CHAPTER 3

RESEARCH METHODOLOGY

3.1. INTRODUCTION

It was clear from the literature review that it would be unethical to use radiographs for this study due to the inherent dangers. A variety of methods for the evaluation of deformities were found in the literature. However, even the gold standard methods showed variations from one researcher to another. Therefore it was decided to make use of non-invasive methods, found to be effective for the screening of deformities, in this study.

ETHICAL CONSIDERATIONS: The protocol was submitted to and approved by the Ethics Committee of the Faculty of Health Science of the University of Pretoria.

3.2. STUDY DESIGN

A case-control study was conducted in Middelburg, Mpumalanga. Adolescents with spinal deformities were compared to adolescents without spinal deformities, with regard to their developmental milestones as babies and other variables which may have contributed towards the development of spinal deformities.

3.3. STUDY POPULATION

All adolescents, male and female, between the ages of twelve and seventeen years, who attended any of the schools in Middelburg, Mpumalanga, were considered part of the total population. The schools were:-

- Dennesig Primary School
- Kanonkop Primary School
- Middelburg Primary School
- CR Swart Primary School
- Kanonkop High School
- Steelcrest High School
- Middelburg High School
- Middelburg Technical High School

3.4. SAMPLING

The sampling frame was pupils from the community who complied with the criteria and volunteered to participate in the study. The sampling was done in the following way:

The school principals in the town of Middelburg, Mpumalanga, were approached for permission to give a lecture on back deformities at each relevant school. This lecture was given to all scholars, aged between twelve and seventeen years, at the specific schools (Appendix A).

Permission was also obtained to hand out an information letter on common spinal deformities (Appendix B) to this group of scholars. The letter had to be given to the scholars' parents. They were also informed about the research study being undertaken in Middelburg , Mpumalanga, in which they could voluntarily participate. No costs would be incurred. The fact that this research would not harm the children in any way, was also explained. The parents were asked to either return the completed volunteer form to the school, or to telephone the researcher. A form granting consent to allow their children to participate in the study, was also attached. Unfortunately two schools did not have the available time for a lecture, but permission was granted to hand out the information letter. Three thousand five hundred letters were distributed to the schools.

All the volunteer forms were collected from the schools by the researcher. Appointments were made by the researcher to meet with the volunteer and his/her mother. All volunteers were included in the study if they complied with the inclusion criteria. A sample size of one hundred and four subjects was obtained. There were sixty one who complied with the inclusion criteria for the cases, and forty three who complied with the inclusion criteria for the controls.

3.5. SAMPLE CRITERIA

EXCLUSION CRITERIA

- Any congenital deformities of the lower limbs, chest or vertebrae
- Any abnormal locomotion such as the permanent use of crutches or a wheel chair
- Any leg length discrepancy of more than ten millimetres[4]
- Previous fractures of vertebrae
- Any spinal deformity of neurological origin
- Any chronic lung disease such as cystic fibrosis, or tuberculosis
- Previous thoracic surgery

INCLUSION CRITERIA FOR CASES

All adolescents who were diagnosed with a spinal deformity by means of postural observation and the physical evaluation (refer to 3.6.2.) of hump size, angle of rotation, deviation from the midline, and kyphosis/lordosis measurements.

INCLUSION CRITERIA FOR CONTROLS

All adolescents who did not present with a spinal deformity according to postural observations and the physical evaluation (refer to 3.6.2.) of hump size, angle of rotation, deviation from the midline and kyphosis/lordosis measurements.

3.6. RESEARCH PROCEDURE

When the subjects and their mothers arrived for their appointments at the physiotherapy practice, they were informed of the research procedures. The informed consent form (Appendix C) was handed to the mothers. Time was allocated for the mothers and subjects to read the informed consent form. Any questions were answered by the researcher. The subjects and their mothers were then asked to sign the informed consent form, if they agreed to participate. Each of the subjects was provided with a pair of shorts to wear. The females also wore halter-neck tops with thin straps, so that the back would be bare. (Figure 1). The physical examination was then started.

Figure 1: Subject dressed in a pair of shorts and halter-neck top

3.6.1. DESCRIPTION OF INSTRUMENTS

- **EXAMINATION ROOM:**

  The same examination room was used for all subjects. The examination couch was solid with hard upholstery. Good overhead lights were available to ensure accurate readings.

- **INCLINOMETER:**

(Baseline digital inclinometer / Saunders electronic inclinometer)

The digital inclinometer (Figure 2) is a portable, hand-held inclinometer designed to measure posture and mobility of the spine. The inclinometer has a liquid crystal screen that shows a digital display of its position. All readings are displayed in degrees and no calibration is needed. There are three buttons on the face of the inclinometer: ON/OFF, ALTERNATE ZERO and HOLD. The inclinometer has two sides, a long base and a short base. The inclinometer can be zeroed in any position by pressing the alternate zero ("Alt Zero") button. The digital display then shows a zero. The reading in the following position will be a reading relative to the zero. The hold button can be pressed to show the reading of the inclinometer in the new position. The inclinometer is powered by a standard nine volt battery, and is not affected by the time of day, normal temperatures or general humidity.

Figure 2: Baseline digital inclinometer

- **MEASURING CANE:**

A metal measuring cane was fixed to the wall. Care was taken that the height was exactly correct. The measuring cane was graduated in centimetres and millimetres.

- **TAPE MEASURE:(Figure 3)**

A new standard, flexible tape measure graduated in centimetres and millimetres was used. The length of the tape measure was one hundred and fifty centimetres.

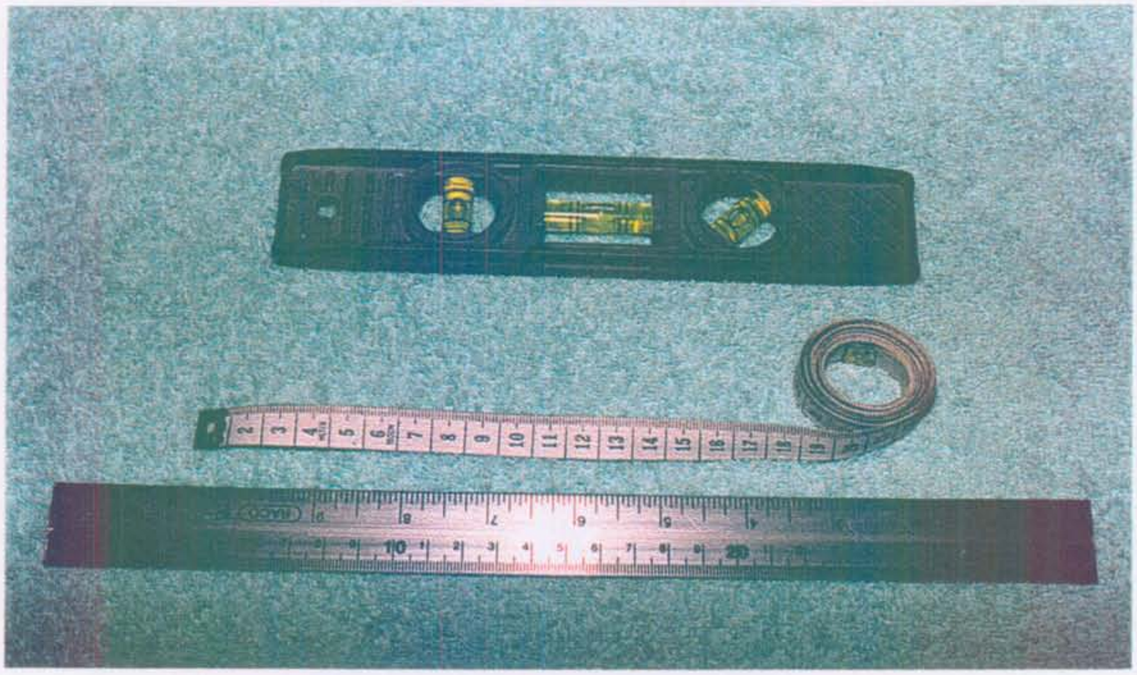

Figure 3: Measuring tape, spirit level and metal ruler

- **SKIN MARKER:**

  A black Artline superfine point marker was used.

- **SPIRIT LEVEL:(Figure 3)**

  A plastic spirit level of twenty five centimetres length, was used.

- **PLUMBLINE:(Figure 4)**

  A thin string with a lead weight was fixed to an overhead arch.

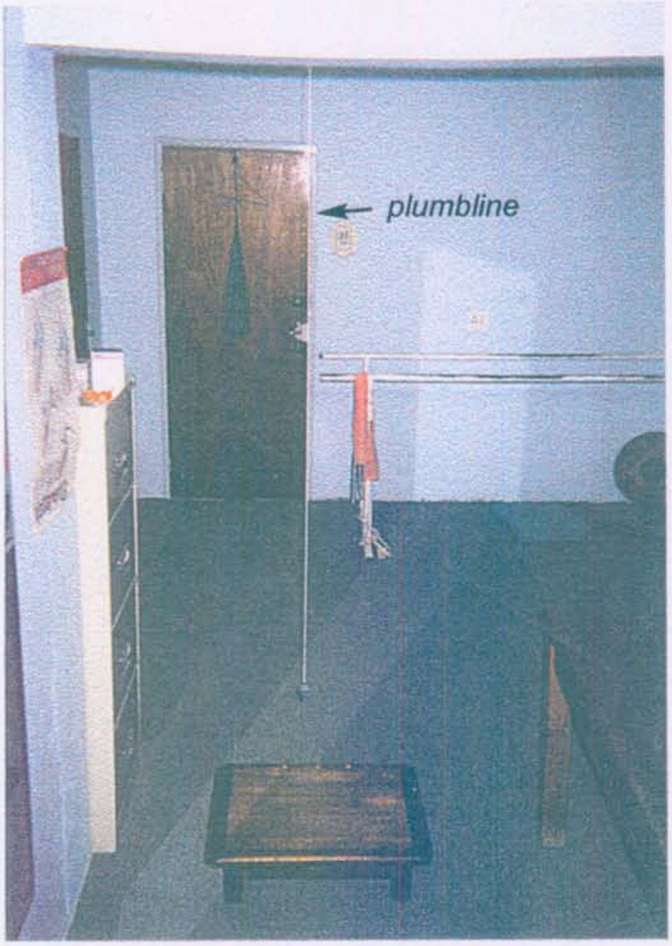

Figure 4: Plumbline

3.6.2. PHYSICAL EXAMINATION

(Evaluation form: Appendix D)

All subjects were dressed similarly: (Figure 1)

MALES: Loose fitting running shorts without shirts and barefoot.

FEMALES: Loose fitting running shorts and halter-neck tops with thin straps, so that the back was exposed.

SUBJECTIVE INFORMATION:

◊ **Age:** The age of the subject was noted in years and months.

◊ **Gender:** The gender of the subject was noted.

◊ **Age of menarche:** In the cases of females the age of menarche was noted in years.

OBJECTIVE EVALUATION:

All measurements were done three times and the mean was determined.

◊ **Height:** The subject was requested to stand with his / her back against a fixed measuring cane. His / her heels had to be against the wall (or as close as possible) and his / her feet had to be together (or as close as possible). A spirit level was placed on the head of the subject to eliminate faulty parallax. The height of the subject was noted in millimetres.(Figure 5)

Figure 5: Measurement of height

- **Leg length discrepancy:** The subject was asked to lie supine on the examination bed. The pelvis was levelled by placing the iliac crests on a straight line. The tips of the anterior superior iliac spines were palpated and marked with a pen. The tips of the medial malleoli were palpated and marked with a pen . A standard tape measure was used to determine the distance between the anterior superior iliac spines and the medial malleolus. The same procedure was followed with the other leg. Any difference between the two legs, was noted.
- **Straight leg raise:** The subject was asked to lie supine on an examination bed. The greater trochanter of the femur was palpated and marked with a pen. The lateral condyle of the distal end of the femur was also marked with a pen and these two points were joined by a line alongside the shaft of the femur. The zero of the inclinometer was determined level to the examination bed. The heel of the relevant leg was placed on the researcher's shoulder and the knee was stabilised in extension with one hand. The leg of the subject was raised by means of the researcher's shoulder, while her other hand maintained the inclinometer alongside the shaft of the femur. The opposite knee of the subject was stabilised by means of the researcher's other knee. The leg being measured was lifted to a level where the onset of tension in the hamstring or calf muscles was felt by the subject. Care was taken that no pelvic rotation took place. A reading on the inclinometer indicated the degrees of hip flexion during straight leg raise and this was noted. The same procedure was followed with the opposite leg. (Figure 6)

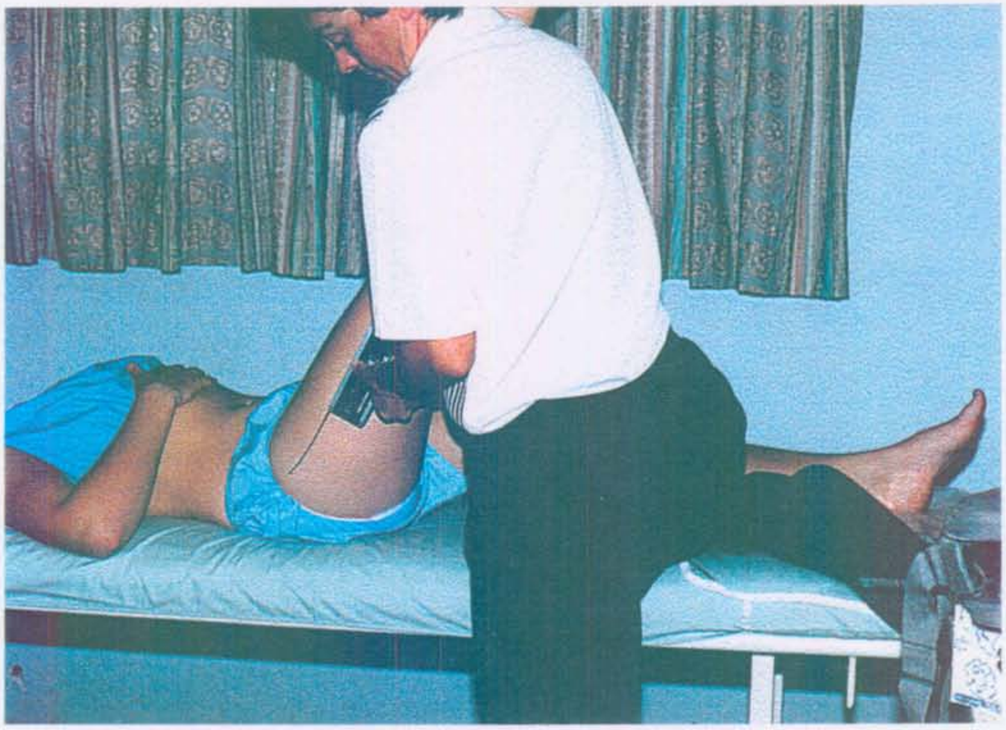

Figure 6: Measurement by means of straight leg raise

◊ **Degrees of hip flexion tightness:** (Thomas test)[53] With the subject still in supine, the inclinometer was zeroed on the level of the examination bed. The subject was requested to flex one hip and knee and to pull the knee onto his/her chest to the end range of movement. The level of the examination bed was used as the zero level for the inclinometer. The inclinometer was placed alongside the shaft of the opposite femur, and a reading on the inclinometer noted. This indicated the degrees of hip flexion contracture. (Figure 7)

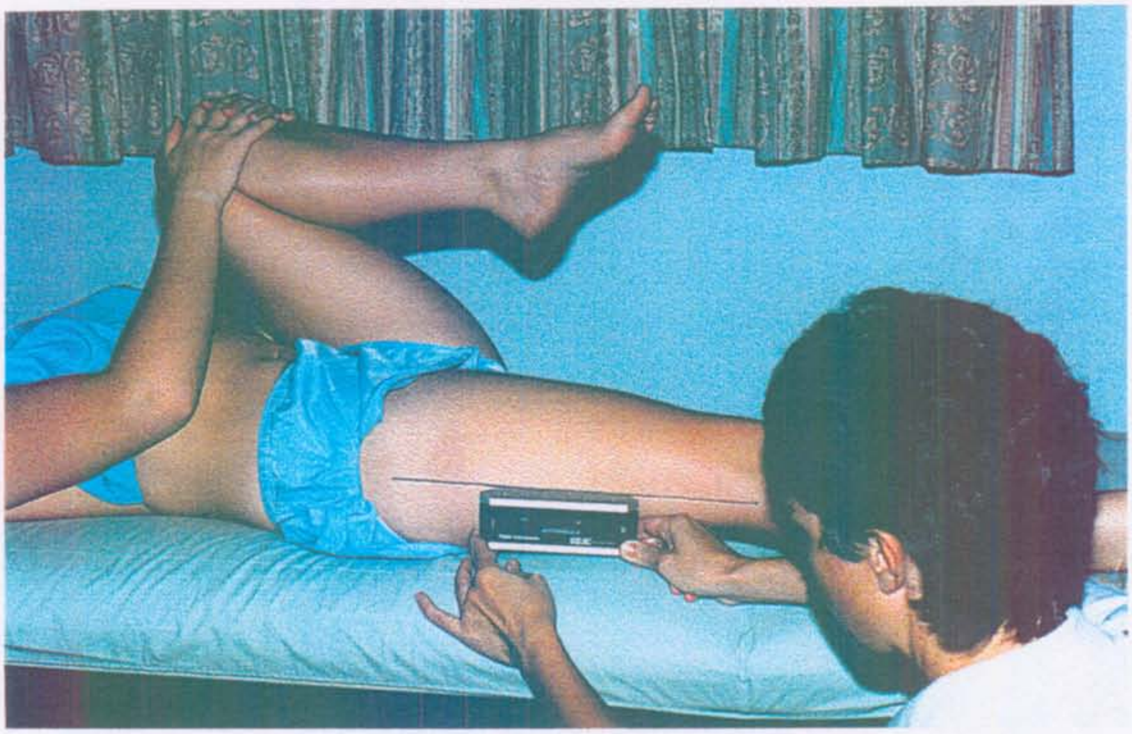

Figure 7: Measurement of hip flexor tightness

◊ **Hump size:** The subject was asked to stand with feet in line with the hips. The toes were placed on a straight line. A mark was made on the floor midway between the two big toes. The subject was requested to place the palms of the hands together and to direct them towards the mark on the floor, placing the chin on the sternum. In this way active trunk rotation was prevented. The subject was asked to flex the trunk up to ninety degrees, pointing the fingers towards the mark. The subject was observed from posterior. The spirit level was placed transversely across the spine in the thoracic area (Figure 8). The spirit level was maintained while a measurement, using a metal ruler graduated in millimetres, was taken. The point where the spirit level was placed, and the point at which the measurement by means of the ruler was made, had to be exactly the same distance from the spine. The same measurement was taken in the thoraco-lumbar region and the lumbar region. The difference in millimetres as well as the side of the hump, was noted.

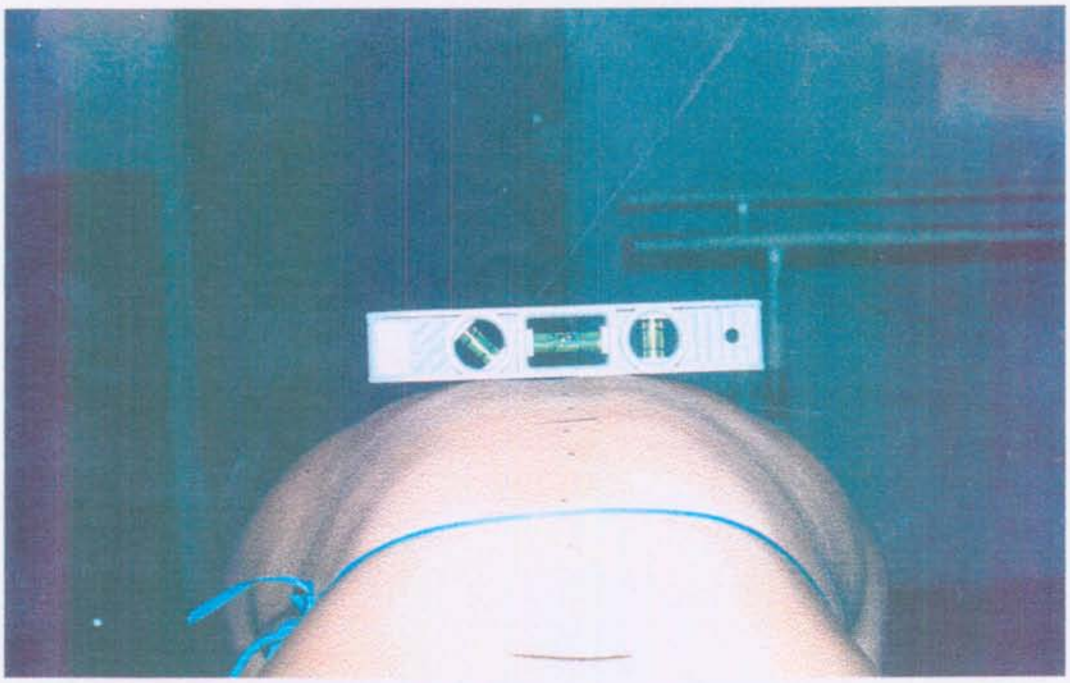

Figure 8: Measurement of hump size

◊ **Angle of trunk rotation:** The rotational prominence or angle of trunk rotation was measured by means of the inclinometer. The subject was requested to stand with the feet in line with the hips. The palms of the hands were placed together and directed to a mark midway between the two big toes and the chin flexed to the sternum. The subject was requested to flex the trunk to ninety degrees. The most prominent part of the hump was measured by means of the inclinometer. The inclinometer was zeroed on a spirit level placed horizontally and then placed across the spine from the hump to the same level on the opposite side of the spine. Any angle was noted. (Figure 9)

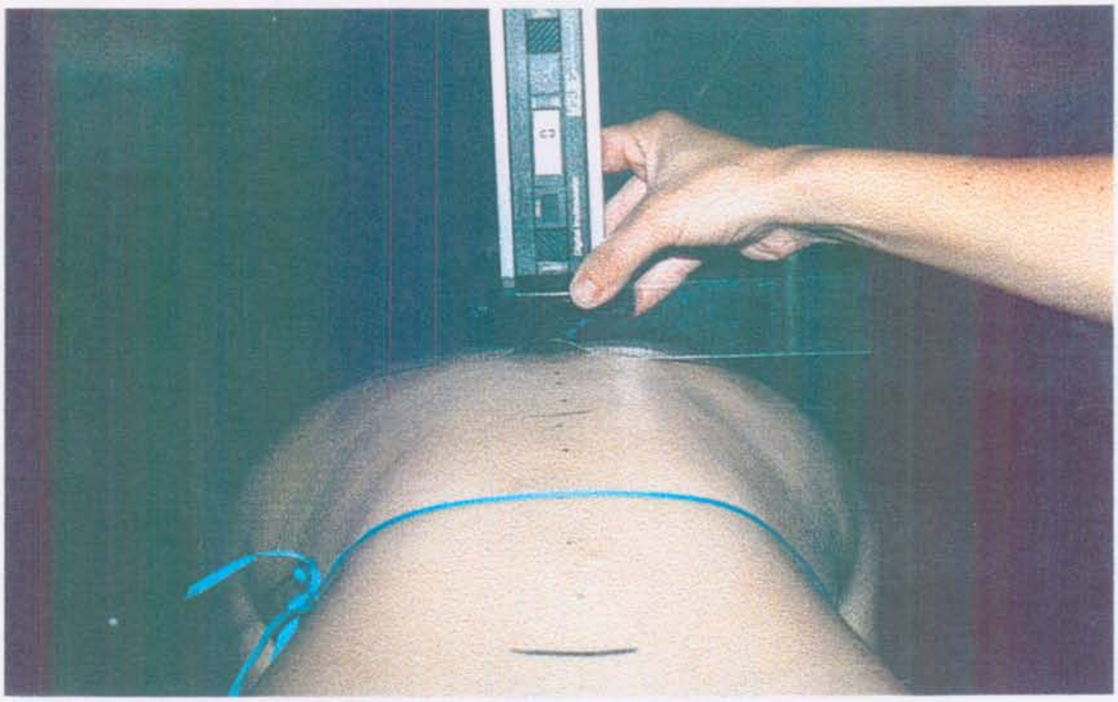

Figure 9: Measurement of trunk rotation

◊ **Plumbline:** The subject was asked to flex forwards in the same way as described previously. The tip of the spinous process of each vertebra, or as close as possible to the tip (in cases where rotation was advanced), was marked with a pen. The subject was asked to stand erect after the markings were completed. A plumbline hanging from the ceiling, was used. The patient was positioned so that the seventh cervical vertebra was aligned with the plumbline. (Figure 10) If there was a deviation of the spine from the plumbline, the distance from the gluteal cleft to the plumbline was measured with the graduated ruler. The side to which the gluteal cleft was shifted in relation to the plumbline, was also noted. The rest of the spine was observed to determine whether there was a deviation from the vertical line. In the case of a deviation, the area of maximum deviation was noted and then measured by means of the graduated ruler.

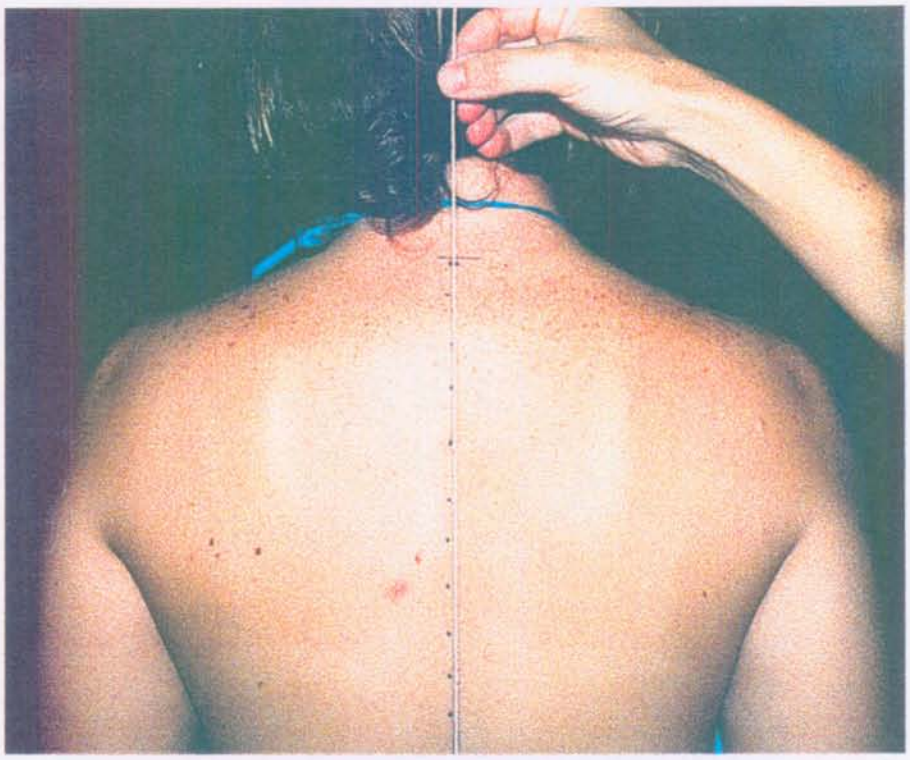

Figure 10: Measurements by means of a plumbline

◊ **Kyphosis / Lordosis :** The sagittal curves of the subject were viewed laterally to determine the start of the normal / abnormal kyphotic and lordotic curves. The subject was asked to stand up straight, but no postural correction was done. The subject was asked to look at a specific point level with the eyes on the opposite wall. The following levels were marked on the subject's back to determine the normal / abnormal sagittal curves: lumbo-sacral junction, thoraco-lumbar junction or the superior end of the lordosis, the cervico-thoracic junction or the superior end of the kyphosis. The digital inclinometer was used to measure the curves in the sagittal plane. All the readings were taken three times and then the average reading was used. The short base of the inclinometer was placed on the lumbo-sacral junction and then zeroed at this point as described in 3.6.1. The inclinometer was then moved to the thoraco-lumbar junction and a reading was taken. This reading was the degree of the lordotic curve. To determine the kyphotic curve the thoraco-lumbar junction or the superior end of the lordosis / inferior end of the kyphosis was used for the zero reading. The inclinometer was then placed on the cervico-thoracic junction to measure the degree of kyphosis present. (Figure 11)

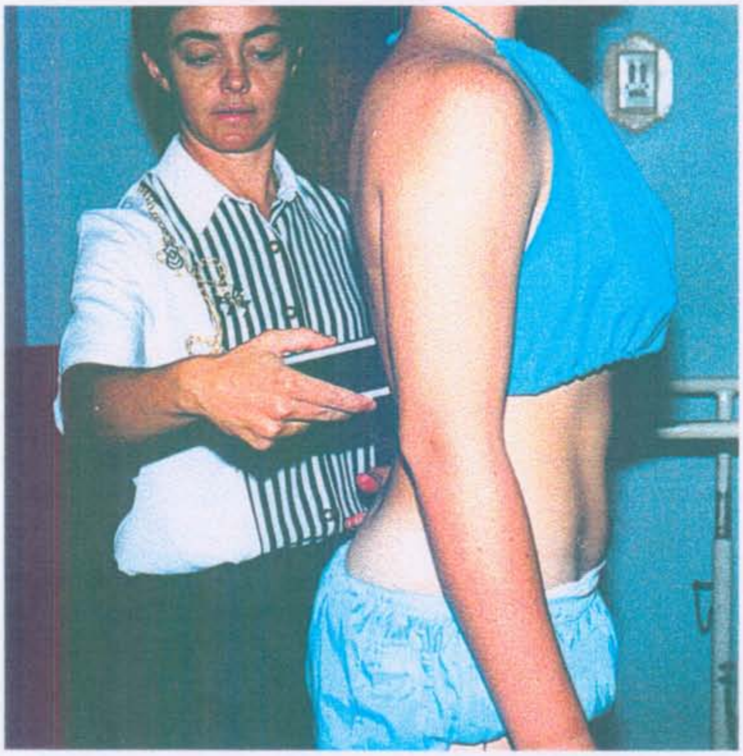

Figure 11: Measurement of kyphosis and lordosis

◊ **Forward head posture:** The subject was viewed from the side with the plumbline hanging on the lateral side in such a manner that the plumbline passed through the centre of the ear. The position of the line as it passed through, posterior or anterior to the shoulder, was observed. If the plumbline passed in front of the shoulder, the subject was considered to have a forward head posture. This was noted. (Figure 12)

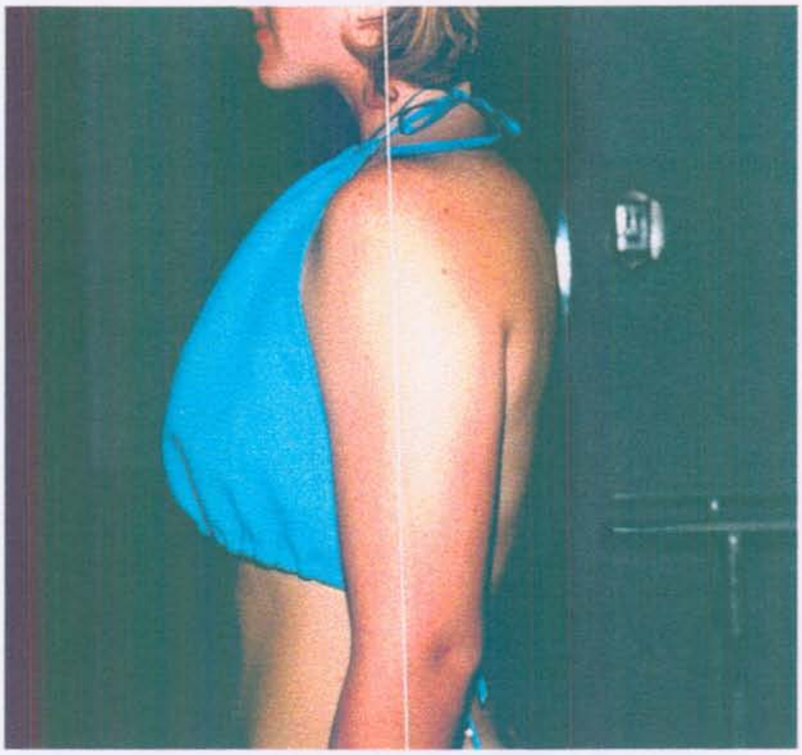

Figure 12: Measurement of forward head posture

◊ **Postural observations:** (Figure 13) The subject, in standing, was observed from posterior for asymmetrical winging of a scapula, and if so, the side of asymmetrical winging was noted. Any shoulder girdle elevation was noted, indicating the elevated side. The arms hanging next to the trunk were observed to determine if one arm was hanging further away from the trunk than the other, and on which side it was further way.

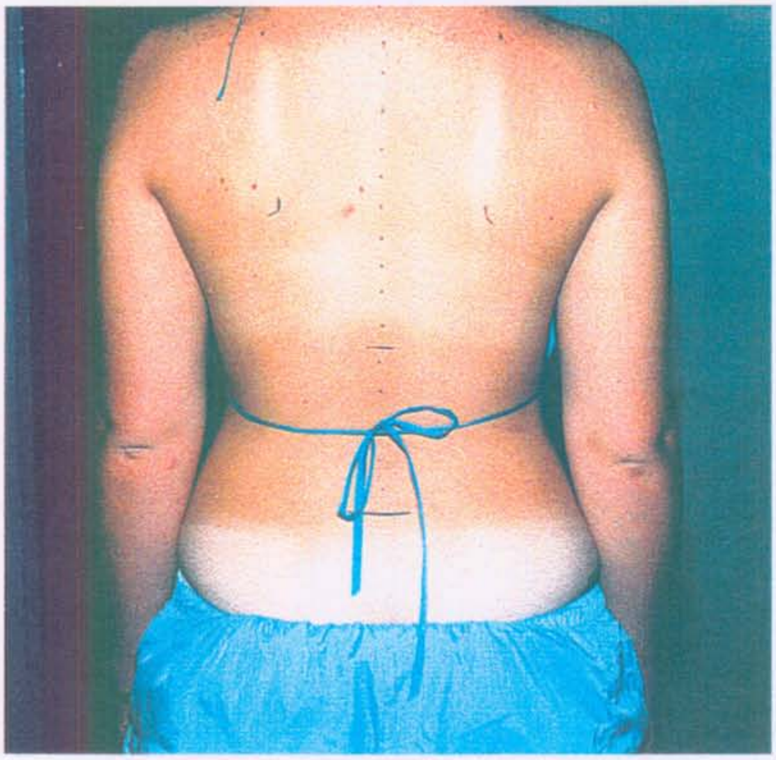

Figure 13: Postural observations

After completion of the physical evaluation, the mother was interviewed in order to obtain the necessary information for the questionnaire. The procedure was conducted in this order to avoid researcher bias when carrying out the objective evaluation. Relevant subjective information which would have been obtained prior to the objective evaluation, may have biased the researcher in her observations and measurements.

3.6.3. QUESTIONNAIRE (Appendix E)

Once the evaluation was completed, the researcher interviewed the mother of the subject and completed the questionnaire. The following data was obtained during the structured interview.

Developmental milestones:

- The age at which the subject sat independently.
- Whether the subject crawled, at what age he/she started crawling, and for what period of time he/she crawled before walking;
- Whether any other way was used to move forward;
- The age at which the subject walked independently.

Use of developmental aids:

- Whether the mother made use of a sit chair / transport chair, and for what period of time per day;
- Whether the mother made use of a walking ring for the subject, and for what period of time per day;
- Whether the mother made use of a "Jolly Jumper" and for what period of time per day.

Other factors:

- The family history concerning kyphosis and scoliosis;
- The gestation period as well as the process of birth (normal, Caesarean section, or normal with instrumentation);
- The preferred lying position of the subject as a baby;
- Hearing problems, and if so, the side of defective hearing, and the age at which the subject developed a hearing problem;
- Defective eyesight, the specific side that was affected, the age at which this problem

started, and whether the subject was far sighted or short sighted;

- Whether the mother knew that her child had a spinal deformity, and when it was first noticed;
- Whether the child had a sudden growth spurt, and at what age it took place.

3.7. PILOT STUDY

The first twelve subjects to make appointments were considered as candidates for the pilot study. After their evaluations were completed, all problems were considered. The data of these subjects were not included in the analysis. The following problems were experienced during the physical evaluation:

- When the plumbline was placed on the seventh cervical vertebra, as described by most of the authors [8,27,32], the free hanging of the plumbline was disturbed in cases of kyphosis. It was then decided to make use of a plumbline hanging from an overhead arch and to orientate the subject so that the spine of the seventh cervical vertebra was in line with the plumbline, as close as possible to the body of the subject, without disturbing the free hanging of the plumbline.
- The researcher attempted to measure the lordotic curve of the cervical spine by means of the inclinometer, but the shortbase of the inclinometer was too long in the case of younger children. The contact of the shortbase on the spinous processes was lost. The forward head posture was then measured by means of a plumbline (as previously described).

The questionnaire was also pre-tested. The mothers of the twelve subjects were interviewed by means of a structured questionnaire. Categories for "not applicable" and "cannot remember" were added to relevant questions. The age categories, (for example, 9-12 months and 12-15 months) had an overlap of one month. The first category was considered up to the day before 12 months, while the latter was considered from the exact day that the baby turned 12 months.

3.8. RESEARCH BIAS

3.8.1. VALIDITY

Although some research articles indicate that non-invasive methods of measuring the spinal curve is not as accurate as radiographs,[122] others show a good correlation between surface measurements and radiographs.[18,63,94] The inclinometer is the non invasive method that has shown the best results regarding accuracy in the measurement of spinal curvature.[18,63,94] Measurements with the inclinometer show a high intra- and inter-tester correlation.[94] Surface measurement of thoracic rotation is a valid method to screen for scoliosis.[10,20] Although radiographs are the most reliable method for the measurement of leg length discrepancy, and other researchers prefer the measurement of relative iliac crest height[54], the method of measurement from the anterior superior iliac spine to the medial malleoli is a valid method.[32,37] The ability to recall developmental milestones such as sitting and walking was found to be good in cases where children were four to five years old.[122] Unfortunately, no study was found that determined the reliability of recall of parents of adolescents.

3.8.2. RELIABILITY

The reliability (also see section 3.8.4.) of each of the objective measurements was controlled by taking three measurements, and then determining the mean. If there was a variation of more than five degrees, or five millimetres, the measurements had to be repeated.

The reliability was further tested by means of blinding. A second observer was trained to repeat the readings of the first ten subjects, thus testing inter-tester reliability.

3.8.3. SELECTION BIAS

Selection bias was eliminated by using all the volunteers who replied. This was a sample of convenience. Although the schools that were approached were multi-racial only the white parents responded to the request for participation. The sample was therefore not representative of the South African population. Selection for the control and case groups was controlled by the specific inclusion criteria for each group. The numbering of the cases and controls was done in a systematic manner. After the objective evaluation was completed, it was determined if the subject was a case or a control according to the results. In each group the consecutive number was then assigned to the subject.

3.8.4. INFORMATION BIAS

INTERVIEWER BIAS: Only one interviewer was used.

INSTRUMENTAL BIAS: The same tape-measure, ruler, spirit level, plumbline and inclinometer were used. No calibration was needed for the inclinometer.[83]

QUESTIONNAIRE BIAS: The questionnaire was pre-tested and a pilot study was done to ensure that all the evaluation techniques were possible. A structured interview was used.

RECALL BIAS: Some mothers had difficulty to remember precise ages of certain developmental stages. Categorised answers, according to normal developmental stages, were used to minimise the recall bias.

MEASUREMENT BIAS: A second researcher was trained to repeat the evaluation of the first ten subjects. Inter-observer reliability was tested by means of a paired t-test. Analysis of data obtained from the two observers showed a significant difference in only four of the variables of the physical evaluation. The measurements of the height of the subjects showed a significant difference (p=0,02). The differences between the two observers differed between zero and five millimetres, but only three of the measurements were three millimetres or more. Only the measurements of the left hip flexion tightness showed a significant difference (p=0,05). These differences varied between zero and 3,7 degrees, and once again only three of the measurements differed by more than two degrees. The measurement of hump size differed in only three of the subjects whilst the other measurements were the same for both researcher and control researcher. The lordotic measurements also differed in only three of the measurements with a significant difference of p= 0,05. All the above mentioned differences were found when evaluating the first four subjects, thus leading to a conclusion, that the measurements of the two observers differed less, as the experience of the second observer improved. Reasons for deviations in only four of the measurements of the variables, could be due to the fact that although the control researcher was trained, she lacked experience in handling the instruments. The importance of accuracy was explained to the second researcher, but perhaps insufficient time was taken to obtain precise measurements. However, the measurements of the study were considered inter-observer reliable for the following reasons:

- differences were observed in only four (4) of the variables measured
- differences never exceeded more than five millimetres or 3,7 degrees
- differences decreased as experience improved.

3.9. STATISTICAL ANALYSIS OF THE DATA

The statistical analyses that were applicable to this study were:

- comparison between means of variables from the case and control groups by paired t- tests.

- examination of relationships of frequencies in 2 X 2 tables by calculating chi square values
- tabular probability values (p values) of all comparisons (means and Chi squares) are given whenever relevant and special note is taken where p=0,01 or less
- Pearson correlation coefficient was used to calculate the correlation between the angle of trunk rotation and the hump size
- a Logit analysis of the variance tables to determine the maximum likelihood of the ages of developmental milestones to predict the development of a spinal deformity

Chi square and t-test values which have tabular p values of 0,05 or less, were regarded as significant. Probability values of 0,05 to 0,1 show a trend of predictability with regard to the variables investigated, and the possible development of deformities. However, it must be remembered that Chi square and t-test values equal to or greater than the 10 % level of probability present differences or associations which are less predictable than when the level is progressively smaller.

3.10. SUMMARY

In the research methodology of this case-control study, sampling was done from schools in the community according to specific inclusion and exclusion criteria. During the research procedure non-invasive methods were used to screen the subjects for any spinal deformities that they may have developed. A structured questionnaire was used to determine the developmental milestones and other possible factors that could influence the development of spinal deformities. The results of the data from the objective evaluation and information obtained from the interviews are given in the next chapter.