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**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

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# **National Horizon Scanning Unit**

## **Horizon scanning prioritising summary**

**Volume 9, Number 4:**

**DXL Calscan Bone Densitometer to  
measure bone mineral density of the os  
calcis.**

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# PRIORITISING SUMMARY

**REGISTER ID:** 000167

**NAME OF TECHNOLOGY:** DXL CALSCAN BONE DENSITOMETER

**PURPOSE AND TARGET GROUP:** BONE DENSITOMETER TO MEASURE BONE MINERAL DENSITY OF THE OS CALCIS

## STAGE OF DEVELOPMENT (IN AUSTRALIA):

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established  |
| <input type="checkbox"/> Experimental             | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational          | <input type="checkbox"/> Should be taken out of use   |
| <input type="checkbox"/> Nearly established       |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- |                              |   |
|------------------------------|---|
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No  |
| ARTG number                  | <input type="checkbox"/> Not applicable |

## INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Sweden	✓		
Finland	✓		
Italy	✓		

## IMPACT SUMMARY:

Demetech AB manufactures the DXL Calscan bone densitometer to measure bone mineral density. The Calscan is available in Europe and was approved for use in May 2004 in the United States (United States Food and Drug Administration, 2005). The DXL Calscan is not yet available in Australia.

## BACKGROUND

In Australia, dual-energy x-ray absorptiometry (DEXA) for the measurement of bone mineral density (BMD) is considered the gold standard for assessing an individual's risk of sustaining an osteoporotic or low trauma fracture. DEXA measures BMD at both the hip and spine and peripheral sites, such as the wrist and finger.

BMD is typically expressed in terms of the number of standard deviations (SD) the bone density falls below the mean for young healthy adults (T score). The WHO uses the cut-off point of  $T \leq -2.5$  SD at the femoral neck or spine to identify patients with osteoporosis, and at risk of low trauma fracture.

Conventional DEXA technology assumes a two-component tissue model consisting of bone mineral and soft tissue. In DEXA technology photo attenuation assumes that the soft tissue overlying, adjacent to and inside the measured bone is similar. However, true soft tissue may

consist of both lean tissue and adipose (fat) tissue with non-uniform absorption properties. The absorption properties of adipose tissue are significantly different from those of both bone and lean soft tissue. Therefore, it is suggested that DEXA technology may over- or underestimate bone density (Bolotin and Sievänen 2001).

Errors in clinical DEXA bone density measurements related to small, non-uniform changes in soft tissue composition and thickness, in addition to variable bone marrow composition, may exceed 20% at typical lumbar vertebral sites, in osteopenic/osteoporotic, postmenopausal, and elderly patients (Bolotin and Sievänen 2001).

The DXL Calscan (illustrated below) combines the conventional DEXA technique with a laser measurement of the heel to estimate the bone mineral density of the heel (os calcis). The laser measurement enables patient-specific calculation to assess the impact from soft and adipose tissues. By comparing the estimated BMD to a physician-selected reference database, a more accurate T-score is calculated (compared to DEXA alone). This provides an estimate of osteoporotic fracture risk (United States Food and Drug Administration, 2005).



Figure 1. DXL Calscan Device, (Printed with permission, Demetech AB, 2005)

The DXL Calscan is a portable device, weighing less than 25 kilograms. One patient scan with DXL Calscan takes 55 seconds to perform. The effective patient dose is 0.02 millirem (mrem)<sup>1</sup>. The heel width is measured by a laser ruler with a maximum power of 5 mW and wavelength 635 nm (United States Food and Drug Administration, 2005). Approximately four hours of training is required for health professionals to learn how to use the device (Salminen et al 2004).

#### **CLINICAL NEED AND BURDEN OF DISEASE**

The estimated prevalence of existing low bone mineral density in an Australian population as defined by WHO criteria (T score  $\leq -2.5$  SD), is 10 per cent (Access Economics Pty Limited 2001). The prevalence of low bone mineral density increases with age. Evidence of osteoporosis does not appear in the Australian population until 15 years of age but it continues to rise in prevalence to 46 per cent in people 75 years of age and over. In all age groups the prevalence of low bone density is higher in females than in males (unpublished data).

In 1998, it was estimated that over 85,000 Australians were disabled due to osteoporosis, with 44 per cent of these classified as severely disabled (Access Economics Pty Limited 2001). As of 2001, it was estimated that over 1.9 million Australians (10% of the population) suffer from osteoporosis and it is predicted that this number will rise to 3 million (13.2%) by 2021 (Access Economics Pty Limited 2001).

Three ongoing prospective cohort studies in Australia have estimated the total number of fractures each year among adults over the age of 60 years at between 51,000 and 73,000

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<sup>1</sup> 0.2.smSV = 20mrem

(Sambrook et al 2002). In 2003 the number of adults aged 65 years and older was approximately 2.5 million (Source: Australian Bureau of Statistics, June 2003), this would translate to a fracture risk in the region of 20.4/1,000 – 29.2/1,000 in this age group. (unpublished data).

## **DIFFUSION**

The measurement of bone mineral density to assess the risk of fracture is commonly used in clinical practice. It is likely that a new tool that addresses limitations of current DEXA instruments and demonstrates greater accuracy in measuring bone mineral density would experience a rapid diffusion.

## **COMPARATORS**

There are two common bone densitometry tests that are utilised for diagnosing osteoporosis and estimating fracture risk. The most widely used measurement of bone mass is dual-energy x-ray absorptiometry (DEXA). The alternative technique is quantitative computed tomography.

## **EFFECTIVENESS AND SAFETY ISSUES**

In a study (level III-2 diagnostic evidence) of 40 postmenopausal women, the BMD measurements of the heel with the DXL Calscan were compared with an ultrasound device and a conventional DEXA instrument (Martini et al 2004). DEXA measurement of the L2-L4 region of the spine resulted in 20 women (50%) classified as osteoporotic and 50% non-osteoporotic. The short-term coefficient of variation of the DXL Calscan was 2.4% and 1.7% in osteoporotic and nonosteoporotic groups respectively.

In another study, calcaneal BMD measurements of a random selection of 38 people with the DXL Calscan were compared to calcaneal, axial (lumbar spine and proximal femur) and total body BMDs (level III-3 diagnostic evidence) measured with DEXA instruments (Hakulinen 2003). In addition, calcaneal ultrasound measurements were conducted. The aim of the study was to compare performance and agreement between instruments. The short-term precision (CV%, sCV%) was 1.24% and 1.45% for the DXL Calscan and 1.28% and 1.60% for the DEXA instrument alone. Both the DXL Calscan and the DEXA calcaneal measurement instruments predicted similar BMD at the femoral neck ( $r^2 = 0.63$  and  $0.52$  respectively) and lumbar spine ( $r^2 = 0.61$  and  $0.64$ , respectively). Calcaneal BMD measurements were significantly lower when measured with the DXL Calscan (19% lower,  $p < 0.01$ ) than those measured with DEXA alone.

In a study (level III-2 diagnostic evidence) of 388 women born between 1920 and 1930, BMD measurements of the hip and spine were taken with DEXA and compared to calcaneal BMD measured with the DXL Calscan (Salminen et al 2004). All 388 women were measured at the calcaneus and the spine. Measurement of the hip was not possible in six women due to bilateral hip joint prostheses. T-score values were calculated for hip measurements with two reference populations for the DEXA instrument and T scores for heel measurements were calculated with two DXL Calscan databases, (an older and a more recent calcaneal reference population). Changing the reference populations affected both the heel and the hip T scores. The T-score values made with the DXL Calscan in relation to the DEXA T scores of the total hip and combinations of measurement sites were analysed. The sensitivity of the DXL Calscan in detecting axial osteoporosis varied between 13% and 92% depending on the DEXA site of measurement, combination of measurement sites and the choice of reference population (Salminen et al 2004).

The authors conclude that the calcaneal BMD measurements obtained with the DXL Calscan may be used to select patients for axial BMD measurements and as a support tool for decision making concerning treatment.

It is important to note that the choice of a reference population will affect the T values assigned to patients as shown in the above study. In the Australian context, the reference population would need to accurately represent BMD values for Australian population groups.

#### **COST IMPACT**

The current MBS fee for bone densitometry using dual energy X-ray absorptiometry, for each of the MBS item numbers 12306, 12312, 12315 and 12321 is \$86.85. There were a total of 150,005 bone densitometry procedures performed from July 2003 – June 2004 for these MBS item numbers and the total Medicare benefit paid was \$10,734,595.

The cost of the DXL Calscan is approximately US \$25,000. The manufacturer reported that there would be cost savings in running the DXL Calscan compared to normal DEXA instruments. This would be a consequence of eliminating the need for a radiographer or technician to take the scans, as nurses can operate the device (personal communication Demetech AB).

#### **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified/raised in the sources examined.

#### **OTHER ISSUES**

No issues were identified/raised in the sources examined.

#### **CONCLUSION:**

In Australia there is a large population group at risk of osteoporosis and bone mineral density measurement is a standard clinical tool used to predict fracture risk. At this stage the quality of evidence for the DXL Calscan is low, although studies have shown that it may be a technically better instrument to use than DEXA instruments.

#### **HEALTH PACT ACTION:**

Monitor

#### **LIST OF STUDIES INCLUDED**

Total number of studies	
Level III-2 diagnostic evidence	2
Level III-3 diagnostic evidence	1

#### **SOURCES OF FURTHER INFORMATION:**

Access Economics Pty Limited (2001). *The burden of "brittle bones" costing osteoporosis in Australia*, Osteoporosis Australia, Canberra, ACT.

Bolotin, H. H. (2001). 'Inaccuracies inherent in dual-energy X-ray absorptiometry in vivo bone mineral densitometry may flaw osteopenic/osteoporotic interpretations and mislead assessment of antiresorptive therapy effectiveness', *Bone*, 28 (5), 548-555.

Demetech AB (2005). "DXL – patented technology for measuring bone density" [Internet] Available from: <http://www.demetech.se/code/solutions.htm> [Accessed 23<sup>rd</sup> March, 2005].

Kullenberg, R. (2003). 'Reference database for dual X-ray and laser Calscan bone densitometer', *J Clin Densitom*, 6 (4), 367-372.

Kullenberg, R. & Falch, J. A. (2003). 'Prevalence of osteoporosis using bone mineral measurements at the calcaneus by dual X-ray and laser (DXL)', *Osteoporos Int*, 14 (10), 823-827.

Martini, G., Valenti, R. et al (2004). 'Dual X-ray and laser absorptiometry of the calcaneus: comparison with quantitative ultrasound and dual-energy X-ray absorptiometry', *J Clin Densitom*, 7 (3), 349-354.

Salminen, H., Saaf, M. et al (2004). 'Bone mineral density measurement in the calcaneus with DXL: comparison with hip and spine measurements in a cross-sectional study of an elderly female population', *Osteoporos Int*.

Sambrook, P. N., Seeman, E. et al (2002). 'Preventing osteoporosis: outcomes of the Australian Fracture Prevention Summit', *Medical Journal of Australia*, 176 (Suppl), S1-16.

United States Food and Drug Administration. (2005). 510 (k) NO: K033550 [Internet] Available from: <http://www.fda.gov/cdrh/pdf3/k033550.pdf> [Accessed 10<sup>th</sup> March, 2005].

**SEARCH CRITERIA TO BE USED:**

Bone Density

Calcaneus/ radiography

Densitometry, X-Ray/ methods

Lasers/ diagnostic use

Osteoporosis/diagnosis