

# Sensitivity and specificity of osteoporosis diagnostics at primary healthcare with Bindex



Karjalainen J.P. (1), Riekkinen O. (1), Schousboe J (2) and Kröger H. (3).



(1) Bone Index Finland Ltd., Kuopio, Finland, (2) Park Nicollet Institute, Minneapolis, MN, USA and (3) Department of Orthopaedics, Traumatology and Hand Surgery, Kuopio University Hospital, Kuopio, Finland.

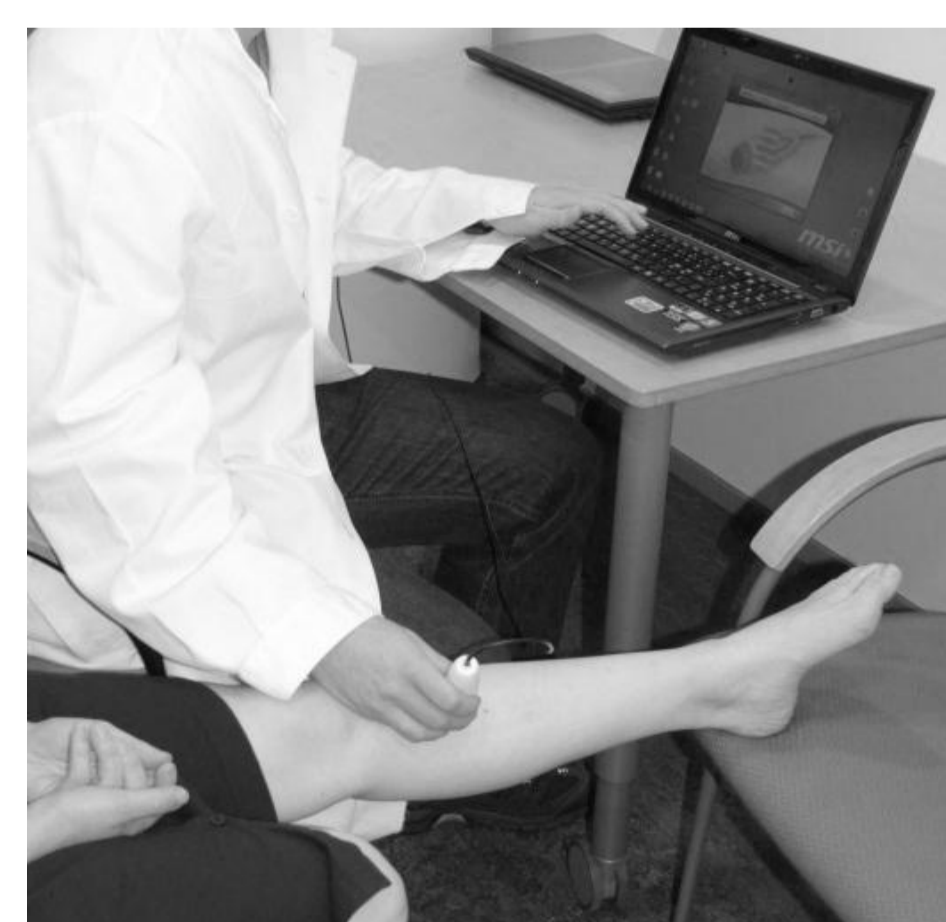


## INTRODUCTION

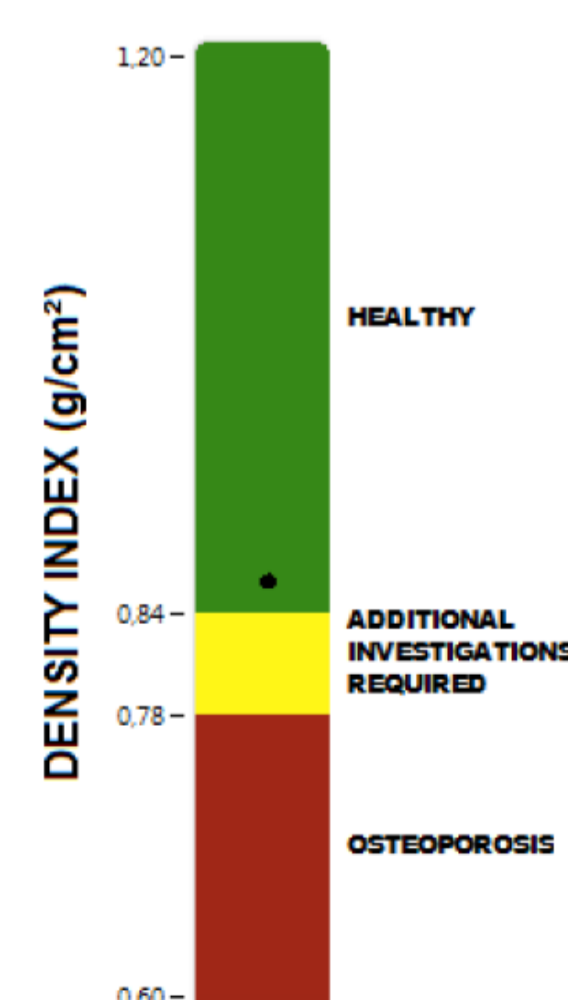
- A new ultrasound based point of care device (Bindex®) has been recently introduced for osteoporosis (OP) screening and diagnostics at primary healthcare (1). Bindex® measures cortical thickness and determines parameter called density index (DI).
- Thresholds (90% sensitivity and specificity, triage approach) for DI in OP assessment have been determined in Finnish Caucasian population along the International Society of Clinical Densitometry (ISCD) guidelines (2). **In this study, the sensitivity and specificity are assessed in data set combining three independent trials.**

## METHODS

- A total of 1830 Caucasian females participated the study (age  $67.2 \pm 8.9$  years, Table 1).
- Subjects were measured with dual energy x-ray absorptiometry (DXA) to determine bone mineral density (BMD) at proximal femur. Further, the cortical thickness was measured at three locations (distal radius, distal and proximal tibia) with Bindex®.
- Subjects were diagnosed with OP when T-score at femoral neck or total proximal femur was below -2.5 (NHANES III reference database).
- A subgroup of 1344 subjects was formed in which the subjects with T-score -2.1 - -2.9 were removed due to the precision error in T-score values and uncertainty of osteoporosis/healthy status (3). In this subgroup, OP was diagnosed when T-score was at or below -2.9.
- Density index (Fig 1) was calculated either by using measurement at one location (DI<sub>1</sub>, proximal tibia) or all three locations (DI<sub>3</sub>).



a)



b)

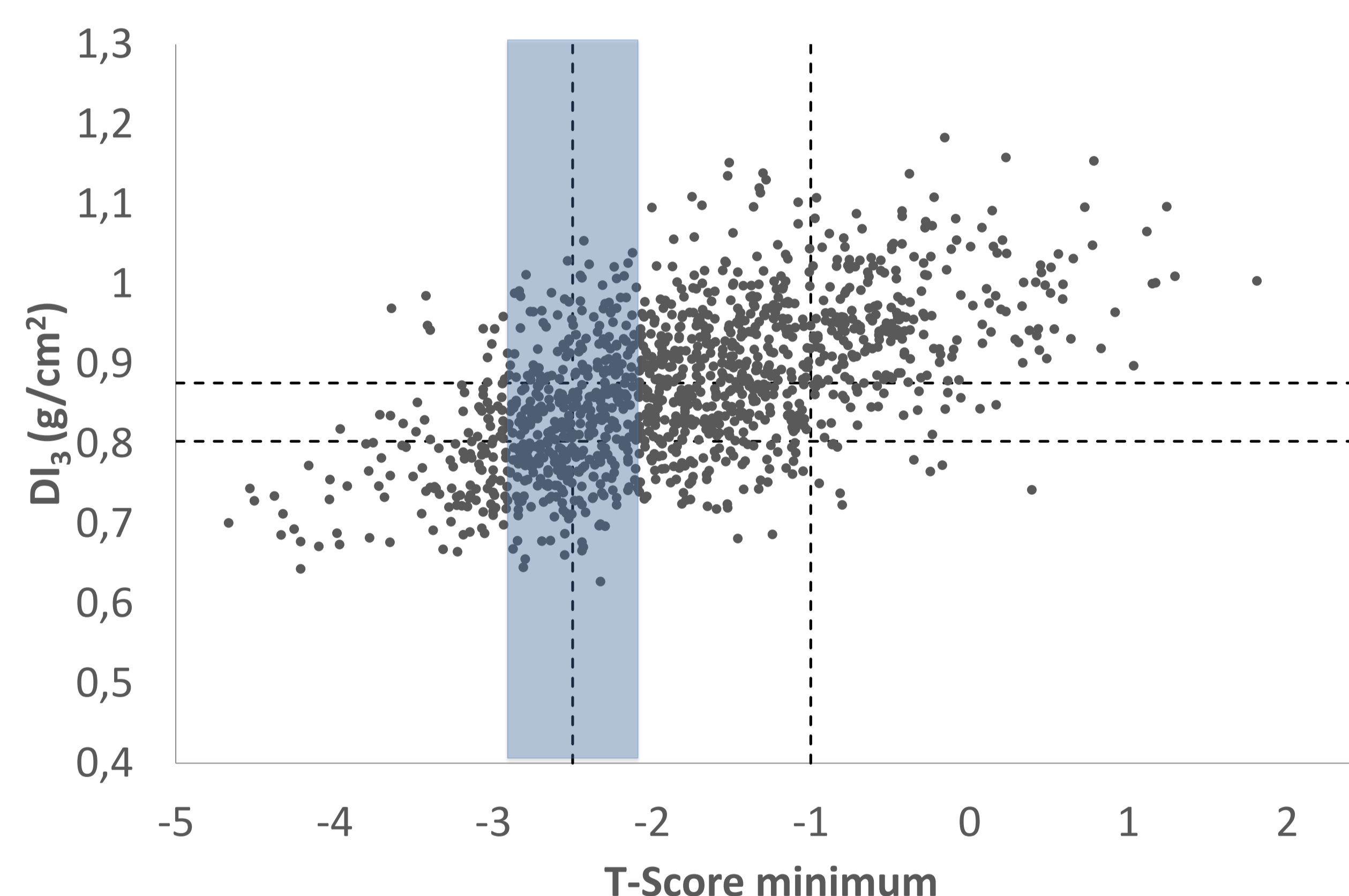
**Figure 1.** (a) Based on cortical bone thickness measurement and subject characteristics, Bindex provides a diagnostic parameter, Density Index. (b) Subjects were classified as healthy (green), osteoporotic (red) or in need of DXA examination to verify diagnosis (yellow) based on earlier determined 90% sensitivity and specificity thresholds (1).

## RESULTS

- A total of 70 to 73% of the subjects could be directly diagnosed by using Bindex® measurement.**
- Sensitivity in OP diagnostics was 82% and 87% for DI<sub>1</sub> and DI<sub>3</sub>, respectively. Specificity was 83% for both DI<sub>1</sub> and DI<sub>3</sub>.
- In the subgroup, sensitivity in OP diagnostics was 90% and 93% for DI<sub>1</sub> and DI<sub>3</sub>, respectively. Specificity was 87% for both DI<sub>1</sub> and DI<sub>3</sub>.**

**Table 1.** Subject characteristics (mean ± SD).

	Healthy (n = 1456)	Osteoporotic (n = 374)
Age (years)	66.5 ± 8.6	70.2 ± 9.5
Weight (kg)	67.1 ± 12.1	59.0 ± 11.0
Height (cm)	161.3 ± 6.6	159.2 ± 6.6
T-score minimum	-1.4 ± 0.8	-2.9 ± 0.4



**Figure 2.** The minimum value of total hip and femoral neck T-score was the diagnostic criteria used in determination for OP. Shaded area depicts the subjects removed (n=486) for sub-group analyses.

**Table 2.** DI<sub>1</sub> and T-score values for the subjects at the different groups in triage approach (mean ± SD).

	< lower threshold	Between the thresholds	> upper threshold
DI (g/cm <sup>2</sup> )	0.742 ± 0.028	0.813 ± 0.019	0.914 ± 0.056
T-score minimum	-2.3 ± 0.9	-1.9 ± 0.8	-1.3 ± 0.9
n (number/%)	436 / 23.8%	567 / 31.0%	827 / 45.2%

## CONCLUSIONS

- The suggested thresholds for the DI were tested in a large population and performance of the technique seems consistent when data from several studies were combined.
- The ultrasound based Bindex measurement for osteoporosis detection shows good performance for OP detection at primary care level.

## REFERENCES

[1] Karjalainen JP, Osteoporos Int 2016, [2] Hans, J Clin Densitom., 2008, [3] Kiebzak, J Clin Densitom., 2007.