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New Ultrasound Device for Bone Assessment. J. J. Kaufman¹, G. Luo^{*1}, R. S. Siffert^{*2}. ¹CyberLogic, Inc., New York, NY, USA, ²Department of Orthopedics, Mount Sinai School of Medicine, New York, NY, USA.

The objectives of this study were to design and fabricate a novel ultrasound device that estimates a new set of parameters --- known as net time delay (NTD) and mean time duration (MTD) --and to examine in both computer simulations and clinically the relationship of the ultrasound parameters to bone mineral density (BMD) as determined with x-ray absorptiometry at the same anatomical site. The new device, known as the QRTTM 2000 --- for Quantitative Real-Time --- is entirely self-contained, portable, and handheld --- being powered by 4 "AA" rechargeable batteries --- and permits near real-time evaluation of the ultrasound parameters and their on-line display to the user. In the simulation study, 3D micro-CT images of 10 human calcaneal trabecular bone cores were further processed using morphological image processing to obtain 36 "samples" in various states of porosity and micro-architecture. Ultrasound simulations in through transmission along the medial-lateral direction of each core were carried out using computational software (Wave3000 Pro, CyberLogic, Inc.). A linear regression to estimate bone mass from the simulated values of the ultrasound parameters produced an R-squared value of 0.985. In a clinical IRB-approved study the QRTTM 2000 was used to measure 85 adult women (age range: 21 --- 82 years) at the heel. BMD at the calcaneus was measured at the same time using DEXA (PIXI, GE). A linear regression --- using the NTD, age and weight associated with each subject produced an R-squared value of 0.78, equivalent to a linear correlation coefficient of 0.88, which represents a significant improvement over present ultrasound bone densitometers, but not nearly as good as the simulation results. Reasons for this have been identified (viz., errors in distance measurement and lack of coincidence between the DEXA and ultrasound regions of interest) and a new device (QRTTM 3500) and experimental protocol to deal with these sources of error are being developed that should improve the accuracy of the ultrasound device over existing technology even more. In addition, an examination of the MTD parameter --- which appears to be sensitive to both mass and architecture --- is being carried out in conjunction with NTD measurements to determine if both parameters together may be used to more accurately estimate fracture risk than bone mass alone. Finally, the *ORT*TM devices were designed to be manufactured at very low cost, and therefore should enable the significant expansion of quantitative ultrasound measurements to, for example, primary care physicians in this country and abroad, including for use in the developing world as well as in spaceflight.