

FEEDBACK TO PATIENTS WITH LOW BONE MINERAL DENSITY AFTER BONE DENSITOMETRY

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MAGISTER TECHNOLOGIAE: CLINICAL TECHNOLOGY

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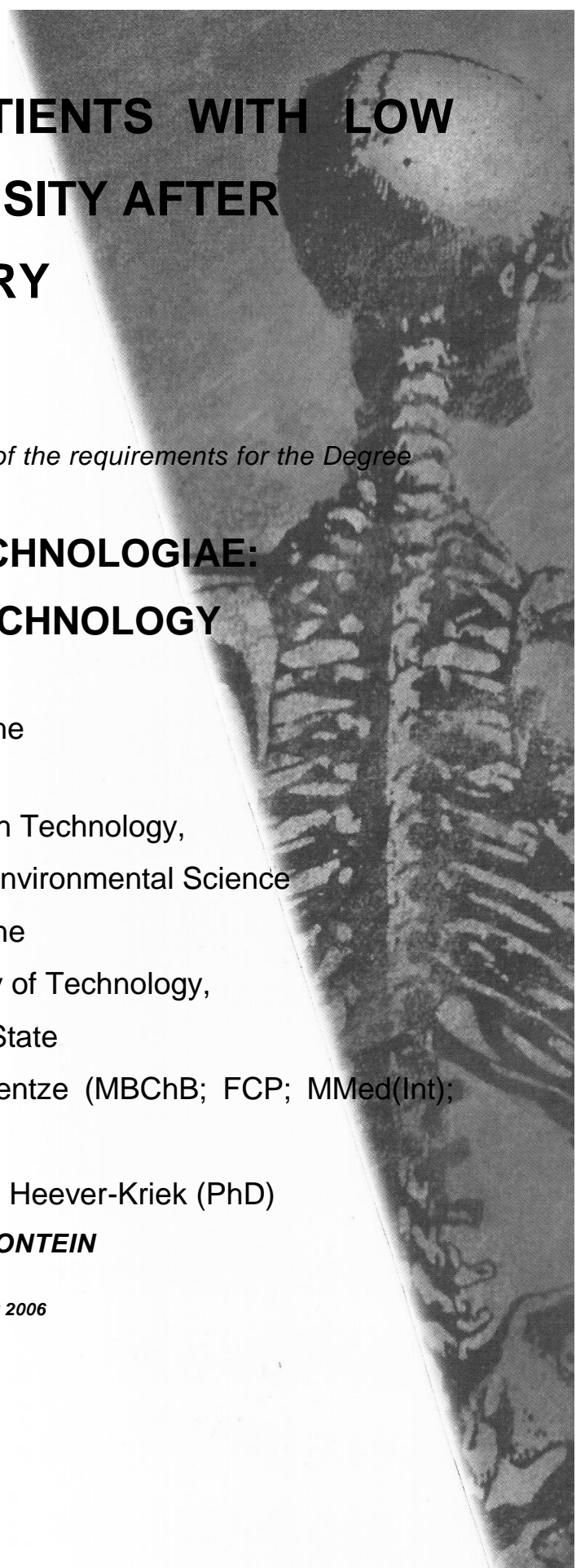
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BLOEMFONTEIN

October 2006



*Osteoporosis is not inevitable
and
is preventable and treatable*



DECLARATION OF INDEPENDENT WORK

I, Susanna Maria Pretorius, identity number _____ and student number 8710352, do hereby declare that this research project submitted to the Central University of Technology, Free State for the Degree MAGISTER TECHNOLOGIAE: CLINICAL TECHNOLOGY, is my own independent work; and complies with the Code of Academic Integrity, as well as other relevant policies, procedures, rules and regulations of the Central University of Technology, Free State; and has not been submitted before to any institution by myself or any other person in fulfilment (or partial fulfilment) of the requirements for the attainment of any qualification.

S.M PRETORIUS

October 2006

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To my Almighty Father in Heaven who gave me the common sense and perseverance to see this project through; “*Glory to Thy Name*”.

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The Lord is my strength and my shield; in Him my heart trusts so I am helped, and my heart exults, and with my song I give thanks to Him. - Ps. 28:7

This project is dedicated to my son, Wilben Pretorius.

You are my inspiration and my greatest treasure on earth!

SUMMARY

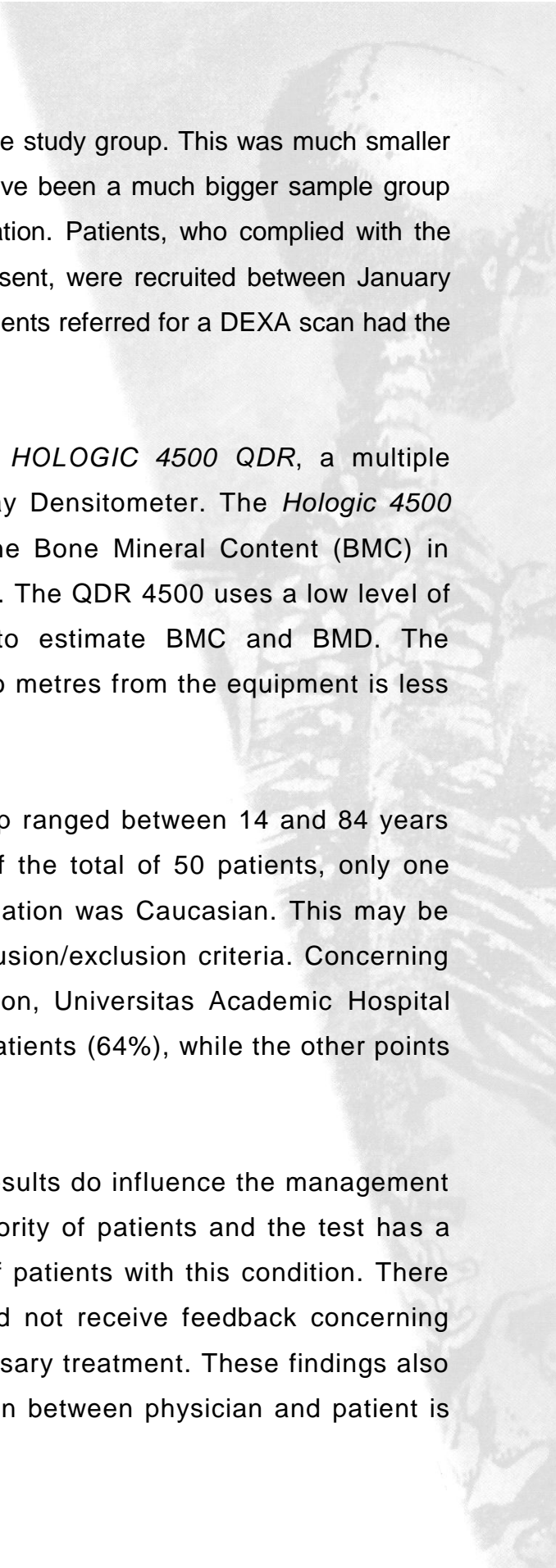
Osteoporosis is defined as a skeletal disorder characterised by low bone mass and micro-architectural deterioration of bone tissue, with the overall focus on bone quality. It affects more than 75 million people worldwide, and cause people to become bedridden with life threatening secondary complications.

An estimated 10 million South Africans, out of a population of 43 million people, are at high risk of developing osteoporosis. In South Africa osteoporosis affects one in three women over 50 and one in five men. Within one year after a hip fracture, up to 20% of the people die, 15-20% needs to be institutionalised and 50% of the remainder will not be able to lead an independent life. The number of fractures is two to three times higher in women than in men due to the hormonal changes that occur after menopause.

The prevalence of osteoporosis increases markedly with age and, based on the bone mineral density at the femoral neck of the hip, approximately 30% of Caucasian women, by age of 75 years will be classified as having osteoporosis.

Dual-Energy X-ray Absorptiometry (DEXA) is the preferred method for measuring BMD. The results of the DEXA scan are scored in comparison with the BMD of young, healthy individuals, resulting in a measurement called a T-score. A T-score of -2.5 or lower is considered to be osteoporosis and T-scores between -0.1 and -2.5 are generally considered to show osteopenia.

The aim of the study was to examine communication between referring physicians and patients who had been referred for a DEXA scan.



A total of fifty patients were included in the study group. This was much smaller than was anticipated. The ideal would have been a much bigger sample group for a bigger representation of the population. Patients, who complied with the inclusion criteria and also gave their consent, were recruited between January 2004 and November 2004. Not all the patients referred for a DEXA scan had the required low BMD.

Bone scans were performed on the *HOLOGIC 4500 QDR*, a multiple detector, fan beam, Dual Energy X-ray Densitometer. The *Hologic 4500 QDR* Bone Densitometer estimates the Bone Mineral Content (BMC) in grams, and the BMD in grams per cm². The QDR 4500 uses a low level of X-rays with two different energies to estimate BMC and BMD. The radiation exposure at a distance of two metres from the equipment is less than one mR/hour.

The age distribution of the study group ranged between 14 and 84 years (average age was 57,2 years). Out of the total of 50 patients, only one was male and the entire patient population was Caucasian. This may be due to the small sample size and inclusion/exclusion criteria. Concerning the references of the patient population, Universitas Academic Hospital (UAH) referred more than half of the patients (64%), while the other points of care referred only 36%.

In this study, it was found that BMD results do influence the management of osteopenia/osteoporosis in the majority of patients and the test has a positive impact on the management of patients with this condition. There was however 22% of patients that did not receive feedback concerning the results of the DEXA and the necessary treatment. These findings also highlighted the fact that communication between physician and patient is

a very important component in using the information provided by this test to its full potential.

The ideal is to identify a low BMD early enough to stop the damaging consequences thereof, but this is not always feasible due to the high costs involved in a DEXA scan. Access to treatment and care is also not readily available to a large section of the population and, in State Hospitals; the availability of drugs to treat osteoporosis is limited due to the high costs.



OPSOMMING

Osteoporose is 'n toestand wat gekenmerk word deur 'n lae beenmassa en verlies aan beenweefsel. Die kwaliteit van been word ook daardeur beïnvloed. Dit affekteer meer as 75 miljoen mense werêldwyd en kan die mobiliteit van 'n persoon aantas met lewensbedreigende gevolge.

Ongeveer 10 miljoen Suid-Afrikaners uit 'n bevolking van 43 miljoen loop die risiko om osteoporose te ontwikkel. In Suid Afrika word ongeveer een uit elke drie vrouens deur osteoporosis geaffekteer en een uit elke vyf mans. Binne een jaar na 'n heupfraktuur kan tot 20% van die pasiënte as gevolg daarvan sterf en 15-20% het versorging nodig. Die res van die pasiënte sal nie meer 'n normale onafhanklike lewe na 'n osteoporotiese fraktuur kan lei nie. Die aantal frakture in vrouens is twee tot drie keer hoër in as in mans as gevolg van die hormonale veranderinge na menopouse.

Die voorkoms van osteoporose verhoog merkwaardig met ouderdom en wanneer daar na die minerale digtheid van die been by die femorale nek gekyk word, sal 30% blanke vrouens teen die ouderdom van 75 jaar met osteoporose geklassifiseer word.

“Dual-Energy X-ray Absorptiometry” (DEXA) is tans die beste metode om die mineraaldigtheid van die been (BMD) te bepaal. Die resultate van die DEXA word vergelyk met die BMD van 'n jong, gesonde individue en word uitgedruk as die “T-score”. 'n “T-score” van -2.5 of laer, word aanvaar as osteoporose en 'n “T-score” tussen -0.1 en -2.5 word beskou as osteopenies.

Die doel van hierdie studie was om kommunikasie tussen die verwysende geneesheer en die verwyste pasiënt te evalueer. Is dit vir die pasiënt

enigsins voordelig om vir 'n DEXA te gaan in terme van terugvoering oor resultate en behandeling indien nodig.

'n Totaal van 50 pasiënte was in die studie ingesluit. Die studiegroep is heelwat kleiner as waarvoor gehoop is en die ideaal sou wees om 'n groter verteenwoordigend van die bevolking te kry. Pasiënte, tussen Januarie 2004 en November 2004, wat aan die insluitingskriteria voldoen het en ook toestemming gegee het, is gewerf. Nie alle pasiënte wat vir 'n DEXA gestuur was, het die verlangde lae BMD gehad nie.

Die prosedure is uitgevoer op 'n *HOLOGIC 4500 QDR DEXA* skandeerder. Dit bereken die minerale inhoud van die been (BMC) in gram, en die BMD in gram per cm^2 . Die *QDR 4500* gebruik 'n lae dosis X-strale met twee verskillende energievlakke om die minerale inhoud (BMC) en minerale digtheid (BMD) in been, te bereken.

Die studiegroep se ouderdomsverspreiding het gewissel vanaf 14 tot 74 jaar (gemiddelde ouderdom, 57,2 jaar). Slegs een pasiënt was manlik en die hele studiegroep was blanke pasiënte. Dit kan wees as gevolg van die klein pasiëntgroep en die insluitings-/uitsluitingskriteria. Verwysings het grootliks vanaf Universitas Akademiese Hospitaal(UAH) gekom (64%), met slegs 36% van die pasiënte vanaf verwysings buite UAH.

In hierdie studie is gevind dat die BMD resultate die hantering van osteoporose/osteopenie beïnvloed en vir die grootste deel van die pasiëntgroep het die uitvoer van die toets 'n positiewe impak op die hantering van hulle lae BMD gehad. Daar was egter 22% van die pasiëntgroep wat geen terugvoer ontvang het met betrekking tot die uitslae van hulle BMD.

Hierdie bevindinge het dit weereens bevestig dat kommunikasie tussen die geneesheer en die pasiënt 'n belangrike rol speel om die resultate verkry, ten volle te benut.

Die ideaal sou wees om die lae BMD groep vroegtydig te kon identifiseer sodat nadelige gevolge van hierdie toestand vroegtydig gestop kan word. Dit is ongelukkig nie altyd uitvoerbaar weens die hoë koste verbonde aan 'n DEXA prosedure. Toegang tot behandeling is vir 'n groot deel van die bevolking nie altyd beskikbaar nie en in die staatshospitale is daar ook 'n beperking op die beskikbaarheid van medikasie weens die hoë koste.



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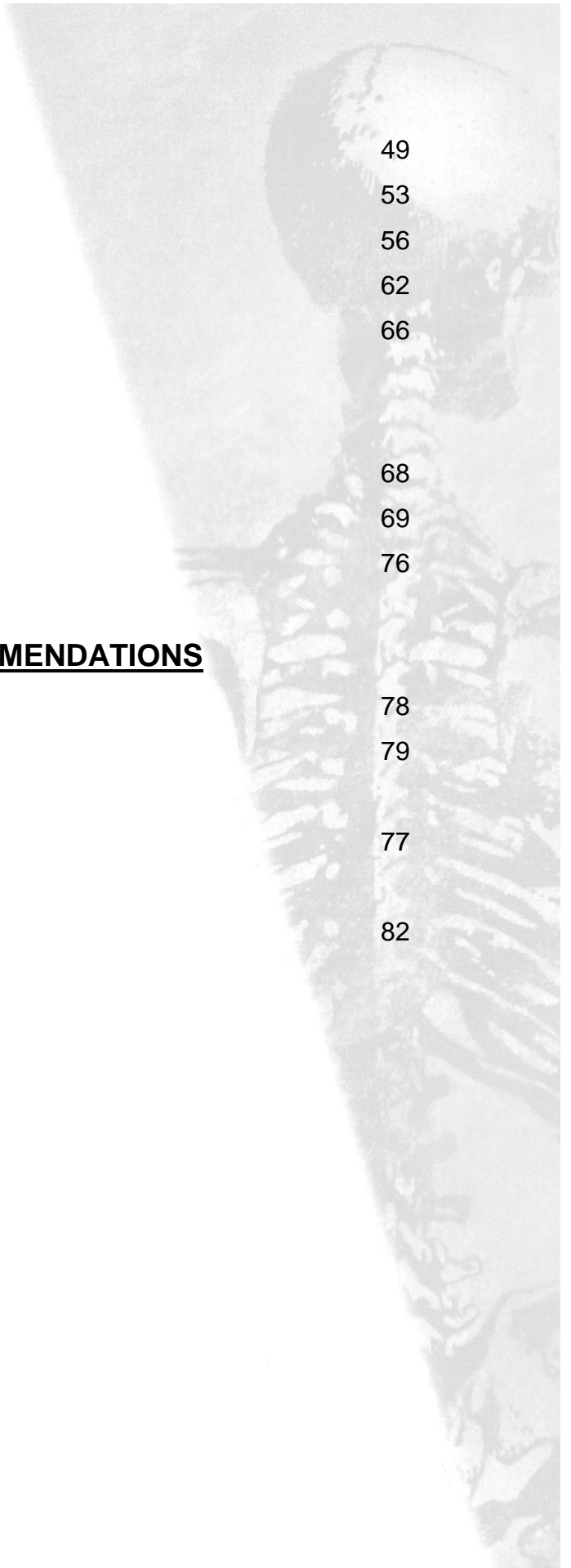
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LIST OF ABBREVIATIONS

BMC	Bone Mineral Content
BMD	Bone Mineral Density
BMI	Body Mass Index
DEXA	Dual Energy X-ray Absorptiometry
DPA	Dual Photon Absorptiometry
IOF	International Osteoporosis Foundation
UAH	Universitas Academic Hospital
WHO	World Health Organization

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CHAPTER 1

INTRODUCTION

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1.1 INTRODUCTION

According to the Osteoporosis Foundation of South Africa, an estimated 10 million South Africans, out of a population of 43 million people, are at high risk of developing osteoporosis (National Osteoporosis Foundation of South Africa, 2004). In South Africa osteoporosis affects one in three women over 50 (more than breast cancer) and one in five men. Within one year after a hip fracture, up to 20% of the people die, 15-20% need to be institutionalised and 50% of the remainder will not be able to lead an independent life. The number of fractures are two to three times higher in women than in men partly due to the hormonal changes that occur after menopause and partly because women have a lower peak bone mass.

In the United States alone, osteoporosis causes approximately 1.5 million fractures a year and is the leading cause of hip fractures (WomensHealthChannel.com, 2006). An estimated 10 million Americans have osteoporosis and another 18 million are likely to develop it. Eighty percent of those who have or will have osteoporosis are women.

Osteoporosis is one of the world's most devastating and common chronic diseases. It causes the bones to become fragile and more likely to break. In spite of the information available, osteoporosis is still not regarded as a health priority in South Africa and countless

sufferers are denied access to suitable treatment and care (HEALTH 24.com, 2006).

In South Africa malnutrition and infections (including the HIV/AIDS pandemic and tuberculosis) are plentiful; and due to this fact, osteoporosis is not at present regarded as a health priority. Unfortunately, access to treatment and care is also not available to a large section of the population; and, in State Hospitals, the availability of drugs to treat osteoporosis is limited due to the high costs (National Osteoporosis Foundation of South Africa, 2003).

Until recently, osteoporosis was regarded as a “boring” disease, believed to be untreatable and the inevitable consequence of old age (Riggs and Melton, 1995). The treatment thereof was largely confined to patients with vertebral fracture syndrome. Hip and Colles’ fractures were usually ignored and the diagnosis thereof was limited to patients with non-traumatic vertebral fractures. This was largely because there was no effective way to measure bone density.

In 1984, the National Institutes of Health (NIH) Consensus Development Conference in America recognized the magnitude of the problem and changed their view on osteoporosis (Riggs and Melton, 1995). It has become clear to physicians that there are effective strategies for treatment and prevention. In recent years interest in osteoporosis has increased dramatically due to the increased availability of treatments.

Public awareness of osteoporosis as a health issue has also increased. However, the usefulness of the patients' test results depends on the communication between the physician and the patient. It is important to understand their test results when starting treatment after the bone densitometry (Fitt *et al.*, 2001).

At present Dual Energy X-ray Absorptiometry (DEXA) is the technique of choice in determining BMD, because of its ability to assess bone mass at both axial and appendicular sites, its high reproducibility, and the very low doses of radiation associated with it (Divittorio *et al.*, 2006). The World Health Organization (WHO, 2003), regards it as the preferred technique for diagnostic purposes.

Osteoporosis is a disorder for which prevention is much better than treatment (Drife and Studd, 1990). Identifying individuals at risk of fracture, prior to fracture occurrence, is a strategy that must be evaluated on a population basis.

Ignorance about osteoporosis is still common among health professionals, patients and the public; therefore education of all these groups is necessary, as osteoporosis is a very disabling disease and the emphasis must be on early diagnosis and intervention as this will be more cost effective than treatment (Jergas and Genant, 1993).

A study conducted by Fitt *et al.* (2001) also investigated this hypothesis and recognised communication and the patient's

understanding of the bone densitometry results as critical components in the initiation of therapy.

1.2 **AIM**

The aim of this study was to examine the communication between referring physicians and patients who had been referred for a DEXA scan.



CHAPTER 2

LITERATURE REVIEW

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2.1 INTRODUCTION

The clinical significance of osteoporosis lies in the fractures that may occur (Kanis, 1994). These fractures are very disabling and can cause death. The major problem in the management of the disease today is that the diagnosis of osteoporosis is most frequently made only when a fracture has occurred. Bone loss is usually very slow and asymptomatic until a fracture has occurred. This means that the disorder has usually been present for many years before it is diagnosed. For this reason, early recognition of osteoporosis is important.

2.2 EPIDEMIOLOGY

Osteoporosis affects more than 75 million people worldwide, and apart from the fractures that occur, it can cause people to become bedridden with secondary complications (Zizic, 2004). These complications may be life threatening to the elderly.

According to the International Osteoporosis Foundation (IOF) the number of osteoporotic fractures in 2000 in Europe alone were an estimated 3.79 million. A study conducted in Switzerland (Health24.com, 2006) showed that the annual costs of hospitalization for osteoporotic fractures were greater than those for myocardial infarction, stroke and breast cancer.

In the USA the fracture risk for Caucasians is higher than for the other ethnic groups. At least 1.5 million fractures each year in the USA are attributable to osteoporosis, including roughly 250 000 hip, 250 000 wrist and 500 000 vertebral fractures (Melton *et al.*, 1990). It is estimated that by the year 2010, 12 million people over the age of 50 will have osteoporosis and 40 million will have a low bone mass. By 2020, this is expected to increase to 14 million osteoporotic cases and 47 million cases of low bone mass.

The prevalence of osteoporotic fractures in Caucasians and Asians in South Africa are similar to those reported from North America and Europe (National Osteoporosis Foundation South Africa, 2004). Black South African, however, have the lowest hip fracture prevalence in the world (National Osteoporosis Foundation South Africa, 2004). According to the Osteoporosis Foundation of South Africa (2004), there are an estimated 10 million people out of a population of 43 million people at high risk of developing osteoporosis.

In Australia 1.9 million people had osteoporosis in 2002. It is projected that by 2006 this figure will be 2,2 million and in the year 2021 it is expected to be 3 million people (National Osteoporosis Foundation of America, 2006).

In 1995, osteoporosis caused more than 150 000 fractures in the United Kingdom alone (Compston *et al.*, 1995).

An IOF survey conducted in 11 countries showed that denial of personal risk by postmenopausal women; the lack of communication about osteoporosis with their physician, and restricted access to diagnosis and treatment before the first fracture result in under diagnosis and under treatment of the disease (International Osteoporosis Foundation, 2005).

2.3 WHAT IS OSTEOPOROSIS?

Osteoporosis is defined as a skeletal disorder characterized by low bone mass and micro-architectural deterioration of bone tissue (Figure 2.1), leading to an increase in bone fragility and susceptibility to fracture (O'Neill *et al.*, 2004). With an overall focus on bone quality well (Bukata and Healey, 2005).

Osteoporosis may present with low bone density and an osteoporotic fracture is one that occurs with minimal or no trauma, i.e. a fall from standing height or less (O'Neill *et al.*, 2002). Because osteoporosis is characterized by a reduction in bone mass that comprises the biomechanical integrity of the skeleton, it leads to an increased risk of fractures. Any bone can be affected, but of special concern are fractures of the hip and spine. Fractures of the proximal femur (hip), the vertebrae (spine) and the distal forearm (Colles) are often linked with osteoporosis (Figure 2.2).

A hip fracture almost always requires hospitalization and/or major surgery. The more serious consequences of vertebral fractures may include loss of height, severe back pain and deformity. The condition develops without warning signs. Most people with osteoporosis do not realize they have the disease until a minor fall results in a broken hip, wrist or vertebra. Prevention of the disease and its associated fractures are essential for health, quality of life and independence among the elderly (World Health Organization, 2003).

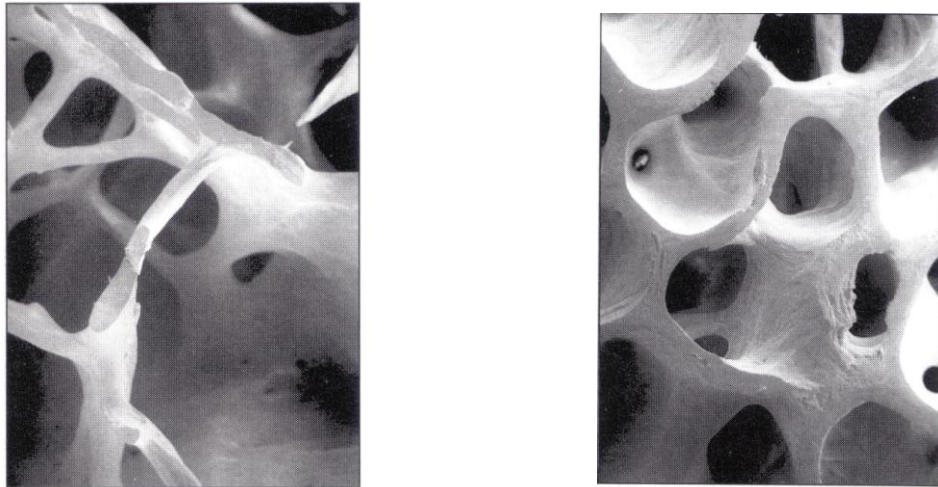


FIGURE 2.1 *SEM of osteoporotic and of normal trabecular bone** (Compston et al., 1995). *SEM = scanning electron micrograph

Two types of bone are affected by Osteoporosis (WomensHealthChannel, 2006):

- ◆ Cortical bone – the compact outer layer of the bone shaft,
- ◆ Trabecular bone – a mesh like inner structure; is found in high percentages in the hip, spine, and wrist; is the most vulnerable to osteoporosis.

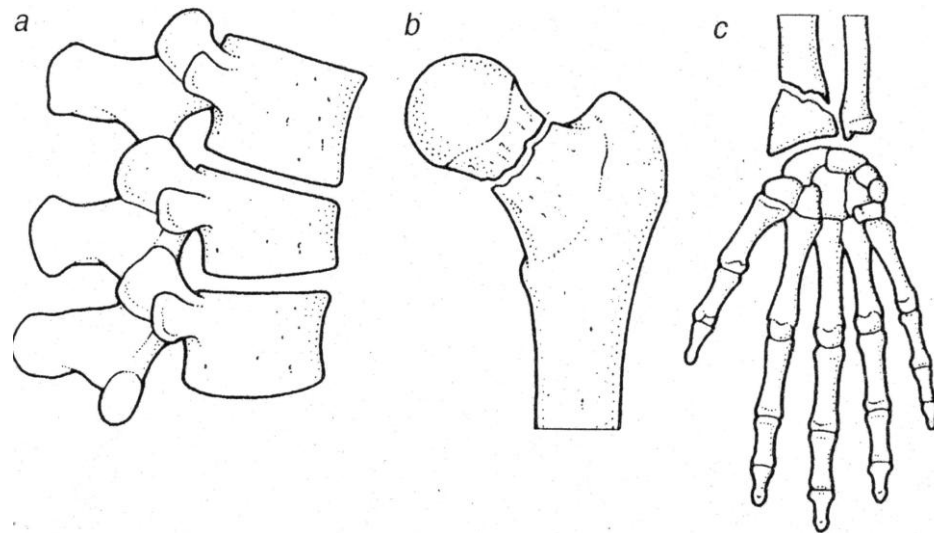


FIGURE 2.2 Typical sites of osteoporotic fractures: a) vertebrae; b) proximal femur; c) distal radius (Woolf, 1994)

The prevalence of osteoporosis increases markedly with age in women and, based on the BMD at the femoral neck of the hip, approximately 30% of Caucasian women, by age of 75 years will be classified as having osteoporosis (World Health Organization, 2003).

Because of the reduction in bone tissue, the bones most likely to break are the weight bearing bones like the hip, spine and sometimes the forearm (Figure 2.2). One out of every three westernised postmenopausal women will have a spinal fracture due to osteoporosis. Up to 20% of hip fracture victims die within a year. Among those living independently before a hip fracture, only half are able to do so after it (World Health Organization, 2003).

Men generally have 20 percent greater BMD than women. Men with osteoporosis and low bone mass totalled over 14 million in 2002 and this figure are expected to increase to over 17 million by 2010 (National Osteoporosis Foundation of America, 2006). Black people have 20 percent greater bone density than Caucasians. Therefore, neither men nor black people are affected with osteoporosis as frequently as Caucasian women, although they can develop the disease (Zizic, 2004).

BMD and bone strength change throughout life (Figure 2.3). Bone density increases during growth, especially in adolescence, and continues to increase in young adulthood even after maximum height is achieved (National Osteoporosis Foundation of America, 1991). It peaks around age 30 for predominantly trabecular bones, such as the vertebrae, and somewhat later for predominantly cortical bones, such as the femur and radius. After bone density peaks, losses begin and continue throughout life. Lifetime losses range from 20% to 30% in men and 40% to 50% in women, and involve virtually all the skeletal sites.

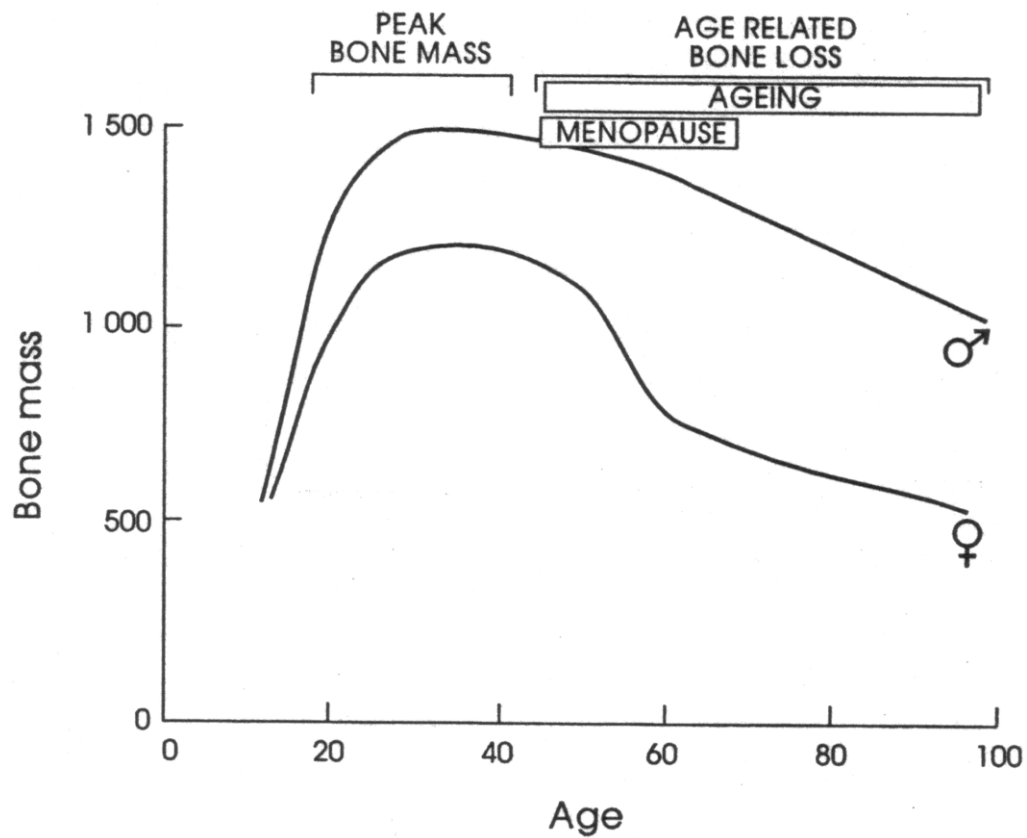


FIGURE 2.3 Changes in Bone Mineral Density with age (Hough, 2000).

Fracture at any site increases the risk of subsequent fracture (Klotzbuecher *et al.*, 2000) and up to 20% of women who have an incident vertebral fracture incur another fracture within one year (Lindsay *et al.*, 2001).

2.4 DIAGNOSIS and ASSESSMENT

Osteoporosis was not classified as a disease until relatively recently, since it was considered to be a condition that expressed itself as fractures (World Health Organization, 2003). Early osteoporosis is not usually diagnosed and remains asymptomatic, therefore it does not become clinically evident until fractures occur.

Measurement of BMD is the most readily available, non-invasive method for assessing osteoporotic fracture risk and is recommended by the World Health Organization for diagnostic purposes (Divittorio *et al.*, 2006).

Bone density is a continuous variable; the lower the bone density, the higher the risk for fracture, and the higher the imperative to intervene with treatment. The cornerstone of diagnosis is the measurement of bone mineral density. Diagnostic thresholds (Table 2.1) offered by the World Health Organization have been widely accepted (Kanis, 1994).

The hip is the preferred site for diagnostic assessment, particularly in the elderly, and Dual-Energy X-ray Absorptiometry (DEXA) is the preferred method, although other sites and methods are useful in assessing the risk and, in some cases, the response to treatment (Kanis, 1994). The emphasis on hip measurement arises from the clinical importance of hip fracture and the strength of the relationship between BMD at this site and the risk of hip fracture.

Prospective studies have shown (Bacon, 1996; World health Organization, 2003; Woolf, 1994), however, that the risk of fracture in general increases progressively the lower the BMD, regardless of measurement site. For each standard deviation decrease in BMD, fracture risk increases by approximately 50%. The ability of BMD to predict hip fractures is better or at least as good as that of the measurement of blood pressure to predict a stroke.

When historical, radiological or clinical findings suggest that osteoporosis is present; bone densitometry by the best available method is indicated to confirm or rule out the diagnosis. Currently, DEXA is the best practical method for measuring BMD. Additional biochemical or hormonal tests should also be considered to elucidate other factors that may be contributing to loss of bone density (Sturtridge *et al.*, 1996).

2.4.1 Bone densitometry is recommended in the presence of:

- ◆ Radiographic evidence of osteopenia and/or vertebral deformity;
- ◆ Loss of height, thoracic kyphosis (after radiographic confirmation of vertebrae deformity);
- ◆ Previous low-trauma fragility fracture;
- ◆ Prolonged therapy with corticosteroids (e.g. prednisolone at 7.5 mg daily for six months);
- ◆ Premature menopause (age <45 years);
- ◆ Prolonged secondary amenorrhoeas (>1 year);

-
- ◆ Primary or secondary hypogonadism;
 - ◆ Chronic disorders associated with osteoporosis;
 - ◆ A maternal history of hip fracture;
 - ◆ A low Body Mass Index (BMI).

2.4.2 Sources of error in the diagnosis of osteoporosis by DEXA (Kanis, 1997).

- ◆ Osteomalacia;
- ◆ Osteoarthritis (spine but also hip);
- ◆ Soft tissue calcification (especially the spine);
- ◆ Overlying metal objects;
- ◆ Contrast media;
- ◆ Previous fracture (spine, hip and wrist);
- ◆ Severe scoliosis;
- ◆ Extreme obesity or ascites;
- ◆ Vertebral deformities due to osteoarthritis or Scheuerman disease;
- ◆ Inadequate reference ranges;
- ◆ Inadequate operating procedures (e.g. calibration region selection, acquisition mode, positioning) (osteopenia).

2.4.3 Site of bone measurements

Although measurements at any particular site are significantly related to measurements at other sites in the same individual, this

does not mean that the choice of site is unimportant (Nordin, 1994).

Certain sites may be of greater diagnostic value than others, but less suitable for longitudinal monitoring because of lower precision. Thus, the femoral neck may be more suitable for initial measurement than the spine because it is not liable to interference by degenerative changes that may affect the spine. However, for sequential measurements, the spine may be more valuable because of its greater precision and response to therapy. The forearm has the advantage of precision but may change less than the spine and may be less predictive of fracture (particularly hip fracture), than the proximal end of the femur. On the other hand, the forearm reflects overall peripheral fracture risk more closely than the spine. It must also be realized that spinal densitometry cannot usefully be applied to crushed vertebrae, nor is forearm densitometry of diagnostic value at a fracture wrist. Therefore, at present it is premature to lay down firm guidance as to choice of measurement site.

2.4.4 Interpretation

The results of the DEXA scan are scored (Table 2.1) in comparison with the BMD of young, healthy individuals, resulting in a measurement called a T-score. A T-score of -2.5 or lower, is considered to be osteoporosis and therefore indicates a high risk of fracture (Nordin, 1994). T-scores between -0.1 and -2.5 are

generally considered to show osteopenia. The risk of fractures is generally lower in people with osteopenia than in those with osteoporosis, but if bone loss continues, the risk of fracture increases.

Men and women with BMD values of 2.5 standard deviations or more below the average for a young healthy population (i.e. osteoporosis), should be offered appropriate intervention. Intervention can also be offered to individuals with osteopenia who have strong risk factors that increase their risk of fracture.

TABLE 2.1 *World Health Organization Classification of Osteoporosis (Kanis, 1994)*

Definition	Criteria
Normal	a value for BMD or BMC within 1 SD of the young adult reference mean
Low bone mass	a BMD or BMC value of more than 1 SD, but less than 2.5 SD below the young adult mean
Osteoporosis	BMD or BMC more than 2.5 SD below the young adult mean
Severe osteoporosis	BMD or BMC more than 2.5 SD below the young adult mean plus one or more fragility fractures

BMD = Bone Mineral Density; BMC = Bone Mineral Content; SD = Standard Deviation

2.5 RISK FACTORS for fractures

At greatest risk for osteoporosis are postmenopausal (including early or surgically induced menopause) white and Asian women who are thin or small and have a positive family history of the disease (Kanis, 1994). While women are more likely than men to develop the disease, all men also suffer from osteoporosis.

“Lifestyle” factors that enhance the likelihood of osteoporosis include smoking cigarettes, abusing alcohol, being sedentary, and consuming too little calcium. Genetic factors however, are also important determinants of peak bone mass (Amin, 2004).

Vitamin D deficiency may contribute to fracture risk in the elderly and premature menopause (surgical or non-surgical) hastens the appearance of osteoporosis (Christiansen, 1993). Estrogen deficiency in premenopausal women, caused, for example, by anorexia nervosa, excessive exercise, and hyperprolactinemia, induce bone loss and may reduce peak bone mass.

Osteoporosis can stem from diseases such as multiple myeloma, severe primary hyperparathyroidism, and hyperthyroidism, from exposure to certain drugs such as glucocorticoids (Figure 2.4) in excess and gonadotropin-releasing hormone agonists and antagonists, and from surgical procedures such as gastrectomy (secondary osteoporosis) (Amin, 2004). Anyone who needs to take glucocorticoid medications for more than 3 months is at risk of developing osteoporosis and fractures. Glucocorticoid medications

have both direct and indirect effects on bone tissue that lead to bone loss. These medications can directly affect bone cells, and thereby slow the rate of bone formation. In addition, the medication can interfere with the body's handling of calcium and affect levels of sex hormones, leading to increased bone loss. The risk factor for these patients is especially high, if other major risk factors are present as well (Amin, 2004).

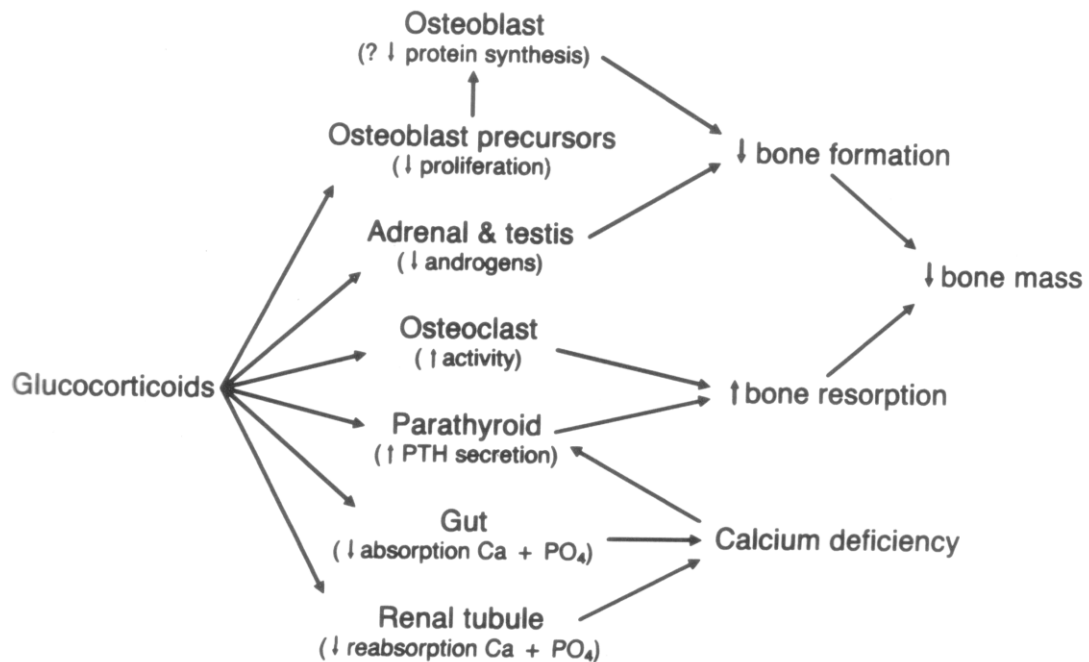


FIGURE 2.4 Probable sites of glucocorticoid effects on calcium metabolism in man and the mechanisms by which these changes produce either bone formation or increased bone resorption (Riggs and Melton, 1995).

Thyroid hormone replacement associated with sub-clinical or clinical hyperthyroidism is also a cause of bone loss (Amin, 2004).

Osteoporosis occurring in middle-aged and elderly men is commonly associated with alcohol abuse, smoking, immobilization, hypogonadism and medications. Low testosterone levels can also be a cause (Fujiwara, 2006). It is, however, possible with the coming of, an aged society, that male patients with osteoporosis are increasing, and it is also important to prevent the disease and treat them (Fukunaga *et al.*, 2006).

Falls are essential precipitating events in hip and other types of osteoporotic fractures. Contributing to the risk of falls are many factors that reduce balance in the elderly, including the effect of aging per se, diseases, and drugs (Christiansen, 1993).

According to the National Osteoporosis Foundation of South Africa, osteoporosis is less common in our Black populations, but unlike the situation in Europe and America, the lumbar bone mass of Black and White South Africans is nearly identical (National Osteoporosis Foundation of South Africa, 2004). The paucity of accurate local statistics on the incidence of osteoporosis and related fractures is a major stumbling block in the drive to prevent and manage the disease optimally. The migration of especially the black population from rural areas to the cities in search of work and an improved life will have further implications on their bone health – the nature of which is uncertain and constitutes an important research topic. In South Africa, where malnutrition and infections (including the

HIV/AIDS pandemic and tuberculosis) are rife; osteoporosis is not regarded as a health priority. Access to diagnosis and treatment is not available to a large section of the population. In state hospitals, the availability of modern drugs to manage osteoporosis is limited because of high costs (National Osteoporosis Foundation of South Africa, 2003).

2.6 METHOD OF MEASURING

Bone is one of the most difficult organs to study and osteoporosis is one of the most common problems of the elderly (Cameron *et al.*, 1999). Until very recently osteoporosis was difficult to detect until a patient presented with a broken hip or a crushed vertebra and by that time it was too late to use preventative therapy. The strength of bone depends to a large extent on the mass of bone mineral present, and the most striking feature in osteoporosis is the lower than normal bone mineral mass.

A simple technique to measure bone mineral mass *in vivo* with good accuracy and precision (reproducibility) was sought and it was hoped that such a technique could be used to diagnose osteoporosis before a fracture occurred and also to evaluate various types of therapy for osteoporosis (Cameron *et al.*, 1999). Since bone mineral mass decreases very slowly, 1 to 2% per year, a very precise technique was needed to show changes.

Several techniques are available at present, but DEXA is the most widely used technique, because of its ability to assess bone mass at both axial and appendicular sites, its high reproducibility, and very low doses of radiation associated with measurement (Mazess *et al.*, 1989). DEXA is based on the method of X-ray spectrophotometry and was first introduced commercially as the direct successor to Dual Photon Absorptiometry (DPA), in 1987. Using the principles of DPA, the radionuclide source in DEXA is replaced by an X-ray tube. Two distinct energy level beams are either generated by the X-ray generator or filtered from an X-ray spectrum (depending on the manufacturer). The main advantages of an X-ray system over a DPA radionuclide system are the shortened examination time due to an increased photon flux of the X-ray and the greater accuracy and precision due to higher resolution and the lack of radionuclide decay. DEXA has taken the place of DPA, thereby reaching great acceptance in clinical medicine and research.

Two X-ray beams with different energy levels are aimed at the patient's bones. When soft tissue absorption is subtracted, the BMD can be determined from the absorption of each beam by bone. Even if DEXA uses X-rays to assess BMD, the radiation doses is approximately 1/30th that of a standard chest X-ray (Cameron *et al.*, 1999)

The preferred anatomic sites for DEXA measurement of BMD include the lumbar spine, proximal femur and whole body, but other parts, such as the forearm and calcaneus, can also be scanned.

The digital image resulting from the measurement allows a gross survey of the region examined. The sophisticated software of all DEXA devices allows one to identify regions of interest with distinct compositions of trabecular and cortical bone such as the femoral neck and Ward's triangle, and the ultradistal or the distal third of the radius. Additionally, fractured vertebrae may be excluded from analysis.

DEXA has a reported precision (reproducibility) in research studies of about 1.0 – 1.5 % at the spine and about 3% at the proximal femur (Jergas and Genant, 1993).

Bone densitometry is useful in diagnosing osteoporosis, in predicting fractures and also in monitoring the patient's response to treatment.

Postmenopausal women lose bone at a rate of approximately 1-2% per year; therefore biennial scans are generally adequate (Amin, 2004). In patients who are likely to have increased bone loss (e.g glucocorticoid treatment), more frequent scans may be indicated. The examination procedure takes up to 10 minutes.

2.7 SOCIO-ECONOMIC aspects

The social burden of osteoporosis varies with the incidence of fractures. Fracture rates vary markedly in different countries, being highest in North America and Europe, particularly in Scandinavia

(Bacon, 1996). The risk of osteoporotic fractures is lower in Africa and Asia, but worldwide projections show that it will probably increase markedly in the future (Gullberg *et al.*, 1997). Approximately 10 million people are at risk of suffering from osteoporosis in South Africa (National Osteoporosis Foundation of South Africa, 2004).

Osteoporosis and the fractures associated with it constitute a major public health concern (Johnell, 1997). Hip fractures account for significant morbidity, disability, decreased quality of life and mortality. The adverse effects of vertebral and forearm fractures on most of the activities of daily living are also significant, although not as great as those of hip fracture. The cost of care is high and the implications for public health expenditure are serious. In both developed and developing countries, osteoporosis will become a major burden as the population ages.

Socio-economic evaluation of osteoporosis can be undertaken to estimate the cost of the disease, the effectiveness of treatments and the effects of strategies to identify patients at high risk, such as screening and case-finding, or to assess global strategies (World Health Organization, 2003). The costs of osteoporosis can be divided into direct (fracture-related) and indirect costs. The indirect costs depend on a number of assumptions, and in particular on the impact of working definitions of osteoporosis based on bone density threshold and on indices of vertebral fractures. The indirect costs of osteoporosis require further investigation. The costs of osteoporosis are considerable and are comparable with those of many other

chronic disorders in women, including breast cancer, arthritis, diabetes and chronic obstructive pulmonary disease. Hip fractures account for more than half of all direct costs.

The total cost of osteoporosis is difficult to calculate because it includes the costs of acute hospital care, loss of working days for family carers, long-term care and medication. Cost estimates are based on many assumptions, making cost comparisons between countries difficult, if not impossible (World Health Organization, 2003).

Up to 20% of victims of hip fracture die within 1 year and fewer than 50% ever regain the functional capability to lead an independent life. The cost of acute fracture care in the USA exceeded \$10 billion in 1990. Early intervention has been shown to reduce the rate of vertebral and hip fractures by 50-70% (World Health Organization, 2003).

Osteoporotic fractures in white, Asian and "mixed race" populations in this country are similar to those reported from North America and Europe. South African blacks, however, have the lowest hip fracture prevalence in the world. No data on the incidence of vertebral fractures in this country have been published and the cost of fracture care and also of selected screening has not been measured (National Osteoporosis Foundation of South Africa, 2004).

Hip fractures are a burden to both the individual and the community and only 50% of patients ever regain the mobility and independence they enjoyed 12 months before the hip fracture occurred (Hansen *et al.*, 1991). In 1997 Johnell predicted that the number of hip fractures worldwide is projected to increase from 1.7 million in 1990 to 6.3 million in 2050 because of the aging of the population; therefore, based on the currency values and a cost of \$21 000, 00 per patient the total cost of hip fractures by the year 2050 will be \$131.5 billion (Johnell, 1997).

The personal and social costs of osteoporosis and its complications in the Western world are enormous and will continue to rise if no measures are taken (Hansen *et al.*, 1991).

2.8 PREVENTION and TREATMENT

Ideally, osteoporosis is a condition that should be prevented from occurring, but this is unrealistic given our present state of knowledge and ability to influence it. At best building strong bones during childhood and adolescence can be the best defense against osteoporosis developing later.

Treating established osteoporosis is difficult, expensive and often disappointing (Canadian consensus on osteoporosis, 2003). It is therefore essential to be able to prevent the disease from developing or to treat the early stage of the disease before

fractures occur. Prevention could be accomplished by treating all women. But the drugs available for prevention of osteoporosis may have long-term adverse effects and are often expensive.

The goal of osteoporosis management must be to prevent fracture (Jaglal *et al.*, 2000).

To prevent osteoporotic fractures, individuals at risk of fractures must first be identified, and then the appropriate interventions to reduce this risk, such as life style modifications and hormone or other drug therapies, must be implemented (Jaglal *et al.*, 2000). Preventative measures aim to stimulate bone formation and to reduce excessive bone loss.

The following health style measures can help to maintain healthy bones (Amin, 2004):

- ◆ A balanced diet, rich in calcium and dairy products; calcium supplements;
- ◆ Regular exercise, preferably weight-bearing; Bone is living tissue and, like muscles, bones should be used regularly or they will deteriorate;
- ◆ Maintenance of eugonadism (in women until age 45-50 years);
- ◆ Cessation of smoking;
- ◆ Decrease in alcohol intake;
- ◆ The avoidance of bone toxic agents;
- ◆ Promotion of vitamin D supplementation and/or adequate time spent outdoors in the case of the elderly;

-
- ◆ Programs aimed at preventing falls among the elderly, and use of hip protectors in those at great risk of falls;
 - ◆ Calcium supplements.

Pharmacological interventions for which there is consistent evidence from randomized controlled trials of antifracture efficacy, include supplementation with calcium and vitamin D in the elderly, and treatment with bisphosphonates in postmenopausal women with osteoporosis (Amin, 2004). Selective estrogen receptor modulators also prevent vertebral fractures. In general, pharmacological interventions are expensive and may have adverse effects. To be most cost-effective, they should therefore be targeted at those at highest risk of fracture. Current ability to predict fractures means that intervention is possible before fracture has occurred. It is, however, never too late to intervene in patients with osteoporosis. Bone loss from glucocorticoid treatment can also be decreased if the patient uses calcium and vitamin D supplements (Amin, 2004).

Osteoporosis poses a problem to clinicians. On the one hand, when bone mass has decreased substantially and fractures occur, osteoporosis is easy to diagnose but difficult, if not impossible, to treat (Hansen *et al.*, 1991). Any substantial reduction in these costs depends on preventing fractures rather than improving the treatment of patients with fractures, and once bone mass has decreased to the point where fractures begin to occur, therapeutic options are limited. Generally accepted treatments for osteoporosis reduce bone resorption; however, these agents may maintain

existing bone mass but cannot increase it substantially. As a consequence, interest has shifted from treating patients with fractures to preventing fractures by preserving bone mass (Melton *et al.*, 1990).

Because most bone treatments do little more than prevent further bone loss, prevention of osteoporosis before it develops is clearly the desirable ideal (Nordin, 1994).

2.9 FUTURE IMPLICATIONS

Until recently, osteoporosis was an under-recognized disease and considered an inevitable consequence of aging (World Health Organization, 2003). Perceptions have changed, as epidemiological studies have highlighted the high burden of the disease and its costs to society and health care systems.

Osteoporosis affects an estimated 75 million people worldwide since both world population and life expectancy are increasing, and this figure is expected to increase by 310% in men and 240% in women by the year 2050 (International Osteoporosis Foundation, 2005).

Preventative strategy will therefore need to be developed and implemented. Family physicians can help with early diagnosis and intervention and should discuss lifestyle modification with patients (Khan, 2003).

In addition to education for physicians, an important theme is the need for patient education. A study by Tellier *et al* highlights the importance of educating patients as well as physicians to increase awareness (Tellier *et al.*, 2001).

Proper diagnosis and management of osteoporosis minimize injury and disability, improve quality of life for patients and reduce cost to society. Rationally targeted methods of screening and diagnosis are safe and cost effective. Harmful side effects and costs of recommended therapies are minimal compared to the harm and costs of untreated osteoporosis (Scientific Advisory Board, Osteoporosis Society of Canada, 1996).

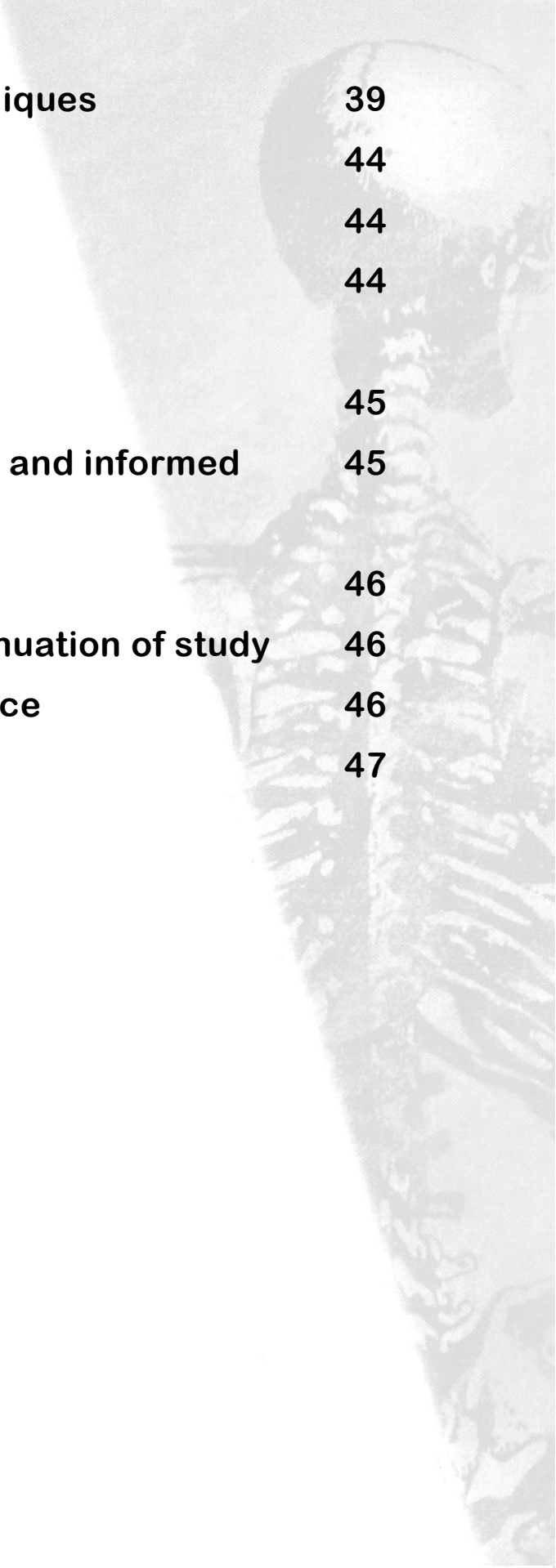
The availability of highly active anti-retroviral therapy to treat patients suffering from AIDS, and the metabolic side effects of this therapy, including its effects on bone, is becoming relevant, according to the National Osteoporosis Foundation of South Africa (National Osteoporosis Foundation of South Africa, 2003).



CHAPTER 3

METHODOLOGY

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3.1 STUDY DESIGN

This is an analytical study that examines the influence of a low BMD result on the treatment of patients classified with either osteopenia or osteoporosis.

3.2 STUDY SITE

The research study was conducted at Universitas Academic Hospital. All the patients were referred by physicians in Bloemfontein, except for 5 patients who were referred by General Practitioners from the rural areas of the Free State.

3.3 STUDY POPULATION

3.3.1 Number of subjects

A total of 50 patients were included. Patients were recruited between January 2004 and November 2004. Patients who complied with the inclusion criteria and also gave their consent (Appendix B) were enrolled.

3.3.2 Inclusion criteria

Patients were included in the study when classified as having osteopenia or osteoporosis according to the WHO criteria (Table 2.1, p18) and:

- ◆ Belonged to any population group
- ◆ Were aged between ages 18-80 years
- ◆ Were of either sex
- ◆ Had a telephone
- ◆ Were prepared to give consent

3.3.3 Exclusion criteria

- ◆ Refuse to participate
- ◆ Not classified as having either osteopenia or osteoporosis
- ◆ No telephone

3.3.4 Justification for inclusion and exclusion criteria

The patient had to give consent before they could be enrolled in the study. This was for ethical and confidential reasons.

To be representative the inclusion criteria included osteopenic or osteoporotic patients from any population group.

The patient had to have access to a telephone in order for us to contact him/her after the 2-month period.

3.3.5 Subject identification

For identification within the study, the patient files were numbered starting with 01. The numeric value was used for the study to ensure the confidentiality of the patient.

3.3.6 Withdrawal

Participation was voluntary and patients could withdraw from the project at any stage without any fear that it would be held against them.

3.3.7 Financial implications for patients

The financial implications were minimal, as the patients were already booked for a routine DEXA. The patients received no remuneration for their participation.

3.4 MEASUREMENT TECHNIQUES, APPARATUS AND FORMS

3.4.1 Pre-study screening

- ◆ Patients were booked for a routine DEXA scan.
- ◆ The nature of the research project was discussed with the patient.

-
- ♦ If the patient agreed on participation, a written consent was given (Appendix B).
 - ♦ The patient and his/her data were weighed against the inclusion and exclusion criteria.

3.4.2 Method of data collection and data analysis

After patient consent was obtained, he/she completed a questionnaire (Appendix A). Data on family history, medical history and lifestyle were obtained. After a 2-month period another questionnaire (Appendix C) was completed by telephone. This follow-up questionnaire collected information on the feedback received from the physician.

3.4.3 Apparatus

The gold standard for quantifying BMD is currently DEXA, which offers the advantages of precision and low radiation doses.

DEXA measures the transmission of X-rays of 2 different photon energies through the body, allowing for the measurement of bone and soft tissue mass (Jergas and Genant, 1993). It has a reported precision (reproducibility) in research studies of about 1.0 – 1.5% at the spine and about 3% at the proximal femur.

Bone scans were performed on the *HOLOGIC 4500 QDR*, a multiple detector, fan beam, Dual Energy X-ray Densitometer (Figure 3.1).

The *Hologic 4500 QDR* Bone Densitometer estimates the Bone Mineral Content (BMC) in grams, and the BMD in grams per cm². The QDR 4500 uses a low level of X-rays with two different energies to estimate BMC and BMD. The radiation exposure at a distance of two metres from the equipment is less than one mR/hour.

The two main components of the *HOLOGIC QDR 4500*, are ¹⁾ the Examination Table Unit (examination table with mattress; mechanical drives to move the table and C-arm; a safety switch, and an operator's control panel) and ²⁾ the C-arm (X-ray source and detector; mechanical drive to rotate C-arm; laser cross-hair indicator for patient positioning), as is illustrated in Figure 3.1.

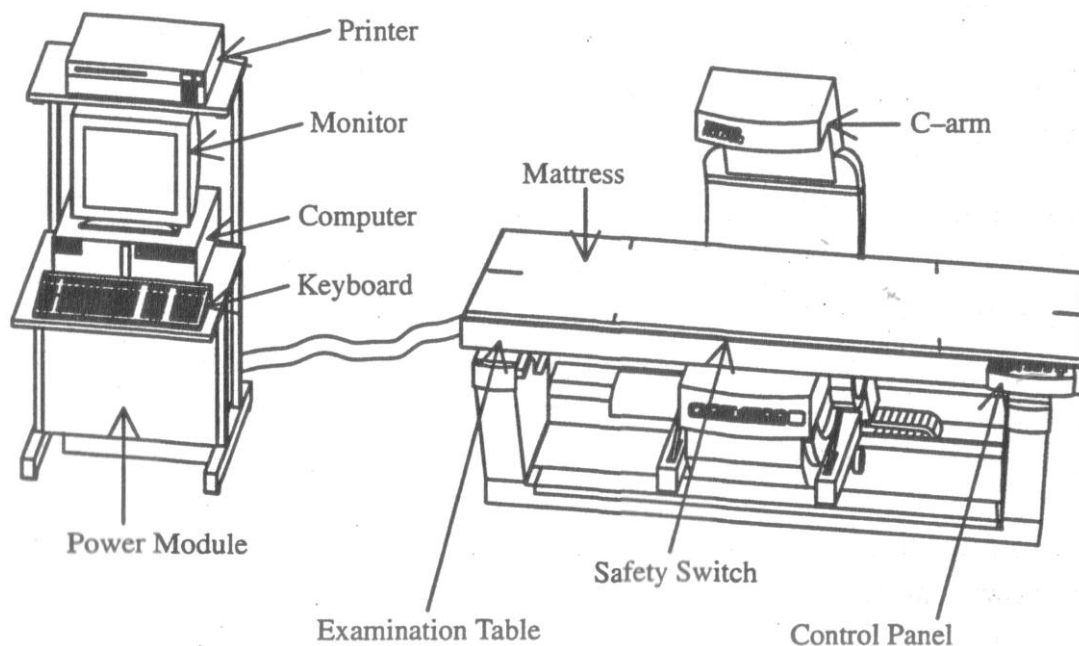


FIGURE 3.1 *Hologic QDR 4500 bone densitometer (Hologic Instructor's Manual, 1996).*

3.4.4 MEASUREMENT TECHNIQUES

Procedure

- ✦ All DEXA scans were performed on a *Hologic 4500QDR*, provided and maintained by *The Scientific Group*.
- ✦ After the patient's demographic data was entered into the computer, the test procedure was thoroughly explained to the patient.
- ✦ Before the patient got onto the examination table, all metal (snaps, zippers, belts, jewelry, buttons, etc.) in the scan area were removed.
- ✦ If the patient had had an X-ray exam with Contrast Medium or a Nuclear Medicine Isotope study within 7 days prior to the bone densitometry, the scan was postponed until seven days after the procedure had been done.
- ✦ If there was any chance that the patient might be pregnant, the scan was postponed until pregnancy was ruled out.
- ✦ Scans of the left or right hip and the lumbar spine were performed within a designated scan area on the examination table of a *Hologic 4500 QDR*.
- ✦ Special positioning aids for the spine and hip scan, aided in positioning of the patient, and also ensured consistent positioning for follow-up scans.

-
- ◆ DEXA uses X-rays to assess bone mineral density, however, under standard operating conditions; the entrance dose to the patient is less than 35 mR, which is approximately the same exposure as a standard chest X-ray.
 - ◆ After the necessary explanation and preparation, the patient was positioned on the bed (Figure 3.2), with the help of positioning aids and a laser beam guide.
 - ◆ The C-arm was positioned correctly over the region of interest (e.g., Hip or Lumbar Spine) before the scanning procedure could begin.
 - ◆ The estimated time for both scans was 10 minutes.
 - ◆ The procedure itself is painless with no discomfort for the patient, except for lying motionless for the period of the scan.
 - ◆ Each patient received a standard scan procedure that consisted of both the spine and the left or right hip (see Figures 3.3 and 3.4).

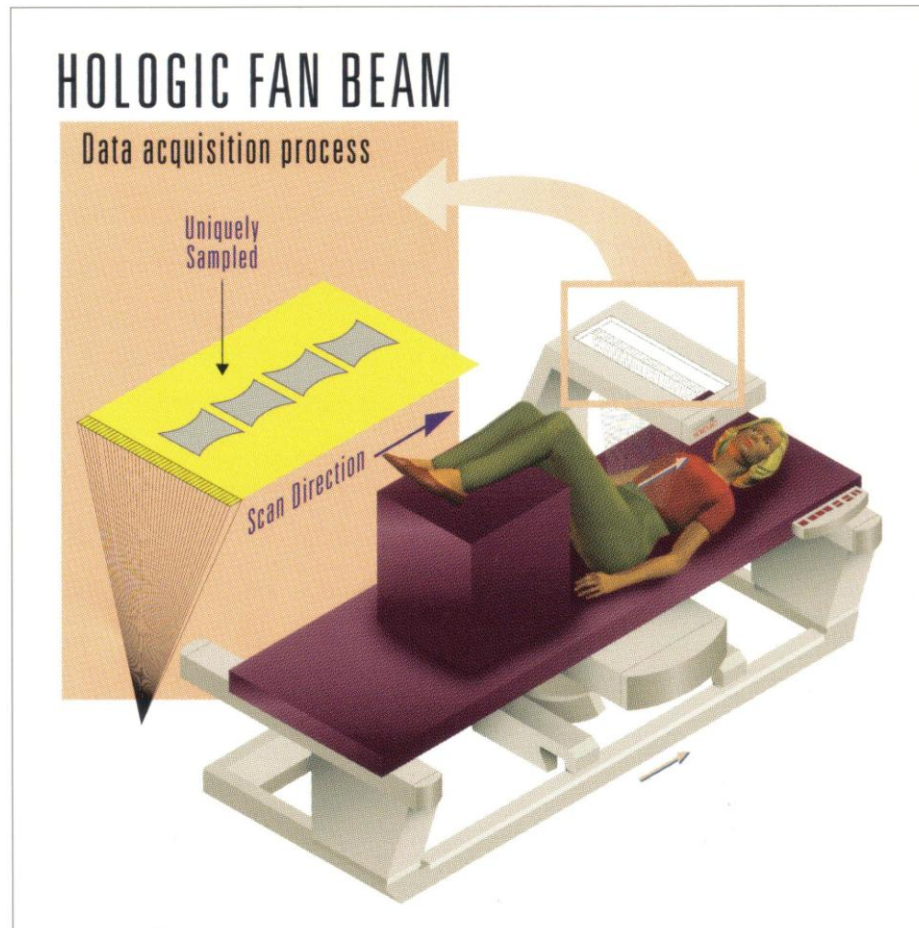


FIGURE 3.2 *Patient positioning during scan procedure (Hologic Instructor's Manual, 1996).*

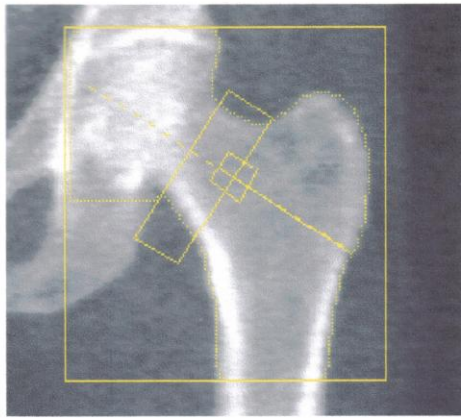


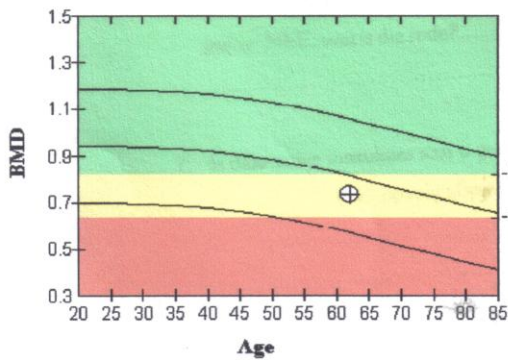
Image not for diagnostic use
Total BMD CV 1.0%

DXA Scan Information:

Scan: 05/20/2004 - A0520040D
 Scan Mode: Fast Array
 Analysis: 05/20/2004 10:25 - Ver 8.26
 Operator: ER
 Model: Hologic QDR-4500C (S/N 47752)
 Comment: baseline

Results Summary:

Total[L] BMD:	0.735 g/cm²						
Peak reference:	78%		T score:	-1.7			
Age matched:	91%		Z score:	-0.6			
Region	Area [cm ²]	BMC [g]	BMD [g/cm ²]	T score	%PR	Z score	%AM
Neck:	4.85	3.31	0.682	-1.5	80%	-0.1	98%
Troch:	11.13	6.27	0.563	-1.4	80%	-0.4	93%
Inter:	15.93	13.88	0.871	-1.5	79%	-0.6	90%
Total	31.91	23.46	0.735	-1.7	78%	-0.6	91%
Ward's:	1.08	0.51	0.469	-2.3	64%	-0.1	97%



Reference Curve: NHA 1 February 97
Age and Sex Matched

Fracture Risk **WHO Classification***

Not Increased Normal
 Increased Osteopenia
 High Osteoporosis

* WHO 1994



FIGURE 3.3 Example of analysed left hip

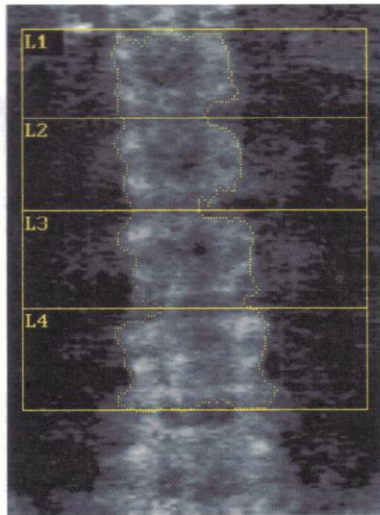


Image not for diagnostic use
Total BMD CV 1.0%

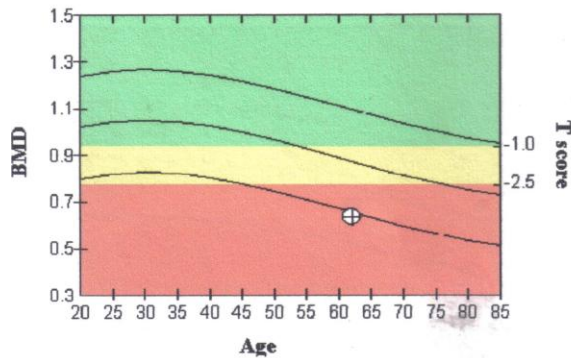
DXA Scan Information:

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 Scan Mode: Fast Array
 Analysis: 05/20/2004 10:21 - Ver 8.26
 Operator: ER
 Model: Hologic QDR-4500C (S/N 47752)
 Comment: baseline

Region	Area [cm ²]	BMC [g]	BMD [g/cm ²]
L1	10.81	5.40	0.499
L2	11.49	6.45	0.562
L3	13.45	7.72	0.574
L4	16.22	13.51	0.833
Total	51.97	33.08	0.637

Results Summary:

Total BMD:	0.637 g/cm ²		
Peak reference:	61%	T score:	-3.7
Age matched:	73%	Z score:	-2.1



Reference Curve: TK 4 November 91
Age and Sex Matched

Fracture Risk	WHO Classification*
Not Increased	Normal
Increased	Osteopenia
High	Osteoporosis

* WHO 1994



FIGURE 3.4 Example of analysed lumbar spine

3.4.5 Quality control

Quality control is performed daily on the *Hologic 4500 QDR* according to the manufacturer's specifications. This is to verify that the *Hologic 4500 QDR* is performing properly and also to ensure accuracy and reliability.

3.4.6 Data sheet

Data of analyzed BMD scans were entered on a patient data sheet before the processing thereof (Appendix D).

3.5 STATISTICAL ANALYSIS

Data were processed, interpreted and sent back to the referring physician. Data from patients that were classified as either osteopenic or osteoporotic, according to the results obtained from the Bone Densitometry, were used.

Bone Density values are expressed in relation to reference data as standard deviation scores: a Z-score representing the number of standard deviations above or below the age and sex matched mean reference value, and a T-score similarly expressed in relation to reference values for young adults (Compston *et al.*, 1995).

Osteopenia is defined as a T-score between -1 and -2.5 and may constitute an indication for prophylaxis, depending on the age of the woman and the risks and benefits of the proposed treatment.

Osteoporosis is defined as a T-score below -2.5 and includes nearly all women who will sustain a fragility fracture. It can be regarded as an absolute indication for intervention.

A statistical analyst from the Department of Biostatistics, University of the Free State, was consulted for assistance with the processing of data.

3.6 ETHICS

3.6.1 Ethical approval

The study protocol and the informed consent used in the study were submitted to the Ethical Committee of the University of the Free State and approval was obtained prior to the start of the study (ETOVS NR 121/03).

3.6.2 Subject information and informed consent

All the patients were informed at the time of the DEXA about the purpose of the research project, after which they signed the informed consent form (Appendix B). Both the information and the consent form were available in English, Afrikaans and South-Sotho.

3.6.3 Safety variables

The study posed no hazard to the participants and as the patients were referred for a routine Bone Densitometry, the study itself had no adverse effects on the patient.

3.6.4 Premature Discontinuation of study

It did not become necessary to discontinue the study prematurely and at no stage during the course of the research did the researcher or the study leaders feel that any patient's confidentiality was compromised or that any unethical procedures had occurred.

3.6.5 Good Clinical Practice (GCP)/Quality assurance

All the clinical work conducted under this protocol was subjected to GCP guidelines.

The declaration of Helsinki's basic principle number 3 states that research should be conducted only by scientifically qualified people and under the supervision of adequately qualified people.

The study was conducted in accordance with the good clinical practice guidelines (GCP) and the declaration of Helsinki (World Medical Association Declaration of Helsinki, 2002).

3.6.6 Confidentiality

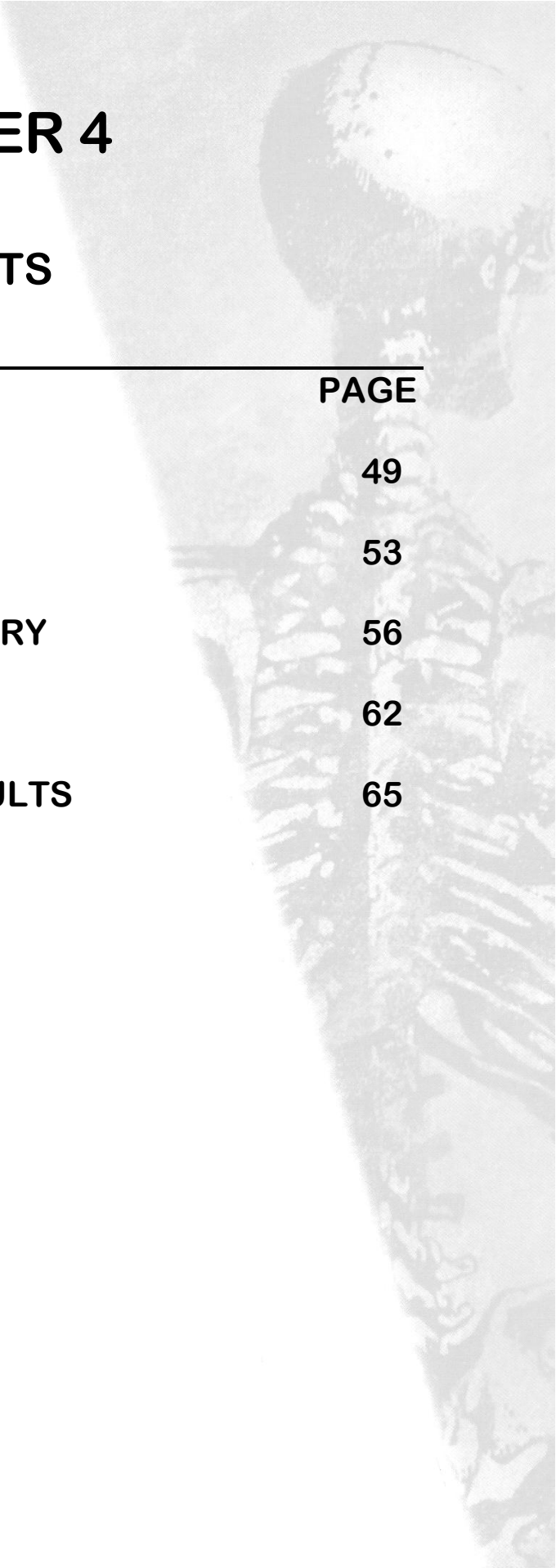
The confidentiality of this study was of utmost importance and at no time during the research was any of the patients' identification made known to any people other than those to whom the patient had given his/her consent.



CHAPTER 4

RESULTS

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4.1 **GENERAL**

A total of 50 patients was included in the research project after the exclusion and inclusion criteria had been met. Only patients who were classified as having osteopenia or osteoporosis, according to the WHO criteria (Table 2.1, p18), were included in the study. This study adhered to these classifications.

During the initial planning of this study 200 patients were planned for, however, due to staff shortage and extra workload, only 50 patients were recruited for the study. Patients were referred by Universitas Academic Hospital as well as by other points of care (Figure 4.1).

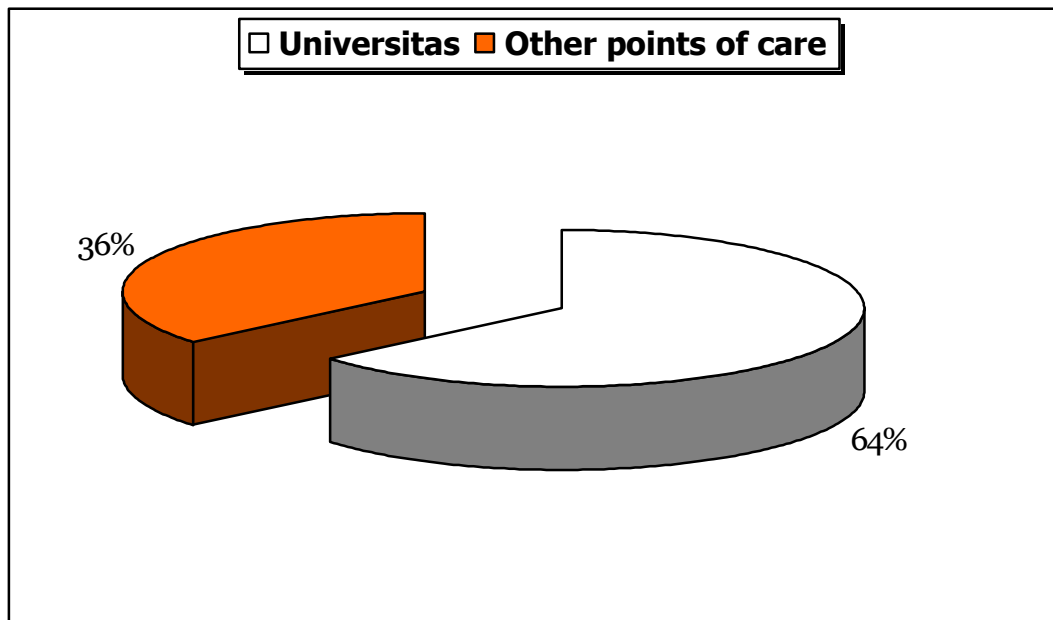


FIGURE 4.1 *Proportion of patients referred from UAH and other points of care.*

The data used in this study were collected from January 2004 up to November 2004. Physicians from Universitas Academic Hospital (UAH) referred 32 patients (64%) and 18 patients (36%) were referred from other points of care (Figure 4.1). All the patients were referred by physicians in Bloemfontein, except for 5 patients who were referred by general practitioners from the rural areas of the Free State. The distribution from the other points of care can be seen in Figure 4.2.

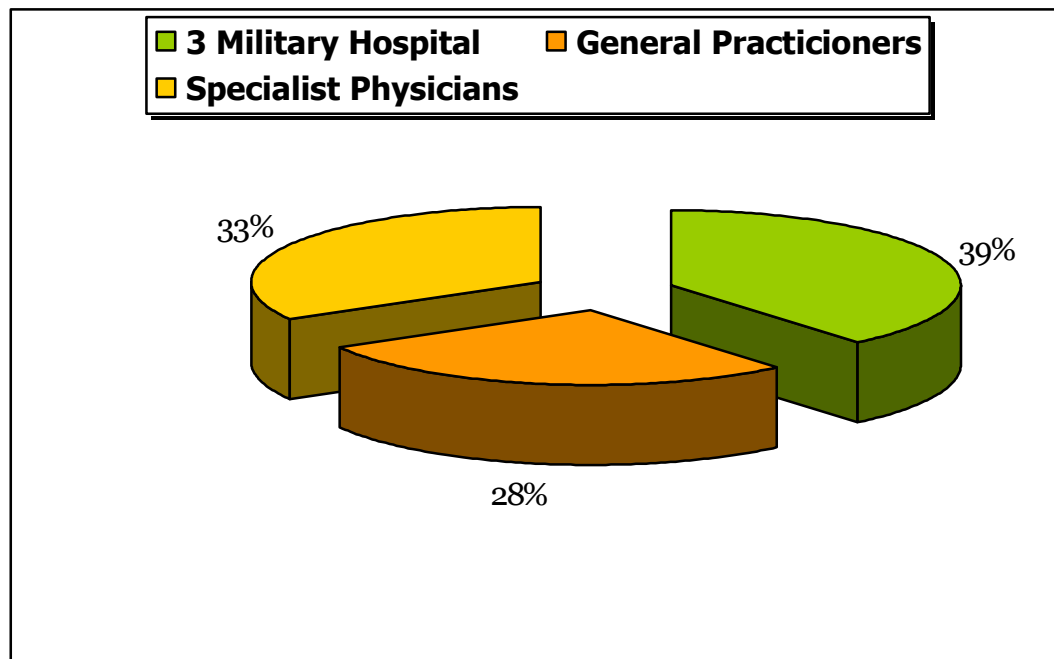


FIGURE 4.2 *Source of patients referred for BMD measurements from other points of care.*

From UAH most patients were referred by the Endocrinology Clinic (Figure 4.3).

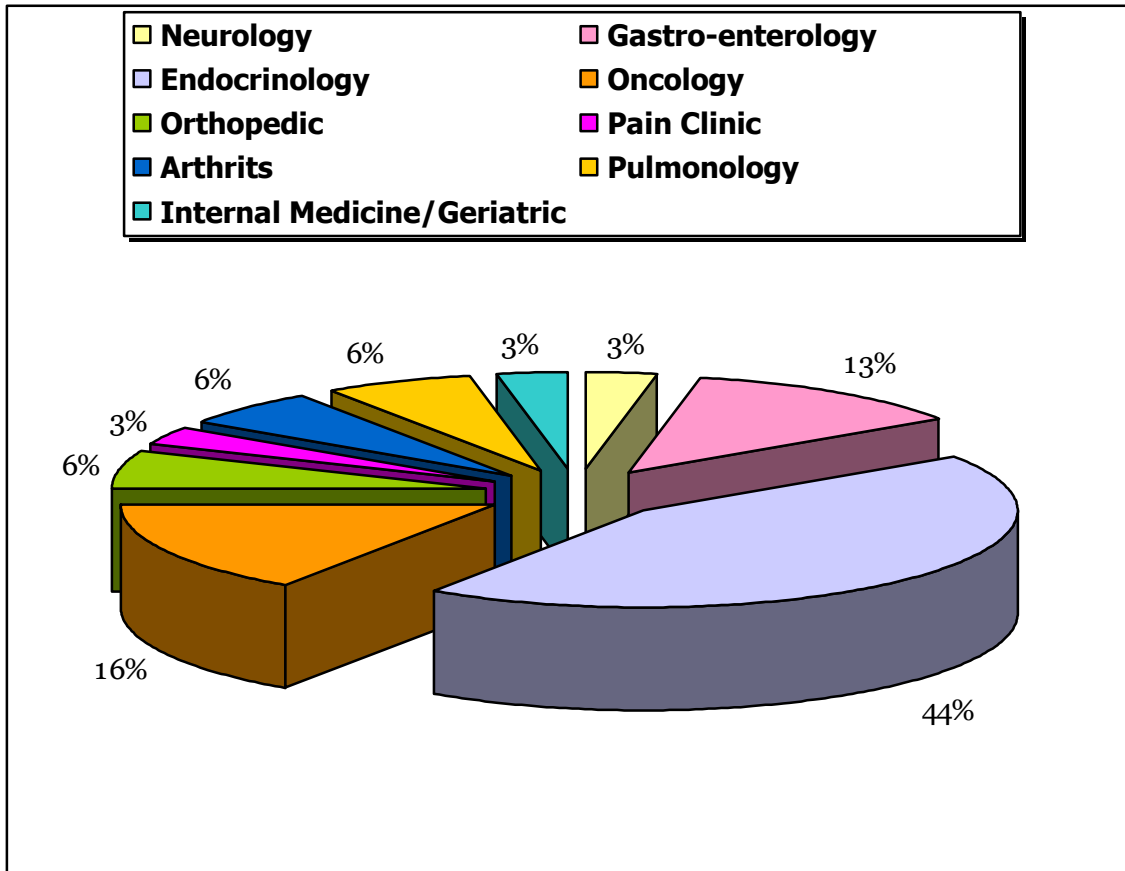


FIGURE 4.3 *Source of referral of patients for BMD measurements from UAH.*

Indications for the referral of the patients for a DEXA scan were very vague and differ greatly. In Table 4.1 the various indications for a DEXA scan, are summarized.

TABLE 4.1 *Summary of the indications for DEXA as on the request forms.*

INDICATION	Number of patients
Routine examination	20(40%)
? Osteoporosis	10(20%)
X-rays show osteoporosis	4(8%)
Patient on cancer treatment	4(8%)
Just ask for DEXA	2(4%)
Back pain	4(8%)
Family history	2(4%)
Pains in hips and knees	1(2%)
Previous fracture	1(2%)
Glucocorticoids use	2(4%)

4.2 PATIENT POPULATION

Forty-nine of the patients in the study population were female (Table 4.2, p50). Their ages ranged between 14 – 86 years of age (average age was 57,2 years). Most patients were between 40 and 70 years old. A small number (8%) of the patients were under the age of 40 years. Ten patients (20%) were between 40 and 50 years; fifteen patients (30%) between 50 and 60, and eleven patients (22%) above 60 years (Figure 4.4).

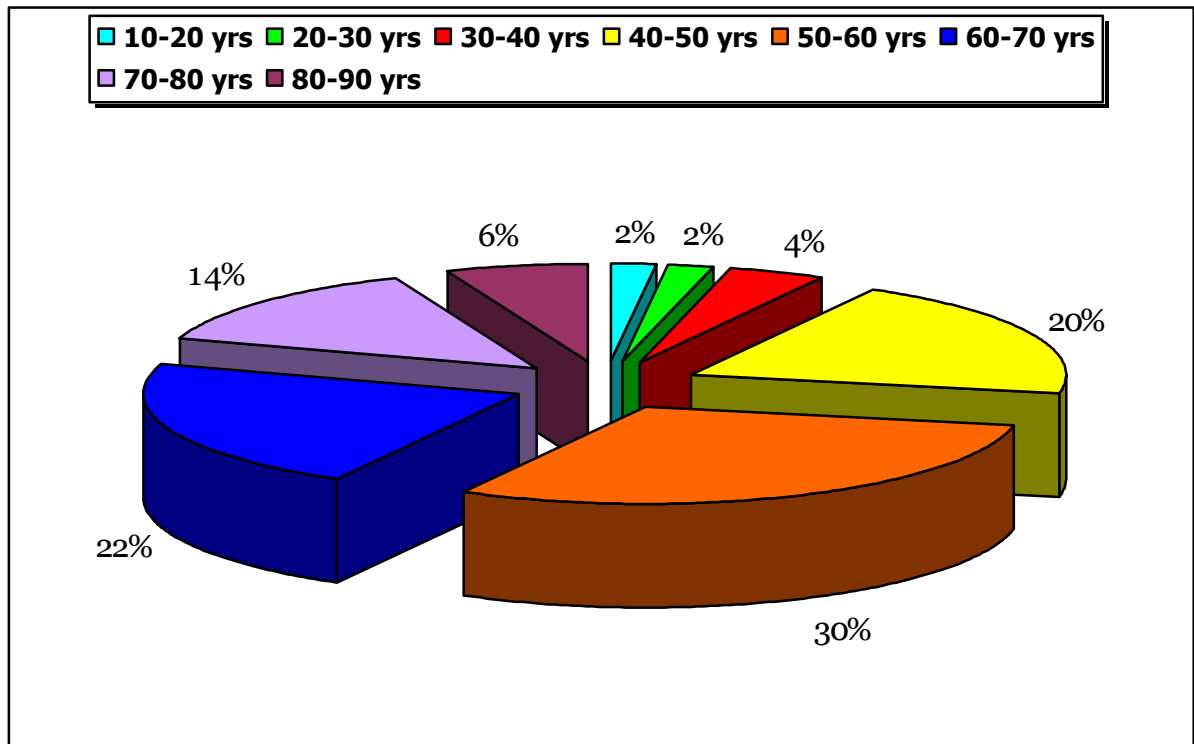


FIGURE 4.4 *Age distribution of study population.*

TABLE 4.2 Summary of patient data. (F-Female; M-Male; BMI-Body Mass Index; SD-standard deviation)

PATIENT NUMBER	GENDER	AGE	Weight (kg)	Height (cm)	BMI	RESULTS
1	F	29	47	156	19	OSTEOPENIA
2	F	61	45	159	18	OSTEOPOROSIS
3	F	48	50	157	20	OSTEOPOROSIS
4	F	78	50	148	23	OSTEOPOROSIS
5	F	47	75	176	24	OSTEOPENIA
6	F	81	88	157	36	OSTEOPENIA
7	F	86	53	162	20	OSTEOPOROSIS
8	F	57	72	162	27	OSTEOPENIA
9	F	79	74	165	27	OSTEOPENIA
10	F	35	55	169	19	OSTEOPENIA
11	F	62	43	150	19	OSTEOPOROSIS
12	F	41	73	162	28	OSTEOPENIA
13	F	56	52	152	23	OSTEOPOROSIS
14	F	58	62	165	23	OSTEOPOROSIS
15	F	62	80	160	31	OSTEOPOROSIS
16	F	69	88	157	36	OSTEOPENIA
17	F	48	79	165	29	OSTEOPENIA
18	F	55	67	160	26	OSTEOPENIA
19	F	64	59	155	25	OSTEOPENIA
20	F	47	72	160	28	OSTEOPENIA
21	F	73	56	159	22	OSTEOPENIA
22	F	31	64	172	21	OSTEOPOROSIS
23	F	70	56	149	25	OSTEOPENIA
24	F	50	59	166	21	OSTEOPOROSIS
25	F	41	86	160	34	OSTEOPENIA
26	F	66	55	164	20	OSTEOPENIA
27	F	42	64	172	21	OSTEOPENIA
28	F	49	44	158	18	OSTEOPOROSIS
29	F	65	96	160	38	OSTEOPOROSIS
30	F	56	68	169	24	OSTEOPOROSIS
31	F	48	57	160	22	OSTEOPENIA
32	F	14	48	162	18	OSTEOPOROSIS
33	F	66	84	158	34	OSTEOPENIA
34	F	56	65	166	24	OSTEOPENIA
35	F	70	71	161	27	OSTEOPENIA
36	F	50	64	152	28	OSTEOPOROSIS
37	F	76	66	159	26	OSTEOPOROSIS
38	F	58	70	152	30	OSTEOPENIA
39	F	63	82	165	30	OSTEOPENIA
40	F	41	61	165	22	OSTEOPENIA
41	F	54	52	154	22	OSTEOPENIA
42	F	53	50	170	17	OSTEOPOROSIS
43	F	58	68	165	25	OSTEOPENIA
44	F	59	90	159	36	OSTEOPENIA
45	F	61	65	162	25	OSTEOPENIA
46	F	54	97	172	32	OSTEOPENIA
47	M	53	78	171	27	OSTEOPENIA
48	F	77	70	153	30	OSTEOPENIA
49	F	62	52	153	22	OSTEOPOROSIS
50	F	81	55	158	22	OSTEOPOROSIS
AVERAGE (n=50)		57.2	65.5	161		
SD			14	6		

Table 4.2 also shows the clinical characteristics and demographic data of the study population. This includes the height, weight and Body Mass Index.

The Body Mass Index (BMI) for each patient was calculated using the following formula, and classified according to Table 4.3:

$$\text{BMI} = \text{weight (kg)} / \text{height}^2(\text{m})$$

TABLE 4.3 *The following classification of BMI was used in the study (WHO, 2000).*

Underweight	A value less than 17.9
Normal	A value of 18 to 25
Overweight	A value of 25.1 – 29.9
Obese (moderate)	A value of 30-40
Obese (severe)	A value more than 40

Thirty(60%) patients of the study population had a normal BMI, and of these, 15(50%) were osteopenic and 15(50%) osteoporotic (Table 4.2).

Nine(18%) patients were classified as being overweight according to their BMI, and of these, 7(78%) were osteopenic and 2(22%) osteoporotic(Table 4.2).

Eleven (22%) patients were moderately obese, and of these 9(82%) were osteopenic and 2(18%) osteoporotic(Table 4.2).

Only 1 patient was underweight according to her BMI and her BMD was in the osteoporotic range (Table 4.2).

4.3 **PATIENT MEDICAL HISTORY**

Illustrated in Table 4.4 are the more relevant medical conditions that may pose a risk for osteoporosis in the study population.

TABLE 4.4 *Risk factors for osteoporosis in study population*









RISK FACTOR	NUMBER of PATIENTS
Glucocorticoid use (more than 6 months)	8(16%)  3 osteopenia 5 osteoporosis
Hormone replacement therapy	18(37%)  13 osteopenia 5 osteoporosis
Hypothyroidism	17(34%)  13 osteopenia 4 osteoporosis
Rheumatoid arthritis	14(30%)  9 osteopenia 5 osteoporosis
Hysterectomy	37(76%)  22 osteopenia 15 osteoporosis
Diabetes	4(8%)  2 osteopenia 2 osteoporosis
Early menopause (<45 years)	17(34%)  15 osteopenia 2 osteoporosis
Smoking history	18(37%)  13 osteopenia 5 osteoporosis

TABLE 4.4 (continued)

Family history of fractures	5(10%)	
≤30 minutes sun exposure	13(26%)	
GIT disturbances*	13(26%)	
Chronic liver disease	2(4%)	
Cancer (4 breast, 1 ovarian)	5(10%)	
Amenorrhoea (>3 months)	3(6%)	

* The GIT disturbances include spastic colon, ulcerative colitis, gastritis and Cohn's disease.
GIT = Gastro-intestinal tract.

When looking at the number of risk factors (Table 4.4) for each patient; 8% of the total patient population had only one risk factor. Table 4.5 illustrates that the biggest percentage of patients had two risk factors.

TABLE 4.5 Number of risk factors in study population

NUMBER OF RISK FACTORS PER PATIENT	NUMBER OF PATIENTS
1	4(8%)
2	18(36%)
3	14(28%)
4 or more	14(28%)

When looking at the physical activity of the study population (Figure 4.5), the following was observed:

- ◆ Twenty-six (52%) of the patients reported levels of physical activity of less than 30 minutes of brisk walking per day.
- ◆ Twenty-four (48%) patients had physical activity levels of more than 30 minutes of brisk walking per day.

The dairy intake of the study population (Figure 4.6) in general, showed the following:

- ◆ Four (8%) of the patients reported no dairy intake.
- ◆ Thirteen (26%) patients' dairy intake was less than 250 ml milk per day as they only used milk in their coffee or tea.
- ◆ Thirty-three (66%) patients' had a dairy intake of 250 ml or more per day in the form of cheese, yoghurt and/or milk

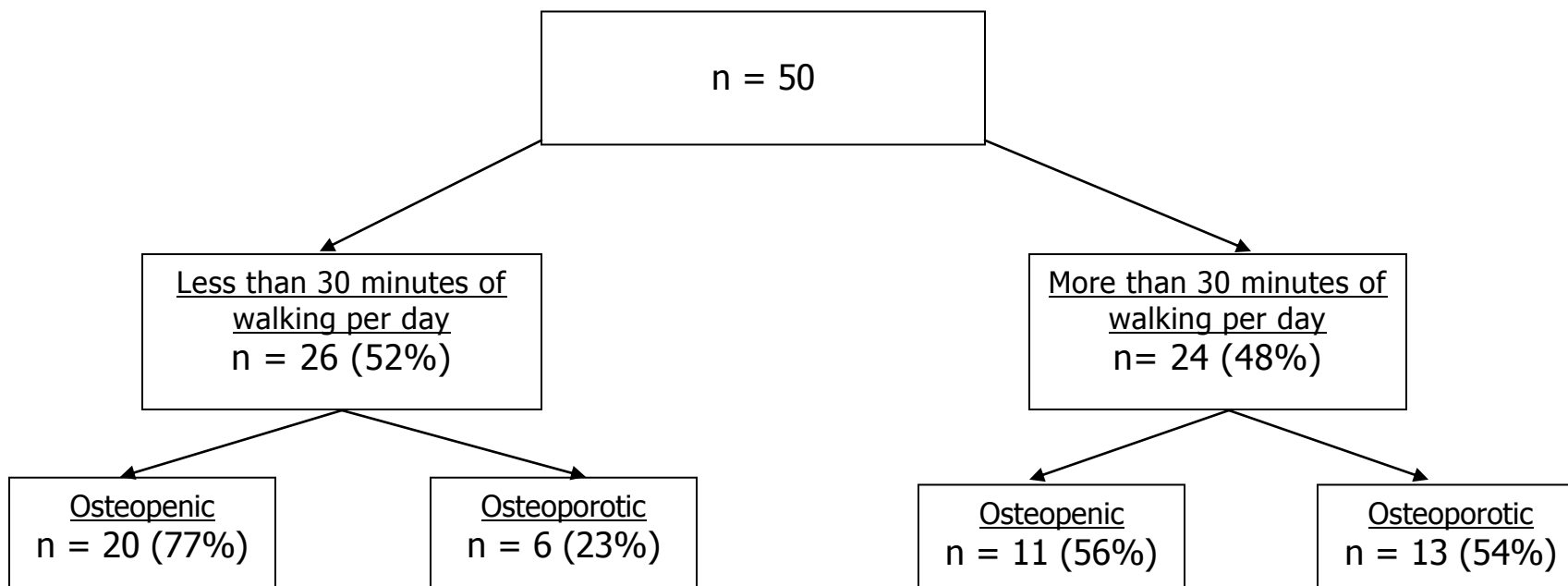


FIGURE 4.5 *Patients characterized according to levels of physical activity*

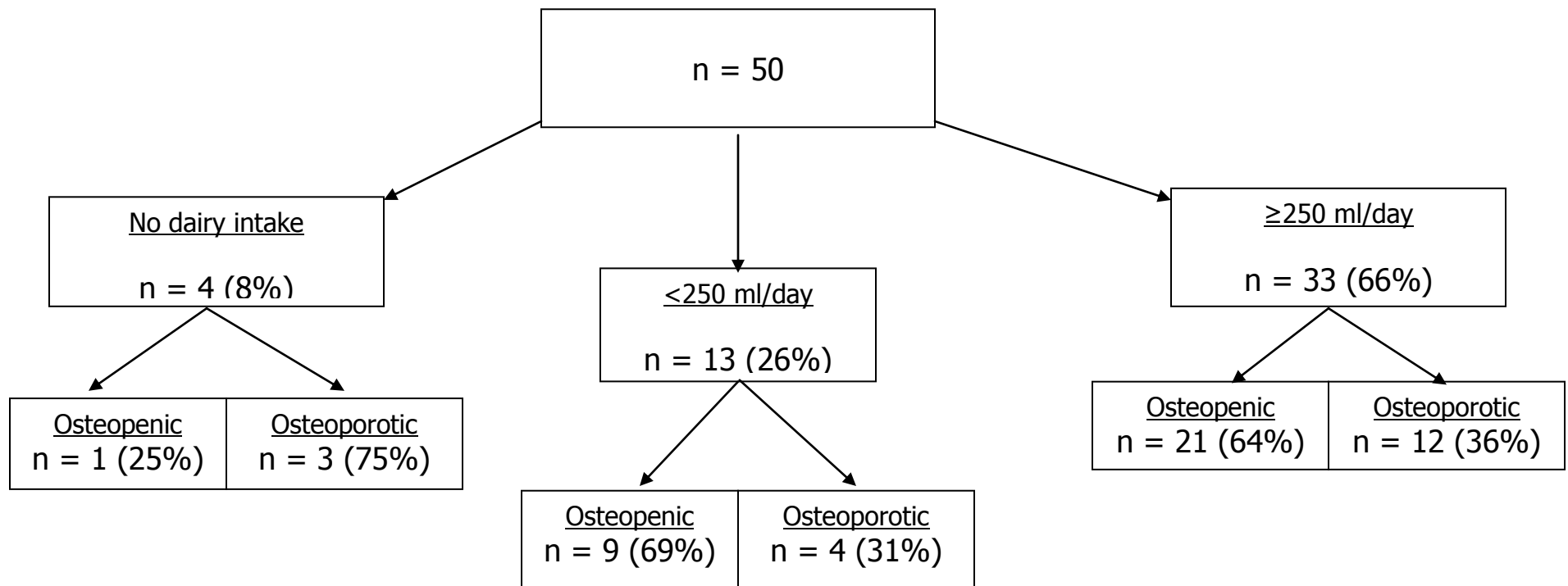


FIGURE 4.6 *Patients characterized according to intake of dairy products*

4.4 **BMD RESULTS**

Out of the 50 patients who had a DEXA scan performed, 31 (62%) patients were osteopenic and 19 (38%) had osteoporosis (Figure 4.7).

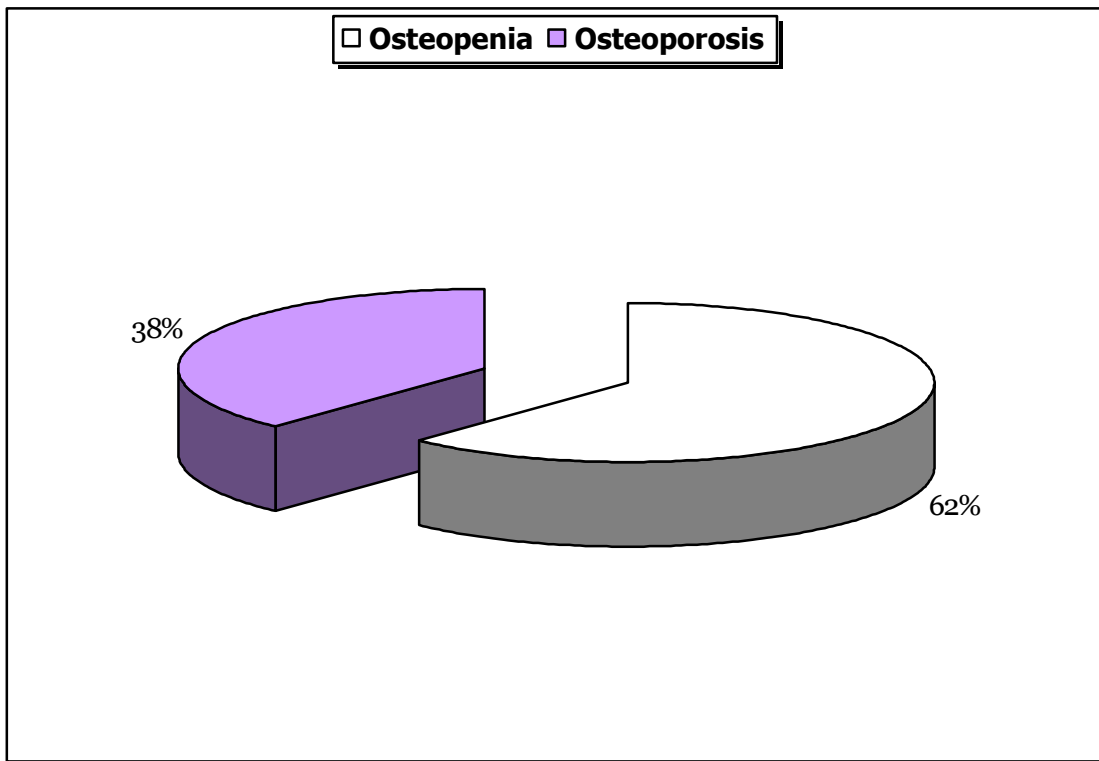


FIGURE 4.7 *Proportion of patients with BMD in the osteopenic range compared to those in the osteoporotic range.*

Patients were classified according to their T-score (Table 4.6) whether they were osteopenic or osteoporotic. This shows the following:

- ◆ Of the thirty-two(64%) patients referred from UAH, 17(53%) and 15(47%) patients had a BMD in the osteopenic and osteoporotic ranges, respectively.
- ◆ Of the 18(36%) patients referred from other points of care, 14(78%) were osteopenic and 4(22%) osteoporotic.

The final BMD results are explained in Figure 4.8.

TABLE 4.6 *T-score and Z-score of individual patients.*

PATIENT nr	T-SCORE		Z-SCORE		RESULTS
	Hip	Lumbar	Hip	Lumbar	
1	-0.6	-2.2	-0.6	-2.2	OSTEOPENIA
2	-2.2	-2.5	-1.2	-1.0	OSTEOPOROSIS
3	-3.3	-4.1	-2.9	-3.4	OSTEOPOROSIS
4	-2.6	-3.5	-0.6	-0.9	OSTEOPOROSIS
5	-0.9	-1.3	0.7	-0.1	OSTEOPENIA
6	0.8	-1.9	0.8	1.2	OSTEOPENIA
7	-2.9	-2.8	N/A	N/A	OSTEOPOROSIS
8	-2.1	-2.4	-0.1	-1.2	OSTEOPENIA
9	-2.1	-1.6	0.0	1.1	OSTEOPENIA
10	-2.2	-2.1	-2.1	-2.0	OSTEOPENIA
11	-2.9	-3.3	-1.8	-1.8	OSTEOPOROSIS
12	-1.9	-1.5	-1.7	-1.2	OSTEOPENIA
13	-3.9	-4.5	-3.1	-3.3	OSTEOPOROSIS
14	-2.2	-3.1	-2.1	-1.8	OSTEOPOROSIS
15	-1.7	-3.7	-0.6	-2.1	OSTEOPOROSIS
16	-0.9	-1.6	0.6	0.5	OSTEOPENIA
17	-1.6	-1.3	-1.2	-0.6	OSTEOPENIA
18	0.4	-1.5	1.1	-0.4	OSTEOPENIA
19	-2.4	-1.4	-1.2	0.3	OSTEOPENIA
20	-1.1	-1.0	-0.7	-0.4	OSTEOPENIA
21	-1.8	-1.0	-0.1	1.2	OSTEOPENIA
22	-2.3	-3.3	-1.4	-1.8	OSTEOPOROSIS
23	-1.2	-2.1	0.3	0.1	OSTEOPENIA
24	-2.8	-2.1	-2.3	-1.4	OSTEOPOROSIS
25	-0.4	-1.6	-0.2	-1.3	OSTEOPENIA
26	-2.2	-1.6	-0.9	0.3	OSTEOPENIA
27	-1.0	-0.8	-0.8	-0.4	OSTEOPENIA
28	-2.0	-2.9	-1.5	-2.2	OSTEOPOROSIS
29	0.4	-2.5	1.7	-0.7	OSTEOPOROSIS
30	-1.4	-3.2	-1.4	-2.0	OSTEOPOROSIS
31	-1.4	-1.1	-1.0	-1.0	OSTEOPENIA
32	-3.5	-3.7	N/A	-2.6	OSTEOPOROSIS
33	-0.9	-2.2	0.4	-0.3	OSTEOPENIA
34	-2.1	-1.2	-1.3	-0.1	OSTEOPENIA
35	-1.4	-1.4	0.1	0.1	OSTEOPENIA
36	-2.2	-2.6	-1.7	-1.8	OSTEOPOROSIS
37	-1.5	-3.0	-0.2	-0.5	OSTEOPOROSIS
38	0.0	-1.2	0.8	0.1	OSTEOPENIA
39	-1.9	-2.3	-0.8	-0.6	OSTEOPENIA
40	-1.1	-1.1	-0.9	-0.8	OSTEOPENIA
41	-2.0	-2.4	-1.3	-1.4	OSTEOPENIA
42	-2.8	-2.2	-2.1	-1.2	OSTEOPOROSIS
43	-0.6	-1.3	0.3	0.1	OSTEOPENIA
44	-1.0	-2.1	0.0	-0.7	OSTEOPENIA
45	-1.5	-1.3	-0.7	-0.5	OSTEOPENIA
46	-1.1	-2.4	-0.4	-1.3	OSTEOPENIA
47	-0.2	-1.7	0.2	-1.2	OSTEOPENIA
48	-1.9	-0.3	0.0	2.2	OSTEOPENIA
49	-2.6	-2.9	-1.5	-1.3	OSTEOPOROSIS
50	-3.2	-3.5	-1.1	-0.8	OSTEOPOROSIS

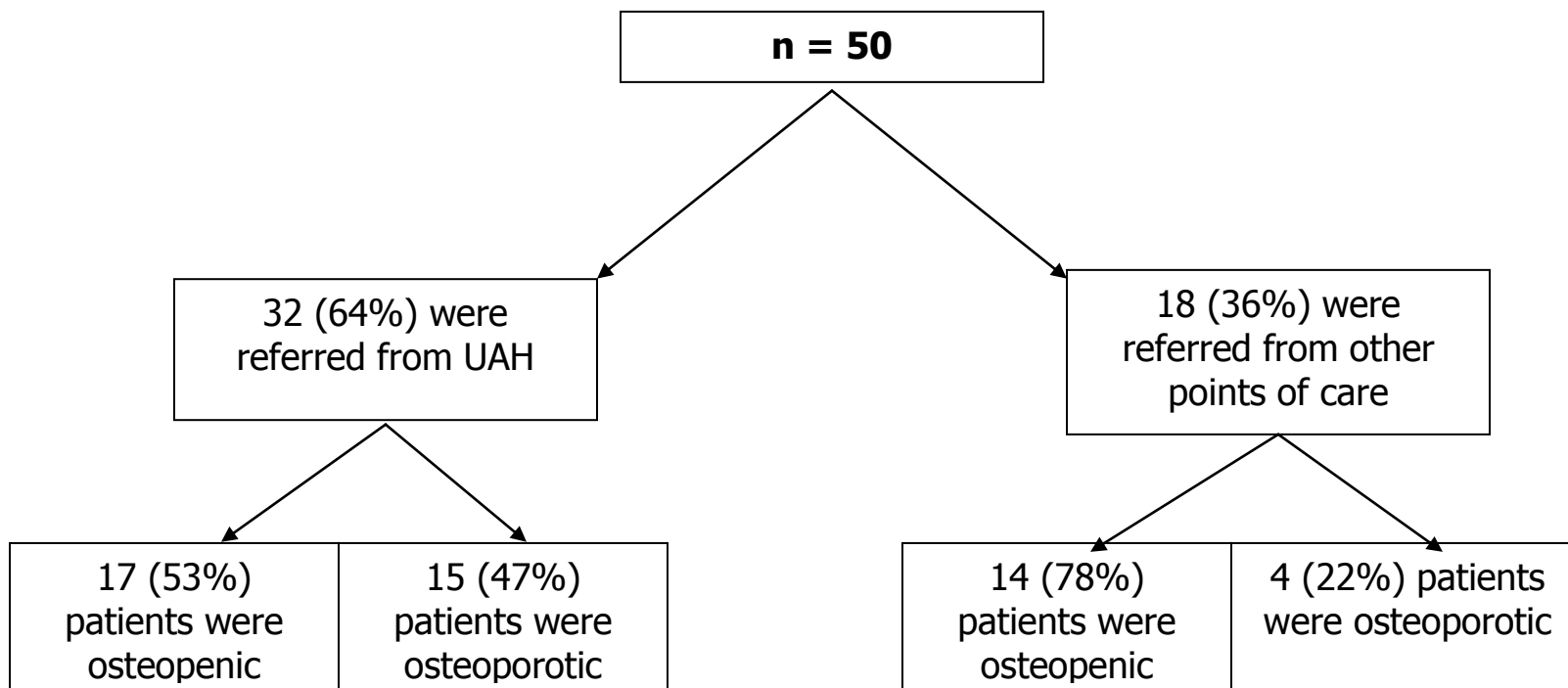


FIGURE 4.8 *Patients classified according to BMD status.*

4.5 FEEDBACK OF BMD RESULTS

Of the 50 patients who had a DEXA scan, only 39(78%) patients received feedback from their physician. The remaining 11(22%) patients had not received feedback two months after the BMD scan was performed. Of these eleven patients, four patients had a BMD in the osteoporotic range (Table 4.7).

After their results was discussed with them, 41% of the patients made changes in their lifestyle (increased exercise level) and 21% increased their dairy intake.

Thirty-one (79%) patients did receive medication as intervention. Two patients did not used their prescribed medication

TABLE 4.7 *Characteristics of patients according to feedback status.*

	Patients who received feedback n = 39 (78%)	Patients who did not receive feedback n = 11(22%)
Referred from UAH	29(91%)	3(9%)
Referred outside UAH	10(56%)	8(44%)
BMD in osteopenic range	24(62%)	7(64%)
BMD in osteoporotic range	15(38%)	4(36%)
Patients offered medication as intervention	31(79%)	
Patients offered no medication	8(21%)	
<u>Lifestyle changes:</u>		
↑Physical activity	16(41%)	
↑Dairy intake	8(21%)	
Medication prescribed but not using it	2(5%)	



CHAPTER 5

DISCUSSION

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5.1 INTRODUCTION

The aim of the study was to examine communication between referring physicians and patients who had been referred for a DEXA scan.

Osteoporosis is a progressive skeletal disease and it causes a reduction in bone mass and the consequent risk of a fracture and is one of the most destructive diseases in the world.

In South Africa osteoporosis is not regarded as a health priority due to malnutrition and infections such as HIV/AIDS and tuberculosis. Access to treatment and care is also a problem for most of the population, and in State Hospitals the availability of drugs to treat osteoporosis is limited due to the high costs (National Osteoporosis Foundation of South Africa, 2003).

Nevertheless, osteoporosis remains a disease for which prevention is much better than treatment (Drife, 1990) and identifying individuals at risk of fracture is a strategy that must be put into practice. Ultimately it will be more cost effective than the treatment itself.

Interest in osteoporosis has increased, but unfortunately, ignorance of this disease is still common among health professionals, patients and the public. The family physician plays an important role in the prevention of osteoporotic fractures.

The implementation of educational programs on osteoporosis can prove beneficial to both the patient and the physician.

5.2 DISCUSSION

A total of fifty patients was included in the study group. This was much smaller than was anticipated but due to staff shortages and the inclusion/exclusion criteria, it was just not feasible. Not all the patients referred for a DEXA scan had the required low BMD. The ideal would have been a much bigger sample group for a bigger representation of the population (Table 4.2).

The age distribution of the study group (Figure 4.4) ranged between 14 and 84 years (average age was 57,2 years). In spite of the small sampling size the study population's ages were representative of most of the age groups. Most patients (25, 50 %) were between 40 and 60 years of age. Twenty-one patients (42 %) were above 60 years of age. This can be a coincidence or as was noted in a study done by Jaglal *et al.* in 2003, it could be that elderly women were less likely to be referred for DEXA. Fifty-two percent of their patients were between 45 and 64 years old while only 28% were 65 and older. The age group distribution correlates well with the data collected for this study.

Also pointed out in the study was that, out of the total of 50 patients, only one was male (Table 4.2).

This can be due to the small patient sample or can support the notion that the majority of patients with low BMD are women partly because of the hormonal changes that occur at menopause and also because of the fact that female patients received more attention when it came to low BMD than did male patients. (WHO, 2003; O'Neill *et al.*, 2004; NOF, 2004; WomensHealthChannel, 2006).

Another fact that became evident in this study was that the entire patient population was Caucasian. Here again it can be contributed to the small patient population size or to the fact that black people are less likely to have a low BMD than Caucasians. Literature mentions that black people are not affected by osteoporosis as frequently as Caucasians (Zizic, 2004). According to the National Osteoporosis Foundation of South Africa (2004), osteoporotic fractures are less common in our black population. South African blacks have the lowest hip fracture prevalence in the world. Another factor that could have contributed to the all-Caucasian study population is that the few black patients that were sent for a BMD did not comply with the inclusion criteria. The race of the patient group was, however, not the primary objective of the study.

Concerning the references of the patient population (Figure 4.1), Universitas Academic Hospital (UAH) referred more than half of the patients (64%). Of these patients, the Endocrinology clinic referred the largest number (44%), while the Oncology clinic and Gastroenterology referred 16% and 13% respectively (Figure 4.3).

The low referral rate from other points of care can be attributed to the fact that the service is also available in the Private Hospitals in Bloemfontein. The other points of care consisted of specialist physicians, general practitioners and 3 Military Hospital (Figure 4.2). They referred only 36% of the total patient population.

Table 4.1 indicates that 68% of the patients were referred for a DEXA scan due to findings during routine examination, direct query of osteoporosis, or X-rays indicating osteoporosis. The largest number of requests stated *Routine DEXA* (40%). Fourteen percent were more specific concerning the clinical data on the request form, e.g. back pain, family history, cancer, prolonged glucocorticoid use and previous fracture.

Risk factors for developing osteoporosis (Chapter 2.2.5) include hormonal imbalances, genetic factors, modifiable risk factors (cigarette smoking, excessive alcohol consumption, high caffeine intake, inactive and sedentary lifestyle.), certain medications and diseases. In the assessment of the patient populations' number of risk factors (Table 4.4), it was noted that 2 or more risk factors (Table 4.5) were present with most of the patients (92%). This correlate with the risk factors mentioned in Chapter 2. Ten percent of the patient group had a family history of fractures. Sixteen percent had a history of glucocorticoid use longer than six months.

Lifestyle factors were also present in some of the patients (37% of the patients had cigarette smoking history).

Concerning what can be found in the literature, it becomes clear that higher levels of leisure time, sports activities, household chores and fewer hours of inactivity, were associated with a significant reduced risk of a hip fracture (International Osteoporosis Foundation, 2005). Physical activity and fitness reduce not only the risk of osteoporosis and fracture, but also for fall-related injuries. Strengthening the back muscles can also reduce the risk of vertebral fractures.

The physical activity levels of the patients in the study population were compared to 30 minutes of brisk walking per day. Twenty-four (48%) patients reported a high activity level, while 26 (52%) patients had a low activity level (Figure 4.5). The findings showed that, of the less active group, 23% were osteoporotic. In the patient group with high activity levels, 54% were osteoporotic. These findings do not concur with the literature where it is stated that regular weight bearing exercise can strengthen bone (Amin, 2004; Jaglal *et al.*, 2000). This may be due to the small patient group or as was pointed out by Christiansen, 1993, that excessive exercise can cause estrogen deficiency in pre-menopausal women with the accompanying risk of a low bone mass.

Calcium supplement has been shown to have a positive effect on the BMD of postmenopausal women and, together with a Vitamin D supplement, it reduces the rate of bone loss and fractures in older male and female adults (International Osteoporosis Foundation, 2005). Lactose intolerance has also been associated with low BMD and the increased risk of fracture due to low dairy intake.

The assessment of the dairy intake of the patients showed that 4 (8%) patients had no dairy intake whatsoever. In this group 75% were osteoporotic. Thirteen (26%) patients had a dairy intake of less than 250 ml per day, of whom 31% were osteoporotic. The high dairy intake group consisted of 33 (66%) patients, of whom 36% had osteoporosis.

The BMI for each patient was also recorded and compared to the BMI classification (Table 4.3). It showed that 30 (60%) of the patients had a normal BMI. Of these 30 patients 50% were osteoporotic. Nine (18%) patients were overweight according to their BMI, and of these patients, 22% were osteoporotic. Eleven (22%) patients were moderately obese and only 18% were osteoporotic. A Low BMI is also a risk factor for developing osteoporosis and the only patient that was underweight, was diagnosed with osteoporosis.

After evaluating the results of the patients according to their BMD T-score (Table 4.6), 19 (38%) were classified with osteoporosis. Of this group, fifteen (47%) patients were referred from UAH and 4

(22%) patients from other points of care (Table 4.8). For these patients medical intervention is important.

For the remaining 31 (62%) osteopenic patients, medical treatment would also have been to their benefit.

As the objective of this study is to determine how BMD results affect the treatment and management of patients identified with either osteopenia or osteoporosis, the emphasis is on communication between patient and physician. This is a very important aspect as it ensures correct treatment for the patient.

The results of this study showed that 39 patients (78% of the study population) did receive their BMD results of which fifteen (38%) were osteoporotic (Table 4.7) and in need of treatment. Of the 22% patients that did not receive feedback, 8% (of the study population) were osteoporotic and should have received treatment (Table 4.7).

Since various researchers (Christiansen, 1993; Divittorio *et al.*, 2006; Hough, 2000; Kanis, 1994; Khan, 2003) have consistently shown that, depending on the drug and the patient population, treatment reduces the risk of vertebral fractures by between 30-65% and of nonvertebral fractures by between 16-53% (International Osteoporosis Foundation, 2005). Should these figures be extrapolated to the findings of the present investigation, patients that would have responded because of treatment is 4.5-9.75 patients in the cases for vertebral abnormalities (fractures) and 2.4-9.75 patients in the cases for non-vertebral abnormalities

(fractures). The corresponding figures for the patients that did not receive feedback that could have benefited according to this notion, relates to figures of 1.2-2.6 and 0.64-2.12 respectively.

In this study it became clear that the treatment of choice was Alendronate and/or a Calcium supplement (all of which have been proven to significantly reduce fracture risk, Diamond, 2002) – results pertaining to the choice of treatment not included because these findings do not fall within the scope of the aim of the present investigation.

The results also showed (Table 4.7) that some of the patients that did receive feedback made an effort to improve their lifestyle by becoming more active (41%) or by increasing their dairy intake (21%).

Fitt *et al.* (2001) state that an alarming proportion of patients did not receive feedback concerning the results of the DEXA and the necessary treatment. These findings highlight the fact that patients in need of treatment do not always receive it. The same trend (4 patients from a study population of 50 patients) can be advocated for the present findings.

In a study conducted by Jaglal *et al.* (2003), it was found that increasing physicians' knowledge and educating patients could lead to improved management of osteoporosis. Unless physicians understand the clinical indications and standards of quality control and reporting, there could be potential for overuse and

inappropriate use of the DEXA technique (Osteoporosis Society of Canada, 1996). The present results suggest trends towards the same type of notions if the facts reported in Table 4.7 are compared to the facts reported in Table 4.1 for example.

5.3 LIMITING FACTORS

Possible limitations identified in the study were:

1. Small sample size.
2. Not everybody had telephone access, especially the patients from the rural areas of the Free State.
3. The follow-up data relied solely on the patient's report, and therefore there may have been some inaccuracies with respect to their recall of the recommendations.



CHAPTER 6

CONCLUSION AND RECOMMENDATIONS

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6.1. CONCLUSION

The results of this study showed that:

1. The majority of patients (78% of the study population) receive feedback from the referring physician on BMD results indicating a significant impact on the management of patients with this condition.
2. The fact that 22% of the study group received no feedback at all shows that there is an important lack of communication between the physician and the patient.
3. Communication between physician and patient is a very important component in using the information provided by this test to its full potential.
4. The patient's understanding of osteopenia/osteoporosis, its management, and the correct treatment thereof, could be very important because for one reason or another, patients were prepared to change their life style dynamics.
5. The physician's understanding of the results, the interpretation and the correct management of a low BMD is also very important.

The ideal is to identify a low BMD early enough to stop the damaging consequences thereof but this is not always feasible due to the high costs involved in a DEXA scan. Access to treatment and care is also not readily available to a large section of the population and, in State Hospitals; the availability of drugs to treat osteoporosis is limited due to the high costs (National Osteoporosis Foundation of South Africa, 2003).

The life expectancy of females is at present higher than in the past, and this higher life expectancy can lead to greater reductions in bone mass (O'Neill *et al.*, 2004). Because a disabling fracture can be a burden to both the individual and the community, the person will still be able to lead a quality life if fractures can be prevented (World Health Organization, 2003).

Communication between physicians and patients is a critical component in the initiation of therapy for a low BMD. The treatment of established osteoporosis and skeletal failure is difficult and effective management of this disease involves prevention – hence early detection.

6.2 RECOMMENDATIONS

Osteoporosis is not part of normal aging although many people continue to believe this is true. A comprehensive national effort aimed at the prevention, diagnosis and treatment of osteoporosis and related fractures is necessary to address this debilitating and

costly disease (National Osteoporosis Foundation of America, 2006). The identification of patients at risk of fracture, prior to fracture occurrence, is the ideal (Fitt *et al.*, 2001). A single determination of BMD can correctly identify the majority of those at risk and DEXA is currently definitely the technique of choice.

An educational plan for patients would be ideal in reducing the burden of illness due to osteoporosis. Better education of health professionals also ensures that patients receive the most appropriate treatment.

A. Basic information that can be to the advantage of a patient with a low BMD:

- ◆ Understanding the results of the BMD measurements.
- ◆ Types of treatment available.
- ◆ Diet, exercise, lifestyle, other risk factors.
- ◆ Methods of preventing falls and fractures.

B. This can be accomplished by:

- ◆ Reading books or leaflets, watching videos or listening to audiotapes.
- ◆ Attending public meetings or patient support groups to learn from other patients with osteoporosis.
- ◆ Reading articles in magazines or newspapers.
- ◆ Watching television programs or listening to the radio.
- ◆ Accessing Web-based information that may be available worldwide.
- ◆ Other activities such as World Osteoporosis day.

Advanced osteoporosis is difficult to treat and the key to successful management thereof is to prevent it (Hough, 2001). Prophylactic treatment aiming to optimise bone mass and to prevent loss must include a healthy diet, regular exercise, cessation of smoking and high alcohol intake.



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APPENDICES

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APPENDIX A

Questionnaire completed together with patient

VRAELYS

PASIËNTINLIGTING

Naam:.....

Geboortedatum:.....

Ouderdom.....Geslag:.....

Massa:.....Lengte:.....

Kontaktelefoonnommer:

Kontakadres:.....

.....

Verwysende dokter:.....

Adres:.....

Indikase vir aanvraag van toets.....

Opmerkings:.....

MEDIKASIE

Gebruik u tans of het u in die verlede enige van die volgende middels gebruik?

1. Kortisoon? Ja / Nee

Naam.....

Daaglikse dosis.....

Tydperk?.....

2. Anti-epileptiese middels? Ja / Nee

Naam.....

Daaglikse dosis.....

Tydperk?.....

3. Hormoonvervangingsterapie? Ja / Nee

Naam.....

Daaglikse dosis.....

Tydperk?.....

4. Antistolmiddels? Ja / Nee

Naam.....

Daaglikse dosis.....

Tydperk?.....

5. Osteoporose medikasie? Ja / Nee

Naam.....

Daaglikse dosis.....

Tydperk?.....

6. Enige ander medikasie? Ja / Nee

a. Naam.....

Daaglikse dosis.....

Tydperk?.....

b. Naam.....

Daaglikse dosis.....

Tydperk?.....

c. Naam.....

Daaglikse dosis.....

Tydperk?.....

GESKIEDENIS VAN SIEKTES**Het u 'n geskiedenis van enige van die volgende siektes?**

1. Longsiektes? Ja / Nee

Tydperk.....

2. Tiroied? Ja / Nee

Tydperk.....

3. Kroniese niersiekte? Ja / Nee

Tydperk.....

4. Diabetes? Ja / Nee

Tydperk.....

5. Osteoporose? Ja / Nee

Tydperk.....

6. Rumatoïede artritis? Ja / Nee

Tydperk.....

7. Siekte van die Spysverteringstelsel? Ja / Nee

Tydperk.....

8. Kroniese lewersiekte? Ja / Nee

Tydperk.....

9. Het u enige ander ernstige siekte gehad?
bv. 'n siekte waarvoor hospitalisasie nodig was.

Spesifiseer.....
.....



PASIËNT GESKIEDENIS

1. Familiëgeskiedenis van fragiliteitsfrakture? Ja / Nee
 (Vader, moeder, broer, suster)
 Spesifiseer (indien ja).....

2. Rookgeskiedenis Nooit
 Voorheen
 Tans
 Jare reeds opgehou?.....
 Hoeveel per dag?.....Hoeveel jare?.....

3. Alkoholgebruik: geen
 daaglik
 weeklik
 maandeliks of minder

4. Fisiese aktiwiteit: Vergelyk met vinnige stap daaglik vir 30 minute daaglik
 weeklik
 maandeliks

5. Liggaamsmassa -indeks:.....

6. Suiweliname: vergelyk met 250 ml melk/dag geen
 daaglik
 weeklik
 Hoeveelheid?.....

7. < 30 minute sonblootstelling per dag Ja / Nee

8. Vroeë menopouse (<45 jaar) Ja / Nee

9. Vorige amenorree (> 3 mnde) Ja / Nee

10. Histerektomie Ja / Nee

Jaar.....

Uterus + eierstokke

Slegs uterus

11. Swangerskappesgeskiedenis:

Hoeveel swangerskappe?.....

Enige miskrame?.....

Aantal kinders gebore?.....

Het u geborsvoed? Ja / Nee

Tydperk.....

PT NR.

QUESTIONNAIRE

PATIENT INFORMATION

Name:.....

Date of birth:.....

Age.....Gender:.....

Weight:.....Height:.....

Contact number:

Contact address:.....

.....

Referring physician:.....

Address:.....

Indication for DEXA.....

Remarks:.....

.

MEDICATION

Do you use or did you use any of the following medication?

1. Cortisone? Y / N
Name.....
Daily dose.....
Time period?.....

2. Anti-epileptics? Y / N
Name.....
Daily dose.....
Time period?.....

3. HRT? Y / N
Name.....
Daily dose.....
Time period?.....

5. Anticoagulants? Y / N
Name.....
Daily dose.....
Time period.....

5. Osteoporotic meds? Y / N

Name.....

Daily dose.....

Time period?.....

6. Any other meds? Y / N

a. Name.....

Daily dose.....

Time period?.....

b. Name.....

Daily dose.....

Time period?.....

c. Name.....

Daily dose.....

Time period?.....

PT NR.

MEDICAL HISTORY

Do you have any of the following diseases?

1. Lung diseases? Y / N

Time period.....

2. Thyroid? Y / N

Time period.....

3. Chronic renal disease? Y / N

Time period.....

4. Diabetes? Y / N

Time period.....

5. Osteoporosis? Y / N

Time period.....

6. Rumatoid arthritis? Y / N

Time period.....

7. GIT diseases? Y / N

Time period.....

8. Chronic liver disease? Y / N

Time period.....

PT NR.

9. Any other serious diseases?

.
Specify.....

.....

PT NR.

PATIENT HISTORY

1. Family history of fractures? Y / N

Specify.....

2. Smoker Never

When stopped?..... Previous

At present

How much p/d?.....Years?.....

3. Alcohol use: none

daily

weekly

monthly

4. Physical activity: (Compare with 30 min brisk walking/day) daily

weekly

monthly

5. BMI:.....

6. Dairy intake (compare to 250 ml milk/day) none

daily

weekly

How much?.....

7. < 30 minutes sun exposure/day Y / N

8. Early menopause (<45 years) Y / N

9. Previous amenorrhoea (> 3 mnths) Y / N

10. Hysterectomy Y / N

Year.....

Uterus + ovaries

Only uterus

11. Pregnancy history:

How many pregnancies?.....

Any miscarriage?.....

How many children?.....

Did you breastfeed? Y / N

Time period.....

APPENDIX B

Ingeligte toestemming/Consent form/Tumellano

INGELIGTE TOESTEMMING

Geagte pasiënt

'n Navorsingsprojek word beplan deur Mev S.M Pretorius en Prof W.F Mollentze om te kyk na die behandeling van osteoporose en daardeur pasiëntsorg te verbeter.

Geen ekstra toetse gaan op u uitgevoer word nie, behalwe die Beendigtheidstoets waarvoor u na ons verwys is.

Om te verseker dat die projek suksesvol sal wees, het ons egter u hulp nodig. Al wat van u verlang word is om 'n kort vraelys te beantwoord en dat u gewillig sal wees om 2 maande vanaf die ondersoekdatum weer gekontak mag word vir opvolgvrage.

U deelname is vrywillig en enige inligting wat verkry word, sal as konfidensieël hanteer word.

Baie dankie vir u bydrae om hierdie studie suksesvol te maak.

Ek,.....,geboortedatum.....,
gee hiermee my toestemming om deel te neem aan die navorsingsprojek
soos aan my verduidelik.

Pasiënt

Datum

Getuie

Datum

INFORMED CONSENT

Dear patient

To consider and improve the treatment of osteoporosis, a research project is been planned by Mrs S.M Pretorius and Prof. W.F Mollentze.

No extra tests will be performed other than the Bone Density test which your physician originally requested.

To ensure the success of the project we ask for your co-operation. We request only that you answer a few questions and that you will be willing to undergo a telephonic follow-up interview within 2 months.

Your participation is voluntary; therefore any information will be handled confidentially.

Thank you for contributing toward the success of the study.

I,.....Date of Birth.....,give permission to take part in the research project as explained to me.

Patient

Date

Witness

Date

TUMELLANO

Bakudi ba ratehang

Ho hlokomela le ho ntshetsa pele phekolo ya lefu la masopo, Mme S.M Pretorius le Profesa W.F Mollentze ba lotha ho etsa dipatlisiso tse ding.

Ha ho na diteko tse ding tse tlang ho etswa ho mokudi ntle le sepidi sa ho sheba masopo, jwale ka ha ngaka e kapile.

Ho bona ntshetso-pele ya dipatlisiso tsena, re kopa tshebedisano mmoho. Re kopa hore o arabe dipotso tse mmalwa le hore o botswe dipotso ka mohala dikgweding tse pedi.

Ho nka karolo ha hao, hotswa ho wena mme tlhahiso-leseding yohle e tla ba lekunutu.

Re lebohela ho nka karolo ha hao dipatlisisong tsena.

Nne.....Tsatsi la tlhaho.....,ke fana ka tumellano ya ho nka karolo dipatlisisong tsena jwale ka ha ke hlaloseditswe.

Mokudi

Letsatsi

Paki

Letsatsi

APPENDIX C

Follow-up questionnaire

TELEFONIESE VRAELYS

PT NR

DIAGNOSE

TELEFOONNR

Staatshospitaal verwysing / Privaat verwysing

1. Het u verwysende dokter enige terugvoer/advies gegee i.v.m. die beëindigheidsstoets wat op u uitgevoer is? Ja / Nee

2. Wat het die dokter aan u gesê? (Pasiënt se eie woorde)

.....

3. Het u enige veranderinge aan u lewenstyl na die ondersoek, gemaak?

Ja /Nee

Dieet	
Oefening	
Rookgewoonte	
Alkoholiname	
Ander	

4. Het u geneesheer enige middels aan u voorgeskryf? Ja / Nee

.....
.....

6. Gebruik u die middels aan u voorgeskryf? Ja / Nee

Indien NEE, wat is die rede?.....

7. Is daar enige instruksies aan u gegee oor toekomstige hantering? Ja/ Nee
(bv. opvolg afsprake, opvolg beëindigheid, ens)

.....

8. Indien pasiënt oorlede is, is afskrif van doodsertifikaat verkry?
NVT / Ja / Nee

APPENDIX D

Data sheet

<u>PATIENT NR:</u>	<u>GESLAG:</u>	<u>OUDERDOM</u>
<u>GEWIG:</u>	<u>LENGTE:</u>	<u>BMI:</u>

A	Verwysing		<i>Staat 1</i>	<i>Privaat 2</i>
B	Geslag		<i>Manlik 1</i>	<i>Vroulik 2</i>
C	Kortisoan		<i>Ja 1</i>	<i>Nee 2</i>
D	Anti-epileptiese middels		<i>Ja 1</i>	<i>Nee 2</i>
E	Hormoonvervanging		<i>Ja 1</i>	<i>Nee 2</i>
F	Anti-stol middels		<i>Ja 1</i>	<i>Nee 2</i>
G	Ander meds		<i>Ja 1</i>	<i>Nee 2</i>
H	Longsiekte		<i>Ja 1</i>	<i>Nee 2</i>
I	Tiroied		<i>Ja 1</i>	<i>Nee 2</i>
J	Niersiekte		<i>Ja 1</i>	<i>Nee 2</i>
K	Diabetes		<i>Ja 1</i>	<i>Nee 2</i>
L	Rumatoiede artritis		<i>Ja 1</i>	<i>Nee 2</i>
N	SVK aantasting		<i>Spast.kolon 1 Nee2 Crohn's3 Maagseer4 verkultitis 5Ulseratcol6 Gastritis7</i>	
O	Lewersiekte		<i>Ja 1</i>	<i>Nee 2</i>
P	Ander ernstige siekte		<i>Mamma Ca 1</i>	<i>Nee 2 Ca ovaria 3</i>
Q	Familiegeskiedenis van frakture		<i>Ja 1</i>	<i>Nee 2</i>
R	Rookgeskiedenis		<i>Nooit 1</i>	<i>Gestaak2 Tans 3</i>
S	Alkoholgebruik		<i>geen 1</i>	<i>daaglik 2 week 3 maand 4</i>
T	Fisiese aktiwiteit>30-minute flink stap per dag		<i>Ja 1</i>	<i>Nee 2</i>

U	Suiweliname ≥ 250 ml/dag		<i>Ja 1</i>	<i>Nee 2</i>	
V	Sonblootstelling < 45 min/dag		<i>Ja 1</i>	<i>Nee 2</i>	
X	Vroeë menopouse (< 45 jaar)		<i>Ja 1</i>	<i>Nee 2</i>	<i>NVT 3</i>
Y	Vorige amenorree (> 3 mnde)		<i>Ja 1</i>	<i>Nee 2</i>	<i>NVT 3</i>
Z	Histerektomie		<i>Ja 1</i>	<i>Nee 2</i>	<i>NVT 3</i>
AA	Swangerskap geskiedenis		<i>0 1 2 3 4 5 6</i>		<i>NVT 7</i>
AB	Geborsvoed		<i>Ja 1</i>	<i>Nee 2</i>	<i>NVT 3</i>
AC	enige terugvoer/advies		<i>Ja 1</i>	<i>Nee 2</i>	
AD	Enige veranderinge self gemaak?		<i>Nee 1 Dieet 2 Oefen 3 Rook 4 Alkohol 5 Dieet+Oef 6</i>		
AE	Enige middels voorgeskryf		<i>Ja 1</i>	<i>Nee 2</i>	
AF	Gebruik middels voorgeskryf		<i>Ja 1 nie goedkeur deur medies 2 Nie by hos beskikbaar 3 Op waglys 4 NVT 5 Nee 6</i>		
AG	Enige instruksies oor toekomstige hantering		<i>Nee 6 mnde opvolg 2 1jaar opvolg 3</i>		
AH	T-score total hip				
AI	T-score total spine				
AJ	Finale resultate		<i>Osteoporose 1</i>	<i>Osteopenies 2</i>	