



## CHAPTER III METHODOLOGY

The National Research Council of Thailand	
Research Library	
Date.....	26 DEC 2012
Record No. ....	E42107
Call No. ....	

The current study consisted of two parts. The first part of the current study was to build up a height loss measuring stadiometer and to test the accuracy and the reliability. The second part was to test the effect of time of day on the VSC response after running on a treadmill.

### 1. Design and setting

A randomized controlled trial was conducted in the Department of Physical Therapy, Faculty of Associated Medical Sciences, Khon Kaen University, Thailand.

### 2. Subjects

Sixty asymptomatic subjects who had the same running experience, aged between 20-39 years, with normal BMI (BMI = 18.5-24.9 kg/m<sup>2</sup>) ([www.nhlbisupport.com/bmi/](http://www.nhlbisupport.com/bmi/)), were screened by the researcher using a screening questionnaire (**Appendix A**). The subjects were required to give written and informed consent (**Appendix B**). The inclusion and exclusion criteria for the experiment were based on those used by Kanlayanaphotporn (2002).

#### Inclusion criteria

Asymptomatic subjects were included if they were males or females and aged between 20-39 years .

**Exclusion criteria** (Kanlayanaphotporn et al. 2002). The subjects were excluded if they

1. Had experienced neck, thoracic or low back pain which required treatment or time off work, study or sport in the past 12 months.
2. Had previous injury to the spine including burns, fractures, dislocation, or had undergone surgery to any parts of their spine.
3. Were currently on medications that would alter imbibition of water in the

intervertebral disc, such as drugs in the groups of anti-inflammatory, prostaglandin inhibitors, steroids and non-steroidal anti-inflammatory drugs.

4. Had difficulty with concentration or were currently on medication that affected their ability to concentrate.
5. Had previous exposure to repeated radiation of the spine.
6. Were diagnosed with a medical condition that affected spinal tissues and structures, such as, diabetes mellitus, ankylosing spondylitis, rheumatoid arthritis, and Scheuermann's disease.
7. Were currently involved in an occupation which entailed heavy manual lifting or whole-body vibration.
8. Were diagnosed with heart disease.
9. Were pregnant.

### 3. Sample size

The sample size was calculated based on a study of Healey et al. (2008). In their study the average of the VSC response in the morning was  $5.4 \pm 1.3$  mm. and the average of the VSC response in the afternoon was  $3.7 \pm 1.7$  mm. Therefore, a pooled variance estimate ( $s_1^2 + s_2^2$ ) from their study was used to calculate the sample size. The effect size (d) in their study was 1.7 mm (Healey et al., 2008). The significant level of lower than 0.05 ( $Z_{\alpha (0.025)} = 1.96$ ) and a power of test at 90 per cent ( $Z_{\beta (0.1)} = 1.28$ ) was used to calculate as follows:

$$n/\text{group} = \frac{(Z_{\alpha} + Z_{\beta})^2 (S_1^2 + S_2^2)}{d^2}$$

$$n/\text{group} = \frac{(1.96 + 1.28)^2 (1.3^2 + 1.7^2)}{1.7^2}$$

$$n/\text{group} = \frac{(10.49)(4.58)}{2.89}$$

$$n/\text{group} = \frac{48.04}{2.89}$$

$$n/\text{group} = 16.624$$

n/group	≈	17
n/group	≈	22 (20% drop out)

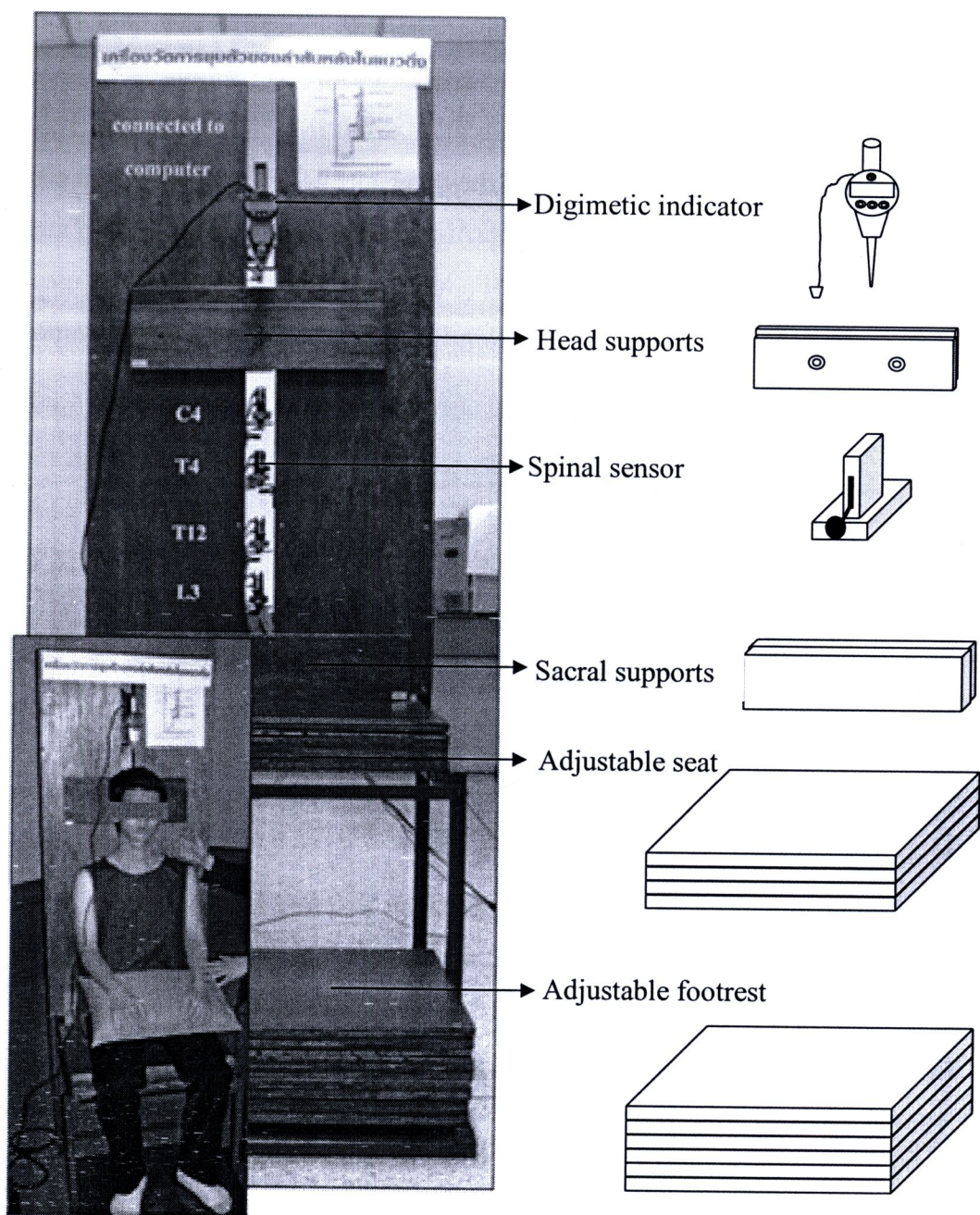
∴ Total sample size = 44

#### **4. Randomization**

Each subject was randomly assigned to one of the two interventions (treadmill running group versus control group) using a stratified randomized allocation (gender).

#### **5. Instrument**

5.1 A height loss measuring stadiometer for measuring the VSC response used in the current study was modified from that invented by Eklund and Corlett (1984). The height loss measuring stadiometer was modified for use in a seated position in the current study (Figure 5). The accuracy and reliability of the equipment measurements were conducted prior to collecting the data.



**Figure 5:** A height loss measuring stadiometer

The height loss measuring stadiometer in the current study consisted as follows:

- A digimetic indicator (ID-C 150, 1050 Digimetic Indicator, Manual No. 3061, Series No. 543, Mitutoyo, Kawasaki, Japan) (Figure 6) can measure the height loss in the range of 50 millimeters with accuracy  $\pm 0.006$  millimeters and record 300 data/min. A pin of the digimetic indicator was directly contacted with each subject's scalp to reduce hair accumulation. The digimetic indicator was interfaced with computer software.



**Figure 6** A digimetic indicator

- The wooden seat was positioned at one third of the stadiometer's height. The wooden seat platform and the related footrest were adjustable so that the subject's ankle, knee and hip joints could be positioned at right angles.

- Spinal sensors for controlling posture during the measurement of the VSC response were used as a feedback system. There were four pressure sensors which contacted the spinous processes of C4, T4, T12, and L3. The positions of the pressure sensors were adjusted for individual subjects while they sat in a relaxed upright posture with their arms resting on a pillow on their laps. When the vertebral levels contacted the microswitches of pressure sensors, corresponding light diodes positioned in the front of the subjects were activated.

- A head support was at the level of the occipital protuberance.

5.2 Treadmill; running trials were completed on a motorized treadmill (Q 50 model) without adjusted inclination.

5.3 A sleeveless waistcoat (Figure 7); Each subject was asked to wear the sleeveless waistcoat with a hole along the middle of the back to allow visualization of the marked spinous processes of the C4, T4, T12 and L3 and to place the spinal sensors to contact with each subject's skin at these levels.



**Figure 7** A sleeveless waistcoat

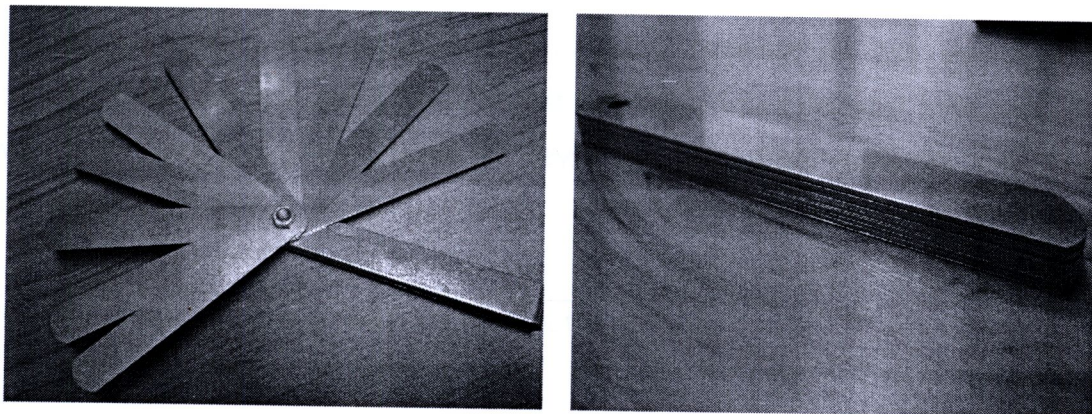
## 6. Procedure

### 6.1 Part 1: Reliability test

#### 6.1.1 Reliability test of the digimetic indicator

Reliability test of the digimetic indicator was conducted by using feeler gauges (Figure 8), which were made from steel and their thicknesses were 0.15, 0.20, 0.25, 0.30, 0.35, 0.40, 0.45, 0.50, 0.55, and 0.60 millimeters. Then the ten feeler gauges were gradually put on in the vertical line, one by one from the maximal to minimal thickness, respectively. Next the digimetic indicator was lowered to contact the feeler gauge for measuring the thickness of the feeler gauge. This step was conducted until the thickness of the ten feeler gauges had been measured. Then the researcher gradually took off the feeler gauges one by one and measured the thickness of the feeler gauge again from the top until the last. The data from the readable digimetic indicator were recorded in the computer every time the feeler gauge was taken off or put on. The researcher repeated this step for three consecutive tests and

then the data were calculated and reported to be the Intraclass Correlation Coefficient ( $ICC_{1,1}$ ).



**Figure 8** Feeler gauges

### 6.1.2 Reliability test of the VSC response measurement

#### A. Intra-tester reliability test

Intra-tester reliability test was conducted in ten asymptomatic subjects. A test design was used to evaluate the reliability of the VSC response. Each subject was asked to put on a sleeveless waistcoat with a hole along the middle of the back and to sit on a stool with hips and knees flexion at right angles. Four marks were placed on the skin overlying the spinous processes of C4, T4, T12 and L3 by using a waterproof pen. Then, each subject was asked to sit in a relaxed upright position on the height loss measuring stadiometer for three sessions for one minute per session. The magnitude of the VSC response in each session was calculated and reported using the Intraclass Correlation Coefficient ( $ICC_{3,1}$ ). The ICC is dimensionless and it ranges between 0.00 and 1.00. Values below 0.50 represent poor reliability, values from 0.50 to 0.75 suggest moderate reliability, and values above 0.75 are indicative of good reliability (Portney & Watkins, 2000).

#### B. The standard error of measurement test

The standard error of measurement test (SEM) was conducted in ten asymptomatic subjects. A test design was used to evaluate the reliability of the VSC response. Each subject was asked to put on a sleeveless waistcoat with a hole along the middle of the back and to sit on a stool with hips and knees flexion at right angles.

Four marks were placed on the skin overlying the spinous processes of C4, T4, T12 and L3 by using a waterproof pen. Then, each subject was asked to sit in a relaxed upright position on the height loss measuring stadiometer for three times with one minute per session. The magnitude of the VSC response in each session was calculated and reported using the SEM test. The SEM was calculated from formula: where  $S_x$  was the pooled standard deviation from three times of the VSC measurement.

$$SEM = S_x \sqrt{1 - ICC_{(3,1)}}$$



### C. The means of standard deviations test

Mean of standard deviations (SDs) of stature measurements on the height loss measuring stadiometer were calculated from ten asymptomatic subjects. The subjects were asked to put on a sleeveless waistcoat with a hole along the middle of the back and to sit on a stool with hips and knees flexion at right angles. Four marks were placed on the skin overlying the spinous processes of C4, T4, T12 and L3 using a waterproof pen. Then, the subjects were asked to sit in a relaxed upright position on the height loss measuring stadiometer for 10 sessions, one minute per session. Each subject was asked to step in and step out for each session of measurement. Stature measurements using the height loss measuring stadiometer were deemed repeatable when a criterion of 10 consecutive stature measurements with a standard deviation of  $< 0.5$  mm was met (Kanlayanaphotporn et al., 2003; Rodacki et al., 2001; Tyrrell et al., 1985). Smaller means of SDs values in relation to the means suggest smaller measurement errors and higher reliability.

### 6.2 Part 2: The effect of time of day and treadmill running group on the VSC response

After the subjects were randomized into either treadmill running or control group, each subject was asked to attend for three separate occasions. The first occasion was a familiarization session and the next two occasions were for the application of the two different times of day (morning and afternoon). On the familiarization session, the subjects had the aim and experimental procedures explained to them and the researcher asked the subjects if they had any questions

regarding the current study. A screening questionnaire fill in complete ensure that they met the inclusion and exclusion criteria. After that they were asked to sign the informed consent for participating in the current study.

**6.2.1 Treadmill running group:** The sequences of the familiarization session in the treadmill running group were as follows:

(1) Subjects were asked to remove their shirt/blouse and to put on the sleeveless waistcoat which allowed visualization of the spine for marking, and then the spinous processes of C4, T4, T12 and L3 were marked while the subjects were in the sitting position.

(2) Subjects were asked to adopt the unloaded position (Fowler's position) for 20 minutes (Figure 9), to eliminate any effects of preloading on the spine before the test (Magnusson and Pope 1996).



**Figure 9** Fowler's position

(3) After that subjects were asked to adopt a comfortable sitting posture: flexed hips and flexed knees in 90 degrees, on the height loss measuring stadiometer. Spinal sensors were adjusted to make contact with the marked spinous processes of C4, T4, T12 and L3 until all the light diodes were lit up. The measurement of the VSC response was measured for one minute.

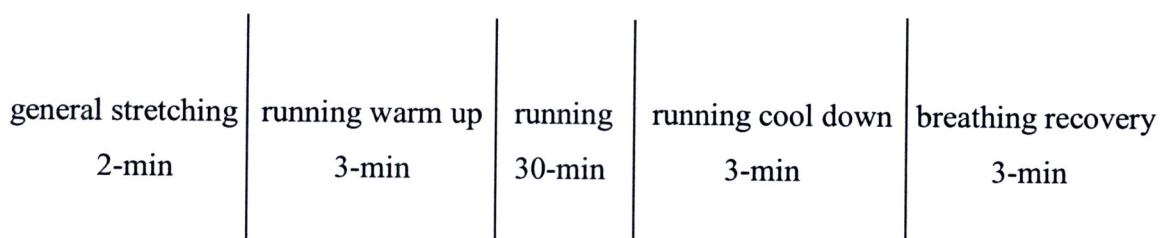
(4) Subjects were asked to run on the treadmill with a speed of at least 7 km/h (Adirek-udomrat et al., 2552a; 2552b) for five minutes.

(5) Subjects were asked to rest after treadmill running for breathing recovery for 3 minutes (Leatt et al., 1986).

(6) Subjects were asked to measure the VSC response on the height loss measuring stadiometer for one minute after running on the treadmill.

The whole familiarization session lasted approximately 25 minutes and it was performed at any time of the day.

On completion of the familiarization session, the subjects were asked to arrive for the subsequent test session within 1-2 hours after waking up (6.00 AM – 8.00 AM) on the next day to minimize the effects of diurnal variation on the VSC response for the first experimental session (Kanlayanaphotporn et al., 2002; Tyrrell et al., 1985). Then, the subjects were requested to come back to the laboratory room in the afternoon (4.00 PM – 6.00 PM) on the next consecutive day for the final test session. All subjects were requested to maintain their normal daily activities and to have a good night's sleep of at least 7 hours. The details of the procedure on the testing session were similar to the procedure on the familiarization session, except the subjects were asked to perform the running process for 41 minutes (2 min for general stretching, 3 min for running warm up, 30 min for running, 3 min for running cool down and 3 min for breathing recovery) (Figure 10) and the duration of the VSC measurement was for 2 minutes.



**Figure 10** The study's organization of activities

**6.2.2 Control group:** The subjects were asked to perform the protocol similar to the treadmill running group, except they were asked to do normal daily activities for 41 minutes instead of performing the treadmill running and to refrain from any strenuous physical activities, such as running. Additionally, the subjects were asked to refrain from a lying position.

## 7. Variables

7.1 The difference of the magnitude of the VSC response before and after running on the treadmill for 30 minutes measured in the morning were compared to those measured in the afternoon.

7.2 The difference of the magnitude of the VSC response before and after running on the treadmill were compared to those in the control group.

## 8. Data management

The magnitude of the VSC response using the means of 150 VSC data points recorded at the end of 30 seconds of the second minute was calculated in each experimental session.

## 9. Data analyses

Demographic data were presented as mean  $\pm$  standard deviations (SD). A paired t-test was used to compare the magnitude of the VSC response within group. An unpaired t-test was used to compare the magnitude of the VSC between groups. For all statistical tests, the threshold of significance was set at  $\alpha \leq 0.05$ . All analyses were performed on SPSS version 17.

