Reliability in Measuring the Range of Motion of the

Aging Cervical Spine

by

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## ABSTRACT

The purposes of this study were to: 1) determine absolute intrarater reliability of using the cervical range of motion device (CROM) for measuring cervical movements in older adults, and 2) determine the intrarater reliability and concurrent validity of the Candrive protocol, which uses a universal goniometer to measure rotation. Forty older adults (75.7  $\pm$  4.7 years of age) were tested in two sessions, one week apart, by two raters. Intrarater reliability scores were good for the CROM protocol (coefficient of variation (CV) values were 5.5% and 6.2 % for cervical rotation). The Candrive protocol values were higher (CV = 7.9 and 9.4%). Concordance analyses suggested that the Candrive protocol was less than good in terms of its validity, particularly when order effects were taken into consideration. In conclusion, the CROM protocol demonstrated good reliability for either group or individual analyses, whereas the Candrive protocol was less reliable and its validity marginal.

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## DEDICATION

I would like to dedicate this thesis and my graduate studies at the University of Manitoba to my parents, Mr. Rajendra Prasad and Mrs. Mridula Sinha. They encouraged and supported me to come here and pursue my master's degree in a very difficult phase of my life.

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## **CHAPTER 1: INTRODUCTION**

## **<u>1.1. Statement of the problem</u>**

Aging is a natural and integral part of life that leads to physiological and functional decline (Talbot et al., 2000). According to the American College of Sports Medicine (ACSM, 2009), flexibility is an important component of fitness and is particularly important for older adults. Full range of motion across any joint is required to move efficiently and to be independent with activities of daily living (ACSM, 2009). Crosssectional studies have demonstrated that range of motion is significantly less across all the joints of the upper limb, lower limb and spine in older adults (60 years and above) when compared to younger adults (Alaranta et al., 1994; Bell and Hoshizaki, 1981; Brown and Miller, 1998; Doriot and Wang, 2006; Feipel et al., 1999; Hole et al., 1995).

Cervical range of motion (especially cervical rotation) is very important for crossing the road and driving (Bennett et al., 2002). In addition, it is also required for leisure activities like playing golf (Coleman and Rankin, 2005) and swimming (Guth, 1995). Pathological and degenerative changes in the aging cervical spine lead to a decrease in its range of motion (Tousignant et al., 2006). The decline in achieving end range of cervical rotation with aging impedes the ability of older drivers to complete tasks like scanning to the rear, backing up, and turning the head to observe blind spots (Malfetti, 1985; Ostrow et al., 1992).

Measurement of cervical range of motion is routinely included in the examination of cervical spine disorders in order to evaluate the progress of the condition and the

effectiveness of a treatment protocol (APTA, 2001). Considering the rapid increase of the aging population and the importance of neck movements for older adults, there is also a need for a reliable testing technique to measure cervical range of motion for older adults and to interpret measurement change in cervical range of motion by health care providers (De Koning et al., 2008; Jordan, 2000).

#### **1.2. Justification for the proposed research study**

The range of motion measurement score of a person must be similar on multiple trials, in order for the test to be reliable (Portney and Watkins, 2009). Also, researchers should report the reliability of a measurement protocol in terms of relative reliability and absolute reliability (Atkinson and Nevill, 1998). Relative reliability scores, usually calculated in terms of a reliability coefficient, help to predict the consistency in the rank of a subject within a group. Absolute reliability scores help to predict the degree to which repeated measurements vary for an individual (Atkinson and Nevill, 1998).

There are different methods to measure cervical range of motion like visual estimation, goniometry (universal goniometer, inclinometer, cervical range of motion (CROM) device), tape measure, video motion analysis, radiographic and photographic methods. Various researchers have reported reliability scores (usually expressed in terms of a reliability coefficient) for each of the six cervical movements by using different measurement devices and methods (De Koning et al., 2008). The accuracy of measurements of cervical movements depends on the method of measurement and the particular range of motion being measured. The main sources of measurement error can

be due to variability in the observer's perceived "neutral" position for the subject, changes in the subject's perceived end point of range of motion, difficulty in identifying the landmarks, subject fatigue and discomfort, and coupled movements (Zachman et al., 1989). Most reliability studies on cervical range of motion are lacking in terms of study design (e.g., sample size, blinding of examiner and recorder, training of the testers, warm up exercises, and number of repetitions and trials) and in the presentation of results (De Koning et al., 2008; Jordan, 2000). In addition, further research is required to report on absolute reliability in measuring cervical range of motion (De Koning et al., 2008).

The CROM device has been extensively studied in subjects with non specific neck pain and on asymptomatic subjects in terms of relative reliability (De Koning et al., 2008). However, only two studies have reported absolute reliability scores using the CROM device in terms of standard error of measurement (Audette et al., 2010; Fletcher and Bandy, 2008). In addition, between day absolute reliability scores of cervical range of motion in terms of standard error of measurement (SEM), coefficient of variation (CV), and limits of agreement (LOA) have not been previously evaluated in older adults.

Inspite of several techniques available, universal goniometers are frequently used by researchers and clinicians because they are easy to use, portable and inexpensive. However, there have been few evaluations of the reliability of the universal goniometer in measuring cervical range of motion. Identification of proper bony landmarks by the observer, and the alignment of the two arms of the goniometer along those landmarks are very important during range of motion measurements with a universal goniometer (De

Koning et al., 2008; Jordan, 2000). Intrarater and interrater relative reliability in previous studies using the universal goniometer have been reported to be poor to moderate for cervical range of motion (Maksymowych et al., 2006; Mayerson, 1984; Youdas et al., 1991; Zachman et al., 1989). However, only one study has reported the absolute reliability in terms of LOA using the universal goniometer on cervical rotation movement in patients with ankylosing spondylosis (Maksymowych et al., 2006).

A person potentially needs 67.6 degrees of cervical rotation to look over the shoulder during driving when backing up (Bennett et al., 2002). Older drivers (70 years and above) usually have to rotate their entire trunk for backing up or reversing the vehicle (Magee, 2002). Thus, measurement of cervical rotation is also an important component of the physical assessment in an ongoing research project, the Canadian Driving Research Initiative for Vehicular Safety in the Elderly (Candrive). The Candrive is a longitudinal research study, and its aim is to determine the medical fitness of older drivers. The Candrive protocol uses a universal goniometer to measure cervical rotation. Because the examiners from the different sites have varying levels of previous experience with measuring range of motion, the method has a rather simplistic approach that minimizes the use of bony landmarks. The absolute and relative reliability of this method using a universal goniometer have not been examined.

Usually, radiography is considered to be the most accurate method to measure cervical range of motion (De Koning et al., 2008; Jordan, 2000). However, according to Chen et al. (1999), it is not possible to obtain a true validation of cervical range of motion

measurements because the radiographic technique has not been subjected to reliability and validity studies. Therefore, no valid gold standard exists. Thus, the only option available to investigators at the present time is to conduct concurrent validity studies to obtain agreement between instruments and procedures (Chen et al., 1999). The CROM device has been previously validated to measure cervical range of motion for cervical flexion and extension and rotation (Audette et al., 2010; Hole et al, 1995; Tousignant et al., 2000; Tousignant et al., 2002). Therefore, in place of a true gold standard the CROM is being used in this study.

## 1.3. Purposes

- 1. To determine the intrarater reliability (absolute and relative reliability) of cervical range of motion measurements obtained using the CROM device in older adults.
- To determine the intrarater reliability (absolute and relative reliability) of the Candrive protocol in measuring cervical rotation using a universal goniometer in older adults.
- 3. To determine the concurrent validity of the Candrive protocol using a universal goniometer with the CROM device.

## **CHAPTER 2: LITERATURE REVIEW**

## **2.1. JOINT FLEXIBILITY**

## 2.1.1. The meaning and importance of joint flexibility

Flexibility, in a broad sense, refers to the range of motion of a single or multiple joints (Alter 1996; Holland et al., 2002; Zakas et al., 2006). A healthy musculoskeletal system (i.e., adequate level of muscular strength, endurance and flexibility) is needed for an individual to efficiently perform all the activities of daily living, and elite athletic and artistic performance (Holt et al., 2008). An individual must have the capacity to operate effectively in response to ordinary and unexpected demands of daily life in order to be considered functionally fit (Netzer and Payne, 1993). The decline in flexibility of the joints with increasing age leads to a decreased ability to perform simple activities (ACSM, 2009; Holland et al., 2002), decreased mobility (Allander et al., 1974; Bergstorm et al., 1985; Boone and Azen, 1979) and decreased quality of life (Morey et al., 1998). Limited or impaired movement can result in further decline of the body (Bortz, 1985). Loss of flexibility of joints in older adults leads to increased risks of fall, injuries, and back pain (ACSM, 2009). In addition, decreased range of motion has been associated with the use of assistive devices and functional dependence (Gersten, 1970).

Flexibility exercise refers to activities designed to preserve or extend range of motion of a joint (ACSM, 2009) and has been prescribed for a long time as an effective means of preventing and treating injuries and to improve performance (Holland et al., 2002). The

benefits of therapeutic uses of stretching were known in the Greek and Roman cultures and yoga postures were first described in the second century A.D. (Holland et al., 2002). According to the ACSM (2009), flexibility exercise forms an important part of the physical activity recommendations for older adults but very few randomized controlled trials have documented the benefits of flexibility exercises in older adults. In addition, only a few researchers have reported the effectiveness of neck flexibility intervention in older adults (Munns, 1981; Ostrow et al., 1992; Raab et al., 1988). A reliable measurement technique is required to interpret measurement change in cervical range of motion by health care providers and researchers (De Koning et al., 2008; Jordan, 2000).

## 2.1.2. Reasons for loss of joint flexibility in older adults

Decline in functional movement is one of the most significant alterations that occur during the aging process (Bemben, 1999). Aging is a normal biological process associated with changes in the elasticity of connective tissues and thus resulting in a significant decrease in flexibility (Campanelli, 1996). The primary anatomical structures responsible for range of motion are cartilage, ligaments, tendons, synovial fluid, muscles and bony structures around a particular joint (Chesworth and Vandervoot, 1989). These structures around the joint undergo structural and functional changes with aging and thus, the joints become less mobile (Bemben, 1999).

Holland et al. (2002) reported that it is very difficult to determine the contribution of each type of tissue (muscles, tendons, and the joint capsule) to the impairment of movement.

However, it has been shown that the elastin component of connective tissue is more resilient than the collagen component, and that there is an increase in the cross linkages of collagen tissue with aging which contributes to some loss in joint mobility (Holland, 1968). Bemben (1999) reported in a review, that in general, the synovial membranes become more fibrous and synovial fluid shows evidence of decreased viscosity with increasing age. In addition, the other common reasons for decreased joint range of motion throughout the life span are mostly musculoskeletal (e.g., osteoporosis, osteoarthritis) and neuromuscular (e.g., Parkinsonian disease) (Holland et al., 2002). Skeletal and connective tissue modifications during the life span can also occur due to trauma, physical activity habits and the occupational demands of an individual (Holland et al., 2002).

## 2.1.3. Flexibility with aging

Numerous studies have shown that there is a gradual decline in flexibility with the onset of adolescence and it continues throughout the lifespan (Alaranta et al., 1994; Moll and Wright, 1971; Netzer and Payne, 1993; Nilsson et al., 1996; Raab et al., 1988; Shephard and Berridge, 1990). As cited in Bell and Hoshizaki (1981) and in Munns (1981), the inverse relationship between flexibility of joints and aging was reported as early as 1955 by Greey and in 1961 by Jervey in their doctoral dissertations. Greey studied the flexibility of selected joints of 510 adult men between 18 and 72 years of age, and reported that flexibility of most of the joints was greatest at 23.5 years and was less in older subjects (Bell and Hoshizaki, 1981; Munns, 1981). Jervey conducted a similar study on 407 women, between 18 and 74 years of age and reported that flexibility was specific for each joint and muscle group, and that the mean flexibility scores were less for older subjects for most of the movements. In particular, Jervey reported that the flexibility of the hamstrings, low back extensors, gastronemius, soleus, shoulder adductors and hip flexors were significantly less in the older subjects when compared to the younger subjects (Bell and Hoshizaki, 1981; Munns, 1981). As cited in Bell and Hoshizaki (1981), Wright measured joint flexibility in men, between 20 and 60 years of age, and reported that knee flexibility was less by 23.2% and spinal mobility by 50% in the older subjects when compared to the younger subjects.

Bell and Hoshizaki (1981) studied 190 subjects between 18 and 88 years of age and reported that hip abduction was 46% lower, hip flexion was 21% lower, knee flexion was 12% lower, and ankle flexion and extension was 23% lower for older adults (age 80 years and above) when compared to the younger adults (20 years) by using a Leighton flexometer. In addition, the authors also reported that cervical flexion and extension (movements were measured together but the method was not described) was less by 17%, cervical lateral flexion by 27% and cervical rotation by 29% by using a universal goniometer with a headset. Netzer and Payne (1993) studied 110 subjects between six and 80 years of age and reported that spinal flexibility was significantly less for the older subjects by using two dimensional video analyses. Alaranta et al. (1994) studied a sample of 508 subjects between 35 and 54 years of age and reported that lumbar flexion was 10% lower and lumbar lateral flexion 19% lower in the older subjects.

Brown and Miller (1998) studied 304 women between 20 and 82 years of age, and reported that trunk flexibility was less in older women, and women in the seventh decade had the lowest flexibility. Doriot and Wang (2006) studied 41 subjects and compared maximum voluntary range of motion of major joints of the upper body and spine between younger (25 to 35 years of age) and older (60 to 80 years of age) adults by using three dimensional video motion analysis. Shoulder external rotation was lower by 42%, shoulder flexion by 25%, shoulder adduction by 10%, right trunk lateral flexion by 26%, left trunk lateral flexion by 33%, left trunk rotation by 14% and right trunk rotation by 16% for the older age group.

It can be said from the previous studies that there is a general trend of a decrease in joint range of motion with increasing age. In addition, maximum range of motion is achieved in the mid to late 20s for both men and women and gradually decreases with advancing age (Holland et al., 2002).

## **2.1.4. Effect of gender on flexibility**

The effect of gender on range of motion is still controversial. In general, women have greater range of motion in most major joints, and women become more flexible during pregnancy because of an increase in the hormone relaxin (Holland et al., 2002). In non pregnant women, Bell and Hoshizaki (1981) measured 17 actions at eight joints (upper limb, lower limb, cervical spine and lumbar spine) and found that women had greater range of motion than men of the same ages throughout the lifespan. Alaranta et al. (1994)

studied 508 subjects between 35 and 54 years of age and reported that lumbar flexion was significantly greater in men than in women of the same age; however there was no significant difference in lumbar extension between men and women.

Doriot and Wang (2006) measured 13 joint actions of the spine and upper limb by using video motion analysis. They concluded that the effect of gender on joint range of motion is very joint specific and movement specific. The authors reported that out of the thirteen movements measured in their study, forearm pronation and wrist adduction were significantly greater in women, and trunk extension was significantly greater in men. In a review, Holland et al. (2000) reported that in general women have greater range of motion in most major joints, especially in the younger age groups due to their anatomy, connective tissue morphology, and some hormonal differences.

#### **2.2. CERVICAL RANGE OF MOTION**

### 2.2.1. Anatomy of the cervical spine

The cervical spine is divided into four anatomical units: the atlas, the axis, the C2-C3 junction and the remaining cervical vertebrae (Pratt, 1996; Bogduk and Mercer, 2000). To carry out activities of daily living, the head has the ability to perform extensive, detailed and very quick motions. In addition to providing this amount of mobility, the cervical spine has to afford some protection to several vital structures including the spinal cord, and the vertebral and the carotid arteries (Pratt, 1996). The two unique articulations present in the cervical spine are the atlanto-occipital joint and the atlanto-axial joint

(Loudon, 2008; Mercer and Bogduk, 2001). The atlanto-occipital joint is between the skull and C1; the two convex occipital condyles articulate with two concave superior facets of the atlas vertebrae. The atlanto-axial joint is between C1 and C2, and is mainly comprised of three joints: median atlanto-odontoid articulation between dens and atlas, and the two lateral joints, between the convex inferior facets of the atlas and the concave superior facets of the axis. The vertebrae C3-C7 are similar to the other joints of the vertebral column (Bodguk and Mercer, 2000).

## 2.2.2. Meaning and importance of cervical range of motion

Cervical motion is defined as the motion of both the head relative to a stationary reference system, and the cervical vertebrae in relation to each vertebra, including the C0-C1 segment, which effectively relates to the motion of the head relative to C1 (Prushansky and Dvir, 2008). The movements of the cervical spine as described by the American Medical Association (AMA) and the American Academy of Orthopedic Surgeons (AAOS) are flexion and extension in the sagittal plane, left and right lateral flexion in the frontal plane, and left and right rotation in the transverse plane (Prushansky and Dvir, 2008). Cervical rotation occurs at the atlanto axial joint and is an important reflection of neck function (Moffett et al., 1989). However, cervical motion is a more comprehensive concept and also includes the coupled movements of the head relative to the trunk (Bogduk and Mercer, 2000; Prushansky and Dvir, 2008). Coupled movements are naturally associated with the primary cervical movements like rotation with lateral flexion and vice versa. The measurement of cervical range of motion is complicated by

the multiaxial joints present in the cervical region, in which movements are controlled by numerous muscles that act across several joints simultaneously (Youdas et al., 1991).

## 2.2.3. Measurement of cervical range of motion

The complex joint structure present in the cervical spine region complicates the identification of the bony landmarks for examiners. In addition, it is also difficult to isolate cervical motion from the coupled movements of the cervical vertebrae and also the thoracic motion. The search for methods and instruments to accurately measure cervical range of motion is still ongoing (Norkin and White, 2009).

At present, universal goniometers appear to be more commonly used in clinical settings (Norkin and White, 2009). Goniometers are versatile devices and have long been used to measure the range of motion of peripheral joints. Devices to measure joint range of motion have been used in France since the early 1900s, and became popular during World War 1 to evaluate military disabilities (Smith, 1982). The device used during the early 1900s, had a central protractor and two long arms (Silver, 1921). The universal goniometer used today has undergone many modifications and is constructed in various forms and sizes but basically it has a central protractor and two arms of varying lengths (Brosseau et al., 1997).

As cited in Defibaugh (1964), visual estimation dates back to 1918 when Cleveland recorded joint angle on circular patterns and designed 35 charts with images of different joints centered on the axis of the circular patterns. This method is simple and easy to use 13

in clinical settings because no special instrument is required; however, the disadvantage is that there are notable variations among different examiners (Hsu et al., 2008; Whitcroft et al., 2010; Youdas et al., 1991).

Using a tape measure to indirectly measure flexibility is also widely used in clinical settings to measure cervical range of motion because it is easy to use and inexpensive. However, its disadvantages are that the measurement can be made only in the coronal and sagittal planes, and cannot be represented by degrees (Hsu et al., 2008).

An inclinometer is a fluid filled goniometer that works on the principle of gravity (De Koning et al., 2008). The fifth edition of the Guides to Evaluation of Permanent Impairment published by the American Medical Association (AMA) requires the use of a double inclinometer method for spinal range of motion measurements (Norkin and White, 2009). More recently, the Electronic Digital Inclinometer (EDI-320) has been used to measure cervical range of motion (Tousignant et al., 2001).

The CROM device has also been widely used by researchers to measure cervical range of motion in asymptomatic patients (Capuano-Pucci et al., 1991; Dhimitri et al., 1998; Hole et al., 1995; Nilsson et al., 1995; Nilsson et al., 1996; Youdas et al., 1992) and symptomatic subjects (Reynolds et al., 2008; Rheault et al., 1992; Tousignant et al., 2006; Youdas et al., 1991). The CROM device is a combination of two inclinometers and a gravity goniometer fixed on a plastic frame. The inclinometers measure cervical range

of motion in the sagittal and frontal planes, and the gravity goniometer measures cervical rotation (Reynolds et al., 2009; Youdas et al., 1992).

The radiographic technique has been found to be an accurate method for evaluation of cervical range of motion (Brown et al., 1976; Jordan, 2000). It leads to quantitative assessment by degrees and has good reproducibility on film. However, it is not used widely because of its cost, the hazards of exposure to X-ray (Jordan, 2000), and because it is only a two dimensional measurement (Hsu et al., 2008).

An electrogoniometer can be used to measure three dimensional movements of the cervical spine by converting angular motion of the joint into an electric signal. As cited in Defibaugh (1964), the electrogoniometer was first invented in 1959 by Karpovich & Karpovich. It is mainly used for research purposes because of its expense and it requires skill to operate. The three dimensional motion of the cervical spine was later evaluated in 1996 by using the 3 SPACE Isotrak System and the authors reported that coupled movements of the cervical spine decrease significantly with increasing age (Trott et al., 1996). Later on, the 3D kinematic method was shown to be a useful and non-invasive method to evaluate neck function in cervical spine disorders and the authors found good reproducibility of this method (Bulgheroni et al., 1998). The Flock of Birds system is an electromagnetic tracking device used to measure neck mobility; it gives a three dimensional measurement and detects coupled movement.

The Multi Cervical Rehabilitation Unit (MCRU) is an apparatus which has an armchair and a headset assembly. The armchair has an adjustable seat height and has the capability to rotate 90 degrees during measurement of lateral flexion. The head set has a potentiometer which is connected to Objective Documentation and Evaluation System (software) which records the maximum active range of motion of the cervical spine (Chiu and Lo, 2002).

Two dimensional and three dimensional video motion analysis is a technique to measure joint range of motion by using video cameras. Reflective markers are placed over the segment of the body being measured and joint angles are calculated from the surface marker trajectories. This method has been used to measure spinal movements, including the cervical spine, along with other peripheral joints (Doriot and Wang, 2006; Netzer and Payne, 1993).

A wide range of scores for cervical range of motion have been obtained by various authors using different instruments and measurement protocols. Disorders of the cervical spine alter the normal active range of motion of the neck (Youdas et al., 1991). In addition, the general trend of a decrease in range of motion of cervical movements with aging is also responsible for the variability in the results obtained in different samples.

## 2.2.4. Reasons for loss of cervical range of motion with aging

The most important cause of the loss of cervical mobility with aging is degenerative changes in the spine (Dvorak et al., 1992; Raab et al., 1988). The aging cervical spine undergoes disc degeneration which leads to a reduction in the intervertebral disc height. Consequently, the bony prominences formed by the neurocentral joints approach one another and eventually touch. There has been evidence for significant radiographic changes in the cervical spine in older adults when compared to younger adults (Holland et al., 2002). The loss of normal cervical lordosis leads to limited neck movements especially neck rotation (Maigne, 2000). Another important reason for the decrease of cervical range of motion with increasing age is the forward flexed posture (Balzini et al., 2003). Acquired forward head posture (FHP) is the excessive anterior positioning of the head in relation to a vertical reference line, involving increased cervical spinal lordosis, protracted shoulders and thoracic kyphosis. This leads to adaptive shortening of the upper trapezius and levator scapulae which leads to a further decrease in cervical range of motion. The other reasons for limited neck range of motion in older adults are connective tissue or neuromuscular disease, and tissue pathology or acquired bony deformity due to trauma or cervical spine surgeries (Maigne, 2000).

## 2.2.5. Cervical range of motion in different age groups

Numerous studies have investigated the effects of age on active cervical range of motion (Doriot and Wang, 2006; Lind et al., 1989; Netzer and Payne, 1993; Shephard and Berridge, 1990; Youdas et al., 1991; Youdas et al., 1992). However, it is difficult to compare their results because of the wide variety of instruments used, differences between the population tested, and the measurement protocols used in these studies. Generally most researchers agree that cervical range of motion decreases with an increase in age.

Lind et al. (1989) reported that cervical extension decreases by five degrees every decade and cervical flexion decreases by one and half degrees every decade by using the radiographic method. Shephard and Berridge (1990) reported a significant decrease in flexibility scores for the cervical spine and other joints from aging in 80 subjects between 45 and 75 years of age by using a universal goniometer. Bell and Hoshizaki (1981) reported a 17% decrease for cervical flexion and extension (this movement was measured together; authors have not described the method of measurement), 27% for cervical lateral flexion and 29% for cervical rotation by using a universal goniometer with a headset.

Youdas et al. (1992) used a CROM device and reported that in general, neck extension decreased by half a degree per year (i.e., five degrees per decade) and there was a decrease of three degrees per decade in the other five types of cervical range of motion

(flexion, left and right lateral flexion, left and right rotation). Hole et al. (1995) studied the effect of age on 84 asymptomatic subjects by using a CROM device and a single inclinometer. The authors reported a decrease of four degrees in cervical flexion and lateral flexion, per decade, and between six and seven degrees per decade, in extension. In addition, the authors also found a loss of four degrees per decade in cervical rotation by using the CROM device and seven degrees per decade by using the single inclinometer method. Nilsson et al. (1996) defined the normal ranges of passive cervical motion for people between 20 and 60 years of age by using a CROM device. The authors reported a significant decrease in passive cervical range of motion between the younger and the older subjects. In addition, they stressed the importance of appropriate measurement protocols while using such normal ranges.

Mayer et al. (1993) failed to find any age related changes in cervical range of motion using an electronic digital inclinometer on 58 normal subjects between 19 and 62 years of age. The authors measured six traditional cervical movements (flexion, extension, left and right lateral flexion, and left and right rotation). The failure to detect any significant changes with age in this study may be because of the lack of age blocks in the study design, and the small sample size. In addition, the oldest subject in this study was only 62 years of age.

Netzer and Payne (1993) studied the effects of age and gender on functional rotation and lateral flexion of the neck and back in 110 subjects between six and 80 years of age, by using two dimensional video analyses. The movements that were videotaped were neck

rotation, neck and back rotation, and neck and back lateral flexion. The authors reported significant decreases in the range of motion of the cervical spine between the oldest and the youngest groups. Doriot and Wang (2006) reported a 15% decrease for cervical flexion, 41% decrease for cervical extension, 49% decrease for left cervical lateral flexion, 41% decrease for right cervical lateral flexion and 28% decrease for left and right cervical rotation when comparing younger and older adults using three dimensional video motion analysis techniques.

Dvorak et al. (1992) reported a decrease in cervical range of motion in 150 healthy subjects between 20 and 65 years of age using a Spine Motion Analyzer (a linkage device that is connected with six potentiometers; software records and converts cervical motion into an angle). Feipel et al. (1999) tried to establish a normal database of active cervical range of motion using a commercial electrogoniometer in 250 asymptomatic subjects between 14 and 70 years of age. The authors reported a significant decrease of all the cervical movements with increasing age. Malmstorm et al. (2003) reported six degrees decrease in cervical range of motion and lateral flexion by using a Zebris system (an ultrasonic three dimensional motion analysis system).

Most of the studies reported a significant decrease in the cervical range of motion with increasing age but the measurement scores depend mainly on the measuring device and its protocol (Jordan, 2000).

## 2.2.6. Effects of gender on cervical range of motion

Many of the same researchers who looked at the effects of age on cervical range of motion have also studied the effects of gender. However, the effect of gender on cervical range of motion is still controversial. Shephard and Berridge (1990) reported no significant gender difference in flexibility scores for the cervical spine in 80 subjects between 45 and 75 years of age by using a universal goniometer. Mayer et al. (1993) reported that only cervical extension was significantly greater in women than in men for the same age group. This study was done on 58 normal subjects with an age range of 17-62 years and the measurements were taken by an electronic digital inclinometer. Later on, Alaranta et al. (1994) measured cervical range of motion by inclinometers and tape measure in 508 subjects (aged 35-54 years) and found that women have significantly more cervical flexion/extension and lateral flexion than men, but cervical rotation is not significantly different.

The researchers working with the CROM device have also not reported any significant gender differences in cervical range of motion within the subjects of same age group. Youdas et al. (1992) studied 337 subjects between nine and 90 years of age and reported that there was no statistically significant gender effect on cervical movements. Hole et al. (1995) reported no significant gender effects in 84 asymptomatic subjects by either a CROM device or a single inclinometer.

Researchers working with sophisticated instruments to measure three dimensional cervical ranges of motion and video motion analysis have also reported equivocal effects of gender on cervical range of motion. Dvorak et al. (1992) used a Spine Motion Analyzer and reported a significant difference in cervical range of motion between men and women of the same decade (between 30 and 39, 40 and 49, and 50 and 59 years of age) but there were no significant differences in cervical range of motion in the age group of 60 years and above, and between 20-29 years of age. Feipel et al. (1999) found no influence of gender on five movements of cervical range of motion by using an electrogoniometer in 250 asymptomatic subjects between 14 and 70 years of age (93 women and 157 men). However, out of the six movements of the cervical spine measured, the authors reported that only left lateral flexion was significantly greater in men. Chen et al. (1999) reported in a review, that the average differences between men and women for five cervical movements (extension, left and right lateral flexion and left and right rotation) were between two and four degrees, but were not statistically significant. However, women have significantly less left lateral cervical flexion than men.

Netzer and Payne (1993) studied 110 subjects (55 men and 55 women) between six and 80 years of age and reported no significant gender effect on functional rotation and lateral flexion of neck and back by using two dimensional video analysis. Doriot and Wang (2006) reported no effect of gender on the cervical movements by using three dimensional video motion analysis techniques. Most of the studies have reported no statistically significant difference in the cervical range of motion between men and

women of same age group (Chen et al., 1999; Hole et al., 1995; Lowery et al., 1992; Netzer and Payne, 1993; Youdas et al., 1992; Tousignant et al., 2002). It is still doubtful that the gender effect on cervical range of motion would be of clinical relevance even if it is statistically significant (Hole et al., 1995; Chen et al., 1999; Feipel et al., 1999).

## **2.3. RELIABILITY**

## 2.3.1. Concepts of reliability and validity

Reliability or minimal measurement error is defined as the reproducibility of values of a test, assay or other measurement in repeated trials on the same individual (Hopkins, 2000). In other words, reliability is the consistency of measurements or of an individual's performance on a test; or the absence of 'measurement error' (Portney and Watkins, 2009). Realistically, some measurement error is always present with continuous measurements. Thus, reliability can be considered as the amount of measurement error that has been deemed acceptable for the effective practical use of a measurement tool. Intrarater reliability is the stability of a method when measured more than once by the same person. Interrater reliability is the stability of a method when measured by different people on the same occasion (Jordan, 2000). Intrarater reliability is generally considered to be better than interrater reliability (Mayer et al., 1993; Love et al., 1998). Validity is the ability of the measurement tool to reflect what it is designed to measure (Atkinson and Nevill, 1998).

#### 2.3.2. Measurement error

The sum total of the systematic error and random error associated with each assessment of measurement error is called the 'Total Error' (Chatburn, 1996). The major problem is when the measurements are done on different occasions; the confounding factor is that real changes can occur in subjects (Jordan, 2000). Systematic bias is defined as the general trend of the measurement to be different in a particular direction (either positive or negative) and can be due to general learning (Coldwells et al., 1994), insufficient recovery between measurements, fatigue effects on tests, biological variation, mechanical variation, and motivation (Hickey et al., 2000). Random error is the large amount of variability caused by biological variation (the same individual can give different measurements over different times), mechanical variation, and inconsistency of the measurement protocol (Coldwells et al., 1994).

#### **2.3.3.** Types of reliability

Relative reliability is defined as the degree to which individuals maintain their position in a sample with repeated measurements. It can be measured by the Intraclass Correlation Coefficient (ICC) and regression analysis (Atkinson and Nevill, 1998). Absolute reliability is defined as the degree to which repeated measurements vary for individuals. It is expressed in actual units of measurement or as a proportion of measured value (dimensionless) and is calculated in terms of Standard Error of Measurement (SEM), Coefficient of Variation (CV) and Limits of Agreement (LOA) (Atkinson and Nevill, 1998).

## 2.3.4. Statistical measures of relative reliability

**Paired t-test**: It is used to test for any significant bias between the tests. The major drawback of using a t-test for the assessment of reliability is that it does not provide an indication of random variation between the tests (Portney and Watkins, 2009).

**Analysis of Variance (ANOVA)**: Like a paired t-test, repeated measures ANOVA is used to compare test retest variation and can be used to measure systematic bias with appropriate post hoc tests (Tukey's Test). The mean square error term can be used in calculation of indicators of absolute reliability (Atkinson and Nevill, 1998).

**Pearson's correlation coefficient**: It measures the strength of the relationship between two variables and indicates the degree of relative reliability (Baumgartner and Horvat, 1991). As discussed in Atkinson and Nevill (1998), the drawbacks of using the correlation coefficient are that it cannot assess systematic bias on its own, and it depends on the range of values in the sample. In addition, it does not measure the agreement between the two variables (Bland and Altman, 1996).

**Spearman's Correlation**: It is based on an individual's rank in test retest analysis and is rarely used in reliability studies. The maintenance of the same rank of individuals in a sample may be rather a strict analytical goal for a measurement tool in sports medicine.

Thus, it has been said that correlation coefficients based on ranks may be more informative for quantification and judgment of relative reliability (Estelberger and Reibnegger, 1995). An advantage of using this test is that there is no assumption of the shape of the data distribution and therefore is less affected by outliers in the data.

**Intraclass Correlation Coefficient (ICC)**: ICC is a reliability index which reflects both degree of correspondence and agreement among ratings (Portney and Watkins, 2009). The most common method of ICC is based on the terms used in the calculation of an 'F' value from repeated measures of ANOVA (Baumgartner and Horvat, 1991). It is defined as the ratio of the true variance and the total variance (Portney and Watkins, 2009).

ICC= <u>True variance</u>
True variance + Error variance
= Total variance – Error variance
Total variance

An ICC close to 1 is said to be reliable (Atkinson and Nevill, 1998). It is always better to calculate confidence intervals for a given ICC (Morrow and Jackson, 1993). Usually an ICC value below 0.5 is considered poor; an ICC between 0.5 and 0.75 is moderate; and an ICC value of 0.75 and above is good (Portney and Watkins, 2009). The advantages of an ICC over the Pearson's correlation coefficient are that it can be used when more than one retest is being compared with a test, it can be sensitive to the amount of systemic bias present in the data, and it allows flexibility in clinical studies because it does not require

the same number of raters for each subject (De Koning et al., 2008; Portney and Watkins, 2009).

Shrout and Fleiss (1979) described different forms and three models of ICC; ICC is usually represented by two subscript numbers (e.g., ICC  $_{2,3}$ ; ICC  $_{3,3}$ ); the first number represents the 'model' and the second number represents the 'form' of ICC. The forms of ICC represents whether the scores are single ratings or mean ratings. If three measurements are used to get the value that is used in the statistical calculation, then the form is 3. In model 1, each subject is assessed by a different set of raters and one way ANOVA is used for statistical calculations. In model 2, each subject is assessed by the same set of raters that are randomly chosen and represent the population. In model 3, each subject is assessed by the same set of raters represent only the raters of interest and the result cannot be generalized to the overall population. A two way ANOVA is used for analyzing model 2 and model 3.

## 2.3.5. Statistical measures of absolute reliability

The measures of absolute reliability provide an indication of variability in repeated tests for individuals, irrespective of where the individuals rank in a particular sample. In addition, the general advantages of absolute reliability over relative reliability is that it is unaffected by the range of measurements. Thus, it is easier to extrapolate the results to new individuals, and to compare the reliability between different measurement tools (Atkinson and Nevill, 1998).

**Standard Error of Measurement (SEM)**: "If a test is administered to one individual for multiple times, then the responses will vary from trial to trial. These differences are a function of random measurement error and it follows a normal distribution. The standard deviation of these measurement errors reflect the reliability of the response and is called the standard error of measurement" (Portney and Watkins, 2009, pg 608). It is expressed in actual units of measurement. The SEM determines how much a score varies on repeated measurements. In addition, it takes into account the within individual variability (Audette et al., 2010). The most common way of calculating this statistics is by means of the following equation:

## SEM = s $\sqrt{1-1CC}$

(s= standard deviation of the set of observed scores on a group of subjects)

This statistic is unaffected by the range of measured values. SEM was called "the intra individual standard deviation" by Bland and Altman (1996); this gives slightly different results depending on the type of error that has been used to calculate ICC (random error or random error + error). The main assumptions are that the population is normally distributed, equally variable, and the data is not heteroscedastic (Atkinson and Nevill, 1998). In heteroscedastic data, there is a relation between the amount of random error and the measured values and it does not follow a normal distribution (Atkinson and Nevill, 1998). The interpretation of the SEM centres on the assessment of reliability within individual subjects (Weir, 2005). The SEM is used to determine if a patient's

performance has truly changed from trial to trial. Values below this threshold will be considered measurement error (Portney and Watkins, 2009).

**Method Error** (**ME**): "It is a measure of discrepancy between two sets of repeated scores, or their difference scores i.e., larger difference scores reflect greater measurement error" (Portney and Watkins, 2009, pg 610).

 $ME = \frac{SD \text{ of the difference scores between time 1 and time 2}}{\sqrt{2}}$ 

**Coefficient of Variation (CV)**: "To account for the relationship between mean and standard deviation, variability across distributions can be compared by using the coefficient of variation" (Portney and Watkins, 2009, pg 610). It can be calculated for groups as well as individuals. Its calculation is based on the 'Mean Square Error' term from an ANOVA table (Bland and Altman, 1996; Hopkins, 1997). This ratio expresses the standard deviation as a proportion of the mean and is unitless.

CV= standard deviation of each individual over 2 trials \* 100

Mean value of each individual over 2 trials

The main assumption is that the degree of agreement between tests depends on the magnitude of measured values. The largest test retest variation occurs in individuals with higher scores on a test (Bland and Altman, 1995). The drawbacks of this test are that CV

of 10% for an individual means that 68% of differences between tests lies within 10% of mean data (for normal distribution). The true variation between the tests may be underestimated for some new individuals. Thus, the standard deviation of the repeated tests must be multiplied by 1.96 before being expressed as CV as this would cover 95% of repeated measurements (Atkinson and Nevill, 1998).CV can also be calculated in terms of method error. For the present study, the CV will be calculated in terms of ME.

 $CV = \frac{ME}{X} * 100$ 

X = mean of all observations for test1 and test2

**Limits of Agreement (LOA)**: "LOA is an alternative to examine the agreement across methods" (Portney and Watkins, 2009, pg 612). The concept of LOA was introduced by Bland and Altman (1995) as an indicator of absolute reliability which is based on the differences of the scores between two trials. "Instead of using standard deviation of the scores directly, they calculated the range within which an individual's difference scores would fall most of the time" (Hopkins, 2000). It is calculated by the following equation:

 $LOA = X \pm 2s$ 

X = the mean differences between the measurements obtained on Time 1 and Time 2 for each movement; s = the standard deviation of those means.

**Minimal Detectable Change (MDC)**: It is the smallest amount of change in a variable that can be considered above the threshold of error expected in the measurement to reflect a true difference (Portney and Watkins, 2009).

MDC % =  $z * SEM * \sqrt{2}$ Z = 1.65 for 90% CI; z = 1.96 for 95% CI CI = Confidence Interval

## 2.4. PREVIOUS RELIABILITY STUDIES ON CERVICAL RANGE OF MOTION

## 2.4.1. Reliability studies using sophisticated instruments and techniques

There have been several reliability studies using various instruments to measure cervical range of motion. Previous studies have demonstrated that instruments like electronic digital inclinometers (EDI-320) and ultrasonographic techniques have good reliability. The 3D Ultrasound Motion Analyzer was found to be reliable for measuring active and passive movements of the cervical spine and suitable for clinical practice (Cagnie et al., 2007; Kristjansson, 2004; Wang et al., 2005) and later validated against X-ray measurements (Strimpakos et al., 2005).

Further, in 2000, the Zebris System and CA 6000 Spine Motion Analyzer were shown to have good test retest reliability and the authors have recommended using these devices with confidence in longitudinal studies (Mannion et al., 2000). Solinger et al. (2000) also

evaluated that changes in the placement of the CA 6000 Spine Motion Analyzer or body posture of the subject does not lead to systematic errors in the measurement of cervical movements.

The FASTTRACK Measurement System was also shown to have good reliability for cervical movements (Jordan et al., 2000), especially for the upper cervical movements (Amiri, 2003). The Flock of Birds system has good reproducibility and has no radiation exposure (Hsu et al., 2008). However, the interrater reliability has been found to be variable even after using a standardized protocol (Assink et al., 2005). The maximal measurement error was found to be two and a half degrees for measuring neck rotation (Koerhuis et al., 2003).

Gelalis et al. (2009) reported ICC for interrater reliability for the inclinometer between 0.91 and 0.96, and ICC for the Magnetic Tracking Device between 0.90 and 0.95. Intrarater reliability was good for the inclinometer (ICC=0.79-0.84) and for the Magnetic Tracking Device (ICC= 0.75-0.87). The intrarater reliability of the Spin T goniometer was found to be good (ICC > 0.96) in measuring cervical movements on 30 healthy Indian subjects between 18 and 65 years of age (Agarwal et al., 2005).

Most of these sophisticated instruments are highly reliable and efficient in detecting the coupled movements associated with the cervical spine movements. However, they lack clinical utility because they are expensive and require highly trained professionals for operation (De Koning et al., 2008). Thus, simpler instruments like the CROM device and

the universal goniometer are used by researchers and practitioners to measure cervical range of motion. Although the universal goniometer is most widely used in research and clinics, only a few researchers have used it to measure cervical range of motion and have reported that it has poor to moderate reliability. There are many studies in the literature using the CROM device, suggesting that it is a reliable instrument to measure cervical range of motion.

## 2.4.2. Reliability studies using the CROM device

The CROM device has been shown to be a reliable tool for measuring total cervical range of motion (Audette et al., 2010; Youdas et al., 1991; Youdas et al., 1992), upper cervical flexion and extension (Dhimitri et al., 1998) and also resting head posture (Hickey et al., 2000). The CROM device can be used in research as well as in clinical settings because it is easy to use and it can be installed quickly on the head to measure six cervical movements without changing the position of the inclinometers (Audette et al., 2010; Youdas et al., 1992). The majority of the literature on measurement of the cervical spine movements by a CROM device were published in the 1990s (Capuano-Pucci et al., 1991; Dhimitri et al., 1998; Hole et al., 1995; Nilsson et al., 1995; Nilsson et al., 1996; Rheault et al., 1992; Youdas et al., 1991; Youdas et al., 1992). Very few studies were published in the 2000s; they are mostly comparative studies of the CROM device with other instruments to measure cervical movements (Audette et al., 2010; Fletcher and Bandy, 2008; Reynolds et al., 2009; Tousignant et. al., 2002; Whitcroft et al., 2010) (Table 1).

Authors	Purpose	Subjects/Examiner	Results
Capuano-	Intrarater and	20 (healthy; mean age =	Intrarater: $r = 0.62-0.91$ for
Pucci et	Interrater	23 yrs)/unknown	most mvts; Interrater: r =
al., 1991	reliability		0.74-0.87 for six mvts
Youdas et	Intrarater and	60 (patients with cervical	Intrarater: $ICC = 0.84-0.95$
al., 1991	Interrater	disorders; age= 21-84	
	reliability	yrs)/11 PTs	Interrater: $ICC = 0.73-0.92$
Youdas et	Intrarater and	337 (healthy; age = 11-97	Intrarater: $ICC = 0.58$ -
al., 1992	Interrater	yrs)/5 experienced PTs	0.99for most mvts by 5 PTs
	reliability		(0.23 for flexion by 1 rater)
			Interrater: $ICC = 0.66-0.90$
Rheault et	Interrater	22 (patients with cervical	Interrater: ICC (1,1)
al., 1992	reliability	spine disorders; mean age	between 0.76 and 0.87
		= 37  yrs)/2  raters (not)	
		described)	
Hole et	Intrarater and	30 (healthy; $age = 21-48$	Intrarater: $ICC = 0.92-0.96$
al., 1995	Interrater	yrs)/final year	
	reliability	chiropractic student	Interrater: $ICC = 0.82-0.94$
Dhimitri	Intrarater and	30 healthy volunteers; age	Intrarater: $ICC = 0.65-0.81$
et al.,	Interrater	= 23-37 years	Interrater: $ICC = 0.89-0.97$
1998	reliability		
Reynolds	Intrarater and	100 subjects (51 men and	r = 0.59 for cervical
et al.,	Interrater	49 women) between 20	rotation; $r = 0.78$ for
2009	reliability	and 40 years of age.	sagittal and frontal plane movements
Fletcher	Intrarater	22 symptomatic and 25	ICC for symptomatic
and	reliability	asymptomatic subjects	subjects, 0.86 and 0.96;
Bandy,		between 21 and 55 years	ICC for asymptomatic
2009		of age.	patients 0.87 and 0.94
Audette et	Reliability	20 healthy subjects	SEM between 1.6 and 2.8
al., 2010		between 23 and 71 years	degrees
	Validity	of age	
Whitcroft	Interrater	100 healthy subjects	ICC between 0.66 and 0.93
et al.,	reliability	between 18 and 87 years	for six movements
2010		of age	

**Table 1**: Previous reliability studies using the CROM device

Notes: r = Pearson correlation coefficient; ICC = Intraclass Correlation Coefficient; SEM = Standard Error of Measurement; mvt = movements; yrs = years; PTs = Physical therapist

Capuano-Pucci et al. (1991) reported the reliability of the CROM device on 20 healthy subjects with a mean age of 23 years. The measurements were taken by two raters on two different occasions and paired t-tests showed that there were no significant differences between testers or sessions. The interrater reliability in terms of ICC was between 0.74 and 0.85 for the six movements of the cervical spine and the intrarater reliability was between 0.82 and 0.91 for most of the movements of the cervical spine for both the raters.

Youdas et al. (1991) determined intrarater and interrater reliability of cervical range of motion measurements using a universal goniometer, a CROM device and visual estimation by using ICC (1,1). The subjects were 60 patients (39 women and 21 men) with orthopedic disorders, between 21 and 84 years of age. The subjects were divided into three groups with 20 in each and the active range of motion in one cardinal plane was assessed in each group. Eleven experienced physical therapists but with no experience in using the CROM device took the measurements. The subject's posture and the measurement techniques were standardized and there was a training session of 60 minutes for the testers. The subjects did a warm up by repeating three movements in each cardinal plane. The intrarater and interrater reliability obtained by using the CROM device and universal goniometer was greater than visual estimation for cervical flexion and extension; the CROM device had much larger ICC values for cervical rotation than the universal goniometer and visual estimation. The ICC for intrarater reliability was

between 0.84 and 0.95 and the ICC for interrater reliability was between 0.73 and 0.92. Thus, it was concluded that the CROM device and the universal goniometer have good intrarater reliability and the CROM device has good interrater reliability as well. So, the authors concluded that the CROM device is preferable when two or more physiotherapists are taking measurements on the same patient.

Youdas et al. (1992) reported the normal values of cervical range of motion across nine decades in 337 healthy subjects (171 women and 166 men) between 11 and 97 years of age. The intrarater reliability was tested by five testers on six subjects from a pool of 30 subjects (age range from 22-56 years). For interrater reliability, the measurements were taken on 20 different volunteers. Three repetitions of the six cervical range of motion were measured in two sessions. The movement sequence was arbitrarily selected by the testers and was recorded by different recorders to prevent bias. The subjects did not do any warm up exercise so that the measurements could be generalized to clinical settings. Instructions were given to the subjects to maintain good posture and position, and to move the head until the movement is stopped by any muscle tightness. ICC  $_{(1,1)}$  was used to determine intrarater reliability of each tester by comparing each triplet of testers. The intrarater and interrater reliability was good for all the cervical range of motions.

Rheault et al. (1992) used a CROM device and evaluated only interrater reliability in 22 subjects (mean age 37 years) with histories of cervical dysfunction. The six cervical motions for each subject were measured twice, by two raters in the same order. The raters

were blinded to each other. ICC  $_{(1,1)}$  ranged between 0.76 and 0.98, and the mean differences between the testers were very low for all six measurements.

Hole et al. (1995) studied the reliability of using the CROM device in 84 asymptomatic subjects. The measurements were taken by two chiropractic students who practiced taking the measurements for a period of six weeks prior to the start of the main study. The ICC for intrarater reliability using the CROM device was between 0.92 and 0.96, and interrater reliability was between 0.82 and 0.94.

Nilsson et al. (1995) reported the interrater and intrarater reliability of the CROM device by using a paired t-test and Pearson's correlation coefficient. The intrarater reliability was between 0.61 and 0.86 ('r' values) and the interrater reliability between 0.29 and 0.66 ('r' values), with the reason being insufficient training of the examiners or inherent methodological problems. Dhimitri et al. (1998) measured the upper cervical range of motion between C1 and C2 by using the CROM device in 30 healthy volunteers between 23 and 37 years of age, and reported intrarater (ICC = 0.65-0.81) and interrater reliability (ICC = 0.89-0.97).

The first study to report on absolute intrarater reliability in young adults using the CROM device was Fletcher and Bandy (2009). This study was done in 22 symptomatic and 25 asymptomatic subjects between 21 and 55 years of age. In this study, the six anatomical movements of the cervical spine were measured once in two sessions by a CROM device and the intrarater reliability reported in terms of ICC  $_{(3,1)}$ . The posture of the subjects

during the measurement of cervical range of motion was given special consideration, and anatomical landmarks were standardized to make the measurements more accurate. The order and direction of the measurement was randomized to prevent the recorders from remembering the measurements but the tester was allowed to read the measurements. The results showed that ICC for symptomatic subjects ranged between 0.86 and 0.96, and ICC for asymptomatic patients ranged between 0.87and 0.94 for different movements of the cervical spine. The SEM for the symptomatic subjects ranged between 2.5 and 4.1 degrees and the SEM for asymptomatic subjects ranged between 2.3 and 4.0 degrees. Thus, it was concluded that the CROM device is reliable and measures obtained for the cervical movements can be reproduced.

Very recently, Audette et al. (2010) reported absolute reliability using the CROM device in 20 healthy subjects between 23 and 71 years of age. The subjects were measured in two sessions 48 hours apart using a standardized protocol. The SEM (in degrees) was 2.2 for extension, 2.8 for flexion, 2.1 for left rotation, 2.6 for right rotation, 1.8 for left lateral flexion and 1.6 for right lateral flexion. However, this study lacks external validity because of the small sample size and the wide age range of the subjects. Whitcroft et al., (2010) reported within day interrater reliability of the CROM device in terms of ICC (between 0.66 and 0.93). However, the measurement protocol was not described and the absolute reliability scores in terms of SEM, CV, and LOA were not reported by the authors.

The sample size in most studies has been between 20 and 30 and a few studies have even fewer subjects because the reliability assessment was part of a larger study (Youdas et al., 1992). Some studies have used Pearson's correlation coefficient (Capuano-Pucci et al., 1991; Reynolds et al., 2009) and others have used ICC (Hole et al., 1995; Rheault et al., 1992; Youdas et al., 1992) to determine intrarater and interrater reliability. The ICC for intrarater reliability ranges between 0.85 and 0.99 for different movements and the ICC for interrater reliability ranges between 0.69 and 0.95 for different movements of the cervical spine (see Table 1).

## 2.4.3. Measurement protocols used in previous studies using the CROM device

Jordan (2000) reviewed 21 articles published between 1981 and 2000 based on the reliability of cervical range of motion measurements and reported that the six anatomical movements of the cervical spine have not been measured individually by most authors for calculating reliability. In addition, the protocols followed in most of the studies are different from those laid down by the American Medical Association (AMA) and the American Academy of Orthopedic Surgeons (AAOS), and thus the reliability of tools are thus very specific to the protocol used. Most authors have used composite movement to find reliability; e.g., flexion and extension were measured in the sagittal plane, lateral flexion to left and right on the frontal plane, and left and right rotation in the transverse plane. Some authors have calculated the mean of two movements i.e., mean of right and left lateral flexion (Alaranta et al., 1994; Jenkinson et al., 1994). There are two studies

Authors	Subjects/ Examiner	Warm up exercise	Number of sessions	Reps within each session	Order of movements
Rheault et al., 1992	22 subjects/2 testers	not mentioned	2	2 reps	not mentioned but it was same for both testers
Youdas et al., 1992	6-intrarater 20-interrater 5 experienced PTs	not done	2, one after the other	3 reps	order arbitrarily selected by testers
Youdas et al., 1991	60 subjects 11 PTs (experienced but not with CROM) 60 minutes training session	3 reps of each movement in each direction	2, one after the other	3 reps	flexion followed by extension measured by CROM, UG and VE in random order
Tousignant et al., 2000	31 healthy subjects/ 2 testers 1 Radiographer	6 reps of each mvt in each direction	1 measured by both testers one after the other	1 rep	flexion followed by extension
Tousignant et al., 2006	55healthy subjects 1 tester trained for 4 sessions (1 hr each session)	1 rep of each mvt in each direction	2, one after the other; Only 2 <sup>nd</sup> trial analyzed	1 rep	random order
Fletcher and Bandy, 2008	22 symptomatic 25 asymptomatic/ 1 tester, experience of 10 yrs with CROM	not mentioned	2, 30 secs rest between trials	1 rep of each 6 mvts	random order
Audette et al., 2010	20 healthy subjects 1 (not mentioned clearly)	1 rep of each mvt in each direction	2, separated by 48 hours; same time of the day	3 reps of each mvt; average of 3 taken	executed consecutively in each direction
Whitcroft et al., 2010	100 healthy subjects/ 2 examiners	Not mentioned	1	10 reps	Not mentioned

**Table 2:** Measurement protocols used in previous studies using the CROM device

Notes: Reps = repetitions; mvt = movements; yrs = years; secs = seconds; PTs = physical therapist; CROM = Cervical Range of Motion device; UG = universal goniometer; VE = visual estimation

in the literature that examined the reliability of the measurement of cervical movements on both individual as well as composite movements; the authors concluded that the measurement of composite movements is more reliable (Nilsson et al., 1995; Nilsson et al., 1996). The Guides to the Evaluation of Permanent Impairment recommends three repetitions of each measurement but it does not say anything about the order of the movements (Prushansky and Dvir, 2008). The measurement protocols used by various researchers are reported in Table 2.

Few studies have included warm up exercises before measuring cervical range of motion. Most studies took the measurement of cervical range of motion in two trials (one after the other on the same day); however, a few studies have done only one trial and examined the reliability of the repetitions. Most studies have not mentioned rest periods between trials. Few studies have taken the mean of three measurements within each trial. Most studies have measured the cervical movements in random order. It is very important to follow a standardized protocol to maintain consistency among repeated measurements and among different examiners.

## 2.4.4. Reliability studies using the universal goniometer

The universal goniometer is a versatile and inexpensive device which is mainly used in clinical practice for joint range of motion measurements. There are very few reliability studies on universal goniometers for measuring cervical range of motion, and varied results have been obtained in different studies due to the utilization of different

measurement protocols (Table 3). The two main drawbacks of universal goniometers for cervical spine movements are the difficulties in aligning its arms relative to the head and body torso, and the identification of proper bony landmarks (Prushansky and Dvir, 2008).

Authors	Purpose	Subjects/ Examiner	Results
Zachman et al., 1989	Intrarater and Interrater reliability	24 (Healthy; age = 6-51 yrs)	Interrater (r): Lt rot = 0.47; Rt rot = 0.52. Intrarater: (rotation) r = 0.60-0.63 for one rater and r = 0.4-0.61 for other rater
Youdas et al., 1991	Intrarater and Interrater reliability	60 (patients with cervical disorders; age = 21-84 yrs)/11 PTs	Interrater (ICC) Lt rot = $0.54$ , Rt rot = $0.62$ Intrarater(ICC): Lt rot = $0.78$ ; Rt rot = $0.90$
Cleland et al., 2006	Interrater reliability Agreement	22 mechanical neck pain; mean age = 41 yrs)/4 physical therapists	Lt rot: ICC = $0.57$ ; SEM = $5.5 \text{ deg}$ Rt rot: ICC = $0.77$ ; SEM = $5 \text{ deg}$
Maksymowich et al., 2006	Intrarater and Interrater reliability	44 Patients (Ankylosing Spondylosis)	Intrarater: ICC = 0.97- 0.98 Interrater: ICC = 0.95
Whitcroft et al., 2010	Interrater reliability	100 (healthy age =18- 87 yrs)/2 authors	ICC = 0.78-0.87

**Table 3:** Previous reliability studies using the universal goniometer

Notes: r = Pearson's correlation coefficient; ICC = Intraclass Correlation Coefficient; SEM = Standard Error of Measurement; mvt = movements; yrs = years; PTs = Physical Therapists; Rt = Right; Lt = Left; rot = rotation; deg = degrees

Zachman et al. (1989) measured cervical range of motion with a universal goniometer in 24 healthy subjects between six and 51 years of age. Two examiners measured six anatomical cervical motions in a seated position and followed a standardized protocol. In order to measure cervical rotation, the fulcrum of the universal goniometer was over the superior aspect of the head, the proximal arm aligned through the glabella, and the distal arm was aligned perpendicular to a midsagittal position along the transverse plane. Reliability was expressed in terms of Pearson's correlation coefficient; interrater reliability ranged between 0.37 and 0.86, and intrarater reliability ranged between 0.31 and 0.83. The interrater reliability for left rotation was 0.47 and for right rotation was 0.52. The intrarater reliability was between 0.60 and 0.63 for one rater and between 0.4 and 0.61 for the other rater for the rotational movements. The SEM using the universal goniometer was between five and 12 degrees. Youdas et al. (1991) reported interrater and intrarater reliability for cervical movements by using a universal goniometer in 60 subjects. For cervical rotation, the fulcrum of the goniometer was over the subject's head, the fixed arm was along the acromion process and the movable arm was aligned with the tip of the nose of the subject. The ICCs for interrater relative reliability for the two examiners for flexion was 0.57, extension was 0.79, left lateral flexion was 0.79, right lateral flexion was 0.72, left rotation was 0.54, and right rotation was 0.62. The ICCs for intrarater relative reliability was between 0.83 and 0.86 for flexion, 0.85 for lateral flexion, and 0.78 for left rotation and 0.90 for right rotation.

Cleland et al. (2006) measured cervical rotation with a universal goniometer in 22 patients with mechanical neck pain. The authors followed a standardized protocol for measuring cervical rotation. However, the details of the placement of the goniometer arms were not provided by the authors. Despite the use of a standardized protocol, the authors reported poor to moderate reliability using the universal goniometer. The interrater relative reliability was reported by ICC  $_{(2,1)}$  and was between 0.57 and 0.75. In addition, the authors also determined the absolute reliability; SEM ranged between 5.5 degrees for left cervical rotation and 5 degrees for right cervical rotation. LOA for left cervical rotation was reported between 0.3 and 15.9 degrees, and for right cervical rotation between 1.6 and 13.5 degrees.

Maksymowych et al. (2006) measured cervical rotation movements using a universal goniometer in patients with ankylosing spondylosis. The subjects were measured in a seated position, on a chair placed against the wall. The stationary arm of the goniometer was fixed against the wall and the movable arm was aligned along the nose of the subject. The intrarater reliability was reported in terms of ICC which was found to be 0.98, and interrater reliability was 0.95. In addition, LOA were between 10.2 and 12.0 degrees for the rotational movements.

Reynolds et al. (2009) used a universal goniometer to measure six cervical movements in 100 subjects (51 men and 49 women) between 20 and 40 years of age. Cervical rotation was measured by placing the universal goniometer on the vertex in a seated position. It was found that a universal goniometer is moderately reliable for measuring cervical

flexion/extension (r = 0.78), and lateral flexion (r = 0.78), but poorly reliable for measuring cervical rotation (r = 0.59). However, the authors have not reported about the raters and the absolute reliability measures of the cervical range of motion measured by the universal goniometer. Whitcroft et al. (2010) have not reported interrater relative reliability using the universal goniometer in terms of ICC (between 0.78 and 0.87). However, the testing was done on the same day and absolute reliability scores in terms of SEM, CV and LOA were not reported.

## 2.4.5. Summary of the literature review

A variety of instruments have been used by different authors to measure cervical range of motion. There is a wide variability in the intrarater and interrater reliability reports using the different instruments and protocols. The CROM device seems to be a reliable tool for measuring cervical range of motion. However, there has been no study to date to report on absolute reliability using the CROM device in older adults. In addition, authors who have reviewed the literature have found only a few studies that have a sample size of 30 subjects or greater. De Koning et al. (2008) found in a review that a proper study design with proper blinding for more internal and external validity is required for reliability in their reliability reports, there is a need of a reliable instrument which can be easily used following a standardized protocol to measure cervical range of motion especially in older adults in research as well as clinical settings. The use of a reliable instrument and

protocol is also important to know the effectiveness of a neck flexibility intervention in older adults.

In general, stretching is advocated by many organizations for older adults and has been shown to be beneficial in improving range of motion. However, very few randomized controlled trials have reported an increase in cervical range of motion following a neck flexibility intervention and all these studies have used different instruments having different reliability scores. A previous study in the Neuromuscular Laboratory at the University of Manitoba (Porter et al., 2008) did not find any significant increase in neck rotation after 12 weeks of intervention as measured by a CROM device, even though shoulder flexibility did increase. Given that the absolute reliability of using the device was not known it is hard to place these results in an appropriate context.

As most of the previous researchers have reported on relative reliability of the CROM device, it is now important to determine its absolute reliability so that the changes in cervical range of motion following a flexibility intervention can be used in future studies for power calculations. Knowledge of absolute reliability measures for cervical range of motion using the CROM device on older adults will also benefit researchers and clinicians by providing an indication of the accuracy of the measures. In addition, the Candrive protocol using the universal goniometer has not been studied in terms of relative and absolute reliability, and this would be important to do since some studies have found intrarater and interrater issues with using the universal goniometer, even with experienced examiners.

## **CHAPTER 3: MATERIALS AND METHODS**

## **3.1. SUBJECTS**

According to previous reviews, the sample size for a reliability study must be between 30 and 40 in order to generalize the results (De Koning et al., 2008; Jordan, 2000). Therefore, the sample size aim for this study was 40 individuals. Because the Candrive project is a study on older drivers aged 70 years and above, for the present study the target population was older men and women, aged 70 years and above.

Older individuals, who expressed an interest in participating in future studies of the Neuromuscular and Aging Laboratory at the University of Manitoba, were contacted by telephone. This included those who were not able to participate in the Candrive research project. Reasons for exclusion from the Candrive project might have included the following: age of their vehicle, amount of time in Manitoba during the year, long term study (five years), and time commitment. Posters outlining the purpose of the study were also put up around places that are frequently visited by seniors like apartment buildings for seniors, shopping malls, churches, and in the various departments of the University of Manitoba.

All the potential subjects were informed about the purpose of the study, the testing sessions and methods, and the potential risks and benefits over the telephone.

## **Inclusion criteria**

- 1. Older adults (70 years and over), who have a valid driver's license and those who are driving at least one time on average per week.
- 2. No history of severe acute neck pain.

## **Exclusion criteria**

The potential subjects who expressed their interest in participating, underwent screening (see Appendix 2 for the screening questionnaire on the phone tracking sheet) over the telephone. The exclusion criteria were as following:

1. Current acute neck pain or neck pain that has changed over last two weeks. The subjects were asked to rate their neck pain verbally on a Numerical Rating Scale (NRS) during their screening over the telephone. The NRS is an 11 point scale and the end points are the extremes of 'no pain' and 'worst imaginable pain' (Williamson and Hoggart, 2005) (see Appendix 1). The subjects were excluded if they rated their current neck pain as 4 or more on the NRS scale.

2. Presence of the following conditions that may limit the range of motion in the cervical spine and/or may interfere with testing:

 Neurological conditions (e.g., cervical neuropathy, cervical disc prolapse, stroke, hemiparesis, motor neuron disease, spinal tumors, multiple sclerosis, Parkinsonism, Alzheimer's disease, myasthenia gravis, or Guillain-Barre syndrome)

- ii. Orthopedic conditions (e.g., history of fracture in cervical or thoracic spine, history of fracture in the shoulder girdle if it has limited cervical range of motion, muscle sprain, recent whiplash injury, spasmodic or congenital torticollis, ankylosing spondylosis, chronic degenerative disorder of spine, senile kyphosis, scoliosis, cervical spinal stenosis, or fibromyalgia).
- iii. Spinal surgeries (e.g., fusion, artificial disc replacement, or presence of internal fixation in the cervical or thoracic spine).
- iv. The presence of acute or unstable cardiac disease because it may interfere with blood flow in the vertebral arteries while testing the end range of motion of the cervical spine.
- v. Presence of a cardiac pacemaker, because the operation of the CROM device requires a magnet to be kept over the chest of the subject. The electromagnetic field created by this magnet can interfere with the set rhythm of the pacemaker.

A study package that included a cover letter, Neck Disability Index (see Appendix 3), a copy of the consent form (see Appendix 4), and a map showing directions to the University of Manitoba, was mailed to all the eligible participants. The Neck Disability Index (NDI) is an instrument for measuring self rated disability due to neck pain or whiplash associated disorders. It has ten questions where individuals rate their level on the following: intensity of pain, personal care, lifting, reading, headaches, concentration,

work, driving, sleeping, and recreation (Vernon and Mior, 1991). Each of the ten sections has six questions (rated between 0 and 5) based on increasing level of severity of the condition. The overall score on NDI is 50 (Vernon and Mior, 1991).

Appointments were scheduled for all the participants who expressed an interest after reading the study package. The subjects were given a parking pass for both sessions and \$10 for their participation in the study. Ethical approval for this study was received from the Education/Nursing Research Ethics Board of the University of Manitoba. All the subjects provided written informed consent.

## **3.2. EXPERIMENTAL DESIGN**

Cervical range of motion was measured in two sessions exactly at an interval of one week (Session 1 and Session 2). The measurement procedure was the same for both sessions. The subjects were given appointments at the same time for session 1 and 2 so as to eliminate any effects resulting from variation in range of motion at different times in a day. Cervical range of motion for each subject was measured by two raters (Rater 1 and Rater 2) for each of the two sessions. Rater 1 followed a standardized protocol using the CROM device and measured five cervical movements (flexion, left lateral flexion, right lateral flexion, left rotation, and right rotation). Rater 2 followed the protocol developed by the Candrive project using the universal goniometer and measured left and right cervical rotation. The order of testing the subjects was blocked between the two raters, within a session and between the two sessions. Thus, the subjects, who were tested by the CROM device first for session 1, were tested first by the Candrive protocol for session 2

(one week apart). Twenty one subjects were tested first by the Candrive protocol and 19 by the CROM device first for session 1, and vice versa for session 2.

## **3.3. INSTRUMENTS**

## 3.3.1. The CROM device

The CROM device (Performance Attainment Associates, Roseville, MN) used in the present study is a commercially available gravity goniometer (Figure 1). It consists of two non-adjustable, gravity inclinometers for measuring cervical motion in the frontal plane (i.e., left cervical lateral flexion and right cervical lateral flexion) and sagittal plane (cervical flexion and cervical extension). Both the inclinometers have 360 degree dials, marked in two degree increments. In addition, it has a single, adjustable, magnetic (compass-like) goniometer to measure left cervical rotation and right cervical rotation. The three goniometers are housed on a plastic frame. The frame is fixed over the head of the subject like glasses and secured to the head with Velcro straps. A magnet is secured over the subject's upper trunk in order to compensate for thoracic movements.

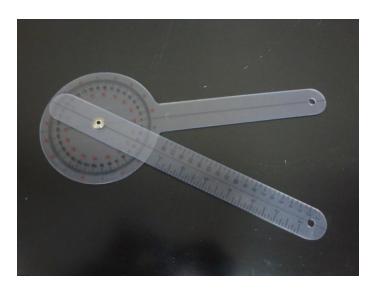
## 3.3.2. Universal Goniometer

A universal goniometer was used in the present study for the Candrive protocol. It has a central protractor of 360 degrees, marked in one degree increments. It has two arms which are 25 centimeters long (Figure 2).

# Figure 1: Photo of the CROM Device



Figure 2: Photo of the Universal Goniometer



## **3.4. TRAINING OF THE TESTERS**

**Rater 1**: A physical therapist was given training with the CROM device following a standardized protocol. She practiced measuring the five cervical movements (flexion, left lateral flexion, right lateral flexion, left rotation, and right rotation) using the device on some staff and colleagues. Intrarater reliability was calculated in terms of ICC, SEM, CV and LOA from the cervical range of motion scores obtained during the practice session. The actual testing session for the present study on the subjects was started after ensuring that the rater was reliable in measuring the five cervical movements.

**Rater 2**: She was a research assistant in the Faculty of Kinesiology and Recreation Management. She did not have any previous experience in using a universal goniometer, similar to some of the Candrive staff. She was given similar training and practice as performed with the Candrive protocol. She independently watched the DVD provided by the Candrive project and then practiced measuring cervical range of motion on some staff and colleagues. She did not practice measuring the movements as extensively as Rater 1 and her reliability was also not assured before starting the testing session on subjects.

## **3.5. PROCEDURE**

## 3.5.1. Measurement of neck pain

Because neck pain was an exclusion criterion for the study, we measured neck pain just before testing in both sessions, in addition to the preliminary telephone screening, to ensure that no subjects were in moderate to severe pain on the day of testing. In addition,

neck pain that varies from week to week could have affected the cervical range of motion of the subjects for the two sessions. Thus, the subjects were asked to rate their neck pain on a Visual Analogue Scale (VAS). VAS is a ten centimeter line; 0 indicates no pain and a score of 10 indicates worst imaginable pain (Williamson and Hoggart, 2005). The inclusion criterion was a score between 0 and 3 on VAS for both the testing sessions, i.e., subjects having mild neck pain or mild neck stiffness were included in the study. For the present study, all the subjects who came for the testing sessions were included because most of them had no neck pain and only a few presented with minimal neck pain, prior to the testing sessions.

## 3.5.2. Measurements taken with the CROM device

Three sets of measurements were taken for each subject during each session, for each of the five anatomical movements of the cervical spine by following a standardized protocol. Systematic error was avoided by randomizing the order of the movements in the first set of measurement during session 1. The subjects selected cards with the five movements of the cervical spine written on them during the first set of measurements of session 1. The same order was followed for the second and third set of repetitions of measurement during session 1. As well, the order of the movements was same for each subject for session 2 (similar to session 1).

The end range of the cervical movements was defined as the point at which the subject's active range of motion was limited by muscle tightness, pain or an associated movement. All measurements of the cervical spine were taken in a seated position. The subject's feet

were positioned flat on the floor and arms resting freely at the sides. The CROM device was mounted over the subject's nose bridge and ear, and secured to the head by velcro straps. The following verbal instructions were given to the subjects:

<u>For posture and to avoid thoracic movement</u>: Sit straight on the chair with proper back position. Do not move your shoulders or change the amount of pressure being applied to the backrest of your chair.

<u>Flexion</u>: Tuck your chin first, then move your head forward and down as far as possible until limited by tightness or discomfort.

Lateral flexion (right and left): Look straight ahead and side bend your neck by moving your ear toward your shoulder as far as possible until limited by tightness or discomfort.

<u>Rotation (left and right)</u>: Turn your head, gazing at an imaginary horizontal line on the wall, as far as possible until limited by tightness or discomfort.

After receiving the verbal instructions for each movement, the subjects then practiced the active range of motion as instructed to understand the end feel of the movement. Once the subject was performing the movement correctly the measurements were made. Some subjects required more instruction and practice than others, before the movements were actually measured and recorded. The subjects were asked to return to the neutral position after recording each movement. The same procedure was repeated for measuring the five movements.

Cervical flexion was recorded with the dial on the sagittal plane of the CROM device and cervical lateral flexion by the dial on the frontal plane. The physical therapist stood behind the subject on a foot stool in order to record cervical rotation by the magnetic goniometer on the top of the head of the subject. If a subject did not follow the instructions correctly for any movement, then the measurement was not taken. The instructions were repeated and the subjects were asked to repeat the movement correctly. Separate data collection sheets were used for session 1 and session 2. The measurements obtained from session 1 were masked for session 2.

## 3.5.3. Measurements taken with the universal goniometer

Three sets of measurements were taken for each subject for left cervical rotation and right cervical rotation using the universal goniometer and the Candrive protocol. Systematic error was avoided by randomizing the order of the movements in each set of measurements, in the same way as described for the CROM device. Cards were selected by the subject with the two movements of the cervical spine written on them to randomize the order of the neck movements in the first set during session 1. The same order was followed for the second and third sets of repetitions during session 1. However, this order was made opposite for session 2, i.e., the subjects who were measured for left rotation first during session 1, were measured for right rotation first during session 2. According to the Candrive protocol, the subjects sat straight on a chair facing the wall. A marker was placed on the wall in front of the subject at the level of the top of the head of the subject (See figure 3). The rater stood behind the subject and placed the universal

goniometer on the top of the head. The stationary arm of the goniometer was aligned with the marker on the wall in front of the subject. The subject was instructed to move the head in the left or right direction. Once the subject achieved the full range of motion, the movable arm of the universal goniometer was aligned with tip of the nose of the subject and the range of motion was recorded. The following verbal instructions were given to the subjects, according to the Candrive protocol:

Left rotation: "Look to the left and gently turn your head to the left side"

Right rotation: "Look to the right and gently turn your head to the right side" Separate data collection sheets were used for both the sessions for rater 2 so that she was masked to the scores measured by her during session 1. Rater 2 was also masked to rater 1 scores.

## **3.6. STATISTICAL ANALYSES**

Statistical analyses were conducted using SPSS 16.0 (SPSS Inc, Chicago, IL), and SigmaPlot 11 (Systat Software Inc, San Hose, CA). Means and standard deviations were calculated for the cervical range of motion measurements by using the CROM device and the Candrive protocol for session 1 and session 2. Using mean scores may reduce the magnitude of error component contributing to the total score because all scores inherently include some random error which either adds to or subtracts from the true score (Portney and Watkins, 2009). To confirm this, repeated measures ANOVA for the three repetitions for each movement measured by the two protocols was done. The p-values for sessions 1 and 2 were between 0.34 and 0.98 for all the movements measured by the two protocols which showed that there was no significant difference between the repetitions for the two sessions. Thus, all variables used in the analyses were means of the repetitions performed (mean of 3 repetitions for the CROM and the Candrive protocol).

Both men and women participated in the present study. Independent t-tests were done between the values obtained for men and women to analyze gender differences. There were no significant differences in the ranges of motion between men and women measured by both the protocols (p-values between 0.12 and 0.89). Thus, for the sake of brevity, data for men and women were combined together for all of the results presentation.

#### **<u>3.6.1. Reliability statistics</u>**

Relative reliability was determined by ICC  $_{(2,3)}$ ; Model 2 (each subject was assessed by an experienced rater) and Form 3 (averages of three measurements were included in the statistical analyses) (Portney and Watkins, 2009). Absolute reliability was calculated in terms of SEM, CV and LOA. All data was visually analyzed by a Bland Altman Plot and examined for heteroscedasticity. In addition, heteroscedasticity was assessed by conducting Pearson correlation coefficients between absolute differences and the means of range of motion scores for session 1 and session 2. Paired t-tests were conducted to look for significant bias between the two sessions (p < 0.05) for both the protocols. Normality of the difference scores was assessed using the Shapiro-Wilk test.

#### **3.6.2.** Validity of the Candrive protocol

Paired t-tests were done to determine systematic variability between the left cervical rotation and right cervical rotation obtained using the CROM device and the Candrive protocol using the universal goniometer. Bland-Altman plots were used to check for heteroscedasticity. SEM, CV, ME, LOA were evaluated between the measurements obtained with the CROM device and the universal goniometer over the two testing sessions. Systematic bias between the two protocols was also calculated as the average difference between the ranges of motion obtained by the CROM protocol and the Candrive protocol.

As evident from the literature review, the measurement of cervical movements depends on the instructions given to the subjects during the testing session regarding posture and anatomical movements of cervical spine. Because there was a difference between the two protocols in terms of instructions, it was anticipated that this could lead to a difference in the performance of the subjects during the testing session. Thus, the effect of order of the testing protocol on cervical range of motion was also tested statistically. Reliability and validity was also demonstrated for the subjects who were first tested by the Candrive protocol during session 1.

## **CHAPTER 4: RESULTS**

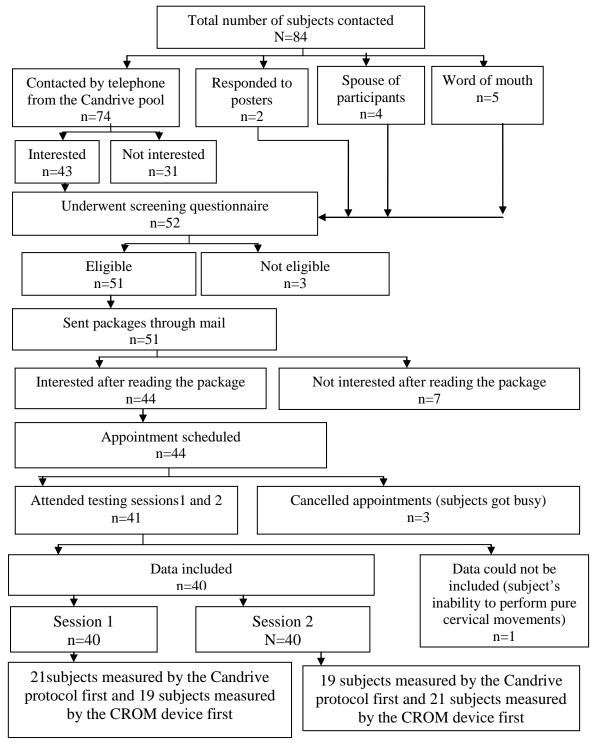
## **4.1. SUBJECTS**

## 4.1.1. Subject recruitment

In total there were 84 potential subjects (see Figure 3). Seventy four people were contacted from the Candrive pool out of which 42 people expressed their interest in this study. Ten people responded from posters and other sources like word of mouth or spouse of the participants. Two subjects were excluded during the telephone screening; one subject's neck pain scored 5 on NRS scale and the other subject who contacted us because of a poster was not a driver. Thus, the study package was sent to 51 subjects. Seven subjects were not interested in the study after reading the package. Finally 44 subjects were given appointments for both sessions but only 41 subjects completed the two sessions. Three subjects cancelled their appointment because they became busy with other things during their appointment time.

Forty one older men and women between 70 and 89 years of age were recruited for the present study, and completed both testing sessions. However, one subject (male, age = 84 years) was unable to perform pure lateral flexion and rotational movements of the cervical spine even after repeated and consistent instructions over session 1 and session 2 (i.e., his cervical lateral flexion movement was associated with a high degree of cervical rotation and cervical extension; rotation movement was associated with lateral flexion and extension movement). His inability to perform pure rotation movements would also rule him out for the Candrive protocol (as it measures only cervical rotation).

Figure 3: Flowchart outlining subject recruitment and numbers of participants at various stages



Thus, his data could not be included for the statistical analyses. For all the results only the 40 eligible subjects' data are presented. The mean age for all subjects was 75.7 years (SD=4.5 years). There were 24 men and 16 women subjects. The mean age for the men was 76.1 years (SD=5.5 years) and the mean age for the women was 75.2 years (SD=3.7 years).

#### 4.1.2. Neck pain measurement

The mean neck pain score on the Numerical Rating Scale (NRS) for all the subjects was 0.3 (SD=1.0) during the telephone screening questionnaire. Thirty seven subjects did not have neck pain (i.e., NRS score=0) and three subjects had mild neck pain (i.e., NRS score between 1 and 2) during their telephone screening. Two subjects were taking medications for arthritis but were pain free or had mild pain during their screening session over the telephone. Two subjects had variable neck pain but the pain intensity was mild (NRS score between 0 and 3). None of the subjects had a history of recent bouts of neck pain but some complained about an occasional mild degree of neck stiffness.

During the start of session 1 and 2, the subjects were again asked to rate their current neck pain on a Visual Analogue Scale (VAS). Twenty five subjects did not have any neck pain (i.e., VAS score=0) and 15 subjects had mild neck pain (i.e., VAS score between 0.01cm and 1.5cm) before starting testing session 1. During testing session 2 (one week apart), 30 subjects did not have neck pain (i.e., VAS score=0) and ten subjects had mild neck pain (i.e., VAS score between 0.01cm and 1.8 cm).

# **4.1.3. Neck Disability Index**

Each section on the NDI has 6 questions which are rated between 0 and 5. The overall score is 50. The subject's score was expressed for each of the 10 sections. However, the data did not follow a normal distribution, and thus the median score for the 10 sections are presented in Table 4. Most subjects rated their neck disability as 0 on most of the sections of the NDI.

NDI (6 questions in each sections)	Median score for each section (Range for each section)
SECTION 1-Pain Intensity	0 (0-2)
SECTION 2-Personal Care (washing, dressing, etc)	0 (0-0)
SECTION 3-Lifting	0 (0-4)
SECTION 4-Reading	0 (0-1)
SECTION 5-Headache	0 (0-3)
SECTION 6-Concentration	0 (0-2)
SECTION 7-Work	0 (0-1)
SECTION 8-Driving	0 (0-1)
SECTION 9-Sleeping	0 (0-3)
SECTION 10-Recreation	0 (0-5)

**Table 4:** Participant characteristics for the Neck Disability Index (n=40)

#### 4.2. RELIABILITY OF USING THE CROM DEVICE

Descriptive information for the cervical range of motion data measured by the CROM device for session 1 and 2 are presented in Table 5. Paired t-tests were done to determine statistically significant differences between the five cervical range of motion values (flexion, left lateral flexion, right lateral flexion, left rotation, and right rotation) obtained for session 1 and 2 by using the CROM device. The measurement scores for flexion and right rotation did not follow a normal distribution and thus, data were analyzed by the Wilcoxon test. However the p-values obtained by the non parametric test were not significant for these two movements. Thus, the p-values presented in table 5 are those obtained by the parametric paired t-test values.

There were no statistically significant differences between for session 1 and 2 for the five cervical movements. However, left and right cervical lateral flexion between session 1 and session 2 measured by the CROM device were very close to the significance level (p=0.06 and p=0.07 respectively).

Cervical range of motion	Session 1 (degrees) Mean (SD)	Session 2 (degrees) Mean (SD)	Average ROM for session 1 and 2 (degrees) Mean (SD)	P- value
Flexion	46.2 (7.0)	45.4 (6.1)	45.8 (6.2)	0.22
Left lateral flexion	27.8 (6.8)	26.7 (6.0)	27.3 ( 6.1)	0.06
Right lateral flexion	25.1 (7.1)	24.1 (6.4)	24.6 (6.5)	0.07
Left rotation	53.1 (8.6)	52.9 (8.1)	53.0 (8.0)	0.89
Right rotation	53.3 (9.2)	54.2 (8.5)	53.7 (8.6)	0.16

**Table 5**: Means and standard deviations (SD) for cervical range of motion using the CROM device (n=40)

Notes: SD = standard deviation; ROM = range of motion; p values calculated from paired t-tests for ROM between session 1 and 2

#### **4.2.1. Between session intrarater reliability**

The Pearson's correlation coefficient between the two sessions for the five movements measured was between 0.82 and 0.89 (see Table 6). The relative reliability was found to be good based on ICC  $_{(2,3)}$  (between 0.89 and 0.94) (Portney and Watkins, 2009). Absolute reliability was reported in terms of CV, SEM, LOA, and MDC. The CV was between 5.5% and 9.5% and SEM was between 1.9 and 3.1 degrees. The LOA was between 5.3 and 9.4 degrees and MDC was between 5.4 and 8.6 degrees for all the five movements measured. The MDC values suggest that we can be 95% confident that measurements outside these calculated ranges would represent a true change in cervical range of motion.

Cervical range of motion	r	ICC (2,3) (95% CI)	CV (%)	SEM ± 95% CI (degrees)	LOA (degrees)	Systematic bias (SD)	MDC (degrees)
Flexion	0.82	0.89 (0.80-0.94)	6.3	2.1 ± 4.1	7.3-8.9	0.8 (4.0)	5.7
Left lateral flexion	0.84	0.90 (0.81-0.95)	9.5	1.9 ± 3.8	6.3-8.5	1.1 (3.7)	5.4
Right lateral flexion	0.89	0.94 (0.88-0.97)	8.9	2.2 ± 4.3	5.3-7.2	0.9 (3.1)	6.0
Left rotation	0.85	0.92 (0.84-0.96)	6.2	3.1 ± 6.1	9.2-9.4	0.1 (4.7)	8.6
Right rotation	0.89	0.94 (0.88-0.97)	5.5	$2.8 \pm 5.6$	7.4-9.3	-1.0 (4.2)	7.8

Table 6: Between session intrarater reliability using the CROM device

Notes: r = Pearson's correlation coefficient; ICC = intraclass correlation coefficient; CV = coefficient of variation; SEM= standard error of measurement; LOA = limits of agreement; CI = confidence interval; MDC = minimum detectable change; Systematic bias = average difference between session 1 and session

The data were also examined by Bland-Altman plots (Figure 4). The spread of the scores

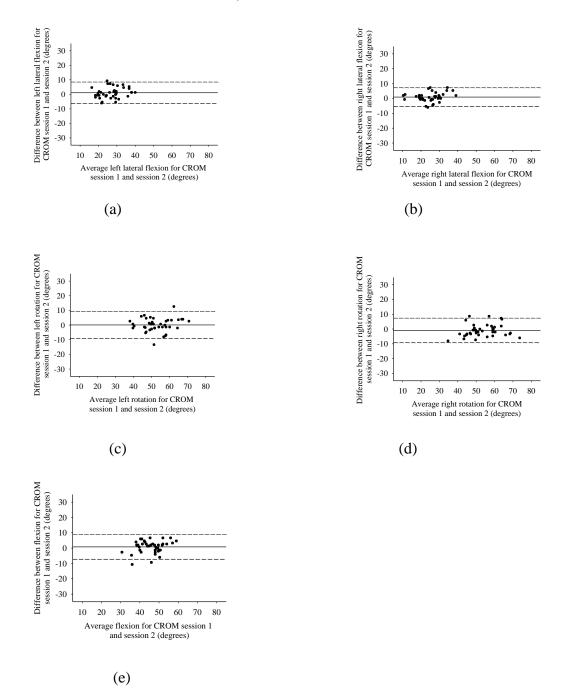
around the zero line (95% of the difference scores fall within two standard deviations

above and below the mean difference scores) suggests that the data is unbiased,

homoscedastic, and there was a good agreement between the two sessions (Portney and

Watkins, 2009).

**Figure 4:** Bland-Altman plot for left lateral flexion (a), right lateral flexion (b), left rotation (c), right rotation (d), and flexion (e) measured with the CROM device. The middle line shows the mean value of the difference scores between session 1 and 2, and the dashed lines show the 95% upper and lower limits of agreement (i.e., two standard deviations above and below the mean difference score).



# 4.2.2. Within session intrarater reliability

Table 7 reports the within day reliability data for the five cervical range of motions measured for sessions 1 and 2. For session 1, the absolute reliability was reported in terms of SEM and was between 1.4 and 1.7 for all the cervical movements measured. The relative reliability was reported in terms of ICC  $_{(2,1)}$  and was found to be good (between 0.95 and 0.97). For session 2, the absolute reliability was reported in terms of SEM and was between 1.4 and 1.7 for all the cervical movements measured. The relative reliability of the session 2, the absolute reliability was reported in terms of SEM and was between 1.4 and 1.7 for all the cervical movements measured. The relative reliability was reported in terms of SEM and was between 1.4 and 1.7 for all the cervical movements measured. The relative reliability was reported in terms of ICC  $_{(2,1)}$  and was found to be good (between 0.94 and 0.97).

	Session 1		Session 2		
Cervical range of motion	ICC (2,1) (95% CI)	SEM (degrees)	ICC (2,1) (95% CI)	SEM (degrees)	
Flexion	0.95 (0.92-0.97)	1.5	0.95(0.91-0.97)	1.4	
Left lateral flexion	0.95 (0.91-0.97)	1.6	0.95 (0.91-0.97)	1.4	
Right lateral flexion	0.96 (0.92-0.97)	1.5	0.94 (0.89-0.96)	1.6	
Left rotation	0.96 (0.95-0.98)	1.7	0.95 (0.92-0.97)	1.7	
Right rotation	0.97 (0.95-0.98)	1.4	0.97 (0.95-0.98)	1.6	

Table 7: Within day intrarater reliability statistics using the CROM device

Notes: ICC = intraclass correlation coefficient; SEM = standard error of measurement; CI = confidence interval

# 4.3. RELIABILITY USING THE CANDRIVE PROTOCOL

Paired t-tests were also done for the two movements (left rotation and right rotation) measured by the Candrive protocol (Table 8). There were no significant differences between session 1 and 2 for the cervical rotation movements measured by the Candrive protocol.

**Table 8:** Means and standard deviations (SD) for cervical range of motion using the Candrive protocol (n=40)

Cervical range of motion	Session 1 (degrees) Mean (SD)	Session 2 (degrees) Mean (SD)	Average ROM for session 1 and 2 (degrees) Mean (SD)	p-value
Left rotation	55.3 (10.7)	53.5 (9.9)	54.4 (9.7)	0.10
Right rotation	52.2 (10.6)	51.1 (9.4)	51.6 (9.5)	0.29

Notes: SD = standard deviation; ROM = range of motion; p-values calculated from paired t-tests for ROM between session 1 and 2

# 4.3.1. Between session intrarater reliability using the Candrive protocol

Table 9 reports the between session reliability data for the cervical range of motion measured. The ICC values were 0.87 for left rotation and 0.89 for right rotation. The absolute reliability was reported in terms of CV, SEM, and LOA, MDC, systematic bias. The CV was 9.4% for left rotation and 7.9% for right rotation. The SEM was 3.5 degrees for left rotation and 3.2 degrees for right rotation. The correlation between the two sessions for the five movements measured was between 0.78 and 0.82. The LOA was between 11.1 and 15.6 degrees and MDC was between 8.8 and 9.7 degrees for the rotation movements.

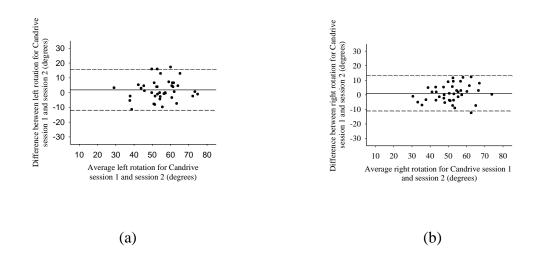
Cervical range of motion	r	ICC (2,3 ) (95% CI)	CV (%)	SEM ± 95% CI (degrees)	LOA (degrees)	Systematic bias (SD) (degrees)	MDC (degrees)
Left rotation	0.78	0.87 (0.75-0.93)	9.4	3.5 <u>+</u> 6.9	11.9-15.6	1.8(6.9)	9.7
Right rotation	0.82	0.89 (0.81-0.94)	7.9	3.2 <u>+</u> 6.2	11.1-13.1	1.0(6.0)	8.8

Table 9: Between session intrarater reliability statistics using the Candrive protocol

Notes: ICC = intraclass correlation coefficient; CV = coefficient of variation; SEM = standard error of measurement; LOA = limits of agreement; CI = confidence interval; MDC= minimum detectable change; Systematic bias = average difference between session 1 and session 2

The data were also examined by Bland-Altman plots (Figure 5). The spread of the scores around the zero line (95% of the difference scores fall within two standard deviations above and below the mean difference scores) suggests that the data is unbiased, homoscedastic, and there was a good agreement between the two sessions (Portney and Watkins, 2009).

**Figure 5**: Bland-Altman plot for left rotation (a) and right cervical rotation (b) measured with the Candrive protocol. The middle lines show the mean value of the difference scores between session 1 and 2, and the dashed lines show the 95% upper and lower limits of agreement (i.e., two standard deviations above and below the mean difference score).



# 4.3.2. Within session intrarater reliability

For session 1, the absolute reliability was reported in terms of SEM and was 4.1 degrees for left rotation and 3.5 degrees for right rotation. The relative reliability was reported in terms of ICC  $_{(2, 1)}$  and was 0.85 and 0.89 for left and right cervical rotation respectively.

For session 2, the SEM and was 3.6 degrees for left rotation and 3.3 degrees for right rotation. The relative reliability was reported in terms of ICC  $_{(2, 1)}$  and was 0.87 and 0.88 for left and right cervical rotation respectively.

Table 10 reports the within day reliability data for the cervical rotation measured for session 1 and 2.

	Session 1		Session 2		
Cervical range of motion	ICC (2,1) (95% CI)	SEM (degrees)	ICC (2,1) (95% CI)	SEM (degrees)	
Left rotation	0.85 (0.77-0.91)	4.1	0.87 (0.77-0.93)	3.6	
Right rotation	0.89 (0.79-0.94)	3.5	0.88 (0.78-0.93)	3.3	

**Table 10:** Within session reliability statistics using the Candrive protocol

Notes: ICC = intraclass correlation coefficient; SEM = standard error of measurement; CI = confidence interval

# 4.4. COMPARING RELIABILITY BETWEEN CROM AND THE CANDRIVE PROTOCOLS.

Paired t-tests for the ICC and SEM values obtained for cervical rotation for session 1 and session 2 between the CROM protocol and the Candrive protocol showed significant differences between the two protocol (p=0.001 for both ICC and SEM values).

# 4.5. CONCURRENT VALIDITY OF THE CANDRIVE PROTOCOL

The measures obtained by using the CROM device demonstrated good relative and absolute reliability. Thus, considering the CROM device protocol as the gold standard, the measures obtained by the Candrive protocol were validated with those obtained by the CROM device. The concordance between the two protocols for session 1 and session 2 were analyzed in terms of Pearson's correlation coefficient, ICC, SEM, CV, LOA and systematic bias. Because the concordance values were very similar for session 1 and session 2, only the concordance data for session 1 has been reported (Table 11).

Cervical range of motion	ICC (2,3) (95% CI)	SEM (degrees)	CV (%)	LOA (degrees)	r	Systematic bias (SD)
Left rotation	0.76 (0.54-0.87)	4.3	11.1	14.7-19.2	0.63	-2.3(8.5)
Right rotation	0.78 (0.59-0.88)	4.2	11.3	15.6-17.9	0.65	1.1(8.4)

Table 11: Concordance between the CROM and the Candrive protocols for session 1

Notes: ICC = Intraclass correlation coefficient; CV = coefficient of variation; SEM = standard error of measurement; LOA = limits of agreement; CI = confidence interval; Systematic bias = average difference between session 1 and session 2; MDC = minimum detectable change; r = Pearson's correlation coefficient; SD = standard deviation

<u>Relative agreement:</u> The relative concordance was reported in terms of ICC and was moderate (0.76 and 0.78 for left and right rotation respectively). The Pearson correlation coefficient between the two protocols for the rotational movements measured was 0.63 and 0.65 for left and right rotation respectively.

<u>Absolute agreement</u>: Paired t-tests were also done between the measures obtained by the CROM device and the Candrive protocol for left rotation and right rotation for session 1 and session 2. Table 12 presents the means and standard deviations (SD) for left and right cervical rotation measured by the CROM device and the Candrive protocol for session 1. There was no statistically significant difference between the left and right cervical rotation measured by the two protocols for session 1.

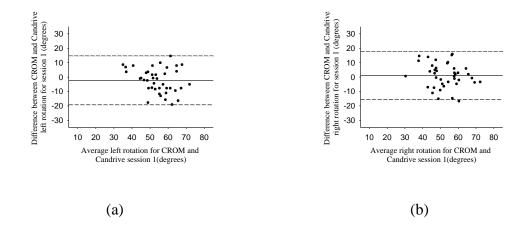
**Table 12:** Means and standard deviations (SD) for cervical rotation measured by the CROM device and the Candrive protocol for session 1

Cervical range of motion	Session	CROM device (degrees) Mean (SD)	Candrive protocol (degrees) Mean (SD)	p-value
Left cervical rotation	Session 1	53.1 (8.6)	55.3 (10.7)	0.10
Right cervical rotation	Session 1	53.3 (9.2)	52.2 (10.6)	0.41

Notes: SD = standard deviation; ROM = range of motion; p-values calculated from paired t-tests for ROM between CROM device and the Candrive protocol for session 1

The CV was 11.1% for left rotation and 11.3% for right rotation. The SEM was 4.3 degrees for left rotation and 4.2 for right rotation. The LOA was very high, between 14.7 and 19.2 for left rotation and right rotation. The data were also examined by Bland Altman plots (Figures 6). The spread of the scores around the zero line (95% of the difference scores fall within two standard deviations above and below the mean difference scores) suggests that the data is homoscedastic and unbiased (Portney and Watkins, 2009). The scores are distributed widely around the mean difference score, suggesting that the agreement between the two protocols is marginal.

**Figure 6:** Bland-Altman plot for average left rotation (a) and right rotation (b) measured with the CROM device and Candrive protocol for session 1. The middle lines show the mean value of the difference scores between the CROM and Candrive protocols for session 1, and the dashed lines show the 95% upper and lower limits of agreement (i.e., two standard deviations above and below the mean difference score).



#### 4.6. Effect of order of testing on cervical range of motion

The order of testing was alternated between rater 1 and rater 2 for session 1 and 2. Twenty one subjects for session 1 and 19 subjects for session 2 were tested first by the Candrive protocol. The subjects who were measured first by the Candrive protocol had a wider variability in their cervical rotations scores than those measured first by the CROM device. Table 13 reports the reliability statistics for rotation movements for subjects measured by the Candrive protocol first for session 1 and the same subjects when measured by the Candrive protocol after the CROM device during session 2. The subjects who were tested by the Candrive protocol first demonstrated weaker correlation coefficients than those who were measured by the CROM device first for session 1 and 2.

<b>Table 13:</b> Reliability data for the 21 subjects who were tested with the Candrive protocol								
first during session 1 and then tested after the CROM device during session 2.								
-				-				

Cervical	r	ICC	CV	SEM	LOA	MDC
range of		(95% CI)	(%)	(degrees)	(degrees)	(degrees)
motion						
Left	0.65	0.78	10.8	4.1	12.0-13.2	11.4
Rotation		(0.46-0.91)				
Right	0.82	0.89	9.0	3.1	15.4-17.5	8.6
Rotation		(0.73-0.95)				

Notes: r = Pearson's correlation coefficient; ICC = intraclass correlation coefficient; CV = coefficient of variation; SEM = standard error of measurement; LOA = limits of agreement; MDC = minimum detectable change

The Pearson's correlation coefficient between the two sessions for the rotation movements measured was between 0.65 and 0.82 (see Table 13). The ICC (2,3) was between 0.78 and 0.63). Absolute reliability was reported in terms of CV, SEM, and LOA. The CV was between 9.0% and 10.8 % and SEM was between 3.1 and 4.1 degrees. The LOA was between 12.0 and 17.5 degrees and MDC was between 11.4 and 8.6 degrees for left and right rotation respectively.

Table 14 reports the validity statistics for left cervical rotation and right cervical rotation when measured by the Candrive protocol first for session 1. The Pearson's correlation coefficient between the two sessions for the rotation movements measured was between 0.59 and 0.48 (see Table 13). The ICC (2,3) was between 0.74 and 0.63. Absolute reliability was reported in terms of CV, SEM, and LOA. The CV was between 12.0% and 13.7 % and SEM was between 4.5 and 5.0 degrees. The LOA was between 17.0 and 22.7 degrees for left and right rotation respectively.

Cervical range of	r	ICC	CV	SEM	LOA(degrees)
motion		(95% CI)	(%)	(degrees)	
Left Rotation	0.59	0.74 (0.35-0.89)	12.0	4.5	17.0 - 19.4
Right Rotation	0.48	0.63 (0.10-0.85)	13.7	5.0	17.3 - 22.7

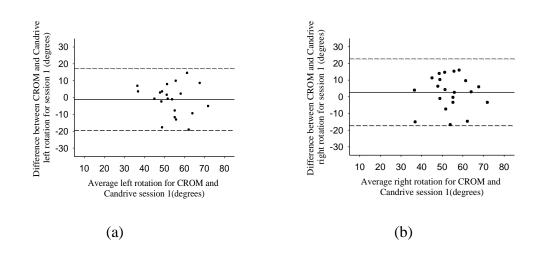
**Table 14:** Concordance data for the 21 subjects who were tested with the Candrive protocol first during the 1<sup>st</sup> session.

Notes: r = Pearson's correlation coefficient; ICC = intraclass correlation coefficient; CV = coefficient of variation; SEM = standard error of measurement; LOA = limits of agreement

Figure 7 represents the Bland-Altman plots for the average cervical left rotation and cervical right rotation (session 1) using the CROM device and Candrive protocol. The spread of the scores around the zero line suggests that the data is homoscedastic (Portney

and Watkins, 2009).

**Figure 7**: Bland-Altman plot average left rotation (a) and right rotation (b) measured for 21 subjects measured first by the Candrive protocol for session 1. The middle line shows the mean value of the difference scores between the CROM device and the Candrive protocol and the dashed lines shows the 95% upper and lower limits of agreement i.e. two standard deviations above and below the mean difference score.



# **CHAPTER 5: DISCUSSION**

Reliability and validity concern all clinicians and researchers who measure joint range of motion, as these are essential qualities for measurement tools and protocols (Tousignant et al., 2000). It is very important to know the reliability of an instrument and the protocol for measuring a construct across different sessions in order to assess the true progress of a condition over time (Audette et al., 2010). The present study was conducted primarily to determine intrarater absolute reliability for measuring cervical range of motion in older adults by using the CROM device and the Candrive protocol using the universal goniometer. In addition, the concurrent validity of the Candrive protocol was determined considering the CROM device as the gold standard. The CROM device was used to measure five cervical movements (flexion, left lateral flexion, right lateral flexion, left rotation and right rotation). The Candrive protocol was used to measure left rotation and right rotation. The intrarater reliability for a standardized protocol using the CROM device for the five cervical movements measured and the Candrive protocol using the universal goniometer for measuring cervical rotation was demonstrated in terms of relative reliability and absolute reliability.

It is very important for a clinician to be aware of the normal joint ROM for different age groups and genders for evaluating the progress due to any kind of intervention (Prushansky and Dvir, 2008). The normative data for range of motion of various joints was first given by the American Academy of Orthopedic Surgeons (AAOS) in 1965, but it is still controversial as the details of the norms were not explained. These values are an

average of four other databases published prior to 1965 and hence the validity of the AAOS values has been questioned by many authors (Fiebert, 1995; Macedo, 2009). The AAOS supplemented their normal reference ROM values with standard deviation values in their publication in 1994 in order to respond to the criticism. The American Medical Association Guides, 1990, presented a range of normal values for cervical spine without any reference to the age of the person. According to this guide, the values of cervical range of motion for a healthy adult is 60 degrees of flexion, 75 degrees of extension, 45 degrees of left and right lateral flexion, and 89 degrees of left and right rotation. The limitation of these values is that they can be assumed to be mean value and their standard deviations and standard errors are not known. The age and gender relation is also not given in the guide (Prushansky and Dvir, 2008). There are many studies that have found the normal range of cervical motion with regard to age and gender and have commented on the flaws of the AMA and AAOS guides (Hole et al., 1999; Youdas et al., 1992). While our subjects' values were less than the norms presented by the AAOS, the five cervical ranges of motion scores obtained by using the CROM device in the present study (flexion=45.8 degrees, left lateral flexion=27.3 degrees, right lateral flexion=24.6 degrees, left rotation=53.0 degrees, and right rotation=53.7 degrees) were similar to the normative values reported by Youdas et al. (1992) for older adults.

#### 5.1. Measurements with the CROM device

Results of this study demonstrated good between day (one week apart) relative and absolute reliability for measuring cervical range of motion by using the CROM device.

This indicates that the cervical range of motion scores generally exhibit consistency for repeated measurements at the group level by using the CROM device. Also, the cervical rotation scores measured by the CROM device were more consistent than those obtained by the Candrive protocol. From our MDC  $_{95\%}$  values, we can be confident that a change larger than 8.9 degrees in any direction will be a true change, when measured with the CROM device.

Despite a fair number of studies reporting on the reliability of the CROM device, there are only two published studies (Fletcher and Bandy, 2008; Audette et al., 2010) found in the literature to demonstrate the reliability of cervical range of motion by using a CROM device in context of measurement error. Fletcher and Bandy (2008) reported the within day (multiple measurements taken within the same experimental session) absolute reliability scores in terms of SEM and LOA. Audette et al. (2010) reported between day SEM and MDC for the CROM device. Our study demonstrated a high correlation between session 1 and 2 (one week apart) for the five cervical movements measured by the CROM device (between 0.82 and 0.89) (Portney and Watkins, 2009). The correlation coefficient was similar to those reported by Capuano-Pucci et al., (1991) for within day intrarater reliability (between 0.82 and 0.91). SEM values describe the limits for change required to indicate a real increase or decrease for a group of subjects following some sort of intervention (Portney and Watkins, 2009). The SEM demonstrated in the present study took a narrow range for the five movements measured by the CROM device. The SEM was between 2.2 and 3.1 degrees for between session reliability (one week apart),

which is very similar to those reported by Fletcher and Bandy (2008) (between 2.3 and 2.8 degrees). However, the two sessions in the study by Fletcher and Bandy (2008) were performed on the same day (one after the other). Thus, direct comparisons of our SEM values could not be made with this study. Audette et al. (2010) reported slightly lower SEM values between 1.6 and 2.6 degrees for 20 adults with a wide age range (23-71 years). Our SEM values suggest that the limits for change required indicating a real increase or decrease for a group of subjects following some sort of intervention will be between 2.2 and 3.1 degrees.

CV expresses typical error as a percentage. Thus, it is useful for comparing reliability between different measures and across different studies. The CV in our study was between 5.5% and 9.5%, and this statistic has not been previously reported. The CV for cervical rotation was between 5.5% and 6.2 % at a group level. The CV for lateral cervical flexion was more (between 8.9 and 9.5%) when compared to the other movements of the cervical spine. Since previous authors have not reported CV associated with cervical range of motion measured with the CROM device; no comparison could be made.

LOA provides an additional and more conservative measure of absolute reliability. It gives information about the confidence limits associated with measurement error. Thus, if an individual's change in score over repeated measurement exceeds the LOA, then it represents a true change (Portney and Watkins, 2009). For the present study, the LOA was between 5.3 and 9.4 degrees for all the movements measured. This is another statistic

that has not been previously reported. MDC values suggest the minimal change required to be 95% confident that the differences between pre and post measurements are due to real change in range of motion (Eliasziw et al., 1994; Portney and Watkins, 2009). The MDC with 95% confidence limits in our study was between 5.4 and 8.6 degrees, which are similar to those reported by Fletcher and Bandy (2008) (between 5.4 and 6.5 degrees). However, Fletcher and Bandy (2008) reported MDC with 90% confidence limits. Audette et al. (2010) reported slightly lower MDC values with 90% confidence limits between 3.6 and 6.5 degrees for 20 adults with a wide age range (23-71 years). Since previous authors have not reported MDC with 95% confidence limits associated with cervical range of motion measured with the CROM device; no comparison could be made.

ICC is extensively reported in the literature to demonstrate the relative reliability for measuring cervical range of motion using the CROM device. The ICC represents the ability of a measurement to differentiate among individuals. However, it is influenced by between individual variation and also number of trials and measurement error (Fletcher and Bandy, 2008). According to Portney and Watkins (2009), ICC should be greater than 0.75 for a measurement to be reliable. In our study, the five cervical movements measured with the CROM device demonstrated good intrarater relative reliability (values). The ICC for the present study was demonstrated in terms of ICC  $_{(2,1)}$  for within session reliability and ICC  $_{(2,3)}$  for between day (one week apart) reliability.

The ICC associated with the five anatomical movements measured (0.81 and 0.89) were very similar to those reported by some previous authors. However, direct comparisons

could not be made because little information exists regarding intrarater reliability using the CROM device in older adults. Also, the ICC models and forms used by different authors are different and the choice of the model is not very clear in those studies. Youdas et al. (1991) reported intrarater reliability in terms of ICC  $_{(1,1)}$  between 0.84 and 0.95 for subjects with cervical spine disorders. Youdas et al. (1992), reported intrarater reliability for 5 different raters in terms of ICC (1,1) between 0.80 and 0.99. However, ICCs as low as 0.23 (cervical flexion) for one rater and 0.58 (right rotation) and 0.60 (right lateral flexion) for another raters were also reported (Youdas et al., 1992). Hole et al. (1995) reported ICC between 0.92 and 0.96 for 2 chiropractor students on healthy subjects. However the model and form of ICC has not been described by the authors (Hole et al., 1995). Fletcher and Bandy (2008) reported ICC (3,1) between 0.87 and 0.94. Audette et al. (2010) reported ICC (3,3) between 0.89 and 0.98. It is also important to examine the 95% confidence intervals associated with the ICCs to gain a better understanding of the reliability of these measurement (Portney and Watkins, 2009). In our study, the lower confidence interval for the five movements using the CROM device did not fall below 0.80 which indicates good reliability between the sessions.

The within session reliability for session 1 and 2 by using the CROM device was better than between day reliability, as would be expected. The relative and absolute reliability statistics within session 1 and within session 2 were almost the same indicating that the movements were consistent within the two sessions. In this study, the SEM values within a session took a narrow range of values (between 1.4 and 1.7). The ICC values

demonstrated in the present study for within session reliability (between 0.94 and 0.97) was higher than the within session ICC reported by Youdas et al. (1991) (between 0.84 and 0.95), Youdas et al. (1992) (between 0.80 and 0.99), and Hole et al. (1995) (between 0.92 and 0.96). Thus, within day reliability was much better than between day reliability (i.e., the movements are more consistent on the same day than measured on different days, in subjects with no neck pain or minimal neck stiffness).

# 5.2. Measurements with the Candrive protocol

Previous researchers have reported moderate reliability in measuring cervical rotation by using a universal goniometer because of difficulty in identifying the bony landmarks. However, universal goniometers are widely used by clinicians because they are simple, portable, and easy to use (Jordan, 2000; De Koning et al., 2008). The Candrive protocol also uses a universal goniometer to measure cervical rotation. This protocol has a simplistic approach and minimises the use of anatomical landmarks and detailed instructions.

The results of the present study suggest a correlation of 0.78 and 0.82 between session 1 and 2 for left and right cervical rotation respectively measured by the Candrive protocol. However, the correlation values were less compared to those demonstrated by the CROM device for cervical rotation (0.85 and 0.89 for left and right cervical rotation respectively) for between day reliability. This suggests that the cervical rotation values obtained by the CROM device were more closely related between the two sessions when compared to those obtained by the Candrive protocol. The ICC values for between session (0.87 and

0.89 for left and right cervical rotation respectively) were lower than those obtained by the CROM device (0.92 and 0.94 for left and right cervical rotation respectively). The SEM values for cervical rotation measured by the Candrive protocol (3.5 degrees for left rotation and 3.2 degrees for right rotation) were slightly higher than those measured by the CROM device (3.1 and 2.8 degrees for left and right cervical rotation respectively). The LOA for between session for the Candrive protocol (11.9-15.6 degrees and 11.1-13.1degrees) was higher than those obtained for the CROM protocol (9.2-9.4 degrees and 7.4-9.3 degrees) for left and right rotation respectively. The values of CV were higher for the Candrive protocol for left and right rotation (7.9% and 9.8% respectively) when compared to the CROM protocol (6.2% and 5.5% for left and right cervical rotation respectively) for the group, which suggests that the movements measured by the Candrive protocol were more variable than those obtained by the CROM device. Some researchers have demonstrated the reliability of universal goniometer for measuring cervical range of motion by using different protocols. Cleland et al. (2006) reported SEM (between 5 and 5.5 degrees) and LOA (between -0.3 and 15.9 degrees) for left and right cervical rotation. However, the Candrive protocol is different from the other protocols for measuring cervical range of motion. Thus, direct comparisons of our result to those studies could not be done.

Also, the ICC values for within day relative reliability (between 0.85 and 0.89) were lower than those obtained by the CROM device (between 0.95 and 0.97) suggesting lesser relative reliability. The SEM values for within day absolute reliability using the

Candrive protocol (3.3 and 4.1 degrees) were higher than those obtained by the CROM device (between 1.4 and 1.7 degrees). Basically, all the statistical variables for the Candrive protocol were less reliable than the CROM protocol suggesting more variability in cervical rotation measured by the Candrive protocol. The deficiency of the Candrive protocol could be related to lack of training given to the rater before the testing session. Rater 1 practiced testing with the CROM device and her reliability was assured before the start of the actual testing session. However, Rater 2, who tested the subjects with the Candrive protocol, did not practice a lot, very similar to other Candrive staff. Thus, the raters using the Candrive protocol for the Candrive research project should practice with the testing protocol before starting the training session in order to assure their reliability.

In addition, the effect of order on the reliability analyses suggest another deficit in the Candrive protocol related to lack of proper instructions given during the testing session. Previous authors have also reported the importance of clear instructions on cervical range of motion to ensure good reliability throughout the study (Audette et al., 2010; De Koning et al., 2008; Jordan, 2000; Youdas et al., 1991; Youdas et al., 1992). For the present study, a standardized protocol was followed to measure cervical range of motion by the CROM device. The instructions given to the subjects before testing with the CROM device were detailed and comprehensive. Instructions were given to the subjects about maintaining a good posture while sitting and a good posture was maintained throughout the testing session. More emphasis was given to the instructions and the subjects were reminded to isolate their head movement from the associated movements of

the shoulders and other cervical movements. One practice trial in the five directions to be measured was also performed before measuring the actual range of motion.

On the contrary, the Candrive protocol uses a universal goniometer to measure cervical rotation which minimises the use of proper anatomical landmarks. In addition, the examiner gives minimal instructions in terms of posture, associated movements and end range of motion, which makes it difficult for subjects to understand and perform the movements correctly and consistently. Identification of proper bony landmark and proper instructions to the subjects about the movements and posture during the testing session are very important for measuring cervical rotation, especially when the measurement has to be taken by a universal goniometer. For the present study, performing a pure lateral cervical flexion and cervical rotation was a difficult movement for some of the older adults. Most of the time, it was associated with the other cervical movements. One subject was unable to perform cervical lateral flexion and cervical rotation, even after repeated instructions and thus, his data could not be included for the statistical analyses. Thus, the Candrive protocol could be modified in terms of instructions and bony landmarks, in order for the testing to be more reliable. This was further confirmed by the testing order effects on the relative and absolute reliability scores.

As the order of testing was alternated between the two protocols (CROM and Candrive), 21 subjects were tested first by the Candrive protocol for session 1. Reliability analyses for those 21 subjects demonstrated higher CV (11.0% and 13.9%) and LOA (12.0 and 17.5 degrees) values for left and right cervical rotation when compared to the CV and

LOA values for all the 40 subjects (CV was 7.9-9.5%; LOA was 11.1-15.6 degrees). Thus, the reliability of the whole group was better when compared to those subjects who were measured by the Candrive protocol first during session 1. This suggest that the measurements taken by the Candrive protocol were affected by the instructions given to the subjects during the CROM testing session, which improved the overall performance of the subjects.

## 5.3. Concurrent validity of the Candrive protocol

The CROM device has been previously validated to measure cervical range of motion against radiography for cervical flexion and extension (Audette et al., 2010; Hole et al., 1995; Tousignant et al., 2000; Tousignant et al., 2002). The results from the present study show that the CROM device has a good relative and absolute reliability. Thus, the CROM device was considered as the gold standard for measuring cervical range of motion.

The results of this study show moderate concurrent validity of the Candrive protocol when compared to the CROM device. Pearson's correlation coefficients for session 1 were 0.63 for left rotation and 0.65 for right rotation between the CROM and the Candrive protocol. Reynolds et al. (2009), measured cervical rotation by placing the universal goniometer on the vertex in seated position and reported the validity of the measures with the CROM device in terms of Pearson's correlation coefficient (r = 0.59). However, the authors have not reported about the raters and relative and absolute reliability measures of the cervical range of motion measured by the universal

goniometer. These measures cannot be directly used for comparison because of the differences in the protocols.

Although the ICCs (0.79-0.82) in the present study suggest good relative concordance between the two protocols (according to criteria found in Portney and Watkins (2009), the concordance values took a wide range. However, the lower confidence limits for validity analyses between the two protocols were 0.54 for left rotation and 0.59 for right rotation, indicating moderate concordance between the two protocols.

The LOA between the measures obtained by the CROM device and the Candrive protocol was 15.4 to 18.2 degrees for left rotation and 11.9 to 16.1 degrees for right rotation. These values suggest that there will be a wide difference (around 10 to 20 degrees) in range of motion values for the left rotation and right rotation obtained by the Candrive protocol. The CV values (9.4% and 9.6% for the left rotation and right rotation respectively) suggest that there will be a variation of around 10% between the cervical rotation values obtained by the two protocols at a group level. The SEM values (3.6 and 3.7 degrees for the left rotation and right rotation respectively) suggest that there will be a variation respectively) suggest that there will be a variation respectively suggest that there will be a variation of around 10% between the cervical rotation values obtained by the two protocols at a group level. The SEM values (3.6 and 3.7 degrees for the left rotation and right rotation respectively) suggest that there will be a variation of around four degrees between the cervical rotation values obtained by the two protocols at a group level. The spread of the scores around the zero point in the Bland-Altman plots (figures 11 and 12) suggests that there is a wide variability in the range of motions measured by the CROM device and the Candrive protocol.

Considering the effect of order of the testing protocol on the measurement scores obtained for the group, validity analysis was also done for the 21 subjects who were first 89 tested by the Candrive protocol during session 1. Results demonstrated that the correlation between the CROM and Candrive scores for these 21 subjects were not good (Pearson's correlation coefficient was 0.59 for left rotation and 0.48 for right rotation). The CV was 12.0% and 13.8% and the LOA was17.1 and 22.7 for left and right cervical rotation respectively. This demonstrates that the cervical range of motion measured by the Candrive protocol varied by almost 20 degrees between those subjects who were first measured by the Candrive protocol and those who were measured by the CROM device first for session 1. The ICC values (between 0.63 and 0.74) indicate moderate concordance of the Candrive protocol with the CROM device. However, the lower and upper confidence limits for ICC (0.35 and 0.89 for left rotation and 0.10 and 0.85 for right rotation), indicates a wide variability in the range of motion scores between the two protocols.

Cervical rotation measured by the Candrive protocol was likely affected by other movements of the cervical spine (like lateral cervical flexion, cervical extension) and thoracic movements and the posture maintained throughout the testing session. Thus, the Candrive protocol on its own demonstrated poor to moderate validity. However, the mean cervical rotation with all 40 subjects measured by the Candrive protocol shows better reliability because there was an effect of order of testing. Also, the average of 40 subjects reduces this variability because of the sample size (40 subjects). The Candrive protocol could be improved by giving proper instructions to the subject regarding the movements,

posture and defining a proper bony landmark. Proper training could be also given to the rater in order to assure better reliability of the Candrive protocol.

# 5.4. Limitations and future directions

There were a few limitations of this study. The first limitation is related to the subjects because the present study was done on a group of older drivers from Winnipeg, Canada. Most of the subjects were active drivers and some of them were driving at least once per week and had no complaints of severe neck pain. Older drivers tend to have more cervical rotation because of driving related tasks, like backing up or reversing the vehicle. Thus, the interpretations of the results can be extended only to healthy older adults (70 years and over). This means that the current results could not be employed for a younger population or for a clinical population with neck pain or cervical pathology. Thus, future researchers could study absolute reliability using the CROM device in younger adults and in patients with symptomatic neck pain.

Secondly, the absolute reliability scores for measuring cervical range of motion by the CROM device may apply only when the protocol used in this study is followed. Similarly, the absolute reliability scores using the universal goniometer will change if a different protocol (other than the Candrive protocol) is used to measure cervical rotation. Thirdly, this study did not measure cervical extension with the CROM device; future researchers could study absolute reliability of cervical extension using the CROM device.

## 5.5. Implications

Ideally, the measurements obtained from a tool must not differ if there is no real change in the range of motion. The CROM device is a reliable and validated instrument to measure cervical range of motion and can be used even in clinical settings but data on its absolute reliability was missing in the literature. The results from this study will help clinicians to measure cervical range of motion using the CROM device on separate days, by providing absolute reliability scores that help to estimate the meaningfulness of the measurements. Also, clinicians and researchers would likely benefit from an estimate of error of measure as it provides an indication of the accuracy of the measure. The measurement procedure utilized in this study could be suitable for clinical settings because it reasonably controls for substantial measurement error.

The results would also have implications within the context of looking at the immediate effects of a neck flexibility intervention on a group of older adults (70 years and over). The use of a reliable tool for the measurement of cervical range of motion is very important in order to determine the effectiveness of a flexibility intervention for cervical range of motion measurements for older adults and also to measure physical fitness of older drivers in driving research like the Candrive project. This study provided the range of values that a cervical movement can take for an individual, when measured repeatedly with a universal goniometer and the Candrive protocol. Thus, researchers using the Candrive protocol could refer to the findings from this study when interpreting the results related to cervical rotation testing.

## **CHAPTER 6: SUMMARY**

The current study adds to the literature by providing detailed information about absolute and relative intrarater reliability of between day measurements for cervical range of motion using the CROM device in older adults (70 years and over). It also confirms the reliability measurements reported in previous studies with the CROM device for measuring cervical range of motion. When used by the same rater, the CROM device is reliable to measure cervical movements. The CROM device seems to be a useful tool to measure cervical range of motion for clinicians and researchers. One of the most common sources of error for measuring cervical range of motion by a universal goniometer is related to its positioning which relates to anatomical landmarks. On the contrary, the CROM device is easy to use because its operation is not based on anatomical landmarks. There is no chance of palpation error as the device is affixed to the head. The device is comfortable to wear because of its light weight design. The dials can be read easily and quickly. Results revealed good reliability for the CROM protocol for measuring cervical range of motion at individual and group level. Future researchers could use the SEM and CV values when interpreting the effect size for neck flexibility interventions in older adults (70 years and over).

The present study also documents the concurrent validity of the Candrive protocol using a universal goniometer to measure cervical range of motion. Different examiners in different cities with varying experience level will be assessing cervical rotation of the older drivers. As the present study demonstrates moderate reliability in the measurement

scores using the Candrive protocol, it will be difficult to relate the cervical rotation values during the annual physical assessments for five years. The results from the present study suggest that the Candrive protocol for measuring cervical rotation has a poor to moderate concurrent validity and it could be improved by giving detailed instructions to the subjects and by improving the experience of the examiners.

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# **APPENDIX 1: PAIN RATING SCALES**

# **1. Numerical Rating Scale**

0	1	2	3	4	5	6	7	8	9	10

No Pain

Worst

Imaginable Pain

## 2. Visual Analogue Scale (10 centimeter line)



Worst pain

### **APPENDIX 2: PHONE TRACKING SHEET**

PHONE TRACKING SHEET						
DATE OF PHONE CALL: Day Month	Year					
LAST NAME:	FIRST NAME:					
ADDRESS:	POST/	AL CODE:				
PHONE NUMBER:	HOME 🗌 WORK 🗌					
GENDER: 🗌 Male 🛛 Female						
DATE OF BIRTH: / / DD MM YYYY	AGE:					
SELECTION CRITERIA:						
<ul> <li>I. Do you have a valid class 5 Manitoba license?</li> <li>II. Are you currently driving at least 1 time per wee</li> <li>III. Are you experiencing any kind of medical condi</li> <li>IV. Do you have a pacemaker?</li> <li>V. Have you ever had any spinal (neck/back) surg</li> <li>VI. Have you had any recent bouts of neck or back</li> <li>VII. Do you have neck or back pain that varies from</li> <li>VIII. Are you currently taking any medications for ne</li> <li>IX. We would like you to rate your current neck pain</li> <li>0 to 10, where 0 is no pain and 10 is the worst is is your current neck pain?</li> <li>X. Qualified to participate? Yes No If M</li> </ul>	tion that is not stable? ery? : pain? o week to week? ck or back pain? n. The scale is from imaginable pain. What	Yes       No         Yes       No				
□ <b>No</b> Why:						
FOLLOW-UP: Response after reading package: Willing to Participate D Date of Appointment: Date: Time D Unwilling to Participate Yes No Why?	Why?					
Interested in future studies?  Yes No						

### **APPENDIX 3: NECK DISABILITY QUESTIONNAIRE**

Date: \_\_\_\_\_

ID#\_\_\_\_\_

Please read instructions:

This questionnaire has been designed to give the doctor information as to how your neck pain has affected your ability to manage everyday life. Please answer every section and mark in each section only the ONE box that applies to you. We realize that you may consider that two of the statements in any one section relate to you, but please just mark the box that most closely describes your problem.

**SECTION 1--Pain Intensity** 

- A.  $\Box$  I have no pain at the moment.
- B.  $\Box$  The pain is mild at the moment.
- C.  $\Box$  The pain comes and goes and is moderate
- D. □ The pain is moderate and does not vary much
- E.  $\Box$  The pain is severe but comes and goes
- F.  $\Box$  The pain is severe and does not vary much

SECTION 2--Personal Care (washing, dressing, etc)

- A.  $\Box$  I can look after myself without causing extra pain
- B.  $\Box$  I can look after myself normally but it causes extra pain
- C.  $\Box$  It is painful to look after myself and I am slow and careful
- D.  $\Box$  I need some help, but mange most of my personal care
- E.  $\Box$  I need help everyday in most aspects of self care
- F.  $\Box$  I do not get dressed, I wash with difficulty and stay in bed

### **SECTION 3-- Lifting**

- A. □ I can lift heavy weights without extra pain
- B. □ I can lift heavy weights, but it causes extra pain
- C. □ Pain prevents me from lifting heavy weights off the floor but I can if they are conveniently positioned, for example on a table
- D. □ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- E.  $\Box$  I can lift very light weights
- F.  $\Box$  I cannot lift or carry anything at all

#### SECTION 4—Reading

- A.  $\Box$  I can read as much as I want to with no pain in my neck
- B.  $\Box$  I can read as much as I want to with slight pain in my neck
- C.  $\Box$  I can read as much as I want to with moderate pain in my neck
- D.  $\Box$  I cannot read as much as I want because of moderate pain in my neck
- E.  $\Box$  I can read as much as I want because of severe pain in my neck
- F.  $\Box$  I cannot read at all

#### SECTION 5—Headache

- A.  $\Box$  I have no headaches at all
- B. □ I have slight headaches which come infrequently
- C. □ I have slight headaches which come in-frequently
- D. 
  □ I have moderate headaches which come frequently
- E.  $\Box$  I have severe headaches which come frequently
- F.  $\Box$  I have headaches almost all the time

#### SECTION 6—Concentration

- A.  $\Box$  I can concentrate fully when I want to with no difficulty
- B. □ I can concentrate fully when I want to with slight difficulty
- C.  $\Box$  I have a fair degree of difficulty in concentrating when I want to
- D.  $\Box$  I have a lot of difficulty in concentrating when I want to
- E.  $\Box$  I have a great deal of difficulty in concentrating when I want to
- F.  $\Box$  I cannot concentrate at all

#### SECTION 7—Work

- A.  $\Box$  I can do as much work as I want to
- B.  $\Box$  I can only do my usual work, but no more
- C.  $\Box$  I can only do most of my usual work, but no more
- D.  $\Box$  I cannot do my usual work
- E.  $\Box$  I can hardly do any work at all
- F.  $\Box$  I cannot do any work at all

#### SECTION 8-- Driving

- A.  $\Box$  I can drive my car without neck pain
- B.  $\Box$  I can drive my car as long as I want with slight pain in my neck
- C.  $\Box$  I can drive my car as long as I want with moderate pain in my neck
- D.  $\Box$  I cannot drive my car as long as I want because of moderate pain in my neck
- E.  $\Box$  I can hardly drive my car at all because of severe pain in my neck
- F.  $\Box$  I cannot drive my car at all

#### SECTION 9—Sleeping

- A.  $\Box$  I have no trouble sleeping
- B. □ My sleep is slightly disturbed (less than 1 hour sleepless)
- C. □ My sleep is mildly disturbed (1-2 hours sleepless)
- D. □ My sleep is moderately disturbed (2-3 hours sleepless)
- E.  $\Box$  My sleep is greatly disturbed (3-5 hours sleepless)
- F. □ My sleep is completely disturbed (5-7 hours sleepless)

SECTION 10—Recreation

- A.  $\Box$  I am able to engage in all recreational activities with no pain in my neck at all
- B.  $\Box$  I am able to engage in all recreational activities with some pain in my neck at all
- C. □ I am able to engage in most, but not all recreational activities because of pain in my neck
- D.  $\Box$  I am able to engage in a few of my usual recreational activities because of pain in my neck
- E.  $\Box$  I can hardly do any recreational activities because of pain in my neck
- F.  $\Box$  I cannot do any recreational activities at all

### **APPENDIX 4: CONSENT FORM**

Reliability of measuring neck
Michelle Porter, PhD
Juhi Sinha, MSc student
Candrive – Canadian Institutes of Health Research

This consent form, a copy of which will be left with you for your records and reference, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

The purpose of this study is to examine the reliability (reproducibility) of two different ways of measuring neck range of motion. Testing will be done in two different sessions of about 1 hour each, about one week apart. One method involves a plastic hat-like device (CROM), and the other involves a plastic tool called a goniometer. You will be asked to perform several different movements of the head through the full range of motion. Prior to performing these movements we will ask you questions about your health background. You will be required to attend two testing sessions at the Max Bell Centre at the University of Manitoba. You will be given parking passes for a University parking lot (free of charge).

Before participating in the study, you will also fill out a questionnaire related to your neck pain and function. This will take about 10 to 15 minutes to complete.

#### Confidentiality

All experimental data associated with you will be identified with a subject number only. All subject files will be kept in a locked filing cabinet. In any written documents (reports or publications) or presentations you will not be identified. All health information provided will comply with the Personal Health Information Act (PHIA) guidelines. The confidential data collected through this study will be kept securely in the laboratory for 7 years after publication before being destroyed.

#### **Benefits**

You will receive information about your own performance on all the flexibility tests, as well as a summary of the overall study findings. This information will be mailed to you after the study has been completed and all the data have been analyzed. You will also receive \$10.00 for your participation in this study.

### Risks

Even though the risk of injury is very low while performing the movement tests, there is a theoretical possibility for injury. If you experience any pain, dizziness or other symptoms during any part of a testing session, you should let us know and testing will be immediately discontinued. As well, even if you do not feel any discomfort, if research staff feels at any time that there is any risk associated with continuing testing then it will be stopped.

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the researchers, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time (in person, over the phone or in writing), and /or refrain from answering any questions you prefer to omit, without prejudice or consequence. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation.

Michelle Porter, PhD 474-8795

Juhi Sinha, MSc student 480-1487

This research has been approved by the Education and Nursing Research Ethics Board. If you have any concerns or complaints about this project you may contact any of the above-named persons or the Human Ethics Secretariat at 474-7122. A copy of this consent form has been given to you to keep for your records and reference.

Participant's Name (print)

Participant's Signature

Date

Researcher and/or Delegate's Name (print)

Researcher and/or Delegate's Signature

Date