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Title: Does the range of motion of the cervical spine increase after mobilisation? A comparison of two Cyriax mobilisation techniques.

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Abstract

Objectives: The aims of this study were to measure changes in Range of Motion (ROM) using two mobilisation techniques (manual traction and antero-posterior (AP) glide) and to compare the magnitude of changes in cervical ROM with two techniques.

Design: Pre- and post-interventional study with crossover design.

Setting: The Rehabilitation Research Laboratory (SUPSI-2rLab) at the University of Applied Sciences and Arts of Southern Switzerland (SUPSI Manno Switzerland).

Participants: Thirty-six healthy volunteers comprised of lecturers and administrative workers at the university were enrolled in the study.

Results: Twenty-four active ROM measurements were taken for all participants (six directions, before and after using the two mobilisation techniques). All of the measurements taken after the mobilisations showed an increase compared to the baseline; however, in six of the 12 directions, the ROM showed a significant difference ($p < 0.05$): right rotation, left rotation, right side flexion after manual traction and right rotation, left rotation and extension after AP Glide. Both the AP glide technique and manual traction proved to be effective in three directions; the comparison between the two techniques showed that there was no significant difference when the post-treatment

Cervical Range of Motion (CROM) results were compared. Extension after AP glide showed the greatest increase in CROM, which supports the use of the technique as originally described.

Conclusion: The present study showed that the two studied mobilisation techniques could immediately increase the CROM in healthy volunteers. In a clinical scenario, the AP glide is applied to gain CROM in extension; the study confirmed that the technique could increase the CROM in that direction. Further studies are needed to show the clinical applicability to neck pain in the patient population.

Table of contents

1. Introduction and aims of the study	pag. 6
1.1 Cervicalgia	pag. 6
1.2 Physiotherapy for cervicalgia	pag. 6
1.3 ROM measurements	pag. 7
1.4 Rationale	pag. 7
2. Background and literature review	pag. 7
2.1 Background	pag. 7
2.1.1 Epidemiology	pag. 8
2.1.2 Occupational activity and participation	pag. 8
2.1.3 Functional anatomy and biomechanics	pag. 9
2.1.4 Aetiology	pag. 13
2.1.5 Symptoms	pag. 13
2.1.6 Diagnosis	pag. 15
2.1.7 Treatment	pag. 16
2.1.8 Prognosis	pag. 17
2.2 Literature review	pag. 17
2.2.1 Review, inclusion/exclusion criteria	pag. 18
2.2.2 Summary of publications and critique	pag. 20
2.2.3 Summary of literature review	pag. 29
3. Methods	pag. 29
3.1 Objectives	pag. 29
3.2 Hypotheses	pag. 29
3.3 Study description	pag. 30
3.4 Variables	pag. 30
3.5 Research design	pag. 30
3.6 Participants	pag. 30
3.7 Spinal mobilisation techniques	pag. 32

3.8 ROM measurement device	pag. 33
3.9 Cervical active movement measurement	pag. 33
3.10 Active movement measurement procedure	pag. 34
3.11 Mobilisation techniques: description of the application for the experiment	pag. 37
3.11.1 The first technique, manual traction	pag. 37
3.11.2 The second technique, AP glide under traction	pag. 38
3.12 Experimental procedure in detail	pag. 42
3.13 Outcome variable	pag. 43
3.14 Statistics	pag. 44
3.15 Quantitative study	pag. 45
3.16 Validity	pag. 46
3.16.1 Internal validity	pag. 46
3.16.2 External validity	pag. 46
3.16.3 Construct validity	pag. 47
3.17 Ethical issues	pag. 48
4. Results	pag. 49
4.1 Demographic and adverse events	pag. 49
4.2 Data obtained from the measurement sessions	pag. 49
4.3 ROM means and p-value	pag. 58
5. Discussion	pag. 62
5.1 Confirmation/rejection of the hypotheses	pag. 62
5.2 Clinical considerations	pag. 63
5.3 The strengths of the study	pag. 65
5.4 The limitations of the study	pag. 66
5.4 Study results summary	pag. 67
6. Conclusion	pag. 67
References	pag. 69

1. Introduction and aims of the study

1.1 Cervicalgia

Cervicalgia can be caused by serious conditions (fractures, infections or tumours), or by mechanical dysfunctions of the cervical anatomical structures: intervertebral discs, zygapophyseal joints, intervertebral ligaments, and spinal muscles. Those dysfunctions are usually regrouped and classified as mechanical cervicalgia (Cleland, 2005), and its main feature is pain in the cervical region, which is often accompanied by a restriction in Range of Motion (ROM) and functional limitations. Physiotherapists commonly treat these features.

1.2 Physiotherapy for cervicalgia

Patients affected by neck problems who request physiotherapy may present with pain (Fernández-Peréz, 2012), stiffness (Ingram, 2015) or a combination of the two (Binder, 2007). An improvement in ROM is one of the desired outcomes of manual therapy mobilisations and manipulations (Bialosky, 2009). Manual spine mobilisation is one of the treatment modalities supported by guidelines (Childs, 2008), good clinical practice recommendations (NICE, 2009), and scientific evidence (Hurwitz, 1996), and is taught in manual therapy courses (Grieve, 1988; Kaltenborn, 2003; Cook, 2011; Hengeveld, 2013; Atkins, 2016) as a treatment for pain and reduced ROM. The authors cited above are teaching different vertebral mobilisation techniques and refer to previous authors to explain the mechanisms of action of the proposed techniques (Cyriax, 1983; Maitland 2005). Spinal mobilisation techniques can be performed by specifically trained physiotherapists and can be more cost-effective than other treatment modalities (Tsertsvadze, 2014).

A recent review (Snodgrass, 2014) showed controversies regarding the improvement in Cervical Range of Motion (CROM) after mobilisation/manipulation. In contrast, a recent clinical trial (Pérez, 2014) showed an equal increase after manipulations and mobilisations.

Musculoskeletal medicine is the approach used for the assessment and treatment of

musculoskeletal conditions, which is at the centre of the Master of Science that will be completed with the current dissertation.

The aim of musculoskeletal medicine mobilisations is to restore full painless function through appropriate mobilisation (Atkins, 2016, p78).

1.3 ROM measurements

ROM and other biomechanical properties of the cervical spine have been measured with many different technological devices: inertial systems, videofluoroscopic techniques, electromagnetic tracking technologies, CROM goniometers, and computerised motion analysis devices (Duc, 2014; Tafazzol, 2014; Theobald, 2012; Audette, 2010; Wu, 2007; Pérez, 2014; Morphett, 2003; Tousignant, 2000; Mannion, 2000). The range of available techniques spans from simple and cheap devices to high definition measurement tools, which are only available for research laboratories. Electromagnetic devices have been demonstrated to be more reliable than inclinometers in measuring the cervical spine motion (Gelalis, 2009).

1.4 Rationale

The increase in CROM after a musculoskeletal medicine mobilisation technique has been experienced by thousands of patients treated by physiotherapists, as those techniques have been taught since the fifties. The adherence to evidence-based practice principles asks the researchers to produce evidence proving the efficacy of the techniques which are currently used in clinical practice to integrate them with clinician experience, aiming at the best clinical decision and treatment (Sackett, 2000). The literature review reported here showed that no evidence has been produced so far to demonstrate that musculoskeletal medicine mobilisation techniques can increase the CROM after their application.

2. Background and literature review

2.1 Background

Cervicalgia. The condition treated with manual therapy by physiotherapists is mechanical neck pain that has been defined as “non-specific pain in the area of the cervico-thoracic junction that is exacerbated by neck movements” (Cleland, 2005).

2.1.1 Epidemiology

Neck pain is a common problem. A systematic review included 75 epidemiological studies (Hoy, 2010) and found that the overall prevalence of neck pain in the general population ranged between 0.4% and 86.8% (mean: 23.1%). The authors suggested interpreting the mean estimates with caution because of the heterogeneity of data. The majority of studies included in the review have verified that the prevalence of neck pain increases with age, reaching its peak in the 35–49 year age group and then decreasing in the older groups, with a higher prevalence of neck pain found among women compared with men. A phone survey in Hong Kong found a lifetime incidence of 75.7% (Chiu, 2012). A large cross-sectional survey (Lebeuf-Yde, 2009) conducted in 2002 on 34,902 twin individuals in the Danish population showed that while 40% of participants had never had any cervical pain, 7% had experienced cervical pain in the previous 1–7 days, 12% had suffered cervical pain in the previous 8–30 days, 10% had cervical pain from 30 days onwards, and 32% had experienced cervical pain at least once during the preceding year. A systematic review of 56 papers calculated the various prevalence estimates. In detail, they found a mean point prevalence (pain at the moment when the questionnaire was filled) of 7.6%, a one-week prevalence (neck pain the previous week) of 12.5%, a one-month prevalence of 23.3%, a six-month prevalence of 29.8%, a one-year prevalence of 37.2%, and a lifetime prevalence of 48.5% (Fejer, 2006). The vast majority of patients affected by neck pain can be treated with mobilisations and exercises. Patients excluded from physiotherapy treatment are those with fractures or serious pathologies, with medical treatment being the most appropriate for that group; only a small number of patients belong to that group. A recent study in Norway (Fredø, 2012) showed the rate of cervical fractures to be 11.8/100,000/year.

2.1.2 Occupational activity and participation

Pain and reduced ROM may affect the quality of life and participation in occupational and recreational activities. A previous study (Linton, 1998) quantified spinal pain in the working age population in Sweden. In total, 2,305 questionnaires were returned to the researchers and a prevalence of spinal pain in the previous year of 66.3% was reported, with lower back being the most common complaint (56%), followed by neck pain (44%). Of those with

spinal pain, 19% took at least one day off work during the previous year, but 8% of the respondents declared a level of sick leave of 15 days or longer. In addition, 15% of those who reported spinal pain said that they took workdays off without officially being sick (vacations, overtime compensation). This finding is important because it suggests that official records may underestimate the degree of work absenteeism. A similar study showed an even worse scenario (Chiu, 2012). The 12-month prevalence of neck pain was 64.6% for the 4640 subjects who responded to a phone interview. A total of 2997 respondents had neck pain at least once in the past 12 months; of these, 17.7% had to limit their social activities and 19% had to limit their work activity.

2.1.3 Functional anatomy and biomechanics

Vertebral column. The author will describe the vertebrae, discs, ligaments, and muscles with appropriate drawings from anatomy textbooks.

Figure 1: The bones of the cervical spine (Netter, 2015).

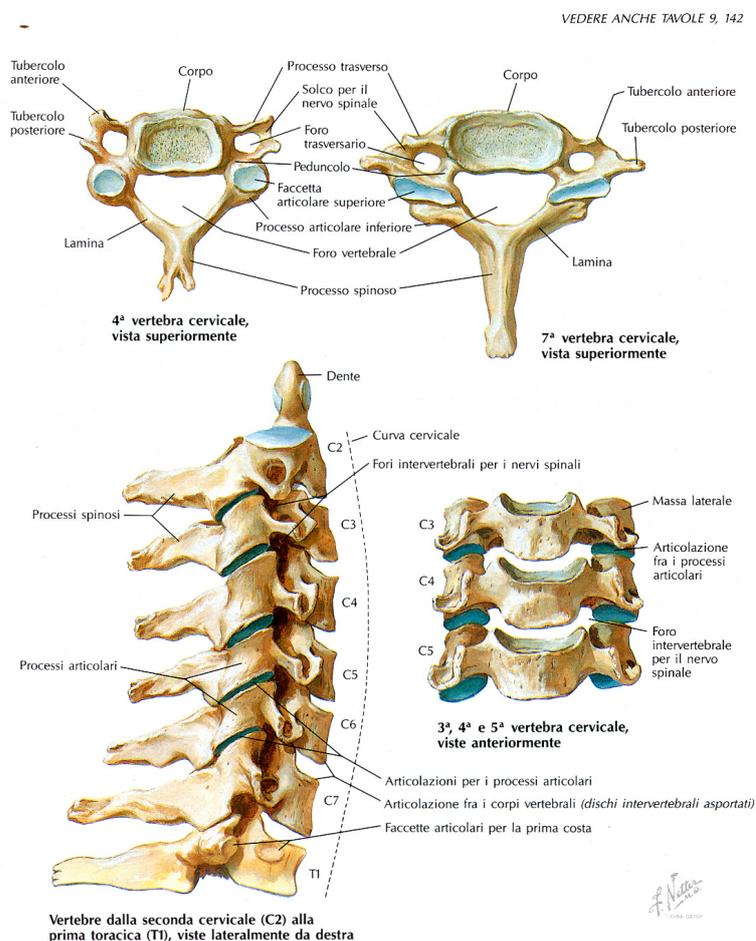


Figure 2: Deep and superficial anterior cervical muscles (Palastanga, 2011).

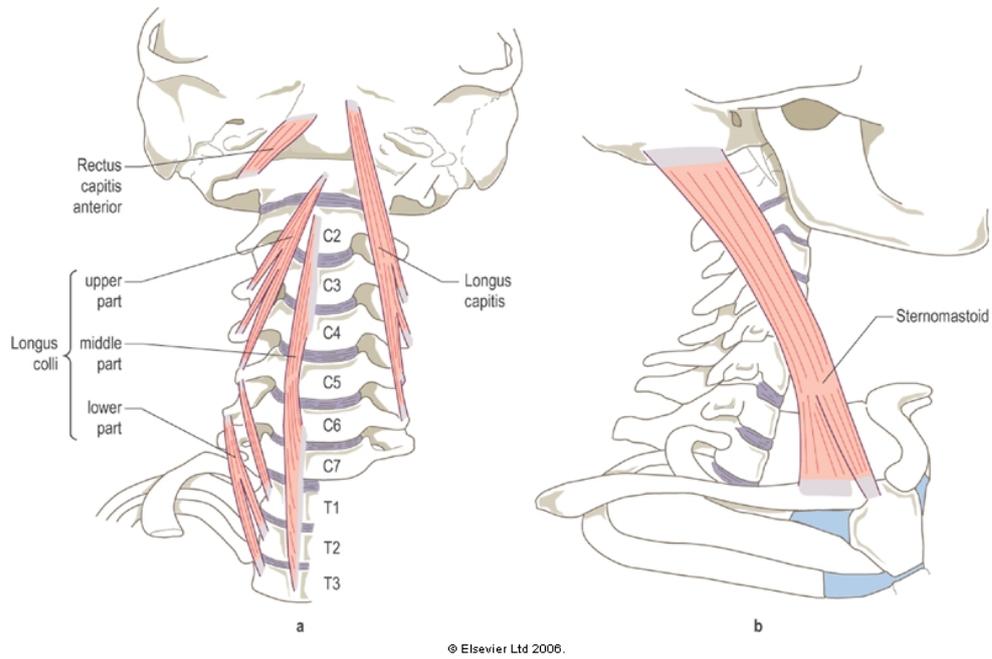


Figure 3: Posterior superficial and deep muscles, anterior deep muscles (Palastanga, 2011).

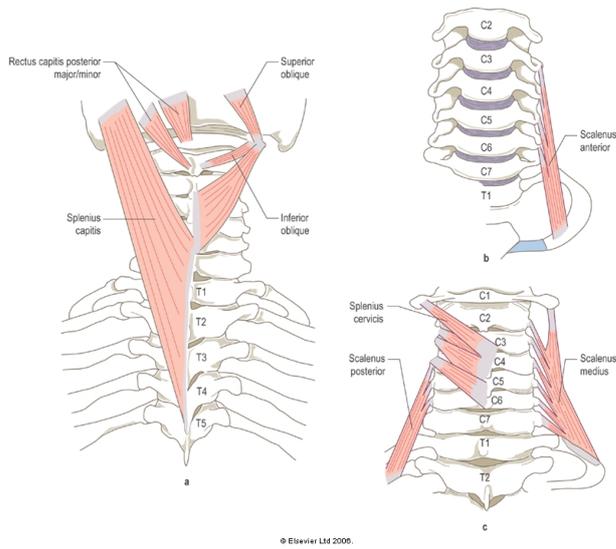
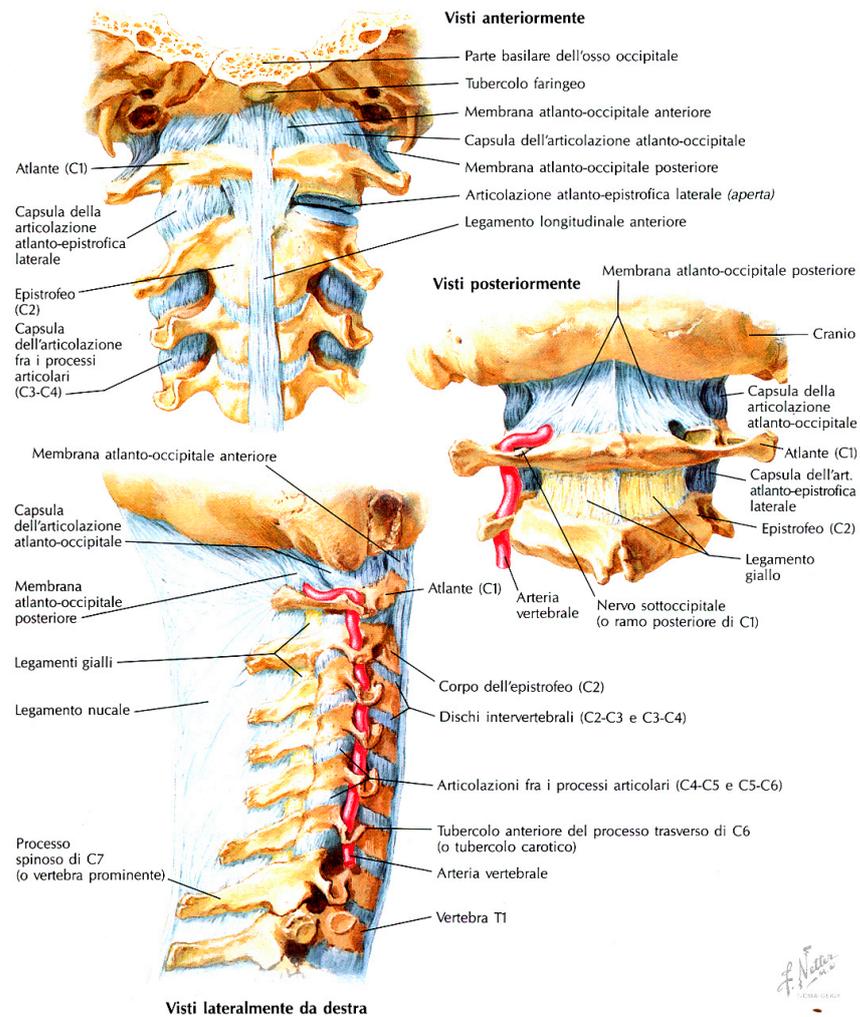


Figure 4: The cervical spine is passively stabilised by a large number of ligaments (Netter, 2015).



A cartilage disc separates the vertebrae. The disc is absent between the occiput and the atlas and between the atlas and the dens. The disc is interposed among all other cervical vertebrae.

The discs absorb mechanical forces from many different directions.

Figure 5: Direction of forces absorbed by the discs (Palastanga, 2011).

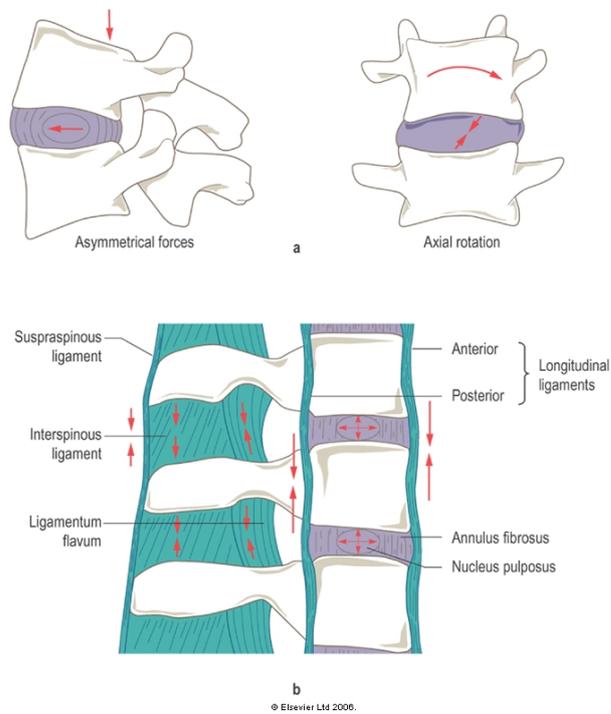
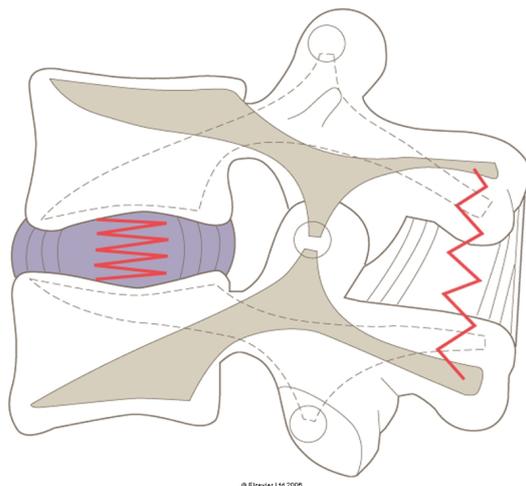


Figure 6: The cervical movements have been represented by several models. The most common considers the disc as a force absorber, the zygapophyseal joints as the fulcrum of the movement and the posterior ligaments as flexion limiters and recoil force producers, which reposition the spine to neutral (Palastanga, 2011).



2.1.4 Aetiology

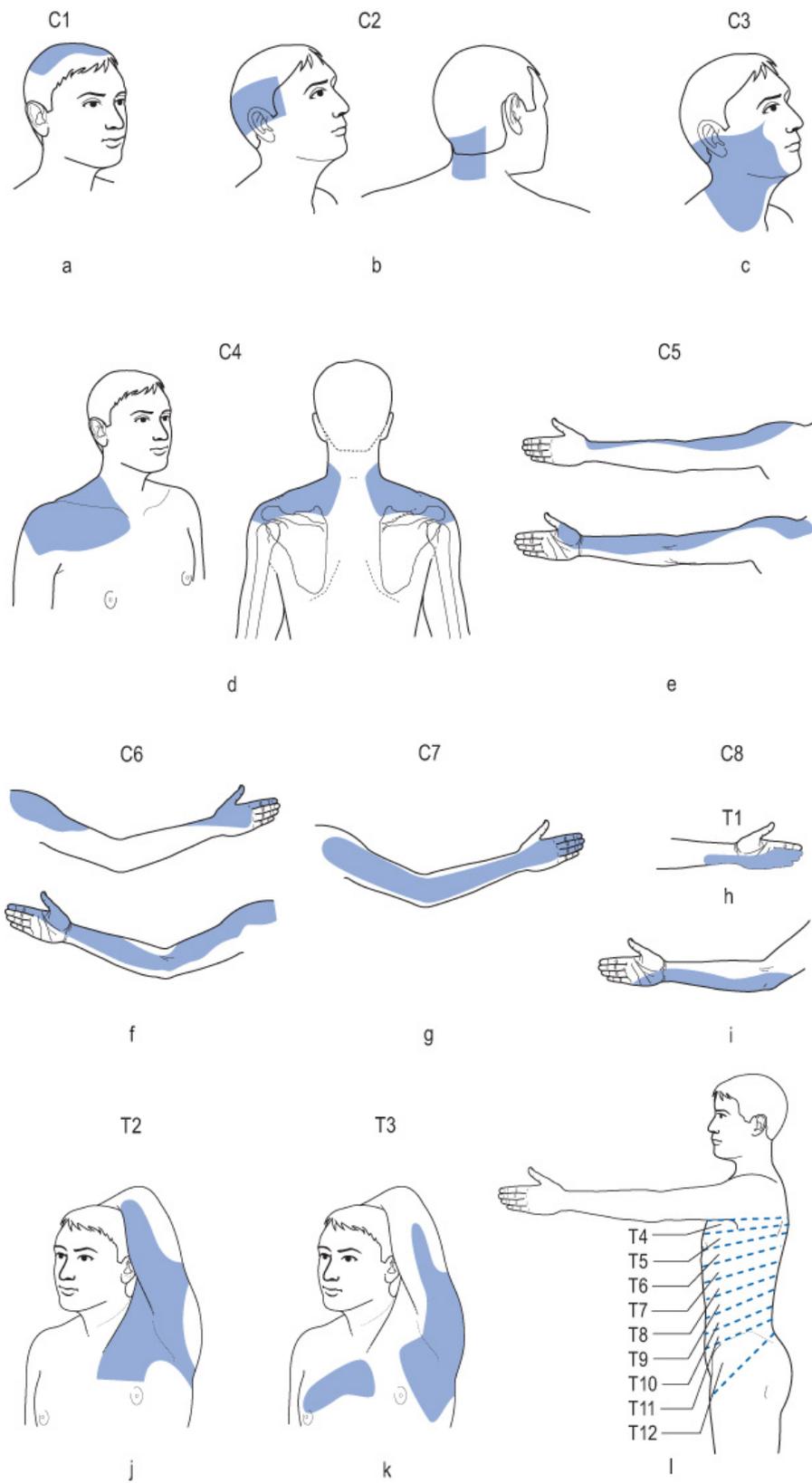
The disc can be considered one of the main sources of pain and reduced ROM. The analysis of specimens from intervertebral discs obtained after disc surgery confirmed the increased secretion of Interleukin 6 and 8, showing a pro-inflammatory response after disc injuries (Burke et al., 2002). A large clinical study involving 500 patients who underwent facets block with local anaesthetic found that facet joint pain was the cause of symptoms for 55% of the patients affected by chronic cervical pain (Manchikanti et al., 2004). Bogduk (2005) classified the vertebral pain described above as *somatic pain syndromes*; those were distinct from *radicular pain syndromes*, where the cause of the symptoms can be allocated into the peripheral nervous system. Studies have demonstrated that mechanical pressure on peripheral nerves could reduce the intra-neural flow and the vasa nervorum efficacy (Gelberman, 1981; Takahashi, 1999). Those phenomena represent the beginning of a cascade of pathophysiological events leading to radicular pain.

2.1.5 Symptoms

Patients affected by neck pain describe pain, muscle weakness, and sensory disturbance in the cervical spine area, between the occiput and the spinous process of C7, but also distant from the structures responsible for the pain, including the shoulder, elbow and wrist (Guzman et al., 2009). Pain distribution follows the rules of segmental reference (Atkins, 2016, p.6). Patients describe pain along dermatomes and the worsening of the condition is demonstrated by pain radiating to the distal end of the dermatome (wrist and thumb), while patients describe resolution of the cervicgia with symptoms in proximal structures (shoulder and cervical spine).

Upper quadrant dermatomes are shown in Figure 7.

Figure 7. Atkins (2016, p.8) with permission.



Health-related quality of life (HRQoL) could be affected by neck pain (Nolet, 2015). The participants in the study affected by six-month duration neck pain had worse HRQoL. Furthermore, the increase of pain and duration of the symptoms were related to a decrease in HRQoL.

2.1.6 Diagnosis

The definition of neck pain states “pain in the neck (neck pain) can be located in the neck itself, or in combination with irradiating pain into shoulder, arm, digits, breast, shoulder blade (cervical radicular pain) and/or head (cervicogenic headache)” (Bartels, 2016). The diagnostic procedure leading to the diagnosis of neck pain incorporates the search for serious pathologies leading to immediate or urgent medical referral, such as vascular neck problems, metastases, fractures, atlanto-axial subluxation, infections, systemic rheumatologic disease, upper motor neuron lesions, congenital abnormalities, and visceral referred pain (Cohen, 2015). Physiotherapists are allowed to perform the assessment procedure. Once those serious conditions have been ruled out, and the signs and symptoms suggest that the patient is affected by somatic pain syndrome producing mechanical neck pain, it is appropriate to treat the patient. Somatic pain syndrome (Atkins, 2016 p.222) can be caused by the discs, the nerve roots, the dural nerve root sleeves, the spinal ligaments and the zygapophyseal joints. A large number of lesions have been found with magnetic resonance imaging in asymptomatic subjects (Matsumoto, 2013), which implies that clinical assessment is the most useful tool for determining the physiotherapy treatment plan. The musculoskeletal medicine approach to assessment is logical and clear and allows for the diagnostic process (Atkins, 2016 p.3). The subjective exam aims at describing the quantity, quality, and extent of the symptoms. Those data are related to the duration of symptoms and the modality of the onset of the neck pain episode. The data obtained with the subjective examination are matched with the results of the objective exam to reach a diagnosis. The objective exam includes a clear and standardised sequence of provocative tests where the concept of selective tension is applied (Atkins, 2016 p.22) and aims to reproduce the symptoms. The movement or movements reproducing the symptoms recognised by the patient allow the practitioner to locate the source of the pain that will be treated (Atkins, 2016 p.22). Musculoskeletal medicine classifies people affected by neck pain into four cervical clinical models (Atkins, 2016 p.243-245). Clinical model 1 is acute torticollis or acute mechanical neck pain in young patients. Clinical model 2 is

mechanical neck pain with recent and sudden onset, and without neural signs and symptoms. This model represents the ideal clinical presentation for the two mobilisation techniques studied in the present dissertation. Clinical model 3 is a history of increasing and worsening episodes, which may represent the progression of the first two clinical scenarios. Clinical model 4 describes the subgroup of patients presenting with chronic neck pain. Musculoskeletal medicine approach for the assessment of mechanical neck pain includes both active movements for pain provocation and pain palpation tests (Atkins, 2016 p.232). For the cervical spine, the pain provocation active tests are the six active cervical movements that were measured by the author in the experiment described in the following chapters.

2.1.7 Treatment

Surgery and injections are medical doctors' treatments of choice for neck pain and the use of those interventions gives the best results for patients affected by serious pathologies or radicular symptoms (Carragee, 2008; Mukai, 2011). For patients affected by mechanical neck pain, a specific pathology cannot be found and surgery is not recommended (Bartels, 2016). The musculoskeletal medicine classification of clinical presentations allows the clinical models to be matched to the treatment procedure (Atkins, 2016 p.243-245). The treatment of choice for mechanical neck pain, clinical model 2, is cervical mobilisation. Mobilisations can cause hypoalgesia and muscle function improvement (Lascurain-Aguirrebeña, 2016), increase the CROM in symptomatic subjects (Reid 2014) and increase patient satisfaction (Gross, 2010). A systematic review (Kay et al., 2015) of 27 trials showed that exercises could have a positive effect in patients suffering from chronic neck pain, even if it was not possible to find high quality evidence to support it. The combination of exercises and mobilisations showed greater short-term pain relief than exercise alone and some evidence supports the combination of exercises and mobilisations for pain reduction and improved quality of life over mobilisation alone for chronic neck pain (Miller, 2010). The passive part of the treatment (mobilisation), which aims to reduce pain and increase the CROM, interacts positively with the active part of the treatment session (exercise), as it allows the patient to correctly perform the prescribed exercises.

2.1.8 Prognosis

A small number of studies have been published on the prognosis of neck pain. A prospective cohort study recruited patients in general practice clinics in Holland (Hoving, 2004). The researchers included 183 patients recruited by 52 general practitioners between 18 and 70 years old. The pain of the admitted patients was reproducible during the assessment and could be classified as mechanical neck pain. The patients were assessed at the end of the 7 week period of the respective treatments and had a one-year follow-up assessment. At 7 weeks, 51.4% of the patients had recovered, while the percentage was 63.5% at one year follow-up. Poor prognosis factors were age (over 40 years) and concomitant low back pain. A Swedish prospective study including 193 patients employed outcome measures that allowed the impairment and disability to be quantified, making the results interesting for health professionals involved in the treatment of patients affected by non-specific mechanical neck pain (Kjellman, 2002). Two groups of patients were enrolled in the study; the first included 123 patients who had been referred for physiotherapy, while the second (n=70) consisted of patients included in a prospective randomised clinical trial comparing physiotherapy and chiropractic therapy as a primary treatment. The outcomes were measured at the time of admission to the study and at a 12-month follow-up. Pain intensity decreased from 49.7 to 30.5. Function measured with the Oswestry score (0 no pain or difficulties, 100 highest score for pain or difficulties) was 23.8 at baseline and 15.8 at follow-up. General health in mm VAS (0 best imaginable, 100 worse pain imaginable) was better, scoring 33.9 at baseline and 26.2 at follow-up.

Therefore, one year after the first assessment, both studies found that the majority of patients recovered and showed good results for the selected outcomes, but not complete recovery for the entire population.

2.2 Literature review

A thorough literature review revealed that there are no publications measuring the variation of CROM on healthy population immediately after the two Cyriax cervical mobilisations that were used in the present study. Three health science databases were searched: PubMed, Cinahl, and Pedro. Even if it was possible to find a number of studies measuring the increase of CROM after many different manual therapy mobilisations and

manipulations, none of them involved the techniques currently employed for a musculoskeletal medicine treatment for cervicalgia.

The result of the review is important as it shows the need for the experiment that is described in the Methods section and gives a rationale for the recruitment of healthy volunteers. The procedure has never been described before and thus needs to be tested before using it on symptomatic patients.

The aim of the experiment described in the present dissertation is to fill the gap in the literature and to give scientific support to the clinical application of the two techniques used in the experimental procedures.

2.2.1 Review, inclusion/exclusion criteria

Database, search keywords, and inclusion criteria were selected to find previous studies with similar experimental procedures, mobilisation techniques, and outcomes.

Studies

Only randomised controlled trials (RCTs) were included in the current review.

Participants

Studies of adults (18 years and older) were included in the review. The search also included asymptomatic volunteers. The author excluded studies of specific neck pain, defined as pain with a specific cause, such as a compression fracture, tumour, metastasis, or infection.

Intervention

Publications with any type of vertebral mobilisation and manipulation were included. The exclusion criteria included fascial manual therapy techniques, osteopathic techniques (strain counterstrain) and induction techniques.

Comparisons

Comparisons were not included in the search string.

Outcome measures

Studies with ROM in association with pain pressure threshold, self-reported pain scales and specific questionnaires as an outcome measure were included.

The search was run on PubMed on the 15th of January 2017. The search string is shown below:

Search (((("Cervical Vertebrae"[Mesh]) AND "Range of Motion, Articular"[Mesh]) AND "Musculoskeletal Manipulations"[Mesh]) AND "Randomised Controlled Trial" [Publication Type] AND ((healthy subjects) OR pain-free) Sort by: Relevance Filters: Clinical Trial; published in the last 10 years; Humans; English

Three publications were retrieved, but none met the inclusion criteria.

With the same keywords on Cinahl, the search showed no results.

On Pedro, the search was run with the keywords cervical spine, healthy subjects, pain-free, mobilisation, and measurement, but no publications were retrieved.

A free search on physiotherapy and manual therapy journals was performed and publications were retrieved with the following search terms: cervical spine, mobilisation, ROM, latest 10 years, RCT. Eight publications were included in the review.



2.2.2 Summary of publications and critique

- Martinez-Segura (2006) published an RCT comparing a single high velocity low amplitude (HVLA) manipulation applied to the cervical spine for manual therapy. Seventy people affected by mechanical neck pain were recruited to the study and randomly divided into two groups: an interventional group and a control group. Inclusion criteria were: suffering from mechanical neck pain of at least 1-month duration, and intervertebral joint dysfunction diagnosed by the experimenter. Exclusion criteria were: contraindications to manipulations, pain with central sensitisation, central and peripheral nervous system lesions, cervical surgery and spinal manipulation within the previous month. Outcome measures were active ROM measured with a goniometer and pain at rest. Manipulations were not applied at the same level for all subjects, as the therapist who was applying the intervention to the patient declared a dysfunctional vertebral level where the intervention was applied. This procedure represents a threat to external validity. The authors applied manual therapy to the control group, describing a manual therapy technique that is similar to a sham technique. Pre- and post-intervention differences in the intervention group showed a reduction in pain and an increase in cervical mobility. When compared with the control group, the intervention group showed a greater improvement of outcome measures. The study contains a serious interventional bias. The declared aim was to compare mobilisations against manipulations, but the study description demonstrates that the comparison was between a sham mobilisation and a manipulation. The described mobilisation could have hardly any effect on the patients; meaning that it was easy to demonstrate that manipulation could produce better results than mobilisation.
- Lin (2012) compared Long's manipulation with Traditional Chinese Massage (TCM). Sixty-three patients were enrolled in the study. Patients were between 18 and 67 years old and had more than a three-month history of mechanical neck pain. Exclusion criteria included manipulation contraindication, neck pain of visceral origin and having received the Long's manipulation in the previous three months. The primary outcome measurement was the Chinese version of the Northwick Park Neck Questionnaire (NPNQ), while secondary outcome measurements included pain intensity, craniovertebral angle and CROM with a goniometer. The treatment

protocol of the two arms included four steps: Step 2 was the HVLA thrust manipulation, while steps 1, 3, and 4 were TCM techniques. The participants received eight treatment sessions. The interventional group included all four steps, while the control group did not undergo the step 2 manipulation. The results of the study showed an immediate improvement in the NPNQ and an immediate increase in the CROM for both groups, but the difference between the groups was significant in favour of the Long's manipulation group. A threat to external validity is represented by the intervention description; it would be very difficult to replicate the study because of the poor description of the interventional protocol. Furthermore, the researchers did not declare the vertebral level where the manipulations were applied, and the manoeuvres were applied where the researcher felt the tension, which means that the choice was subjective and probably at different levels between sessions and patients.

- The study by Reid (2014) is an RCT comparing the effects of sustained natural apophyseal glides (SNAGs) with self-SNAG exercises against passive joint mobilisation (PJM) with ROM exercises, and placebo. The participants were affected by chronic cervicogenic dizziness for 3 months or longer. A thorough clinical examination conducted by a physiotherapist and an otoneurologist led to the inclusion of only volunteers affected by cervicogenic dizziness who were not presenting any contraindication to manual therapy, were not pregnant, and could read English. The main outcome measures were CROM, head repositioning accuracy, and balance. The CROM was measured with a goniometer. The study showed an improvement in the CROM for the group treated with SNAGs, and the effects were maintained for 12 weeks after the treatment. The research could not find any significant effect on head repositioning accuracy and there was no conclusive effect for SNAGs or PJM on balance. The authors reported the possibility that the CROM device was not sensitive enough to detect small changes in the head repositioning accuracy. Another reason not stated by the authors and more related to the rehabilitative culture could be that head repositioning is a motor control skill. Studies have shown that passive mobilisations may show good results for pain and mobility but motor control skills need to be addressed with specific training (O'Learly, 2003; Falla, 2004).
- Espí-López (2014) ran an RCT with 84 patients evaluating the effects of manipulative and manual therapy treatments on patients affected by tension-type

headache. Inclusion and exclusion criteria were clearly stated. All participants were diagnosed with either Episodic Tension-type Headache (ETTH) or Chronic Tension-type Headache (CTTH). The treatment techniques were suboccipital soft tissue inhibition (manual therapy) and occiput-atlas-axis manipulation. The patients were divided into four groups: group 1 received manual therapy treatment, group 2 received manipulative treatment, group 3 received a combination of both treatments, and group 4 received no treatment. The main outcome measures were pain perception assessed with the McGill Pain Questionnaire and cervical mobility measured with a goniometer. The patients showed an improvement after the intervention for both the main outcome measures and the frequency of headache episodes. Manual therapy showed good results for ROM improvement, but manipulation and the combination of manual therapy with manipulation had better results for the reduction of pain intensity. All of the interventional groups gave better results than the control group. Two important limitations can be found in the study. The description of the manual therapy intervention was poor; the authors provided no pictures or detailed descriptions of the handholds and patient/therapist position. It seems that the technique had been described for the first time in that study. This makes the experiment impossible to replicate. The control group was a “no treatment” group, and it is likely that the volunteers understood that the intervention was not administered, which could have influenced the answers to the questionnaire.

- The RCT published by Pérez (2014) compared three different interventions in patients affected by chronic neck pain. Inclusion criteria were pain anywhere in the posterior area of the cervical spine of more than 12 weeks duration. Exclusion criteria were the contraindications to manual and manipulative therapy. The three interventions were HVLA thrust manipulation, oscillatory postero-anterior mobilisation and SNAG active assisted mobilisation. Each participant received four treatments over a period of two weeks. The primary outcome measure was pain intensity measured with VAS. The secondary outcome measures were the Neck Disability Index, the active CROM with a goniometer and the Global Rating of Change Scale (GRCS). All participants showed the same improvement at all of the follow-up assessment sessions: immediately after treatment, and one, two, and three months after treatment. The investigators could not answer the title question, and they could not establish whether one technique is better than

others. The method contains several weak points. The authors did not declare the cervical level at which the interventions were applied. The manipulations and mobilisations were applied at vertebral levels that the researchers considered hypomobile, and the researcher assessed the vertebral levels during the experimental sessions. This means that the point of application was not standardised and was probably not only different between patients but also in the different sessions for the same patient. That procedure implies that the external validity of the study results is compromised. Furthermore, the RCT inclusion criteria should be questioned; chronic patients affected by a musculoskeletal pain lasting more than 12 weeks can be included in the central sensitisation pain mechanism patient group (Smart, 2012). Passive treatment is usually not considered the treatment of choice for that subgroup of patients. Internal validity is compromised by the selection of patients.

- Lluch et al. (2014) compared the immediate effects of an assisted movement treatment followed by active treatment for chronic idiopathic pain against a passive treatment by assisted exercises. Inclusion criteria were a history of neck pain ≥ 3 months during the previous year and pain intensity of $\geq 3/10$ on a Numerical Pain Rating Scale (NPRS). Exclusion criteria were manual therapy contraindications. Outcome measures were CROM over six movements (extension, flexion, left and right rotations, left and right side bending), pain pressure threshold and bilateral sternocleidomastoid, and anterior scalene and splenius capitis activation detected with the use of surface electromyography. Eighteen patients divided into two groups received two different treatments only once and for a short time. The patients in the active treatment group performed three minutes of specific exercises. The investigator assisted the volunteer for the first minute, but the exercises were performed independently in the following two minutes. Patients in the passive mobilisation groups received two minutes of mobilisation followed by one minute of assisted exercises, as in the active group. Both groups showed no change in CROM and a significant improvement in the pain pressure threshold. Only the exercise group showed a significant reduction of sternocleidomastoid and anterior scalene activation, with no difference for splenius capitis. The result is not surprising as the outcome that showed the greater improvement is related to muscle control, which can be enhanced only with exercises leading the patient to an improvement in voluntary inhibition of

selected muscles when asked to perform specific motor tasks. The aim of the study was to prove that the recovery of correct motor control of an area affected by pain does not automatically follow a pain-relieving treatment. Apparently, the study results support the hypothesis of the authors, but the sample size, which was neither calculated nor stated, was very low (18 patients) and hardly allowed the results of the experiment to be generalised to the entire population (external validity).

- Creighton (2014) measured and compared the increased CROM and the reduction in pain intensity, and measured the adverse reactions (AR) after two non-thrust cervical mobilisations. The study was a quasi-randomised trial including 30 participants with painful and restricted cervical rotation. The participants were randomly assigned to two interventional groups. The two techniques applied were aimed at the facet joints at the C7-T1 level and differed in the direction of the force applied to the joints. One technique was a gliding technique, while the other is a traction technique. The CROM was measured with a goniometer and pain was measured with an NPRS. The mean age of the participants was 58.37 and all of them were referred to an outpatient clinic for cervicalgia physiotherapy treatment. At the time of admission, all patients reported pain at the end of the range of cervical rotation, but not with the head in mid position. The clinical presentation was described as mechanical neck pain. The results of the study showed increases in cervical rotation ROM, a statistically significant reduction of pain intensity, no differences between the two techniques, and absent AR after the two mobilisation techniques. The authors acknowledged that two mobilisation techniques could not represent a stand-alone treatment for neck pain and need to be incorporated into a wider treatment plan. Nevertheless, the study showed that the use of these treatments is safe and helpful to reduce pain and increase the cervical rotation ROM. The study contained several limitations: the same researcher who ran the patient assessment applied the cervical mobilisations, thus he was not blinded; the number of patients was low; the researchers did not show the power calculation to demonstrate the possibility to statistically compare the two techniques; and the setting represented a threat to external validity because the patients were aware of receiving an intervention aimed at relieving their neck pain, which may have caused a placebo effect that can partially justify the study results. These limitations minimise the possibility of generalising the study results to the neck pain

population.

- Ganesh (2015) compared the effects of a Maitland mobilisation technique with exercises against Mulligan SNAGS with exercises and exercises alone. Inclusion criteria were neck pain for less than 12 weeks, cervical reduced ROM in extension, side flexion and rotation, and neck symptoms reproduced with passive accessory mobilisation movements, while the exclusion criterion was contraindications to manual therapy. The 60 participants were divided into three groups that received the three interventions.
 - The intervention protocol:
 - The exercise group. The exercise program contained many different exercises for many sets of repetitions. The patients had 10 sessions with a therapist and were asked to continue with exercises for four weeks after the end of the two weeks with the therapist.
 - The Maitland passive treatment group. The treatment description was detailed and accurate, and the patients in this group followed the same exercise regime as the exercise group.
 - The Mulligan treatment group. The treatment description was detailed and accurate, and the exercise program was the same of the exercise group.

Outcome measures were ROM with a goniometer and the Neck Disability Index.

The study design presents some limitations:

- The researchers calculated a sample size of 72, with 24 patients for each group, but only 60 patients completed the experiment.
- The clinical presentation of patients admitted to the study was too heterogeneous. Spine symptoms are classified as acute until the sixth week. Including patients affected by pain and ROM reduction from week 1 to week 12 means that patients in both the acute and early chronic phases were admitted. The researchers did not state how many patients were in the early phase of their neck pain and how many had been affected for more than 6 weeks. Patients in their early chronic phase of neck pain can experience a greater benefit from exercises than mobilisation.

The study conclusion states that it is not possible to quantify better results for one

group compared to the others. This is not surprising, but it is mainly related to the protocol. All participants were involved in the exercise program that was very intense and accurate, targeting all of the different neck structures. They were also asked to continue with the exercise program for four weeks after the end of the treatment. When the investigators assessed patients for the final follow-up at week 12, all had performed the exercise program for 6 weeks in total. The patients in the Maitland mobilisation group received passive mobilisation for 30 seconds for each hypomobile level (not stated by the authors but possibly not more than 2/3 levels) for ten sessions. The patients in the Mulligan group received six mobilisations for 10 sessions. Internal validity was compromised by the study design as the patients received a small number of short and simple sessions of mobilisations while being asked to perform long sessions of exercises for many weeks. Even if the authors suggest that the outcomes were equal in all groups, the graph of pain and the graph of Neck Disability Index (NDI) show better results for the exercise group at 12 weeks. It is possible that the investigators were too concerned with obtaining the resolution of the neck pain for all participants in the study and subsequently designed a study too similar to a treatment session than a scientific experiment aimed at verifying the original hypothesis.

Table 1 - a

Author, year	Martinez-Segura, R., 2006	Lin, J. H., 2012	Reid, S. A., 2014	Espí-López, G. V., 2014	Pérez, H. I., 2014
Study design, aim of the study	RCT, to analyse the immediate effects on neck pain and active CROM after a single cervical HVLA manipulation or a control mobilisation procedure in mechanical	RCT, to compare the effectiveness of Long's manipulation with TCM and TCM alone on pain, craniovertebral angle and ROM.	RCT, to evaluate and compare the effects of 2 manual therapy interventions on cervical spine ROM, head repositioning accuracy, and balance in patients	RCT, the purpose of the study was to evaluate the efficacy of manipulative and manual therapy treatments with regard to pain perception and neck mobility in patients with tension	RCT, the purpose was to compare the effectiveness of three manual therapy techniques: HVLA, mobilisation and SNAG in patients with chronic neck pain.

	neck pain subjects.		with chronic cervicogenic dizziness.	type headache.	
No. of patients	70	63	86	84 - divided into three groups	51
Interventions	HVLA thrust.	Long's manipulation and traditional Chinese massage.	SNAG, PJM, placebo	Mobilisation and manipulations	Manipulation, mobilisation, SNAG.
Comparisons	Manual mobilisation	TCM	Placebo	The two techniques alone or combined	Comparison among the groups.
ROM measure, study outcome	Pre post assessment of active CROM and pain	NPQ, CROM, craniovertebral angle.	CROM device (goniometer)	CROM device not specified	Visual analogue scale (VAS), NDI, global rating of change and CROM.
Study results	The manipulation technique increased ROM more than mobilisation technique.	The Long's manipulation group showed better results on every outcome measure.	SNAGS increased CROM more than PJM and placebo.	Manual therapy increased ROM, but manipulation and manipulation with manual therapy had better results for neck pain.	Inconclusive, it was not possible to find one treatment that increased the ROM more than others.

Table 1 - b

Author, year	Lluch, E., 2014	Creighton, D., 2014	Ganesh, G. S., 2015
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Study design, aim of the study	RCT, to compare the immediate effects of an assisted plus active cranio-cervical flexion exercise (exercise group) versus a passive mobilisation plus assisted cranio-cervical flexion (mobilisation group) on performance of the cranio-cervical flexion test, CROM and pain in patients with chronic neck pain.	Quasi-RCT, to measure the increase of CROM, the reduction of pain and the presence of adverse reactions with two different cervical mobilisation techniques.	RCT, the objective of this work was to compare the effectiveness of Maitland and Mulligan's mobilisation and exercises on pain response, ROM and functional ability in patients with mechanical neck pain.
No. of patients	18 - divided into two groups	30 - divided into two groups	60 - divided into three groups
Interventions	Mobilisation and exercise	Two mobilisation techniques.	Maitland mobilisation, Mulligan mobilisation, exercises.
Comparisons	The exercise alone or combined with mobilisation	Comparison between the two groups.	Comparison among the groups.
ROM measure, study outcome	Exercise performance, cervical Range of Motion measured with a Multi Cervical Unit and pain	CROM measured with CROM, pain measured with NPRS, adverse reactions after the mobilisation techniques.	Pain, CROM, functional ability.
Study results	The study was inconclusive for ROM.	The two manipulation techniques increased the ROM, but it was not possible to find an intervention better than the other.	All the groups improved when compared with the baseline for all the outcome measures. It was not possible to find an interventional group better than the others.

2.2.3 Summary of literature review

All publications showed increases in CROM after the treatment, regardless of the treatment techniques applied. The analysis of the studies showed that the effects on CROM of musculoskeletal medicine cervical mobilisation techniques have never been quantified before and the two techniques that the investigator applied in the present dissertation have not been used for any previous study. As the increase in movement amplitude is one of the desired effects of the treatment and as it has never been quantified before, the proposal for the present project was approved in SOMM3. Finally, the majority of the studies quantifying the CROM employed goniometers or devices, which were less accurate than the electromagnetic equipment used in the current study.

3. Methods

3.1 Objectives

The aim of this quantitative study (Bryman, 2012 p.157 p.160 p.175; Carter, 2016 p.56) was to investigate whether mobilisation of the cervical spine would increase the active ROM after mobilisation of the cervical spine in healthy subjects. For the first time, the researcher measured the immediate increase of the cervical active ROM after the two selected techniques with electromagnetic equipment (Fastrak Polhemus).

3.2 Hypotheses

From the title of this dissertation, "Does the ROM of the cervical spine increase after mobilisation? A comparison of two Cyriax mobilisation techniques", it is possible to state two null hypotheses.

First, the two selected spinal mobilisations do not immediately increase the active ROM of the cervical spine.

Second, the comparison of the increase in the ROM between the manual traction and anteroposterior (AP) glide under traction will result in no difference.

3.3 Study description

The experiment described in the current dissertation is a quantitative study.

3.4 Variables

The *independent variable* of the study presented here is the mobilisation technique to increase the cervical vertebrae mobility. The variable has two levels: traction and AP glide (Carter 2016 p.68).

The *dependent variable* is CROM. This variable is dependent because its values depend on changes to the independent variable. ROM is one of the typical dependent variables in physiotherapy. The cervical vertebrae ROMs were measured in degrees, and the measured angle was the angle between the sensor positioned on the head and the sensors positioned on the trunk of the volunteers.

3.5 Research design

The experiment was a pre- and post-interventional study, with crossover design (Kumar, 2014 p.136, p.151; Polgar, 2008). All volunteers received both mobilisation techniques in two different sessions, and were randomly assigned to one of the two manoeuvres for the first session and to the other for the second. The washout period was two weeks. The active CROM was measured before and after cervical mobilisation. That study design was applied because the volunteers were asymptomatic and the same people could belong to both groups given the appropriate washout period between the first and second sessions. Since all of the participants were not symptomatic it was not appropriate to compare the interventional groups with a placebo.

3.6 Participants

The selection of subjects was crucial. The investigator chose to enrol healthy volunteers between 40 and 60 years old for the study. Applying a mobilisation technique to young asymptomatic people with full ROM, because of their age, greatly reduced the possibility of seeing a difference in the amplitude of active movements before and after the

performance of the mobilisation technique (Powers, 2008). A recent study showed that a physiological reduction in active ROM occurs in those between 40 and 50 years old (Swinkels, 2014). Furthermore, a previous article reported a gradual age-related reduction in the passive ROM in working age women (Salo, 2009). Applying the mobilisation techniques to subjects showing a physiologically restricted active CROM is more likely to demonstrate the possibility of gaining some degree of mobility after the chosen mobilisation techniques.

Inclusion criteria:

- Age between 40 and 60 years old.
- Cervical pain-free ROM in extension, flexion, left and right rotation, left and right lateral flexion.

Exclusion criteria

- Lack of consent in receiving the mobilisation.
- Diagnosis of rheumatoid arthritis.
- Pregnancy.
- History of chronic cervical pain, shoulder pain, and headache (chronic pain).
- Cervical pain, shoulder pain, and headache in the last month (acute pain).
- Cervical and shoulder injuries in the last three months.
- History of central nervous system injuries.
- History of upper limb peripheral nervous system injuries.
- Positive history of blood clotting disease.

Sample Size

Since there are no quantified data in the literature on the cervical variability of the ROM after musculoskeletal medicine mobilisations, 36 volunteers were recruited as a convenience sample. A convenience sample represents the participants who can be easily recruited by the researcher. The volunteers for the experiment were recruited from lecturers and secretary workers at SUPSI considering their proximity to the laboratory, the low cost and the time frame between the local Ethics Committee authorisation and the deadline of the dissertation. The recruitment followed a few simple steps: the candidates were informed about the study and all those who consented to participate in the study were assessed for eligibility. Every candidate who met the inclusion criteria was enrolled in the experiment (Setia, 2016; Field, 2006).

3.7 Spinal mobilisation techniques

Two Cyriax (Cyriax, 1983; Atkins, 2016 p.251 and 253-256) techniques of cervical mobilisation were selected. The two techniques differ in their mechanical principles. The first technique is manual traction (straight pull) and can be described as a passive accessory movement defined as movements that a person cannot perform actively but that can be performed on that person by an external force (Maitland, 2005). During the mobilisation the physiotherapist applies a force to the cervical spine in an upward direction; it does not imply main movements at the zygapophyseal joints, but a reduction of the compressive force on the discs and zygapophyseal joints. The second technique, AP glide, is an antero-posterior mobilisation with traction. It is a passive physiological movement defined as movements that the patient can actively perform by themselves (Maitland, 2005). The technique, in the first part, is a physiological movement combining upper cervical flexion with lower cervical extension (retraction Fig. 8) followed by the opposite movements during the second phase of the technique to return to the starting position. The technique, while keeping a comfortable quantity of traction, takes the cervical spine from neutral to retraction and back to neutral.

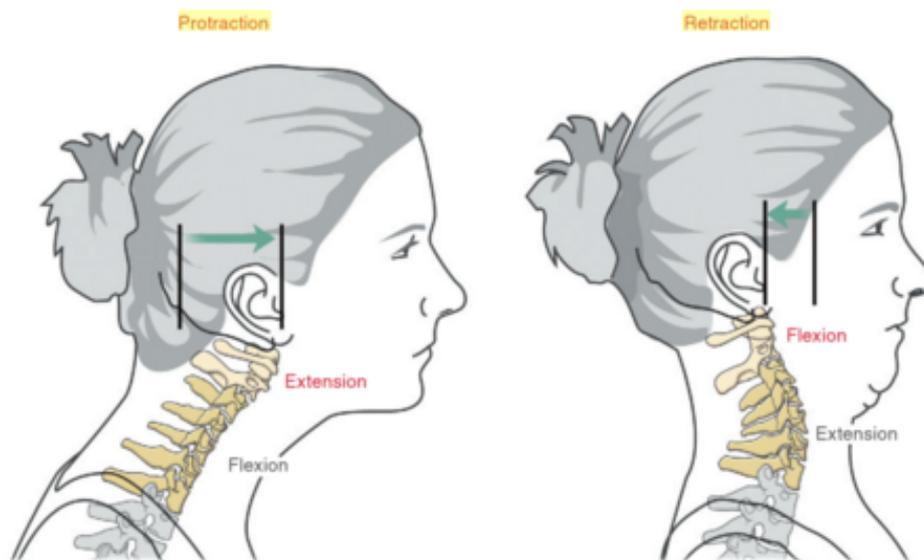


Figure 8: Cervical protraction and retraction. (Neumann, 2013).

This gentle mobilisation technique moves the zygapophyseal joints of both upper and lower cervical vertebrae as far as their end of range in flexion and extension, respectively, while performing a retraction movement.

3.8 ROM measurement device

The Fastrak Polhemus electromagnetic technology movements were first introduced in the 1980s to quantify articular movement (Pearcy, 1989) and were implemented in the following years (Hughes, 1996). Polhemus has shown good results (Koerhuis et al., 2003; Pearcy & Hindle, 1991) with reliability tests, and has good face validity (Kumar, 2014 p.214) since it accurately measures articular motion. So far, this measurement technology has been applied to study lumbar spine mobility (Mannion, 1999), scapula mobility (Fayad, 2006), gait with the pendulum test in patients affected by post stroke spasticity (Bohannon, 2009), ankylosing spondylitis (Jordan, 2004), and acetabular cup orientation in adults (Boulay, 2014). The CROM was measured in a comparative study in asymptomatic individuals and those with whiplash (Dall'Alba, 2001). Other studies using Fastrak Polhemus compared qualitative parameters of movement. Movement patterns were between a group of patients affected by whiplash-associated disorders and healthy subjects (Woodhouse, 2008) and the repositioning acuity between similar groups (Sjölander, 2008). Fastrak Polhemus has never been used to compare the active CROM before and after the two musculoskeletal medicine mobilisation techniques used for the present study.

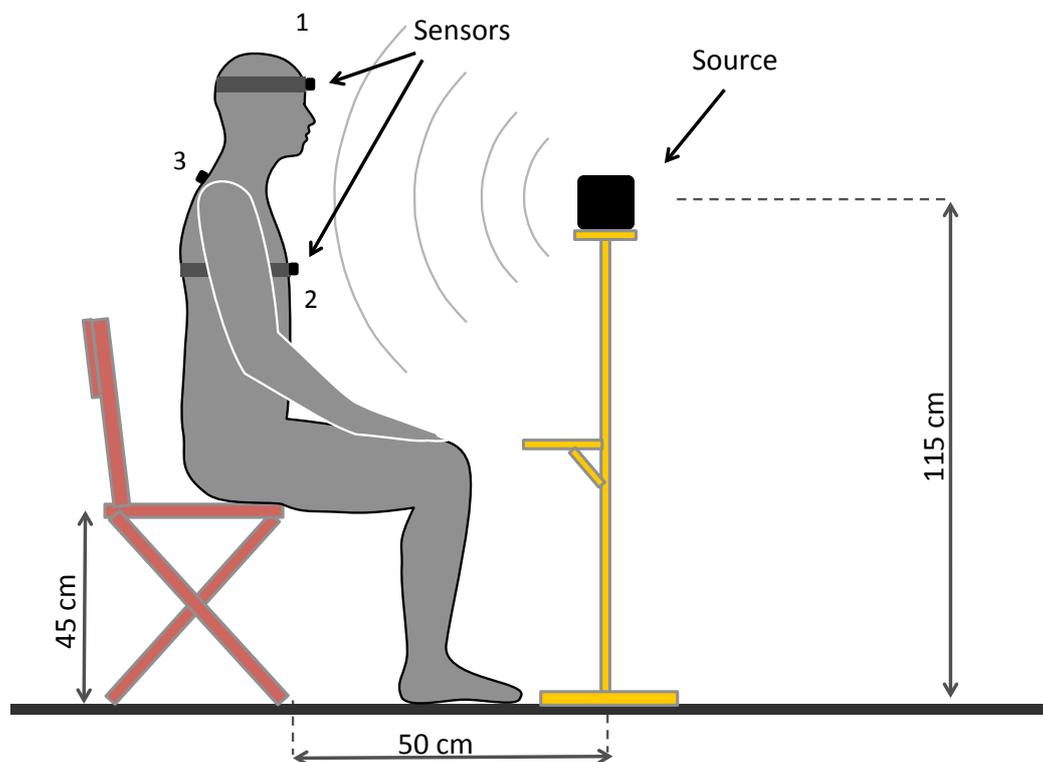
3.9 Cervical active movement measurement

The experiment was performed at the University of Applied Sciences and Arts of Southern Switzerland (SUPSI Manno Switzerland) in the Rehabilitation Research Laboratory (SUPSI-2rLab) with a non-invasive electromagnetic device (Virtual Reality Rehabilitation System, Khymeia, Padova, Italy). The non-invasive electromagnetic device integrates three motions and is measured by Polhemus-G4, which tracks the position and orientation of sensors relative to a source in three dimensions. The system has been used to measure the cervical active ROM (Trott, 1996) and was shown to be accurate to within $\pm 2.5^\circ$ (Koerhuis et al., 2003; Pearcy & Hindle, 1991).

3.10 Active movement measurement procedure

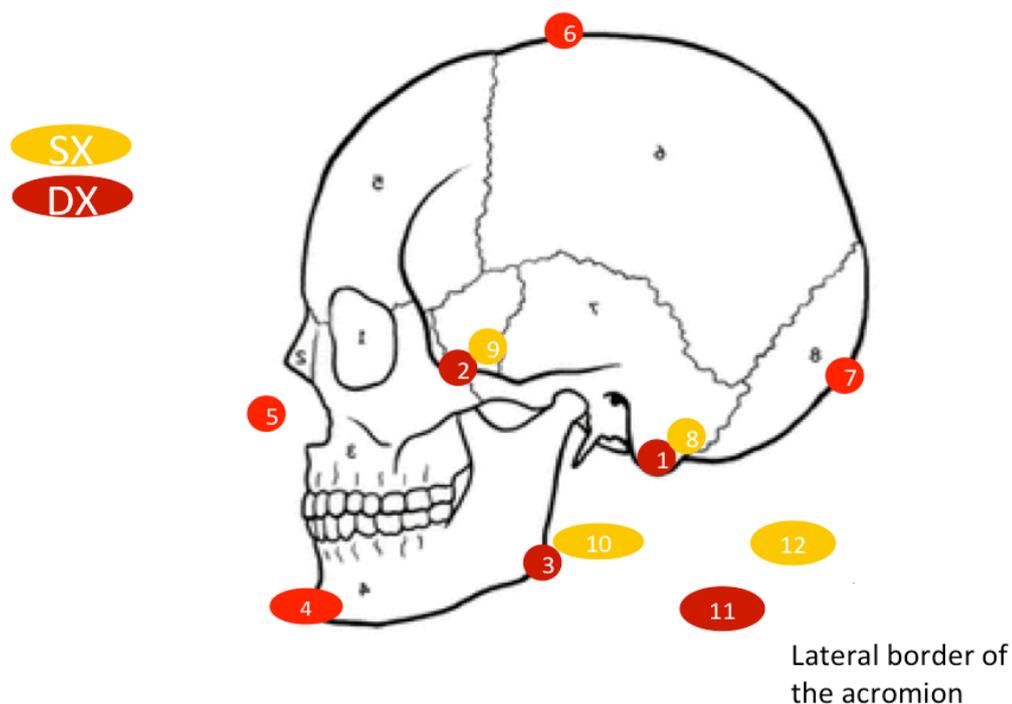
The volunteers were asked to sit on a wooden chair in front of the table where the electromagnetic source was placed. The chair needed to be wood to prevent electromagnetic interference and signal distortion caused by metal. In the experiment described here, three sensors were used. One sensor was on the head, fixed to an adjustable semi-rigid plastic headband similar to that described in a previous study (Amiri et al., 2003). The headband was placed around the forehead of the subjects so that the sensor was aligned with the bridge of the nose, approximately over the glabella (see Figure 9). Two additional sensors were placed on the trunk, one anteriorly, on the body of the sternum, and the second posteriorly, on the T3 spinous process. The three-segment model for assessment of ROM has been confirmed by a study that used a similar device for similar purposes (Rudolfsson, 2012). The wires were secured with tape to prevent traction on the sensors. The electromagnetic source was positioned on a box over a wooden table at a height of 120 cm from the floor, at the level of the head of the patient (Cattrysse et al., 2012).

Figure 9.



The sensors were attached to a transmitter (hub), with a wireless connection to a portable PC, which continually recorded the position of the sensors relative to the source at 120 Hz during each cervical active mobility test. The researcher used custom-made software for the angles computation and to format and store the data for 3D analysis of the neck movements. The software is owned by SUPSI-2rLab and was implemented by the bio engineer of the research team from MatLab[®] software. Measurements were taken from a neutral starting position (reference point of origin on the VRRS system). Bony landmark recordings (Figure 10) preceding the active tests set the angle precision and accuracy of the sensors. The figure shows the position of the bony landmarks. The right side was recorded first and the left side second. Numbers indicate the sequence of recording of the bony landmarks. The procedure was applied for all subjects.

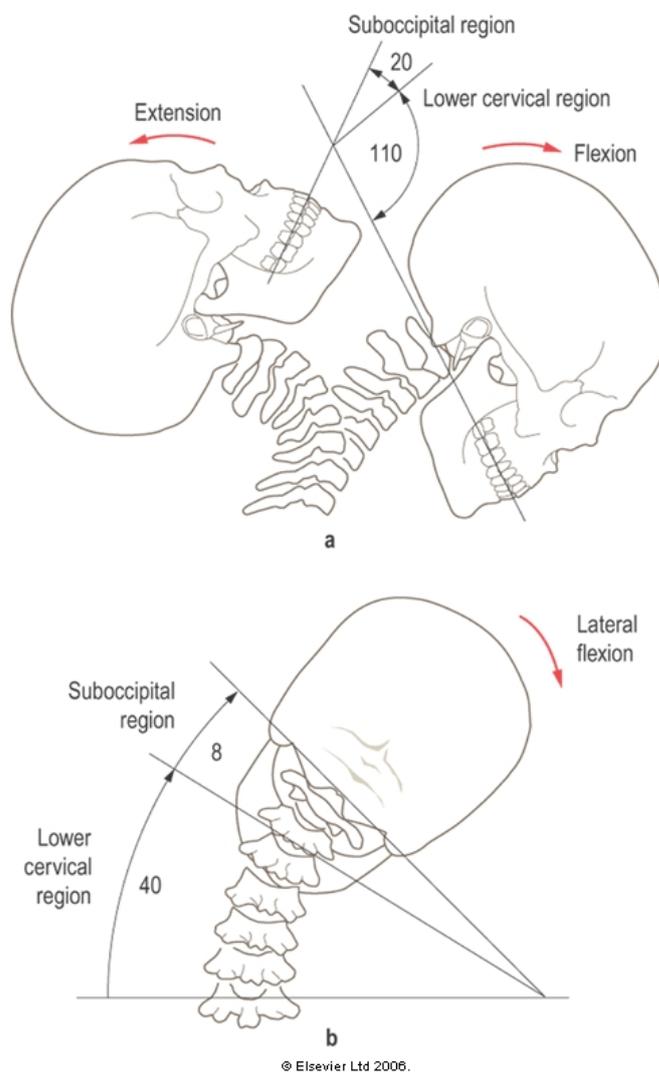
Figure 10



The position and Euler angle data were filtered with a low-pass Butterworth filter (2nd order) using a cut-off frequency at 6 Hz (Grip et al., 2007). The data were dual-passed with the filter in both directions (anti-causal filtering) in order to prevent group delay.

The software receiving the data from the sensors interpreted the trunk (represented by the sensors on T3 and the sternum) as fixed and the head as the moving segment. The mechanical model is shown in Figure 11.

Figure 11 (Palastanga, 2011).



The amplitude of movement of the cervical tract as a whole is calculated from these data. The six active movements and the two mobilisation techniques are global cervical spine movements, which means that the modality of measurements and the cervical vertebrae movements were exactly matched.

The following procedure was applied in previous studies (Saíz-Llamosas, 2009; Audette, 2010; Creighton, 2014).

The volunteers were asked to sit and the electromagnetic sensors were applied. The experimenter asked participants to look straight ahead to establish the starting position or neutral position. Subsequently, the researcher asked the subjects to move their head in six directions: extension, flexion, right rotation, left rotation, right side bending and left side bending. The sequence of the movement directions was randomly decided for every session in order to avoid influencing the study results.

3.11 Mobilisation techniques: description of the application for the experiment

3.11.1 The first technique is manual traction (commonly called Straight Pull). Atkins et al. (2016 p.251) described it as the original Cyriax technique (picture 1).

The procedure for the mobilisation technique was as follows:

- The couch was raised so that it was approximately level with the investigator's hips.
- The patient was positioned in supine with the shoulders level with the head of the couch and the investigator supported the head in their hands.
- Two security belts stabilised the trunk of the volunteers on the couch. It was necessary to apply counter-pressure at the same time as the researcher applied manual traction by restraining the movement of the patient's shoulders towards him. The belts replaced the second operator, as originally described by Atkins et al. (2016 p.251).
- One of the investigator's hands cupped the occiput, allowing the head to tip into slight extension. The cervical spine itself remained in a neutral position.
- The other hand rested comfortably around the patient's chin, avoiding the trachea, and the forearm laid along the side of the face.
- The investigator placed both feet directly under the patient's head and bent both knees. The position of the feet in relation to the couch was adjusted according to the volunteer's size. With small volunteers, the feet were positioned near the end of the couch and with volunteers with heavy body structure, the feet were positioned 20 cm far from the head of the couch. The traction was applied using body weight, leaning out with straight arms.

- The technique was performed slowly, establishing the traction for several seconds.
- The manoeuvre ended by pulling the investigator back to the upright position and releasing the traction.
- After six repetitions, the volunteers were asked to sit up slowly and have a rest for one minute.

Picture 1 - Manual traction Atkins (2016, p. 251) with permission.



3.11.2 The second technique is AP glide under traction, which was described by Atkins (2016 p. 254-256), developing the original Cyriax technique (Pictures 2–3).

The procedure for the mobilisation technique was as follows:

- The couch was placed a little lower than hip height.

- The patient was positioned on the couch as for the previous technique.
- Two security belts were used to stabilise the trunk of the volunteers on the couch. It was necessary to apply counter-pressure at the same time as the investigator applied the manual traction by restraining the movement of the patient's shoulders towards him. The belts replaced the second operator, as originally described by Atkins et al. (2016 p. 254-256). The quantity of traction applied for this technique was considerably inferior compared to the force applied in the previous technique, but the stabilisation was still required.
- The operator stood sideways to the patient with both feet parallel and close to the couch under the patient's head.
- One hand was cupped below the occiput and the forearm supported the weight of the head while cradling it against the investigator's abdomen.
- The other hand was positioned on the chin to be able to apply both traction and retraction. The spreading of the index finger and thumb made a bridge. The web (the part of the hand between the first and second metacarpal) was applied to the chin and the remaining fingers were curled so that they tucked around and under the chin. The elbow of the mobilising arm was positioned perpendicularly above the hand on the chin.
- The researcher leaned out sideways as far as possible to apply traction.
- Once traction was established, the knees were bent, which applied pressure over the chin to take the chin into the maximum retraction and produce the AP glide, while avoiding pressure from the knuckles against the larynx.
- The second part of the technique was to allow the chin to return to neutral, avoiding protraction and releasing the traction.
- After six repetitions the volunteers were asked to sit up slowly and have a rest for one minute.

Picture 2 – AP glide under traction Atkins (2016, p. 254-256) with permission. Starting position.



Picture 3 – AP glide under traction Atkins (2016, p. 254-256) with permission. Retraction.



3.12 Experimental procedure in detail

Volunteers were recruited from lecturers and administrative workers at SUPSI, where the experiment took place. An e-mail including a description of the experiment and the informed consent form with the inclusion and exclusion criteria, was sent to each volunteer. The experiment was approved by the Comitato Etico Cantonale Ticino Svizzera, which is the competent institution for the experiments taking place at the Rehabilitation Research Laboratory (SUPSI-2rLab) in SUPSI Manno, Switzerland. A total of four measurements in two sessions were performed for each volunteer. During each session, two measurements were performed: one before the technique and one after. The total time of each of the two sessions was approximately 40 minutes, divided into the following steps:

- Introduction of the experimental procedure. The experimenter, who was a physiotherapist with 18 years of experience in the clinical application of the two techniques read the inclusion and exclusion criteria and asked the participant if any accidents had occurred between having read the e-mail and the present time (**5 min**)
- The volunteer was asked to sit on the wooden chair and the sensors were positioned (**5 min**)
- Anatomical landmark recording (**5 min**)
- Measurement of the active ROM of each movement from neutral to the end of range and return to neutral of cervical (flexion, extension, right rotation, left rotation, right side bending and left side bending). (**5 min**)
- Removal of sensors and volunteer positioning on the treatment couch (**5 min**)
- One of the following techniques was performed (**5 min**):
 - Manual traction (Straight Pull).
 - AP glide under traction.
- The volunteer was asked to sit on the wooden chair and the sensors were repositioned (**5 min**)
- The measurement procedure was applied after the technique (**5 min**).
- The order of the techniques was randomised for each measurement session in order to avoid bias in the data analysis. Using the random number generator of IBM SPSS, the researcher assigned the subjects randomly to one technique for the first session and the other technique during the second session.

Standardisation of the procedure is a big issue when an experiment involves manual therapy techniques. The original description of both techniques included two operators: one performing the technique and the second stabilising the patient. The author acknowledged that it is not possible to exactly quantify the traction applied to the volunteers, because special devices that are not available would be needed. The best available option to reduce the experimental procedure variables and threats to internal validity was to standardise the counter-pressure applied to the subject with the use of comfortable sports car seat belts.

Pictures of the laboratory setting for the experiment are shown in Appendix 1.

Before starting the sessions with volunteers, the investigator rehearsed the procedure with colleagues. The manual mobilisation procedure described above, for external validity, mimicked the clinical application of techniques. It was immediately discovered that the three repetitions that were originally planned in the dissertation proposal were not sufficient for asymptomatic subjects. The result of physiotherapy techniques is dose-dependent. Recent studies have shown that with a diagnosed musculoskeletal condition, the amount of repetition could influence the treatment outcomes (Østeras, 2013). The aim of the study is to document the increase in mobility of the cervical spine after two mobilisation techniques. In agreement with the staff of the research laboratory, the investigator decided to increase the number of repetitions from three to six. This modification to the treatment protocol cannot be considered bias, but an adaptation to the real conditions of the volunteers that were all asymptomatic at the moment of the experimental procedure.

3.13 Outcome variable

The ROM was computed as the angle between the head and the trunk (Figure 11) and was computed in the three orthogonal planes: sagittal, coronal, and transverse. Each angle was measured with respect to the neutral position of the head of the subject that was established at the beginning of the measurement procedure.

3.14 Statistics

The distribution of the ROM was tested for normality with the One-Sample Kolmogorov-Smirnov Test. The results showed that the distribution in 21 out of 24 ROM resulting from the measurement session followed a normal Gaussian distribution of the value. The author therefore decided to perform the Paired samples t-test. The Paired samples t-test is used to compare the means of two populations with similar characteristics. Two samples are present in which observations in one sample can be paired with observations in the other sample; there is a one-to-one correspondence (or pairing) between the samples (McCrum-Gardner, 2008). The study has a cross-over design that implies repeated measures of the same subjects. In practical experimental situations, the Paired samples t-test is used to compare before and after observations on the same subjects when the data distribution is normal and the standard deviation of the sample is known. The definition is matching the structure of the present study.

The investigator chose to calculate the p-value to describe the difference between ROM variations. Since the book by Fisher (1928) was published, p-value has been widely used in health science research to describe the results of studies (JAMA, 2016).

The p-value is defined as the probability that the null hypothesis is true, obtaining a result equal to or more extreme than that which was actually observed. P stands for probability and measures how likely it is that any observed difference between groups is due to chance. P can take any value between 0 and 1. Values close to 0 indicate that the observed difference is unlikely to be due to chance, whereas a p-value close to 1 suggests that the difference between the groups can be caused by chance (Dorey, 2010; Dorey 2011). To quantify the strength of evidence against the null hypothesis, Fisher (1950) advocated for $P < 0.05$ to be a standard level for concluding that there is evidence for the hypothesis tested. The value is named α and is an agreed upon value in the scientific community, but is not an absolute rule (Carter, 2016 p.272).

For null hypothesis one, the author tested the levels of the dependent variable before and after the mobilisation techniques in order to ascertain whether the ROM of the various active movement directions was significantly different after the treatments. α was set to 0.05. For null hypothesis two, the two techniques were tested against each other to determine whether one is more effective than the other. The author used IBM SPSS Statistics V.24, New York, USA; the report is in Appendix 4.

3.15 Quantitative study

The five methodological issues describing a quantitative study are presented below (Carter, 2016 p.58):

Theory. Physiotherapists apply manual therapy techniques to reduce pain and increase ROM for patients affected by neck pain. Increases in ROM and decreases in pain are the desired outcomes of vertebral manual mobilisations. In a clinical setting, musculoskeletal medicine is applying global vertebral mobilisations to achieve the same desired outcomes. As the measurement procedure needs to be tested on healthy volunteers first, the reduction of pain cannot be measured with the present study.

Selection. The age group where neck pain has the highest incidence is 35–49 years old (Hoy, 2010). A group of healthy volunteers between 40 and 60 years old was selected for the study. The age of the volunteers overlaps with the largest neck pain age group in order to increase the generalisability of the result.

Measurement. In order to reach a high grade of precision in measurement of the CROM of the subjects, the author employed Polhemus Fastrak for the present study. The device was used as the gold standard for a similar study aiming to test another measurement instrument (Audette, 2010). This confirms the quality of the electromagnetic device used for the data collection.

Manipulation. The study design allows a direct cause-effect relationship between the mobilisation techniques and the immediate variation in CROM to be established.

Control. The experimental procedure was standardised. In each session, the mobilisation was repeated the same number of times using the same experimenter. All of the treatment sessions were performed on the same treatment couch; the volunteers were stabilised with the same belts, the same words were used to ask the volunteers to perform the active movements, and the movements were measured with the same electrodes applied to the same bony landmarks. The participants were randomly assigned to one manoeuvre in one session and to the other for the second session, and the sequence of active movements was randomised for every participant.

3.16 Validity

3.16.1 Internal validity

The experimental procedure was designed in order to reduce the threats to internal validity. The aim of the procedure described above is to carefully monitor the intervention received by the volunteers during the experimental session to demonstrate that a causal relationship exists between independent and dependent variables (Carter, 2016 p.76).

The following threats to internal validity were considered:

- History. Events unrelated to the mobilisations that may occur between the two sessions and may plausibly change the dependent variable. All volunteers were asked to report accidents, trauma, or neck pain occurring before and between the two sessions.
- Maturation. Changes within the participant. When participants receive more than one treatment session, they may respond differently to later treatments than to earlier treatments. The two techniques were performed in a randomised order to minimise that threat. The two mobilisation sessions were performed two weeks apart.
- Testing can be considered a threat to internal validity when repeated testing can result in changes to the dependent variable. The cervical active ROM was randomised for each measurement session and repeated only once before and once after the mobilisation.
- Instrumentation. Changes in the measuring tools themselves may be responsible for changes in the dependent variable. The set of measuring tools was never changed during all of the experimental sessions, and each session started with calibration of the software and sensors in relation to the volunteer's bony landmarks.

3.16.2 External validity

The experimental external validity concerns asymptomatic people. This is well known since the aim of the study is to demonstrate that it is possible to quantify a desired outcome of the two mobilisation techniques described above and to test the experimental procedure.

- The selection of asymptomatic volunteers limits the generalisability of the study

results to the population affected by cervicalgia. This is one of the limits of the experiment.

- The setting did not represent a threat to external validity, as the treatment couch chosen is the same as those currently used in ordinary clinical settings.

3.16.3 Construct validity

Construct validity is concerned with the meaning of variables within a study. The CROM (dependent variable) is one of the most important desired outcomes of manual therapy treatments (independent variable). The most common threats to construct validity were considered.

- Construct underrepresentation in the dependent variable was taken into account, as ROM was the only measured outcome. The threat of construct underrepresentation was considered when preparing the experiment protocol. In the clinical setting, physiotherapists perform the mobilisation techniques chosen for the experiment (independent variable) to gain ROM.
- Experimenter expectancies that can induce the Pygmalion effect. The reduction in the number of words and the use of the same sentences to instruct the subjects for the active movement measurement controlled that threat.
- Interaction between different treatments. Only one technique was performed for each session.
- Interaction between testing and treatment is a threat to construct validity when a test itself can be considered an additional treatment. The active movements performed at the end of the range are often part of the exercises for neck pain. In each experimental session, the six active movements were performed once before and once after the mobilisation technique. Two repetitions cannot be considered a treatment. Furthermore, the sequence of the active movements was randomised to avoid the possibility that the sequence itself could become the cause of the increase in CROM.

3.17 Ethical issues

The health of the participants in the experiment was the first consideration of the researcher during the recruitment phase and the experimental phase. The aim of the study was to generate scientific knowledge that may benefit individuals in the future.

Acting in the best interest of the subjects in the experiment was the responsibility of the researcher.

The researcher strictly followed all of the ethical principles of the Declaration of Helsinki.

The research satisfied the conditions stated in the Framework for Research Ethics updated in September 2012:

- The research was of high quality
- There was a goal of valuable knowledge
- The research generated the knowledge that was sought
- The research necessitated the use of human subjects who had a favourable balance of potential benefits over the risk
- There was a fair selection of subjects
- Measures were in use to protect privacy and confidentiality
- Research was designed in a way that the dignity and autonomy of research participants were protected and respected at all times
- Subjects were recruited with a detailed information sheet clearly describing the experimental procedure and the inclusion/exclusion criteria
- Subjects gave their informed consent or refused to participate
- The right of the volunteers to withdraw from the experiment procedure was guaranteed at any time

After receiving the formal approval of the research proposal by Middlesex University, the researcher applied for the approval of the Ethics Committee of Middlesex University for the dissertation project. After receiving this approval, the author applied for and received approval of the Ethics Committee in Canton Ticino Switzerland (Appendix 2), where the experiment took place.

The researcher followed the recently amended Swiss law and followed the rules stated by KOFAM (Koordinationsstelle Forschung am Menschen) for experimental procedures

involving human beings, applying to the Comitato Etico Cantonale (Ethics Committee in Canton Ticino Switzerland). The researcher also used all of the procedures and modules in Italian that the Canton Ticino requires for research projects taking place in Ticino (Normativa cantonale generale) and followed the Swiss Federal Recommendation for ethics in research on human beings (Normativa Federale).

Appendix 3 includes the Italian version of the information and informed consent form that was used to enrol the volunteers and that was approved by the Ethic Committee.

4. Results

4.1 Demographic and adverse events

Thirty six volunteers agreed to participate in the study. The mean age of the participants was 46.75 (SD +/- 6,259); there were 16 males and 20 females. All of them participated in both sessions and no participants dropped out of the study. After the sessions of mobilisation, no participants reported any unwanted side effects. The participants tolerated the two mobilisation techniques.

4.2 Data obtained from the measurement sessions

Tables 1, 2, and 3 show all of the data obtained during the 72 sessions: the CROM in right and left rotation, flexion and extension, right and left side bending before and after two mobilisation techniques. Some boxes do not contain data because of device malfunction.

The measuring device produced a graph for each session (Figure 12), visualising the angle of the movement and numeric data representing the ROM between the starting position and the end of range of each active movement.

Figure 12: right and left rotation for one subject, before and after one of the mobilisation techniques.

