Introduction

Osteoporosis is a disease defined by low bone density. It is a “silent” disease in that it often exists undiagnosed until a fracture occurs. The best way to identify patients with osteoporosis before fractures occur is through a bone density exam. In recent years, spine and femur bone density measurements have gained acceptance as the clinical “gold standard” by which physicians diagnose osteoporosis, evaluate fracture risk, and monitor skeletal changes. The most commonly used clinical technique is dual-energy x-ray absorptiometry (DXA), which is capable of measuring bone density at virtually any skeletal site. Yet despite the relative availability of DXA systems, the recent report from the US Surgeon General suggests the majority of individuals at risk for osteoporosis have not had a bone density test.1 While there are 20 million women aged 65 and older in the United States, Medicare reimbursed for only 2.6 million bone mineral density tests in 2002. Meanwhile, the hospitalization rate for osteoporosis-associated vertebral fractures for this demographic group, as reported for 2002 by Health People 2010, remains virtually unchanged since 1998 at 17.4 (age adjusted per 10,000 standard population aged 65 years and older). Clearly, use of DXA alone has not been sufficient to reduce the fracture rate in this most vulnerable segment of the population. There are several potential reasons for this phenomenon of under diagnosis, including the cost of the BMD test, convenience (i.e. proximity to a DXA system), as well as public and health care provider awareness.

Fortunately, there are alternatives to DXA to aid physicians in diagnosis of osteoporosis. The International Society for Clinical Densitometry (ISCD) has confirmed that peripheral bone density measurements have value for assessing fracture risk and identifying patients who should be considered for a DXA measurement and/or treatment.2 Of the available techniques for peripheral densitometry, quantitative ultrasound (QUS) measurement of the heel (calcaneus) is one of the best methods for assessing fracture risk in men and postmenopausal women. QUS works by passing a high frequency sound wave through the bone; the speed and attenuation of the transmitted sound is directly related to the properties of the bone. The primary advantage of QUS is the absence of ionizing radiation, so that QUS measurements can be performed virtually anywhere and by anyone (with minimal operator training). The heel is the measurement site of choice for QUS, as it is easy to access, has very little overlying soft tissue, and has a relatively uniform size and structure. Equally important, the heel is a highly trabecular, weight-bearing site. QUS devices exist for measuring other skeletal sites (such as the hand and forearm), but the evidence supporting these measurements is not as strong as that available for the heel. Today, the large majority of QUS systems installed around the world measure the heel, due to the superior fracture prediction abilities of the calcaneus measurement.3

The use of heel ultrasound to aid diagnosis of osteoporosis

As detailed above, heel QUS measurements have many advantages for programs designed to increase public awareness, identify those at a high risk of fracture, and determine which individuals should be referred for a DXA exam. However, a useful test must be both sensitive and specific for detecting the desired clinical variable. A sensitive test is one that correctly identifies all subjects at risk and avoids “false negative” readings (a normal result in an individual who is actually at high risk). However, sensitivity alone is not enough – the measurement must also be specific to be clinically useful. For example, a test may be sensitive simply by identifying everyone measured as having a high risk. This would be a sensitive test in that it would capture all individuals at high risk (there would be no false negatives), but the test is not efficient because it refers all individuals to DXA including those who are actually at low risk. Such a test does nothing to reduce the number of people identified for additional follow-up. A specific test is one that minimizes “false positives” by reducing the number of people identified as high risk whose result is subsequently not confirmed. In practice, a useful procedure attempts to balance sensitivity and specificity, though a
A highly sensitive test is usually preferred. In other words, it is better when assessing a population to have a false positive reading than a false negative reading. While a false positive result may create temporary anxiety for the patient until the diagnostic test is completed, a false negative reading will result in a high-risk patient being dismissed without any indication of their high-risk status.

In their 2001 position development conference, the ISCD recommended that peripheral densitometry devices be used for testing and risk assessment rather than for the definitive diagnosis of osteoporosis. The strategy is to use the QUS T-score to classify individuals as low risk (not likely to have osteoporosis), high risk (i.e. high likelihood of having osteoporosis and thus in need of a central DXA for diagnosis) and a middle category of moderate risk where additional measurements (specifically DXA) should be considered depending on other risk factors. Ideally, these risk categories would coincide with existing T-score definitions proposed by the World Health Organization for use with central DXA.

Specifically, T-scores of –1.0 or above would represent low risk, -2.5 and lower would represent high risk, and T-scores between –1.0 and –2.5 would indicate the moderate risk where additional measurements (specifically DXA) should be considered. Published research has shown that not all peripheral densitometers provide T-scores that are consistent with spine and femur DXA or with each other. Figure 1 shows the large differences in T-scores obtained from different peripheral systems compared to spine and hip values. It is clear that not all peripheral densitometry systems provide the same results, and that many devices yield T-scores significantly different from those obtained at the spine and femur.

**Figure 1. Differences in T-scores Reported by Peripheral Densitometers**

*Figure 1.* Differences in T-scores Reported by Peripheral Densitometers

### Achillesʼ Testing Protocol

![Achilles Testing Protocol](image)

Because of differences in T-scores obtained from different peripheral devices, the ISCD has recommended that specific T-scores using the 90% sensitivity criterion be obtained for each peripheral densitometry device. Of all the peripheral devices on the market, the Lunar Achilles QUS systems were designed specifically to give T-scores (using the Stiffness Index) that are closely aligned with the DXA T-scores at the spine and hip. Furthermore, the Achilles InSight provides a real-time ultrasound images of the heel to ensure the measurement is performed at the correct region of the calcaneus.

Multiple studies performed with the Lunar Achilles QUS system confirm that 90% sensitivity for detecting osteoporosis at the spine and hip can be obtained using an Achilles T-score referral threshold of –0.8 to –1.2, which is centered on the WHO definition of low bone (T-score of –1.0). Furthermore, these studies have shown that using an Achilles T-score of –2.5 or lower provides excellent specificity (greater than 90%) for identifying only those high risk subjects in need of additional testing and/or treatment. Based on these studies, individuals with Achilles T-scores above –1.0 should be considered at low risk for having osteoporosis and, depending on the presence of additional risk factors, asked to return for a repeat measurement at some future point. Those with an Achilles T-score of –2.5 or lower should be considered at a higher fracture risk based on the peripheral measurement alone, although other risk factors should be considered as well. For those individuals with an “intermediate” Achilles T-score between –1.0 and –2.5, a central DXA test should be recommended to determine the spine and hip bone density. The decision of whether or not to refer for a central DXA should include other factors including the individual’s age and additional risk factors such as those recommended by the National Osteoporosis Foundation (Table 1). Even in individuals where a treatment decision is made based on the peripheral measurement and risk factors, a central DXA measurement may be recommended to monitor therapeutic response. This QUS protocol is outlined in Figure 2.

**Figure 2. QUS Testing Protocol**

*Figure 2.* QUS Testing Protocol

### Differences in peripheral densitometers

**Women: 65 and older**

- Achilles

**Men: 70 and older**

- Achilles

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**Risk Factor Assessment**

- DXA

- Normal
- Osteopenia
- Osteoporosis

- Prevention

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**Image not for diagnosis.**
The National Osteoporosis Foundation recommends BMD testing for all Caucasian women aged 65 and older regardless of risk factors. In addition, the NOF recommends that younger postmenopausal Caucasian women with more than one risk factor (as shown in Table 1) have a bone density test. In their 2001 position development conference, the ISCD expanded on the NOF recommendation to include all women 65 and older regardless of race. More recently, the US Preventive Services Task Force also recommended that women aged 65 and older be tested routinely for osteoporosis and that women at high risk for fractures begin testing at age 60. Finally, experts agree that postmenopausal women of all races who present with fractures are at high risk for subsequent fractures and should have a bone density test.

For men, no professional organization has published consensus guidelines for osteoporosis testing, although several experts in the field have made recommendations. As with women, men presenting with a history of low trauma fracture are at risk for subsequent fracture and should be considered for additional testing and/or treatment. Men with any of the risk factors shown in Table 2 are also at a high risk for fracture and should be tested for osteoporosis. Finally, it has also been suggested that physicians consider routinely testing men aged 70 and older, as this is the age when fracture rates increase most rapidly.

In summary, osteoporosis testing should be considered for the following individuals:
1. All women aged 65 years and older.
2. Postmenopausal Caucasian women under 65 with 1 or more risk factors (Table 1).
3. All men aged 70 years and older.
4. Men under 70 with one or more risk factors (Table 2).
5. Men and women with personal history of low trauma fracture.

**Conclusions**

Experts agree that spine and hip DXA is the gold standard for the diagnosis of osteoporosis. According to recommendations from several professional societies, women 65 and older and men 70 and older, as well as younger men and women with additional risk factors for osteoporosis, should have their bone density measured. However, despite the availability of DXA systems in most cities, a large number of high-risk individuals are still not getting bone density tests. The US Surgeon General’s Report on Osteoporosis highlights the need for additional measures to stem the tide of a growing osteoporosis epidemic. Accessibility to DXA devices, as well as poor public awareness, are major contributors this dilemma. Experts have agreed that peripheral densitometry measurements can be used for identifying high-risk individuals when appropriate criteria are used. Of all the available techniques for peripheral testing, heel ultrasound has significant advantages over other peripheral devices, as it is easy to use, is an excellent predictor of hip and spine fracture, and avoids the use of ionizing radiation. The Lunar Achilles offers the additional advantages of rapid assessment (10 seconds or less), T-scores that are aligned with WHO guidelines for spine and femur measurements, and (in the case of the Achilles InSight) a real-time image of the heel for confident positioning. To aid in the diagnosis of osteoporosis, use of Achilles T-scores corresponding to the WHO classifications identifies moderate and high-risk individuals in need of additional testing with DXA.

**References**

2. Miller PD, Njeh CF, Jankowski LG, Lenchik L (2002) What are the standards by which bone mass measurement at peripheral skeletal sites should be used in the diagnosis of osteoporosis? J Clin Densitometry 5:539-545.

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**Table 1: Major Risk Factors for Osteoporosis in Caucasian Women**

<table>
<thead>
<tr>
<th>Risk Factor</th>
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<tbody>
<tr>
<td>Personal history of low-trauma fracture as an adult</td>
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<tr>
<td>History of fragility fracture in a first-degree relative</td>
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<tr>
<td>Low body weight (&lt; about 127 lbs)</td>
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<td>Current smoking</td>
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<td>Use of oral corticosteroid therapy for more than 3 months</td>
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**Table 2: Major Risk Factors for Osteoporosis in Men**

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<tr>
<th>Risk Factor</th>
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<tbody>
<tr>
<td>History of low-traumatic fracture (hip, vertebrae, or wrist)</td>
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<tr>
<td>Osteopenia seen on plain radiograph</td>
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<tr>
<td>Glucocorticoid use of 5 mg or more per day for longer than six months</td>
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<tr>
<td>Hypogonadism (glucocorticoid-induced or following orchietomy)</td>
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<td>Hyperparathyroidism</td>
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