Australian Government

Department of Health and Ageing

Australia and New Zealand Horizon Scanning Network

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National Horizon Scanning Unit
Horizon scanning prioritising summary

Update Number 2

DXL Calscan Bone Densitometer for the measurement of bone mineral density of the os calcis

June 2006

AHTA

Adelaide Health Technology Assessment

[add ISSN]
[add Publications Approval Number]

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The production of this *Horizon scanning prioritising summary* was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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UPDATE 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):

☒	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number
☒	No	
☐	Not applicable	

INTERNATIONAL UTILISATION:

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

IMPACT SUMMARY:

Demetech AB maufactures 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 the individual 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≤-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 under-estimate 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 potentially more accurate T-score is calculated (compared to DEXA alone). This provides an estimate of osteoporotic risk fracture (United States Food and Drug Administration, 2005).

Figure 1. DXL Calscan Device, (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 (mnrem)[1]. 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 ≤ -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 (MSAC 2004).

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) would 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 (Sambrook et al 2002). In 2003 the number of adults aged 65 years and older was

[1] 0.2.smSV = 20mnrem

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 (MSAC 2004).

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 20 women non-osteoporotic. The short-term coefficient of variation of the DXL Calscan was 2.4% and 1.7% in osteoporotic and non-osteoporotic groups respectively.

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 bi-lateral 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.

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.

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, 10.03.05).

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.

APRIL 2005 – 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. Therefore, it is recommended that this technology is monitored.

APRIL 2005 - 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] Avaialable from: http://www.demetech.se/code/solutions.htm [Accessed March 23rd 2005].

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.

Medical Services Advisory Committee (2004). *Bone densitometry testing 2004. MSAC reference 19.* [unpublished] Commonwealth Department of Health and Ageing, Canberra, ACT.

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 March 10th 2005].

SEARCH CRITERIA TO BE USED:

Bone Density
Calcaneus/ radiography
Densitometry, X-Ray/ methods
Lasers/ diagnostic use
Osteoporosis/diagnosis

NOTE:

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≤-2.5 SD at the femoral neck or spine to identify patients with osteoporosis, and at risk of low trauma fracture.

JUNE 2006 UPDATE - EFFECTIVENESS AND SAFETY ISSUES

Kullenberg (2003) obtained a reference database for the DXL Calcsan by taking the calcaneal BMD measurements of 993 healthy women and 459 healthy men recruited from Southern Sweden (level IV diagnostic evidence). The mean age of women in the study was 48.2 years (± 15.2 years), while for men the mean age was 47.0 years (± 15.2 years). In addition to forming a reference database, the study assessed the test-retest reliability of the DXL Calscan. In order to assess in vivo precision, the DXL Calscan was calibrated weekly against a solid, water-based, human-like phantom1. The coefficient of variation between these measurements (0.5%) indicated a high level of precision. In vitro precision, determined from duplicated measurements on 35 participants from the total study group, was also very high (coefficient of variation 1.2%).

In a more recent study, Blake et al (2005) investigated the diagnostic qualities of a number of peripheral DEXA (pDEXA) devices, including the DXL Calscan (level III-2 diagnostic evidence). Broadly, the study was designed to establish upper and lower thresholds for pDEXA devices that would allow for the confident diagnosis of osteoporosis in patients. The thresholds were calculated in accordance with guidelines from the UK National Osteoporotic Society, which recommend that osteoporosis at the hip or spine be identified with 90 per cent sensitivity and 90 per cent specificity. Patients with peripheral BMD measurements below the relevant lower threshold are likely to have osteoporosis at the hip or spine, while patients with measurements above the relevant upper threshold are unlikely to have osteoporosis. For those patients recording peripheral BMD measurements between the two diagnostic thresholds, a full hip and spine BMD examination is recommended so that a definitive diagnosis can be reached.

In the study, white females aged 55-70 years referred for BMD examination were enrolled. For each pDEXA device, at least 70 women with osteoporosis at the hip or spine and 70 women without osteoporosis were recruited. Hip and spine BMD measurements were made using axial DEXA systems (gold standard). In total 140 women (70 osteoporotic and 70 non-osteoporotic) underwent BMD measurement using the DXL Calscan (mean age 62.2 years). The upper threshold T-score was found to be -1.4 (95% CI: -0.9 to -1.6), while the lower threshold T-score was found to be -2.7 (95% CI: -2.5 to -3.5). Using these threshold values, 50 per cent of women between the ages of 55 and 70 meeting the criteria for BMD examination would require follow-up axial DEXA. The follow-up percentage required for the DXL Calscan was higher than for the other pDEXA devices examined (range 39 - 48 %), although differences were not statistically significant.

[1] The term phantom can be used to refer to a model, especially a transparent one, of the human body or any of its parts. Phantoms are particularly useful for assessing the precision of measuring equipment. Unlike the human body, in a phantom the underlying quantity of measurement can be assumed to remain constant over successive measurements.

Diagnostic results for the DXL Calscan first reported in Blake et al (2005) were investigated further by Thorpe and Steel (2006). Based on the upper and lower diagnostic thresholds of both the dominant and non-dominant heels, the referral rates for the DXL Calscan were recalculated to be 52.9 per cent for the non-dominant heel, and 58.6 per cent for the dominant heel. Of the seven women without osteoporosis who were classified as osteoporotic using the threshold values of either heel, six had severe axial osteopenia (BMD T-score just greater than -2.5). The authors also provide information on the stability of the DXL Calscan, as indicated by in vivo and in vitro precision. Short-term in vivo precision was estimated from 60 scans using an appropriate phantom, 30 with repositioning of the phantom and 30 without, and was found to be 0.75 per cent (coefficient of variation). Long-term in vivo precision was estimated using daily single phantom scans over a period of six months, and was found to be 0.73 per cent (coefficient of variation). Finally, in vitro precision was assessed by repeated measurements of 67 of the 140 participants (19 osteoporotic, 48 non-osteoporotic), and was found to be 1.19 per cent. The results suggest that the reliability and precision of the DXL Calscan is comparable to that of many standard axial DEXA systems.

JUNE 2006 - CONCLUSION:

In November 2004 the UK National Osteoporosis society (NOS) recommended a triage approach for the use of peripheral DEXA devices that involved defining upper and lower thresholds so that patients with osteoporosis at the hip or spine could be identified with 90 per cent sensitivity and 90 per cent specificity. While studies have demonstrated the DXL Calscan to be a highly reliable measuring device, application of the NOS guidelines would require approximately 50 to 60 per cent of women eligible for bone densitometry to receive follow-up BMD measurement using axial DEXA. The cost implications of such an approach are unknown.

JUNE 2006 - HEALTHPACT ACTION:

Given the lack of evidence highlighting the advantages of the DXL Calscan over axial DEXA systems, whether in terms of cost or accuracy of diagnosis, it is recommended that the technology is archived.

JUNE 2006 - SOURCES OF FURTHER INFORMATION:

Blake, G. M., Chinn, D. J. et al (2005). 'A list of device-specific thresholds for the clinical interpretation of peripheral x-ray absorptiometry examinations', *Osteoporos Int*, 16 (12), 2149-2156.

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

Thorpe, J. A. & Steel, S. A. (2006). 'The DXL Calscan heel densitometer: evaluation and diagnostic thresholds', *Br J Radiol*, 79 (940), 336-341.

LIST OF STUDIES INCLUDED

Level III-2 diagnostic evidence	2
Level IV diagnostic evidence	1