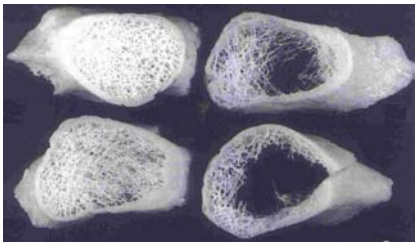
Periodic Bone Monitoring: When, How and Why



Deterioration of bone

Management of Osteoporosis

Monitoring changes in the bone is an essential part of osteoporosis management. Periodic monitoring tracks the process of slow bone loss in a woman's body after menopause, and follows bone status in men and younger women. With regular bone monitoring, it is easy to detect any significant changes that occur in the bone – changes which require close medical attention and possibly intervention.

Bone mass and bone strength increase throughout childhood to a peak in mid-life. Decline in bone strength follows, starting at age 40, but picks up speed only later in life. In women, bone strength declines drastically after menopause with the loss of the protective effect of estrogen on bone. Hormone replacement therapy (HRT) is commonly prescribed for post-menopausal women to help maintain this protective effect. These post-menopausal women are candidates for regular monitoring to track the process of bone loss and the effects of HRT treatment on bone. For all women during the early postmenopausal years, bone assessment is recommended every two to three years.

In some patients, extensive changes in the bone may occur, due to factors ranging from the positive effect of extensive weight-bearing physical activity or treatment with positive bone-affecting agents to the negative effect of steroid treatment. For these patients, bone should be assessed at shorter time intervals.

Monitoring Bone Status with Sunlight Omnisense® 7000S/8000S

Sunlight Omnisense® is a reliable tool for the periodic assessment of bone. Its excellent precision and its unique multi-site measurement capacity contribute to its ability to accurately reflect changes in the bone over time, whether these changes are due to aging, disease, or treatment.

Precision: An Essential Factor in Monitoring

The precision of Omnisense, evaluated in a number of studies, is consistently high. Omnisense's precision indicates its ability to measure a parameter repeatedly and produce the same results. This precision is an essential factor in the device's monitoring ability, because it enables the identification of measurement results that indicate actual changes in the bone.

Omnisense boasts an *in vivo* precision for repeated measurements in the same subject of CV (Coefficient of Variation) of 0.40 at the radius and 0.45 to 0.81% at other sites.[1] [2] [3] [4]This high precision permits a meaningful assessment of changes in bone status over time, when compared to reference database values or previous measurements.

Omnisense's low precision error in comparison with the expected annual change in a patient's measurement permits its use for monitoring in the early years following menopause.[5]

Multi-Site Measurement: A Key to Enhancing Monitoring Ability

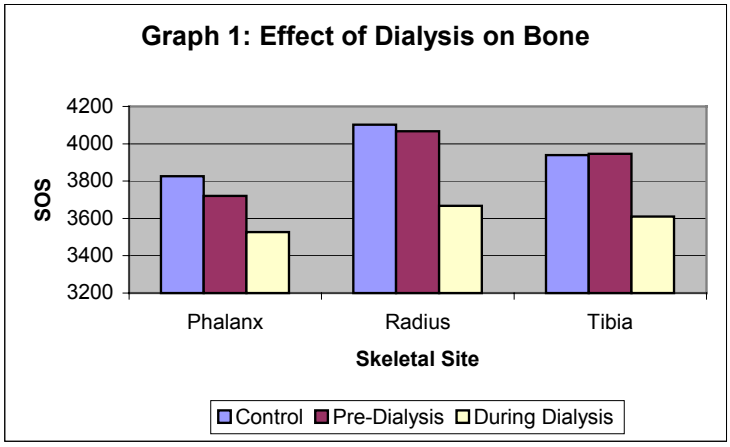
Omnisense is the only quantitative ultrasound bone measurement device capable of measuring bone at multiple skeletal sites.[4] This is an important advantage in bone monitoring because treatment may affect bone characteristics at a different rate at different skeletal sites.[a] Effective monitoring of treatment for osteoporosis therefore requires information from different skeletal sites.

Multi-site measurement permits a comprehensive look on the skeleton, using different sites that reflect different combinations of cortical and cancellous bone and weight bearing and non-weight bearing bone. These sites also differ in the extent that bone characteristics such as porosity and cortical thickness are reflected in the bone.[6] The ability to measure several sites with different bone characteristics plays an important role in accurate bone monitoring.

Omnisense Monitoring Capabilities

Sensitivity to Disease and Treatment Effects

Omnisense can clearly differentiate between subjects using HRT and age-matched controls, and between subjects suffering from bone-affecting diseases and age-matched controls. This sensitivity to changes in the bone indicates monitoring ability.



A series of comparative studies has found that patients suffering from a number of bone-affecting diseases have low SOS values in comparison to controls. One study which measured the effect of dialysis on bone found a significant difference in bone SOS between dialysis subjects and controls at all skeletal sites (Graph 1).[7]

[a] This could explain site-to-site discordance between results, as SOS measurements at different sites depend on the various bone parameters to differing degrees.

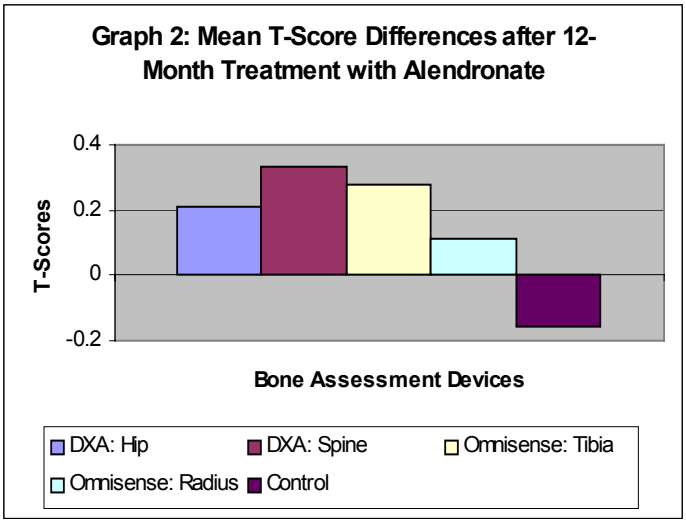
Other studies showed similar results, including one study that found SOS results for hyperthyroid and hypothyroid patients significantly lower that the results for control subjects with no metabolic thyroid effect.[8] The secondary osteoporosis demonstrated by these studies can result from hyperparathyroidism, hyperthyroidism, lactase deficiency, or use of dialysis.

Significant results have also been shown in a number of comparative studies researching the effect of hormone replacement therapy (HRT) and metabolic disorders on bone. These studies showed that women undergoing HRT had high SOS results in comparison to age-matched controls not under treatment.[9 10 11 12]

The results of these secondary osteoporosis and HRT studies demonstrate a uniquely useful sensitivity to bone changes.

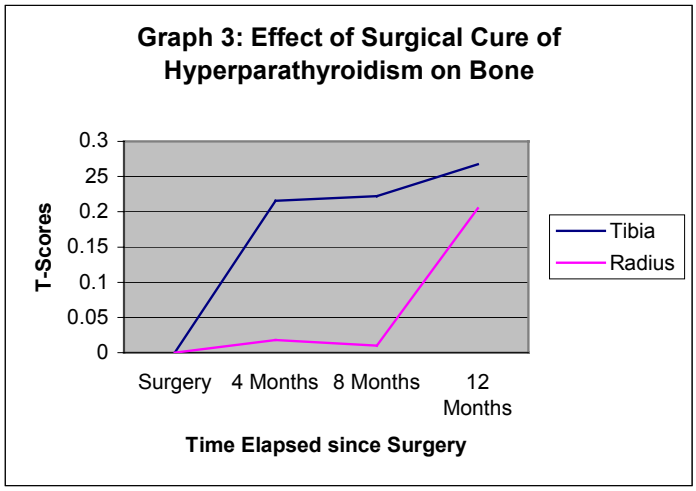
Sensitivity to Bone Changes over Time

In addition to results shown in comparative studies, Omnisense has demonstrated a sensitivity to changes over time that enables periodic monitoring of bone changes.



In one longitudinal study, a positive effect on bone due to treatment with Alendronate over a 12-month period was detected by Omnisense. The treatment group showed a significant ($p<0.05$) increase in T-scores at two out of four skeletal sites when measured by Omnisense before treatment and after the commencement of treatment (Graph 2).[13]

In another longitudinal study, a significant bone gain was detected by Omnisense as early as four months after surgical cure of primary hyperparathyroidism (PHPT). results. [14] (Graph 3) The group of hyperparathyroid patients showed a significant increase in bone SOS at two skeletal sites following a successful surgical cure of the disease.



Periodic Bone Monitoring Means Omnisense

With its ability to identify the results of treatment and to track changes over time, Sunlight Omnisense® is an accurate and precise tool for the periodic monitoring of bone. Its sensitivity permits frequent monitoring of bone – with time intervals as short as six months between measurements. With treatment results documented by Omnisense, physicians can be confident that they are treating their patients' osteoporosis in the best possible way.

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