

The DXL Calscan heel densitometer: evaluation and diagnostic thresholds

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ABSTRACT. The DXL Calscan (Demetech AB) is a new dual energy X-ray absorptiometry device for determining heel bone mineral density (BMD). The system is based on the standard technique of dual energy X-ray absorptiometry (DXA), using a fan beam configuration, but introduces an additional laser measurement of heel thickness intended to improve accuracy. We have examined the utility, *in vitro* and *in vivo* performance of the DXL Calscan and established triage thresholds based on the UK's National Osteoporosis Society guidelines on peripheral densitometry. The Calscan proved convenient, easy to use and was stable over time and within a range of operating temperatures. Short-term *in vitro* precision as %CV, with phantom repositioning, was 0.75% and long term precision 0.73%. Precision *in vivo*, determined from duplicate right heel scans of 67 subjects, was 1.19%. Effective radiation dose to the patient was $<0.1 \mu\text{Sv}$ per scan. 140 white females (70 osteoporotic and 70 non-osteoporotic), aged 55–70 years underwent scans of both heels. Subjects were defined as osteoporotic or non-osteoporotic on the basis of axial DXA (spine L2–L4 and total hip). Triage thresholds for reassurance-referral or referral-treatment were 0.391 g cm^{-2} and 0.306 g cm^{-2} for non-dominant and 0.395 g cm^{-2} , 0.294 g cm^{-2} for dominant heel, respectively. The non-dominant heel proved slightly superior to the dominant for triage purposes. Of the seven non-osteoporotic subjects misclassified as osteoporotic by Calscan of either heel, six had severe axial osteopenia. If operated by trained personnel and used in appropriate populations exhibiting risk factors, the Calscan is well suited for use in the management of post-menopausal osteoporosis.

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Measurement of bone mineral density (BMD) by dual energy X-ray absorptiometry (DXA) is now well established as the method of choice for osteoporosis assessment [1–3]. BMD assessment of the lumbar spine and hip by DXA represents the current gold standard due to the greater associated morbidity and mortality of fractures at these two sites, superior fracture prediction [4, 5] and response to treatment [6]. In addition to axial assessment, there are a variety of DXA devices available for measuring BMD in the forearm, heel and hand.

The DXL Calscan (Demetech AB, Solna, Sweden) is a new peripheral device for calcaneal BMD assessment, based on fan beam DXA. The Calscan also incorporates a laser measurement of heel thickness to improve the accuracy of calcaneal BMD. Standard DXA assumes a two compartment model of tissue masses, the first bone and the second a composite of lean and adipose tissue at an assumed constant ratio. This assumed ratio does not allow for fluctuations in lean and adipose tissue proportions that have been demonstrated to occur at the spine [7] and are likely to occur at the calcaneus or elsewhere [8, 9]. This leads to calcaneal DXA providing a precise but potentially inaccurate estimate of BMD, with the degree of inaccuracy dependent on body mass index [8].

These inhomogeneities can be corrected by solving the BMD equation as a three component model of bone, lean and adipose tissue. Swanpalmer [10, 11] described how a third X-ray energy could achieve this, but concluded that a significantly higher photon count (and hence scan times) would be required to maintain an acceptable degree of precision.

Jonson [12] deduced that if the combined width of all three components were known, *e.g.* the width of the heel, the ratio of soft to lean tissue could then be derived and corrected for. The laser heel width measurement on the Calscan provides this additional dimension allowing the derivation of BMD from a three component model, whilst theoretically maintaining DXA precision [13].

As with other peripheral DXA (pDXA) devices [14], the Calscan is smaller, portable, cheaper and has a lower radiation dose than axial densitometers. However, pDXA results at the calcaneus cannot be interpreted using the WHO definition [15] and do not correlate perfectly with bone density at either spine or hip. The imperfect correlation can lead to pDXA misclassifying subjects to the opposite diagnostic group to which they would have been classified by axial DXA [16–18], particularly for subjects with BMD scores close to diagnostic thresholds. Hence considerable debate remains over how such peripheral devices might best be employed in the clinical setting. The UK-based National Osteoporosis Society (NOS) has recently stated

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that current evidence supports the use of peripheral devices in a triage rather than diagnostic role, and has established a method for determining the required triage thresholds [19, 20]. The aim of this study was to determine the *in vitro* and *in vivo* operating conditions of the Calscan and to establish triage referral thresholds based on the NOS guidelines.

Materials and methods

The DXL Calscan bone densitometer (Figure 1) utilizes a fan beam, dual energy X-ray source and a solid state detector to perform a scan of the heel. A region of interest is positioned automatically by the software to derive BMD. A concomitant measure of heel thickness is obtained using the laser reflection to correct for variations in the soft to lean tissue ratio. The Calscan, at 25 kg in weight and 80 cm long by 43 cm wide and 33 cm tall, is relatively compact and easy to transport and includes wheels at one end and a carry handle. As with all X-ray equipment, the Calscan is potentially subject to changes in tube temperature after performing an acquisition, and as a portable device it may also be subject to fluctuations in performance due to environmental changes. To counter this, the software (version 1.3.1) requires a warm-up acquisition when the device is switched on and a 4 min cooling down period after each acquisition.

In vitro methodology

Phantom based studies were conducted to test the effect of temperature, stability following relocation and to determine *in vitro* precision. The DXL-Calscan comes with a manufacturer-supplied phantom, made from shaped pieces of aluminium depicting the calcaneus, embedded in acrylic. Short term precision was determined as percent coefficient of variation (%CV) from 30 scans with phantom repositioning and 30 without. The device was operated according to the manufacturer's instructions. All measurements were taken on the same day. Accuracy was calculated from comparison with the phantom's stated BMD of 0.347 g cm^{-2} , established from a central reference machine, corresponding to a T-score



Figure 1. The Demetech DXL Calscan and phantom.

of -2.1 . Long term *in vitro* precision was determined using daily single phantom scans acquired over a period of 6 months as part of routine quality assurance.

Sixteen tests were conducted to assess the effects of ambient temperature, device movement or tube heating on accuracy or precision. For each test the device was disconnected, moved to a different room, warmed up and a phantom scan acquired as soon as the warm-up was complete. The device was given a further 30 min to stabilize, then a second phantom scan was acquired and the device powered down and allowed to cool for 30 min before beginning the next test. Temperature was measured on an alcohol room thermometer throughout. Electrical, laser safety and radiological protection surveys were also carried out.

In vivo methodology

Subjects

Females attending for routine BMD of spine and hip were approached for participation in this study. These were referred on the basis of agreed local risk criteria which are broadly in agreement with those of the Royal College of Physicians [1]. The study was approved by the local research Ethics Committee and informed consent was obtained. All subjects were white and between the ages of 55 years and 70 years (Table 1). A total of 140 women were recruited.

Axial DXA assessment

Subjects underwent BMD of lumbar spine and hip using a GE-Lunar Prodigy (GE-Lunar, Madison, WI) as part of their routine examination and clinical management was determined on the basis of the results. In our centre, DXA of the right hip is performed unless contraindicated. For the purposes of this study, if the lower of either L2-L4 spine or total hip BMD T-score values was below -2.5 , the subject was classified as osteoporotic. Otherwise they were classified as non-osteoporotic. When lumbar vertebrae showed clear signs of degenerative changes, the individual vertebrae affected were excluded from the lumbar spine results. Four subjects had individual vertebrae excluded – one osteoporotic and two non-osteoporotic subjects with degenerative changes of L4 and one non-osteoporotic subject with changes at L3. For eight other subjects (four osteoporotic, four non-osteoporotic by final diagnosis), two or more vertebrae on the same subject showed

Table 1. "Evaluation and Diagnostic Thresholds of the DXL Calscan". Mean (standard deviation) subject demographic variables for whole group, osteoporotic and non-osteoporotic subjects, respectively

	Whole group	Osteoporotic	Non-osteoporotic
<i>n</i>	140	70	70
Age (years)	62.7 (4.5)	63.2 (4.3)	62.2 (4.7)
Height (cm)	159.4 (6.5)	159.2 (7.0)	159.5 (6.0)
Weight (kg)	64.3 (10.7)	62.6 (11.1)	66.0 (10.1)
BMI (kg m^{-2})	25.3 (3.9)	24.7 (3.9)	26.0 (3.9)

BMI, body mass index.

degenerative changes. For these eight subjects the spine results were disregarded and diagnosis was made by total hip DXA alone. In one case this caused the subject to move from the osteoporotic to non-osteoporotic group. Recruitment continued until 70 osteoporotic and 70 non-osteoporotic subjects were enrolled.

Calcaneal DXA assessment

BMD of both heels was obtained using the DXL Calscan. To determine *in vivo* precision, 67 of the 140 subjects underwent a repeat acquisition of the right heel, with repositioning between each. The calcaneal regions of interest (ROI) were manually checked and, if deemed necessary, ROI position was corrected as per the user manual instructions. For the repeat Calscan acquisition, the second scan for each subject was analysed on a separate day to the first to reduce the possibility of operator bias during any ROI repositioning.

Results

Operational utility

The time from scan initiation to appearance of the results is 94 s, with an additional 4 min required to allow the X-ray tube to cool before another acquisition can be taken. The Calscan is able to image either heel from the same side of the device making it easier for the patient and minimizing floor space required where both heels are to be scanned. As for all equipment using ionizing radiation, the Calscan requires a standard radiation safety assessment but also an additional laser safety assessment. The footwell of the Calscan was of an open design, and had the advantage of allowing the operator to manually assist the positioning of the heel. The open design allowed easy access for the operator and was comfortable for the patient, but did require some attention to achieve the ideal positioning.

In vitro results and environmental effects

Short term *in vitro* precision (coefficient of variation) was 0.76% CV (mean BMD $0.347 \pm 0.0026 \text{ g cm}^{-2}$) with phantom repositioning, 0.75% ($0.347 \pm 0.0025 \text{ g cm}^{-2}$) without. Long term precision was 0.73%. The device was accurate, with no measurable difference between mean phantom BMD as measured on our machine compared with that of the central reference machine.

Average phantom BMD and precision for the 32 environmental scans was 0.347 g cm^{-2} and 0.62% CV. Average phantom BMD and precision for the 16 scans taken as soon as possible after a warm-up scan, *i.e.* after the enforced 4 min cooling down period between scans, was 0.347 g cm^{-2} and 0.65% CV. For the 16 scans acquired after the tube had been allowed to cool for half an hour, average BMD was 0.348 g cm^{-2} and 0.61% CV.

During the 32 scans of the 16 environmental tests, the room temperature varied from 21.3°C to 26.9°C, the upper value being slightly outside the manufacturer's recommended operating range of 15°C to 25°C.

Comparison of the results recorded at the 16 highest temperatures (range 23.8°C to 26.9°C) with the results at the 16 lowest (21.3°C to 23.8°C) did not change phantom BMD or precision significantly. For the 16 higher temperature scans, phantom BMD and precision was 0.347 g cm^{-2} and 0.64% CV, respectively. For the 16 lower temperature scans, phantom BMD and precision was 0.348 g cm^{-2} and 0.58% CV, respectively.

Radiation and laser safety

The effective radiation dose to the patient was $<0.1 \mu\text{Sv}$ per scan and a controlled area of 0.5 m was defined around the device in order to comply with IRR 1999 [21]. At this distance, scatter dose to the operator would not exceed annual dose limits, even at maximum scan throughput. The laser assessment found the Calscan laser itself to be class 2 by UK/European/US standards and thus capable of causing eye damage, but the location of the laser within the footwell removed the possibility of accidental exposure and so the laser was deemed to be safe (class 1), provided the Calscan outer casing was in place. The permanent filtration and laser class were not marked on the casing as is required to comply with UK/EU standards [22, 23]. A laser warning label was added to the Calscan and local rules were established that reflective objects should be kept clear of the footwell, as stated in the user manual. No other laser precautions were deemed necessary. No safety problems with the laser occurred during the project, but it was noticed that opaque black hosiery could produce spurious BMD results, although other hosiery did not.

In vivo results

Subject demographics and bone density results are summarized in Tables 1 and 2, whilst coefficients of determination (adjusted R^2) between key variables are shown in Table 3. Mean *in vivo* BMD of the right heel for all 67 subjects (19 osteoporotic, 48 non-osteoporotic) given repeat measurements was 0.357 g cm^{-2} (range 0.186–0.518 g cm^{-2} , standard deviation 0.074 g cm^{-2}). Mean absolute difference between paired results was 0.0046 g cm^{-2} (range 0–0.018 g cm^{-2}). Calscan precision for the 67 subjects as %CV (derived from root mean square) was 1.19%.

Taking the osteoporotic and non-osteoporotic precision groups separately, mean BMD for the 19 osteoporotic subjects was 0.299 g cm^{-2} (0.186–0.437 g cm^{-2} , SD 0.065). Mean absolute difference was 0.0042 g cm^{-2} (0–0.012 g cm^{-2}). Precision was 1.30%CV. For the 48 non-osteoporotic precision subjects mean BMD was 0.392 g cm^{-2} (range 0.281–0.518 g cm^{-2} , SD 0.061). Mean absolute difference was 0.0048 g cm^{-2} (0–0.0018 g cm^{-2}). Precision was 1.09%CV.

Establishing triage thresholds

In the revised NOS guidelines on peripheral DXA, Blake et al [20] recommend the use of peripheral devices in a triage role as an adjunct to axial DXA and suggest a

Table 2. "Evaluation and Diagnostic Thresholds of the DXL Calscan". Mean (standard deviation) DXA bone density and T-score results for whole group, osteoporotic and non-osteoporotic subjects, respectively

		Whole group	Osteoporotic	Non-osteoporotic
Spine L2–L4	BMD	0.948 (0.173)	0.822 (0.070)	1.076 (0.152)
	T-score	–2.10 (1.45)	–3.15 (0.59)	–1.03 (1.26)
Total hip	BMD	0.832 (0.122)	0.774 (0.092)	0.892 (0.121)
	T-score	–1.39 (1.02)	–1.88 (0.77)	–0.89 (1.01)
Non-dominant heel	BMD	0.356 (0.064)	0.328 (0.054)	0.383 (0.062)
	T-score	–1.96 (0.97)	–2.37 (0.82)	–1.53 (0.93)
Dominant heel	BMD	0.356 (0.064)	0.328 (0.050)	0.383 (0.065)
	T-score	–1.96 (0.97)	–2.38 (0.75)	–1.54 (0.99)

Units: BMD (g cm^{-2}); T-score (St Dev).
BMD, bone mineral density.

Table 3. "Evaluation and Diagnostic Thresholds of the DXL Calscan". DXA BMD Correlation (adjusted R^2 value)

	Spine L2–L4	Total femur	Dominant heel	Non-dominant heel
Spine L2–L4	1	0.379	0.285	0.276
Total femur		1	0.331	0.350
Dominant heel			1	0.905
Non-dominant heel				1

method for defining the two triage thresholds required. The upper of the two thresholds is set at a point above which only 10% of osteoporotic subjects would fall, whilst the lower threshold is a point below which only 10% of non-osteoporotic subjects would fall. Subjects who fall above the upper threshold would be assumed non-osteoporotic, whilst subjects who fall below the lower threshold assumed osteoporotic. Subjects falling between the two would be recommended for referral for axial DXA.

Using the 140 subjects in this study, the upper and lower thresholds for Calscan for the non-dominant and dominant heels are shown in Figure 2. The proportion of subjects in the equivocal group, and therefore requiring axial DXA, is shown in Table 4. Based on these thresholds of 0.391 g cm^{-2} and 0.306 g cm^{-2} for the non-dominant and 0.395 g cm^{-2} and 0.294 g cm^{-2} for

the dominant heel, the referral rates for the Calscan in this group were 52.9% (non-dominant) and 58.6% (dominant), but with an error margin of $\pm 9\%$ due to the small sample size. Of the seven non-osteoporotic subjects misclassified as osteoporotic by Calscan of either non-dominant or dominant heels, six had severe osteopenia (axial T-score < -2).

A better estimate of the expected referral rate can be drawn from comparing our derived thresholds (and confidence intervals) to the mean and standard deviation of the Calscan reference data. The reference data are drawn from a population of 993 Swedish women between 15 years and 85 years of age [24] (381 between 50 years and 69 years), albeit a population without known risk factors. If we assume a hypothetical referral group with an even distribution of subject ages from 55 years to 70 years and the same spread and trend in BMD results as the Swedish reference group, the expected mean referral rate at the non-dominant heel would be 36.7%. Adjusting for the distribution of ages seen in our 140 subjects, the figure would be 36.8%.

Discussion

The Calscan proved reliable, precise, accurate and easy to use. Calscan performance was stable within a normal range of room temperatures, and was not affected by recent movement of the device. There was no difference

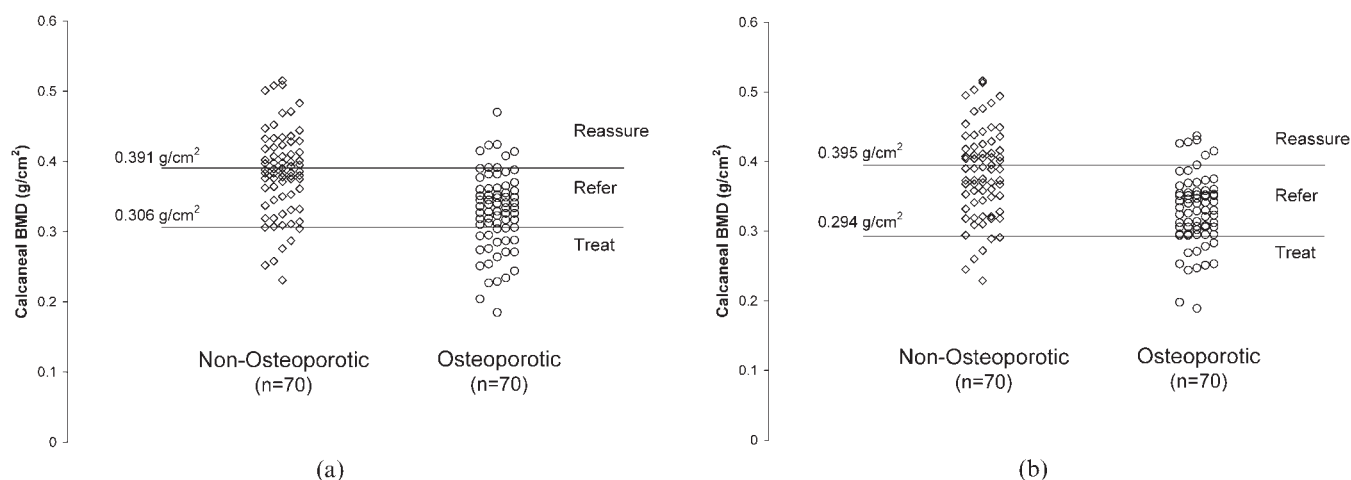


Figure 2. (a) DXL Calscan upper and lower triage thresholds for the non-dominant heel. (b) DXL Calscan upper and lower triage thresholds for the dominant heel.

Table 4. "Evaluation and Diagnostic Thresholds of the DXL Calscan". Referral by number of subjects

		Non-dominant heel	Dominant heel
Thresholds:	Upper	0.391 (-1.4)	0.395 (-1.4)
	Lower	0.306 (-2.7)	0.294 (-2.9)
Units: BMD (T-score). BMD in g cm^{-2} . T-score in standard deviations			
Above upper threshold: reassure	Non-osteoporotic	30	31
	Osteoporotic	8	7
Between thresholds: refer	Non-osteoporotic	33	32
	Osteoporotic	41	50
Below lower threshold: treat	Non-osteoporotic	7	7
	Osteoporotic	21	13
Units: number of subjects			
Referral rate		52.9%	58.6%

in performance when acquiring scans in quick succession, or with 30 min breaks between them, with the enforced 4 min period between scans appearing sufficient time for the X-ray tube to cool. Radiation dose to patient and scatter dose to operator were low and the device requires only a small controlled area. There is no lower limit of applicability and the Ionising Radiation Regulations still apply, requiring therefore the advice of a radiation protection advisor, device risk assessment, production of local rules, written procedures and appropriate training of staff.

At 1.19% CV, precision *in vivo* for our 67 precision subjects as a whole was slightly superior to the 1.24% for the Calscan and 1.28% for the GE-Lunar PIXI reported by Hakulinen et al [8], who performed repeat scans on 38 (18 male, 20 female) subjects with a mean (SD) age of 59.7 years (± 9.4 years). Although at 1.30% CV the precision for our 19 osteoporotic precision subjects is poorer than the 1.09% for the 48 non-osteoporotic subjects, at 0.0042 g cm^{-2} versus 0.0048 g cm^{-2} , the mean absolute error per repeat measurement was actually lower for the osteoporotic than for the non-osteoporotic group, and so the difference in precision can be explained by the difference in the mean BMD scores for the two groups. As with all DXA systems, attainment of good precision requires technical staff to be trained, experienced and to practice good technique.

We found the coefficient of determination (R^2) with spine and total hip DXA to be 0.28 and 0.35 at the non-dominant heel. Correlation at spine was lower than the 0.59 reported by Martini et al [25], or the 0.61 reported by Hakulinen [8]. It is not clear if this is due to differences in the sample groups and the small size of the Martini and Hakulinen samples.

Using T-scores, the upper and lower triage thresholds as defined by the NOS method for the Calscan were at -1.4 and -2.7, respectively, for the non-dominant heel. These T-scores are only applicable to post-menopausal white women aged 55-70 years who meet the normal criteria for axial bone densitometry examination. As with all T-scores, the exact threshold values depend on the reference range. Were this to be changed, then the T-scores would need to be recalculated from the underlying BMD scores of 0.391 g cm^{-2} and 0.306 g cm^{-2} . In addition, the T-score thresholds of any peripheral devices employed in a triage role are likely to become more negative with advancing subject age [20], but the unreliability of spine DXA in subjects over 70 years of age makes the calculation of peripheral threshold values

problematic for such a group, without resorting to total hip BMD alone.

There continues to be a growth in demand for bone densitometry services through increased awareness of health professionals and the public, rising healthcare costs of fragility fractures and the development and introduction of new bone protective treatments. The provision and availability of such services, however, remains patchy and inconsistent. In an area where demand on axial DXA is exceeding capacity, peripheral DXA could prove useful in a triage role to ensure best and most cost effective use of this resource. However, a comprehensive analysis of the resource implications of such an approach is required. Applying the triage thresholds to the population used for this evaluation would suggest that over 50% would require referral for axial DXA. As indicated, the study was not powered to provide an accurate assessment of referral proportion and the true figure is probably below 40%. Provided the cost per case for the heel DXA measurement is less than 60% that of a spine and hip measurement, there should be a net saving. Where the peripheral device is community or primary care based, there may be an increase overall in patients identified due to the more accessible nature of the service which would reduce the potential cost savings and also increase the burden on the prescribing budget.

Where there is no access to axial DXA locally, peripheral DXA may play a role in identifying those at risk of fragility fracture provided it is used with care and in appropriate populations with clearly identified clinical risk factors. The Calscan device appears suitable for either role using the thresholds derived in this study. There is a high proportion (95%) of the more metabolically active trabecular bone in the calcaneus [15] which would suggest that this site is sensitive to mechanisms affecting bone metabolism. This, together with the advantage of being a weight bearing bone, should better reflect the changes occurring at the spine and hip than at other peripheral sites. The moderate correlation between the heel and axial sites observed in this study may be due to sample bias as the subjects were drawn from those attending for bone densitometry. The lack of agreement observed generally between sites is also partly due to the varying trabecular to cortical ratios with the spine being 50% trabecular and hip 40%.

There is no published evidence to date that patients commenced on treatment on the basis of falling below the lower triage threshold by pDXA could be monitored

by pDXA. Ringe et al demonstrated promising results in heel BMD with ibandronate [26], but they employed a non-standard technique and do not compare the observed 15% increase at 2 years with the least significant change. It is also known that some bone protective treatments are only effective in reducing fractures in those defined osteoporotic by hip BMD [27]. There are no data yet on effectiveness of treatments in those targeted by the pDXA triage technique although use of the derived lower pDXA threshold provides 90% confidence that the patient would be found osteoporotic by spine and hip, with almost all the remainder severely osteopenic by spine or hip.

Use of peripheral devices in a triage role as an adjunct to an established axial DXA service could bring substantial benefits to both patient and healthcare providers, and the Calscan is well suited for this purpose. However, it should be operated only by qualified personnel, used in selected populations and results interpreted in conjunction with clinical risk factors for fragility fracture.

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