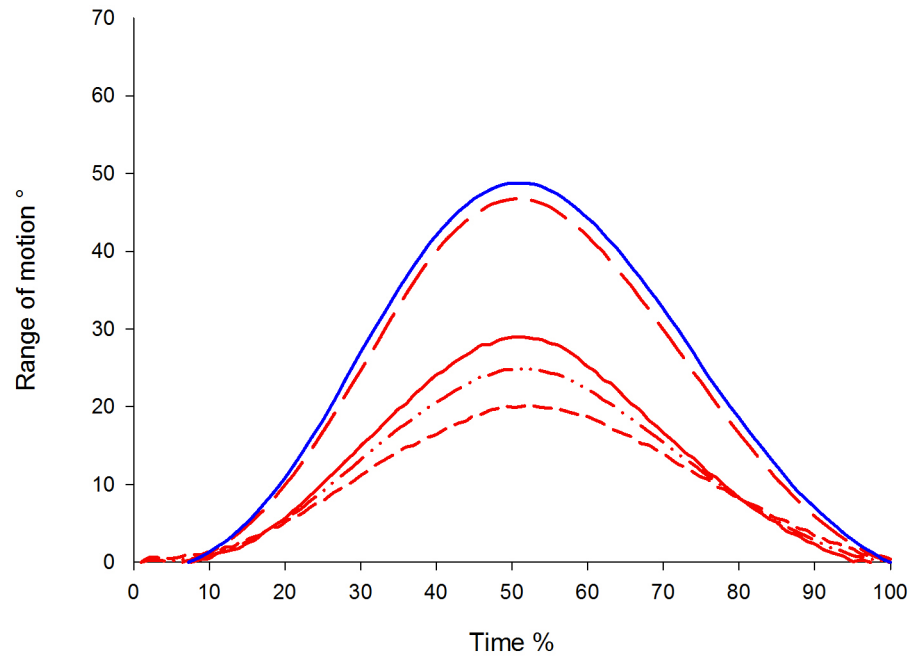
This kinematic model was designed to measure differences between people with NSLBP and healthy people, as well as to aid in diagnosis, given the poor correlation between medical images and symptoms in NSLBP patients. Outputs of this model could be used as primary kinematic outcome measures in future clinical trials of OMT efficacy. Using this model, we generated various kinematic curves and data for each spinal segment in various movement directions for the ROM (Figure 7) and speed (Figure 8).

Figure 7. Kinematic curves from the kinematic model of the spine for ROM during a trunk flexion task (n=10 trials) from a sitting position

A. Results for one acute NSLBP patient



B. Results for one chronic NSLBP patient



C. Results for one healthy subject

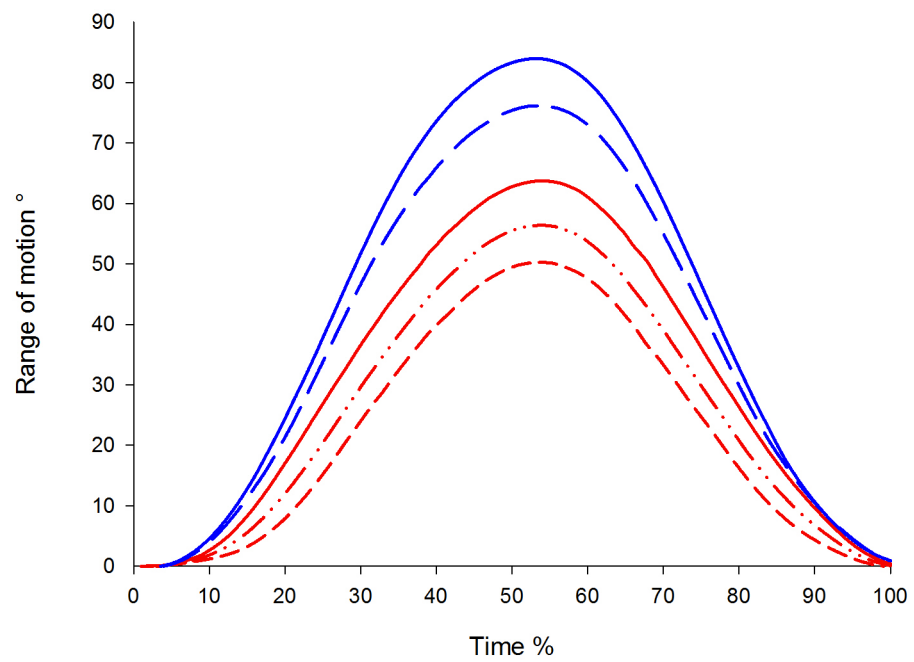
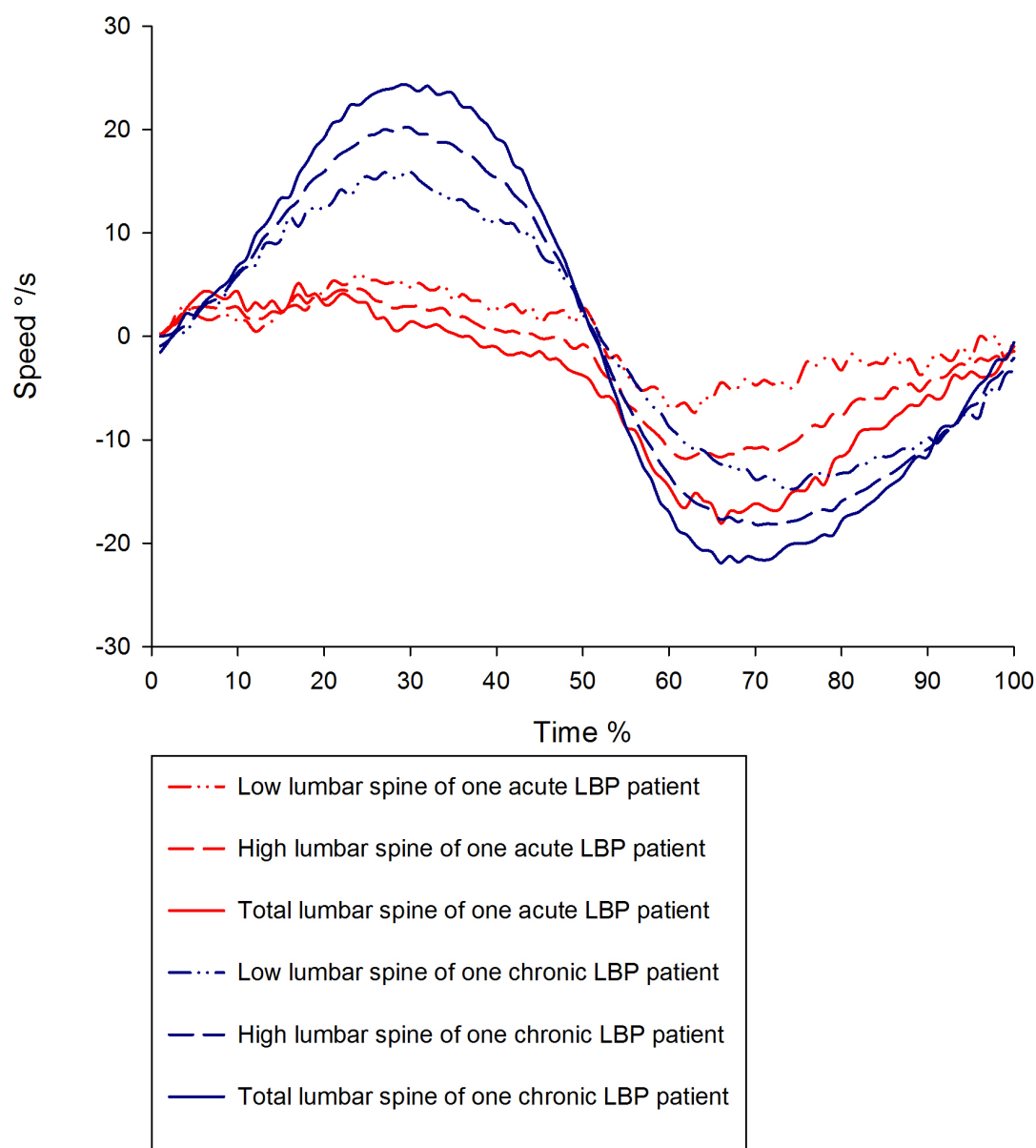


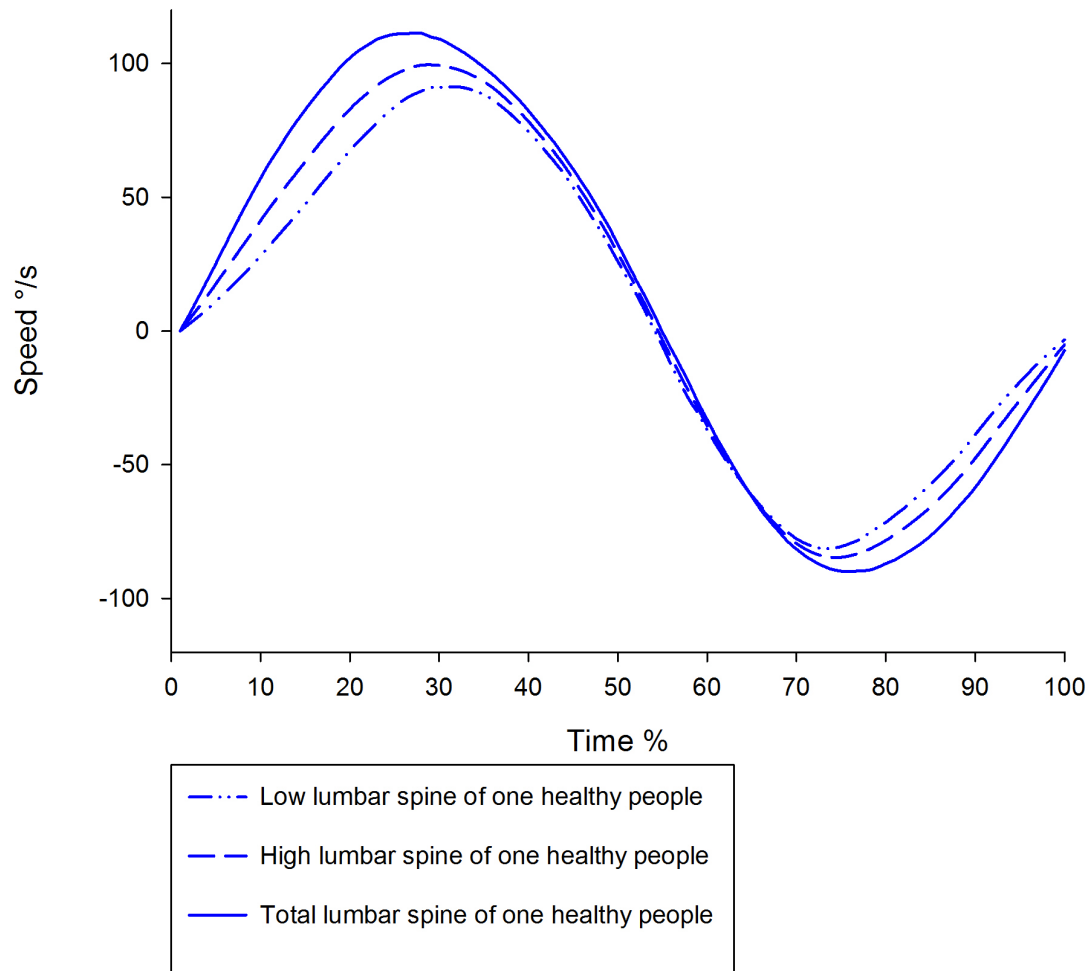
Figure 8. Kinematic curves from the kinematic model of the spine for speed during a trunk flexion task (n=10 trials) from a sitting position

A. Results from one acute and one chronic NSLBP patient



(red curves of one acute LBP patient with mean smoothness = 0.30; blue curves of one chronic LBP patient with mean smoothness = 0.54, see Discussion section 2.2)

B. Results from one healthy subject



(blue curves of one healthy subject with mean smoothness = 0.63, see Discussion section 2.2)

5. CONTEXT AND OBJECTIVES OF THE RESEARCH

LBP is a complex issue with high prevalence, and it requires a multidimensional approach towards assessment and treatment. This Introduction has described an integrative approach utilising a range of research tools that might help people with LBP. These tools have been used in published studies and on-going investigations. This multidimensional approach might contribute to the definition of new levels of evidence for specific OMT interventions for specific subgroups of people with NSLBP.

The main objective of this thesis is to study the efficacy of using OMT for NSLBP, which is addressed through the following **aims**:

1. To establish a **background on OMT** within our team, and to improve our **knowledge of the effects of OMT in NSLBP**
2. To create a **quantitative assessment tool** for measuring kinematic patterns in subjects with NSLBP who have mechanical pain behaviours, and for determining the effects of OMT
3. To test the reliability of a standardised **objective clinical examination** aimed at identifying the direction(s) of trunk movement impairment and spinal level(s) of involvement; and, based on these findings, to perform a clinical study on **mobilisation with movement** (MWM; a novel OMT technique) within a subgroup of NSLBP patients.

This thesis is organised into three sections:

Section 1: Evidence for the use of orthopaedic manual therapy for patients with low back pain

The research was initiated with a **systematic review** of the literature to summarise existing evidence on the efficacy of OMT in NSLBP disorders, and to evaluate the quality of the methodology and design of previous clinical trials (Chapter I, published in the *Journal of Manual and Manipulative Therapy*). This overview helped us to identify potential avenues for future research in OMT and to elaborate the protocol of a RCT analysing the efficacy of OMT, presented in the final section of this thesis.

Section 2: Development of a kinematic model of the spine

We developed and validated a **kinematic model of the spine**: (I) to analyse kinematic variables of various spinal segments in NSLBP patients with mechanical pain behaviour patterns compared to healthy people, and (II) as a source of objective outcome measures for future clinical trials to evaluate OMT interventions of the spine (Chapters II and III, published in the *Journal of Rehabilitation Medicine*, and Chapter IV, published in the *Journal of Back and Musculoskeletal Rehabilitation*).

Section 3: Clinical physical examination and evaluation of the efficacy of orthopaedic manual therapy for patients with low back pain

Clinical objective examination in OMT incorporates **combined movement** procedures to identify the dominant painful pattern of movement and symptomatic spinal level(s) (Chapter V, published in the *Journal of Manipulative and Physiological Therapeutics*). The purpose of the objective evaluation is to choose the most appropriate OMT technique(s) for NSLBP patients by using an integrative EBP approach. Effects of this treatment may be objectively measured by an analysis of the kinematic model of the spine, as described in Section 2.

MWM is a novel-growing concept in the field of OMT and clinical practice, but it remains sparsely studied in the literature. In the MWM concept, the **sustained natural apophyseal glide** (SNAG) has become increasingly popular,^{62,67} despite the poor level of evidence about the procedure, mostly due to a lack of clinical studies. Hence, this thesis includes a randomised placebo-controlled trial on the effects of MWM in a subgroup of patients with NSLBP of mixed stages. Outcomes of this intervention were evaluated by using the tools developed in the previous sections of this thesis (Chapter VI, accepted for publication in the *Journal of Manipulative and Physiological Therapeutics*).

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Section 1

Evidence for the use of orthopaedic manual therapy for patients with low back pain

CHAPTER I

Efficacy of manual therapy and exercises for different stages of nonspecific low back pain: Current evidence from the literature

Benjamin Hidalgo, Christine Detrembleur, Toby Hall, Philippe Mahaudens, Henri Nielens

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ABSTRACT

Objectives: to review and update the evidence for different forms of manual therapy (MT) for patients with different stages of nonspecific low back pain (LBP).

Data sources: MEDLINE, Cochrane-Register-of-Controlled-Trials, PEDro, EMBASE.

Methods: two independent reviewers according to Cochrane and PRISMA guidelines conducted a systematic review of MT with a literature search covering the period of January 2000 to April 2013. A total of 360 studies were evaluated using qualitative criteria. Two stages of LBP were categorized; combined acute–subacute and chronic. Further sub-classification was made according to MT intervention: MT1 (manipulation); MT2 (mobilization and soft-tissue-techniques); and MT3 (MT1 combined with MT2). In each sub-category, MT could be combined or not with exercise or usual medical care (UMC). Consequently, quantitative evaluation criteria were applied to 56 eligible randomised controlled trials (RCTs), and hence 23 low-risk of bias RCTs were identified for review. Only studies providing new updated information (11/23 RCTs) are presented here.

Results:

Acute–subacute LBP: STRONG-evidence in favor of MT1 when compared to sham for pain, function and health improvements in the short-term (1–3 months). MODERATE-evidence to support MT1 and MT3 combined with UMC in comparison to UMC alone for pain, function and health improvements in the short-term.

Chronic LBP: MODERATE to STRONG-evidence in favor of MT1 in comparison to sham for pain, function and overall-health in the short-term. MODERATE-evidence in favor of MT3 combined with exercise or UMC in comparison to exercise and back school was established for pain, function and quality-of-life in the short and long-term. LIMITED-evidence in favor of MT2 combined with exercise and UMC in comparison to UMC alone for pain and function from short to long-term. LIMITED-evidence of no effect for MT1 with extension-exercise compared to extension-exercise alone for pain in the short to long-term.

Conclusion: This systematic review updates the evidence for MT with exercise or UMC for different stages of LBP and provides recommendations for future studies.

Introduction

After headaches and chronic fatigue, low back pain (LBP) is the most reported complaint, with more than 80% of the population reporting LBP at some point in their life.^{1,2} In developed countries, LBP has enormous and growing indirect and direct costs for society and public health organizations.^{3,4}

The majority of LBP cases are described as nonspecific as there is no identifiable pathology on radiological imaging.² Indeed there is a poor correlation between findings on radiological imaging and symptoms, with a radiological diagnosis identified in only 15% of cases.⁵⁻⁹ Hence, LBP is often a symptom of unknown origin and etiology.^{2,5,10,11}

Many factors have been identified as possible causes or contributing factors to LBP. For example nociceptive inputs, particularly in acute-subacute conditions from various spine structures can cause pain, including zygapophysial joints, intervertebral discs and sacroiliac joints.^{5,12-14} In chronic LBP, psychosocial factors are of prime importance in explaining the prolongation of pain.^{2,15,16} Additional factors linked to chronic LBP include obesity and physical deconditioning associated with sedentary lifestyles.^{2,17} Moreover, genetic factors have been strongly linked to LBP through their influence on pain perception and psychosocial factors.^{2,18}

In general terms, in the case of acute LBP, reports suggest that 75-90% of cases recover within 6 weeks irrespective of medical intervention, whereas up to 25% are at risk of developing chronic pain and disability.^{1,2} Indeed, many individuals with LBP have a number of persisting or recurring symptoms.^{1,5,8,19} Chronic LBP therefore represents a considerable challenge because recovery is unlikely to occur, despite considerable medical advances.²⁰

In physical therapy practice, various forms of manual therapy (MT) are currently used to manage LBP.^{7,21-23} Manual therapists use a range of treatment approaches including various passive techniques such as mobilisation and manipulation as well as a variety of different forms of exercise. The use of these approaches, along with clinical reasoning based on the bio-psycho-social model, represent the essence of MT (www.ifompt.com).²⁴

This systematic review (SR) focuses on the effects of commonly used MT approaches identified through a comprehensive evidence based search strategy of low-risk of bias clinical trials. Three categories of passive MT techniques are defined; MT1 (lumbopelvic manipulation: high-velocity-low-amplitude thrust) MT2 (non-thrust lumbo-pelvic mobilisation and soft-tissue techniques),²⁵⁻²⁷ and MT3 (combination of MT1 and MT2). We also considered passive MT techniques (MT1-3) combined or not with exercise (specific or general) or combined with usual medical care (UMC) (stay active, reassurance, education and medication).^{11,27,28}

The popularity and use of MT for the management of LBP has grown, in part supported by the inclusion of MT in various clinical practice guidelines.^{5,10,23,29} This is despite uncertainty regarding the levels of evidence for the effectiveness of different approaches in MT at different stages of LBP.^{5,7,10,22,29-36}

Previous SRs have reported that in general terms, MT is considered better than a placebo treatment or no treatment at all for LBP.^{7,30,35-40} These reviews failed to establish levels of evidence for other forms of treatment such as UMC or exercise in comparison to MT.^{35,37,39,40} In addition, previous SRs have not investigated which MT approaches “(MT1-3)” when combined with UMC or “exercise” are more effective for LBP. The present SR updates previous reviews, and is the first to focus specifically on different MT approaches for different stages of LBP. New findings, as well as new evidence to inform findings from previous systematic reviews,⁴¹⁻⁴⁵ are presented.

Methods

This SR was conducted in accordance with the PRISMA and Cochrane-Collaboration-Back-Review-Group (CCBRG) updated guidelines for SR.^{46,47}

Search strategy

A literature search of RCTs published in English between 2000 and 2013, on the efficacy of MT in the treatment of LBP was conducted independently by two reviewers in four electronic databases: MEDLINE, Cochrane-Register-of-Controlled-Trials, PEDro, and EMBASE. The detailed search strategy in MEDLINE is presented in Appendix 1, and was adapted to search in the three other databases.

Based on information revealed in the titles and abstracts, a first selection of articles was performed using the inclusion criteria described below. A final selection was conducted after a blinded critical appraisal of the quality of the studies. A consensus was reached at each step (Figure 1) on the studies to be included. In cases of disagreement, a third reviewer made the necessary decision.

Inclusion criteria

Study design

RCTs from the period of January 2000 to April 2013 were included only if (I) they presented a low-risk of bias, (II) if LBP cases treated with MT were compared to a randomised control-group (CG) receiving either no treatment, a placebo procedure, or another effective therapy for LBP and (III) if the randomisation methods was appropriated and clearly reported, with

moreover (IV) a single (assessors blinded) or quasi-double-blind design (assessors and patients blinded).

Patients

LBP is distinguished on the basis of the duration of the pain episode: acute (< 6 weeks), subacute (6-12 weeks) and chronic (> 12 weeks).^{2,29} However, this distinction may not be satisfactory and it has been argued that categorization should be on the basis of other factors including location, symptoms, duration, frequency, and severity.⁴⁸ In this SR, we used a combination of duration, location and symptoms to specify the study population:

- Studies were included if subjects were males and females aged between 18-60 years suffering from acute-subacute (0-12 weeks) or chronic (>12 weeks) LBP. Acute and subacute categories were combined because of their similarities in contrast to chronic LBP category, where psycho-social factors appear more important.^{16,49,50}
- LBP is defined as pain in the lower back between the lowest ribs and inferior gluteal folds.^{46,51} Given that people with LBP may present with radicular pain, LBP is defined according to the following Quebec-Task-Force (QTF) classification: (1) LBP alone (QTF 1), (2) LBP with radiating pain into the thigh but not below the knee (QTF 2), (3) LBP with nerve root pain without neurologic deficit (QTF 3), or (4) LBP with nerve root pain with neurologic deficit (QTF 4).⁵² In the present SR, only trials that contained patients in classes QTF 1-3 were included.

Interventions

Among the included trials, we considered 3 categories of the most common MT techniques represented in the intervention groups. MT1 comprised high-velocity-low-amplitude thrust of the lumbo-pelvic region with “cavitation”.^{7,21,22,27,37,53} MT2 comprised mobilisation and soft-tissue-techniques including “myofascial”, “myotensive” or “harmonic” techniques on the lumbo-pelvic region.^{22,27,37,54} MT3 comprised the combination of MT1 and MT2. Furthermore, sub-categorization of groups MT1-3 was based on the addition or not of exercises either specific (for example based on directional preference, stabilization, and motor control) or general (for example global strengthening, cardiovascular endurance, stretching and range-of-motion exercises) or UMC.^{1,21,32,55}

Control groups

The control groups received no treatment, placebo, UMC, or exercise.

Outcome measures of effectiveness

The outcome measures were classified according to the CCBRG recommendations: pain, function, overall-health and quality of life (Table 1). Timing of the follow-up measurements was defined as very-short-term (end of treatment/discharge to 1 month), short-term (1–3 months), intermediate-term (3 months–1 year), or long-term (1 year or more).^{46,47,51}

Table 1 Classification of outcome measures and Cochrane Collaboration Back Review Group (CCBRG) levels of evidence for evaluating interventions^{46,47}

Outcome measures	Validated assessment tools
Pain	Visual Analogue Scale or Numerical Pain Rating Scale
Functional disabilities	Oswestry Disability Index, Roland Morris Disability Questionnaire, Fear Avoidance Belief Questionnaire, Disability Rating Index, or Patient Specific Function Scale
Overall-health improvement	Short form health survey
Quality of life	Patient Satisfaction with Care, Modified Zung Self-Rated Depression Score and State Trait Anxiety Inventory, return to work, sick leave, and medication use, adverse effects
Strength of evidence	Conditions description
Strong	Consistent findings from multiple 'high quality trials' = level A
Moderate	Consistent findings among multiple 'low quality trials' corresponding to moderate quality in this systematic review = Level B, and/or one level A
Limited	One level B
Conflicting	Inconsistent findings among multiple trials
No evidence	No trials

Quality assessment

Two independent reviewers assessed the risk of bias, methodological quality, data-extraction and clinical relevance of each trial.

Quantitative and qualitative criteria were assessed by applying the CCBRG criteria.^{46,47} Quantitative risk of bias was assessed using an 11-point check-list (see Appendix 1).⁴⁷

Qualitative criteria were: a clear distinction and separation between combined acute-subacute and chronic LBP categories at baseline; a detailed description of the MT intervention allowing the reviewers to classify the MT techniques according to MT1-MT3 classification system; and a single-blind (assessors blinded) or quasi-double-blind (assessors and patients blinded) design.

We considered as “high-quality” those RCTs with quasi-double-blind designs that met at least 9/11 of the CCBRG criteria. “Low-quality” RCTs status was assigned to studies of single-blind design with a minimum score of 7/11 (Table 2 and 3). The dichotomy of classification into “high” or “low” qualities study is required when using the system of CCBRG to determine the strength of evidence (Table 1) and must be clearly described. To reduce the number of studies included in this SR, only studies that present new findings or update previous SR are described. Moreover similarly to another SR,⁵⁶ to facilitate clarity of

presentation, RCTs were only included if they were of low-risk of bias, and either high quality (indicated by a “A”) or moderate quality (indicated by a “B”).

Strength of evidence and clinical relevance

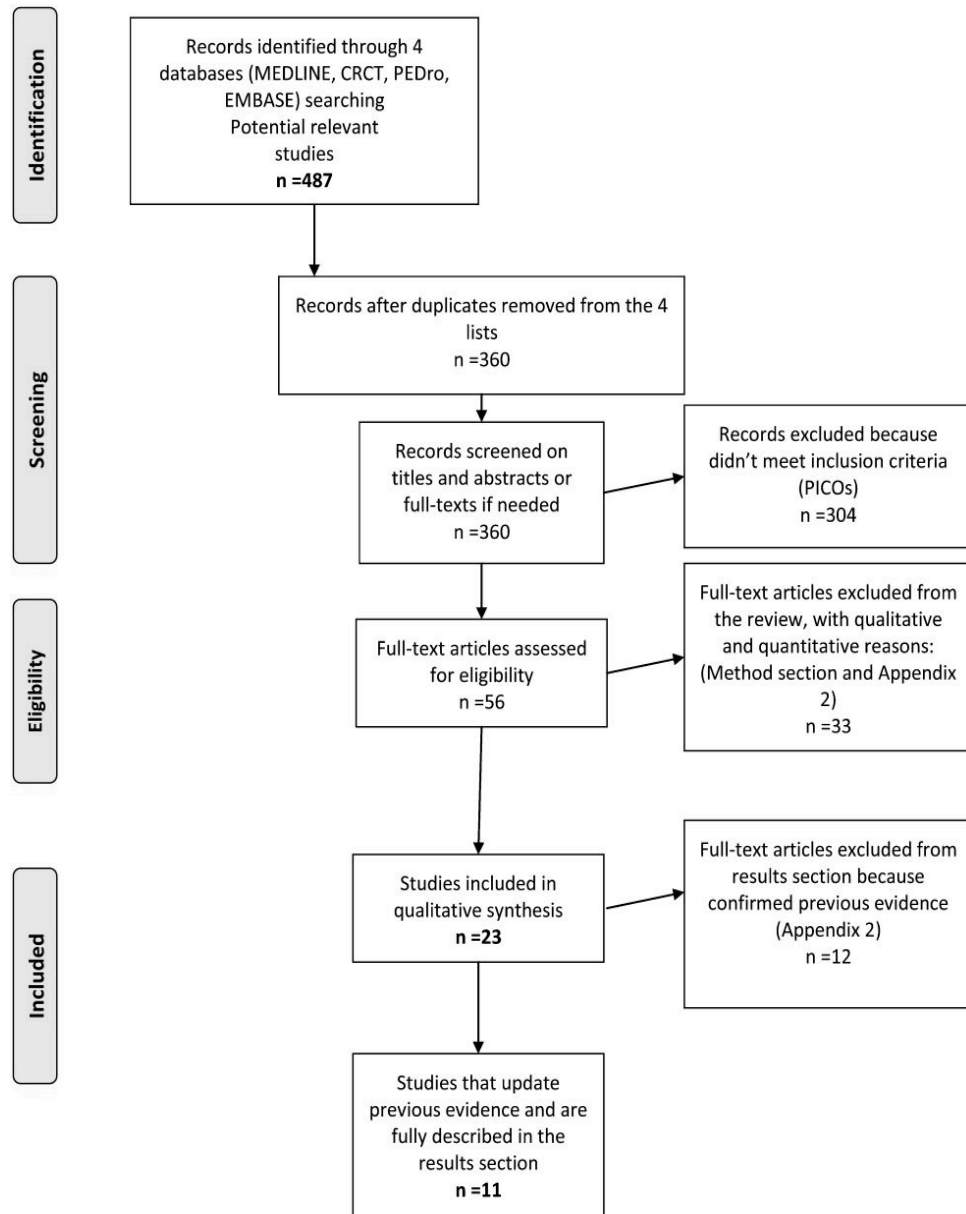
Strength of evidence was determined by grouping similar “Patients Interventions Comparisons Outcomes Study design” (PICO) to provide an overall level of evidence (Table 1) on the efficacy of the MT techniques (Table 4). Based on CCBRG guidelines,^{47,51} the effect sizes were independently collected or calculated by two authors, and used to assess the clinical relevance of MT interventions on outcome measures. We report the between groups means of difference ($MD = mean A - mean B$) or Cohen’s standardised means of difference ($SMD = mean A - mean B / mean SD$). In this SR, the clinical relevance was determined by two conditions and scored by “YES” in favor of the intervention group; if there was significant difference between groups ($p < 0.05$) associated with between groups effect sizes equal or superior to the minimal clinically important difference (MD) or moderate to large effect (SMD) on specific outcome measure (Tables 2 and 3).

Results

Two reviewers performed the initial selection of articles based on keywords. Upon discussion, the reviewers achieved consensus on inclusion of 56 trials that met the selection criteria based on their titles and abstracts. After critical appraisal of these 56 studies, 23 RCTs were retained (Figure 1). Only 11/23 of these RCTs were found to have new evidence or updated previous SRs and are fully presented here. Appendix 2 and Table 4 presents a summary of the remaining 12 RCTs that are not detailed in this results section.

The studies’ characteristics and effect sizes on outcome measures are presented for acute-subacute (Table 2) and chronic LBP (Table 3). A qualitative SR was undertaken on the 11 low-risk of bias RCTs, 5 studies were classified as level A quality, and 6 as level B quality

Figure 1. PRISMA flowchart of inclusion



Effects of interventions on acute and subacute LBP

MT versus sham-MT

Santilli *et al*,⁵⁷ Hoiriis *et al*,⁵⁸ von Heymann *et al*,⁵⁹ (studies rated as level A quality) assessed the effects of MT1 in comparison to sham-MT1 in patients with acute LBP.

Santilli *et al*⁵⁷ compared lumbo-pelvic rotational manipulation toward the pain-free direction to simulated manipulation not following any specific pattern and not involving rapid thrust. The frequency of treatment was 5 days per week until pain relief occurred or up to a maximum of 20 sessions of 5 minutes. For LBP up to 3 months, MT1 was more effective in decreasing local pain, radiating pain, and the duration of pain with clinical relevance ($p < .0001$ and means of difference of 1.8). No statistically significant differences were found for overall-health improvement and psychosocial outcomes. At 6 months, the percentage of pain-free patients was significantly higher in the MT1 group with means difference of 22% for local pain ($p < .005$) and of 35% for radiating pain ($p < .001$). Two patients, one in MT1 and one in sham-MT1, were dissatisfied with treatment and stopped.

Hoiriis *et al*⁵⁸ investigated the effects of lumbo-pelvic manipulation in prone or side-lying position combined with a drug placebo, in comparison to sham-MT1 combined with a muscle relaxant or with a drug placebo. Sham-MT1 consisted of manual light pressure on the lumbar spine in both positions (prone and side-lying). All groups received 8 visits over 2 weeks and showed significant improvements in pain relief and disability ($p < .0001$) and depression scores ($p < .0001$). Clinically relevant differences between groups could only be identified in favor of the intervention group for pain relief in the very short term with $p < .05$ and standardised means difference of 0.70. However, further evaluation revealed that the perception of true MT was significantly higher ($p < .05$) in the intervention group than in either of the two control groups. Indeed, the sham maneuver did not closely approximate the manipulation technique.

Von Heymann *et al*⁵⁹ explored the efficacy of lumbo-pelvic rotational manipulation in side-lying position and placebo-diclofenac in comparison to Sham-MT1 with diclofenac or placebo-diclofenac. Sham MT1 was performed using real manipulation in a prone position but at the incorrect location (i.e. on a non-dysfunctional sacro-iliac-joint) to mimic as closely as possible the intervention being tested. This sham procedure is not supposed to have any influence on the lumbar dysfunction and is not believed to harm the patient. All groups received 2-3 visits over a 1-week period. There was a clear and clinically relevant difference at very-short-term follow up (9 days) between the groups ($p = 0.013$), the intervention group showed a standardised means difference of 0.60 on functional improvement with similar

result for pain and quality of life. No adverse effects or harm were reported in this study. These results suggested that real MT1 had clinically superior effects than NSAID and placebo interventions.

MT with UMC versus UMC alone

Bishop *et al*⁶⁰ and Cruser *et al*⁶¹ (studies rated as level B quality) compared respectively MT1 (2-3 sessions per week over four weeks) and MT3 (1 session per week over four weeks) combined with UMC, to UMC alone in patients with acute LBP from QTF 1-2.

Bishop *et al*⁶⁰ reported clinically relevant differences in favor of the intervention group in terms of functional improvement ($p=.002$ and mean difference of 2.6) at 16 and 24 weeks, but there were no significant differences for pain and physical functioning. In the short-term (4weeks), Cruser *et al*⁶¹ determined clinically relevant differences in favor of MT3 compared to UMC alone for pain now ($p=.025$ and SMD of 1.04) and pain typical ($p=.020$ and SMD of 0.88) and a standardised means difference of 0.56 for function associated with significantly greater satisfaction with treatment and overall-health improvement ($p<.01$). The authors concluded that compared to UMC, MT1⁶⁰ and MT3⁶¹ combined with UMC provides clinically greater improvement in function and pain relief.

Table 2 Summary of articles for patients with acute-subacute LBP

AUTHORS sample size LBP status	Methodological quality of studies	Intervention + co-intervention	Comparison group + co-intervention	Outcomes measures of interest	Clinical relevance status on timing outcomes: between groups <i>P</i> value and effect sizes
Santilli <i>et al.</i> ⁵⁷ (2006) N=102 ALBP 1-3	Level A 10/11 Care provider not blinded	MT1 5 times per week for maximum 4 weeks	Sham MT1 5 times per week for maximum 4 weeks	Local and radiating pain (VAS) Time to pain free status Overall-Health (SF-36) Pain (VAS)	YES: at 45 days, <i>P</i> <0.0001 and MD=1.8; at 90 days, <i>P</i> <0.0001 and MD=1.8 YES: At 180 days, for local pain: <i>P</i> <0.005 and MD=22% and for radiating pain: <i>P</i> <0.0001 and MD 35% NO: non-significant differences between groups YES: 4 weeks, <i>P</i> <0.05 and SMD = 0.70
Hoiris <i>et al.</i> ⁵⁸ (2004) N=192 ALBP 1	Level A 9/11 Care provider not blinded?	MT1 + drug placebo 7 sessions over 2 weeks for all groups	Sham MT1 + myorelaxant drug Sham MT1 + placebo drug Sham MT1 + placebo drug	Functional disabilities (ODI) Pain (VAS)	NO: at 4 weeks, NS and SMD=0.35 (MT1 vs myorelaxant), 0.29 (MT1 vs placebo) YES: at 9 days between groups <i>P</i> =0.013 and MD=2.0
Von Heymann <i>et al.</i> ⁵⁹ (2013) N=101 ALBP 1-2	Level A 10/11 Care provider not blinded	MT1 + drug placebo 2-3 sessions over 1 week for all groups	Sham MT1 + diclofenac	Functional disabilities (RMDQ) Quality of life (SF-12, work-off) Functional disabilities (RMDQ)	YES: at 9 days between groups <i>P</i> =0.013 and SMD=0.60 NO: non-significant differences between groups
Bishop <i>et al.</i> ⁶⁰ (2010) N=88 ALBP 1-2	Level B 8/11 Care provider and patients not blinded, no intention -to-treat-analysis	MT1 + UMC 2-3 sessions over 4 weeks	UMC alone	Functional disabilities (RMDQ)	YES: at 16-24 weeks, <i>P</i> =0.002 and MD = 2.6
Cruser <i>et al.</i> ⁶¹ (2012) N=63 ALBP 1-3	Level B 9/11 Care provider and patients not blinded	MT3+UMC 4 sessions over 4 weeks	UMC alone	Pain (VAS) Functional disabilities (RMDQ)	YES: at 4 weeks: for pain now, <i>P</i> =0.025 and SMD=1.04; for pain typical, <i>P</i> =0.020 and SMD=0.88 YES: at 4 weeks: <i>P</i> =0.026 and SMD=0.56

Note: ALBP=acute LBP; ASLBP=acute and subacute LBP; 1=LBP alone, 2=LBP radiating not below knee, 3=LBP radiating below knee without neurologic deficit. MT=manual therapy; MT1=spinal manipulation, MT2=spinal mobilization techniques; MT3=MT1+MT2. UMC=usual medical care. NS=non-statistically significant difference. SMD=between groups standardized mean of difference; MD=between groups mean of difference. Yes=*P*<0.05 + moderate-large effect size (SMD, MD) in favour of MT. VAS=Visual Analogical Scale; NPRS=Numerical Pain Rating Scale; ODI=Oswestry Disability Index; RMDQ=Roland-Morris Disability Questionnaire; SF-36=short-form-health-survey.

Effects of interventions on chronic LBP

MT versus sham-MT

Ghroubi *et al*⁶² and Senna *et al*⁶³ (studies rated as level A quality) investigated, respectively, the effectiveness of MT1 in a side-lying position (painful side-up) and MT1 in supine position (toward the painful side), as compared to sham-MT1 (mimic of lumbo-pelvic manipulation without final impulsion to provide minimal likelihood of therapeutic effect); on pain, function and overall health in patients with chronic LBP from QTF 1-2. True-MT1 of 4 sessions spread over one month for Ghroubi *et al*⁶², or 16 sessions over 1 month for Senna *et al*⁶³, led to significant improvements for pain ([Ghroubi *et al*⁶² reported standardized mean difference of 0.86 at 4-8 weeks with $p < .001$]; [Senna *et al*⁶³ reported means difference of 1.9 at 10 months with $p < .005$]), for functional outcomes ([Ghroubi *et al*⁶² reported standardised means difference of 0.40 at 4-8 weeks with $p < .001$]; [Senna *et al*⁶³ reported means difference of 18.9 at 10 months with $p < .001$]). Only Senna *et al*⁶³ reported an overall-health improvement of means difference of 7.8 at 10 months ($p < .001$). The authors^{62,63} concluded that MT1 is clinically effective in treating patients with chronic LBP in the short-term, but to obtain long-term benefit on all outcome measures requires maintenance of MT1 every 2 weeks.⁶³

MT combined with other interventions

Niemistö *et al*³² (rated as level B quality) investigated the effects of combined MT2 (myotensive lumbo-pelvic mobilization techniques) with exercises (stabilising exercise to correct lumbo-pelvic rhythm) and UMC in comparison to UMC alone (patient education, stay active approach, ergonomic instruction, home general exercises, and educational-booklet) in patients with chronic LBP from QTF 1-3. They found that the intervention group provided clinically relevant improvements in pain relief ($p < .001$ and standardised means difference of 0.60) and function ($p = .002$ and standardised means difference of 0.45) from the short to long-term (up to one year). However, there were no significant differences between the groups in terms of the quality-of-life and medical costs.

Aure *et al*⁴⁹ (rated as level B quality) evaluated the effectiveness of MT3 (consisting of mobilisation and rotational manipulation in side-lying position from T10 to the pelvis) combined with specific and general exercise in comparison to exercises only in patients with chronic LBP from QTF 1-3. Both groups received 16 sessions of 45 minutes over 8 weeks. The results

showed statistically significant improvements in terms of pain reduction and function in both groups. However, there was a greater improvement in all outcome measures for the intervention group leading to clinically relevant differences in the very-short to long-term on pain (at one year: $p < .05$ and means difference of 1.5) and functional improvement (at one year: $p < .05$ and mean difference of 9), as well as for return to work rate (at 2 months; $p < .01$ means difference of 40 %).

Cecchi *et al*³⁴ (rated as level B quality) compared one group receiving MT3 combined with UMC, to another group receiving back school with UMC to another group receiving individual physiotherapy (passive and assisted mobilisation, active exercises, massage, and proprioceptive-neuromuscular-facilitation) with UMC in patients with chronic LBP of type QTF 1-2. The results showed that MT3 led to clinically relevant decrease in pain (at 12 months: $p < .001$, standardised means of difference of 0.7 and 1.1) and a greater functional recovery (at 12 months: $p < .001$, standardised means of difference of 0.70 and 0.73) than the two control groups at long term. But, the intervention group (MT3) received significantly more treatment than the two control groups at follow-up. Pain recurrence and drug intake were also significantly reduced in the MT3 group ($p < .001$).

Rasmussen *et al*⁶⁴ (rated as a level B quality) compared the effects of combined MT1 (in a side-lying position at the lumbar level of reduced movement) with exercises (2 different extension exercises performed as often as possible during the day and at least once per hour), to the extension exercises alone in patients with chronic LBP classified as QTF 1-3. Both groups showed clinically relevant back and leg pain reduction, and no difference between the groups could be observed at the one month and one year follow-ups. Importantly, four patients in the intervention group and three in the control group reported worsening of back pain after 4 weeks, 3 months and one year.

Table 3 Summary of articles for patients with chronic LBP

AUTHORS Sample size LBP status	Methodological quality of studies	Intervention group + co-intervention	Comparison group + co-intervention	Outcomes measures of interest	Clinical relevance status on timing outcomes: between groups p-value and effect sizes
Ghroubi <i>et al.</i> ⁶² (2007) N=64 CLBP1	Level A 9/11 Care provider not blinded? for ITT	MT1 4 sessions per week over 1 month	Sham MT1 1 session over 1 month	Pain (VAS) Functional disabilities (ODI)	YES: at 4 weeks, $P<0.001$ and SMD=0.86; 8 weeks, $P<0.001$ and SMD=0.54 YES: at 8 weeks, $P<0.001$ and SMD=0.40 YES: at 10 months, $P<0.005$ and MD=1.9
Senna <i>et al.</i> ⁶³ (2011) N=93 CLBP1-2	Level A 10/11 Care provider not blinded	MT1 non-maintained MT1 maintained 3 sessions per week over 1 month for all groups, with 1 session/2 weeks during 9 months for MT1 maintained	Sham MT1 UMC 1 session of 60 minutes over 1 month Exercise	Pain (VAS) Functional disabilities (ODI) Overall-Health (SF-36) Pain (VAS) Functional disabilities (ODI) Pain (VAS)	YES: at 10 months, $P<0.001$ and MD=18.9 YES: at 10 months, $P<0.001$ and MD=7.8 YES: at 1 year, $P<0.001$ and SMD=0.60 YES: at 1 year, $P=0.002$ and SMD=0.45 YES: at 1 year: $P<0.05$ and MD=1.5
Niemistö <i>et al.</i> ³² (2003) N=204 CLBP1-3	Level B 8/11 Care provider and patients not blinded? for ITT	MT2 + exercise and UMC 4 sessions of 60 minutes over 1 month	UMC 1 session of 60 minutes over 1 month	Pain (VAS) Functional disabilities (ODI)	YES: at 1 year: $P<0.001$ and SMD=0.60 YES: at 1 year, $P=0.002$ and SMD=0.45 YES: at 1 year: $P<0.05$ and MD=1.5
Aure <i>et al.</i> ⁴⁹ (2003) N=49 CLBP1-3	Level B 9/11 Care provider and patients not blinded	MT3 + exercise 2 sessions of 45 minutes per week over 8 weeks for each group	Exercise	Pain (VAS)	YES: at 1 year: $P<0.05$ and MD=1.5
Cacchi <i>et al.</i> ³⁴ (2010) N=210 CLBP1-2	Level B 9/11 Care provider not blinded	MT3 + UMC 4-6 sessions of 20 minutes/ week over 4-6 weeks	Back school + UMC Physiotherapy + UMC 15 sessions of 60' over 3 weeks	Functional disabilities (ODI) Quality of life: Return to work Pain (NPRS)	YES: at 1 year: $P<0.05$ and MD=9 YES: at 1 month, $P<0.01$ and MD=40% YES: at 1 year, $P<0.001$ and SMD=0.7 (MT3+UMC vs Back school+UMC), and SMD=1.1 (MT3+UMC vs physiotherapy + UMC)
Rasmussen <i>et al.</i> ⁶⁴ (2008) N=72 CLBP1-3	Level B 8/11 No for patient and care provider blinded and? for ITT	MT1 + extension exercises 3 sessions over 1 month + everyday exercise over 1 month.	Extension exercises alone Everyday exercise over 1 month	Functional disabilities (RMDQ) Back and leg pain (VAS)	YES: at 1 year: $P<0.001$ and SMD =0.7 (MT3+UMC vs Back school+ UMC) and SMD=0.73 (MT3+UMC vs physiotherapy+UMC) NO: at 1 month and 1 year, NS differences for all outcomes measures

Note: CLBP=chronic LBP; 1=LBP alone, 2=LBP radiating not below knee, 3=LBP radiating below knee without neurologic deficit. MT=manual therapy, MT1=spinal mobilization techniques, MT3=MT1+MT2. MT3+specific and general exercises. UMC=usual medical care. NS=non-statistically significant difference. SMD=standardized mean of difference, MD=between groups mean of difference. Yes= $P<0.05$ + moderate-large effect size (SMD, MD) in favour of MT. VAS=Visual Analogical Scale, NPRS=Numerical Pain Rating Scale, ODI=Oswestry Disability Index, RMDQ=Roland-Morris Disability Questionnaire, SF-36=short-form-health-survey.

Table 4 Summary findings from systematic review for MT combined or not with exercise or usual medical care for LBP. Strength of new and updated evidence is shown in underlined and in bold text. Confirmation of previous evidence shown in bold text

Categories of MT interventions vs comparison group	Quality of evidence (A=high; B=moderate)	Strength of evidence for interventions
ACUTE (<6 weeks) and SUBACUTE (6–12 weeks) LBP		
MT1 vs Sham MT1	3 RCTs, Level A ^{57–59} <i>n</i> =395	<u>STRONG evidence in favour of MT1 in comparison to sham MT1 for acute LBP, for PAIN, function, overall-health and quality of life improvements in the short-term (<3 months).</u>
MT1 and MT3 combined with UMC vs UMC alone	2 RCTs Level B ^{60,61} <i>n</i> =151	<u>MODERATE evidence in favour of MT1 and MT3 combined with UMC in comparison to UMC alone for PAIN, functional improvement and quality of life from very-short to short-term in patients with acute LBP.</u>
MT1 with ROM exercise vs MT2 with exercise or exercise alone	2 RCTs Level B <i>n</i> =243 (Cleland <i>et al.</i> , 2009; Childs <i>et al.</i> , 2004)	<u>MODERATE evidence in favour of MT1 with exercise as compared to MT2 with exercise or exercise alone for pain relief and function improvement at very-short-term and short-term. Functional improvement is also present at intermediate-term (6 months) in a specific subgroup of patients with acute-subacute LBP.</u>
MT3 combined with exercise 'early' vs the same intervention 'delayed'	1 RCT Level B <i>n</i> =102 (Wand <i>et al.</i> , 2004)	<u>LIMITED evidence in favour of an early intervention of MT3 combined with exercise in comparison to the same intervention delayed, on functional status and overall improvement at very-short-term and on overall improvement at intermediate-term in patients with acute LBP.</u>
MT3 with UMC vs UMC alone	2 RCTs Level B <i>n</i> =339 (Curtis <i>et al.</i> , 2000; Juni <i>et al.</i> , 2009)	<u>MODERATE evidence for no difference between MT3 combined with UMC in comparison to UMC alone, for pain reduction, functional recovery, and improvement in quality of life for very-short to intermediate-term in acute LBP.</u>
MT3 combined with exercise vs UMC alone	1 RCT Level B <i>n</i> =402 (Hay <i>et al.</i> , 2005)	<u>LIMITED evidence for no difference between MT3 combined with exercise vs UMC alone in terms of pain reduction and improvements of function from short to long-term in patients with acute-subacute LBP.</u>
MT2 vs Sham ultra sound	1 RCT Level A <i>n</i> =240 (Hancock <i>et al.</i> , 2007)	<u>MODERATE evidence for no difference between MT2 and sham ultra sound in terms of pain reduction and functional improvements from very-short to short-term in acute LBP population.</u>
MT3 combined with interferential therapy vs MT3 or interferential therapy alone	1 RCT Level B <i>n</i> =240 (Hurley <i>et al.</i> , 2004)	<u>LIMITED evidence for no difference between MT3 associated with interferential therapy and MT3 alone or interferential therapy alone in terms of pain reduction, functional improvements, and quality of life improvement in patients with acute-subacute LBP.</u>
CHRONIC LBP (>12 weeks)		
MT1 vs Sham MT1	2 RCTs Level A ^{62,63} <i>n</i> =157	<u>MODERATE-STRONG evidence in favour of MT1 as compared to sham MT1, in terms of pain reduction, functional improvements and overall-health improvement at SHORT-term to INTERMEDIATE-term in patients with chronic LBP.</u>
MT3 combined with exercise or with UMC vs exercise alone and back school	2 RCTs level B ^{34,49} <i>n</i> =259	<u>MODERATE evidence in favour of MT3 combined with exercise or with UMC as compared to exercise alone and back school in terms of pain and function and quality of life improvement from short to long-term in patients with chronic LBP.</u>

Table 4 Continued

Categories of MT interventions vs comparison group	Quality of evidence (A=high; B=moderate)	Strength of evidence for interventions
MT2 combined with exercise and UMC vs UMC alone	1 RCT Level B ³² n=204	<u>LIMITED evidence in favour of MT2 combined with exercise and UMC in comparison to UMC alone</u> in terms of pain reduction and function improvement from short to long-term in patients with chronic LBP.
MT1 with extension exercise vs extension exercise alone	1 RCT Level B ⁶⁴ n=72	<u>LIMITED evidence for no difference between MT1 combined with extension exercise in comparison to extension exercise alone</u> in improving pain in the short-term and long-term in patients with chronic LBP.
MT2 vs UMC MT2 vs acupuncture	1 RCT Level B n=262 (Cherkin <i>et al.</i> , 2001)	LIMITED evidence in favour of MT2 as compared to UMC and acupuncture in terms of pain, function, and quality of life from short-term to long-term in patients with chronic LBP.
MT3 vs exercise	2 RCTs Level B n=452 (Ferreira <i>et al.</i> , 2007; Critchley <i>et al.</i> , 2007)	MODERATE evidence for no difference between interventions in terms of pain reduction, functional recovery and quality of life improvement in patients with chronic LBP.
MT3 vs Sham MT3	1 RCT Level A n=91 (Licciardone <i>et al.</i> , 2003)	MODERATE evidence for no difference between interventions in terms of pain reduction, functional improvement, and patient satisfaction with care in very short-term and intermediate-term for patients with chronic LBP.

Note: MT=manual therapy; MT1=manipulation; MT2=mobilization and soft-tissue-techniques; MT3=MT1 + MT2. UMC=usual medical care; exercise=specific and/or general exercise.

Discussion

The purpose of this SR was to assess and update the evidence pertaining to the effectiveness of different MT approaches in isolation or when combined with exercise or UMC in the management of LBP. Thus, this SR deviates and provides clinicians and researchers with new information compared with other recent high quality SRs^{41,43,45} which are focused more on manipulation. A detailed summary of these updated findings, as well as the strength of their evidence and level of agreement with existing studies, are presented in Table 4.^{7,30,35-38,41,43,45}

In comparison to recent SRs^{36,41,43,45}, the present results highlight a number of new issues in the management of LBP with MT:

Firstly, in comparison to previous reports of limited-evidence^{41,43} showing no-difference between true and sham manipulation, the results of this SR show moderate to strong evidence^{57-59,62,63} for the beneficial effects of MT1 in comparison to sham-MT1. These differences are demonstrated in terms of pain relief, functional improvement, and overall-health and quality of life improvements in the short-term for all stages of LBP.

Secondly, in patients with acute-subacute LBP, in contrast to the previous reports of limited evidence of no-difference for manipulation combined with other interventions,⁴¹ we determined moderate-evidence^{60,61} to support MT1 and MT3 combined with UMC, in comparison to UMC alone, for pain, function, overall-health and quality of life.^{60,61}

Thirdly in patients with chronic LBP, in contrast to the previous reports of varying quality evidence (ranging from limited to strong) that manipulation has short term efficacy when combined with other interventions⁴³, we found moderate evidence^{34,49} in support of the use of MT3 combined with exercises or UMC, in comparison to exercise alone or back-school, for pain, function and return to work from short to long-term. In addition limited evidence³² supports the use of MT2 combined with exercises and UMC, in comparison to UMC alone, for pain and function from short to long-term. Finally, there is limited evidence of no-difference in efficacy for MT1 combined with extension-exercises, in comparison to extension-exercises alone for pain.⁶⁴

The highest quality clinical research study is the conventional RCT. These studies have good internal validity but at the expense of external validity. An alternative for “real world” application is a pragmatic RCT which has good external validity but poor internal validity.⁶⁵ Pragmatic clinical trials are becoming a frequently used tool to evaluate complex interventions.⁶⁶ Another possibility is to extend the conventional RCT to retain some of its key advantages (e.g. Cochrane criteria shown in Appendix 1), and use a “quasi-double-blind” design to make a realistic compromise between internal and external validity. The CONSORT guidelines should also be considered to develop high quality study designs.⁶⁷

One of the key issues in MT research is developing a plausible placebo or sham technique. A sham manipulation should be an appropriate placebo procedure because it mimics interaction between the intervention, the patient, the practitioner and the environment. Moreover, researchers need to conceptualize placebo not only as a comparative inert intervention, but also as a potential mechanism to partially account for treatment effects associated with MT.⁶⁸

In the present SR, only 5 studies were placebo-controlled, 4 of them using sham adjustment,^{31,57,58,62,63} while 1 used a real manipulation at the incorrect spinal level to achieve an authentic placebo response.⁵⁹ Further research is required to identify a plausible placebo response.

In the majority of RCTs addressing the effectiveness of MT, LBP patients are treated as a homogeneous group while recent research suggests that people with LBP in fact comprise a heterogeneous group.^{40,65,69} Consequently, the concept of subgrouping among people with LBP is growing in the MT literature.⁶⁵ Classification of patient into sub-groups and the application of specific MT interventions for each sub-group have been shown to be more efficient.^{28,69-74} For example, a treatment based classification system to identify MT for people with LBP is one form of subgrouping.²⁸ The Start-Back-Tool is another approach that aims to sub-classify according to psychosocial issues, and has been found to be more effective than a non-subgrouping approach.^{75,76} Moreover, the patients’ beliefs and expectations regarding treatment effects of MT interventions has also shown to be an important predictor of treatment outcome.⁷⁷ Targeted MT for specific subgroups is important because of the heterogeneity of people with LBP, future clinical trials should address the “wash-out” effect of applying treatments for un-classified LBP.⁷⁸

In terms of quality of the MT management, MT should always be based on evidence-based-practice, which incorporates patient values (bio-psycho-social influences), clinical expertise and reasoning on part of the clinician, as well as the best available clinical research evidence.^{5,79-81} It could also be useful to establish a minimum level of practical skills across the range of commonly used MT techniques to manage people with LBP, and to improve clinical reasoning skills dealing with the complexity of LBP.⁶⁵ Future studies should incorporate clinical expertise as a factor in treatment trials for LBP.

Limitations

The results of our SR should be interpreted in the light of some limitations. Firstly, there was heterogeneity in the RCTs evaluated in this study including the data presentation and outcome measures. Consequently, a meta-analysis enabling pooled statistics of effect was not possible. Furthermore, the strength of evidence comprising this SR is limited (particularly for the stronger level of evidence) due to the difficulty of a true double-blind study design and because of the limited number of high quality studies. Finally, only studies published in English from 2000 to 2013 were reviewed, leading to the possibility of relevant articles existing in other languages or before 2000.

Conclusions

This SR, based on low-risk of bias studies, has provided a comprehensive review of different MT approaches in patients with different stages of LBP, informing evidence-based-practice. Based on the results of this SR, a variety of manual procedures combined or not with other interventions, including exercise, may improve patient management. The summary findings of this review are both comprehensive and novel and may be used to guide clinical practice and future studies of this topic.

Recommendations for future research to investigate MT include pragmatic high quality RCTs to maximize the application of results to clinical practice and to reflect the complexity of clinical reasoning and multi-modal management of MT. Future studies should also investigate targeted MT for specific subgroups of people with LBP, and continue to address the complex issue of the best placebo procedure in MT trials.

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Appendix 1

Search strategy in MEDLINE

In MeSH (MEDLINE), "Manual Therapy" was used as a free-term. The result of the MeSH Heading was "Musculoskeletal-Manipulations" and we added "Low-Back-Pain" to the MEDLINE search box as follows: "Musculoskeletal-Manipulations"[Mesh] AND "Low-Back-Pain"[Mesh] AND ("humans"[MeSH-Terms] AND ("male"[MeSH-Terms] OR "female"[MeSH-Terms]) AND Randomized-Controlled-Trial[ptyp] AND English[lang] AND "adult"[MeSH-Terms] AND "2000/01/01"[PDat] : "2013/04/01"[PDat])

Risk of bias assessment

Criteria list for methodological quality assessment from Cochrane Collaboration Back Review Group

- A Was the method of randomization adequate? Yes/No/Don't know
- B Was the treatment allocation concealed? Yes/No/Don't know
- C Were the groups similar at baseline regarding the most important prognostic indicators? Yes/No/Don't know
- D Was the patient blinded to the intervention? Yes/No/Don't know
- E Was the care provider blinded to the intervention? Yes/No/Don't know
- F Was the outcome assessor blinded to the intervention? Yes/No/Don't know
- G Were cointerventions avoided or similar? Yes/No/Don't know
- H Was the compliance acceptable in all groups? Yes/No/Don't know
- I Was the dropout rate described and acceptable? Yes/No/Don't know
- J Was the timing of the outcome assessment in all groups similar? Yes/No/Don't know
- K Did the analysis include an intention-to-treat analysis? Yes/No/Don't know

Operationalization of the criteria list

A: A random (unpredictable) assignment sequence. Examples of adequate methods are computer generated random number table and use of sealed opaque envelopes. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should not be regarded as appropriate.

B: Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.

C: In order to receive a "yes," groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurologic symptoms, and value of main outcome measure(s).

D: The reviewer determines if enough information about the blinding is given in order to score a "yes."

E: The reviewer determines if enough information about the blinding is given in order to score a "yes."

F: The reviewer determines if enough information about the blinding is given in order to score a “yes.”

G: Cointerventions should either be avoided in the trial design or similar between the index and control groups.

H: The reviewer determines if the compliance to the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s).

I: The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and dropouts does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a “yes” is scored. (N.B. these percentages are arbitrary, not supported by literature).

J: Timing of outcome assessment should be identical for all intervention groups and for all-important outcome assessments.

K: All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of noncompliance and cointerventions.

Appendix 2

Studies that confirmed previous evidence (1) and studies that have been excluded from the SR (2)

1. Authors, Journals and quality score of included studies that confirmed previous evidence (Table 4)			
ACUTE-SUBACUTE LBP		CHRONIC LBP	
Childs <i>et al.</i> ¹ Ann Intern Med (2004)		Licciardone <i>et al.</i> ⁹ Spine (2003) level A (9/11)	
level B (9/11)			
Cleland <i>et al.</i> ² Spine (2009) level B (8/11)		Cherkin <i>et al.</i> ¹⁰ Arch Intern Med (2001) level B (9/11)	
Wand <i>et al.</i> ³ Spine (2004) level B (9/11)		Ferreira <i>et al.</i> ¹¹ Pain (2007) level B (8/11)	
Curtis <i>et al.</i> ⁴ Spine (2000) level B (8/11)		Critchley <i>et al.</i> ¹² Spine (2007) level B (9/11)	
Jüni <i>et al.</i> ⁵ Ann Rheum Dis (2009) level B (9/11)			
Hay <i>et al.</i> ⁶ Lancet (2005) level B (9/11)			
Hancock <i>et al.</i> ⁷ Lancet (2007) level A (10/11)			
Hurley <i>et al.</i> ⁸ Spine (2004) level B (9/11)			
2. Authors, Journals and qualitative and/or quantitative criteria for reason of exclusion			
Bogefeldt <i>et al.</i> ¹³ Clin Rehabil (2008)	Outcome: only sick leave	Hertzman-Miller <i>et al.</i> ¹⁴ Am J Public Health (2002)	Patients: Mixed LBP status. Intervention: No for categorization of MT
Cairns <i>et al.</i> ¹⁵ Spine (2006)	Intervention: no for categorization of MT (6/11 Cochrane-list)	Hondras <i>et al.</i> ¹⁶ JMPT (2009)	Patients: Mixed LBP status
Chiradejnant <i>et al.</i> ¹⁷ Aust J Physiother (2003)	Patients: mixed LBP status (6/11 Cochrane-list)	Hsieh <i>et al.</i> ¹⁸ Spine (2002)	Patients: Mixed LBP status
Chown <i>et al.</i> ¹⁹ Physiother (2008)	5/11 Cochrane-list	Hurwitz <i>et al.</i> ²⁰ Spine (2002)	Patients: Mixed LBP status. Intervention: No for categorization of MT
Eisenberg <i>et al.</i> ²¹ Spine (2007)	Intervention: no for categorization of MT	Kilpikoski <i>et al.</i> ²² Adv Physiother (2009)	Patients: Mixed LBP status
Ferreira <i>et al.</i> ²³ Man Ther (2009)	4/11 Cochrane-list	Konstantinou <i>et al.</i> ²⁴ JMPT (2007)	Patients: Mixed LBP status (6/11 Cochrane-list)
Flynn <i>et al.</i> ²⁵ Spine (2002)	5/11 Cochrane-list	Kool <i>et al.</i> ²⁶ Arch Phys Med Rehabil (2007)	Intervention: No for categorization of MT. Outcomes: no adequate outcomes
Geisser <i>et al.</i> ²⁷ Clin J Pain (2005)	5/11 Cochrane-list	Miller <i>et al.</i> ²⁸ JMMT (2005)	Intervention: No for categorization of MT
Giles and Muller ²⁹ Spine (2003)	Patients: mixed neck and LBP	Mohseni-Bandpei <i>et al.</i> ³⁰ Phys Ther (2006)	6/11 Cochrane-list
Goldby <i>et al.</i> ³¹ Spine (2006)	Intervention: no for categorization of MT (6/11 Cochrane-list)	Nagrale <i>et al.</i> ³² JMMT (2012)	Intervention: No for categorization of MT (neurodynamic)
Grunnesjo <i>et al.</i> ³³ JMPT (2004)	'No' for co-intervention (steroid injections only in IG)	Niemisto <i>et al.</i> ³⁴ Spine (2005)	Patients: Mixed LBP status. (6/11 Cochrane-list)
Haas <i>et al.</i> ³⁵ Spine J (2004)	6/11 Cochrane-list	Paatelma <i>et al.</i> ³⁶ J Rehabil Med (2008)	Patients: Mixed LBP status
Hagen <i>et al.</i> ³⁷ Spine (2003)	Intervention: no for categorization of MT	Parkin-Smith <i>et al.</i> ³⁸ Arch Phys Med Rehabil (2012)	'No' for assessor blinded (7/11 Cochrane-list)
Hallegraeff <i>et al.</i> ³⁹ Percept Mot Skills (2009)	'No' for assessor blinded (7/11 Cochrane-list)	Rasmussen-Barr <i>et al.</i> ⁴⁰ Man Ther (2003)	Patients : mixed LBP status (6/11 Cochrane-list)
Hancock <i>et al.</i> ⁴¹ Eur Spine J (2008)	'No' for assessor blinded (8/11 Cochrane-list)	Riipinen <i>et al.</i> ⁴² J Rehabil Med (2005)	Outcomes: no adequate outcomes
Hemmila <i>et al.</i> ⁴³ JMPT (2002)	Intervention : no for categorization of MT (4/11 Cochrane-list)	Team UBT. ⁴⁴ BMJ (2004)	Patients: Mixed LBP status

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Section 2

Development of a kinematic model of the spine

CHAPTER II

Reliability and validity of a kinematic model of the spine during active trunk movements in healthy subjects and patients with chronic nonspecific low back pain

Benjamin Hidalgo, Maxime Gilliaux, William Poncin, Christine Detrembleur

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ABSTRACT

Objectives: To develop a standardized, reliable, valid spine model of active trunk movements that accurately discriminates kinematic patterns of patients with chronic nonspecific low back pain from those of healthy subjects.

Design: Comparative cohort study.

Subjects: Healthy subjects (n = 25) and patients with chronic nonspecific low back pain (n = 25) aged 30–65 years.

Methods: Subjects performed 7 trunk movements from a seated position at non-imposed speed during 2 sessions. Nine markers on bony landmarks measured range of motion and speed of 5 spinal segments, recorded by 8 optoelectronic cameras.

Results: Both groups showed good–excellent reliability in all movements for range of motion and speed of all spinal segments (intraclass correlation (ICC), 0.70–0.96; standard error of measurement, expressed as a percentage, 19.4–3.3%). The minimal detectable change in the patient group was 16.7–53.7%. Range of motion and speed in all spinal segments for trunk flexion, rotation, and flexion with rotation differed significantly between groups ($p < 0.001$), with large/ very large effect sizes (Cohen's $d = 1.2$ – 2). Binary logistic regression yielded sensitivities/specificities of 92%/84% for range of motion and 92%/80% for speed.

Conclusion: Kinematic variables are valid, reliable measures and can be used clinically to diagnose chronic nonspecific low back pain, manage treatment, and as quantitative outcome measures for clinical trial interventions.

Introduction

Back disorders are the most frequently reported musculoskeletal problems and are the third most common bodily symptom, after headache and tiredness.¹⁻² The annual prevalence of low back pain (LBP) is estimated at 55% among French population aged 30-64 years.³⁻⁴ Approximately 60-80% of people in Western society will experience LBP at some stage in their life.^{1,5} Indeed, LBP is a considerable public health problem, due to work absenteeism and tremendous health care costs.⁵⁻⁷ From a physical medicine perspective, 55% of people suffering from LBP consult a physiotherapist or other health care professional in France.⁸ In the United States, LBP is the second highest cause of consultation among physiotherapists and the second highest reason for work absenteeism.^{5,9}

LBP may be due to serious spinal pathology (e.g., spinal tumor or infection), rheumatologic disease, or true nerve root pain. These causes of low backache are referred as specific LBP and represent less than 7% of all LBP. However, a definitive diagnosis is not possible in 80% of cases of low backache. In such cases of nonspecific LBP (NS-LBP), the pain is caused by a mechanical disturbance of the musculoskeletal structures or back function, or by degenerative changes of the vertebral column.¹⁻³ When NS-LBP is present for more 3 months, the disorder is labeled as non-specific chronic LBP (NS-CLBP). Approximately 10% of acute NS-LBP becomes NS-CLBP, which affects 7% of the U.S. population.¹⁻⁶

Traditionally, the classification of LBP has been based on anatomopathology and the diagnosis involves clinical examination, X-ray, and/or magnetic resonance imaging. However, weak correlations exist between the medical imaging and symptoms of patients with LBP, with only 15% of the LBP patients showing such a correlation.¹⁰ Furthermore, in 25% of asymptomatic subjects, real signs of herniated discs are found on medical imaging. Others authors estimate that only 10-20% of LBP diagnoses are accurate and arise from a well-identified origin.¹¹

Perhaps due to its diagnostic failure and the lack of sub-classifying the heterogeneous population with NS-LBP, the best care for NS-LBP remains controversial and considerable variability exists in its management across medical disciplines. On the contrary, it is well established that the classification of NS-LBP disorders into homogenous subgroups is likely to perform efficacy of adapted treatments.¹²⁻¹³ Therefore, the classification based on anatomopathology may not be the most effective method of classification system for NS-CLBP to target treatment. Consequently, the information collected from the clinical examination may be useful in identifying subgroups of NS-LBP patients and managing specific treatment strategies.¹⁴⁻¹⁵

In clinical practice, one of the most common classification system for NS-LBP is the examination based on active trunk movements in various directions.¹⁴⁻¹⁷ As an illustration, the valid and reliable Movement Impairment Classification System (MICS) proposed by O'Sullivan is based on impairment related to symptoms and mechanical factors (e.g. pain, asymmetry, misalignments, loss of range of motion, patterns of coordination) observed during a standardized examination of trunk motions in various planes; single or combined.¹⁴⁻¹⁸ Therefore, the classifications are categorized according to the direction(s) of movements and alignments that seem to increase a subject's NS-LBP symptoms and influence the quality of movement.¹⁴⁻¹⁸ These clinical examinations could also be (i) achieved with clinical assessment tools (e.g. goniometer), (ii) complemented with instrumented tools (e.g. electro goniometer, electromagnetic or optoelectronic systems).^{15,19-20}

According to previous findings,^{13,21-23} manual therapy (MT) and active rehabilitation (AR) appear to be a promising approach to treat subgroups of NS-LBP and considerable evidence suggested the presence of movement impairments in patients with NS-LBP.¹³⁻¹⁸ Kinematic analyses of the trunk movements could be potentially useful outcome measures for quantifying specific kinematic patterns to assess the efficacy of a multidimensional therapeutic approach including MT and AR.^{15,19-20,24-26}

Nevertheless, these findings require confirmation by independent data sets to raise the overall level of evidence before they can be validated and used to help in diagnosis or to become a valid outcome measure for specific rehabilitation therapies in clinical trials.²⁰ Several back kinematic tools have been previously used,^{15,19-20,24-26} however fewer such tools have been applied with optoelectronic camera systems, which can measure kinematic patterns with high accuracy.¹⁵ As previous studies^{19-20,24-26} have generally focused on the low back area, the kinematic assessments on the full spine of various active trunk motions from a sitting position in a subgroup of NS-CLBP has never been validated with instrumented measures.

Using an optoelectronic camera system, we sought to develop a standardized and reliable spine model including 5 spine segments of active trunk movements that would be sufficiently accurate to discriminate kinematic patterns of patients with NS-CLBP from those of healthy subjects. Inspired from classification system during clinical examination (e.g. MICS) in case of NS-LBP, we used a setup of 7 trunk motion tasks from a sitting position. This position is interesting to reduce the influence of hip motions,²⁷⁻²⁸ pelvic asymmetry,²⁹⁻³⁰ hamstring contracture^{28,30-31} and better targets the movements of the lower spine during trunk movements.^{28,32}

To determine the quality of our kinematic spine model, we aimed: (I) to evaluate the intra-examiner reliability of our active trunk motion measurements in healthy subjects and those with NS-CLBP, (II) to study the responsiveness of the model, and (III) to determine the sensitivity and specificity of ROM and speed (SPEED) measurements during active trunk movements.

Methods

Subjects

The cohort comprised 25 healthy subjects aged 30-60 years and 25 subjects with NS-CLBP aged 30-65 years. Anthropometrics data are shown in Table 1.

Table 1. Baseline characteristic of healthy and NS-CLBP subjects

Group	n	M/F	Age (years)	BMI (kg/m ²)	VAS T ₀	VAS T ₁
Healthy	25	10/15	40 (11)	23.3 (2.5)	/	/
NSCLBP	25	12/13	42 (9)	25.2 (3.2)	2.4 (1.7)	2.5 (1.5) NS

Data are shown as the mean (SD). VAS represents pain score according to a 10-point scale during the first (VAS T₀) or second (VAS T₁) session. NS = non-significant difference with t-paired test ($p=0.44$); ICC (VAS T₀-T₁) = 0.85

The NS-CLBP group included men and women recruited from Saint-Luc University Hospital, including patients who have been suffering from a NS-CLBP with or without radiating pain into the thigh but not below the knee, for at least 12 weeks. Moreover, they were required to present through the clinical examination several impairment directions (≥ 2 on 7 directions) during active trunk movements from a sitting position.

The healthy subjects had no incidences of NS-LBP for 6 months prior the experiment. The Ethic Committee of the University of Louvain approved the protocol for this study.

Protocol and Material

Seven trunk motion tasks were used that involved the whole spine and were performed at a non-imposed speed. Eight infrared cameras (ELITE-BTS) registered the 3D positions of 9 reflective markers placed on bony landmarks. Each task consisted of 10 trials for each session (2 sessions around 1 week apart). From the positions of the markers, customised software calculated the range of motion (ROM) and the SPEED of each spinal segment for each subject and each trial. The mean and standard deviation (SD) were calculated for each variable ($n = 10$).

All trunk movements were executed from a sitting position on a stool and the height of the stool was adjusted for each subject in such a way that the angle between the hip and the trunk reached 120°. This amplitude was chosen to help in maintaining the physiological curvature for the starting position. From this starting position, subjects performed successively a set of 7 different direction tasks (the same as during clinical examination) described below (Tasks and instructions).

Placement of markers

Standardised marker placements were positioned as follow: 5 markers on spinous processes of S2, L3, T12, T7, and C7; 2 markers were placed on the anterior-superior-iliac-spinous process (ASIS) right and left; and 2 markers were placed on the acromio-clavicular (Ac) joints right and left. The examiner who placed the markers was an experimented manual-therapist in order to enhance as possible palpatory accuracy. Moreover to reduce the approximation of bony landmarks palpation described into the literature, the distance between the markers of each subject were (I) measured from C7 as a reference (easy to find spinous process, the most prominent in head flexion) (II) recorded and (III) reported from the first to the second session.

Kinematic spine model

A spine model was elaborated that included the pelvic and shoulder girdles (Figure 1A, B). The whole spine was divided into various segments: high thoracic spine (HTS: C7 - T7), low thoracic spine (LTS: T7 - T12), high lumbar spine (HLS: T12 - L3), low lumbar spine (LLS: L3 - S2), total lumbar spine (TLS: T12 - S2), and shoulder segment (SS: AcRight - AcLeft). Each spinal segment was considered as rigid and homogenous, delimited by proximal and distal markers as illustrated in Figure 1. This modeling procedure is similar to that of Larivière et al.³³ and Gombatto et al.¹⁵ The selected variables are the range of motion (ROM) and the SPEED of each spinal segment.

Tasks and instructions

Subjects were asked to fulfill conscientiously the following 4 rules, regardless of the task: Subjects must (1) be in a physiological sitting position (with respect to curvatures) at the beginning and end of each movement; (2) aim to make the movement at non-imposed (spontaneous) speed and as far as possible; (3) keep the ischiatic tuberosities in contact with the stool; (4) and strictly respect the specific plane of motion, depending of the trunk movement task. Each movement was repeated 15 times and recorded after the fifth movement (n = 10 trials). Subjects were also instructed to perform each task according to the following instructions:

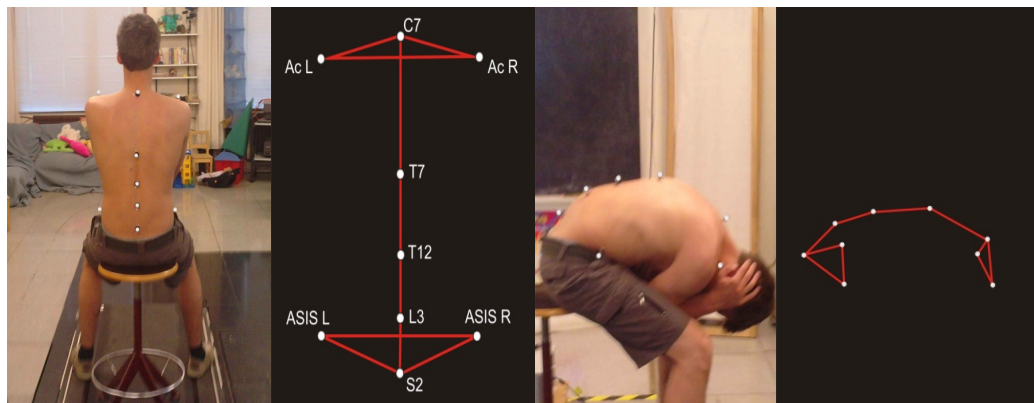
Anterior trunk flexion: Subjects positioned themselves with hands placed on the ears and elbows forward, and then flexed the trunk as far as possible with respect to the sagittal plane (Figure 1).

Lateral trunk side bending left and right: Subjects crossed their arms on the chest, and then inclined the trunk in the frontal plane.

Rotation left and right: Subjects crossed their arms on the chest, and rotated head and shoulders to the side as far as possible, while respecting the transversal plane.

Anterior trunk flexion with left and right rotation (rotated pelvis): The subject sat on the stool with the pelvic rotated at 30° to the left or right, and the subject was given the same instructions as in the anterior flexion task.

Figure 1. Kinematic spine model during anterior trunk flexion



Placement of markers in the sitting position and model representation. The girdles are represented by 2 triangles, where the pelvis is delimited by S2 and the EIAS, and the shoulders are delimited by C7 and both acromio-clavicular (Ac) joints. Low lumbar spine (LLS: S2-L3), high lumbar spine (HLS: L3-T12), total lumbar spine (TLS: S2-T12), low thoracic spine (LTS: T12-T7), and high thoracic spine (HTS: T7-C7). Illustration of the flexion task from the sitting position to the end of the ROM. Illustration of the flexion task from the sitting position to the end of the range of motion.

Data Analysis

Each spinal segment was analyzed according to the mean ROM and the mean SPEED. The mean ROM (°) corresponded to the range of the angular displacement of each spinal segment during 10 trials. At each frame, the angular displacement of motion in the sagittal plane (YZ) and frontal plane (XZ) was calculated from the vertical axis (Z) localized on the proximal marker of each segment, according to:

$$\Theta_{YZ} = \tan^{-1} \frac{Y_p - Y_d}{Z_p - Z_d} \text{ and } \Theta_{XZ} = \tan^{-1} \frac{X_p - X_d}{Z_p - Z_d}$$

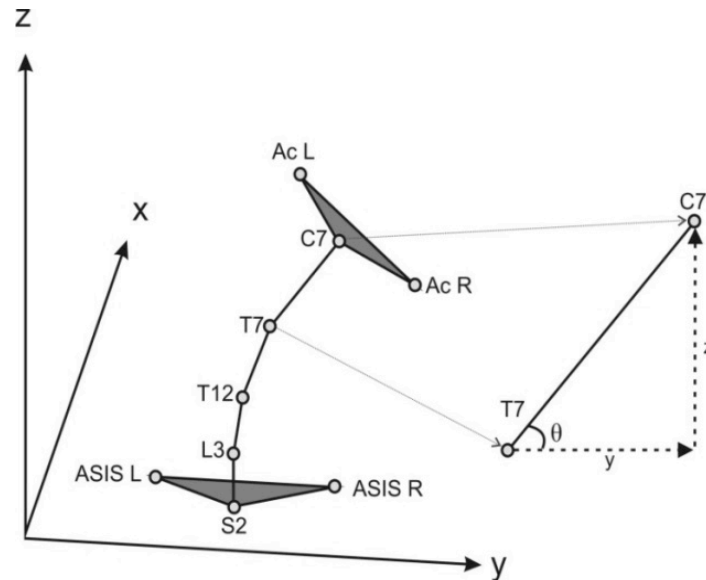
The angular displacement in the transversal plane (XY) relative to the horizontal axis (Y) was calculated, localized on the proximal marker of each segment according to:

$$\Theta_{XY} = \tan^{-1} \frac{X_p - X_d}{Y_p - Y_d}$$

In these equations, Y, Z, X are the coordinates in the horizontal, vertical, and lateral directions, respectively; p is the proximal marker of the segment; and d is the distal marker.

Figure 2 illustrates the calculation of the angular displacement in the lateral side-bending task for one frame. The mean SPEED (° s⁻¹) was calculated from the finite derivative of the angular displacement of 10 trials for each task.

Figure 2. Illustration of angle calculation in the lateral side-bending task



Side bending is performed in the frontal plane, and the angular displacement of each segment is calculated from the Z (vertical) and Y (horizontal) axis. A zoomed image of the angular displacement of the upper thoracic segment (C7 – T7) is presented in the right part of the figure.

Statistical Analysis

To assess the reliability, subjects were invited for a second session separated from the first session by around 1 week (6.3 ± 1.5 days). To prevent an eventual bias in the kinematic variables due to a significant change in pain score, each patient was contacted before the second session and it was asked if they were in a similarly state of pain before the second acquisition of data. Moreover, the visual analog score (VAS) of back pain was measured (Table 1) for our NS-CLBP patients before starting each session, t-paired test and intraclass correlation coefficient (ICC) was calculated showing no significant difference between both sessions ($p=0.44$, $ICC=0.85$). The same examiner evaluated each subject during both sessions. Reliability assessments were performed according to a method described by Wagner et al.³⁴ by the ICC and the standard error of the measurement (SEM).

The ICC assesses variations in the population sample within and between patients.³⁴ The ICC parameters used were the ICC consistency. These ICCs were calculated under a 2-way mixed model in SPSS (SPSS v16.0 for Windows; SPSS Inc., Chicago, IL, USA). According to Shrout

and Fleiss,³⁵ an ICC >0.75 indicates excellent reliability; ICC of 0.40-0.75 indicates fair to good reliability; and ICC <0.40 indicates poor reliability.

The SEM estimates the nonsystematic variance,³⁴ which include natural fluctuations in the kinematic patterns in a single patient and the potential non-reproducibility of the optoelectronic system itself. As a measure of within-subject variability across repeated trials, SEM expresses the measurement error in the same units as those of the original measurement.

$$SEM = SD_x \sqrt{(1-R_x)}$$

The SEM was calculated as: SEM, where SD is the standard deviation for all observations, x expressed sessions 1 and 2 and R is the test-retest reliability coefficient (ICC) for session 1 and 2.

Measurement error also was expressed as the SEM%, the within-subject standard deviation as a percentage of the mean, which was defined as:

$$SEM\% = \frac{SEM}{mean} \times 100$$

Where mean is the mean for all of the observations in sessions 1 and 2. The SEM% indicates measurement error independent of the units of measurement. The SEM% represents the limit for the smallest change that indicates a real improvement for a group of subjects.³⁴

Responsiveness is the sensitivity to change of outcome measures and was assessed from the SEM using the minimal detectable change (MDC). MDC₉₅ represents the change of the variables falling outside of the measurement error and the magnitude of change necessary to exceed the measurement error of 2 repeated sessions (T₀ and T₁) at a specified confidence interval (CI) of 95%SEM, where 1.96 is the 2-sided table z value for the 95% CI and is used to account for the variance of the 2 measurement sessions.³⁴

$$MDC_{95} = 1.96 \times \sqrt{2} \times SEM$$

So that the MDC could be independent of the units of measurement, it was expressed as a percentage (MDC%), which was defined as:

$$\text{MDC\%} = \frac{\text{MDC95}}{\text{mean}}$$

The MDC% represents the smallest change that indicates a real change in a single individual.³⁴

Comparison between groups (Table 3): To compare both groups, a Student's *t*-tests were used on the overall means of the ROM and SPEED of each spinal segment variables (n= 42). The effect size with the standardised means of difference (SMD) described by Cohen was calculated to compare the magnitude of the difference between both populations:

$$\text{SMD} = \frac{\text{mean A} - \text{mean B}}{\text{mean SD}}$$

Where mean (A) is the mean of the healthy group, mean (B) is the mean of the *NS-CLBP* group, and mean SD (standard deviation) is the mean from SD (A) and SD (B).

To obtain an index that allowed discriminate both groups, binary logistic regression analyses (Forward Likelihood Ratio Stepwise in SPSS) were computed with the variables showing significance in Student's *t*-tests (n=26) as independent variables and as dependant variable the status from inclusion criteria (0 = healthy, 1 = *NS-CLBP*). Prior, this analysis the variance inflation factor (VIF>10) was estimate on the 26 pre-selected variables to remove variables showing stronger correlation, 17 variables were finally selected and computed in the logistic regression.³⁶

Sensitivity and specificity were determined with the Receiver Operating Characteristic (ROC) curves construction (MedCalc v.11.5 Software) with the Logit Score (LS) of ROM and SPEED (best discriminant variables form the binary logistic regression) of each subject of the experiment. The greatest Youden index (Y=sensitivity+specificity-1) was chosen as a decision criterion to choose the most appropriate cut-off score for both logit score (ROM and SPEED).³⁷

Generalization of our results for people not tested in the experiment could be assessed using the probability method ($\alpha = .05$) equation based on the logit score with any subject (Table 4).

Results

Reliability and responsiveness

Table 2 shows results of the ICCs, SEM% and MDC% values for each segment within each task for ROM and SPEED variables of both groups. Means and standard deviations are presented in Table 3.

In overall, the healthy group (n = 25) showed good to excellent reliability for all tasks and spinal segments in terms of ROM and SPEED variables, with the worst and best ICCs values from 0.60 – 0.96; the SEM% were from 19.4% – 3.3% and the minimal and maximal values for MDC% were from 9.3% – 53.8%.

In overall, the NS-CLBP group (n = 25) demonstrated good to excellent reliability for all tasks and segments in terms of ROM and SPEED variables, the worst and best ICCs values were from 0.77– 0.96; the SEM% were from 19.4% – 4.3% and the minimal and maximal values for MDC% were from 11.8% – 53.7%.

Table 2. Reliability and responsiveness results of trunk movement tasks

Trunk task	Healthy (n=25)			Chronic NS-LBP (n=25)		
	ICC	SEM%	MDC%	ICC	SEM%	MDC%
Flexion						
ROM						
LLS	0.91	5.9	16.6	0.87	12.8	35.4
ULS	0.91	4.8	13.4	0.87	10.6	29.5
TLS	0.90	4.5	12.5	0.86	9.6	26.7
LTS	0.89	3.9	10.9	0.92	7.1	19.9
UTS	0.89	4.1	11.4	0.90	7.3	20.4
SPEED						
LLS	0.93	8.8	24.4	0.82	16.9	46.9
ULS	0.94	7.1	19.6	0.84	13.2	36.7
TLS	0.94	6.3	17.5	0.89	10.1	27.9
Lateral side-bending	L/R	L/R	L/R	L/R	L/R	L/R
ROM						
LLS	0.86/0.96	11.5/13.7	32.1/38	0.92/0.81	13.7/19.4	38.1/53.7
ULS	0.90/0.85	7.6/9.1	21.2/25.1	0.94/0.96	9.8/6.1	27.3/16.7
TLS	0.91/0.87	6.8/7.1	18.8/19.8	0.93/0.93	9.5/8.4	26.4/23.3
LTS	0.80/0.70	6.3/5.8	17.5/16.3	0.94/0.95	6.2/4.3	17.3/11.8
UTS	0.76/0.60	6.4/6.5	17.8/18.1	0.85/0.90	7.5/5.9	20.8/16.3
SPEED						
LLS	0.77/0.75	15.6/19.4	43.4/53.8	0.90/0.77	15.3/18.8	42.5/46.4
ULS	0.84/0.70	9.4/16.9	26.1/46.8	0.91/0.85	11.7/9.9	32.6/27.3
TLS	0.87/0.72	8.2/15.1	22.8/46.6	0.90/0.86	12.1/10.3	33.4/28.4
Rotation	L/R	L/R	L/R	L/R	L/R	L/R
ROM						
SS	0.70/0.96	6.5/4.7	18.1/12.9	0.81/0.87	11.8/9.2	32.8/25.4
Flexion with rotation	L/R	L/R	L/R	L/R	L/R	L/R
ROM						
LLS	0.82/0.92	8.4/9.7	23.3/27.1	0.93/0.91	10.4/11.9	29.1/33.2
ULS	0.85/0.90	6.4/8.4	17.9/23.3	0.93/0.92	9.5/11.3	26.4/31.3
TLS	0.86/0.88	5.4/7.1	15.2/19.7	0.93/0.92	8.6/11.3	23.9/31.3
LTS	0.85/0.89	4.1/5.1	11.6/14.2	0.93/0.94	8.1/6.9	22.4/19.1
UTS	0.88/0.93	3.3/3.8	9.3/10.4	0.92/0.81	7.8/14.4	21.7/39.9
SPEED						
LLS	0.85/0.87	13.8/12.5	38.3/34.6	0.92/0.87	10.8/14.8	29.9/40.9
ULS	0.82/0.85	12.9/11.1	35.8/30.7	0.90/0.75	10.1/14.1	27.7/39.2
TLS	0.78/0.84	12.6/10.8	34.9/29.9	0.89/0.75	9.8/7.5	27.2/20.8

NS-LBP: non-specific low back pain; ROM: range of motion (in degrees); SPEED: velocity (in degrees/s); LLS: lower lumbar spine (S2–L3); ULS: upper lumbar spine (L3–T12); TLS: total lumbar spine (S2–T12); LTS: lower thoracic spine (T12–T7); UTS: upper thoracic spine (T7–C7); SS: shoulder segment (acromioclavicular Left–acromioclavicular Right); ICC: intraclass correlation coefficient; SEM%: standard error of measurement, expressed as a percentage; MDC%: minimal detectable change, expressed as a percentage; L/R: left and right.

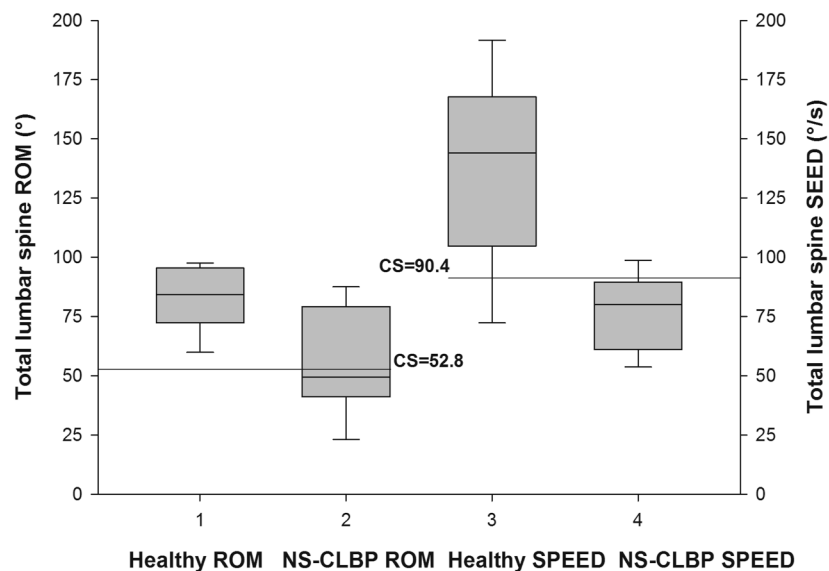
Comparison between groups

When comparing ROM and SPEED segments variables of the healthy subjects to the NS-CLBP patients (Table 3), all of the p-values were highly significant ($p < 0.001$) for the anterior flexion test for all spinal segments, except for the SPEED of the low lumbar spine segment ($p = 0.003$). Very large effect sizes were observed with SMD from 0.9 – 1.4.

For the trunk rotation task (left and right), the ROM variable of the shoulder segment (SS) showed a significant p-value ($p < 0.05$) for the left rotation and a high significant p-value ($p < 0.001$) for the right rotation, with a SMD of respectively 0.6 and 1.3.

The trunk flexion with rotation task demonstrated high significant p-value ($p < 0.001$) for all spinal segments and both variables, with higher effect sizes SMD from 1.2 – 2 (Figure 3).

Figure 3. Boxplots illustration for ROM and SPEED variables in both groups during trunk flexion with rotation (right) for the total lumbar spine

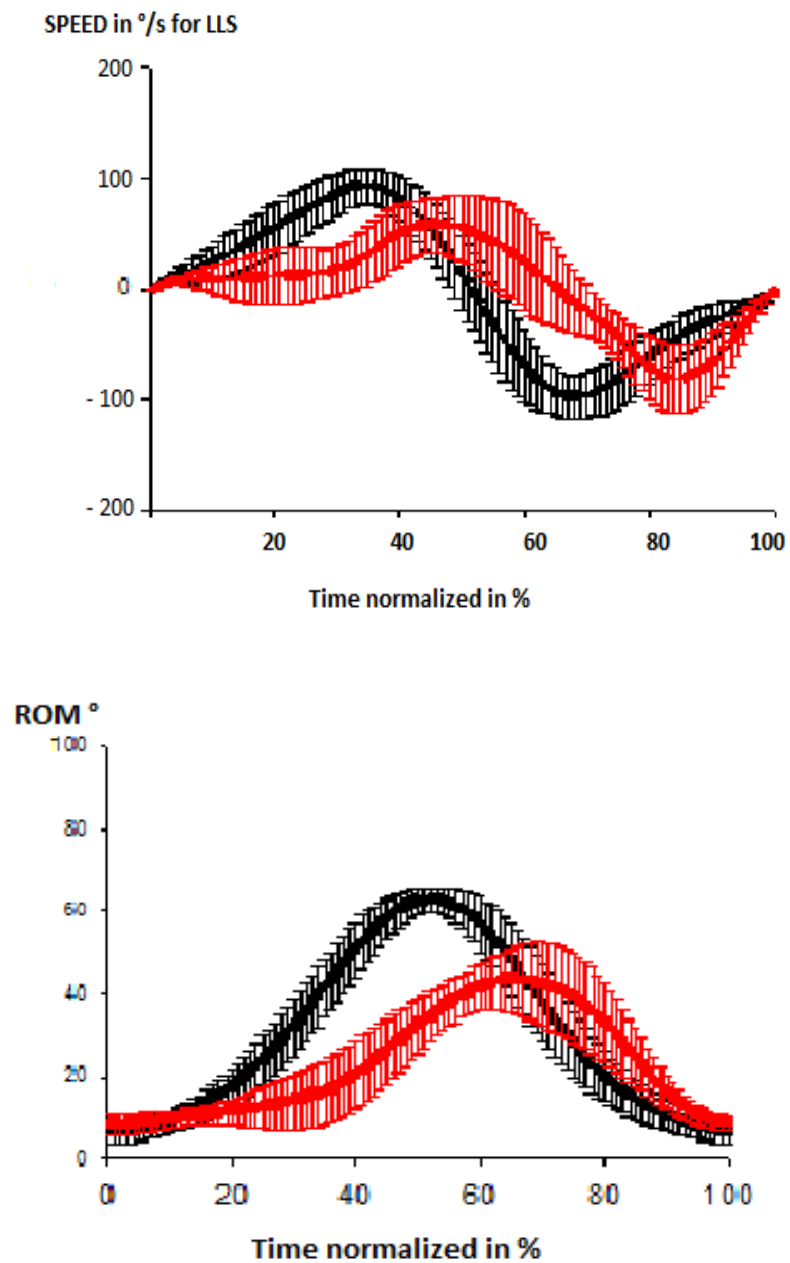


CS: cut-off score

For the lateral side-bending test, the majority of ROM and SPEED variables of all spinal segments were not normally distributed or significant but with very weak statistical power or not significant ($p > 0.05$).

Results from the binary logistic regression showed that the most discriminant variables were for ROM the low thoracic spine for flexion test (F LTS °), shoulder segment for right rotation test (RR °), the total lumbar spine for flexion with left rotation test (FL TLS°) and for the SPEED, the total lumbar spine segment in flexion with right rotation (FR TLS°/s) (Table 3).

Figure 4. Typical mean curves illustration for SPEED and ROM during trunk flexion with rotation (10 trials) for the Low Lumbar Spine



Red curve of one NS-CLBP patient; Dark curve of one healthy subject

Table 3. Healthy controls vs. NS-CLBP with binary logistic regression

Trunk task	Healthy (n=25) Mean (SD)	Chronic NS-LBP (n=25) Mean (SD)	SMD Effect size	β	Standard error	Constant
Flexion						
ROM						
LLS	73.1 (15.8)	53.8 (16.3)***	1.2			
ULS	81.9 (15.9)	60.9 (16.8)***	1.3			
TLS	92.2 (14.9)	69.4 (16.8)***	1.4			
LTS ^a	110.4 (14.1)	85.4 (20.4)***	1.4	-0.074	0.039	Step 1: 7.05
UTS	122.4 (15.2)	100.1 (22.0)***	1.2			
SPEED						
LLS	120.7 (42.4)	88.1 (32.1)**	0.9			
ULS	139.6 (40.9)	101.1 (31.8)***	1.1			
TLS	159.3 (40.8)	117.6 (34.3)***	1.1			
Rotation (left)						
ROM						
SS	57.6 (10.2)	50.6 (12.1)*	0.6			
Rotation (right)						
ROM						
SS ^a	65.6 (10.4)	50.6 (12.6)***	1.3	-0.111	0.045	Step 2: 12.34
Flexion with rotation (left)						
ROM						
LLS	61.2 (13.3)	39.6 (15.7)***	1.5			
ULS	71.6 (13.1)	47.4 (17.3)***	1.5			
TLS ^a	82.6 (12.8)	55.8 (18.4)***	1.7	-0.059	0.034	Step 3: 17.77
LTS	98.2 (11.8)	70.3 (21.2)***	1.7			
UTS	108.7 (10.5)	82.9 (22.5)***	1.5			
SPEED						
LLS	96.9 (32.9)	63.5 (23.1)***	1.2			
ULS	115.6 (32.7)	77.8 (22.7)***	1.3			
TLS	134.9 (33.3)	94.1 (25.7)***	1.4			
Flexion with rotation (right)						
ROM						
LLS	61.1 (14.8)	39.4 (18.8)***	1.3			
ULS	71.7 (14.3)	46.9 (20.6)***	1.4			
TLS	81.9 (13.9)	54.7 (22.8)***	1.5			
LTS	98.5 (11.6)	69.9 (25.1)***	1.6			
UTS	110.8 (10.4)	85.8 (30.9)***	1.2			
SPEED						
LLS	98.1 (37.2)	60.2 (28.1)***	1.2			
ULS	116.4 (38.5)	66.1 (20.6)***	1.7			
TLS ^b	135.4 (40.3)	76.1 (18.2)***	2	-0.063	0.018	Step1: 6.19

* $p < 0.05$; ** $p < 0.005$; *** $p < 0.001$. ^aMost discriminant ROM variables; ^bmost discriminant SPEED variable.

SMD: standardized mean of difference (Cohen's d); NS-LBP: non-specific low back pain; ROM: range of motion (in degrees); SPEED: velocity (in degrees/s); LLS: lower lumbar spine (S2–L3); ULS: upper lumbar spine (L3–T12); TLS: total lumbar spine (S2–T12); LTS: lower thoracic spine (T12–T7); UTS: upper thoracic spine (T7–C7); SS: shoulder segment (acromioclavicular Left–acromioclavicular Right).

Sensitivity and specificity

Logit Scores (LS) from the binary logistic regression for ROM and SPEED showed a sensitivity of 92% and specificity of 84% with a cutoff score of -0.65 for LS ROM and of 92% and 80% with a cutoff score of -0.35 for LS SPEED (Table 4).

Table 4. Sensitivity and specificity with ROC curve analysis

Logit score	Sensitivity/ specificity %	Cut-off value	Area under ROC curve Mean [95% CI]	Standard error	p-value	Probability ($\alpha=0.05$)
LS ROM = $17.77 - (0.074 \times \text{LTS}^\circ) - (0.11 \times \text{SS}^\circ) - (0.059 \times \text{TLS}^\circ)$	92/84	-0.6507	0.95 [0.85–0.99]	0.028	<0.0001	$P = \frac{e^{\text{LS rom}}}{1 + e^{\text{LS rom}}}$
LS SPEED = $6.19 - (0.063 \times \text{TLS}^\circ/\text{s})$	92/80	-0.3544	0.90 [0.77–0.96]	0.050	<0.0001	$P = \frac{e^{\text{LS speed}}}{1 + e^{\text{LS speed}}}$

$p > 0.5$ indicates patient affected by chronic non-specific low back pain.

ROC: receiver operating characteristic; CI: confidence interval; LS ROM: logit score for range of motion; LTS[°]: lower thoracic spine ROM in flexion; SS[°]: shoulder segment ROM in right rotation; TLS[°]: total lumbar spine ROM in flexion with left rotation; LS SPEED: logit score for speed; TLS[°]/s: total lumbar spine speed in flexion with right rotation.

Discussion

According to the literature,^{15,20,24–31} our kinematic spine model and trunk movements protocol revealed good to excellent reliability and sensitivity/specificity for ROM and SPEED to discriminate NS-CLBP patients.

It must be highlighted that only the lateral trunk side-bending task (left and right) did not reach the statistical power of 0.8 for the majority of the variables, or are not normally distributed or are not significantly different. As a consequence, even if reliable, we believe that this test may not be adapted to discriminate subjects suffering from NS-CLBP and has been removed from table 3 for more simplification. Even if, differences between LBP and control groups in patterns during trunk motion in side bending performed from a sitting position has been proved in another study.²⁸

It should be noted that previous studies^{20,24–29,31} have mainly assessed the lumbar spine segment and only in one direction of trunk movement from a standing position. In the present study, the decreased of ROM and SPEED observed in all tasks (7 directions) and in all spinal

segments were expected only for the NS-CLBP group and may reflect localized disorders of the lumbar spine (Figure 4).

Marras et al.^{20,24} described speed and acceleration from a standing position as sensitive variables to distinguish CLBP but not the ROM. Compared with healthy subjects, a specific “motion signature” has been observed on kinematic variables during active trunk movements from LBP patients, which revealed the musculoskeletal status of the spine with a very good sensitivity and specificity.^{20,24} Our results showed similar findings for SPEED variables, however ROM variable was also very sensitive, probably due to the sitting reference position and the use of Logit Score from the binary logistic regression.

In the thoracic spinal segments, our results presented divergences from the results of Larivière et al.,³³ they showed an increase in mobility of the thoracic spine during trunk flexion in CLBP patients. These authors proposed the existence of compensations as a consequence of the loss of flexibility of the lumbar spine. However, our results demonstrated a significant stiffness of the thoracic spine (decrease of ROM) in the NS-CLBP group compared to the healthy group. A possible explanation for this discrepancy may be methodological differences between the studies. The previous trials³³ used a standing position, from which it is likely that subjects were stimulated to compensate with the thoracic spine to reach the floor with their hands during flexion.^{28,30-31} Moreover, the reduced flexibility of the hamstring, which is naturally encountered with aging, may have limited the lumbar spine during the forward bending task from a standing position.³¹

The tasks used in our protocol were chosen on the basis of biomechanical³⁸⁻⁴⁰ and classification system evidences for NS-LBP.¹⁴⁻¹⁸ For example, the anterior flexion task increases the load on the vertebral disc and may cause back pain due to the enhancement of neural compression. Moreover, the posterior fibers of the annulus and posterior ligaments are thought to provide resistance.³⁸ Side-bending of the trunk decreases the ROM in subjects with LBP generated by painful hernia and/or facet joints.^{15,26,28,39} Rotations are focused on the thoracic-lumbar hinge because of the very small biomechanical motion in rotation for the lumbar spine.³⁹ The anterior trunk flexion task with rotated pelvis increases the pelvic constraints, due to the inferior and superior ilio-lumbar ligaments. This scenario leads to lumbar stiffness, especially at the lower lumbar spine, decreasing the ROM during the flexion movement.⁴⁰

Initially, a trunk extension task was included in our kinematic protocol, because this task increases the load at the facet joints in degenerative vertebrae³⁹ and is used in MICS for NS-LBP.¹⁴⁻¹⁸ However, during our preliminary study, trunk extension from a sitting position revealed poor reliability (ICCs from 0.25 – 0.60). Furthermore, the subjects also described it as difficult or dangerous. Therefore, this task was deleted from our protocol.

In a preliminary study, performance of the anterior trunk flexion at an imposed speed following a metronome rhythm showed poor reliability ($ICC < 0.40$ and $SEM\% > 20\%$) of the variables for all the spinal segments as compared to performance at a non-imposed speed. Moreover, the reproducibility of the non-imposed speed during trunk movements has been proven in several previous trials,^{20,24-31} therefore, the use of an imposed speed was removed from our protocol.

Trunk movement tasks with spinal segments variables (ROM and SPEED) that present good to excellent reliability ($ICC \geq 0.7$, $SEM\% \leq 15\%$) with the best discrimination between both populations in using logit scores (LS) for ROM and SPEED may be helpful as quantitative kinematic outcome measures to support in diagnosis any patient or to measure improvement in future clinical trials. Our results provide additional insight evidence into the future use of kinematic spine motion models with an optoelectronic system to help in diagnose subgroups of NS-LBP in a classification system and to better target specific treatment (e.g., MT, AR) adapted to movement impairments and motor control as well as measure the therapeutic effects with the MDC and/or LS in clinical practice for a single patient or in clinical studies for a sample of patients with the SEM and/or LS.

Authors have generalised results from the sample tested to people not tested with the LS for sensitivity and specificity and the probability equation (Table 4). Nevertheless, findings of people not tested should be interpreted cautiously because of the small sample size of this study. Therefore, it's recommended for a future trial using our model to raise the sample size of both groups and to integrate SPEED variables for the thoracic spine to improve the index of LS speed.

Conclusion

The quantitative analysis of kinematic motion patterns in subgroups of patients with chronic NS-LBP during trunk movements in different directions is of major importance because it can help clinicians to identify motion patterns that may contribute to chronic NS-LBP disorders and target interventions according to the quality of movement. The kinematic spine model and standardised protocol including 7 trunk motion tasks demonstrated good to excellent reliability. However, only 4 tasks were selected for inclusion in the final protocol. The LSs of ROM and SPEED variables may be used as quantitative outcome measures to aid in the diagnosis and assessment of patients with chronic NS-LBP before and after physical therapy (e.g. MT) in clinical practice and research. To our knowledge, such analyses have not been used in randomised clinical trials assessing the efficacy of physical therapies in NS-LBP subgroups.

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CHAPTER III

Use of kinematic algorithms to identify people with chronic nonspecific low back pain from asymptomatic subjects: validation study

Benjamin Hidalgo, Henri Nielens, Maxime Gilliaux, Toby Hall, Christine Detrembleur

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ABSTRACT

Objective: To determine whether kinematic algorithms can distinguish subjects with chronic nonspecific low back pain from asymptomatic subjects and subjects simulating low back pain, during trunk motion tasks.

Design: Comparative cohort study.

Subjects: A total of 90 subjects composed 3 groups; 45 chronic nonspecific low back pain patients in the CLBP group; 45 asymptomatic controls people in the asymptomatic controls group. 20/45 subjects from the asymptomatic controls group composed the CLBP simulators group as well.

Methods: During performance of 7 standardized trunk motion tasks 8 infrared cameras recorded 6 spinal segments from the kinematic spine model. Two logit scores, for range of motion and speed, were used to investigate differences between the groups. Group allocation based on logit scores was also calculated, allowing the assessment of sensitivity and specificity of the algorithms.

Results: For the 90 subjects (pooled data), the logit scores for range of motion and speed demonstrated highly significant differences between groups ($p < 0.001$). The logit score means and standard deviation (SD) values in the asymptomatic group ($n = 45$) and chronic nonspecific low back pain group ($n = 45$), respectively, were -1.6 (SD 2.6) and 2.8 (SD 2.8) for range of motion and -2.6 (SD 2.5) and 1.2 (SD 1.9) for speed. The sensitivity and specificity ($n = 90$) for

logit score for range of motion were 0.80/0.82 and for logit score for speed were 0.80/0.87, respectively.

Conclusion: These results support the validity of using 2 movement algorithms, range of motion and speed, to discriminate asymptomatic subjects from those with low back pain. However, people simulating low back pain cannot be distinguished from those with real low back pain using this method.

Introduction

Chronic nonspecific low back pain (CLBP) is a growing problem in Western industrialised countries, which brings diagnostic and treatment challenges.¹⁻⁴ From a diagnostic point of view, in general, people with CLBP have no clear patho-anatomical features distinguishing them from asymptomatic subjects. For example, there is a poor correlation between features seen on spinal imaging and symptoms of low back pain (LBP).^{1,3,5} Thus, diagnosis of non-specific LBP is based mainly on subjective and physical clinical examination criteria.^{1-3,6-9} Kinematic analysis of trunk motion appears promising in the diagnosis and discrimination of people with non-specific LBP.^{1,9-12} Some of these features may also enable differentiation into treatment specific sub-groups, which may have value in the management of LBP.¹³

Our previous study¹² showed that kinematic tools are useful in identifying impairments in people with CLBP, both quantitatively (range of motion, speed and acceleration) and qualitatively (motion signatures), when single and combined planes of movement are investigated.^{1,10-13} The study identified 2 kinematic algorithms (logit scores) that could be used to distinguish people with CLBP from asymptomatic controls on the basis of a binary logistic regression analysis.¹² The first algorithm is an index for range of motion (ROM) and the second is an index for speed of movement (SPEED). The sensitivity and specificity of the logits for these algorithms has been reported previously.¹² To our knowledge, no studies have investigated whether movement algorithms can correctly identify people simulating LBP from those with actual LBP in order to address the external validity (i.e. the generalisability) of the research findings.

The aim of this study was to evaluate the external validity and generalisability of previously reported algorithms in the quantitative assessment of spinal movement impairment in an independent sample of asymptomatic controls, people simulating LBP, and those with CLBP.

Methods

Subjects

This study comprised 90 subjects, of whom 50 were from a previous investigation (25 healthy controls and 25 subjects with CLBP),¹² together with 40 new subjects (20 asymptomatic subjects who represented the healthy simulators and 20 with CLBP). Anthropometric data are shown in Table 1.

The CLBP group included men and women recruited from Cliniques Universitaires St-Luc (Woluwé - Saint - Lambert, Belgium). At the time of the experiment, these subjects had CLBP with or without radiating pain no further than the knee (Quebec Task force 1–2 categories) for at least 12 weeks and had clinical physical examination features of spinal movement impairment.

The asymptomatic subjects had no history of LBP for at least 6 months prior to the experiment. The human research ethics committee of the institution approved the study protocol.

Table 1. Baseline characteristics of asymptomatic subjects and chronic nonspecific low back pain patients (CLBP)

	Asymptomatic controls and LBP simulators	CLBP	Asymptomatic controls from previous study	CLBP from previous study
M/F, <i>n</i>	11/9 (<i>n</i> =20)	11/9 (<i>n</i> =20)	10/15 (<i>n</i> =25)	12/13 (<i>n</i> =25)
Age, years, mean (SD)	39.9 (13.5)	45.1 (11.6)	40 (11)	42 (9)
Body mass index, mean (SD)	23.5 (2.8)	27.4 (3.5)	23.3 (2.5)	25.2 (3.2)
Visual analogical scale, mean (SD)	0.2 (0.4)	2.9 (1.7)	0	2.5 (1.5)
Oswestry disability index (%)	1.6 (1.8)	17.9 (8.2)	0	19.8 (8.6)

Protocol and material

Seven standardised trunk motion tasks, described below, were assessed in the kinematic spine model, and recorded by 8 infrared cameras (ELITE-BTS, Milan, Italy). The kinematic spine model, the trunk movement standardisation procedure, data collection and statistical analysis have been described in a previous study.¹²

All subjects were asked to follow 4 rules during movement tasks, which were performed in a seated position: (I) begin and end each movement with a neutral spine posture; (II) to move at a self-determined (spontaneous) speed through the largest possible range; (III) to maintain contact between the ischial tuberosities and the stool; (IV) and to adhere strictly to the plane of motion specified by each task. Each movement was repeated 15 times and recorded after the fifth movement (n=10 trials). Twenty asymptomatic subjects formed the LBP simulators group. These subjects were asked firstly to perform all the trunk tests in a natural way (asymptomatic controls) and, secondly, to repeat the task simulating CLBP (simulators) while carrying out each movement task.¹⁴

The trunk motion tasks were as follows:

Anterior trunk flexion: Subjects positioned themselves with their hands over their ears and their elbows forward, and then flexed the trunk as far as possible with respect to the sagittal plane.

Lateral trunk side-bending left and right: Subjects crossed their arms on their chest, and then inclined their trunk in the frontal plane.

Rotation left and right: Subjects crossed their arms on their chest, and rotated their head and shoulders to the side as far as possible, while respecting the transverse plane.

Anterior trunk flexion with left and right rotation (rotated pelvis): The subject sat on the stool with the pelvic rotated 30° to the left or right, and the subject was given the same instructions as in the anterior flexion task.

Statistical analysis

Comparison of the kinematic variables between groups was carried out using 1-way analysis of variance with pairwise multiple comparison procedures (Holm-Sidak method, factor groups) (Sigmastat® 3.5, Systat Software, San Jose, USA) (Table 2).

Binary logistic regression analysis was previously used to evaluate the kinematic spine model in each group, with 2 logit scores (LS) calculated for ROM and SPEED (see Table 3).¹² For this, we calculated an index to enable discrimination between groups using binary logistic regression analyses (stepwise forward likelihood ratio in SPSS). These analyses were applied only to variables found to differ significantly by Student's t-tests (n=26). These variables were assigned as independent variables, and group membership (0 = healthy, 1 = chronic LBP) was the dependent variable. Before regression analyses were performed, the variance inflation factor (VIF) was estimated for each of the 26 selected variables, in order to remove variables with strong correlation (VIF > 10); 17 variables were finally selected and included in the logistic regression.¹²

The generalisability of our previous results to correctly identify people with the use of LS was the main goal of this study. Therefore, we investigated the sensitivity and specificity of the previously determined algorithms using the probability equation (Table 3) on the 40 new subjects in the present study, with the following equation:

Sensitivity = true positives / (true positives + false negatives)

Specificity = true negatives / (true negatives + false positives)

Following this, the overall sensitivity and specificity were calculated by pooling the results of LS for ROM and SPEED from both studies (n=90 subjects) using the receiver operating characteristic (ROC) curves (MedCalc software, version 11.5, Mariakerke, Belgium).

Results

The results of the between-groups' comparison of kinematic variables of each spinal segment in each task as well as for kinematic algorithms (ROM and SPEED) are shown in Table 2.

Concerning the LS for ROM (n=40), a highly significant difference was found between the groups with p-value < 0.001 (power of 1.000 with alpha = 0.05). The mean and standard deviation (SD) of LS for ROM was -0.47 (SD 2.5) in the asymptomatic control group (n=20); 3.2 (SD 3.4) in the CLBP group (n=20); and 5.6 (SD 3.5) in the LBP simulator group (n=20).

In addition, the LS for SPEED demonstrated highly significant differences between the groups, with p-value < 0.001 (power of 1.000 with alpha = 0.05). The mean of LS for SPEED was -2.9 (SD 2.5) in the asymptomatic control group; 1.1 (SD 2.5) in the CLBP group; and 2.1 (SD 2.1) in the LBP simulator group.

When matching subjects of both the current and previous studies (n=90), the comparison between the asymptomatic subjects (n=45) with those with LBP (n=45) revealed highly significant differences ($p < 0.001$; power of 1.000 and $\alpha = 0.05$) for the LS's ROM and SPEED. The means and SD values for the combined asymptomatic group and CLBP group, respectively, for LS ROM were -1.6 (SD 2.6) and 2.8 (SD 2.8); and for LS SPEED were -2.6 (SD 2.5) and 1.2 (SD 1.9).

Table 2. Asymptomatic controls and low back pain (LBP) simulators vs chronic nonspecific low back pain patients, one-way analysis of variance of each spinal segment in each task

				Comparisons for factor		
	Asymptomatic controls (n=20) Mean (SD)	CLBP (n=20) Mean (SD)	CLBP simulators (n=20) Mean (SD)	Asymptomatic controls vs LBP	CLBP vs LBP simulators	CLBP simulators vs asymptomatic controls
Trunk tasks						
<i>Flexion</i>						
ROM						
LLS, °	49.1 (17.1)	45.6 (22.8)	32.2 (17.2)	No	No	Yes*
HLS, °	55.1 (16.7)	49.8 (22.6)	37.6 (18.6)	No	No	Yes*
TLS, °	61.8 (16.7)	54.1 (22.9)	42.9 (20.4)	No	No	Yes*
LTS, °	80.5 (17.2)	68.9 (22.1)	52.5 (23.9)	No	Yes*	Yes***
HTS, °	91.8 (17.5)	76.7 (23.9)	60.2 (23.3)	Yes*	Yes*	Yes***
SPEED						
LLS, °/s	128.7 (49.1)	87.1 (40.7)	59.7 (27.5)	Yes**	Yes*	Yes***
HLS, °/s	142.1 (48.5)	91.8 (42.1)	67.4 (28.5)	Yes***	No	Yes***
TLS, °/s	162.1 (48.1)	103.1 (43.6)	80.3 (30.1)	Yes***	No	Yes***
<i>Rotation, left</i>						
ROM						
SS, °	83.1 (12.8)	64.2 (13.9)	57.1 (13.5)	Yes***	No	Yes***
<i>Rotation, right</i>						
ROM						
SS, °	81.2 (11.9)	67.1 (12.2)	54.5 (13.4)	Yes***	Yes**	Yes***
<i>Flexion with rotation, left</i>						
ROM						
LLS, °	39.3 (15.3)	30.9 (17.3)	23.8 (16.3)	No	No	Yes**
HLS, °	45.4 (14.4)	35.8 (18.1)	28.1 (17.3)	No	No	Yes**
TLS, °	52.1 (14.2)	40.5 (19.1)	32.4 (18.8)	No	No	Yes***
LTS, °	69.5 (15.5)	54.9 (19.8)	42.9 (21.4)	Yes*	No	Yes***
HTS, °	81.2 (17.9)	65.4 (21.1)	51.3 (20.8)	Yes*	Yes*	Yes***
SPEED						
LLS, °/s	109.5 (46.4)	66.9 (36.4)	47.9 (27.5)	Yes***	No	Yes***
HLS, °/s	122.7 (45.5)	74.1 (38.6)	54.3 (29.1)	Yes***	No	Yes***
TLS, °/s	142.7 (45.2)	86.6 (40.8)	65.1 (32.1)	Yes***	No	Yes***
<i>Flexion with rotation, right</i>						
ROM						
LLS, °	41.1 (13.1)	29.7 (18.1)	22.9 (16.1)	No	No	Yes***
HLS, °	47.2 (11.9)	33.9 (18.5)	26.7 (17.3)	Yes*	No	Yes***
TLS, °	54.1 (11.4)	38.1 (19.5)	30.6 (18.9)	Yes**	No	Yes***
LTS, °	73.2 (11.7)	51.9 (19.5)	43.4 (20.7)	Yes***	No	Yes***
HTS, °	84.8 (13.2)	61.7 (20.2)	49.1 (22.5)	Yes***	Yes*	Yes***
SPEED						
LLS, °/s	111.4 (39.2)	63.1 (35.9)	46.7 (26.1)	Yes***	No	Yes***
HLS, °/s	124.4 (38.7)	69.4 (37.5)	52.6 (28.4)	Yes***	No	Yes***
TLS, °/s	144.1 (38.9)	80.8 (40.1)	64.6 (33.1)	Yes***	No	Yes***
LS ROM	-0.47 (2.5)	3.2 (3.4)	5.6 (3.5)	Yes***	Yes*	Yes***
LS SPEED	-2.9 (2.5)	1.1 (2.5)	2.1 (2.1)	Yes***	No	Yes***

All pairwise multiple comparison procedures (Holm-Sidak method), comparison for factors (groups): * $p < 0.05$; ** $p < 0.005$; *** $p < 0.001$. ROM: range of motion (°); SPEED: velocity (°/s). LLS: low lumbar spine (S2–L3); HLS: high lumbar spine (L3–T12); TLS: total lumbar spine (S2–T12); LTS: low thoracic spine (T12–T7); HTS: high thoracic spine (T7–C7); SS: shoulder segment (AcLeft–AcRight); SD: standard deviation; LS ROM: logit score for range of motion; LS SPEED: logit score for speed.

Using the probability equation presented in Table 3, we calculated the probability that each new subject in this study had LBP.

Table 3. Kinematic algorithms and probability equations from previous study¹²

Logit score	Sensitivity/ specificity, %	Cut-off value	Area under ROC curve (95% CI)	Standard error	p-value (area = 0.5)	Probability ($\alpha = 0.05$)
LS ROM = $17.77 - (0.074 \times \text{LTS}^\circ) - (0.11 \times \text{SS}^\circ) - (0.059 \times \text{TLS}^\circ)$	92/84	-0.6507	0.95 (0.85-0.99)	0.028	< 0.0001	$P = \frac{e^{\text{LS ROM}}}{1 + e^{\text{LS ROM}}}$
LS SPEED = $6.19 - (0.063 \times \text{TLS}^\circ/\text{s})$	92/80	-0.3544	0.90 (0.77-0.96)	0.050	< 0.0001	$P = \frac{e^{\text{LS SPEED}}}{1 + e^{\text{LS SPEED}}}$

$p > 0.5$ = patient affected by chronic non-specific low back pain. ROC: receiver operating characteristic; CI: confidence interval; LS ROM: logit score for range of motion; LTS[°]: lower thoracic spine ROM in flexion; SS[°]: shoulder segment ROM in right rotation; TLS[°]: total lumbar spine ROM in flexion with left rotation; LS SPEED: logit score for speed; TLS^{°/s}: total lumbar spine speed in flexion with right rotation.

For the index of LS ROM:

- asymptomatic controls (n=20): 8 were positive and 12 were negative; 60% of healthy controls were correctly classified.
- LBP simulators (n=20): 19 were positive and 1 was negative; 5% of healthy simulators were correctly classified.
- CLBP (n=20): 4 were negative and 16 were positive; 80% of LBP subjects were correctly classified.

Based on the data of asymptomatic controls and CLBP subjects, the sensitivity was 0.80, with specificity 0.60. Positive predictive value (PPV) was 0.67 and negative predictive value (NPV) 0.75.

For the index of LS SPEED:

- asymptomatic controls (n=20): 2 were positive and 18 were negative; 90% of healthy controls were correctly classified.
- LBP simulators (n=20): 20 were positive and 0 was negative; 0% of healthy simulators were correctly classified.
- CLBP (n=20): 7 were negative and 13 were positive; 65% of LBP subjects were correctly classified.

Based on the data of asymptomatic controls and CLBP subjects, the sensitivity was 0.65 and specificity 0.90, with PPV 0.87 and NPV 0.72.

Using LS of ROM and SPEED with ROC curves analysis on all subjects of both studies (n=90), we calculated an overall sensitivity/specificity:

- For LS ROM: sensitivity was 0.80 (0.65–0.90) and specificity 0.82 (0.68–0.92) with a cut-off score of 0.77 (area under the ROC curve: 0.88 with standard error: 0.03 and significant level $p < 0.0001$; youden index: 0.62).
- For LS SPEED: sensitivity was 0.80 (0.65–0.90) and specificity 0.87 (0.73–0.95) with a cut-off score of 0.11 (area under the ROC curve: 0.88 with standard error: 0.03 and significance level $p < 0.0001$; youden index: 0.66).

The LS pooled values of each subject for groups CLBP (n=45) and asymptomatic controls (n=45) are shown in Figures 1 and 2.

Figure 1. Scatter plot graph of pooled data for logit scores of ROM of asymptomatic controls (n=45) and chronic non-specific low back pain subjects (n=45)

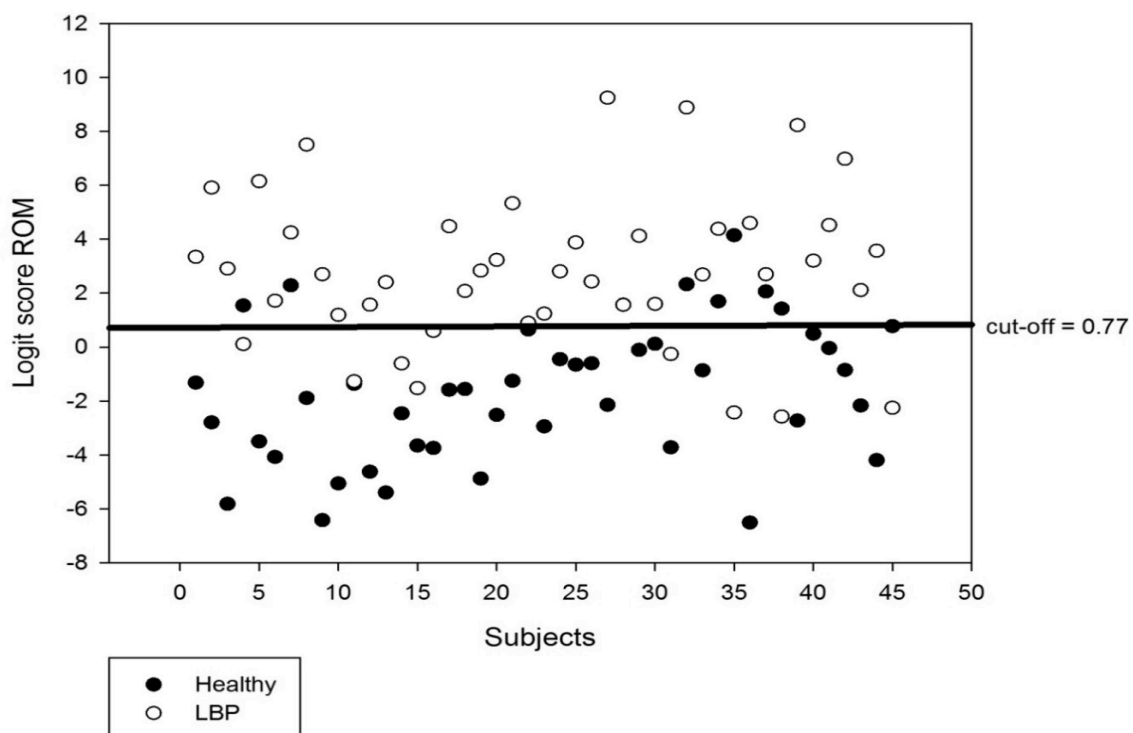
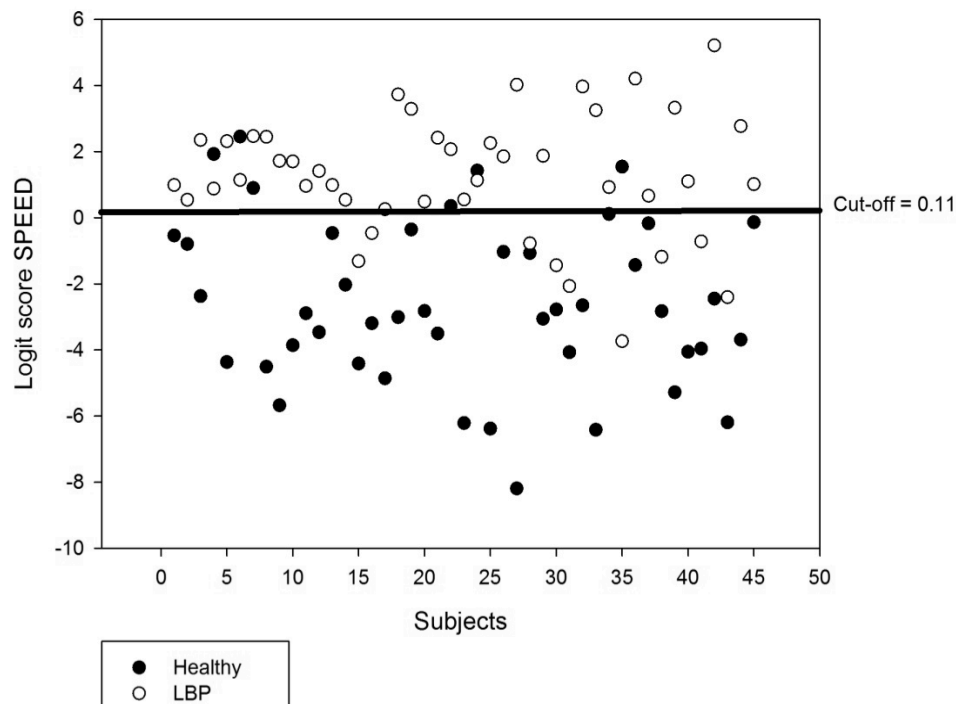


Figure 2. Scatter plot graph of pooled data for logit score of SPEED for asymptomatic controls (n=45) and chronic non-specific low back pain subjects (n=45)



Discussion

The kinematic algorithms ROM and SPEED clearly discriminated the groups with highly significant differences. In comparison with people with CLBP, the kinematic values for people voluntarily simulating LBP were lower, and the LS differed significantly (Table 2). When the healthy subjects tried to simulate CLBP, they were unable to mimic the true kinematics of people with chronic LBP. During each movement task the healthy subjects exaggerated the spinal movement impairments, as if they were affected by an acute LBP.

The present findings also confirm those of the previous study concerning the data from the trunk lateral flexion task, which did not differ significantly between the groups. This task was once again not useful in discriminating subjects with chronic LBP, at least when carried out in a seated position.¹²

The sensitivity and specificity of both LS (ROM and SPEED) were previously found to be excellent in discriminating people with CLBP.¹² However, when applying the previously determined probability equation to a new independent sample of subjects, we found only a moderate to good level of sensitivity and specificity. Despite this, when data from both studies are pooled, the ROC curves analysis of both LS (ROM and SPEED) revealed improved overall sensitivity and specificity. The results of the present and previous study¹² indicate that the algorithms ROM and SPEED provide useful discrimination between populations. These kinematic measures may be helpful in sub-grouping people with movement impairment in LBP, which may have potential benefit in future clinical trials. For example, the targeting of specific interventions, such as manual therapy, might be better suited to people with certain movement impairments identified through these algorithms. This requires further investigation.

The present study has several limitations. Simulating CLBP is problematic because of the inherent multifactorial nature of CLBP, which influences the kinematic outputs during movement. Subjects may have had difficulty imagining and carrying out the simulation of CLBP. In the case of CLBP, pain may arise from a variety of causes. The cognitive interpretation of pain has multiple psycho-social influences (e.g. misrepresentation of body schema, anxiety, depression, education, beliefs, negativism, catastrophisation, lifestyle). In turn, this may influence central sensitisation, resulting in altered “outputs”, in particular movement behaviors and patterns of impairment seen when examining patients with CLBP.^{2,3,15} All these elements are very difficult, if not impossible, to simulate in our sample of LBP simulators. Moreover, we should not forget a possible more important Hawthorne learning effect in the subjects simulating LBP that may have influenced the simulated patterns of movement.

In conclusion, these results validate the use and generalizability of both kinematic algorithms for the discrimination of spinal movement impairments between healthy controls and patients with CLBP. However, subjects who were simulating CLBP could not be correctly classified by our method. This validation study supports the use of this method to objectively evaluate the efficacy of physical manual therapy treatment in future clinical trials.

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CHAPTER IV

Effects of proprioceptive disruption on lumbar spine repositioning error in a trunk forward bending task

Benjamin Hidalgo, François Gobert, Dominique Bragard, Christine Detrembleur

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ABSTRACT

Background: Various inputs of proprioception have been identified and shown to influence low back proprioception sense.

Objective: To investigate the effect of disrupting proprioception on lumbar spine repositioning error during forward bending.

Methods: Healthy-subjects (n = 28) and patients with non-specific chronic low-back pain (n = 10) aged between 20–50 years. Subjects performed 5 repetitions of a lumbar repositioning task targeting 30° of trunk-forward-bending from a seated-position with different proprioceptive disturbances administered to the low back. Video analysis of skin reflective markers measured lumbar spine range-of-motion. A control-task was performed without any proprioceptive disturbance, while the remaining 4 tasks were electro-stimulation, vibration, taping and sitting on an unstable surface.

Results: The healthy group showed significantly altered repositioning error when compared with the control task (p = 0.004): control-task vs. taping-task, vibration-task and unstable-sitting. In the NS-CLBP group, one motor-task showed significant difference in control-task vs. taping-task (p = 0.004). Comparison between the NS-CLBP and matched-healthy groups revealed that the NS-CLBP subjects had larger repositioning-error (p = 0.009) for control, taping and vibration tasks.

Conclusion: Proprioceptive disturbances had the most significant effect in increasing repositioning-error among healthy subjects. The between-groups analysis confirmed evidence consistent with the literature of greater repositioning-error in people with NS-CLBP than healthy subjects.

Introduction

Low-back pain is a common musculoskeletal disorder.¹⁻³ The population most at risk is active people in industrialized countries.²⁻³ Up to 75% of the working population suffers at least once in their lives from low-back pain and approximately 14% suffer pain lasting for more than 2 weeks.¹⁻³ In the United-States, low-back pain ranks second among the reasons for seeking medical attention³ leading to important medical costs and economic consequences.¹⁻⁵

The sources of non-specific low-back pain (NS-LBP) are multiple and lack diagnostic precision in 80 % of cases.²⁻³ The Postural-structural-biomechanical model is currently used for evaluation of low-back pain and rationalizes the application of physical therapy and/or pharmacological treatment; however this model has recently been questioned.⁴ Indeed, medical images and clinical tests do not always correlate with low-back pain status.⁴⁻⁷ Therefore, new assessment tools are necessary to help in understanding the problematic of NS-LBP patients.⁵⁻⁷

Motor control disorders are common problems in chronic NS-LBP. The hypothetical underlying mechanism could be a deficiency of proprioception in these patients.⁸⁻¹³ Proprioception is considered as “the knowledge of the positions of body segments and the movement of body in space”.¹³ Since proprioception is essential for motor control of the trunk it should be quantitatively evaluated. Therefore, the developments of accurate tools providing a quantifiable measure of spinal proprioception are required.⁶⁻⁷

Several studies have investigated motor control and lumbar proprioception.⁶ For example, one study focused on the detection of trunk motion during passive movements induced by an electromechanical device¹³, while a further study used a force-platform to evaluating postural-balance with external stimulations.¹⁰⁻¹² Another common assessment of proprioception is the measurement of active and/or passive repositioning error (RE, i.e. the difference between a target position and the reached position of the patient) using kinematic-tools.^{6,9,13-20} These studies¹³⁻²⁰ showed conflicting evidence about a higher RE in chronic NS-LBP patients. This discrepancy could also be due to different protocols used to measure RE. However, the main tendency supports the hypothesis that reposition sense is altered in patients with chronic NS-LBP when compared to healthy subjects,^{13,17-20} while a minority revealed no differences.⁹

The aims of this study were to investigate the effects of various proprioceptive disturbances (i.e. electro-stimulations, vibrations, taping on the low-back area or sitting on unstable support) on RE in healthy and chronic NS-LBP subjects and to compare RE accuracy between both groups. To our knowledge, the introduction of various proprioceptive disturbances on both these populations while simultaneously performing RE motor tasks have never been undertaken in the same study.

Methods

Subjects

The cohort was composed of 28 healthy subjects aged 26 ± 9.8 years (mean + SD) with a body mass index (BMI) of $23.18\% \pm 2.64$ (14 male and 14 female).

The non-specific chronic low back pain (NS-CLBP) group was composed of 10 patients aged 34 ± 8.9 years with BMI of $22.34\% \pm 3.09$ (5 male and 5 female).

To compare both groups, a matched-healthy group of 10 subjects was composed from the healthy subjects. Anthropometric data are reported in Table 1.

Table 1. Baseline characteristics of healthy subjects and those with chronic non-specific low back pain

Group	<i>n</i>	M/F	Age (years)	BMI (kg/m ²)	VAS	Pain duration (months)
Healthy	28	14/14	27.7 (9.7)	23.1 (2.4)	/	
NS-CLBP	10	5/5	33.8 (7.5)	22.4 (2.9)	3.4 (0.9)	11.4
Matched	10	5/5	30.0	22.9		(4.7)
Healthy			(11.7)NS	(2.2)NS		

Data are shown as the mean (standard deviation). NS-CLBP, non-specific chronic low back pain; M, male; F, female; BMI, body mass index; VAS, 10-point visual analogue scale pain score (present pain); NS, non-significant difference between NS-CLBP and Matched Healthy (Student *t*-test, $p > 0.05$)

Healthy subjects were recruited on a voluntary basis and had no history of NS-LBP in the 12 months prior to the experiment.

The NS-CLBP group included patients recruited from Saint-Luc University Hospital (Brussels, Belgium) with chronic (≥ 6 months) NS-LBP without pain radiating into the leg. The Visual Analogue Scale (VAS) score of the chronic NS-LBP group represents the pain on the day prior to the experiment and was 3.4 ± 0.9 . The mean duration of pain was 11.4 ± 4.7 months.

Exclusion criteria for both groups were vestibular diseases, pregnancy, diabetes, neurologic disorders, specific low-back pain and having no history of musculoskeletal system surgery in the low-back area. The Ethics Committee of the “Université Catholique de Louvain” approved the study protocol and informed consent was obtained from subjects prior to testing.

Protocol and material

Placement of markers and kinematic spine model: The following standardised marker locations were used: two markers were placed on the spinous processes of S2 and T12.

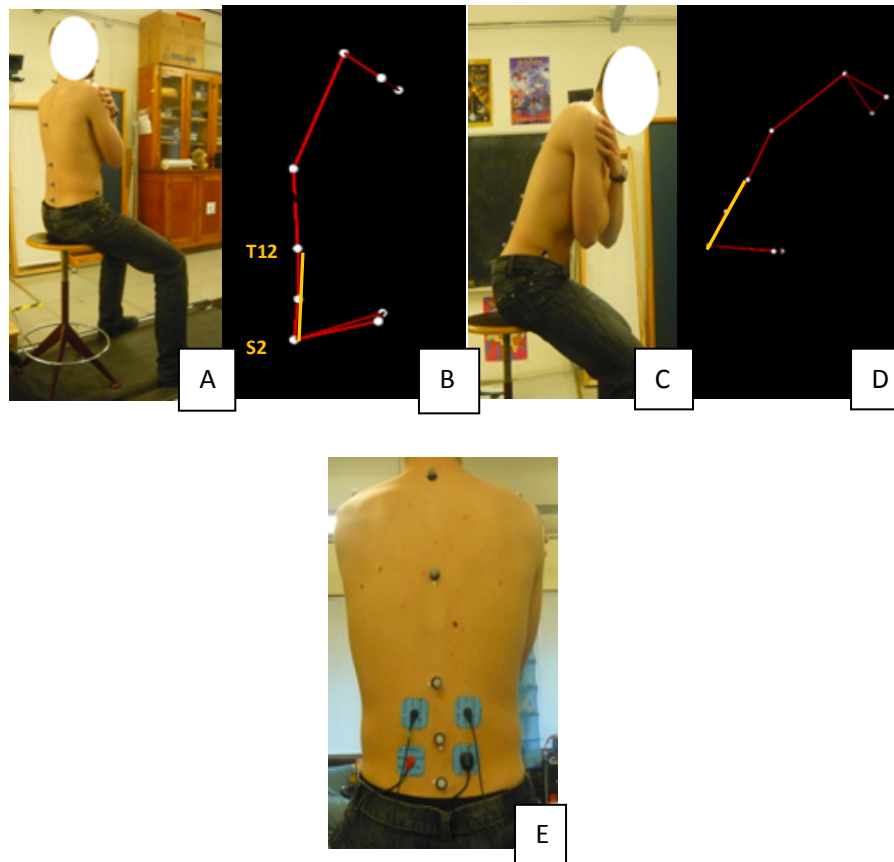
The segment between S2-T12 was considered as rigid and homogenous, delimited by proximal (S2) and distal markers (T12) as illustrated in Figure 1. The selected variable is the range of motion (ROM) and corresponded to the range of the angular displacement of the spinal segment during each trial. At each frame, the angular displacement of motion in the sagittal plane (XZ) was calculated from the vertical (Z) and lateral axis (X) located on the proximal marker of the segment, according to:

$$\Theta_{XZ} = \tan^{-1} \frac{X_p - X_d}{Z_p - Z_d}$$

Similarly to Wilson et al.,²³ only the low-back segments (S2-T12) from the spine model⁷ were used to calculate the torso angle in the sagittal plane given the trunk position in flexion.²³ Placements of markers on bony landmarks, the spine model (Figure 1) and method of angles calculation are well described in details elsewhere in Hidalgo et al.⁷

The testing protocol included five trunk repositioning error tasks and was performed at a non-imposed speed (spontaneous speed). All trunk repositioning error tasks were executed from a seated position on a stool; the height of the stool was adjusted for each subject to create a 130° angle between the thigh and trunk, allowing the maintenance of normal physiological curvature by anterior pelvic tilt in the starting position (corrected position) (Figure1A). From this position, subjects successively performed the five tasks described below.

Figure 1. Illustration of the repositioning error in control and TENS tasks conditions



A: starting position of control task, B: spine model, C: target position at 30° of control task, D: spine model, E: illustration of electrodes placement for TENS task. The acquisitions and calculation of torso-angle were made only on two markers of the spine model on S2 (proximal) and T12 (distal) spinous process.

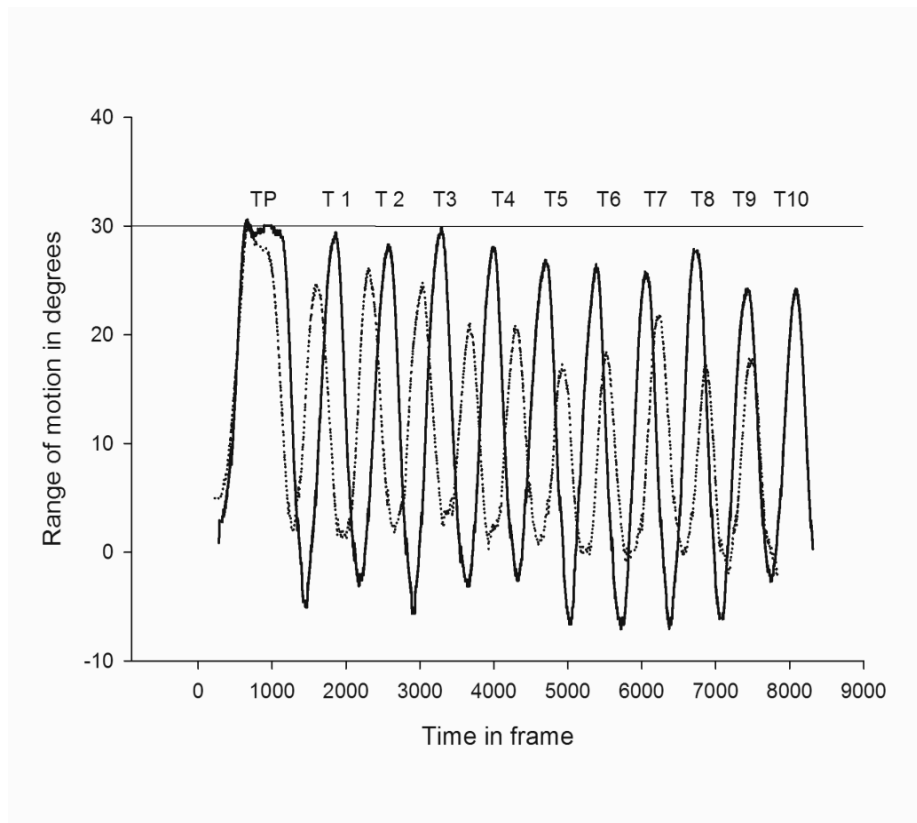
Tasks and instructions:

To minimise proprioceptive feedback from the lower limbs and pelvis,^{9,24} the subjects were sitting in a standardised position described here above. Both feet were placed on marks to keep the knees and feet apart in standardized positions and both upper limbs were crossed in front of the chest with the hands on the contralateral shoulder.

Subjects were asked to follow the following five rules during each task: (1) begin each movement in a seated position with corrected spine posture (2) maintain this curvature while moving (3) move at their own pace (4) aim for the target position of 30° and (5) keep the eyes closed except for the initial warm-up trial.

The repositioning error task (RE): As shown in Wilson et al.,²³ subjects were instructed and trained to bend forward while trying to hold the spine physiological position to the target position of 30° ROM indicated by an audio-signal. The subjects paused for 3 seconds, to memorize the target position. The subjects were instructed to move to the target position and return to the starting position 10 times as precisely as possible (Figures 1 and 2).

Figure 2. The repositioning error in control and vibration tasks, illustration of one healthy subject



The RE and proprioception disturbance tasks:

Five RE tasks were carried out. The first task was the control task (CT) with the eyes closed/blindfolded and 4 other tasks with eyes closed/blindfolded and standardised proprioceptive perturbation inputs. To limit bias due to a training phenomenon,^{16,20} the order of the motor tasks, with the various proprioception disturbances, was randomised for each patient.

The control-task (CT): The RE was estimated without external perturbation and with the eyes closed/blindfolded to exclude visual inputs (Fig.1A, C).

The vibration- task (VT): Prior to the vibration RE task, vibrations were applied at 50 Hz for 3 minutes on the skin in the L3 region over the paravertebral muscles. Vibration was applied with a vibrating massage device.

The electro-stimulation task (TENS T) (Figure 1E): During the repositioning test, electro-stimulations were conducted with four electrodes placed around L3 marker. The device used was a Compex Mi Sport© and the electro-stimulation program was Rehabilitation Reinforcement. This program alternated two types of contractions: isometric and shock contractions. Intensities of stimulation were the same for each subject corresponding to 15 units on the screen of the apparatus for isometric contractions and 30 units for shock contractions.

The taping task (TT): Two bands of elastic tape (*Elastaband*©, width: one and a half inches) were placed on both sides over and along the paravertebral muscles (from T12 to S2) and two other bands were placed in a cross over L3.

The unstable sitting task (UT): This task was carried out on an unstable surface, comprising of a swissball © of 38 inches of diameter.

Data and kinematic recording analysis

The Elite 3D track-system (BTS, Italy) was used to record the positions of the reflective markers by eight infrared cameras recording at a frequency of 200 Hz. Based on the positions of the markers (proximal = S2 and distal = T12), a customised program established the displacement of the lower-back segment (between S2 and T12 spinous process) as a function of time.⁷

Repositioning error for each trial was evaluated from lower-back displacements according to the equation:^{15,23}

$$RE = RP_i - TP$$

Where *i* represents the number of trials (*n* = 10), “RP” the reached position, “TP” the target position at 30° ROM and finally “RE” is the repositioning error (Figure 2). Mean value of absolute algebraic RE, representing the mean of deviation between reached and target-positions, was calculated for every task as well as standard deviation (SD), representing the variability of reached positions.

Statistical analysis

To assess the reliability of the repositioning error task (CT) at target position of 30° ROM, 15 subjects from our cohort executed the repositioning error tasks without perturbation and with eyes closed. The tasks were performed three times with an interval of 5 minutes between sessions.

Intraclass correlation coefficient (ICC) was used to measure reproducibility of intra- and inter-subject variability⁷ during tasks (SPSS software).

To assess the effect of disturbance on RE, within-group comparisons were made between the 4 proprioceptive disturbances and the CT and were calculated with one-way repeated measures ANOVA (Table 2).

Between-groups comparisons (matched-healthy and NS-CLBP groups) on RE motor tasks were estimated with two-way repeated measures ANOVA (Table 3). To compare both groups, the subjects of the NS-CLBP group (n=10) were matched with 10 subjects from the healthy group according to gender, BMI and age (Table 1).

Results

Reliability

The reliability of the measurement of RE was excellent (ICC = 0.94) during the control task.

Within-group difference in motor tasks

The healthy group showed significantly altered RE measurement between motor tasks (p-value = 0.004, statistical-power = 0.8): Multiple Comparisons versus Control-Group (Holm-Sidak method) determined differences for: CT vs. taping-task (p-value = 0.003; standardized mean of difference [SMD] = 0.8), CT vs. vibrations-task (p-value = 0.01; SMD = 0.6), CT vs. unstable-sitting-task (p-value = 0.001; SMD = 0.7).

In the NS-CLBP group, RE was slightly affected by proprioceptive disturbances (p-value = 0.047, statistical-power = 0.5), the 4 proprioceptive disturbances had almost no significant effects except that post-hoc analysis with Multiple Comparisons versus Control Group (Holm-Sidak method) determined a significant difference for CT vs. taping-task (p-value = 0.004, SMD = 0.5).

Table 2. Within group comparison with one-way repeated measures ANOVA

Motor tasks	Healthy (n=28)	NS-CLBP (n=10)
	Mean (SD)	Mean (SD)
	in degrees	in degrees
Control task	2.8 (2.0)	4.3 (2.6)
Taping task	4.4 (2.4) **	7.9 (5.0) **
Vibration task	4.2 (2.8) *	5.1 (2.8)
TENS task	3.3 (2.1)	5.5 (4.3)
Unstable sitting task	4.6 (3.5) **	5.8 (2.5)
Between tasks	$p = 0.004$; $P = 0.8$	$p < 0.05$; $P = 0.5$

* $p < 0.05$; ** $p < 0.005$ within group post hoc analysis in comparison to control task (Holm-Sidak method)

P = power; SD = standard deviation

Between-groups differences in motor tasks

Between-groups comparison showed that NS-CLBP subjects had larger RE in the tasks from those of the matched healthy group (p -value = 0.009, statistical-power = 0.8), multiple comparison procedures (Holm-Sidak method) determined that these differences between groups were for control (p -value = 0.03), taping (p -value = 0.006) and vibrations-tasks (p -value = 0.03).

Table 3: Between groups comparisons with two-way repeated measures ANOVA

Between matched healthy (n=10) and NS- CLBP (n=10)	Difference of means in degrees	p-value
Control task	2.5	0.03*
Taping task	3.2	0.006*
Vibration task	2.3	0.03*
TENS task	1.7	0.14
Unstable sitting task	1.9	0.08
Between groups	2.4	0.009 * P = 0.8

*p < 0.05 between groups comparison post hoc analysis within tasks (Holm-Sidak method); P = power

Discussion

The major goal of this study was to measure the effect of various forms of perturbations on the lower back “proprioceptive system” during RE tasks. The design of this study concerning proprioceptive inputs during RE tasks was carried out in a fashion consistent with Stillman, who described five inputs of proprioception; from cutaneous tissues, articulations, muscle, tendon and visual inferences.²⁵ Mann et al., studied the effect of visual privation on postural stability. Their results showed that NS-CLBP patients are better able to compensate proprioception deficiency using vision to perform postural stability.²⁶ Therefore, each test was performed with the eyes closed to exclude bias related to vision. Newcomer et al.,¹⁵ and McNair et al.,²⁷ evaluated the effect of a lumbar support (an elastic lumbar brace) on repositioning error in a standing position. They observed that CLBP subjects who wore a brace had decreased RE. Theoretically, the brace stiffens the lumbar spine and decreases all movements from this portion of the spine. Moreover, no high quality evidence has tested the effect of taping on proprioception and stabilisation.²⁸ In our study, tape showed that it had a significant influence on RE in both samples.

It was hypothetically assumed that there would be greater perturbation on RE tasks with electro-stimulation, but no significant effect on either population were established. As described by Paillard et al.,²⁹ Golgi-tendinous-organ activity could be modified and neuromuscular activity increased, with the aim of disturbing the length/tension relationship of paravertebral muscles and therefore the real position of the spine. Grunnesjö et al.³⁰ and many other experts⁸⁻³¹ agree that CLBP can be caused by a deficit of proprioception. The deficit of proprioception could be affected by an increase in muscle spindle sensitivity, producing an erroneous signal of spinal position.³⁰ Despite any significant effects of electro-stimulation on RE, our results supports the hypothetical mechanism described above and reflect that the low level of change demonstrated in the present study are probably due to lower intensity levels of the electro-stimulation used in this studies protocol.

Li et al., studied whole-body vibration at 5Hz applied to a healthy population for 20 minutes prior to measurement of RE in trunk flexion executed from a sitting position with a target position of 30° ROM. Their results were in concordance with our study showing a significantly larger mean RE after vibration application in a healthy population.³² Differences between both studies arose from the application of vibrations on lumbar paravertebral-muscles only, with a frequency of 50 Hz for 3 minutes. Moreover, we also studied the effect of vibration perturbation on NS-CLBP patients and no significant effect on RE was found. Brumagne et al., demonstrated that vibration applied to paravertebral muscle led to an increase of RE in healthy subjects and therefore provided evidence that muscle spindles are major elements of lumbar proprioceptive ability.³³ On the other hand, Brumagne et al., found that muscle vibration in LBP subjects decreased the RE. Previous and present evidence suggested that LBP and healthy subjects are different in the way they process spindle information.³³ For Hill et al., the effects of vibration on the spine is a very complex issue depending on the axis, frequency, amplitude, duration, and soft-tissue health that could influence the spine's response to vibration.³⁴ There is a long history of investigation to determine the effect of vibration on the spine. Nevertheless, clinical data shows mixed effects and conflicting-evidence.³⁴

To our knowledge, no study has directly examined active RE while sitting on an unstable surface, such as the Swissball. Some authors have, however, examined trunk muscular³⁵ or re-equilibration¹⁴ in healthy-subjects during an equilibration task on a rocker-board. The first study,³⁵ described above, showed that trunk muscle activation was more important during unstable sitting position. The second study¹⁴ described an effect of gender and age on equilibration, but in the present study we did not find any effect for gender. The unstable sitting task on the Swissball showed a significantly larger mean RE when compared to the CT in healthy subjects. Moreover, we could again observed that for the NS-CLBP group; unstable sitting did not increase RE.

Proprioceptive disturbances clearly raise doubt about the accuracy of RE tasks in healthy subjects, and to a much lesser extent in the NS-CLBP group. This can perhaps be explained by the fact that proprioception is already disturbed in the LBP patients and it is not possible to add further disruptive effects artificially.

In accordance with the literature,¹⁵⁻²² there was significant difference for active RE tasks between both populations, the NS-CLBP group showed larger RE than healthy subjects. Literature reports that pain-free subjects have a RE of around 1-2 degrees, while LBP patients have an error about twice as great, probably due to altered proprioceptive input from the lumbar spine.²¹ Impaired proprioception may contribute to the worse RE accuracy in patients with LBP.³³ Moreover, previous work on peripheral joints has revealed that proprioception is affected by muscular or joint injuries or degeneration.¹⁷

Conversely, two other studies^{9,13} also using active RE, have found no differences between both populations. This conflicting evidence between studies is probably due to protocol and design variations. As an illustration, Assel et al., studied active RE in healthy and CLBP subjects using a longer segment between S2 and T7,⁹ thus including the low-thoracic spine for evaluation from a sitting position but in a physiological curvature repositioning task. Lee et al., used a similar active RE but from a side-lying position.¹³ Results showed no difference between groups. These studies assessed spinal proprioception with major differences between patient positions and task from our protocol.

The small sample in NS-CLBP group, in comparison to healthy subjects, could, within NS-CLBP group, slightly bias outcome measures, but between-group comparisons showed good statistical power.

Conclusion

Artificial proprioceptive perturbations had effects on the RE sense of the lumbar spine in healthy subjects, increasing RE during trunk forward bending. In contrast, subjects with NS-CLBP seemed to be unaffected by almost all perturbations on RE tasks, probably because proprioceptive alterations resulting from LBP cannot be further influenced by external perturbations or could be dependent on stimulation intensities. Between-group comparisons showed larger RE for the NS-CLBP group in 3 RE tasks.

The present study confirms evidence that patients with CLBP have larger active RE than healthy subjects. Further studies are necessary to evaluate the impact of different intensities of proprioceptive disturbance on RE, to investigate RE in different sub-groups of NS-CLBP such as motor control impairment or instability. Indirectly, these results may also have clinical implications and confirm the importance of RE in people with LBP.

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Section 3

**Clinical physical examination and evaluation of the efficacy of
orthopaedic manual therapy for patients with low back pain**

CHAPTER V

Inter-tester agreement and validity of identifying lumbar pain provocative movement patterns using active and passive accessory movement tests

Benjamin Hidalgo, Toby Hall, Henri Nielens, Christine Detrembleur

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ABSTRACT

Objective: The purpose of this study was to evaluate the interexaminer agreement and validity of active and passive pain provocation tests in the lumbar spine.

Methods: Two blinded raters examined 36 participants, 18 of whom were asymptomatic and 18 reported subacute nonspecific low back pain (LBP). Two types of pain provocation tests were performed: (1) physiological movements in single (flexion/extension) and, when necessary, combined planes and (2) passive accessory intervertebral movement tests of each lumbar vertebra in prone with the lumbar spine in neutral, flexion, and extension position.

Results: The interobserver agreement in both groups was good to excellent for the identification of flexion ($\kappa = 0.87-1$) or extension ($\kappa = 0.65-0.74$) as the most painful pattern of spinal movement. In healthy participants, 0% was identified as having a flexion provocative pattern and 8.8% were identified as having an extension provocative pattern. In the LBP group, 20% were identified as having a flexion provocative pattern vs 60% with an extension provocative pattern. The average interexaminer agreement for passive accessory intervertebral movement tests in both groups was moderate to excellent ($\kappa = 0.42-0.83$). The examiners showed good sensitivity (0.67-0.87) and specificity (0.82-0.85) to distinguish participants with LBP using this combined examination procedure.

Conclusion: The use of a combination of pain provocative tests was found to have acceptable interexaminer reliability and good validity in identifying the main pain provocative movement pattern and the lumbar segmental level of involvement. These pain provocation tests were able to distinguish participants with LBP from asymptomatic participants and may help clinicians in directing manual therapy treatment.

Introduction

Low back pain (LBP) has a high prevalence in Western societies. It is estimated that up to 84% of the European population will experience, at least once in a lifetime, an episode of LBP, with the prevalence of chronic LBP approximately 23%.¹⁻³

Most of LBP is described as nonspecific because a radiologically identified cause for pain can only be determined in a small minority of cases. Indeed, there is a poor correlation between findings on radiologic imaging and symptoms, with a radiologic diagnosis identified in only 15% of cases.^{2,4,5}

Hence, based on imaging, nonspecific LBP is defined by the lack of a recognizable, specific pathology and is usually of unknown origin and etiology.^{1-3,6} However, despite this evidence, nociceptive factors have a major role in acute and subacute nonspecific LBP conditions. For example, various structures in the lumbar spine are recognized as causative of LBP due to their innervation.³ In particular the zygapophysial joints, intervertebral disks, and sacroiliac joints have been determined as nociceptive sources in 15%,⁷ 40%,⁸ and 30% of LBP^{2,9,10} cases, respectively. However, the clinical evaluation of patients with LBP should not focus on pathoanatomical data alone.³ For example, psychosocial factors play a major role in explaining the development of chronic back pain.^{3,11} Therefore, generally speaking, in the case of nonspecific LBP, determining a pathoanatomical diagnosis for pain is unhelpful, particularly when used to drive the management strategy.¹² As a consequence, there has been a call to better define LBP into distinct subgroups by the development of classification systems based on clusters of signs and symptoms relevant to physical therapy.^{6,12,13}

Several classification systems for LBP have been proposed, but only 4 systems meet the criteria for tailoring directly manual therapy management and which have been evaluated scientifically.^{12,14,15} These 4 systems are the McKenzie (MK) LBP classification system,¹⁶⁻¹⁸ the Treatment-Based Classification system,^{6,19,20} the movement system impairment classification for LBP,^{14,21} and the motor control impairment or the classification-based cognitive functional approach.^{11,22-24} Nevertheless, the best system for sub classification of people with LBP has not yet been determined.

The MK and treatment-based classification systems interpret the patient's symptom behavior with a series of single and repeated spinal movements and sustained postures performed during clinical examination. The goal of the assessment is to identify the directional pattern that worsens and improves the patient's symptoms. These modalities of physical examination provide a basis for the patient's LBP classification and treatment (e.g., repeated spinal movements and sustained positions or passive spinal mobilization and manipulation,

stabilisation exercises, or traction).¹⁴ In all of these classification systems, the sagittal plane is of major importance to determine specific patterns.

Orthopedic manual therapy (OMT) management for an individual patient is driven by evidence-based practice and the results obtained from the clinical examination of the patient together with clinical reasoning.^{2,6,25,26} Therefore, the clinical examination should have evidence of sufficient reliability and validity. However, there are few physical assessments that demonstrate evidence of such qualities.^{2,4}

Furthermore, there is a generally considered poor correlation between movement impairment and the presence and severity of LBP.^{11,24}

There are at least 3 general domains in the clinical assessment of articular dysfunction in LBP: observation of movement and posture, motion palpation for spinal segmental mobility, and pain provocation tests.⁴ Investigations of the reliability of these procedures indicate greater reliability for tests of pain or symptom provocation rather than observation or motion palpation.^{2,4,12,13,27} For example, a systematic review reported moderate evidence regarding the identification of bony landmarks by palpation, and weak evidence for the evaluation of segmental mobility and segmental dysfunction requiring treatment in the lumbar spine.⁴

The literature suggests that those tests that are the most reproducible, in clinical examination of the lumbar spine, are those that are based on symptom reproduction.^{2,4,17,19,27} More specifically, the interexaminer reliability of pain response during repeated lumbar spinal movements (in flexion/extension) is the only procedure to show moderate evidence of high reliability.⁴ Therefore, when a physical examination is based on the response to symptoms, reliability is good, whereas when it is based on palpation to detect mobility, reliability is generally low.^{4,27} Moreover, several studies of good methodological quality have demonstrated the validity of movement tests to discriminate people with LBP from healthy asymptomatic participants using tests of active spinal movement.^{5,22,24,28}

One form of pain provocation testing that is commonly used in OMT clinical examination is active movement tests in single or combined planes. The concept of combined movements (CM) testing was originally developed by Edwards²⁹ and is an expansion of the routine clinical examination. Another form of pain provocation testing is passive accessory intervertebral movement (PAIVM) testing. In the concept proposed by Edwards, information gained from single and combined planes active movement examination is used together with PAIVM tests performed in different lumbar spine positions to determine a pain provocative direction that is more specific to the patient's problem and is also more functional.^{2,25,29-31}

This pain provocative direction directs manual therapy management, which aims to reduce pain through restoring pain-free range of motion in the specific direction. There have been no studies to date that have investigated the interexaminer agreement or validity of this approach to examination of LBP.

Therefore, the purpose of this study was to investigate the reliability and validity of pain provocation tests to identify a pain provocative direction. Specifically, we examined the combination of active trunk movements with PAIVM of the lumbar spine to determine a pain provocative direction of flexion and/or extension and the involved lumbar levels. We also sought to investigate whether these tests of pain provocation could be used to distinguish participants with LBP from asymptomatic participants.

Methods

Study Population

Two groups of participants were investigated (Table 1): a group of healthy asymptomatic participants ($n = 18$) and a group of patients with subacute nonspecific LBP ($n = 18$). The inclusion criteria for the asymptomatic group were as follows: aged between 20 and 65 years, body mass index (BMI) less than 30 kg m^{-2} and no back pain for at least 6 months. Asymptomatic participants were recruited on a voluntary basis in response to posters placed around the hospital. The inclusion criteria for the LBP group were as follows: aged between 20 and 65 years, BMI less than 30 kg m^{-2} , and the presence of nonspecific LBP for at least 4 weeks.³² A medical doctor confirmed the diagnosis of nonspecific LBP. The Roland Morris Disability Questionnaire was used to measure disability. Exclusion criteria included the presence of red flags, rheumatologic diseases, neurologic deficits, and a history of spinal surgery. Patients were recruited from outpatient clinics at the Saint-Luc University Hospital (Belgium) and had symptoms in the low back area and/or irradiation into the lower limb but not below the knee. Patients were excluded from the study if they had a visual analog scale score for pain greater than or equal to 7/10 on the day of the experiment. Each patient participated in the study on a voluntary basis and provided written informed consent, following the principles of the Declaration of Helsinki. This study had ethical approval from the Commission d'éthique Hospitalo-Facultaire de l'Université de Louvain-La-Neuve, Brussels, Belgium.

Table 1. Baseline characteristics of healthy subjects and those with nonspecific low back pain

	Healthy asymptomatic participants (n = 18), mean (SD)	Participants with LBP (n = 18), mean (SD)
Height (cm)	170.1 (9.2)	172.7 (6.5)
Weight (kg)	67.2 (11.9)	70.3 (12.3)
BMI (kg/m ²)	23.1 (2.9)	23.5 (3.4)
Age (y)	32 (8.3)	38 (9.8)
Sex (female)	9	9
Present pain (VAS)	–	2.9 (1.3)
Roland Morris Disability score	–	8.4 (3.3)
Duration of pain (wk)	–	6.3 (2.9)

VAS, visual analog scale.

Assessment Procedures

Two blinded observers with postgraduate qualifications in manual therapy performed the evaluation. One examiner had 10-year postgraduate clinical expertise in OMT, and the other was a novice (degree in OMT but without clinical experience). A third observer recruited the participants, confirmed participant eligibility for each group, and was the only person aware of the participant's group status.

Each participant was examined on a single occasion by both examiners who were blind to each other. During this assessment, 2 types of pain provocation tests were performed: first, active movement pain provocation tests in standing and, second, PAIVM tests in prone. Active movement comprised single-plane repeated active trunk movements including sustained positioning and overpressure in flexion and extension to reproduce or increase pain. If there were no pain during these spinal movements, then CMs of the trunk were performed.^{2,20,25,29,31,33}

Passive accessory intervertebral movement tests were applied to each lumbar vertebrae (from L1 to L5) in prone position with the lumbar spine in neutral, flexion, and extension.^{27,29,31,33,34}

Both examiners performed all tests successively on the same day, with a short break for the participant between examiners (10 minutes). The following 2 factors were randomised: order of examiner, and the order of PAIVM tests or active movement tests.

Battery of Tests

Participants were asked not to inform the examiner of their group allocation. In addition, examiners used standardised communication to question participants in a similar manner on the presence of pain.

Single and combined active trunk movements

The aim of the active movement examination protocol was to provoke pain (and therefore identify the pain provocative direction), in such a way that progressive strains were placed on the lumbar spine as follows: the patient started in a standing position and performed a maximum of 10 trunk flexion movements, maintaining the knees in extension (Figure 1A). The participant determined a comfortable movement velocity. During the repetition until the 10th, the examiner asked the participant about the presence of pain onset or pain increase. If no pain was provoked, then the participant's spine was sustained in an end-range flexion position for a maximum of 10 seconds, or until pain was provoked.^{2,16,17,19,33} In the absence of pain onset or pain increase, the examiner then applied overpressure (Figure 1B) and again seeking the status of pain. The same procedure was repeated for the movement of trunk extension (Figures 1D, E). If these procedures did not influence pain, then CM were evaluated.^{29,31,33,35} The participant was directed to move to a position of flexion or extension, combined with assisted lateral flexion to the left and right (Figures 1C, F). The CM used were as follows: flexion with lateral flexion left, flexion with lateral flexion right, extension with lateral flexion left, and extension with lateral flexion right.^{29,33}

Following these routine clinical examination procedures, the examiners were required to identify the most pain provocative direction (flexion or extension) for each participant.

Figure 1. Single and Combined Active Trunk Movements



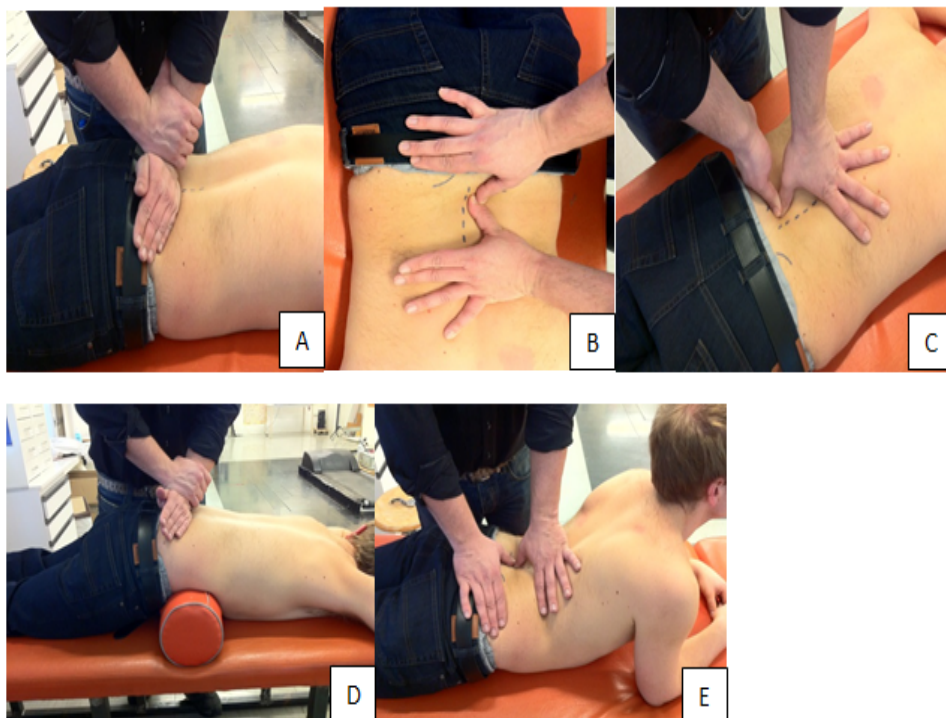
A: Active flexion with repeated movements (maximum 10 repetitions) and sustained position; B: Sustained flexion with overpressure; C: Combined movements in primary flexion then secondary lateral-flexion left; D: Active extension with repeated movements (maximum 10 repetitions) and sustained position; E: Sustained extension with overpressure; F: Combined movements in primary extension then secondary lateral-flexion right.

Passive Accessory Intervertebral Movement

Prior to the examination, the skin overlying each lumbar spinous process was marked with a visible dermographic pencil using a previously developed method.²⁷ After this, 5 types of oscillatory PAIVM were applied to each lumbar vertebra: posteroanterior (PA) pressure on each spinous process (Figure 2A), as well as PA pressure on the left and right zygoapophyseal joints (Figure 2B) and lateral pressures applied on the left and right sides of each spinous process (Figure 2C). The method of application has been previously described.^{16,20,27,31,33,34} All accessory motion tests were applied in 3 different prone positions: neutral (e.g., Figure 2A), flexed over a 20-cm cushion cylinder (e.g., Figure 2D), and an extended position achieved through the patient resting on their elbows (e.g., Figure 2E).^{29,31}

To improve the standardisation of force applied by the examiners,³⁶ each PAIVM test was standardized according to the grades of Maitland.^{33,34} The grades applied were progressive oscillatory pressure from grades III to IV. The end point for each test was either pain or end-range resistance with a grade IV pressure, whichever came first. Although these tests are used to assess for hypomobility or hypermobility, this aspect of testing was not included and we only assessed for pain provocation. Any pain response was recorded as a positive response. The examiner recorded the dichotomous pain response (present or not), vertebral level at which pain was provoked, and type of accessory movement that provoked pain. The manual examination by PAIVM tests when accompanied by a verbal participant response had previously been demonstrated to be highly accurate in detecting the lumbar segmental level responsible for a participant complaint.^{37,38} All vertebrae were tested from L1 to L5, and all accessory movements performed on each vertebral level.

Figure 2. Passive accessory intervertebral movements



A: Postero-anterior pressure on spinous process in neutral prone position; B: Lateral pressure on the spinous process in neutral prone position; C: Postero-anterior pressure on the zygapophyseal joint in neutral position; D: Postero-anterior pressure on a spinous process in flexion prone position; E: Lateral pressure on the spinous process in extension.

Clinical classification rule

Both examining therapists were required to state whether the participant they had tested had LBP or not, determined by the presence of a painful pattern of flexion or extension coupled with pain on PAIVM tests.

Hence, a clinical classification rule (CCR) was developed to identify the presence of LBP. This consisted of 3 criteria that were all required to be positive:

Criteria 1: active movement tests. A predominant pain provocative movement direction (flexion or extension) during single, repeated, sustained, or overpressure tests (Figures 1A, B, D, E), or if required in a CM direction (flexion or extension combined then with lateral flexion right or left; Figures 1C, F). After these single or CM tests, the assessors had to establish the most painful pattern of spinal movement: that is, positive = flexion or extension and negative = no painful pattern.

Criteria 2: passive movement tests. At least 2 adjacent vertebral levels provoked pain on PAIVM tests (Figures 2A- C): that is, positive = 2 painful adjacent vertebral levels and negative = 0 or 1 painful vertebral level.

Criteria 3: pain provoked by PAIVM was made worse at the specific vertebral level, by flexing or extending the spine (Figures 2D, E), with the direction in concordance with the direction of active pain provocative movement previously identified in criteria 1: that is, positive = concordance and negative = no concordance

Statistical analysis

Interexaminer agreement for single and CMs and the identification of the pain provocative direction (Table 2) as well as PAIVM tests (Table 3) were calculated by using the percentage of agreement (%A) and κ test (MedCalc software, version 11.5; MedCalc, Mariakerke, Belgium). In some situations, when the prevalence of a given response to a test is either very high or very low, the interpretation of the κ statistic does not satisfactorily reflect the true level of agreement.³⁹ Other statistical tools have been developed to account for this, such as “prevalence-adjusted bias-adjusted κ ” (PABAK),⁴⁰ which corrects for this type of bias. κ and PABAK were interpreted according to the classification of Blum et al⁴¹ (Table 4).

The validity of our CCR for each examiner was determined by assessing sensitivity and specificity using the following equations:

$$\text{Sensitivity} = \text{true positives} / (\text{true positives} + \text{false negatives})$$

$$\text{Specificity} = \text{true negatives} / (\text{true negatives} + \text{false positives})$$

Sensitivity refers to the ability of the CCR to correctly identify those patients with LBP. Specificity refers to the ability of the CCR to correctly identify those patients without LBP.³⁷

One-way analysis of variance (ANOVA) with all pairwise multiple comparison procedures (Holm-Sidak method) (Sigmastat 3.5; Systat Software, Inc, San Jose, CA) was performed in each group on the prevalence of positive responses during PAIVM with comparison for factor 2: levels of vertebra (L1, L2, L3, L4, L5). Two-way ANOVA with all pairwise comparison procedures (Holm-Sidak method) was performed as well with comparison for factor 1: groups (Healthy and LBP) and for factor 2: levels of vertebra (Table 5). The first author performed all statistical analyses.

Results

Interobserver agreement

Single and combined active trunk movement tests in standing

In healthy participants, the interexaminer agreement of classification of flexion or extension pattern was good to excellent, with PABAK values of 0.65 to 1.00 and %A between examiners ranging from 82.4% to 100%. Moreover, 0% of healthy participants were identified as having a flexion pattern, whereas 8.8% were identified as having an extension pattern. In participants with LBP, the interexaminer agreement of classification of flexion or extension pattern was good, with PABAK values of 0.73 to 0.87 and %A ranging from 86.7% to 93.3%. In the LBP group, 20% were identified as having a flexion pattern, whereas 60% had an extension pattern (Table 2).

Table 2: Reliability of pain provocation direction during trunk movements

	Healthy asymptomatic participants				Participants with LBP			
	%A	κ	PABAK	%+	%A	κ	PABAK	%+
Repeated flexion	100	–	1	0	86.7	0.45	0.73	13.3
Flexion with overpressure	100	–	1	0	80	0.34	0.6	16.6
CM (F-LFR) ^{a b}	100	–	1	0	100	–	1	0
CM (F-LFL) ^{a b}	100	–	1	0	93.3	0	0.87	3.3
Repeated extension	100	–	1	0	100	–	1	6.6
Extension with overpressure	94.1	0	0.88	5.8	80	0.65	0.62	50
CM (E-LFR) ^{a c}	82.4	–0.09	0.65	2.9	93.3	0	0.87	3.3
CM (E-LFL) ^{a c}	94.1	0	0.91	2.9	93.3	0	0.87	3.3
Identification of flexion pattern	100	–	1	0	93.3	0.63	0.87	20
Identification of extension pattern	82.4	0	0.65	8.8	86.7	0.74	0.73	60

%A, percentage agreement between raters; %+, percentage of participants with a positive test result; *E-LFL*, extension then lateral flexion left; *E-LFR*, extension then lateral flexion right; *F-LFL*, flexion then lateral flexion left; *F-LFR*, flexion then lateral flexion right; *PABAK*, prevalence-adjusted bias-adjusted κ .

^a Only if previous test results were negative.

^b Tests performed in all healthy participants and in 71% of participants with LBP.

^c Tests performed in 94% of healthy participants and in 43% of participants with LBP.

Passive accessory intervertebral movements

Interexaminer agreement for PAIVM from L1 to L5 in healthy participants (neutral, flexion, and extension positions) was good for PA pressure on the spinous process, with PABAK of 0.76 and a %A of 87.9%; for PA pressure on the right zygoapophyseal joint, agreement was good, with PABAK of 0.72 and 85.9 %A; for PA pressure on left zygoapophyseal joint, agreement was good, with PABAK of 0.75 and 87.9%A; and for lateral pressure on the right and left sides of the spinous process, agreement was excellent, with PABAK of 0.83 and 91.4%A, respectively (Table 3).

The interexaminer agreement for PAIVM from L1 to L5 in participants with LBP (neutral, flexion, and extension positions) for PA pressure on the spinous process was moderate, with PABAK of 0.45 and 72.5 %A; for PA pressure on the right zygoapophyseal joint, agreement was moderate, with PABAK of 0.48 and 73.8%A; for PA pressure on left zygoapophyseal joint, agreement was moderate with PABAK of 0.46 and 73.4 %A; for lateral pressure on the right side of the spinous process, agreement was moderate, with PABAK of 0.45 and 77.1 %A; and for lateral pressure on the left sides of the spinous process, agreement was moderate, with PABAK of 0.52 and 76.0 %A (Table 3).

Table 3. Reliability of pain provocation with PAIVM from L1 to L5

Healthy asymptomatic group

PA on spinous process							PA on zygapophyseal joint right						PA on zygapophyseal joint left		
% A	CI95%	κ	CI95%	PABAK	CI95%		% A	CI95%	κ	CI95%	PABAK	CI95%	% A	CI95%	κ
μ	87.9	85.9-89.9	0.21	0.10-0.32	0.76	0.72-0.80	85.9	83.2-88.5	0.29	0.15-0.43	0.72	0.67-0.77	87.9	87.1-88.6	0.33

LBP group

PA on spinous process							PA on zygapophyseal joint right						PA on zygapophyseal joint left		
% A	CI95%	κ	CI95%	PABAK	CI95%		% A	CI95%	κ	CI95%	PABAK	CI95%	% A	CI95%	κ
μ	72.5	65.7-79.3	0.43	0.31-0.54	0.45	0.31-0.58	73.8	71.5-76.1	0.42	0.34-0.49	0.48	0.43-0.52	73.4	70.8-76.0	0.43

%A, percentage agreement between raters; CI, confidence interval; LBP, low back pain; PA, posteroanterior; PABAK, prevalence-adjusted bias-adjusted κ ; μ , mean of neutral, flexion, and extension prone positions (from L1 to L5).

Table 3. (continued)

			Lateral pressure right side of spinous process						Lateral pressure left side of spinous process					
CI95%	PABAK	CI95%	% A	CI95%	κ	CI95%	PABAK	CI95%	% A	CI95%	κ	CI95%	PABAK	CI95%
0.14-0.52	0.75	0.74-0.77	91.4	90.6-92.2	0.45	0.33-0.57	0.83	0.81-0.85	91.4	89.3-93.3	0.42	0.39-0.46	0.83	0.79-0.87

			Lateral pressure right side of spinous process						Lateral pressure left side of spinous process					
CI95%	PABAK	CI95%	% A	CI95%	κ	CI95%	PABAK	CI95%	% A	CI95%	κ	CI95%	PABAK	CI95%
0.36-0.50	0.46	0.41-0.52	77.1	74.1-80.2	0.43	0.33-0.52	0.45	0.32-0.58	76.0	68.1-84.0	0.46	0.29-0.63	0.52	0.36-0.68

One-way ANOVA in the asymptomatic group showed that there was a significant difference ($P < .001$) between levels of vertebra concerning the prevalence of positive tests and that L5 was significantly different from L1, L2, L3, and L4. Similar results ($P < .001$) in the LBP group were found, with significant differences between L5 and L1, L2; L4 and L1; and L3 and L1. Two-way ANOVA determined that the prevalence of positive tests was different ($P < .001$) between both groups (Table 5).

The detailed values of PAIVM, interexaminer agreement, and prevalence of positive tests by vertebra are respectively presented in Tables 3 and 5.

Table 4. Interpretation of the κ according to the classification of Blum et al⁴¹

Agreement	κ
Excellent	0.81-1
Good	0.61-0.80
Moderate	0.41-0.60
Weak	0.21-0.40
Negligible	0-0.20
Poor	<0

Table 5: Prevalence of positive responses during pain provocation with passive accessory intervertebral movement tests

	Healthy asymptomatic participants						Participants with LBP					
	PA	PA zyg. j. R	PA zyg. j. L	Lat. side P. R	Lat. side P. L	Means	PA	PA zyg. j. R	PA zyg. j. L	Lat. side P. R	Lat. side P. L	Means
L1 neutral	5.8%	5.8%	5.8%	0.0%	2.9%	4.1%	33.3%	16.6%	33.3%	23.3%	13.3%	24.0%
L1 flexion	2.9%	0.0%	0.0%	2.9%	0.0%	1.2%	20.0%	6.6%	20.0%	30.0%	16.6%	18.6%
L1 extension	11.7%	2.9%	5.8%	5.8%	0.0%	5.2%	46.6%	40.0%	33.3%	26.6%	40.0%	37.3%
L1 means	6.8%	2.9%	3.9%	2.9%	1.0%	3.5%	33.3%	21.1%	28.9%	26.6%	23.3%	26.6%
L2 neutral	0.0%	14.7%	11.7%	2.9%	2.9%	6.4%	40.0%	33.3%	40.0%	30.0%	33.3%	35.3%
L2 flexion	5.8%	8.8%	8.8%	0.0%	2.9%	5.3%	30.0%	23.3%	36.6%	30.0%	30.0%	30.0%
L2 extension	2.9%	17.6%	17.6%	5.8%	2.9%	9.4%	53.3%	36.6%	40.0%	40.0%	30.0%	40.0%
L2 means	2.9%	13.7%	12.7%	2.9%	2.9%	7.0%	41.1%	31.1%	38.9%	33.3%	31.1%	35.1%
L3 neutral	5.8%	5.8%	8.8%	8.8%	8.8%	7.6%	46.6%	30.0%	43.3%	40.0%	40.0%	40.0%
L3 flexion	8.8%	11.7%	5.8%	11.7%	11.7%	9.9%	33.3%	36.6%	50.0%	36.6%	43.3%	40.0%
L3 extension	8.8%	17.6%	11.7%	14.7%	14.7%	13.5%	60.0%	46.6%	46.6%	46.6%	43.3%	48.6%
L3 means ^a	7.8%	11.7%	8.8%	11.7%	11.7%	10.3%	46.6%	37.7%	46.6%	41.1%	42.2%	42.9%
L4 neutral	8.8%	11.7%	5.8%	20.5%	14.7%	12.3%	36.6%	40.0%	40.0%	53.3%	46.6%	43.3%
L4 flexion	14.7%	8.8%	11.7%	17.6%	23.5%	15.3%	40.0%	33.3%	43.3%	43.3%	43.3%	40.6%
L4 extension	14.7%	17.6%	17.6%	11.7%	20.5%	16.4%	50.0%	36.6%	46.6%	43.3%	50.0%	45.3%
L4 means ^a	12.7%	12.7%	11.7%	16.6%	19.6%	14.7%	42.2%	36.6%	43.3%	46.6%	46.6%	43.1%
L5 neutral	20.5%	20.5%	20.5%	23.5%	29.4%	22.9%	46.6%	40.0%	45.0%	50.0%	43.3%	45.0%
L5 flexion	11.7%	17.6%	52.9%	64.7%	58.8%	41.1%	43.3%	33.3%	43.3%	53.3%	56.6%	46.0%
L5 extension	20.5%	23.5%	20.5%	17.6%	23.5%	21.1%	46.6%	36.6%	36.6%	53.3%	50.0%	44.6%
L5 means ^{a,b}	17.6%	20.5%	31.3%	35.3%	37.2%	28.4%	45.5%	36.6%	41.6%	52.2%	50.0%	45.2%

Lat. side. P. R/L, lateral (transverse) pressure on spinous process right/left; PA, PA pressure on spinous process; PA zyg. j. R/L, PA pressure on zygoapophyseal joint right/left.

^a $P < .001$ between L5 and L1-2, L4 and L1, and L3 and L1 in the LBP group (statistical power = 1).

^b $P < .001$ between L5 and L1-4 in the healthy group (statistical power = 1).

Diagnostic accuracy of LBP classification

The sensitivity and specificity of identifying a person with LBP using the proposed CCR were, respectively, 0.87 and 0.82 for the experienced examiner and 0.67 and 0.85 for the novice. The combined sensitivity and specificity were, respectively, 0.77 and 0.84.

Discussion

In accordance with previous studies,^{2,4,5,17,19,22,23} this study found good interexaminer agreement for active movement tests of the trunk in asymptomatic participants and patients with LBP. The reliability of identification of the most painful pattern (flexion or extension) was also found to be at least good, which is comparable with other studies investigating movement classification systems in people with LBP.^{5,17,19,20,22,23}

In the present study, CM tests were applied in a higher percentage of asymptomatic participants than in patients with LBP. In our protocol, we decided to stop the progressive strain of spinal movement at pain onset or pain increase. Most participants with LBP experienced pain during single, repeated, or sustained active movement tests or with the application of overpressure. Hence, CM tests were less frequently required in participants with LBP. The reproducibility of CM testing has been studied by Haswell et al.³⁵ Paradoxically, the results showed poor agreement between raters, which is in contrast to our results. The reason for this difference remains unclear and may be related to differences in the frequency that CM tests were performed or alternatively in differences in examiners training and participants characteristics.

In accordance with a previous study,⁴² the prevalence during clinical examination of positive responses to PAIVM tests was higher for the lower lumbar vertebrae than for the upper lumbar vertebrae in both groups. However, the results of a 2-way ANOVA demonstrated that the prevalence of positive responses from testing each lumbar vertebra was more frequent in participants with LBP, probably because of specific underlying pain mechanisms in this population. The topographical differences in pain responses in both groups could perhaps be explained by the increased predominance of biomechanical strain and pathoanatomical features in the lower lumbar area when compared with upper lumbar levels.^{43,44} Another explanation might be due to the transition from the mobile lumbar spine to relatively rigid pelvis, placing physiological stress on the lower lumbar segments, sensitizing those segments. The presence of positive PAIVM tests in asymptomatic people highlights the importance of identifying more than 1 vertebral level as symptomatic, as adopted in this study. In addition, this highlights the importance of using a combination of factors such as the CCR when distinguishing people with LBP.

There are few studies, to our knowledge, that have reported on the relative frequency to which each vertebral level contributes to LBP. However, based on the clinical observation of vertebral levels that commonly receive surgery, zygoapophyseal injections, or intervertebral discography, the lower lumbar spine would appear to be the more common source of symptoms.⁴² The precise location of pain origin in the spine of patients with LBP is of major importance to manual therapists. The L4 and L5 vertebral levels, which are frequently found to have pathology in LBP people, have also been reported to be the most common vertebral levels to provoke concordant pain during epiduroscopy.⁴²

The results for interexaminer agreement for tests of PAIVM are at least comparable with or better than those obtained in previous studies.^{27,36-38,45} Previous studies reported either weak to moderate or moderate to good agreement for intraobserver reliability when testing PA pressures only on the spinous process ("spring test"). Schneider et al²⁷ also reported similar levels of interexaminer agreement for palpation of the zygoapophyseal joints, although they grouped levels into upper and lower lumbar levels rather than a specific vertebral level.

Similarly to Phillips and Twomey³⁷ and in terms of manual diagnostic accuracy, the validity (sensitivity and specificity) of our CCR to identify people with LBP can be rated as good, especially for the evaluator with better clinical experience. The sensitivity for the novice examiner was slightly less than that found for the experienced examiner. Therefore, the novice examiner should be more careful to interpret a negative result (because of a higher chance of false-negative findings) when testing LBP people with the CCR. The results of this study suggest that pain provocation using the CCR, when accompanied by a verbal participant response,³⁷ is an important component of physical examination to distinguish people with LBP from healthy participants. This information may be important when one considers the poor correlation between medical imaging and LBP, and the poor correlation between information gained from magnetic resonance imaging and clinical examination in people who have LBP.^{5,42,46}

Limitations and futures studies

There is a major limitation of our report. Validity is usually determined by comparing the results of a new test against a criterion standard. Unfortunately, there is no pathoanatomical criterion standard in the case of nonspecific LBP.³ Furthermore, in the present study, the patient's own report of pain was used during pain provocation tests because verbal response during manual diagnosis has previously been validated in unilevel lumbar spinal block procedures.³⁷ This approach may constitute an important limitation of internal validity, but because the method is easily transferable to a clinical context, it provides substantial external application. Nevertheless, a recent study highlights the interest of epiduroscopy as an external reference to help diagnose the vertebral level of pain in people with LBP, but this invasive investigation may be beyond the reach of most manual therapy research.⁴²

A further limitation of our study was that we mainly assessed for flexion and extension pain provocation patterns. Combined movements evaluation typically seek to identify other patterns of pain provocation (i.e., lateral flexion left and right combined with flexion or extension).

Future studies could investigate the reliability of these patterns. Moreover, owing to the impossibility of blinding patients to the clinical examination and the consequential potential Hawthorne effect, patients' verbal response to pain provocative tests may have been influenced.

In manual therapy, there are various concepts for the management of LBP including MK,¹⁶ Maitland,^{30,34} Mulligan,⁴⁷ and various forms of spinal manipulation among others with different mechanisms of action.^{26,30,48-52} Even if the principles of treatment vary from one method to another, the underlying principles of manual therapy are to reduce pain. It is essential that the treatment, regardless of the concept, is performed on the basis of a reliable and valid clinical examination protocol aimed to correctly classify LBP. The results of the current study using pain provocative tests provide confidence that aspects of CCR examination used in this study are valid and reliable and can therefore be used in clinical practice to direct patient management. Nevertheless, future studies are needed to confirm the value of this examination protocol. Future studies should integrate more patients with different LBP disorders (e.g., in acute and chronic phases) and with more examiners.

Conclusion

This study demonstrated that the use of the CCR (3 positive criteria arising from active and passive pain provocative tests) was found to have good interexaminer reliability and validity to identify the most provocative lumbar spine movement direction as well as the lumbar segmental levels of involvement.

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CHAPTER VI

Short-term effects of Mulligan mobilisation with movement on pain, disability and kinematic spinal movements in patients with nonspecific low back pain: A randomised placebo controlled trial

Benjamin Hidalgo, Laurent Pitance, Toby Hall, Christine Detrembleur, Henri Nielens

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ABSTRACT

Objective: To determine the efficacy of lumbar Mulligan sustained natural apophyseal glides (SNAGs) in patients with nonspecific low back pain (LBP) with respect to two new kinematic algorithms (KA) for range of motion (KA-R) and speed (KA-S) as well as pain, functional disability, and kinesiophobia.

Methods: This was a randomized placebo controlled trial with two arms in accordance with CONSORT-guidelines. 87 subjects with nonspecific LBP were assessed and 32 fulfilled criteria for the application of lumbar SNAGs. Subjects, blinded to allocation, were randomized to 2 groups; real-SNAG (n = 16) and sham-SNAG (n = 16). All patients were treated during a single-session of real/sham SNAG (3 X 6 repetitions) to the lumbar spine in a sitting position in a flexion direction. Two new KA from a validated kinematic spine model were used and recorded with an optoelectronic device. Pain at rest and during flexion, as well as functional disability and kinesiophobia were recorded by self-reported measures. These outcomes were blindly evaluated before, after treatment, and at 2-week follow-up in both groups.

Results: 4 of 6 variables demonstrated significant improvement with moderate to large effect-sizes (ES) in favor of the Real-SNAG group: KA-R ($p=.014$; between groups ES Cliff's $\delta=-.52$), pain at rest and during flexion (VAS: $p<.001$; ES $=-.73/--.75$), functional-disability (Oswestry Disability Index: $p=.003$ and ES $=-.61$). Kinesiophobia was not considered to be significant (Tampa scale: $p=.03$) but presented moderate effect size ES $=-.46$. KA-S was not significantly different between groups ($p=.12$) with a small ES of $-.33$. All the 6 outcome measures were

significantly different ($p \leq .008$) during within group analysis (before and after treatment) only in the Real-SNAG group. No serious or moderate adverse events were reported.

Conclusion: This study provides evidence that lumbar spine's SNAGs have a short-term favorable effect on KA-R, pain and function in a targeted group of patients with nonspecific LBP. Further studies are required to validate these findings and to further investigate kinesiophobia and KA-S, as well as the long-term effects of SNAGs for LBP.

Introduction

Low back pain (LBP) is one of the most common musculoskeletal disorders for which patients consult medical care.¹ It is also the most important cause of disability and absenteeism with increasing prevalence leading to a major socio-economic impact on society.²⁻⁴ These facts highlight the importance of finding effective and validated treatments for this disabling condition.

Two broad categories of LBP are recognised. When a specific patho-anatomical origin is identified such as a tumor or fracture, LBP is labelled as specific and requires appropriate medical care such as specific medication or surgery. On the other hand and more commonly, in up to 90% of cases no precise specific origin for pain can be identified; such LBP is consequently described as nonspecific.¹

LBP is managed by a variety of treatment modalities^{5,6} including Orthopaedic Manual therapy (OMT). This form of treatment has been recommended in national guidelines, for example in the United States,⁷ and is also frequently used in clinical practice in various countries.^{8,9} As demonstrated by recent systematic reviews, OMT management combined with usual medical care provides better results as compared to usual medical care alone for all stages (acute/sub acute or chronic) of LBP.^{7,10}

A novel growing concept in the field of OMT and clinical practice, which remains sparsely studied in the literature, is "Mobilisation With Movement" (MWM),¹¹⁻¹³ originally developed by Mulligan.¹¹ The main indication for MWM is movement impairment due to pain and/or stiffness. The therapeutic goal is to rapidly reduce pain and to increase range of motion (ROM). The principle of this treatment is simple, in that the manual therapist performs a sustained passive segmental glide of the involved joint, while the patient actively moves in the impaired direction.¹¹⁻¹³ Mulligan^{11,12} purported a biomechanical basis for the efficacy of MWM in reducing pain and improving ROM, but there may be other explanations for their effects including neurophysiological mechanisms. Mulligan MWM techniques can be applied to both peripheral and spinal joints. When applied to the spine, MWM are called Sustained Natural Apophyseal Glides (SNAGs).¹¹⁻¹³ The current study focuses on SNAGs and their effects on the lumbar spine.

It has been reported that many physical therapists in the UK manage their patients with LBP by using SNAGs as a part of their physical intervention.¹⁴ This is despite the poor level of evidence, through lack of clinical studies, for the efficacy of lumbar SNAGs for LBP.¹⁵ Indeed, only three studies reported on the effects of lumbar SNAGs,¹⁶⁻¹⁸ with only 2 investigating the biomechanical effects.^{16,17} The first, a placebo controlled trial¹⁶ was carried out on 49 asymptomatic subjects. SNAGs were applied during flexion in sitting at 2 lumbar levels by an experienced examiner in a single session and failed to demonstrate an increase in lumbar ROM

measured by a 3-dimensional electro goniometer. In contrast, the second placebo controlled trial¹⁷ investigated 26 people with LBP during flexion and who were suitable for SNAGs, recording ROM using double inclinometry. A single session of SNAGs demonstrated a significant increase of 7° lumbar flexion ROM greater than placebo, but no change in pain scores. Obviously, in view of the paucity of literature regarding lumbar SNAGs, and in comparison with its widespread clinical use, further investigations are necessary to study lumbar SNAGs' efficacy, as well as indications when used for people with LBP.

Recent studies from our research team^{3,19,20} have investigated spine kinematics in people with LBP using an optoelectronic measurement system. A kinematic spine model was developed where the shoulder girdle and spine were divided into 6 segments: shoulder girdle, upper thoracic and lower thoracic spine, upper and lower lumbar spine, and the last segment comprising the whole lumbar spine (combining the upper and lower lumbar spine segments). Each segment was considered to be rigid and homogenous. Kinematic variables speed and ROM were evaluated during movement in all planes. ROM and speed variables showed a highly significant difference ($p < 0.001$) between healthy subjects and those with chronic non-specific LBP in all spinal segments during flexion and combined movements. These studies provided evidence for the validity of the kinematic spine model in distinguishing people with LBP.

From our previous studies, two new kinematic algorithms ROM (KA-R) and speed (KA-S) were identified as having a potential interest in future clinical studies addressing the effectiveness of OMT interventions applied to the spine in ways other than simply looking at the effects on pain and disability.^{19,20} Moreover, it has been proposed that future clinical studies should target their interventions on a more homogeneous subgroup of patients with LBP to improve clinical outcomes, as well as effect sizes for outcome measures.¹⁰

Based on these findings, we used the kinematic spine model to assess whether lumbar SNAGs were able to improve the kinematic features of trunk movement in a targeted group of subjects with LBP. The main goal of this clinical study was to compare the immediate and short-term effects of a single session of SNAG to a sham SNAG (placebo) treatment applied to the lumbar region, on 2 primary outcome measures, kinematics (KA-R and KA-S), and 3 secondary outcome measures; pain, function, and kinesiophobia in a subgroup of people with LBP. The hypothesis were that outcomes would be more favorable in the real SNAG intervention for primary and secondary outcome measures during between groups analyses, with additional improvements expected within each group over time.

Method

Design

This study was a single-center (Cliniques Universitaires Saint-Luc, Brussels, Belgium), prospective, randomised and placebo-controlled trial with two arms and with blinded patients and evaluator. The design of this clinical trial followed the recommendations of the CONSORT statement.²¹ The study was approved by the local ethic committee board of the University of Louvain (UCL) and was registered in ClinicalTrials.gov : NCT02128607.

Subjects

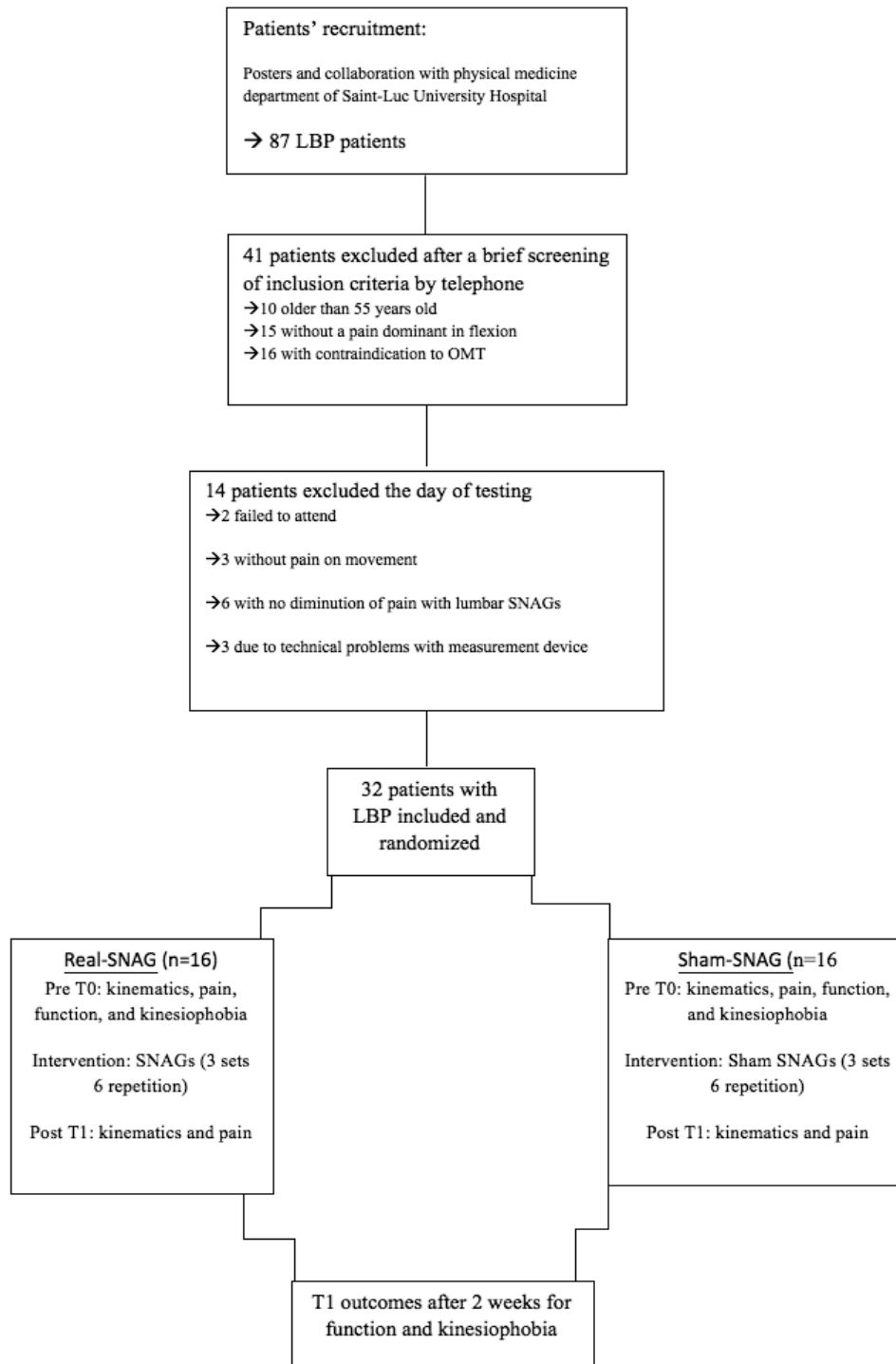
Eighty-seven people with LBP were initially recruited from "Cliniques Universitaires Saint-Luc". Of these, thirty-two were included in the study based on specific criteria. Stratification based on pain mechanisms has been previously recommended.²² These criteria were combined with indications for the application of lumbar SNAGs.^{11,12} The inclusion criteria were subjects aged between 20 and 55 years, who complained of LBP mostly provoked by trunk flexion at any stage (acute to chronic), which did not radiate lower than the knee. The subjects were selected where lumbar flexion was the most provocative movement using a standardized physical examination method aimed to identify lumbar pain provocative movement patterns using active and passive accessory movement tests.²³ Finally, the pain associated with trunk flexion had to be reduced by the application of a central lumbar SNAG applied through the spinous process. Patients were excluded if they presented with any known contraindication to OMT (e.g. tumor, fracture, osteoporosis, infection, rheumatic diseases, or herniated disk).

Thirty-two people with LBP were included in the trial and were randomly distributed in two arms: one group receiving the lumbar SNAG treatment (n = 16) and the other receiving a sham lumbar SNAG (n = 16). Randomization was performed by stratified randomization with blocks of random numbers under sealed opaque envelopes previously prepared, in a fashion of 4 subsets, each subset containing 8 envelopes, aimed to balance the stages of LBP for each group during the process of the study.

Material and outcome measures

The outcome measures were trunk ROM and speed, as well as pain at rest and during trunk flexion just before and just after a single session of treatment. The impact of the intervention at very short-term (2 weeks) on functional disability and kinesiophobia was also evaluated. Six variables were assessed before (T0) and after treatment (T1) (Figure 1). The same examiner blindly assessed all the following outcome measures.

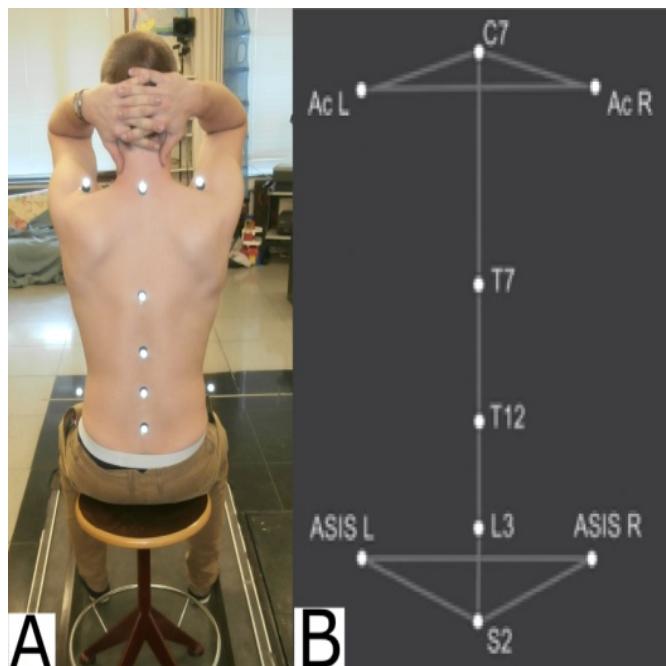
Figure 1. Flow chart of the study process



Kinematic measures

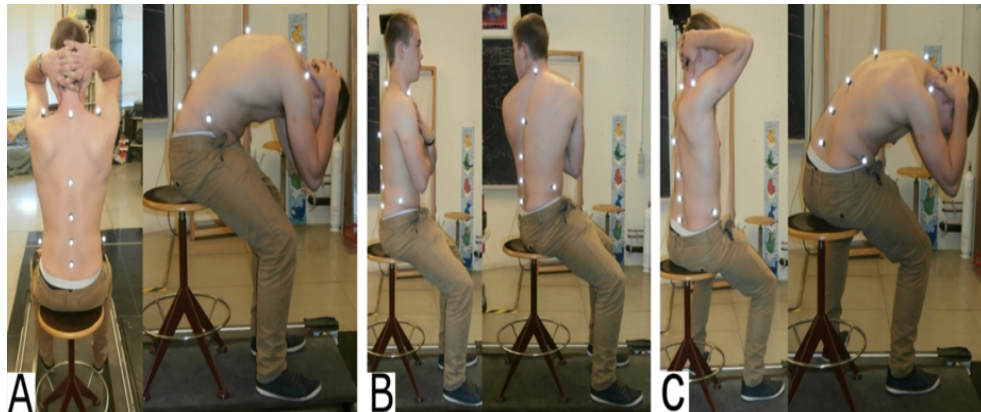
Kinematic variables were the primary outcome measures and were evaluated using an optoelectronic device (Elite-BTS) composed of eight infrared cameras capable of recording the 3D-positions of 9 reflective markers placed on bony landmarks on the trunk according to a validated kinematic spine model,^{19,20} at a frequency of 200 Hz and accuracy of 0.1 mm. This model (Figure 2) sub-divides the shoulder girdle, spine and pelvic girdle into various segments. The test procedure and recording conditions have been described previously.^{19,20} Briefly, trunk movements were assessed in a sitting position; trunk flexion, left and right rotation, and combined movement of trunk flexion associated with left and right rotation of the pelvis (Figure 3). Each trunk movement was performed and recorded 10 times.

Figure 2. The kinematic model of the spine



(A): Position of the patient and the nine reflective markers, (B): kinematic spine model and segments: pelvic girdle (ASIS L-S2-ASIS R); low lumbar spine (S2-L3); high lumbar spine (L3-T12); total lumbar spine (S2-T12); low thoracic spine (T12-T7); high thoracic spine (T7-C7); shoulder girdle (Ac L-C7-Ac R)

Figure 3. Trunk motion tasks



(A) starting position and trunk flexion, (B) starting position and Left / Right rotation, (C) starting position and combined movement of trunk flexion with pelvic rotation to the left / right.

A binary logistic regression analysis had previously determined segments and trunk movements of the kinematic spine model that were the most discriminant for LBP.^{19,20} The final results were two kinematic algorithms, one for ROM (KA-R) and one for speed (KA-S) according to the following equations (see^{19,20} for more information):

$$\text{KA-R} = 17.77 - (0.074 \times \text{LTS}^\circ) - (0.11 \times \text{SS}^\circ) - (0.059 \times \text{TLS}^\circ)$$

$$\text{KA-S} = 6.19 - (0.063 \times \text{TLS}^\circ/\text{s})$$

Where KA-R, kinematic algorithm for ROM; LTS[°], lower thoracic spine ROM in flexion; SS[°], shoulder segment ROM in right rotation; TLS[°], total lumbar spine ROM in flexion with left rotation; KA-S, kinematic algorithm for speed; TLS[°]/s, total lumbar spine speed in flexion with right rotation.

Self-reported measures

Self-reported measures were the secondary outcome measures. Pain at rest (present pain), as well as pain during trunk forward bending from a standing position was recorded using a 10 cm visual analogue scale (VAS) just before and just after the intervention. Functional disability was

assessed with the use of the Oswestry Disability Index (ODI) before intervention and 2 weeks after. The score was expressed in percentage terms (%). Kinesiophobia was assessed with the Tampa scale.

Intervention

First through a standardized clinical examination incorporating combined movements evaluation,²³ the examiner determined if the patient had greater pain during active trunk flexion than extension, as well as the most painful vertebral level (with passive accessory intervertebral movements). This combined movements examination procedure has previously been described and validated to identify the most painful pattern of trunk movement, as well as the lumbar segmental level(s) involved.²³

Secondly, the evaluator determined whether the patient responded positively to a seated lumbar SNAG applied through the spinous process of the involved vertebra.¹³ To do this, the examiner had four attempts to increase ROM and reduce pain by at least 2/10 on the VAS. As recommended,¹³ the evaluator applied the SNAG on the spinous process of the vertebra that was the most painful during combined movements examination. Glide force was applied parallel to the apophyseal articular surface (cranial direction). If the effect obtained was not sufficient, the examiner was allowed to vary the intensity and/or direction (vector of applied force) of the SNAG. In addition, the evaluator could change the central vertebral level of lumbar SNAG application.¹³ If, after four trials, the SNAG application did not provide the desired effect, the patient was excluded from the study (Figure 1).

In both groups, during the treatment, the patient was placed in a standardized seated position (hips and knees in 90° flexion) on a table with feet supported, stabilized with a belt around the waist (Figure 4).^{11,16} Three sets of six repetitions were performed in the Real-SNAG and sham (placebo) intervention. A single inexperienced physiotherapist (novice in the use of SNAGs) applied the treatment procedure in both groups and was therefore not blind to the patient's group allocation. Both the treating therapist and evaluator were trained for 16 hours to ensure correct application of the study protocol by two experienced manual therapists.

In the Real-SNAG group, the therapist followed published guidelines for SNAG application.¹¹⁻¹³ The therapist applied a gliding force with the hypothenar eminence placed on the spinous process of appropriate lumbar vertebral level while the patient performed the limited trunk flexion movement until onset of pain before returning to the starting position (Figure 4). The cranial glide force was maintained throughout all the movement in both direction (forward

bending and back from bending) and with each repetition. Communication was maintained with the patient to ensure that no pain was felt during the treatment.

In the Placebo group, the Sham-SNAG intervention replicated the same procedure used in a previous study.¹⁶ The technique mimicked the Real-SNAG, only with two differences: the therapist placed his hypothenar eminence on the spinous process of the above vertebral level and applied minimal glide force in a caudal direction.

Figure 4. SNAGs application from a sitting position



Standardised position of the patient and therapist showing the belt placement during the application of the real and sham lumbar SNAG

Statistical analysis

Statistical analysis was carried out using SigmaStat 3.5. Estimation of the required sample size was calculated on the basis of the Minimal Detectable Change 95% (MDC95) of the primary outcome measure (KA-R and KA-S)²⁰ with a desired power of 0.80 and an alpha level of 0.05; we obtained an estimation of the required sample size for each group to be 16 patients. Similarity of baseline measures between groups (T0) was assessed using a Student T-test. Our main hypothesis was the comparison between the groups for primary kinematic outcome

measures and for self-reported outcome measures. We used Mann-Whitney Rank Sum Test on the means of difference (T0-T1) of the Sham and Real group for statistical evaluation as the majority of the variables failed to demonstrate a normal distribution. We performed a specific alpha correction for inflated type-1 error with null hypothesis rejection using a Bonferroni correction. For primary outcome kinematic measures (KA-R and KA-S), this correction was 0.05/2, indicating $p < 0.025$ was the required level for significance. For the secondary self-reported measures (VAS rest, VAS flexion, ODI, TAMPAs) the correction was 0.05/4, indicating $p < 0.0125$ was the required level for significance. The clinical effect size for between groups analysis was evaluated with a non-parametric effect size, Cliff's delta.²⁴ This score can range from -1 to 1; where 1 indicates all observations from the sham-SNAG group are greater than all observations from the real-SNAG group. Conversely, -1 indicates that all observations from the sham-SNAG group are less than all observations from the real-SNAG group. Finally, 0 indicates perfect overlap, with equality of observations between the groups.²⁴ Cliff's delta is calculated with R software and are presented with a confidence interval (CI) of 95% and categorized in small, moderate, large, and very large effect sizes.²⁴ We also ran an exploratory analysis for the secondary within-group hypothesis (between baseline and final evaluation) in the sham and real-SNAG group following the same statistical method described above but with a Wilcoxon Signed Rank Test.

Results

The number of patients included and excluded, as well as the reasons of exclusion during the process of the study is reported in Figure 1. Anthropometric data and variable outcomes at baseline of included patients are described in Table 1. The period of participants enrollment was from February 2014 until June 2014, the end of follow-up was July 2014. The trial was ended in July 2014 because the required sample size was reached.

Table 1. Anthropometric data and outcome variables at baseline

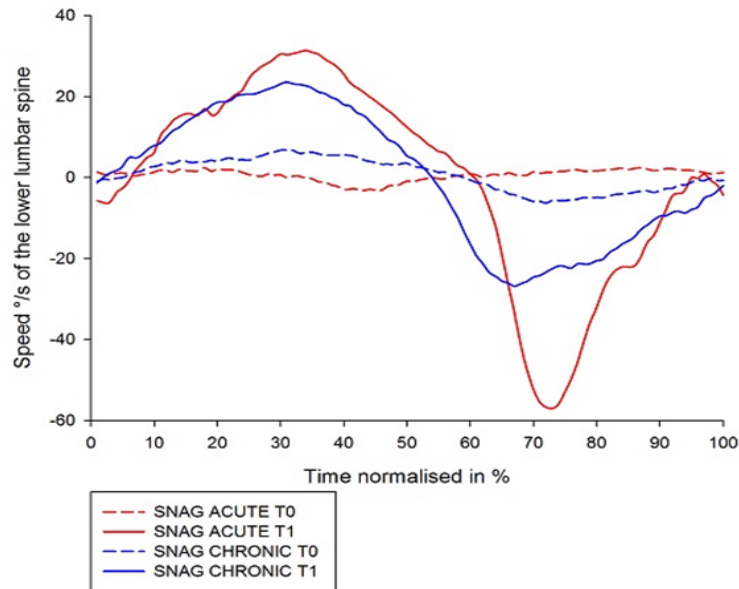
	Sham-SNAG (n=16)	Real-SNAG (n=16)
Male / Female	7/9	9/7
	Means (SD)	Means (SD)
years	40.7 (10.2) ^{NS}	37.8 (9.7)
BMI (kg/m ²)	25.1 (3.3) ^{NS}	24.1 (2.6)
LBP duration (months)	19.7 (19.4) ^{NS}	21.0 (21.2)
KA-R (T0)	3.5 (2.9) ^{NS}	4.9 (3.2)
KA-S (T0)	2.1 (1.4) ^{NS}	2.4 (1.9)
VAS at rest (present pain) T0	2.5 (1.7) ^{NS}	3.0 (1.8)
VAS flexion (pain in trunk flexion) T0	5.1 (1.6) ^{NS}	5.6 (1.8)
ODI (T0)	22.9 (10.7) ^{NS}	22.4 (12.2)
Tampa scale (T0)	42.1 (6.2) ^{NS}	43.7 (6.3)

BMI: body mass index; KA-R: kinematic algorithm for range of motion; KA-S: kinematic algorithm for speed; T0: baseline; VAS: visual analogue 10 cm scale; ODI: Oswestry disability index; NS: non-significant difference between groups with Student T-test.

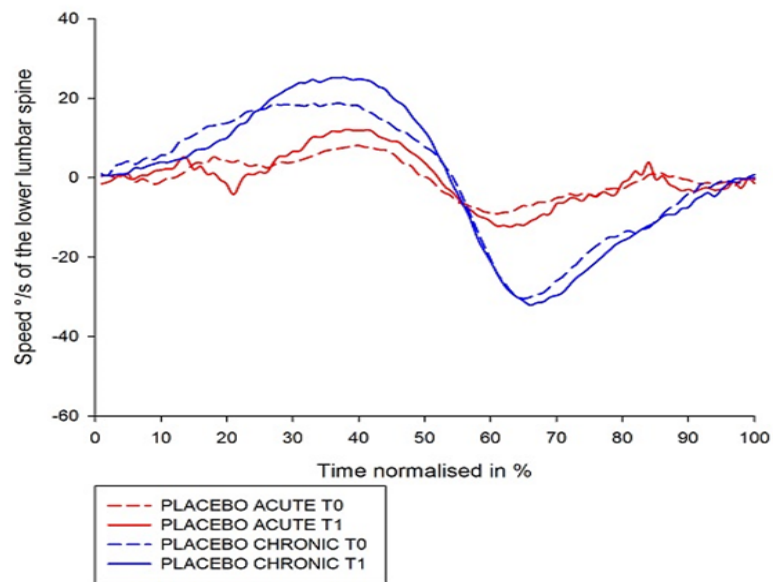
Subjects with non-specific LBP included in this study had a mixed pain history: 63% were chronic, 21% acute, and 16% sub acute. No significant differences on outcome measures were present at baseline between groups (Table 1). No serious or moderate adverse events were reported in either group during the study.

The graph of speed curves (°/s) of the lower lumbar spine segment during trunk forward bending in one typical acute LBP patient and one typical chronic LBP patient from the Real-SNAG (Figure 5A) and Sham-SNAG (Figure 5B) group is presented in figure 5.

Figure 5. Typical speed curves before and after intervention



A: Speed curves of the lower lumbar spine segment (S2-L3) during trunk forward bending before (baseline) and after (final evaluation) Real-SNAG for one typical (best responder) acute LBP patient (red curve) and one typical chronic LBP patient.



B: Speed curves of the lower lumbar spine segment (S2-L3) during trunk forward bending before (baseline) and after (final evaluation) Sham-SNAG for one typical (best non-responder) acute LBP patient (red curve) and one typical chronic LBP patient.

Between groups comparison

Primary kinematic outcome measures

KA-R demonstrated a significant difference ($p<.025$) in favor of the Real-SNAG group with large clinical effect size ($p=.014$ and $ES=-.52$). In contrast, KA-S demonstrated no significant difference ($p>.025$) with only small clinical effect size ($p=.118$ and $ES=-.33$).

Secondary self-reported outcome measures

Pain (VAS) at rest and during lumbar spine flexion demonstrated a significant difference ($p<.0125$) in favor of the Real-SNAG group with large clinical effect size ($p=.001$ and $ES=-.73$; $-.75$). Functional disability (ODI) also demonstrated a significant difference ($p<.0125$) in favor of the Real-SNAG group with large clinical effect size ($p=.003$ and $ES=-.61$). In contrast, there was no significant difference between groups for Kinesiophobia (Tampa scale) ($p>.0125$), with only a moderate clinical effect size favoring the real-SNAG group ($p=.03$ and $ES=-.46$).

Table 2: Between groups analysis on primary kinematic and secondary self-reported outcome measures

Outcome measures	Sham-SNAG (n=16)	Real-SNAG (n=16)	p-value	Effect size (Cliff's Delta) with confidence interval (CI95%)
	Median (interquartile range)	Median (interquartile range)		
KA-R	0.05 (-0.73 : 0.59)	-0.88 (-2.91 : -0.44)	.014*	-.52 (-.77 : -.12)
KA-S	-0.05 (-0.88 : 0.63)	-0.65 (-1.45 : -0.03)	.118	-.33 (-.65 : .09)
VAS rest	0 (0 : 0.5)	-1 (-2 : -1)	<.001#	-.73 (-.91 : -.35)
VAS flexion	0 (-1.5 : 0)	-3 (-3 : -1.5)	<.001#	-.75 (-.90 : -.44)
ODI	0 (-2 : 2)	-5 (-8 : -1)	.003#	-.61 (-.83 : -.23)
TAMPA	0 (-2 : 1)	-6 (-9.5 : -0.5)	.03	-.46 (-.76 : .01)

KA-R: kinematic algorithm for range of motion. KA-S: kinematic algorithm for speed. VAS rest: visual analogue scale (pain) at rest. VAS flexion: visual analogue scale (pain) during trunk flexion. ODI: Oswestry Disability Index (functional disability). TAMPA: TAMPA scale for kinesiophobia. * Significant difference between groups, corrected level of $p<0.025$ for primary kinematic outcome measures (KA-R and KA-S). # Significant difference between groups, corrected level of $p<0.0125$ for secondary self-reported outcome measures.

Within group comparison (secondary explanatory hypothesis)

Primary kinematic outcome measures

KA-R and KA-S before and after the intervention improved significantly in the Real-SNAG group (respectively: $p=.001$; $p=.008$) but not in the Sham-SNAG group (respectively: $p=.86$; $p=.63$).

Secondary self-reported outcome measures

There were significant improvements in the real-SNAG group for all secondary outcome measures following the intervention. Pain (VAS) at rest and during lumbar spine flexion before and after intervention improved significantly in the Real-SNAG group ($p<.001$) but not in the Sham-SNAG group (respectively $p=.56$; $p=.15$). Functional disability (ODI) before and 2-weeks after the intervention improved significantly in the Real-SNAG group ($p=.002$) but not in the Sham-SNAG group ($p=.84$). Kinesiophobia (Tampa scale) before and 2-weeks after the intervention improved significantly in the Real-SNAG group ($p=.004$) but not in the Sham-SNAG group ($p=.23$).

Table 3: Within group analysis before and after treatment

Outcome measures	Sham-SNAG (n=16)			Real-SNAG (n=16)		
	Median (interquartile range) at T0	Median (interquartile range) at T1	P-value	Median (interquartile range) at T0	Median (interquartile range) at T1	P-value
KA-R	3.28 (1.36-6.41)	3.69 (0.82 : 5.81)	.86	4.85 (2.56 : 7.23)	2.44 (-0.57 : 5.32)	.001*
KA-S	2.27 (0.65-3.42)	1.68 (0.87 : 2.72)	.63	2.59 (0.66 : 4.14)	1.09 (-0.12 : 2.63)	.008*
VAS rest	2 (1.5-3.5)	2 (1.5 : 4)	.56	3 (1 : 4)	1.5 (0.5 : 3)	<.001#
VAS flexion	5 (4-6)	4 (3-5 : 5)	.16	5.5 (4 : 6.5)	3 (2 : 4)	<.001#
ODI	20 (16-27)	20 (17 : 27)	.84	21 (13 : 34)	14 (12 : 25)	.002#
TAMPA	41 (38-45)	41.5 (36.5 : 45)	.23	44 (40 : 50)	38.5 (34.5 : 42.5)	.004#

KA-R: kinematic algorithm for range of motion. KA-S: kinematic algorithm for speed. VAS rest: visual analogue scale (pain) at rest. VAS flexion: visual analogue scale (pain) during trunk flexion. ODI: Oswestry Disability Index (functional disability). TAMPA: TAMPA scale for kinesiophobia. * Significant difference between baseline and final evaluation within groups, corrected level of $p<0.025$ for primary kinematic outcome measures (KA-R and KA-S). # Significant between baseline and final evaluation, corrected level of $p<0.0125$ for secondary self-reported outcome measures.

Discussion

Our results suggest substantial improvements favoring lumbar SNAG's as compared to placebo for KA-R, pain at rest and during trunk flexion, as well as for functional disability. In contrast, KA-S and kinesiophobia showed no significant difference between groups. Despite this, within group explanatory analysis demonstrated highly significant differences in all outcome measures before and after intervention only in the real-SNAG group.

It may be hypothesised that a larger sample size may have resulted in significant differences between groups for KA-S also. However, our prospective calculation of sample size provided an estimate of 16 patients within each group for kinematic outcome measures. With such a small sample, the statistical effect of possible atypical responses is greater. Indeed, almost all patients from our sample (80%) improved their speed (KA-S) in both groups after the intervention. However, a small percentage (20%) of subjects demonstrated the opposite response, and decreased speed during trunk-movements after lumbar real and sham SNAG therapy. Moreover, the mix of different stages of LBP included in our sample, from acute to chronic, is another factor that may explain the observed non significant between groups effect on KA-S.

When comparing the current results to previous studies reporting on the effects of Mulligan techniques, most of them have investigated the effects of MWM on peripheral joints²⁵⁻³⁰ or on the cervical spine.³¹⁻³³ However, there are few published reports investigating effects with respect to the lumbar spine. Indeed, only two studies have addressed the effects of lumbar SNAGs on ROM and pain. The first study,¹⁶ a placebo controlled trial, showed no-significant improvement in active trunk flexion ROM after lumbar SNAGs in asymptomatic people. However, it is problematic to compare those results in asymptomatic people (where the SNAG technique could not be applied according to the technique guidelines¹¹⁻¹³) with the present study on people with LBP. The second study,¹⁷ investigated patients with LBP and showed a significant increase in trunk flexion ROM, but no significant reduction in pain after the application of lumbar SNAGs. Our results show that lumbar SNAGs reduced pain at both rest and during active trunk flexion, and also increased trunk ROM. The effectiveness of SNAGs was not limited to just pain reduction and improved ROM, but also to improved functional disability and kinesiophobia in people with LBP. However, long-term effects were not analyzed in this study. It would be interesting to analyze long-term effects of lumbar SNAGs in future studies.

In the study of Konstantinou et al.,¹⁷ the placebo was a passive modality (patient lying on the table). The authors made this choice in order to avoid the influence of an active placebo on the quality of trunk movement probably because repeated active spinal movements could be considered as a self-treatment for LBP.^{34,35} However, the authors could not distinguish the

possibility that patients in the SNAG group have improved only through repetition of movements rather than SNAG technique application. Moreover, an active placebo as in our study mimicked as closely as possible a real treatment. In our protocol, the same total number of active trunk movements was performed in both groups, in order to distinguish the effect of real and sham SNAGs from the simple effect of repeated active trunk movements.

The exact mechanism of potential action for lumbar SNAGs is not known as no studies have yet investigated this. However, there are proposed biomechanical and neurophysiological mechanisms. Biomechanically, there are some similarities between postero-anterior mobilisation (PA) undertaken in prone lying and a SNAG. Lee and Evans³⁶ reported that a PA on the L5 spinous process induced anterior translation of the L5 vertebra and flexion at the L5-S1 segment. The biomechanical effects of a lumbar SNAG may be enhanced by the cranial direction of the glide along the facet joint plane, together with the active trunk movement. Another proposed mechanism of action may be through correction of a positional fault. Mulligan hypothesized that lack of normal facet gliding in flexion may distort the disc^{11,12} and provoke pain. Hence improving facet gliding may normalize forces on the disc, relieving pain.

Zusman^{37,38} has described a rationale for the pain relief provided by manual therapy based on the theory of extinction and habituation. Pain may be considered as a form of aversive memory that once present could be more and more easily recalled. Behaviorally, a conditioned fear response may be reduced in intensity through extinction, a form of learning characterized by a decrease in a conditioned response when the conditioned stimulus that elicits it is repeatedly non-reinforced^{37,38} such as might occur during SNAGs. In our sample of people with LBP, trunk flexion was the most painful movement. The real SNAG intervention provided exposure to the painful movement in the absence of any overt danger, which is fundamental to interventions used in the extinction of aversive memories,^{37,38} but this was not the case for the sham SNAG intervention. Progressive mobilization may also desensitize the nervous system through habituation. The mechanism involves a progressive decline in the ability of the presynaptic nerve terminal to transmit impulses. In the subjects from this study, non-noxious sensory input from the repeated real lumbar SNAG may have competed with and replaced pain sensitization, returning the nervous system to a normal state.³⁸

There may be various mechanisms of action for lumbar SNAGs at different stages of LBP. In our sample there was a mix of stages, with the majority being chronic in nature. As we have discussed, SNAGs may have neurophysiological as well as mechanical effects, which may have implications for acute and chronic LBP. However, it is beyond the scope of this study to identify the mechanisms underscoring the positive changes seen from SNAGs.

These proposed mechanisms of action described here might explain the significant difference observed on outcome measures in favor of real SNAG interventions. However, for

Kinesiophobia there was no significant difference for between groups analysis after Bonferroni correction despite significant improvement in the real-SNAG group for within group analysis. This might be explained by the nature of the sham intervention in which the subjects were still exposed to the painful stimulus during trunk flexion, and thus, may maintain a conditioned fear response. Moreover, another often-debated issue is the quality of the placebo procedure used in physical therapy trials because that might explain the results in favor of the real intervention. Placebo in manual therapy and in non-pharmacological trials is still a very complex issue to address since a good quality placebo needs to mimic as closely as possible the real intervention without its specific effect with patients still believing that they have received the real treatment.¹⁰

Limitations and futures studies

There are several potential limitations to this study's findings. One is the limited clinical experience of the treating therapist in the use of SNAGs that may have influenced the effectiveness of the intervention.^{39,40} However, SNAGs are simple techniques that require minimal training, so this is not believed to be a substantial factor in the outcome of the technique. Moreover, some caution is required when interpreting the outcome measures in favor of the real SNAG group, as the 95% CI covers a wide range of possibilities in terms of effect size. Finally, a potential bias could be present during the initial selection of patients as they were required to respond positively to the SNAG application, before inclusion and randomization to one of the groups. This procedure may have the potential to subconsciously inform the patients of the real SNAG effects during the selection. However, this procedure is consistent with the widespread recommendations of stratification of care for LBP patients,^{10,22} as well as the integration of the clinical reasoning in manual therapy trials.^{10,15,22,37,39}

To corroborate the positive changes of lumbar SNAGs seen in this study, future studies should further investigate the effects on speed of trunk-movements and kinesiophobia, long-term efficacy, and possible mechanisms of action. Moreover, correlations between primary kinematic outcomes measures and secondary clinical outcome measures should be investigated. Finally, more studies are required to identify potential responders to validate the clinical application of this form of manual therapy.

Conclusion

This is the first randomised placebo controlled trial that has investigated the short-term effects of lumbar SNAGs on two new kinematic algorithms of trunk movements (KA-R and KA-S), as well as pain, functional disability and kinesiophobia in patients with non-specific LBP. While the results show a significant improvement in KA-R, pain, and functional disability in favor of lumbar SNAGs, some caution is required when interpreting these data, as the 95% CI covers a wide range of possibilities in terms of clinical effect size. Hence this study provides preliminary

evidence that lumbar SNAGs have immediate and short-term efficacy in the treatment of a targeted group of patients with nonspecific LBP.

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GENERAL DISCUSSION AND CONCLUSIONS

The evidence-based model and practice of patient care have received much attention. However, there are some criticisms of EBM use by healthcare clinicians, teachers and researchers around the world. For example, the authors of the paper '*Evidence based medicine: a movement in crisis?*'¹ argue that it is now more than 20 years since the EBM Working Group announced a **new paradigm** for teaching and practicing medicine. It was suggested that tradition and theoretical reasoning from basic sciences would be replaced by evidence from high-quality RCTs and observational studies, in combination with clinical expertise and the needs of patients. Many people who supported EBM in principle at that time have argued that the movement is currently facing a serious crisis. Several reasons have been cited for this crisis, including the following: the evidence-based quality mark has been misappropriated by conflicts of interest^r, the volume of evidence and clinical guidelines have become unmanageable^s, statistically significant benefits may be marginal in clinical practice, inflexible rules and technology-driven prompts may produce care that is management-driven rather than patient-centred^t, and evidence-based guidelines often map poorly to complex multimorbidity^u.¹

Some authors have proposed changes to the EBM paradigm to create 'real EBM', in which the ethical care of the patient is a top priority, evidence is individualised in a format that clinicians and patients can understand (based on expert judgment rather than mechanical rules), and decisions are shared through meaningful conversations in the context of a humanistic and professional **strong clinician-patient relationship**.¹ Moreover, in all educational fields, including university settings and postgraduate continuing education, the EBM model should be incorporated into an integrated curriculum that promotes reflection, criticism and **clinical reasoning** of cases alongside the application of evidence to fit an EBP approach.

1. FROM SECTION 1

Section 1 presents the results of a systematic review of available evidence regarding the efficacy of OMT in patients with NSLBP, in terms of pain, function, disability and overall health. This review covers a wide range of the ICF domain for LBP in terms of body structures, body

^r Such as: bias from the authors due to financial supports and interests and/or philosophical beliefs

^s Particularly for LBP, as it is a multidimensional and a complex disorder

^t Application of clinical prediction rules for spinal manipulation and stabilisation for LBP patients may not correspond to patients' expectations

^u Complex chronic NSLBP patients, who often have comorbidities, e.g. depression, obesity, fibromyalgia, irritable bowel syndrome and urinary incontinence

functions, activities and participation. Previous systematic reviews have frequently recommended studies of the **cost-effectiveness** (an environmental factor in the ICF model) of the use of OMT to manage musculoskeletal disorders. A recent systematic review addressed this topic and found limited evidence in favour of the economic advantage of passive OMT techniques, combined or not with other interventions, compared to classical unidimensional interventions (i.e. usual medical care, spinal stabilisation and advice to stay active).²

1.1. Design of clinical studies in an EBM model

Lumping^v and splitting^w research designs are two important processes for improving the methodology of RCTs. The **splitting design** is a patient-centred approach that closely follows the normal clinical practice of complex intervention within an EBP approach. This design is recommended because the way by which different therapies (e.g. general exercise vs. specific exercise in patients with chronic LBP) obtain similar results is not always understandable. Moreover, there is growing evidence of the considerable heterogeneity among patients diagnosed with the same medical condition (i.e. NSLBP).³

Interest in and evidence for subdividing/splitting patients into meaningful groups has been discussed with the presentation of an integrative approach to care for LBP. Future observational or clinical studies should present data based on the identification of patient subgroups, using stratification of care with classification systems (i.e. based on risk, pain mechanisms and treatment responsiveness). All classification systems from the integrative approach have demonstrated sufficient reliability and validity to be used in future studies of physical therapy. Targeted OMT for specific subgroups using merged classification systems should be useful for patients (Table 1). Such an integrative approach is consistent with the latest evidence. As developed in the first chapter, there is a moderate level of evidence regarding the short-term efficacy of combining spinal mobilisation/manipulation with directional exercises compared to traditional medical care for pain, function and health improvements in acute-subacute NSLBP.⁴ In the case of chronic NSLBP, there is moderate evidence that spinal mobilisation/manipulation combined with exercises or usual medical care is superior to exercises and back-school for short- and long-term pain relief, function and quality of life improvements.⁴

^v Put LBP patients in an indiscriminate group and treat as alike without regard for particularity

^w Divide LBP patients based, e.g. on classification systems and match treatments to patient subgroups

Table 1: Integrative approach with an example of merging stratification classification systems in OMT to treat one patient with acute NSLBP^A and one patient with chronic NSLBP^B

Stratified care approach	Research setting and patient characteristics	Key stratification method	Patients groups and matched treatment	Flexibility of the concept and evidence
Prognosis Start Back Tool (SBT)	Primary care/first contact care patients with LBP of all duration	Self-reported brief screening tool (SBT) based on physical and psychosocial features	<u>1.LOW RISK</u>= patient has a good prognosis with UMC (reassurance, medication, education, advice to stay active) <u>2.MEDIUM RISK^A</u>: patient has a possible poor prognosis (physical issues forming an obstacle for recovery) without additional physical therapy (OMT), treatment as for low risk + evidence based OMT <u>3.HIGH RISK^B</u>: patient has a probable poor prognosis because of psycho-social issues forming an obstacle for recovery, treatment as for low and moderate risk with deeper bio-psycho-social assessment and treatment (e.g. CB-CFT)	Guidance for all LBP patients in 3 subgroups to receive adapted types and intensity of treatments. Derivation studies, validation study (one high quality RCT), impact analysis (one high quality implementation study), external validation of SBT [Foster et al. 2013].
Treatment responsiveness Treatment Based Classification (TBC)	Patients attending physical therapy for LBP of all duration (except for spinal manipulation subgroup)	Based on standardized physical evaluation process and updated criteria, mechanical responses (clinical signs and symptoms) observed during assessment	<u>1.SPINAL MANIPULATION^A</u>: positively respond to thrust manipulation (no evidence of superiority of one manipulation technique over another) following two criteria (pragmatic application of clinical prediction rule [CPR]), that includes no symptoms below the knee and recent onset of symptoms (<16 days), prevalence of CPR in LBP population ranged between 29-48% [Werneke et al. 2010; Brennan et al. 2006]. <u>2.DIRECTIONAL EXERCISE^A</u>: Positively respond to repeated movements or sustained postures when centralization is present specifically for LBP patients with referred pain in the lower limb. Prevalence in LBP population ranged between 31-87% [Werneke et al. 2010]. <u>3.STABILISATION^B</u>: CPR was developed for this kind of	Guidance for acute NSLBP, derivation, validation studies of high quality but no cost-effectiveness and implementation studies [Foster et al. 2013; Delitto et al. 2012]. Moderate to strong evidence for spinal manipulation within this subgroup of LBP patients has been determined in a systematic reviews on manual therapy [Delitto et al. 2012; Hidalgo et al. 2014]. Guidance for acute and chronic NSLBP, numerous studies support centralisation (directional preference) as an important prognostic factor and classification category for identifying patients who respond favorably to specific centralisation treatment [Werneke et al. 2010]. Guidance for acute and chronic NSLBP, several high-quality

			exercise according to 3 or 4 positive criteria (age<40 years old, average left and right SLR > 91°, positive aberrant trunk movements, positive prone instability test). The prevalence in acute/subacute LBP population is 24% [Werneke et al. 2010; Brennan et al. 2006].	reviews indicated some benefit of specific stabilisation exercise programs for patients with chronic NSLBP [Haladay et al. 2013]. But there is only one derivation study for the CPR for stabilization and no validation study.
			4. <u>TRACTION</u> : signs and symptoms of nerve root compression and no movements centralize symptoms [Fritz et al. 2007].	Guidance for acute and chronic LBP, but results from a SR established no impact of traction on pain intensity, functional status, global improvement and return to work among people with LBP [Wegner et al. 2013].
<i>Underlying mechanisms</i> Classification based cognitive functional therapy (CB-CFT)	Primary and secondary care patients with recurrent, persistent chronic LBP	A mix of clinical assessment and self-report questionnaires to identify symptom-provoking and modifiable cognitions, movement and lifestyle behaviors	Three subgroups are proposed: 1. <u>DOMINANT PSYCHOSOCIAL FACTORS^B</u> : Patient centered bio psychosocial education, body relaxation, active coping strategies and graded exposure integrated with treatment 2 and 3 2. <u>SPECIFIC PATHOLOGIES</u> : (e.g. spinal stenosis), education, reassurance, beliefs and evidence concerning the pathology and targeted functional training, specific to symptom provoking functional characteristics and pain behaviors identified 3. <u>MALADAPTIVE MOTOR CONTROL PATTERNS^B</u> (either movement impairments or motor control impairments) Placed physical activation directed by patient preferences and integrated with treatment 1 and 2	Guidance for chronic LBP, with derivation and validation studies (one RCT), but no cost-effectiveness or implementation studies [Foster et al 2013; Vibe Fersum et al. 2013].

Beliefs and expectations regarding treatment used	Primary and secondary care patients with LBP of all duration	Patient's expectation is related to a variety of common interventions for LBP and determines the influence that specific expectations about an OMT treatment might have on self-report of disability.	BELIEFS that the proposed treatment may help for the problem:	- Spinal mobilization and manipulation^A - Directional exercise^A - Stabilization^B - Traction - CB-CFT^B	Guidance for spinal manipulation and exercises, derivation study: the findings indicate that patients seeking intervention for LBP expect active interventions and manual therapy to significantly help improve their pain more than interventions like traction, rest, surgery, or medication [Bishop et al. 2011].
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1.2. Limitations of stratification systems of care for LBP

Although stratified care for LBP is increasingly recognised in research and clinical practice,⁵ and although chronic NSLBP is understood to be a multidimensional biopsychosocial disorder,⁶ no more than 10% of validated classification systems include a biopsychosocial framework.⁷ Most classification systems do not consider the multiple dimensions of interaction essential for a comprehensive classification of chronic NSLBP.⁸⁻⁹ Early classification systems focused on pathoanatomy (the biomedical model) to determine a structure contributing to the peripheral nociceptive inputs, using anaesthetic diagnostic blocks. Poor agreement between the clinical identification of nociceptive inputs and diagnostic injections was found. Moreover, this approach is limited in its ability to direct NSLBP management because it does not consider contributors to pain persistence. Furthermore, interventions based on the hypothesis that persistent peripheral sensitisation of spinal structures is the cause of chronic NSLBP have been associated with poor outcomes.⁹

Because of these aforementioned limitations, classification systems in physical therapy have progressed to include pain responses to movement and tissue loading, such as are used in the TBC system¹⁰⁻¹⁵ described in the Introduction. Although treatments matched to the TBC system in the acute-subacute stages of NSLBP offer better results than unmatched treatments,¹⁴ one study found that the TBC system produced results in chronic NSLBP that were only equivalent to those achieved by guideline-based care.¹⁵ To facilitate the management of complex chronic NSLBP, the TBC system evaluates the psychosocial dimension, but only in terms of fear-

avoidance.¹⁶ In this regard, the TBC approach is unlikely to be adequate in driving the management of patients with more complex multidimensional profiles of LBP.⁹

McKenzie's movement-based classification system¹⁷⁻¹⁸ bases its assessment and treatment of LBP on pain responses to lumbar mechanical loading, including the effects of different postures and repeated movements. Examination determines if a directional preference (flexion or extension) occurs with a centralisation phenomenon^x. Patients with NSLBP are classified as 'mechanical responders' or 'not-responders'.^{17,18} However, it is difficult to classify all NSLBP patients by this method because centralisation occurs in only 52% of people with chronic NSLBP and 70% of people with acute-subacute NSLBP.¹⁹

The TBC and McKenzie classification systems are both based on pain responses to movement and tissue loading, and both assume that dominant peripheral nociception inputs are the cause of LBP. Therefore, these systems are unidimensional in their method.⁹

Improved understanding of the psychosocial contributions to pain and disability has resulted in classification systems that target prognostic risk factors of poor outcome in LBP. For example, the SBT is a screening method that is based on pain characteristics, functional impairment and psychosocial factors (Table 1).²⁰ There is strong evidence to support its use to target care, even if the tool does not always address broader multidimensional contributors to chronic NSLBP,^{9,20} does not consider movement, and does not include quantitative sensory testing^y. Despite its limitations in terms of tailoring treatment for individual complex presentations of LBP, there is the potential to integrate the SBT with other classification systems in the presented **integrative approach** (Table 1) to enhance the targeted care of NSLBP.⁹

In parallel with the development of other classification systems for NSLBP, there has been an interest in determining the neurophysiological mechanisms underlying pain.²¹ Initial work, which accredited nociceptive aspects of chronic NSLBP, has expanded to consider neuropathic and central nervous system mechanisms underlying persistent nociception. Smart et al.²² proposed a neurophysiological classification system that categorises subjects' pain as nociceptive, peripheral neuropathic, or central sensitisation. However, this system has not been validated

^x Distal to proximal reduction in pain or symptoms

^y Altered pressure pain threshold, heat and cold pain threshold, pinprick and nylon monofilament stimulations

alongside quantitative sensory testing and, although it considers psychosocial dimensions, it fails to consider the lifestyle and movement dimensions.⁹

Finally, as previously described (Table 1), O'Sullivan²³⁻²⁵ described CB-CFT as a flexible biopsychosocial classification system for profiling across multiple relevant dimensions^z, to facilitate targeted care based on the dominant factors in individual profiles. However, to date, only one RCT on patients with chronic LBP has demonstrated superior long-term clinical outcomes for CB-CFT compared to standard OMT.²⁶ The CB-CFT process constitutes a first-level selection of people with LBP to identify red flags and specific or nonspecific disorders. Identified chronic NSLBP disorders are further differentiated on the basis of their **pain characteristics** reflecting either mechanical or nonmechanical pain. This differentiation is made during routine clinical examination, where patients report their pain characteristics linked to aggravating and easing factors during movements and loading tests.^{9,23-25} Some patients may have a mixed pain profile, but for others the clinical distinction is very clear. It is postulated that the groups may have different underlying neurophysiological mechanisms. **Mechanical pain** may be more related to processes of major peripheral sensitisation of inputs of persistent nociceptive structures and some degree of central sensitisation-dependent activity. In contrast, **nonmechanical pain** may be due to more extensive changes in pain processing by the central nervous system. The CB-CFT also considers other dimensions, such as psychosocial (Table 2), pain type (Table 3), lifestyle and movement-related factors.²⁵

A major aspect that is often not routinely included in these classification systems and in research is the pain stage of nonspecific LBP (i.e. acute-subacute/chronic). Most RCTs and classification systems presented above include mixed LBP of different pain durations (Table 1), although the pain mechanisms, as described below, may be different between the categories of NSLBP.

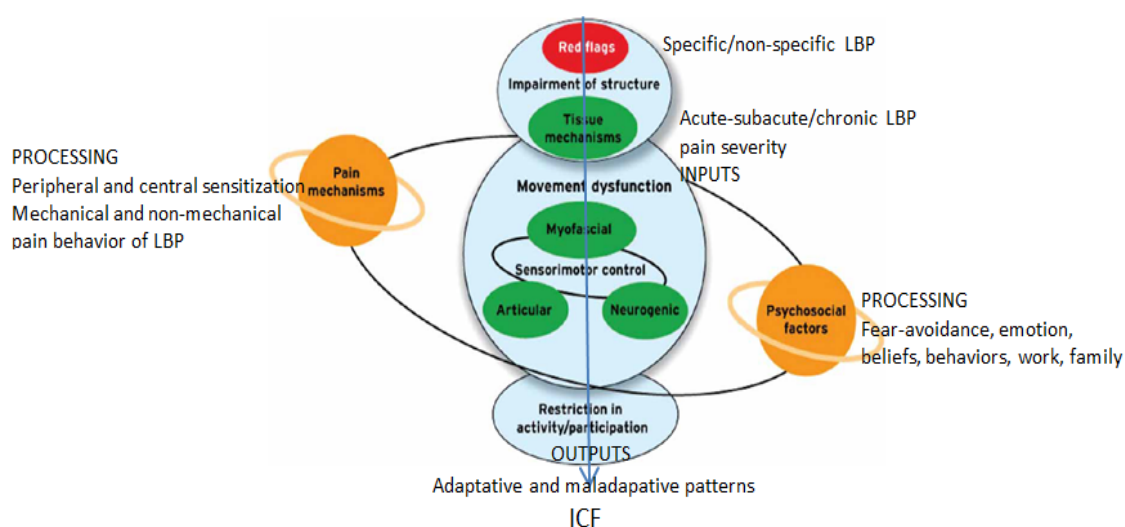
1.3. Clinical reasoning in orthopaedic manual therapy

It is increasingly being recommended that clinical reasoning be integrated into OMT clinical studies.²⁷ Clinical reasoning in OMT must involve a multidimensional patient-centred approach, rather than a disease-centred one.

^z Pain characteristics, psychophysical, psychological, social, lifestyle, movement, comorbidities

The **planetary model** is a didactic representation model of pain drivers. This model integrates, in a vertical plane, the ICF components (blue arrow in Figure 1), psychosocial factors and pain mechanisms surrounding the vertical structure, reflecting their continuous interaction with different components of the vertical plane. This model could help manual therapists to obtain a comprehensive overview and build clinical reasoning and decision-making skills while managing a patient's musculoskeletal disorders. It also aims at developing a more efficient method to treat patients.²⁸

Figure 1: Planetary model, adapted from Danneels et al.²⁸



Clinical reasoning is one part of the expert component from an EBP approach. This concept is composed of subjective and objective examinations to determine the main hypothesis and plan OMT after discussion with the patient. The initial subjective examination (anamnesis) and observation could help to: (I) identify the **stage of the LBP** (acute-subacute/chronic), (II) classify

the **pain severity and irritability**^{aa}, and (III) exclude **serious spinal pathologies** (red flags).²⁹⁻

³¹ People with major **psychosocial issues** (yellow flags) and **activity avoiders** are identified (Figures 1, 2, Table 2). These two steps may help to enhance safety before the objective (physical) examination²⁹⁻³¹ and comprise a first screening to understand if the NSLBP patient needs a physical therapy approach with the application of TBC or a multidisciplinary functional cognitive-behavioural approach.

Table 2: Clinical assessment of psychosocial factors associated with LBP^{bb}

Attitudes and Beliefs about Back Pain Belief that pain is harmful or disabling resulting in fear-avoidance behavior, e.g. the development of guarding and fear of movement Belief that all pain must be abolished before attempting to return to work or normal activity Expectation of increased pain with activity or work, lack of ability to predict capability Catastrophising, thinking the worst, misinterpreting bodily symptoms Belief that pain is uncontrollable Passive attitude to rehabilitation
Behaviors Use of extended rest, disproportionate 'downtime' Reduced activity level with significant withdrawal from activities of daily living Irregular participation or poor compliance with physical exercise Avoidance of normal activity and progressive substitution of lifestyle away from productive activity Report of extremely high intensity of pain, e.g. above 10, on a 0 to 10 Visual Analogue Scale Excessive reliance on use of aids or appliances Sleep quality reduced since onset of back pain High intake of alcohol or other substances (possibly as self-medication), with an increase since onset of back pain Smoking
Compensation Issues Lack of financial incentive to return to work History of claim(s) due to other injuries or pain problems History of extended time off work due to injury or other pain problem (e.g. more than 12 weeks) History of previous back pain, with a previous claim(s) and time off work Health professional sanctioning disability, not providing interventions that will improve function Experience of conflicting diagnoses or explanations for back pain, resulting in confusion Diagnostic language leading to catastrophising and fear (e.g. fear of ending up in a wheelchair) Dramatization of back pain by health professional producing dependency on treatments, and continuation of passive treatment Number of times visited health professional in last year (excluding the present episode of back pain) Expectation of a 'techno-fix', e.g. requests to treat as if body were a machine Lack of satisfaction with previous treatment for back pain Advice to withdraw from job
Emotions Fear of increased pain with activity or work

^{aa} High or low irritability, as it could influence the starting position/direction of treatment

^{bb} http://www.chiro.org/LINKS/GUIDELINES/FULL/NEW_ZEALAND/Guide_to_Assessing/full_text.html

Depression (especially long-term low mood), loss of sense of enjoyment More irritable than usual Anxiety about and heightened awareness of body sensations (includes sympathetic nervous system arousal) Feeling under stress and unable to maintain sense of control Presence of social anxiety or disinterested in social activity Feeling useless and not needed
Family Over-protective partner/spouse, emphasizing fear of harm or encouraging catastrophising (usually well-intentioned) Solicitous behavior from spouse (e.g. taking over tasks) Socially punitive responses from spouse (e.g. ignoring, expressing frustration) Extent to which family members support any attempt to return to work Lack of support person to talk about problems
Work History of manual work, notably from the following occupational groups: fishing, forestry and farming workers; construction including carpenters and builders; nurses; truck drivers; laborers Work history, including patterns of frequent job changes, experiencing stress at work, job dissatisfaction, poor relationships with peers or supervisors, lack of vocational direction Belief that work is harmful; that it will do damage or be dangerous Unsupportive or unhappy current work environment Low educational background, low socioeconomic status Job involves significant bio-mechanical demands, such as lifting, manual handling heavy items, extended sitting, extended standing, driving, vibration, maintenance of constrained or sustained postures, inflexible work schedule preventing appropriate breaks Job involves shift work or working 'unsociable hours' Absence of interest from employer

Next, the ***dominant pain type/mechanism*** should be identified^{9,29-32} (Figure 1, Table 3), as follows:

- **Inputs:** nociceptive, inflammatory, neuropathic pain
- **Processing:** functional (peripheral) or central sensitisation and the cognitive-affective mechanisms of pain, including: catastrophisation, fear-avoidance, psychological stress, beliefs, work status and satisfaction
- **Outputs:** autonomic (dermatome, scleratome, myotome), motor (adaptive or maladaptive patterns), mechanical and nonmechanical pain behaviour, neuroendocrine and immune systems

Table 3. Definition of pain types and mechanisms, adapted from Rabey et al.⁹

Pain type	Definition	Pain mechanisms	Example in LBP
Nociceptive	Pain from actual or potentially tissue damaging event and activated from nociceptors	In response to noxious stimuli, C or A afferents stimulate central nervous nociceptive pathways	Provoke appropriate behavioural responses (adaptive) to limit damage e.g. instability catch during trunk flexion
Inflammatory	Pain due to tissue injury and subsequent inflammation	Innocuous stimulation of low-threshold afferents can produce pain (allodynia). Response to noxious stimuli is magnified (hyperalgesia). Spontaneous and evoked pain. Underlying allodynia and hyperalgesia is chemically mediated peripheral nociceptor sensitisation and central sensitization	Leads to hypersensitivity, a biologic function favouring healing (adaptive). e.g. antalgic position due to disk prolapse like lateral shift position
Neuropathic	Pain arising as a direct consequence of a lesion or disease affecting the somatosensory system	Spontaneous pain evoked by noxious and innocuous stimuli in areas consistent with nervous system	Lumbar radiculopathy which could demonstrate neurophysiological signs (paresthesia, paresis, decreased motor reflex) and associate findings on imaging
Functional/peripheral sensitisation	In functional pain there is no clear source of noxious stimuli and minimal evidence of inflammation. Abnormal central nervous system processing is considered the disease itself	Characterized by spontaneous pain, and pain evoked by persistent noxious and innocuous stimuli	Mechanical chronic NSLBP with maladaptive patterns and localized hyperalgesia or allodynia
Central sensitisation	Amplification of neural signalling within the central nervous system that elicits pain hypersensitivity	Involves peripherally triggered, activity-dependents, predominantly heterosynaptic plasticity causing long-lasting spinal cord hyper excitability. Typically central sensitisation normalises as peripheral lesions resolve; however it may become aberrant, persisting beyond initiating stimuli	Non-mechanical chronic NSLBP with hyperalgesia or allodynia in widespread areas Central sensitization is common to inflammatory, neuropathic and functional pain in NSLBP

Finally, in an EBP approach, it is important to try to integrate: (I) the clinician's clinical expertise and reasoning, (II) best evidence from an integrative approach and (III) a strong relationship between the clinician's and patient's needs and preferences, based on meaningful

communication. This integrative process enables determination of the **therapeutic goals**,³⁰⁻³² which likely will be further adapted during the treatment sessions.

In the case that **dominant input** components are responsible for NSLBP, hypotheses about the possible pain types and symptoms (e.g. nociceptive sources with mechanical behaviour) can be formulated.³⁰⁻³¹ Most conditions presented by people with acute-subacute NSLBP are mechanical in origin (i.e. nociceptive sources from zygapophyseal joints, disks and sacroiliac joints).^{12,33} In contrast, in patients with chronic NSLBP, an identifiable nociceptive source of pain can be determined in only 50% of cases.³¹

Mechanical LBP, which is the predominant form of NSLBP, has been defined as having a clear and consistent anatomical focus, with pain proportionate to a mechanical behaviour (i.e. consistently provoked and relieved with specific activities, movements and postures).²⁵ Under these circumstances, it is hypothesised that predominant nociceptive inputs preside (Table 3). Mechanical nociceptive pain is thought to arise from articular structures, which are likely to respond to techniques that are passive (spinal mobilisation/manipulation), active/passive (mobilisation with movement or muscle energy technique) or active (directional exercise).^{12,30-31} Most of these interventions are present in the TBC system. It is also likely that muscular or neurological structures contribute to the nociceptive sources (Figure 1) and may need appropriate management.^{12,30-31}

To determine whether the patient has a **dominant processing component**, various tools addressing psychosocial influences (Table 2) and pain mechanisms could be used^{cc}. These features are evaluated concurrently during the subjective examination. Management for people in this category should consist of a functional cognitive-behavioural therapy approach incorporating a substantial pain education component. Failure to identify a processing component in the patient's presentation is likely to lead to treatment failure, as dominant processing mechanisms have been shown to be important predictors of risk of chronicity in people with LBP.^{12,25-31}

^{cc} Orebrö or SBT, Fear Avoidance Beliefs, Tampa Scale (kinesiophobia), Catastrophizing Scale questionnaires, Central Sensitisation Inventory

In some individuals, LBP is driven by **dominant output** mechanisms, such as functional **maladaptive patterns** during flexion (Table 1) (i.e. a passive flexion^{dd} or active extension^{ee} pattern).^{23-26,29-32,34} The goal of OMT in the first case is to improve motor control and cognitive postural education with a guided exercises approach. In the second case, the goal is to promote functional paravertebral muscle relaxation by decreasing cognitive physical hypervigilance.²³⁻²⁶ Hands-on treatment techniques may be helpful in both patterns, but only as adjunctive therapy to relieve any nociceptive symptoms.^{12,30-31} In the case of **adaptive patterns** resulting from inputs (i.e. pain and restricted ROM in a combined movement direction, antalgic position or instability catch during trunk movement), TBC or active/passive OMT techniques could be applied as in the case of dominant input components (Tables 1 and 3, Figure 1).¹²

In clinical practice, each person complaining of NSLBP typically presents with a combination of the above three categories of pain mechanisms. However, there is often a dominant component that can be identified to enable more targeted OMT intervention for the patient.

1.4. Best practice for nonspecific low back pain

One potential reason for failure of clinical practice to manage LBP patients effectively may be a lack of adherence to current evidence. This oversight might be due to a dominant biomedical (anatomopathological) approach to the care of people with LBP, with a failure to consider and manage LBP from a biopsychosocial perspective.^{12,29,35}

Best practice for the management of acute LBP should involve an initial diagnosis based on a triage process to screen for serious pathology (specific LBP and red flags) and consideration of the disorder from a biopsychosocial perspective, including assessment for psychosocial risk factors for chronic LBP. Tailored OMT management should then be applied, according to the presentation. This approach may empower patients as active participants in their recovery and discourage inappropriate radiologic investigation (Figure 3).^{12,29,31}

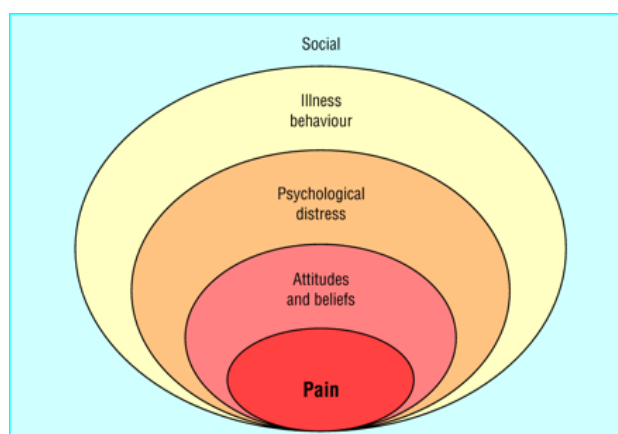
In his discussion of the **best practice for management of chronic LBP**, Peter O'Sullivan²³⁻²⁵ proposed a shift from biomedical beliefs to a new paradigm in which the therapist has greater skills and knowledge across several domains. Skills and knowledge should include, for

^{dd} Localised hypermobility of the lumbar spine during trunk flexion and sitting posture

^{ee} Localised hypomobility of the lumbar spine due to paravertebral muscle guarding during trunk flexion and sitting posture

example: better understanding of the complex multidimensional nature of chronic NSLBP; development of effective communication skills^{ff} to explore the patient's story, pain behaviour, pain beliefs, fears, life stresses, coping strategies and psychosocial factors; development of an effective patient-centred therapeutic relationship that is within a biopsychosocial framework, to identify the primary drivers of pain and disability; identification of maladaptive cognitive behaviours^{gg}; identification of neurophysiological processes, such as central and peripheral sensitisation; development of a broad categorisation of chronic NSLBP disorders based on the presence of dominant psychosocial, neurophysiological, lifestyle and movement behaviours that act as drivers for the disorder; and development of multidimensional and multidisciplinary flexible interventions that target maladaptive cognitive, lifestyle, pain and movement behaviours in an integrated manner.²⁴ The goal of this approach is to focus less on treating only structures or signs/symptoms, particularly for chronic NSLBP disorders, and to improve targeting of the different combinations of attitudes, beliefs, and cognitive, pain, lifestyle and movement behaviours that underlie and drive disorders (Figure 2, Tables 1, 2).^{24,26}

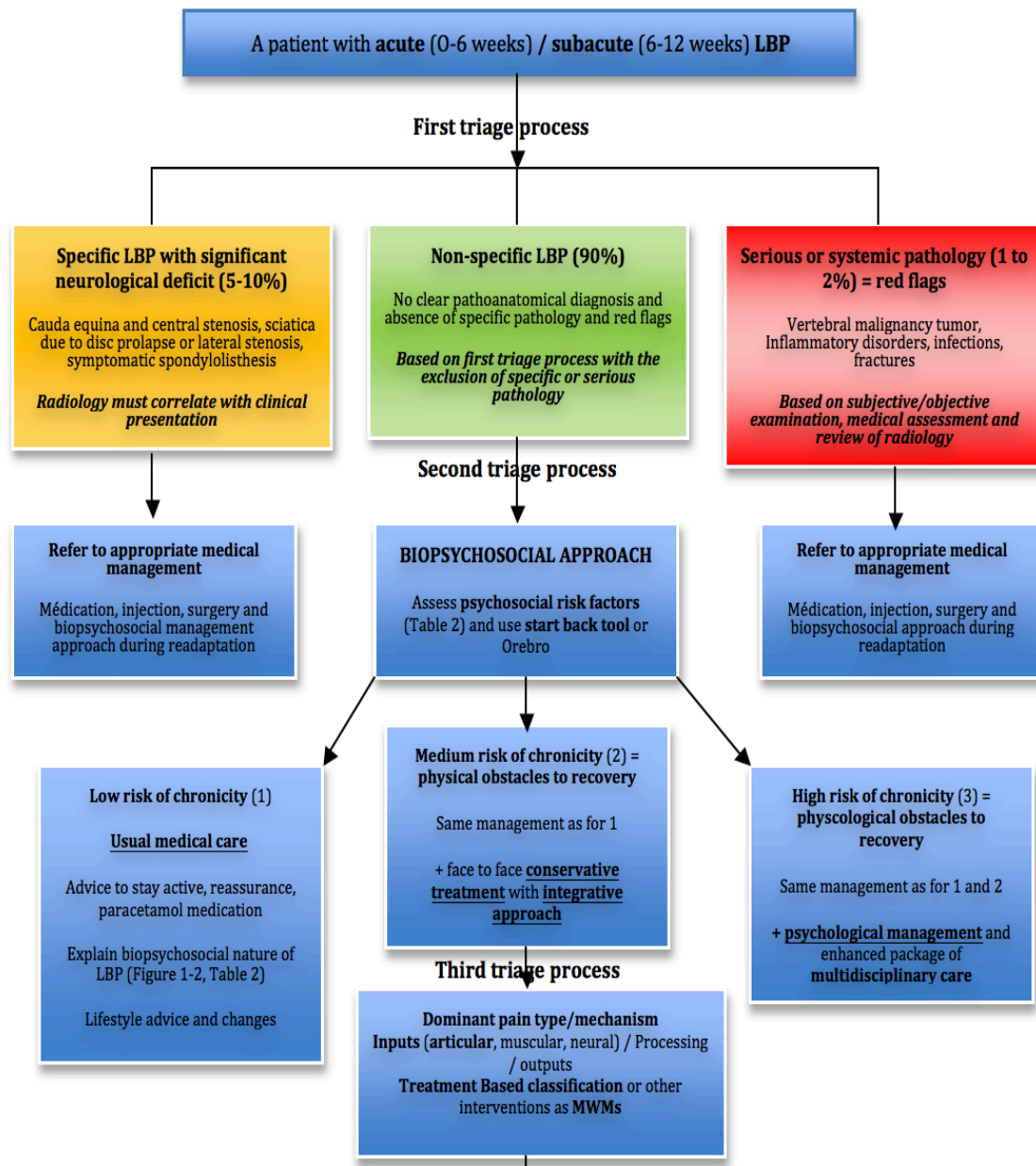
Figure 2: Biopsychosocial model of the clinical presentation and assessment of LBP and disability³⁵

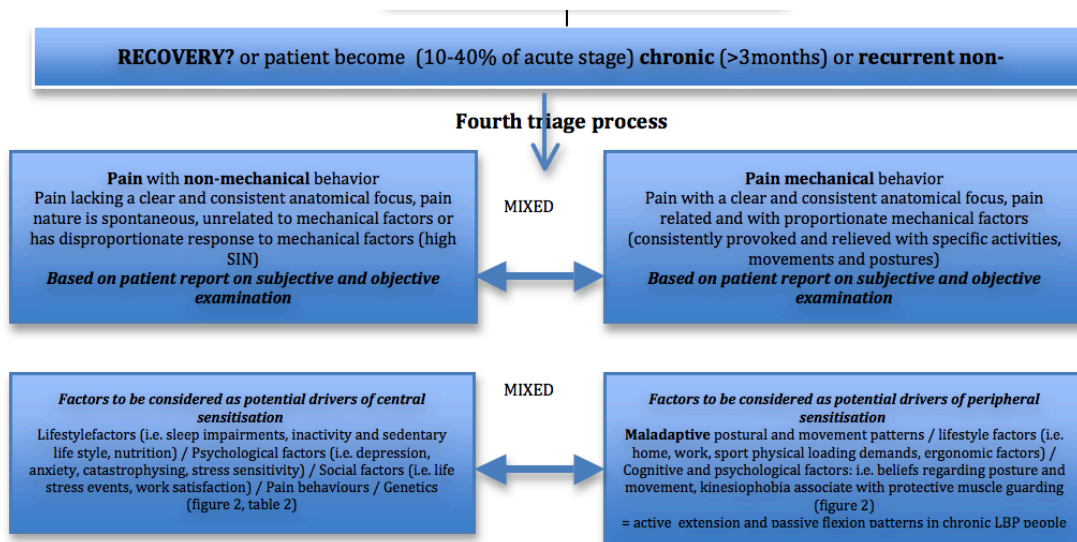


^{ff} Such as empathy, reflective questioning and motivational interview techniques

^{gg} Negative beliefs, coping, stress responsiveness, hypervigilance, catastrophising, anxiety, depression

Figure 3. Proposed comprehensive biopsychosocial integrative approach for screening and targeting management of LBP patients, adapted from O'Sullivan^{25,29}





In conclusion, following the development of this major part of the thesis, we are able to make methodological recommendations to improve future RCTs.

- (1) Homogeneous subgroups of LBP patients should be used, with the application of an **integrative approach** (based on validated classification systems) and more accurately targeted OMT. Patient samples should be better described in terms of duration (acute-subacute/chronic), symptom location and mechanical vs. nonmechanical pain behaviours.
- (2) The best practice of OMT intervention(s) should be described in detail, with justification from a clinical reasoning perspective.
- (3) The active OMT intervention should be compared to: sham OMT; an ideal or plausible placebo procedure (e.g. similar procedure without an active effect and with patient blinding); the same OMT intervention with a nontargeted group; or another usual or novel intervention. Blinding should be used in the assessment of biopsychosocial features (e.g. ICF Core Set for LBP). Moreover, validated quantitative outcome

measures (e.g. kinematic analysis) should complement the usual self-reported measures.

In general, clinical trials must be of good methodological quality but also patient-centred for direct applicability to routine clinical practice, which will require improved education of health professionals who will use this treatment approach.

2. FROM SECTION 2

Through three observational studies, a kinematic model of the spine was validated. This model addressed: (I) trunk ROM, and (II) speed of various spinal segments, (III) RE in NSLBP patients with mechanical pain behaviours when performing trunk movements from a sitting position compared to healthy subjects. This tool is an objective movement-based analysis that generates **kinematic outputs** in terms of movement quality ('motion signature' graphs of speed, ROM curves of the lumbar spinal segments and RE curves) and movement quantity, including RE and kinematic algorithms for the ROM (KA-R) and speed (KA-S) of trunk movements. These three kinematic variables (RE, KA-R, KA-S) may be used in clinical trials as quantitative outcome measures for the evaluation of various OMT interventions.

2.1. Kinematic variables as outcome measures

During the objective examination of LBP patients, an important part of the clinical reasoning is the visual assessment of posture and spinal curves, lumbopelvic and trunk movement coordination during functional movements, as well as the clinical measurement of ROM to assist in identifying patterns of dysfunction.³⁶ These patterns could be adaptive or maladaptive and are associated with pain, disability, beliefs and fear of movement.²³⁻²⁹ Most clinicians, probably due to a common paradigm, think that identifying and correcting coordination of maladaptive movement, combined or not with maladaptive posture, can improve pain, function and activity limitations.³⁶⁻³⁷ Fortunately, advances in technology are creating opportunities to quantify the

relationship between posture/movement coordination and pain behaviours, as well as the influences of cognitive and psychological factors on movement^{hh, 36-37}.

The most frequently used kinematic variables for LBP are the lordosis angle, ROM of the lumbar spine, lumbar vs. hip contribution to flexion/extension, pelvic tilt angle, speed of lumbar flexion and lumbopelvic or lumbar spine proprioception (position/reposition accuracy).³⁶ A recent meta-analysis identified lumbopelvic kinematic analysis as a useful measurement approach in people with LBP. On average, LBP patients had significantly large to very large effect sizes for reduced lumbar ROM in all directions (except extension) and proprioception on position-reposition accuracy. They also moved more slowly than healthy people. However, there were no significant differences in variability of the lordosis angles (lumbar posture), extension ROM or lumbar vs. hip contribution to movement (i.e. lumbopelvic rhythm). However, a nonsignificant but consistent effect favoured reduced lumbar compared to hip contribution to flexion for those with LBP has been determined.³⁶⁻³⁷

The reduced speed of lumbar movement has been linked to fear of movement and shown to persist after recovery in a subgroup of LBP patients with a persistent fear of movement.³⁸ This last point might partially explain the nonsignificant difference for KA-S in our RCT on MWM in NSLBP people (Section 3, Chapter VI).

Future clinical studies should consider kinematic variables as interesting outcomes for specifically addressing localised functional movement patterns of LBP patients (i.e. specific body structures, body functions and activities of the ICF model, described in Introduction section 4.2) to complement classical self-reported measures of other features of the biopsychosocial model (activities and participation in ICF model), such as pain scalesⁱⁱ and questionnaires^{jj}.

2.2. Perspectives for kinematic analyses

The KA-S is a comprehensive quantitative variable of speed indicating whether patients are moving slowly or quickly. However, the quality of speed curves/forms is another movement

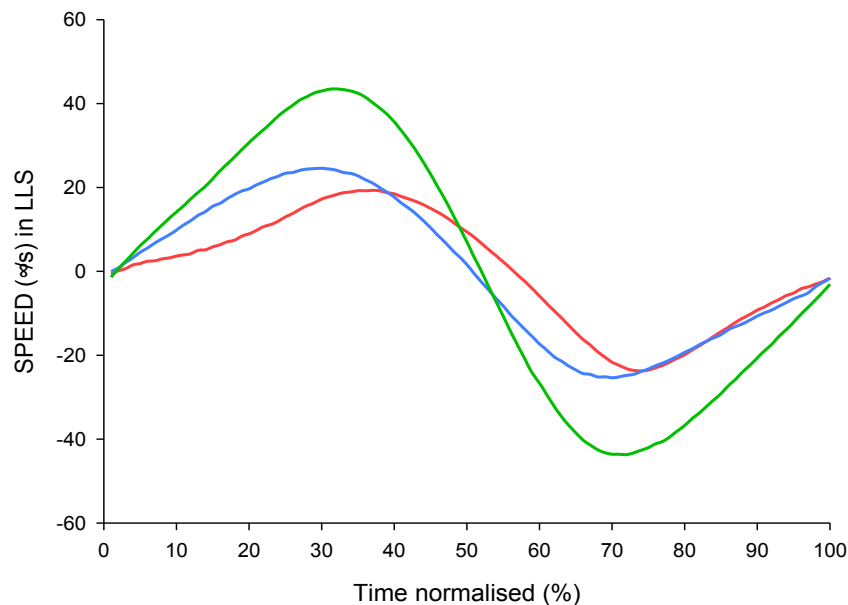
^{hh} Beliefs regarding posture and movement, kinesiophobia associated with protective muscle guarding

ⁱⁱ For example, the visual analogue numeric pain-rating scale (VAS)

^{jj} For example, SBT, Fear Avoidance Beliefs questionnaire, Tampa Scale for Kinesiophobia, Patient Specific Functional Scale, Catastrophising Scale, Central Sensitisation Inventory, Hamilton Anxiety Rating Scale, Hamilton Depression Rating Scale, Oswestry Disability Index, Roland-Morris Disability Questionnaire

characteristic that may be objectively addressed by the calculation of **smoothness**. The smoothness corresponds to the ratio between the speed and peak speed, with ratios closer to 0 indicating less smooth movements. It is a measure of parametric continuity along the speed curve.³⁹ Parametric continuity is distinct from geometric continuity (i.e. targeting variations of speed on a time parameter trace curve). A speed curve describes the motion of an object with a parameter of time, and must have continuity for the object to have a finite acceleration.⁴⁰ An observational study based on retrospective data for 60 subjects is currently in progress to compare the smoothness of lumbar spine speed curves (motion signature) between patients with acute and chronic NSLBP and healthy people (Figure 4).

Figure 4: Speed curves and smoothness of the lower lumbar spine in healthy and patients with acute / chronic NSLBP (n=60) during trunk flexion with left pelvic rotation



LLS: lower lumbar spine (S2-L3); **red curve: 20 acute LBP patients** (smoothness = 0.37); **blue curve: 20 chronic LBP patients** (smoothness = 0.43) and **green curve: 20 healthy people** (smoothness = 0.49). ANOVA one way determined significant differences between groups ($p < .05$, $p < .005$, $p < .001$) (preliminary results)

Another interesting method of kinematic analysis that has recently appeared in the literature used a **dynamical system approach** to address coordination and neuromuscular control between segments in LBP patients. This approach, developed by Spinelli et al. (2015),³⁷ analyses movement control and coordination. Using this method, clinicians and researchers can determine aberrant movements by people with LBP, helping them to categorise functional movement patterns and monitor changes before/after therapy.³⁷

This method combines 'continuous angular displacement motion curves' (Figure 5A) to generate 'angle-angle'^{kk} (Figure 5B) and 'coupling angle-movement cycle' graphs^{ll} (Figure 5C), which provide information about coordinated movement between body segments. 'Phase-plane'^{mm} graphs provide information about the neuromuscular control of the segment. An increasing or decreasing smooth period represents typical neuromuscular control, whereas a sudden increase or decrease in angular velocity with resulting 'cusps'ⁿⁿ is probably indicative of aberrant movement and poor control.³⁷

^{kk} Angular movement of one body segment against another

^{ll} Quantifying the relative change in motion between data points in a standardised manner over the movement task

^{mm} Use of angular displacement and speed of the same segment

ⁿⁿ Pointed end where two curves meet

Figure 5: Kinematic graphs in a dynamical system approach for one healthy subject³⁷

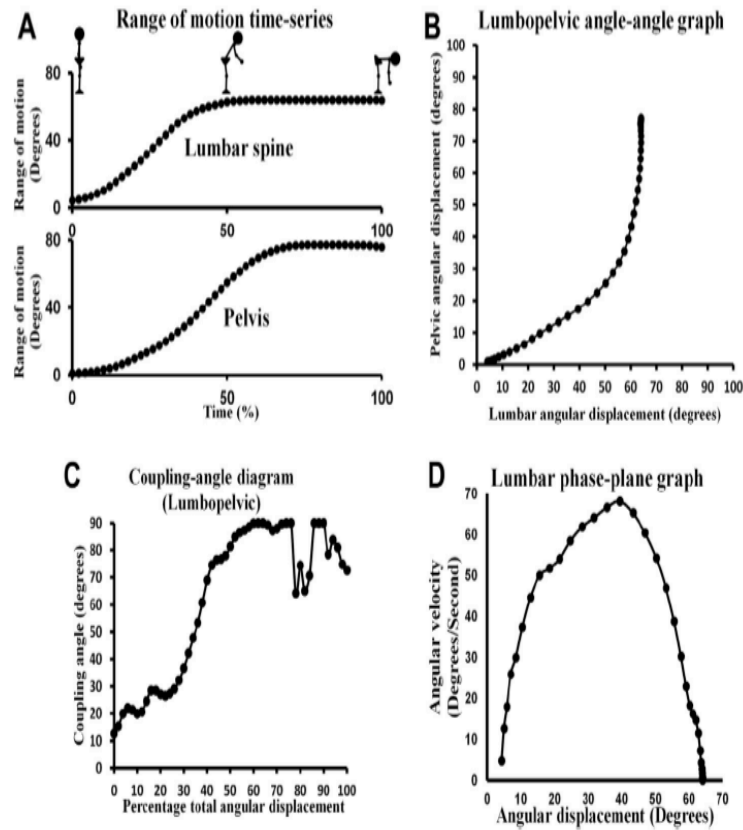


Fig. 2. Data collected from a trial of trunk forward bend in a subject without a history of low back pain. (A) Continuous angular displacement motion curves used to generate the angle-angle graph. (B). Angle-angle graph during standing forward bending. The slope of the line in this graph indicates the relationship or coordination of movement between the two segments. (C) Coupling angle-movement cycle graph during a forward bend movement. (D) Phase-plane graph of the lumbar spine during standing forward bend demonstrating typical smooth control of movement.

Using our kinematic model of the spine, we can easily generate **angle-angle graphs** between the low (S2-L3) and high (L3-T12) lumbar spine segments. These data could be used to address **coordination**³⁷ during trunk flexion (Figures 6, 7), as these segments may differ biomechanically.^{36,41}

Figure 6: Angle-angle graph between ROM of the low (LLS) and high (HLS) lumbar spine during trunk flexion in 20 acute NSLBP patients, 20 chronic NSLBP patients and 20 healthy subjects

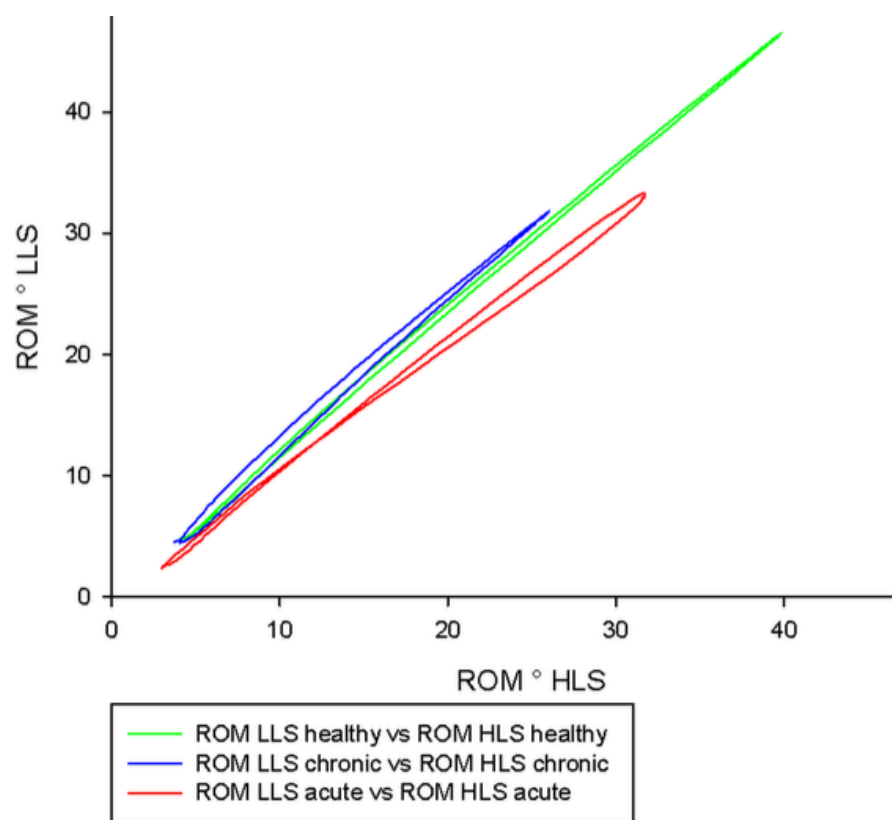
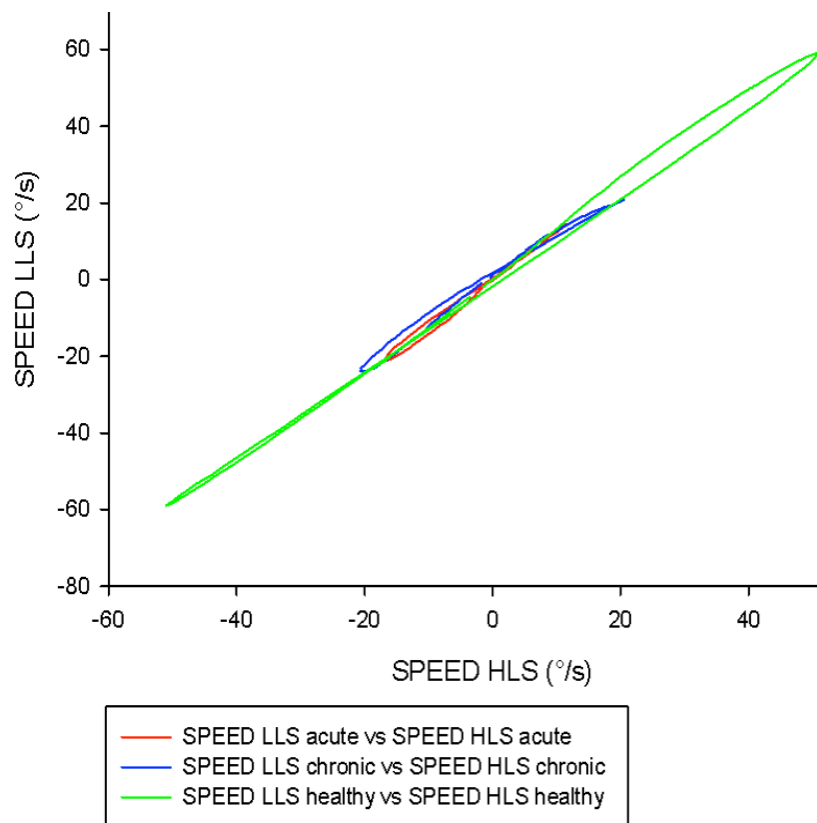
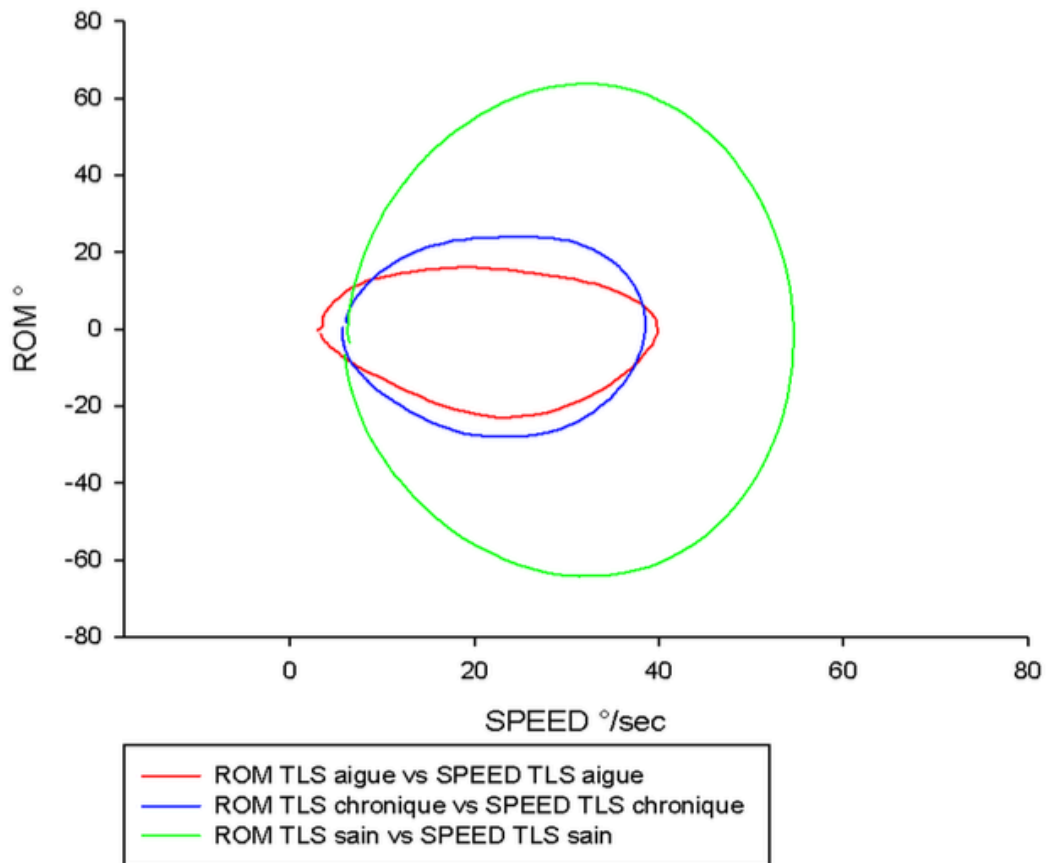


Figure 7: Angle-angle graph between speed of the low (LLS) and high (HLS) lumbar spine during trunk flexion with left rotation in 20 acute NSLBP patients, 20 chronic NSLBP patients and 20 healthy subjects



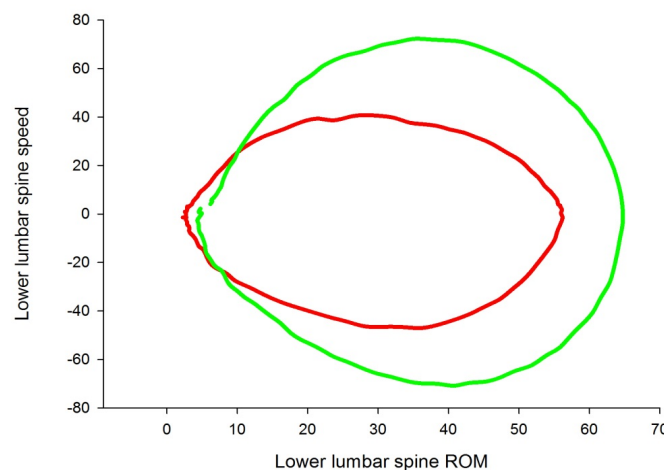
We are also able to generate **phase-plane graphs**, to analyse the **neuromuscular control**³⁷ of the low, high or total lumbar spine segments. These graphs can be created for the entire duration of trunk flexion (Figure 8) or only in the forward/backward bending phase, as specific patterns could appear during forward or backward movement from flexion due to pain provocation in one or both directions.

Figure 8: Phase-plane graph of the total lumbar spine segment during trunk flexion with left rotation in 20 acute NSLBP patients, 20 chronic NSLBP patients and 20 healthy subjects



This method of kinematic analysis can be used to measure OMT effects and to monitor changes before/after spinal manipulation, as proposed in Figure 9.

Figure 9: Illustration of a phase-plane graph of the low lumbar spine segment during trunk flexion for one acute mechanical NSLBP patient^{oo} before and after two sessions of spinal manipulation



The patient bent (forward and backward) in flexion five times from a sitting position. Red and green circles represent neuromuscular control of the low lumbar spine (S2-L3) before and after OMT intervention, respectively.

^{oo} This acute NSLBP patient (a 45-year-old man) was profiled as moderate risk by SBT and positive on CCR (4/5) for spinal manipulation, with a dominant articular input nociceptive pain mechanism identified by combined movement assessment. An active flexion (primary) and left side-bending (secondary) pain pattern (confirmed by PAIVM on L4-L5 vertebral segments) was determined by the CCR. The patient was treated in accordance with his expectations during two sessions over 1 week of combined (flexion/left side-bending and rotation) lumbar spinal manipulation (grade 5) in a side-lying position on the L4-L5 intervertebral segment. VAS score at rest was 6/10 before and 2/10 after OMT.

The kinematic model of the spine looks promising and could be adapted from two to three dimensions (e.g. by using an electromagnetic device, such as Fast-track) to analyse movement compensation in all planes during movement in a given direction. This model can be applied to analyse patients in clinical practice, as well as to aid in objective examinations and in following the patient's evolution during OMT interventions. Future studies in people with LBP could integrate the hip/pelvis contribution, to generate coupling-angle graphs to study lumbopelvic rhythm coordination, and could be combined with paravertebral muscle electromyography. Other functional tasks could be studied, such as sitting, standing forward bending, sit-to-stand, lifting, squatting, and walking. However, a **key question** remains in studies reporting the quantitative kinematic analysis of people with LBP: Is the reduction in proprioception, ROM, speed of movement or maladaptive lumbopelvic patterns the result or the cause of LBP?³⁶

In conclusion, the kinematic data highlight the importance of using a patient-centred approach within a biopsychosocial framework. Kinematic variations probably arise from multidimensional and individual origins, and they could be consequential (adaptive patterns), causative (maladaptive patterns) or even mixed. Variables derived from kinematic analyses are interesting outcomes for addressing the body functions and activities of LBP patients. These outcomes can be used to complement classical self-reported measures on other features of the biopsychosocial model, such as pain scales or questionnaires. Future research might include measurement of the correlations between kinematic measures and other tools addressing components of the ICF Core Set for LBP, such as the Oswestry Disability Index, Patient Specific Functional Scale, Tampa Scale (Kinesiophobia) or the Fear Avoidance Beliefs Questionnaire, Central Sensitisation Inventory, in specific subgroups of LBP patients classified with an integrative approach.

3. FROM SECTION 3

Two clinical studies are presented in this thesis. One reports the reliability and validity of **combined movement** procedures, which extend the routine objective examination of the lumbar spine. The other study is a randomised, placebo-controlled trial of good methodological quality (8-9/11 on the Cochrane Collaboration Back Review Group checklist) that investigated **MWM** in a subgroup^{pp} of patients with LBP.

3.1. Evaluation of combined movements

The first study aimed to determine the most painful direction of movement (flexion or extension) that needed to be improved by OMT, as well as the vertebral level(s) that may contribute to the specific direction of impairment. Once the direction and level are determined, various forms of OMT could be applied to improve findings determined during the combined movement assessment. Information gained from this assessment may contribute to the therapist's clinical reasoning. This procedure is an evaluation of the articular planet (Figure 1) of the structure and function of the lumbar spine, adapted for people with mechanical LBP disorders.

After the first and second triage processes (Figure 3) are completed, the combined movement test results must be clinically reasoned within TBC, to select an adapted and targeted therapy or MWM. Findings from the manual assessment may also help in directing treatment. For example, the end-feel sensation during PAIVM testing of hypomobile vertebral segments may indicate a need for more passive techniques, whereas hypermobility may indicate a need for more active techniques.⁴²

3.2. Mobilisation with movement

MWM is a relatively new active/passive technique in OMT. MWM on the lumbar spine is innovating by the application of a passive vertebral glide, or **SNAG**, while the patient actively moves in the impairment direction, which should be rendered pain-free. MWM may progress depending on the functional or specific comparable signs of the LBP patient. This technique might act on various pain mechanisms, resulting in less pain in the impairment direction.

^{pp} Based on pain mechanism with a predominant flexion pattern released during an application of central SNAG (see inclusion criteria of Chapter VI)

However, as previously discussed (Section 3, Discussion of Chapter VI), the biomechanics and neuropsychophysiological mechanisms of action of MWM require further research. There are published guidelines but no classification systems for the application of MWM,⁴³ partly because this is a new concept.

During this RCT, variables from a developed kinematic model of the spine were used as the primary outcome measures to address specific components of the ICF domain for LBP (see Introduction section 4.2). The kinematic analysis was complemented by secondary self-reported outcome measures addressing other factors of the ICF domain for LBP, such as the VAS score, as well as functions, activities and participation on the Oswestry Disability Index and Tampa Scale.

In conclusion, the **combined movement** procedure and **MMW** might be easily integrated into the **clinical reasoning** during the objective examination for every patient with mechanical NSLBP (Figure 3). If the CCR is positive and the response is positive^{qq} during the application of SNAGs according to findings of the combined movement procedure, then MWM is probably indicated, either in isolation or complemented with other OMT interventions from the TBC if needed.

4. THESIS CONCLUSIONS

In summary, this thesis questioned the efficacy of **OMT** for **LBP** patients following the steps^{rr} of the EBP process⁴⁴ through three major sections.

Section 1 presented the results of a **systematic review** of evidence for OMT: (I) in acute-subacute LBP, with strong evidence in favour of spinal manipulation vs. sham for pain, function and health improvements in the short term, as well as moderate evidence in favour of spinal mobilisation/manipulation combined with usual medical care vs. usual medical care alone for

^{qq} Pain during movement is reduced and/or ROM in the impaired direction is improved

^{rr} Namely, ask an important question about the care (OMT efficacy) of LBP people; acquire the best available evidence regarding the question and critically appraise the evidence for validity and applicability of OMT to the LBP problem; apply the evidence by engaging in collaborative health decision making with the affected LBP individual(s) and/or group(s); appropriate decision making integrates the context, values and preferences of the care recipient, as well as available resources, including professional expertise; assess the outcome and disseminate the results.

pain, function and health improvements in the short term; (II) in chronic LBP, with moderate to strong evidence in favour of spinal manipulation vs. sham for pain, function and overall health in the short term; moderate evidence in favour of spinal mobilisation/manipulation combined with exercise or usual medical care vs. exercise and back-school for pain, function and quality-of-life in the short and long terms; limited evidence in favour of spinal mobilisation combined with exercise and usual medical care vs. usual medical care alone for pain and function from the short to long term; and limited evidence of no effect for spinal manipulation with extension-exercise vs. extension-exercise alone for pain in the short to long term. This section highlighted the importance of the quality of the clinical study design, including classification into subgroups with targeted OMT interventions (splitting design) and the complex issue of the placebo procedure in OMT trials.

Section 2 investigated a **kinematic model of the spine** in LBP patients during various trunk movements from a sitting position. Kinematic variables were valid and reliable measures, with the tasks of trunk flexion, rotation and flexion with rotation being the most discriminant. Effects of disrupting proprioception on lumbar spine RE during forward bending were studied. Proprioceptive disturbances had the most significant effect in increasing RE among healthy people. Consistent with the literature, greater RE was observed in people with chronic LBP compared to healthy subjects. Three kinematic variables were established: algorithms for ROM (KA-R) and speed (KA-S), as well as RE. These variables could be used to aid in diagnosis and/or to monitor changes during physical therapy programs in LBP patients, and as quantitative outcome measures for OMT interventions in clinical trials.

Section 3 presented an original and standardised clinical pain provocation examination of the lumbar spine in a **combined movements** fashion, aimed at reliably finding the direction and vertebral level(s) of treatment. On the basis of this examination and evidence described throughout the thesis, a RCT was conducted to analyse the efficacy of a **novel** specific method of **OMT**, namely **MWM**, in NSLBP patients with a mechanical pain flexion pattern. This clinical study aimed to raise the level of evidence from limited to moderate for the use of **central SNAG** in a subgroup of NSLBP patients.

In summary, this thesis provides information to help unravel the complex puzzle of LBP. This project has brought me great personal and professional satisfaction, as well as improved knowledge in the assessment and management of patients with LBP. Manual therapy is an art developed through clinical practice, as well as a science developed through fundamental and clinical research. All of the knowledge acquired during my PhD is combined with my previous experience and will directly impact my clinical practice, research and teaching, which will become even more focused on a biopsychosocial patient-centred approach to LBP management. In the future, I hope to continue to write scientific articles, contributing further towards solving this puzzle. Clinical research is of major importance because it directly drives clinical practice and education towards evidence-based OMT practice in a way that helps many patients, students and health professionals.

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Summary of the thesis

This thesis on the study of the efficacy of **orthopaedic manual therapy** (OMT) for patients with **nonspecific low back pain** (LBP) was developed by following the steps of an evidence-based practice process through three major sections. The Introduction defines the debilitating disorder of LBP and OMT, and describes an integrative approach for the stratification of care in LBP patients.

Section 1 presents a **systematic review** that updates the best evidence of OMT efficacy in terms of pain, functions, activities and participation. The findings allow us: (I) to establish different levels of evidence for this form of therapy, (II) to understand the complexity of LBP and (III) to affirm the importance of the study design quality in OMT trials (e.g. splitting design, complexity of the placebo procedure and integration of clinical reasoning).

Section 2, which is composed of three studies, investigates a **kinematic model of the spine** to help in the diagnosis of LBP patients, as well as outcome measures for future investigations of OMT in LBP patients. This kinematic tool permits a valid assessment of body structures (lumbopelvic and thoracic vertebral column, muscles of the trunk and pelvic regions), body functions (mobility in a vertebral segment, control of complex voluntary movements, proprioceptive function) and activities (bending, maintaining a body position).

Finally, **Section 3** presents two clinical studies. The first is a reliability study on a standardised and original pain provocation examination of the lumbar spine in a **combined movement** fashion. This examination provides the direction and vertebral level(s) of treatment. On the basis of this reliable objective examination and evidence described throughout this thesis, a randomised controlled trial was conducted. This last study questions the short-term efficacy of a novel form of OMT, namely **mobilisation with movement**, on primary kinematic outcome measures (kinematic algorithms for range of motion and speed) and secondary self-reported outcome measures (pain, function, activities and participation) in LBP patients with a mechanical pain pattern in flexion. The results of this investigation raise the overall level of evidence from limited to moderate in favour of using central sustained natural apophyseal glides in LBP patients.

In conclusion, the different points and perspectives developed along this thesis contribute towards solving the complex puzzle of LBP within a patient-centred approach. Manual therapy is an art developed through clinical practice, as well as a science developed through fundamental and clinical research. **Clinical research** is of major importance because it directly drives clinical practice and education towards an **evidence-based OMT practice** within the biopsychosocial framework, thereby aiding many patients, students and health professionals.

Benjamin Hidalgo