Number Two in a Series

Review

Peripheral Ultrasound Measurements: Advantages of Dry Technology

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Practical barriers have limited clinical adoption of ultrasound technology in the assessment of osteoporosis. In order to assure the adoption of heel ultrasound into clinical practice, Hologic has developed an alternative "dry" technology, eliminating the practical and performance issues plaguing older, water-based systems.

Scientific data has firmly established the value of heel ultrasound measurement in the assessment of patients at risk for osteoporosis. In two large prospective clinical studies, each involving more than 5,000 subjects, it was found that heel ultrasound measurements were strongly predictive of risk for future hip fracture, the most costly and debilitating consequence of osteoporosis.[1,2] Devices used in the studies validating the predictive value of heel ultrasound are difficult to use in a clinical environment, because they require the use of a temperature stabilized water bath to acoustically couple sound waves to the heel. This "water-based technology" requires the patient to insert a foot into a pool of water for the measurement. Specific requirements of water-based technology include:

- Temperature-stabilized water
- Water mixed with a surfactant to improve skin wetting
- Storage, insertion, removal, and replacement of water, between every patient

The requirements of water-based technology, unfortunately, result in practical and performance-related drawbacks, which have limited ultrasound's adoption into routine clinical practice. Key limitations of water-based technology are:

Key limitations of water-based technology are: size and weight, difficulty of use, time and performance.

- Size and Weight. Water-based devices are large and cumbersome, weighing up to 70 lbs. Periodic transport to outreach clinics, where access to testing would benefit the patient population most, is difficult or impossible.
- Difficulty of use. The necessity of storing and changing the water-surfactant mixture between patients is too rigid a requirement for a busy clinical practice.
- Time. Water-based systems require as long as 5-10 minutes of "settling time" in order to reach a stable value,[3-5] lengthening examination times considerably.
- Performance. The accuracy of speed of sound (SOS) measurements is compromised since accurate assessment of heel width is not possible.

Sahara and the Dry Approach

In order to assure the adoption of heel ultrasound into clinical practice, Hologic developed an alternative "dry" technology, eliminating the practical and performance issues plaguing older, water-based systems. The result is a waterless heel ultrasound system, the Sahara® Clinical Bone Sonometer. Sahara was designed with the clinical user in mind: small and lightweight (22 lbs.), completely portable, and easy to use (one button operation).

Sahara has been validated scientifically with superior performance in both precision and accuracy.

Aside from the convenience of dry technology, Sahara has been validated scientifically with superior performance in both precision and accuracy.

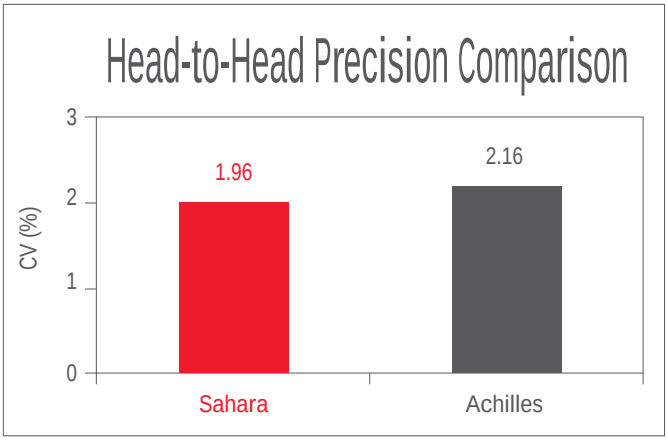

Figure 1. Precision results from Sherwood.[6] Seventy (70) females were measured twice on each system.

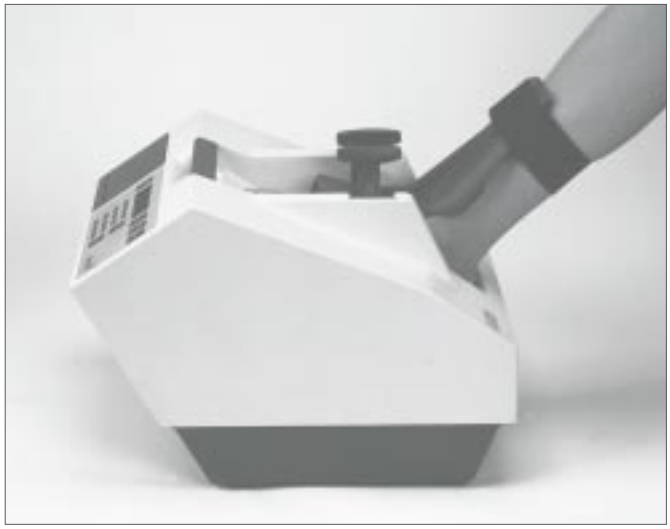

Figure 2. The Sahara easy-to-use foot positioning aide is designed to assure repeatable positioning and results.

Superior Precision

In a direct comparison measuring the same patients on Sahara and Lunar's Achilles, Sherwood[6] concluded Sahara has superior precision (Fig. 1). Further, Sherwood found Sahara precision was superior to Achilles:

- On a short-term basis (70 women measured twice on a single day), and
- On a long-term basis (5 women measured weekly for a year).

In a direct comparison measuring the same patients on Sahara and Lunar's Achilles, Sherwood concluded Sahara has superior precision.

These superior precision results were due to two (2) primary factors:

- Superior reproducibility of foot positioning. Foot positioning is critical for obtaining highly reproducible heel ultrasound measurements,[7] and is especially important in clinical environments, where staff may not be solely dedicated to performing ultrasound examinations. The Sahara foot positioning aide (Figure 2) was designed to assure both simplicity and reproducibility.
- The "settling time" required for water-based results. While some water-based devices have optional measurement times as short as 30 seconds to 1 minute, it is widely acknowledged that BUA and SOS measurement results do not stabilize for several minutes.[3,4,5,7] Consequently, BUA and SOS results are inherently inaccurate on wet systems that have measurement times of less than 5-10 minutes.[3,4,5,7] This phenomenon is well accepted scientifically,[3,5,7] and is even acknowledged by one of the manufacturers of a water-based system (Lunar).[4] For example, the operators manual for the Lunar Achilles system states, "the heel may need to be kept in the water bath for 2 to 5 minutes to achieve a stable reading."[8]

BUA and SOS results are inherently inaccurate on wet systens that have measurement times of less than 5 to 10 minutes.

To reduce the influence of settling time on measurement results, Achilles+ combines SOS and BUA to form a third parameter, referred to as "Stiffness." This combination parameter assumes that the known inaccuracies of the BUA and SOS parameters will cancel one another to improve precision.

For water-based systems, the combination of BUA and SOS does in fact reduce the adverse impact of settling time on precision. However, *precision remains strongly dependent on the relationship between measurement time and settling time.* Precision results reported in published studies are almost always obtained using longer measurement times (3 minutes or more).[5] To date, there are no published results of precision with the measurement times currently advertised by Lunar.

Precision studies on water-based systems are almost always obtained with measurement times of 3 minutes or more.

In contrast, Sahara's dry approach bypasses these limitations for superior, consistent precision. Moreover these measurements are obtained in under 10 seconds.

Superior Accuracy

Speed of Sound (SOS, measured in meters per second) is the ratio of the heel's width divided by the time required for the ultrasound pulse to travel through the heel. Accurate knowledge of the patient's heel width is critical to obtaining accurate SOS mea-

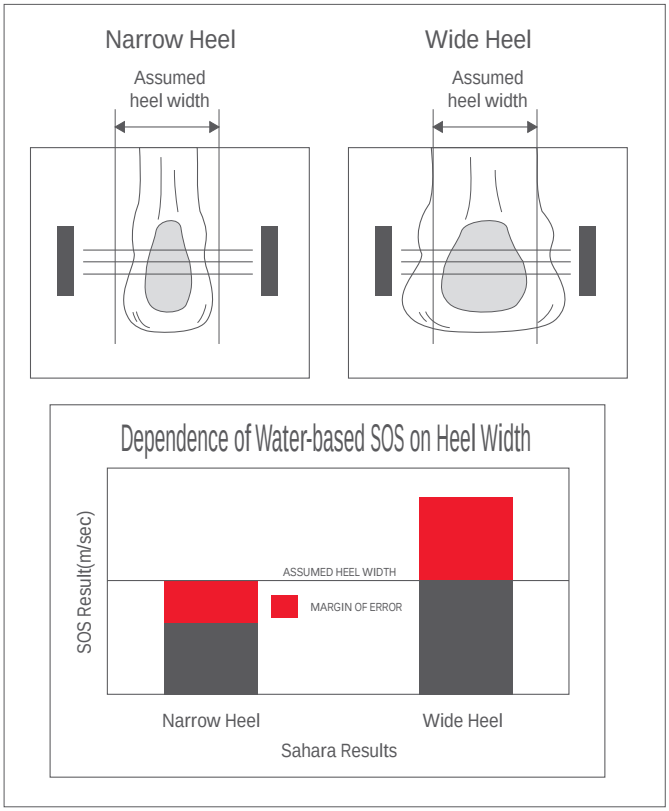

Figure 3. SOS results for different widths of the same material are different when water-based technology is used. Results are different because water-based systems cannot reliably measure heel width and must assume a constant heel width for all patients.

surements:[9] Water-based systems however, assume all patients have the same heel width. This assumption is made for quite practical reasons: measuring the width with a fixed transducer design, while possible via sound reflections, would further degrade precision.[9]

SOS = (heel width) / (transit time through heel)

The consequence of assuming a constant heel width for all patients is that SOS results will vary (Fig. 3) depending on heel width. SOS results are only accurate for the assumed heel width (4 cm for Achilles). Furthermore, measurement errors increase depending on how different the patient's true heel width is from the assumed value.

The systematic errors made by assuming a constant heel width are clinically significant; heel widths vary by nearly a factor of two in a typical population.

The systematic errors made by assuming a constant heel width are clinically significant; heel widths vary by nearly a factor of two in a typical population.[10] Figure 4 illustrates how water-based SOS results can vary dramatically over the wide range of heel widths in a typical female patient population. Similar results were reported by

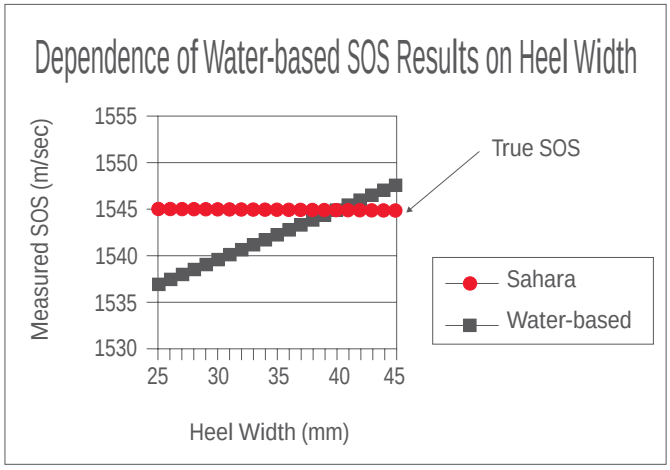

Figure 4. Dependence of water-based SOS results are on heel width vs. Sahara SOS results. Results are computed for heel widths in the typical range found in a female population.[10] Similar results have been reported by Brandenburger.[9]

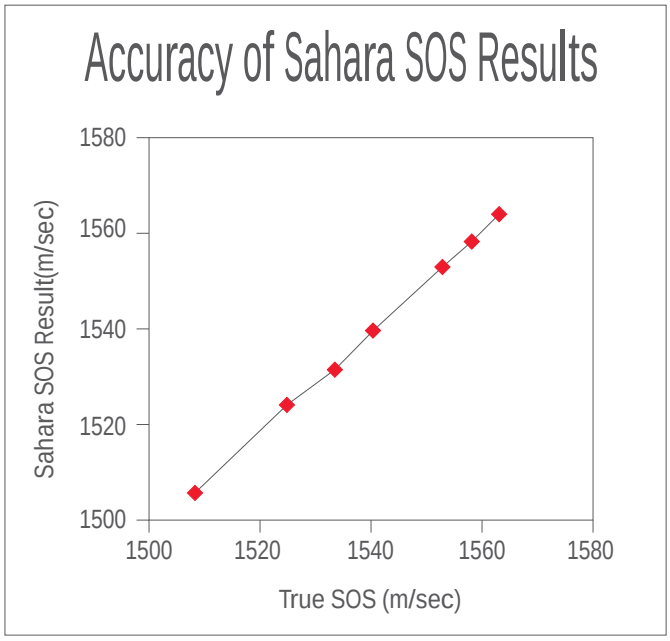

Figure 5. Accuracy of Sahara SOS results was demonstrated across the clinical range of results using known standard SOS values for a water-filled phantom.[13]

Brandenburger.[9] The difference in results between a narrow heel and a wide heel can be as large as 1/3 of a population standard deviation, or T-score. The magnitude of this error is clinically relevant for two reasons:

- The error can be as large as 40–50% of the difference between controls and hip fracture subjects.[11] These errors can be confused with the differences between normal and osteoporotic patients. The practical clinical question arising from this: Is the patient's low value

Sahara makes a direct mechanical measurement of heel width, providing consistent, accurate SOS results, independent of heel width.

due to osteoporosis, or a narrow heel width?

- Two patients with identical SOS results on Sahara may have as much as a 1/3 T-score difference on a water-based system, due entirely to the patients' heel widths. These two patients could easily be classified differently using the World Health Organization (WHO) criteria for assessment of patients using T-scores.[12] One of the patients might have had a T-score of -0.8 ("normal" by the WHO criteria), and the other might have a T-score of -1.1 ("osteopenia," or low bone mass by WHO). Such misclassification could impact clinical management.

In contrast, Sahara makes a direct mechanical measurement of each patient's heel width, providing consistent, accurate SOS results, independent of variability in heel width.

Wilson[13] substantiated the accuracy of Sahara SOS results over the range of clinically observed values (Figure 5). This study demonstrates the absolute accuracy of Sahara SOS results, and combined with the independence of Sahara results to heel width, validates the conclusion that Sahara heel ultrasound measurements are inherently more accurate than those obtained using water-based systems.

Conclusions

Sahara's dry approach is the enabling technology for the proliferation of heel ultrasound into clinical medicine. Patient access to ultrasound densitometry via the private office, mobile, and home-based environments is critical to addressing the growing problem of osteoporosis, as a substantial portion of the population at risk has limited access to more expensive x-ray based diagnostic methodologies.

The benefits of access for the patient population grow daily due to the availability of an increasing array of effective therapeutic agents for the treatment and prevention of osteoporosis. Sound scientific data has demonstrated that Sahara's design overcomes both the inconvenience and performance barriers precluded widespread adoption of ultrasound-based bone measurement into clinical medicine. ■

The Sahara Clinical Bone Sonometer

Intended Use/Indications: The intended use of the Sahara Clinical Bone Sonometer is to perform a quantitative ultrasound measurement of the calcaneus (heel bone), the results of which can be used in conjunction with other clinical risk factors as an aid to the physician in the diagnosis of osteoporosis and medical conditions leading to reduced bone density, and ultimately in the determination of fracture risk. Sahara measures the speed of sound (SOS, in m/s) and broadband ultrasonic attenuation (BUA, in dB/MHz) of an ultrasound beam passed through the heel, and combines these results to obtain the Quantitative Ultrasound Index (QUI). The output is also expressed as a T-score and as an estimate of the Bone Mineral Density (BMD, in g/cm^2) of the heel.

Caution: Federal (U.S.A) Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Sahara should not be used to assess patients whose skin is abraded and/or have an open sore in the area that comes into contact with the system. Sahara ultrasound coupling gel should be used in accordance with the directions for use specified in the User's Guide. Other coupling gels should not be substituted. The Sahara User's Guide provides detailed information regarding the relationship between heel BMD estimates obtained by Sahara and by the Dual Energy X-Ray Absorptiometry (DXA) technique.

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