



# The **accuDEXA™** Bone Densitometer

# Why the finger? (science)



- Over 50 years of clinical acceptance using finger
- Initial HRT monitoring studies performed on finger with positive results

*Lindsay R, Hart DM, Clark DM. The minimum effective dose of estrogen for prevention of postmenopausal bone loss. Obstet Gynecol, (1984) 63(6): 759-63.*

- BMD Declines with aging, 40-90 y.o.

Site	Decline (Standard deviation decrease per decade)
accuDEXA of finger	0.7
total hip	0.4
femoral neck	0.4
1/3 radial site	1

*Mulder JE, Michaeli DA, Flaster ER, Siris E. A comparison of bone mineral density of the phalanges with bone mineral density of the lumbar spine, hip and forearm for the assessment of osteoporosis in postmenopausal women. Journal of Clinical Densitometry, 3(4): 373-381.*

# Why accuDEXA?



- Measures BMD using *DXA*
- Most affordable
- Easiest to use
  - no external computer
  - quick throughput (1-1/2 minutes)
- No discomfort for patient
  - readily available site / easy positioning
  - no gels or water bath / easy to maintain
  - scan time less than 15 seconds
- Lowest Radiation, 1/150,000th of chest x-ray
- Small footprint (less than 2 ft<sup>2</sup>)





### accuDEXA BONE DENSITOMETRY REPORT

Date: 04/22/98 11:11 AM

Version 1.1 (04/22/98) Serial # 395

Patient ID	123
Gender	Female
Age	50 years
Ethnicity	Caucasian

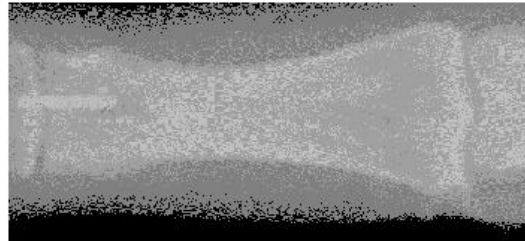


Image not for diagnosis

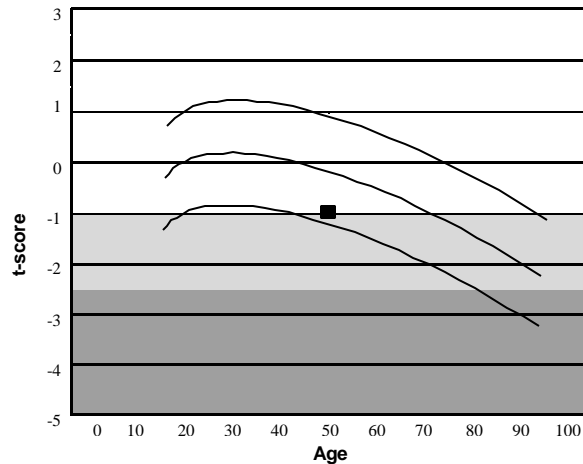
Calibration status: Passed

#### BMD Test Results

BMC	2.146 g
Area:	3.865 cm <sup>2</sup>
BMD:	0.555 g/cm <sup>2</sup>

z-score	-0.5	92%	Age-matched BMD
t-score	-1	85%	Relative to YHN
Analysis	Normal		Based on WHO guidelines

Female Caucasian reference curve



Legend

t-score	Analysis
t > 1	High BMD
1 ≥ t > -1	Normal
-1 > t > -2.5	Osteopenia
t < -2.5	Osteoporosis



- Professional Report
- FDA fracture risk approval

# Precision



- In-vivo precision is within 1%

*Faulkner KG, Shea M, McClung MR. Machine and Operator Precision of the accuDEXA  $\hat{O}$  Bone Densitometer. TRANS ASBMR, 1998.*

- As precise as central technology (0.8-3.2%)

*Lilley J, Walters BG, Heath DA, Drolc Z. In Vivo and In Vitro Precision for Bone Density Measured by Dual Energy X-ray Absorption. Osteoporosis Intl (1991), 1:141-146.*

- Much more precise than ultrasound (3-5%)

# Precision



- Given published annual changes at finger, BMD can be tracked biannually with 85% confidence level (matches Medicare guidelines)

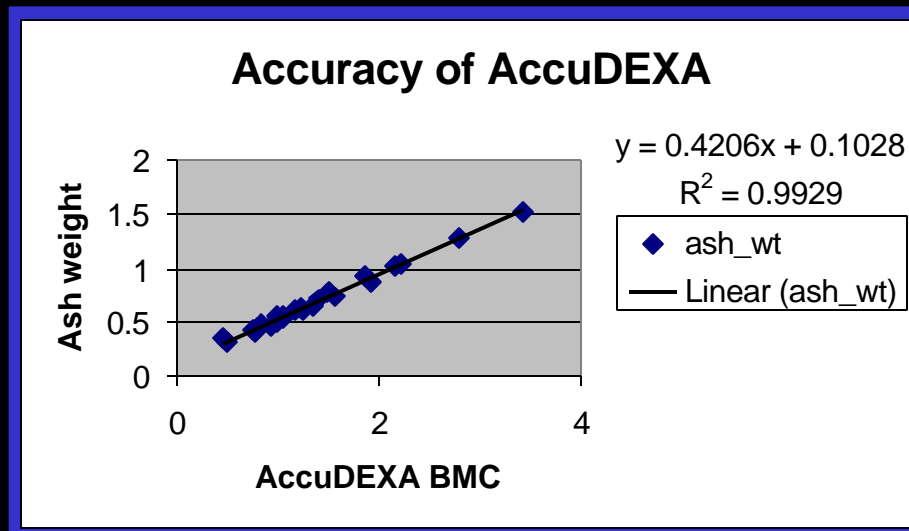
*Matsumoto C, Kushida K, Yamazaki K, Imose K, Inoue T. Metacarpal Bone Mass in Normal and Osteoporotic Japanese Women Using Computed X-ray Densitometry. Calcified Tissue Int (1994), 55:324-329.*

*Bonnick SL. Bone Densitometry in Clinical Practice. Humana Press, 1998, pp.90.*

# Accuracy



- Most accurate DXA: 99% correlation with bone ash
- 1.8% accuracy error



*Michaeli DA, Mirshahi A, Singer J, Rapa FG, Plass DB. A new x-ray based osteoporosis screening tool provides accurate and precise assessment of phalanx bone mineral content. Journal of Clinical Densitometry, 1998.*

# Correlation



- Correlation to peripheral technology: RA, Forearm DXA & SXA, ( $0.80 < r < 0.94$ )

*Michaeli DA, Mirshahi A, Singer J, Rapa FG, Plass DB. A new x-ray based osteoporosis screening tool provides accurate and precise assessment of phalanx bone mineral content. Journal of Clinical Densitometry, 1998.*

- Correlates about as well to hip as spine correlates to hip

*Mulder JE, Flaster ER, Michaeli D, Siris E. Comparison of bone mineral density of the phalanges, lumbar spine, hip and forearm for the assessment of osteoporosis in Postmenopausal Women. JCD, Winter 2000.*

	accuDEXA	Lumbar Spine	Total Hip	Femoral Neck	Radius
accuDEXA	1	0.546	0.557	0.532	0.73
Lumbar Spine		1	0.672	0.643	0.536
Total Hip			1	0.896	0.583
Femoral Neck				1	0.547
Radius					1

# Diagnostic Agreement

*Does it really matter?*



- Within the limitations of single-site measurements, BMD measured by accuDEXA has adequate sensitivity to identify women with low BMD at the femoral neck.

*Mulder JE, Michaeli DA, Flaster ER, Siris E. A comparison of bone mineral density of the phalanges with bone mineral density of the lumbar spine, hip and forearm for the assessment of osteoporosis in postmenopausal women. Journal of Clinical Densitometry, In Press, Winter 2000.*

- Based on Receiver-Operator Curve analyses, accuDEXA of the phalanges and DXA of the lumbar spine have similar ability to detect low BMD at the femoral neck
- Alternatives
  - *In “screening environment” utilize cut-point of -1.0*
    - *Sensitivity for femoral neck osteoporosis 85%, Specificity 49%*
  - *In stand-alone environment utilize cut-point of -2.0*
    - *Identifies roughly 50% of individuals who will fracture (NORA)*

# NORA



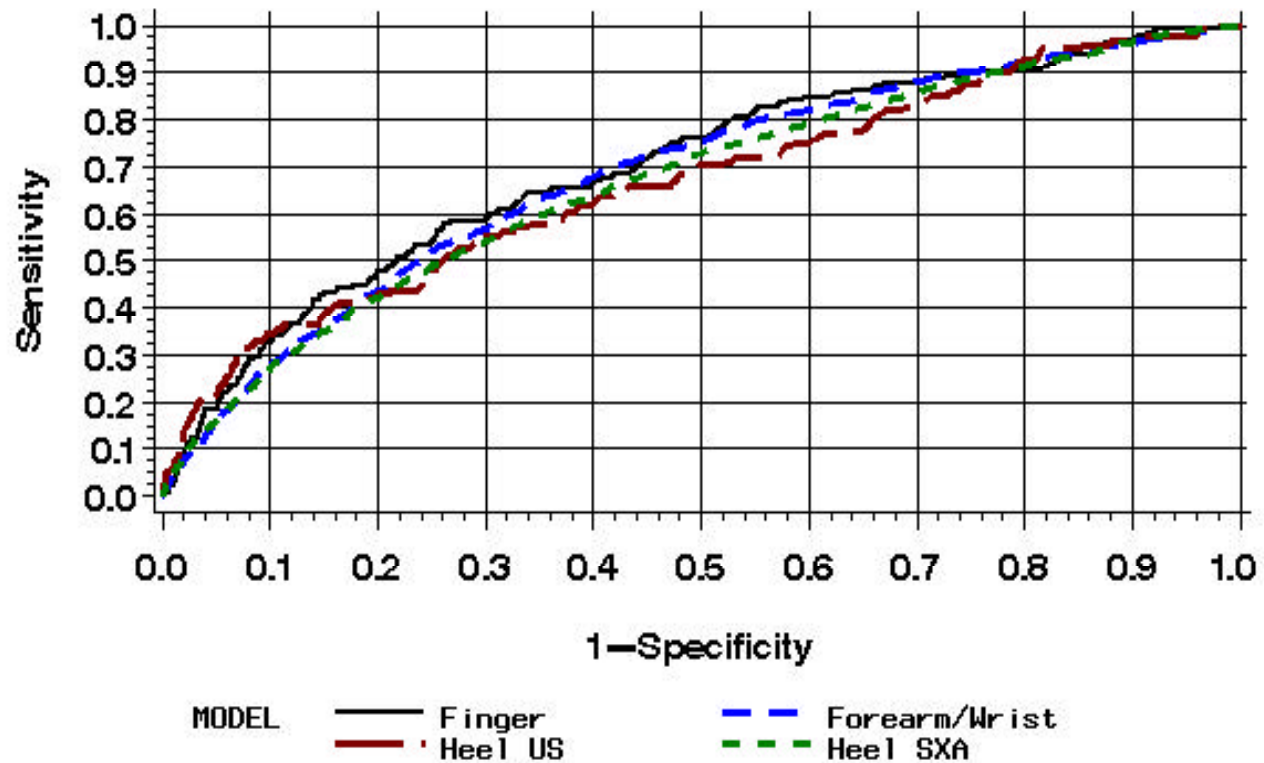
- accuDEXA one of four devices
- 200,000 randomized participants, prospective study of global fracture
- Postmenopausal women 50 years or older
- Caucasian (89%), African American (3.9%), Hispanic (3.5%), and Asian participants (1.0%)
- No previous diagnosis of osteoporosis and no BMD in preceding 12 months
- Limitation: Self-reported fractures
- Prevalence of disease by accuDEXA of 13.5%, as compared to 16% previously established at hip

# NORA ROC Curve for Osteoporotic Fractures



## ROC Curve

Osteo fractures — Adjusted for age



# A Comparison



Technology	Precision	Accuracy error- BMC	Radiation (uSv)	Estimated Exam Time
hip DXA	1 - 2%*	4 - 8%*	0.6 - 5.9	15 min
spine DXA	1%*	4 - 8%*	2.9	15 min
forearm DXA	<1% - 2%**	4.3% - 5.2%**	0.1	7 min
ultrasound	3%***	n/a	n/a	3 min
AccuDEXA	<1%	1.80%	0.0003	1 min

\* Grampp et al. Radiological Diagnosis of Osteoporosis. Eur. Radiology, 7(Suppl 2): 1997.

\*\* Hagiwara, S. et al. Dual X-Ray Absorptiometry Forearm Software: Accuracy and Intermachine Relationship. JBMR, 9( 9) 1994.

\*\*\* Manufacturer's literature