SCIENTIFIC ARTICLES ON OSCARE SONO AXIAL TRANSMISSION ULTRASOUND TECHNOLOGY

The newest articles from 2011-2016 are in vivo studies demonstrating the correlation of Oscare measurement results with radius cortical thickness and mineral density within the cortex as well as subcortically, and the ability of the Oscare measurement to discriminate fractures. The articles from 2004 and 2008 are modelling and phantom studies related to the development of the measurement methodology and technology. The articles from 2002-2003 are the first studies on the new method including both in vivo and phantom measurements.

R. Pfaffen, S. Soares, A. Casmarrinha-Vieira, M. Metzger, O. Lamy, D. Hans, "Assessment of a New Low Frequency Quantitative Ultrasound (QUS) of the Radius", Poster presented at the International Society of Clinical Densitometry meeting 1.-4.6.2016

The aims of this study were to evaluate the precision of the OsCare Sono® device as well as its relationship with 1/3 radius bone mineral density as assessed by DXA. OsCare Sono® was used to measure the axial speed of low frequency ultrasound (V_{LF}) at the radius. A total of 45 women were included (mean age of 66.3 years). The mean 1/3 radius BMD T-score was -1.23 ± 1.43. Each woman had 3 QUS measurements in a row with repositioning. A built-in quality assessment of the OsCare Sono® signal was used to score the measurement quality (Poor, Good or Excellent).

For about 98% of the women, all 3 measurements were qualified as Excellent or Good and were subsequently included into the statistical analysis. The intra-operator RMS-CV of a skilled technologist was 0.33% (RMS-Standard deviation 12.2 m/s) and the multi-operator RMS-CV, including 3 technologists (1 skilled and 2 beginners), was 0.41% (RMS-SD 15.4 m/s). V_{LF} was explaining up to 67 % of the 1/3 radius BMD (r = +0.82).

Conclusion: The reported precision for this new QUS device of the radius is good. The very good correlation with 1/3 radius BMD thanks to the use of low frequency ultrasound may make this device suitable for a potential surrogate of pDXA if clinical performance is at least equal in the fracture prediction and/or to help finding those individuals at a high risk for osteoporosis.

M. Määttä, P. Moilanen, J. Timonen, P. Pulkkinen, R. Korpelainen, T. Jämsä, "Association between low-frequency ultrasound and hip fractures – comparison with DXA-based BMD", BMC Musculoskelet Disord, 15:208, 2014

This study investigates the association between speed of low-frequency ultrasound measured from tibia and the occurrence of fractures. The measurement from the tibia has a wider standard deviation than the measurement from the radius which is the method used in the commercial Oscare product, however despite this the study is able to show an association between ultrasound velocity and hip fractures with an odds ratio of 3.3.

Background: New methods for diagnosing osteoporosis and evaluating fracture risk are being developed. We aim to study the association between low-frequency (LF) axial transmission ultrasound and hip fracture risk in a population-based sample of older women.

Methods: The study population consisted of 490 community-dwelling women (78-82 years). Ultrasound velocity (V(LF)) at mid-tibia was measured in 2006 using a low-frequency scanning axial transmission device. Bone mineral density (BMD) at proximal femur measured using dual-energy x-ray absorptiometry (DXA) was used as the reference method. The fracture history of the participants was collected from December 1997 until the end of 2010. Lifestyle-related risk factors and mobility were assessed at 1997.

Results: During the total follow-up period (1997-2010), 130 women had one or more fractures, and 20 of them had a hip fracture. Low V(LF) (the lowest quartile) was associated with increased hip fracture risk when compared with V(LF) in the normal range (Odds ratio, OR = 3.3, 95% confidence interval (CI) 1.3-8.4). However, V(LF) was not related to fracture risk when all bone sites were considered. Osteoporotic femoral neck BMD was associated with higher risk of a hip fracture (OR = 4.1, 95% CI 1.6-10.5) and higher risk of any fracture (OR = 2.4, 95% CI 1.6-3.8) compared to the non-osteoporotic femoral neck BMD. Decreased VLF remained a significant risk factor for hip fracture when combined with lifestyle-related risk factors (OR = 3.3, 95% CI 1.2-9.0).

Conclusion: Low V(LF) at mid-tibia was associated with hip fracture risk in older women even when combined with lifestyle-related risk factors.

P. Moilanen, M. Määttä, V. Kilappa, L. Xu, P.H. Nicholson, M. Alén, J. Timonen, T. Jämsä, S. Cheng, " Discrimination of fractures by low-frequency axial transmission ultrasound in postmenopausal females", Osteoporos Int, 24(2):723-730, 2013.

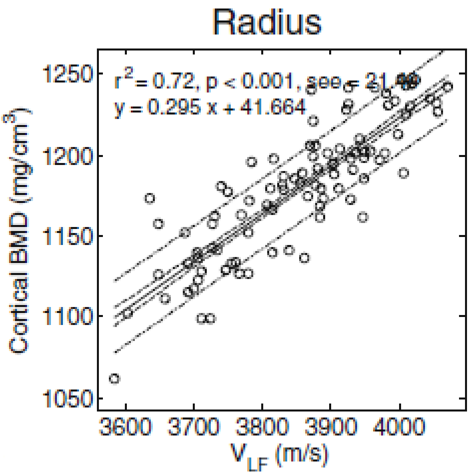
The aim of the study was to evaluate the ability of low-frequency axial transmission ultrasound to discriminate fractures retrospectively in postmenopausal women. The study involved 95 female subjects aged 45-88 years, whose fracture information was gathered retrospectively. The fracture group was defined as subjects with one or more low or moderate energy fractures. The radius and tibial shaft were measured with a low-frequency ultrasonometer to assess the velocity of the first arriving signal. Site-matched pQCT was used to measure volumetric cortical and subcortical bone mineral density and cortical thickness. DXA was used to measure areal BMD for the whole body, lumbar, spine and hip.

The majority of the fractures were in the upper limb. V(LF) in the radius (but not in the tibia) discriminated fractures with an age and BMI adjusted odds ratio of 2.06 (95% CI 1.21-3.50, $p<0.01$), better than pQCT or DXA.

V. Kilappa, P. Moilanen, L. Xu, P.H. Nicholson, J. Timonen, S. Cheng, "Low-frequency axial ultrasound velocity correlates with bone mineral density and cortical thickness in the radius and tibia in pre- and postmenopausal women", Osteoporos Int 22(4):1103-13, 2010.

LF US provides enhanced sensitivity to thickness and endosteal properties of the cortical wall of radius and tibia compared to using higher frequencies (e.g. 1 MHz). The aim of this study was to evaluate the extent to which LF measurement reflects cortical thickness and bone mineral density. LF US velocity was compared to site matched pQCT measurements. The study included 159 premenopausal and 95 postmenopausal females.

V(LF) correlated best with cortical bone mineral density in postmenopausal females in the radius (R=0,85, p<0.001), but significantly also with subcortical bone mineral density (R=0.759) and with cortical thickness (R=0.761), p<0.001. Similar trends but weaker correlations were found for tibia and for premenopausal women.



P. Moilanen, "Ultrasonic guided waves in bone", IEEE Trans. Ultrason. Ferroelect. Freq. Contr., 55(6): 1277-1286, 2008.

Recent progress in quantitative ultrasound (QUS) has shown increasing interest toward measuring long bones by ultrasonic guided waves. This technology is widely used in the field of nondestructive testing and evaluation of different waveguide structures. Cortical bone provides such an elastic waveguide and its ability to sustain loading and resist fractures is known to be related to its mechanical properties at different length scales. Because guided waves could yield diverse characterizations of the bone's mechanical properties at the macroscopic level, the method of guided waves has a strong potential over the standardized bone densitometry as a tool for bone assessment. This paper discusses the promises and challenges related to bone characterization by ultrasonic guided waves.

P. Moilanen, V. Kilappa, P.H.F. Nicholson, J. Timonen, S. Cheng, "Thickness sensitivity of ultrasound velocity in long bone phantoms", Ultrasound Med Biol 30: 1517-1521, 2004.

One approach to bone disease diagnosis such as osteoporosis is to measure the velocity of ultrasound propagating axially along long bones. In this study, the variation in velocity as a function of radial position was assessed using two polyvinyl chloride (PVC) bone phantoms with cross-sectional geometry similar to the human tibia but differing in medullary cavity diameter. Two ultrasonometers were used: these were a commercial device operating at a relatively high frequency (HF) of 1.25 MHz and a prototype low frequency (LF) device operating at approximately 200 kHz. The LF measurements showed a larger variation with radial position, with changes in velocity of up to 20% occurring around the phantom compared with changes of only 4% at most for HF. The LF velocity correlated strongly with local thickness (r(2) = 0.81) but HF velocity did not. The results demonstrate that LF measurements have a greatly enhanced thickness sensitivity. Using LF, it may therefore be possible to assess bone thickness as a function of radial position and hence to determine the distribution of bone around the long axis.

P. Moilanen, P.H.F. Nicholson, T. Kärkkäinen, Q. Wang, J. Timonen, S. Cheng, "Assessment of the tibia using ultrasonic guided waves in pubertal girls", Osteoporos Int, 14: 1020-1027, 2003.

The purpose of this study was to compare low frequency ultrasonic guided wave measurements with established ultrasound and bone density measurements in terms of their ability to characterize the tibia in pubertal girls. Subjects were 12-14-year-old girls (n=106) who were participating in a calcium and vitamin D intervention study. A prototype low frequency pulse transmission device consisting of a uniaxial scanning mechanism and low frequency transducers orientated perpendicularly to the limb was used to measure two ultrasound velocities in the tibia. The first velocity, V1, was that of the first arriving signal, similar to that measured by existing commercial tibial ultrasound devices. The second velocity, V2, was that of a slower wave propagating at 1,500-2,000 m/s, which has been shown elsewhere to be consistent with the lowest order antisymmetric guided mode in the bone. In addition, commercial ultrasound devices (Omnisense, Sunlight Ltd.; QUS-2, Quidel Corp.) were used to measure the speed of sound (SOS) in the tibia and the radius and attenuation (BUA) in the calcaneus. Cortical bone cross-sectional area (CSA), mineral density (BMD) and cortical thickness (cTh) of the tibia were measured using pQCT, site-matched to the ultrasound measurements. Both V1 and V2 correlated significantly with cortical BMD and with cTh and CSA. On the other hand, tibial SOS correlated with BMD, but not with cTh and CSA. These results indicate that the prototype device using guided waves captures aspects of tibial cortical bone geometry in addition to bone density, thereby potentially offering increased diagnostic information compared to existing tibial ultrasound devices.

P.H.F. Nicholson, P. Moilanen, T. Kärkkäinen, J. Timonen, S. Cheng, "Guided ultrasonic waves in long bones: modelling, experiment and in vivo application", Physiol Meas, 23: 755-68, 2002.

Existing ultrasound devices for assessing the human tibia are based on detecting the first arriving signal, corresponding to a wave propagating at, or close to, the bulk longitudinal velocity in bone. However, human long bones are effectively irregular hollow tubes and should theoretically support the propagation of more complex guided modes similar to

Lamb waves in plates. Guided waves are attractive because they propagate throughout the bone thickness and can potentially yield more information on bone material properties and architecture. In this study, Lamb wave theory and numerical simulations of wave propagation were used to gain insights into the expected behaviour of guided waves in bone. Experimental measurements in acrylic plates, using a prototype low-frequency axial pulse transmission device, confirmed the presence of two distinct propagating waves: the first arriving wave propagating at, or close to, the longitudinal velocity, and a slower second wave whose behaviour was consistent with the lowest order Lamb antisymmetrical (A0) mode. In a pilot study of healthy and osteoporotic subjects, the velocity of the second wave differed significantly between the two groups, whereas the first arriving wave velocity did not, suggesting the former to be a more sensitive indicator of osteoporosis. We conclude that guided wave measurements may offer an enhanced approach to the ultrasonic characterization of long bones.