

STUDY CONCLUSIONS - SONICBONE'S COMPACT ULTRASOUND DEVICE IS SAFE, NON-INVASIVE, RADIATION FREE AND HIGHLY REPRODUCIBLE. ITS BA ASSESSMENT IN A POPULATION OF CHILDREN ATTENDING PEDIATRIC ENDOCRINOLOGY CLINICS IS COMPARABLE TO BA BY G&P METHOD AND CAN OVERCOME ITS DRAWBACKS.

INTRODUCTION

Skeletal maturity assessment, defined also as bone age (BA), has an important role in pediatric endocrinology. BA assessment is based on the interpretation of hand X-ray scans according to the published standards of Greulich and Pyle atlas (GP).

This method is the accepted standard for assessing skeletal maturation, **but it is susceptible to wide inter and intra individual variability of its interpretation and exposure to radiation.**

AIM

To evaluate an ultrasound based device, SonicBone, for safety, reproducibility and concordance to the GP method.

METHODS

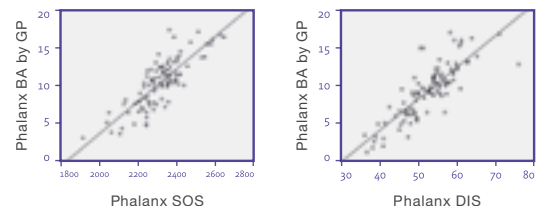
- This is a cross sectional study, designed to include three phases of data analysis, while all participants were recruited consecutively from children attending pediatric endocrinology clinics and were randomized for the data analysis sections to two groups of 100 participants and 50 participants, respectively, only after completion of recruitment.
- First Phase: correlation between speed of sound (SOS) and distance (DIS) parameters of SonicBone and BA by GP, in a group of 100 children (Analysis).
- Second Phase: establishment of an algorithm for incorporation of objective patient and SonicBone parameters quantitative data, to provide a numeric result of the BA in years and months, defined as BA by SonicBone.
- Third phase: comparison of BA by GP and BA by SonicBone, in the similar, randomly assigned group of 50 children (Validation)
- **X-ray scans were evaluated independently by 4 pediatric endocrinologists according to G&P. BA by GP is the mean of those Readings.**
- SonicBone assessments were performed by two observers.

RESULTS

Demographic, clinical and body composition parameters of study population

	All	Analysis Group	Validation Group	P value
Number	150	100	50	
Gender (f)	74	51 (50%)	23 (50%)	0.34
Pre-puberty*	46	39 (39%)	17 (34%)	0.33
BMI SDS	0.2 ± 1.4	0.3 ± 1.3	-0.1 ± 1.48	0.09
Age (y)	10.6 ± 3.3	10.5 ± 3.2	10.9 ± 3.4	0.85
Mean BA Wrist (y)	10.0 ± 3.4	10.1 ± 3.2	10.0 ± 3.8	0.20
Mean BA Metacarpal (y)	10.1 ± 3.5	10.1 ± 3.3	10.0 ± 3.8	0.26
Mean BA Phalanx (y)	10.3 ± 3.4	10.3 ± 3.2	10.3 ± 3.7	0.47

Pearson correlation between BA by G&P, SOS and DIS demonstrated a significantly high correlation in all areas. As shown in the phalanx site:



- An algorithm including age, gender, SOS and DIS for each skeletal location, wrist, carpal and phalangeal was established, with R square of 0.87, p<0.004.
- **BA by SonicBone was highly correlated with BA by GP, with R square of >0.946 and p value <0.0001 for all locations.**
- 91% of participants expressed their preference to perform BA examination at the physician's office using ultrasound technology rather than using X-ray.

