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Indications For Use: FRAX 10-Year Fracture Risk Software Option for GE Lunar Bone Densitometers
The FRAX 10-Year Fracture Risk software option is an accessory to currently marketed GE Lunar bone densitometer devices, which are intended to estimate the bone mineral density and body composition (lean and fat tissue mass) of patients when medically indicated by their physicians.

This software option is intended to provide an assessment of 10-year fracture risk. The option provides an estimate of 10-year probability of hip fracture and 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture). This estimate is based on the patient's age, sex, country, ethnicity, height, weight, femur neck BMD T-score, and the presence or absence of several risk factors and is computed using the FRAX Fracture Risk Assessment Tool endorsed by the World Health Organization (WHO). The tool has been validated for men and post-menopausal women between 40 and 90 years old. The output is provided in a separate screen display and report that can be viewed or printed or exported to an optional physician report generator tool.

The results can be used by a physician in conjunction with other clinical risk factors as an aid in the diagnosis of osteoporosis and medical conditions leading to reduced bone density, and ultimately in the assessment of fracture risk.

About GE Healthcare

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help our customers to deliver better care to more people around the world at a lower cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

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GE Healthcare

FRAX

A new clinical tool for identifying patients at high risk of fracture

FRAX: Individualized fracture risk assessment

FRAX® fracture risk tool

Provides an estimate of 10-year probability of a major fracture (clinical spine, wrist, proximal humerus and hip) or hip alone. This estimate is based on femoral neck BMD and clinical risk factors as shown in the table below.

Licensed from the World Health Organization (WHO), FRAX has been seamlessly integrated into the enCORE software (version 13.31) to make it easy to calculate and comply with new osteoporosis guidelines incorporating FRAX.

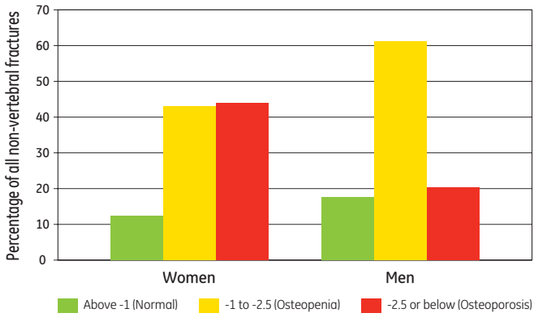

Figure 1: Percentage of non-vertebral, hip, upper humerus and wrist fractures that occurred in men and women with osteoporosis, osteopenia or normal BMD using gender specific T-scores.5

Risk factors included in the WHO fracture risk assessment model[1]
Age
Gender
Personal history of fracture
Femoral neck BMD
Low body mass index (kg/m^2)
Glucocorticoid therapy
Secondary osteoporosis (e.g., rheumatoid arthritis)
Parental history of hip fracture
Current smoking
Alcohol intake 3 or more drinks/day

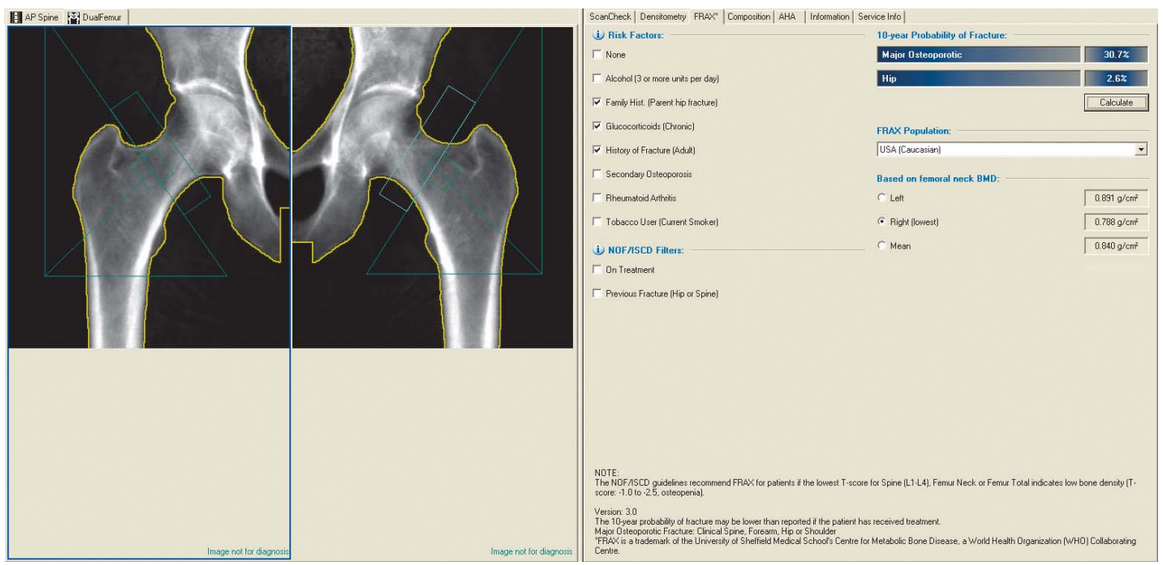

Figure 2: FRAX tool as implemented in the enCORE software.

Identify those most at risk

The FRAX model is useful in identifying the subset of patients in the low bone mass category most likely to benefit from treatment (those with a T-score of –1 to –2.5, categorized as having osteopenia). This is an important advance, since the majority of fractures do not occur in patients with osteoporosis.[1] (See Figure 1)

The FRAX model also includes men and different ethnicities, two groups within which osteoporotic fractures are increasing. However, osteoporosis testing and intervention have been largely neglected.[2]

The FRAX model also aids in identifying persons with co-morbid conditions that increase fracture risk, and targets these high-risk subjects for intervention.[3]

Enhanced fracture-risk communication: Better shared decision-making

Compared to BMD T-scores ***alone***, the use of 10-year fracture probability may provide a better basis for shared decision-making between patient and physician.[2]

Intervention thresholds for the USA

A recent economic analysis by the National Osteoporosis Foundation (NOF) found that osteoporosis treatment would be cost-effective for patients with a 10-year fracture probability of 3% or higher or a 10-year probability of a major osteoporosis-related fracture of 20% or higher.[1,4] However, it must be emphasized that a patient's estimated fracture probability cannot be the sole basis for treatment decisions.[2]

References:

1. National Osteoporosis Foundation. *2008 Clinician's Guide to Prevention and Treatment of Osteoporosis.* Washington, DC: National Osteoporosis Foundation.
2. Dawson-Hughes B, Tosteson ANA, Melton LJ III, et al. *Implications of absolute fracture risk assessment for osteoporosis practice guidelines in the USA.* Osteoporos Int 2008;19:449-458.
3. Siris E, Delmas PD. *Assessment of 10-year absolute fracture risk: a new paradigm with worldwide application.* Osteoporos Int 2008;19:383-384.
4. Tosteson ANA, Melton LJ III, Dawson-Hughes B, et al. *Cost-effective osteoporosis treatment thresholds: The United States perspective.* Osteoporos Int 2008;19:437-447.
5. Schuit, SCE, van der Klift M, Weel AEAM, et al. *Fracture incidence and association with bone mineral density in elderly men and women: The Rotterdam Study.* Bone 2004;34:195-202.

Guidelines incorporating FRAX:

The National Osteoporosis Foundation (NOF) ***Clinician's Guide to prevention and treatment of osteoporosis 2008.***
www.nof.org/professionals/NOF_Clinicians_Guide.pdf

European guidance for the diagnosis and management of osteoporosis in postmenopausal women. Kanis JA, Burlet N, Cooper C, Delmas PD, Reginster, JY, Borgström F, Rizzoli R, on behalf of the European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO). Osteoporos Int (2008) 19:399-428.

Osteoporosis: Clinical guideline for prevention and treatment (UK) [National Osteoporosis Guideline Group (NOGG) on behalf of the Bone Research Society, British Geriatrics Society, British Orthopaedic Association, British Society of Rheumatology, National Osteoporosis Society, Osteoporosis 2000, Osteoporosis Dorset, Primary Care Rheumatology Society, Royal College of Physicians and Society for Endocrinology)]
www.iofbonehealth.org/health-professionals/national-regional-guidelines/references.html#ref_12

Other informational resources on FRAX:

FRAX Identifying people at high risk of fracture.
16-page report aimed to bring understanding of FRAX to health professionals, policy makers, and interested laypersons. Authored by Eugene McCloskey, International Osteoporosis Foundation.
www.iofbonehealth.org/publications/frax.html

WHO On-Line Fracture Risk Assessment Tool
www.shef.ac.uk/FRAX

IOF FRAX Educational Slide-kit.
www.iofbonehealth.org/health-professionals/frax.html