

Case Study

Correlation and precision of measurements using the Achilles EXP II



Hypothesis:

Results from the Achilles* EXP II are equivalent to those obtained with the Achilles Express. Furthermore, the precision of the Achilles EXP II is equivalent to or better than that of the Achilles Express.

Subjects:

Subjects were recruited from GE Healthcare and Oakwood Village, a Continuing Care Retirement Community. Data from a total of 75 subjects, spanning an age range of 18-95 years, were collected to compare results from Achilles EXP II and Achilles Express.

Method:

All measurement procedures were done according to procedures outlined in the Operator's Manual. Subjects had three repeat ultrasound measurements on each unit during one visit. There were three Achilles EXP II units and three Achilles Express units in the study. The measurement was performed on the calcaneus bone of the right foot. If the foot was smaller than US size 6, a shim was used to position the foot for measurement.

Simple regression of Achilles EXP II and Achilles Express Stiffness Index values was used to determine whether there are statistically significant ($p < 0.05$) differences between slope and intercept and the identity values of one and zero respectively.

The precision of the two devices was calculated by pooling variances on individual subjects, weighted according to the number of scans on that subject. Coefficients of Variation (%CV) were calculated with respect to the mean values over the study population.



Results:

The goal of the study was to meet the following acceptance criteria:

- Stiffness Index (SI), Speed of Sound (SOS), and Broadband Ultrasound Attenuation (BUA) collected.
- Verify the equivalence in Stiffness Index (SI) measurement between Achilles EXP II and Achilles Express ultrasonometers.
- Report Achilles EXP II has the equivalent or better precision than Achilles Express.

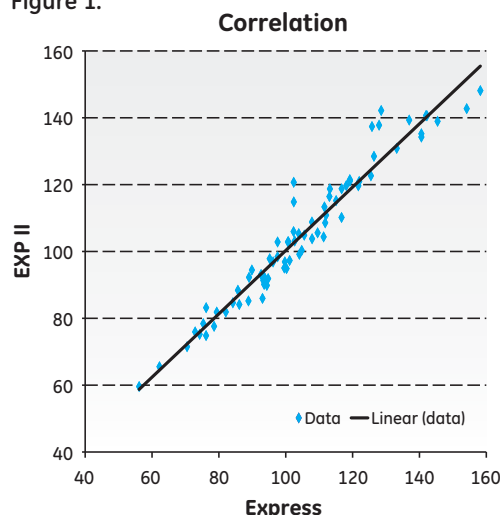
A total of 75 subjects, spanning a wide range of SI, were included in the comparison.

Results have shown that the SI measured by Achilles EXP II is highly correlated to Achilles Express ($r=0.97$). The slope and intercept of the correlation showed no difference with identity values of 1 and 0 with a 95% confidence level.

Figure 1.

The precision of the Achilles EXP II units in this study is 1.74%, which is less than the 1.82% precision as reported on the Achilles Express units.

Figure 1.



Conclusion:

Results from the Achilles EXP II are equivalent to those obtained on the Achilles Express. Precision of the two devices is also equivalent.

Note: The correlation of the Achilles EXP II to the Achilles Express is high ($r=0.97$). While the correlation between the two devices is high, there could be differences on the same patient between Express and the EXP II.

Typically, the differences will be negligible, but statistically speaking, using Bland-Altman analysis, the 95% limits of agreement will be within ± 1 T-score

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