



PERFORMANCE EVALUATION OF THE ACHILLES INSIGHT: PRECISION, ACCURACY, AND COMPARISON TO CENTRAL DXA

E. Hosszu¹, S. Meszaros², V. Ferencz², C. Horvath².

¹Department of Pediatrics, Semmelweis University, Budapest, Hungary, ²Department of Internal Medicine, Semmelweis University, Budapest, Hungary.

INTRODUCTION

Quantitative ultrasound (QUS) of the os calcis is accepted as an effective low-cost method to assess osteoporotic fracture risk. Heel ultrasound measurements have been shown to predict fractures in several prospective studies [1,2]. However, not all heel ultrasonometers have equivalent clinical utility. Differences in technology, coupling, imaging capabilities, measurement time, precision, and relationship to central (spine and hip) DXA measurements exist between systems. GE Lunar Achilles, Achilles + and Achilles Express ultrasonometers are widely used with over 6,000 systems installed worldwide. In this in vivo study, we evaluated a new imaging ultrasonometer, the Achilles InSight (Figure 1), in terms of its precision, accuracy and comparability to central DXA measurements. An additional objective of this study was to identify the T-score cutpoint on the Achilles InSight which identifies 90% of individuals with osteoporosis (T-score ≤ -2.5) at spine or hip, based on recent recommendations of the International Society for Clinical Densitometry (ISCD) on the use of peripheral densitometry (including heel QUS) [3].

Finally, the precision of the Achilles InSight was evaluated using conventional ultrasound coupling gel as well as an alternative coupling agent, isopropyl alcohol (70%), an easily applied agent that evaporates quickly for minimal clean-up.

METHODS

Fifty-two females referred for spine and femur density measurement were evaluated in this study. Subject age ranged from 23 to 76 years, with an average age of 55 ± 10 years. Each subject had spine and hip DXA measurements using the Lunar Prodigy (GE Medical Systems) as well as heel ultrasound measurements using Lunar Achilles InSight (GE Medical Systems). Stiffness Index values for InSight were obtained for each subject using both conventional ultrasound gel and 70% isopropyl alcohol as the coupling agent. All measurements and analyses were performed by a trained technologist. Sensitivity was assessed by comparing the InSight T-score results to the Prodigy values using a paired t -test. Using ISCD recommendations for peripheral screening [2], the 90% sensitivity cutpoint was determined for detecting osteoporosis (T-score ≤ -2.5) at the spine (L2-L4) or hip (Femur Total) by ROC analysis with the ROCKIT program.

The in vivo precision study comparing the alcohol and gel coupling agents was performed on 59 subjects (52 females and 7 males). Subject age ranged from 23 to 76 years, with an average age of 55 ± 10 years. For each subject the Stiffness Index was measured three times each on the same heel with isopropyl alcohol (70%) and with conventional ultrasound gel. The foot was repositioned between each measurement. Subjects were measured at two separate sessions with random selection of gel or alcohol in the first session and use of the other coupling agent in the second session. The precision (RMS standard deviation for the repeat measurements) was calculated for both coupling agents.



Figure 1. Lunar Achilles InSight

RESULTS

Fourteen of the 52 subjects measured on both the Prodigy and the InSight were found to have osteoporosis, i.e. a T-score ≤ -2.5 at the spine or hip. The ROC analysis of the ultrasound results showed the 90% sensitivity cutpoint at a T-score of -0.6 for the alcohol (Figures 2A and 2B) and at -0.5 for the gel (Figures 3A and 3B). At these cutpoints, the specificity of the InSight was 32% and 35%, respectively. Average T-score for the InSight was -1.4 ± 1.1 using alcohol and -1.2 ± 1.3 using gel coupling. This difference was statistically significant ($p < 0.01$), though considered of little clinical importance.

The results of the precision study (Table 1) showed that the InSight was equally precise using either isopropyl alcohol or conventional coupling gel. The repeat measurement precision (% CV) was 1.8% for alcohol and 1.7% for gel. There was no significant difference in precision error between the alcohol and gel ($p = 0.39$) based on an F-test comparing the two results.

Table 1. Repeat measurement precision (%CV) for Stiffness Index (SI) using alcohol and gel coupling agents.

	Mean	SD	CV	var	df	Mean	SD	CV	var	df	F	p(F)
Stiffness Index	84.6	1.41	1.67%	2.00	113	81.8	1.45	1.78%	2.11	114	1.054	0.390

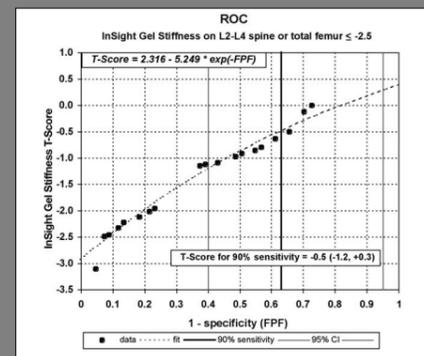
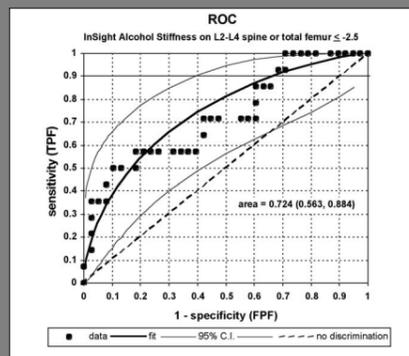


Figure 2. ROC analysis of the alcohol Stiffness Index data. A. Sensitivity plotted against (1 - Specificity) together with the 90% sensitivity cutoff line. B. (1-Specificity) values plotted against T-score cutoff values provided by the ROCKIT analysis program.

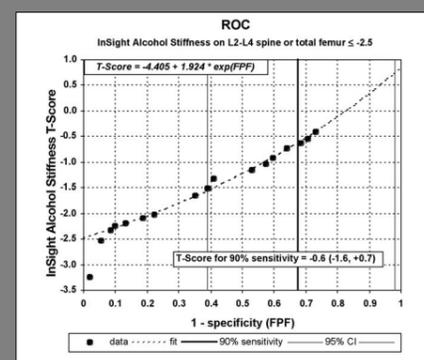
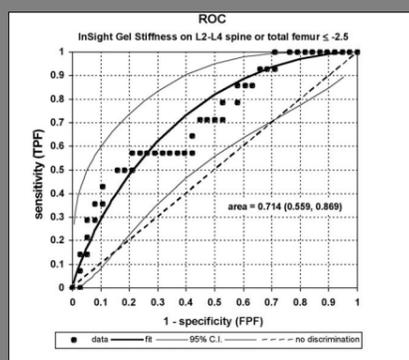


Figure 3. ROC analysis of the gel Stiffness Index data. A. Sensitivity plotted against (1 - Specificity) together with the 90% sensitivity cutoff line. B. (1-Specificity) values plotted against T-score cutoff values provided by the ROCKIT analysis program.

CONCLUSION

We conclude that the Achilles InSight is an accurate and precise imaging ultrasonometer, with precision errors for Stiffness Index of 1.8% and 1.7% for alcohol or gel, respectively. Based on ISCD recommendations, the Achilles InSight can be used as an effective screening tool with a T-score cutpoint of -0.6 for referring patients for spine and femur DXA assessment, providing better than 90% sensitivity for detecting patients with osteoporosis at the spine or hip. In situations where central DXA systems are not readily available, Achilles InSight is a useful screening tool to identify those patients who should be considered for spine and hip density measurements.

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