

PREMIER Bone Assessment for the First Months of Life



Bone Assessment for Pre-term Babies- A Foundation for Healthy Bones

Monitoring the bones of pre-term infants to track their bone development is a key to healthy bones from infancy through old age. Many pre-term babies suffer from delayed bone mineralization, including a significant number of pre-term infants with Osteopenia of Prematurity. Bone monitoring is an essential step towards providing the nutrients and physical stimulation needed by some pre-term infants.

Bone mineralization in utero takes place mostly during the third trimester of pregnancy. Babies born pre-term miss out on much of this intrauterine bone development, and are born with inadequate mineralization. This condition, described as Osteopenia of Prematurity, is correlated with an increased risk of fracture in the neonatal period.¹ Furthermore, the already low bone mineralization of very pre-term babies decreases after birth, while full-term babies enjoy accelerated bone mineralization in utero at the same gestational age.² Immobilization and steroid treatment during their frequently prolonged stay in NICUs further reduces the bone mineralization of pre-term infants.³

Diagnosis of the disease and the monitoring of diagnosed infants permit timely intervention by physicians to aid in bone development.

Current Pre-Term Bone Assessment Methods

Current methods for bone assessment for premature infants include Serum ALK-P, radiography, and dual X-ray absorptiometry. Various drawbacks limit the use of all of these bone assessment methods for pre-term infants.

Serum ALK-P

Serum ALK-P tests are the method most commonly used today to follow the disease. The test, which requires drawing a blood sample to test for serum ALK-P levels, is invasive, often presenting a problem for pre-term infants. In addition, the detection of low serum phosphate and serum calcium levels can be used to demonstrate Osteopenia once it has been diagnosed, but do not identify any variations in bone mineralization in infants or provide information about progress of the disease or fracture risk.

Radiography

Radiographic tests are currently used to diagnose rickets of prematurity. However, these tests detect changes only after bone mineral content has been reduced by 30%, restricting their use in screening and diagnosis. Their use of ionizing radiation as well as their essential subjectivity and resultant imprecision are also drawbacks to their use.

Dual-Energy X-ray Absorptiometry

Dual-energy X-ray absorptiometry (DXA) testing, often used for bone assessment in adults, is rarely used for pre-term bone assessment. Its use of radiation, the necessity for the sedation and transfer of tiny infants to the device, and its lack of a reference database for pre-term infants, all constitute serious disadvantages.

PREMIER: The Optimal Method for Pre-term Bone Assessment

PREMIER is the only device that offers ultrasound-based bone assessment for the diagnosis and monitoring of Osteopenia of Prematurity. Designed to match the needs of these babies and the professionals who care for them, PREMIER is mobile, user-friendly, radiation-free, accurate, and sensitive to small changes in bone mineralization. It uses the proprietary Omnipath[®] technology, which measures the speed of sound along the bone, a parameter that is related to various structural characteristics of the bone^{4 5} and correlated with fracture risk in adults.^{6 7} This method, quick, radiation-free, and non-invasive, eliminates the effect of soft tissue on measurement. It is distinctively suited to the measurement needs of premature infants.

Accurate Measurement

PREMIER's low measurement error provides sensitivity to small changes in the bone.⁸ The observed weekly SOS change for pre-term babies is 13m/sec, larger than the device's precision error. This enables accurate monitoring of the bones of pre-term infants at frequent intervals.

Unique Pre-term Reference Database

PREMIER's reference database of pre-term infants enables comparison of bone assessment results with reference data and permits real-time diagnosis of Osteopenia. The reference database showed SOS to be significantly correlated with gestational age and birth weight, with the smaller, younger pre-term babies showing significantly lower SOS scores than their older, heavier counterparts.^{9 10} SOS values are inversely correlated with Serum ALK-P results.⁸

Precise Measurement

PREMIER's low measurement error provides sensitivity to small changes in the bone.¹¹ The observed weekly SOS change for pre-term babies is 13m/sec, larger than the device's precision error. This enables accurate monitoring of the bones of pre-term infants at frequent intervals.

Especially Designed for the NICU

Mobile and ultrasound-based, PREMIER is formulated for use with pre-term infants. Its probe system enables the use of the device for an infant inside an incubator, greatly facilitating its utilization in NICUs. Its painless, non-invasive measurement method is quick and patient-friendly.

PREMIER For a Healthy Future

The combination of accuracy, reliability, safety, and convenience make PREMIER the ideal solution for bone assessment of pre-term infants. With pre-term infants

suffering from reduced bone mineralization for at least six years after birth,¹² this bone assessment is an essential component in a healthy future for pre-term babies.

References

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