

Designing and implementing a portable ultrasound bone densitometer

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Abstract

Osteoporosis is a disease characterized by a low bone mass that increases the risk of fracture. The dual energy X-ray absorptiometry (DXA) bone densitometer is considered as the gold standard to measure bone mineral density (BMD). In Syria, the DXA is costly, not widely available and coupled with a strong reluctance among patients concerning exposure to ionizing radiation. On the other hand, several recent studies found that Quantitative Ultrasound (QUS) is useful in diagnosing osteoporosis and giving accurate information about the qualities of bone. This study aims to design and implement a portable ultrasound bone densitometry to measure BMD. The device is portable (0.4 kg), much less expensive and does not have any harmful effect of ionizing radiation. The device contains a pair of ultrasound transducers HC-SR04 to send and receive ultrasound waves through the bone. The received signals were amplified and digitally recorded using the Arduino platform. The device was designed using a pre-designed model using CAD software, with wild range motion so it could be appropriate for many patients of different ages. The device was tested on many healthy individuals and patients of different sexes, aged 18–85 years, and also calibrated and validated with a known BMD value supplied by the DXA bone densitometer. The results demonstrated that our device is sensitive enough to distinguish between healthy and patient individuals by using low-cost instruments. Accordingly, the proposed device may have a good opportunity in the future to be considered an effective low-cost portable bone densitometer.

Keywords: Arduino, Bone Mineral Density, Osteoporosis, Portable densitometer, Ultrasound.

Introduction

Osteoporosis is a common disease that affects the bones and makes them weak due to a decrease in the density and mass (organic and inorganic components), leading to bone fragility and making the risk of human bone fractures increases¹. Osteoporosis is recognized as a serious public health problem, with about 200 million people being affected worldwide. In the United Kingdom, 33.33% of women and 8.33% of men suffer from osteoporosis. The number of patients with osteoporosis is expected to increase alarmingly in

the Middle East and Africa, where the incidence of osteoporotic fractures is expected to quadruple in a number of countries as the population ages². In Syria, osteoporosis was diagnosed in 6.23% of the lumbar spine and 2.72% of the femur neck of Syrian women between 50 and 59 years of age³.

A bone mineral density (BMD) test is used to measure the bone density. BMD is measured in units of g/cm². Instead, it is proposed to define osteoporosis on the basis of two numbers (T-score and Z-score)⁴. The T-score is a chart showing the

standard deviation of the patient's bone density with healthy, young individuals of the same sex in a specific area. A (T-score < -2.5) refers to osteoporosis. The Z-score depends on the similarity of the bone density among people of the same age and sex as the patient in a specific area ⁵.

The dual energy X-ray absorptiometry (DXA) is the traditional technique for measuring BMD due to its good precision, fast scan, and stable calibration ⁶. However, DXA is expensive, immobile and exposes patients to ionizing radiation. In Syria, there are 20 DXA machines, and these are only available in urban centers. The cost of a DXA scan is 50 USD, and the length of waiting time for DXA scan is 1 day ⁷. Those limitations create barriers to examine larger populations for osteoporosis. Ultrasound has recently been proven to be an effective alternative to DXA ^{8,9}. It is simple to use, nonionizing, inexpensive and able to provide additional information of bone strength ^{10, 11}. Quantitative Ultrasound (QUS) technology is becoming a useful tool for osteoporosis screening. It gives you more information regarding the bone state in addition to BMD. The literature illustrates that QUS devices can be used to a similar extent as measured by DXA to estimate bone mineral status and osteoporosis, but could not decide correctly if QUS is the best and more reliable because it needs more statistics. In fact, QUS and DXA have different approaches to determining bone tissue architecture. Moreover, the parameters of QUS change with bone density, structure and composition unlike DXA which relates to bone density only. QUS therefore provides additional

information on some bone quality considerations compared to DXA ¹².

Several studies found that QUS is useful in diagnosing osteoporosis and giving accurate information about the qualities of bone. On another hand, those systems and devices suffer from the big size, occupy a place, are not cheap and are not portable. This study comes to handle the big size and portability barriers of ultrasound-based BMD devices by proposing and implementing a prototype of portable BMD using low cost instruments. Accordingly, this study aims to design and implement a portable ultrasound bone densitometry to measure BMD. The device is portable (0.4 kg), much less expensive and does not have any harmful effect of ionizing radiation. The device contains a pair of ultrasound transducers HC-SR04 to send and receive ultrasound waves through the bone. The received signals were amplified and digitally recorded using the Arduino platform. The device was designed using a pre-designed model using CAD software, with wild range motion so it could be appropriate for many patients of different ages. The device was tested on many healthy individuals and patients of different sexes, aged 18–85 years, and also calibrated and validated with a known BMD value supplied by the DXA bone densitometer. This article is organized as follows. The methods describe the ultrasound measurement methodology, including the device design, calibration and the clinical study protocol. Then, the results are addressed, followed by a discussion and conclusion.

Materials and Methods

Design and implementation of ultrasound bone densitometer

The block diagram of the proposed design of the ultrasound bone densitometer is given in Fig 1. It consisted of a pair of ultrasound transducers (HC-SR04 circuit) operating at a frequency equal to 40 KHz, one acted as a wave transmitter, whereas, the other acted as the receiver. The device is powered by 9V battery with a voltage regulator. The Arduino microcontroller platform was chosen to provide the overall control logic. The result is displayed on a LCD display.

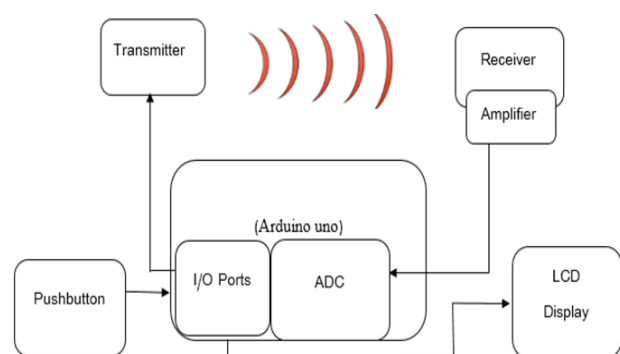


Figure 1. Block diagram of the proposed densitometer

The most important consideration while designing this device was the cost. After researching commonly used ultrasonic sensors on the market, we found out the HC-SR04 was the best solution. The connection between Arduino¹³, Ultrasound TX & RX and HC-SR04 is illustrated in Fig 2.

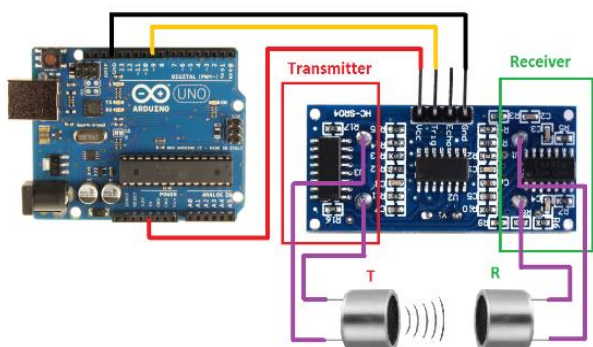


Figure 2. Connection between Tx, Rx, HC-SR04 and Arduino.

The HC-SR04 uses a non-contact ultrasonic sonar system consisting of an ultrasonic transmitter, receiver and high gain amplifier circuit. The transmitters emit a high-frequency ultrasonic sound equal to 40 kHz, which bounces off any nearby solid objects, and the receiver listens for any return echo. In our research, we use the principle of penetration, not reflection because the transmitter and receiver were fixed in the same plane as the axes.

Structural design of the device

CAD software was used to produce a realistic 3D model of the portable device as shown in Fig 3. The design of the device takes into consideration the following:

- The transmitter and receiver are placed in a straight line.
- The design allows individuals of all ages to use the device, thanks to the presence of fixed and moving parts.
- The device is entirely self-contained and portable.
- The device requires minimal training to use.

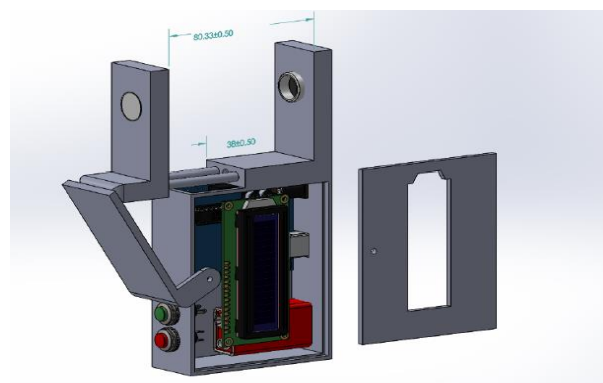


Figure 3. Device model in CAD software.

We used the wood to construct the box-about 5 x 12 cm, so that the circuits and the different components could be placed into it as shown in Fig 4.



Figure 4. The portable Device.

Because the device has a moving part, the maximum bone thickness (scan depth), that the ultrasound sensors could handle is 8 cm.

Measuring and calibration process

A gel was used on the measurement place to ensure good acoustic conduction and provide a cooling material regarding any induced thermal effect of the ultrasound. The generated 40 kHz ultrasound signal was propagated through the ulna bone, and it reached the receiver. After reaching, the received signal was amplified by a high gain amplifier. Finally, the received attenuated ultrasound signal was digitized and read by the Arduino Uno microcontroller Platform whose analog-to-digital converter (ADC) resolution is 10-bits.

The device was calibrated to values obtained by conducting a measurement on a sample of two persons (patient and healthy). Since low bone density allows greater penetration of the sound waves (less attenuation), the two measured values should be different. These values were found to be 518 and 513 which corresponds to the healthy and patient subject respectively (513 value refers to low bone density because the architecture of the amplifier circuit makes the output voltage goes down when receiving the ultrasound signal according to its amplitude).

These calibration values are then used in the final programming code used to program the Arduino Platform. The programs were developed using Arduino integrated development environment (IDE). T-scores are calculated in two ways:

1. Mapping the output according to experimental values

This method depends on the digital values which refer to the patient (tested by DEXA before) and healthy people then used to calculate any new measurement according to the experimental mapping formula based on ref. ¹⁴:

$$density = \frac{(new_{val} - min_{val}) * ((4) - 1 * (-4))}{(max_{val} - min_{val}) + (-4)} \quad 1$$

Where:

Density: T-score

new_{val} : The digital value that received from the current person.

max_{val} : Maximum calibration value.

min_{val} : Minimum calibration value.

4, -4 : are T-score bone density scale limits.

Fig 5 illustrates the different bone density levels ¹³. The T-score of less than -2.5 SD has been defined as osteoporosis. T-score between -1.0 and 2.5 SD has been classified as osteopenia, and normal case belongs to values that are higher than -1 ¹⁵.

Results and Discussion

The ultrasound machine's transmitter emits sound waves at a frequency of 40 kHz in pulses

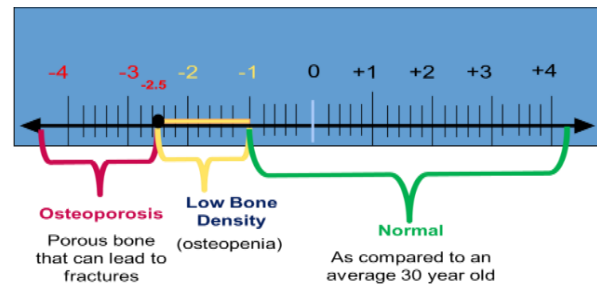


Figure 5. T-score bone density scale ¹⁴.

To more comprehensively determine the risk of fractures for people over the age of 40, the World Health Organization has developed a tool that a doctor can use to measure a person's risk of bone fractures over a period of 10 years, and it is a calculator that is available electronically via the Internet or on paper, it's called FRAX Tool. This calculator is based on a person's bone density test results, in addition to other risk factors.

2. Build new BMD graph based on our values

In this approach, we use the principle of the BMD variation graph that embedded inside DEXA devices (which describe the bone density variation of population in a specific area) containing standard deviation and the difference between BMD values of patients and healthy young adults. So, to calculate current T-score from the graph we have to use the formula ¹⁶:

$$Tscore = \frac{patient's\ BMD - population\ peak\ BMD}{standard\ deviation\ (SD)\ of\ population\ peak\ BMD} \quad 2$$

Statistical analysis

We compared the average of two independent male/female groups to determine if there is a significant difference between observations using an unpaired t-test. The $p < 0.05$ value was considered a statistically significant threshold and accordingly, we can reject the null hypothesis about no distinct difference between groups. The repeatability and reproducibility of the measurements were examined using one sample t-test where $p < 0.05$ refers to highly significant results.

toward the human body. Ultrasound penetrates the human body and hits living parts between various

body components. Fluid is between the skin layer and bone.

Some of the ultrasonic waves are reflected at the boundaries between the components of the human body and return to the transmitter, while the rest of the ultrasonic waves continue to penetrate deep into the human body and reach another layer, where they are separated and reflected from all will be sent to the organization and fed back to the sensors. In our case, we're betting here on sound waves that penetrate all tissues to reach the other side, allowing the receiver to elicit them and after some amplification stages, amplify them.

In this study, twenty one subjects (both men and women aged ≥ 18 y) living in Al Qadmous, Syria were participated. The basic health history of

each subject was obtained with the help of a simple questionnaire. Each subject was measured three times at the heel and the wrist with our device and the data were averaged and saved. Table 1 lists the results of our device at the heel and wrist for each subject. The values ranged from 516.83 to 524, representing highly dense bone to osteoporotic conditions respectively. The statistical analysis of male and female groups shows high significance ($p < 0.05$) between the groups by scanning the heel, while the wrist shows a big similarity between the two groups ($p > 0.95$). Those findings state that the heel is better considered an important area for measurements concerning the two genders. Based on one sample t-test, we found the repeatability of results with statistical significance ($p < 0.001$).

Table 1. BMD values of subjects as a digital output of our device and mapped values according to the reference DXA scan.

Age	Sex	Digital output		Mapped values	
		Heel ($p=0.0261$)	Wrist ($p>0.95$)	Heel	Wrist
21	Female	520.33	520.17	4	4
22	Female	520.33	520.17	4	4
40	Female	518	517.8	3.33	3.19
42	Female	518	517.8	3.33	3.19
52	Female	517.17	517.5	2.77	3
52	Female	517.17	517.5	2.77	3
54	Female	517.67	517.5	3.11	3
61	Female	517.17	517.6	2.77	3.06
18	Male	521.83	519	4	4
19	Male	521.83	518.9	4	3.93
23	Male	521	518.67	4	3.77
23	Male	524	518.67	4	3.77
43	Male	518.67	518	3.77	3.33
48	Male	518.67	517.8	3.77	3.19
53	Male	518	517.8	3.33	3.19
60	Male	518.67	517.7	3.77	3.13
62	Male	518.67	517.7	3.77	3.13
63	Male	518.67	517.33	3.77	2.88
64	Male	518.67	517.33	3.77	2.88
85	Male	517.5	516.83	3	2.55

By applying the Eq 2 we could map our device output values to a DXA T-scores. The calibration has been achieved using a known T-score of -3 reported by DXA scan for a 64-year-old woman who has osteoporosis. The digital value measured by our device for this woman was 513.

After mapping digital values with the reference DXA scan, we obtained the results which shown in Table 1.

Fig 6 illustrates the changes in BMD for healthy people according to age and site of measurement expressed with T-score. This graph

shows how the bone density decreases with age. This can be explained by the fact that bones gradually lose their density and strength with increasing age. We note also that the wrist bone in our methodology gives a more accurate diagnosis of

osteoporosis. This can be understood by the fact that the magnitude and frequency of ultrasound waves are more effective in wrist bone (less thick and dense than the heel one).

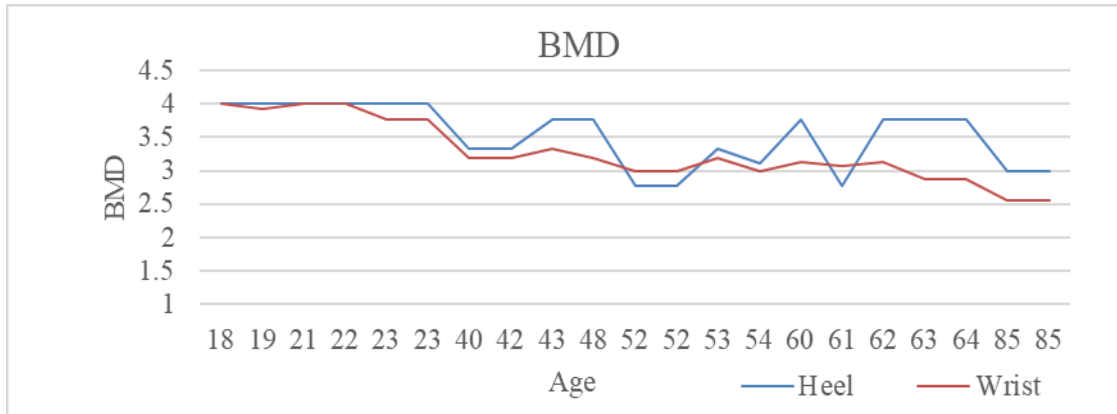


Figure 6. Age-related changes in bone density.

Next, we analyzed how the bone density measured in the wrist bone changes according to

gender in healthy individuals. As Fig 7 shows, women have lower bone density than men.

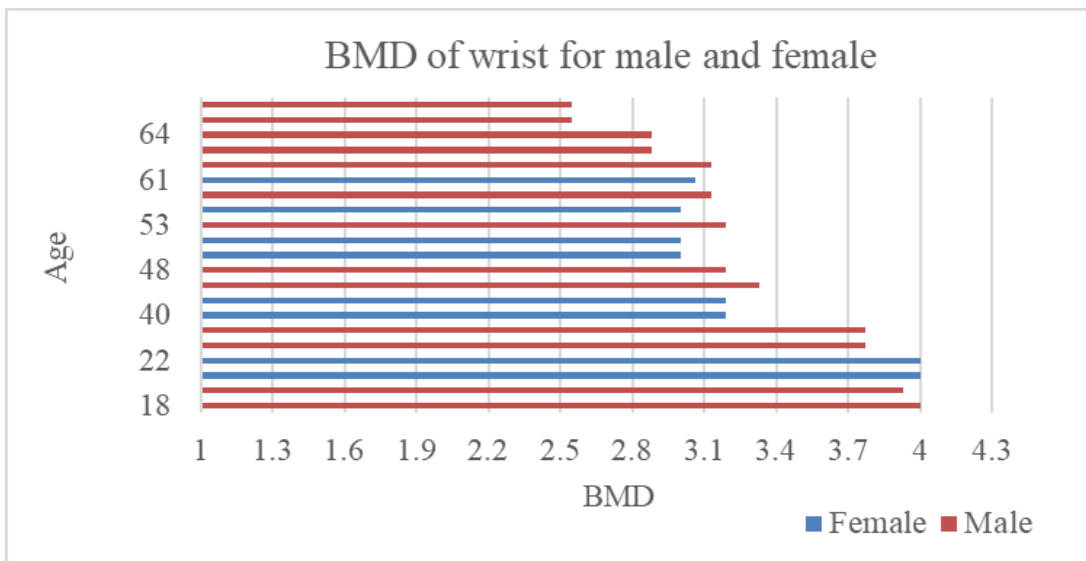


Figure 7. Gender age-related changes in bone density of healthy individuals.

The comparison between the outcomes of the proposed device and a reference DXA device based on measurements obtained from nine patients (Fig 8) proves the similarity between results with ± 0.5 of difference. The similarity between the results of DXA and the proposed device ranged between 88-95% which gives a confidence interval of 10%. The

results show the state of bone density with age, and these results are considered satisfactory in terms of relative values since aging has an effect on bone structure. Therefore, we can say that the principle used in this research has proven its effectiveness despite the modest equipment.

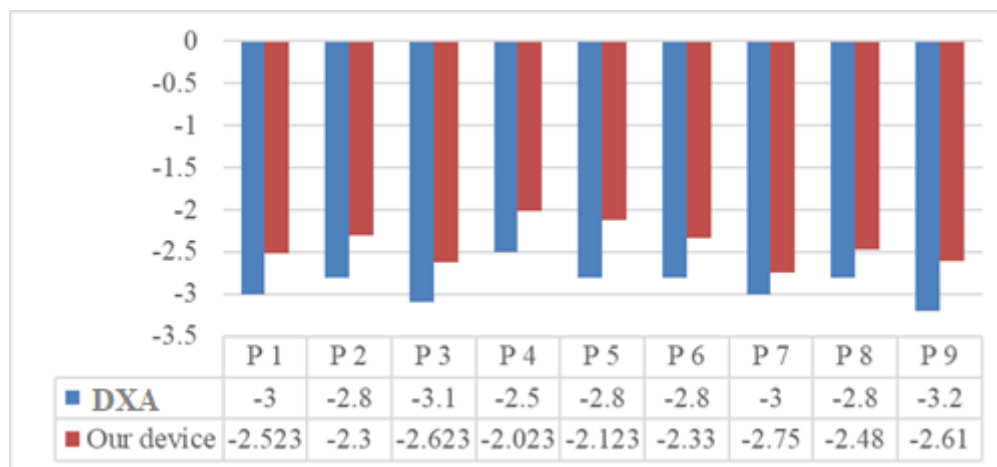


Figure 8. Difference between DXA and our device.

By Comparing our results with clinical research ^{12,17} that uses (QUS) for bone mineral assessment and other statistical research within any community, we can notice the nearly similar diversity of BMD between young and elder people

and patients, which ensure that the proposed device may have a good opportunity in future to be considered an effective low-cost portable bone densitometer.

Conclusion

Although the results of our study clarify that our device is sensitive to bone mass, the device demonstrated that using ultrasound to scan the bone won't give us all the information we could gather with a DXA scan. However, it gives us a clear enough overview of whether we should be concerned for the patient. Further research is still required for QUS to be utilized effectively for the best outcome. By calibrating the device with a reference DXA scan, we could measure bone density and show the result instantly. Because of its low-cost, mobility and safety, ultrasound is a promising tool for assessing more people. In our future work, equipment will be improved in terms

of the accuracy and sensitivity of the receiver and the capacity of the transmitter. More efforts will be made to build an automated system depending on artificial intelligence algorithms (enhance values classification using a clinical dataset for training) so can get more precise results about bone density status and embed the whole system within the microcontroller so we can get a high-efficient portable device. Since this type of device needs periodic calibration, the limitation of this work is about finding a more reliable way to calibrate periodicity and compare its results to a reference device like DXA.

Authors' Declaration

- Conflicts of Interest: None.
- We hereby confirm that all the Figures and Tables in the manuscript are ours. Furthermore, any Figures and images, that are not ours, have been included with the necessary permission for

- re-publication, which is attached to the manuscript.
- Ethical Clearance: The project was approved by the local ethical committee in Al-Andalus University for Medical Sciences, Tartous, Syria.

Authors' Contribution Statement

Conceptualization, S M and E I; methodology and investigation, S M; formal analysis, E I, S M, and F

M; software, S M; writing—original draft preparation, S M; writing—review, editing and

supervision, E I and A S A, F M.

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تصميم وتنفيذ جهاز محمول لقياس كثافة العظام بالموجات فوق الصوتية

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الخلاصة

هشاشة العظام مرض يتميز بانخفاض كتلة العظام مما يزيد من خطر الإصابة بالكسور. يعتبر مقياس كثافة امتصاص الأشعة السينية ثنائي الطاقة (DXA) بمثابة المعيار الذهبي لقياس كثافة المعادن في العظام (BMD). في سورية، يعد DXA مكلفاً وغير متوفر على نطاق واسع ويقتصر بتردد قوي بين المرضى فيما يتعلق بالتعرض للإشعاع المؤين. من ناحية أخرى، وجدت العديد من الدراسات الحديثة أن الموجات فوق الصوتية الكمية (QUS) مفيدة في تحديد تشخيص هشاشة العظام وإعطاء معلومات دقيقة حول صفات العظام. كان الهدف من هذه الدراسة هو تصميم وبناء جهاز قياس كثافة العظام بالموجات فوق الصوتية لقياس كثافة المعادن بالعظام. الجهاز محمول (0.4 كيلو غرام) وهو اقل تكلفة بكثير وليس له اي اثر ضار من الاشعاعات المؤينة. تم تصميم الجهاز باستخدام زوج من أجهزة توليد واستشعار بالموجات فوق الصوتية HC-SR04 لإرسال واستقبال الموجات فوق الصوتية عبر العظم ثم تضخيمها وقراءتها رقمياً باستخدام منصة Arduino. تم تنفيذ الجهاز باستخدام نموذج مُصمم مسبقاً باستخدام برنامج CAD، مع رأس قياس متحرك بحيث يمكن أن يكون مناسباً للعديد من المرضى من مختلف الأعمار. تم اختبار الجهاز على العديد من الأفراد الأصحاء والمرضى من مختلف الجنسين، الذين تتراوح أعمارهم بين 18 و 85 عاماً، كما تمت معايرته والتحقق من صحته باستخدام قيمة كثافة المعادن بالعظام التي يوفرها مقياس كثافة العظام DXA. أظهرت النتائج أن أجهزتنا حساسة بدرجة كافية للتمييز بين الأفراد الأصحاء والمرضى باستخدام أدوات منخفضة التكلفة. وفقاً لذلك، قد يكون للجهاز المقترح فرصة جيدة في المستقبل ليتم اعتباره مقياس كثافة عظام محمول فعال ومنخفض التكلفة.

الكلمات المفتاحية: أردوينو ، كثافة المعادن في العظام، هشاشة العظام، مقياس كثافة محمول، الموجات فوق الصوتية..