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

FRAX

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

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Our healthymagination vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access and improving quality and efficiency around the world. Headquartered in the United Kingdom, GE Healthcare is a $17 billion unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employs more than 46,000 people committed to serving healthcare professionals and their patients in more than 100 countries. For more information about GE Healthcare, visit our website at www.gehealthcare.com
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.

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.7

Guidelines incorporating FRAX:


Other informational resources on FRAX:


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

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

References:

Risk factors included in the WHO fracture risk assessment model:

- Gender
- Age
- Personal history of fracture
- Femoral neck BMD
- Low body mass index (kg/m²)
- Glucocorticoid therapy
- Secondary osteoporosis (e.g., rheumatoid arthritis)
- Parental history of hip fracture
- Current smoking
- Alcohol intake 3 or more drinks/day
- Secondary factors (diagnosed conditions known to affect bone strength) 
  - Ascorbic acid (vitamin C)
  - Calcium supplements (vitamin D)
  - Glucocorticoid therapy
  - Thyroid therapy
  - Oestrogens
  - Parathyroid hormone

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

<table>
<thead>
<tr>
<th>Fracture Incidence</th>
<th>Women Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10%</td>
<td>10-20%</td>
</tr>
<tr>
<td>20-30%</td>
<td>30-40%</td>
</tr>
<tr>
<td>40-50%</td>
<td>50-60%</td>
</tr>
<tr>
<td>60-70%</td>
<td>70-80%</td>
</tr>
<tr>
<td>80-90%</td>
<td>90-100%</td>
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Figure 2: FRAX tool as implemented in the enCORE software.