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Design of A Novel Device Measuring Testicular Consistency, Size and Temperature and Classification Algorithm Analysis of Data Compared to Urologist Examinations

Merve Örer[1], Mehmet Çağrı Soylu[1]*, Emre Can Akınsal[2], Oğuz Ekmekçioğlu[2]

[1]Biological & Medical Diagnostic (BioMeD) Sensors Laboratory, Department of Biomedical Engineering, Erciyes University, Kayseri, 38030, Turkey
[2]Faculty of Medicine, Department of Urology, Erciyes University, Kayseri, 38030, Turkey
*Corresponding Author: Mehmet Çağrı Soylu

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Keywords
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Background and Objective: Infertility is a health problem that can be seen all over the world, originating from both men and women. In male infertility, many tests and examinations are performed in order to find the treatment method to solve the problem. The first of these is the physical examination, and the clinician cannot obtain numerical data and make comparisons as a result of this examination.
Methods: In this study, it is aimed to design a system that will reveal the physical differences of the testicles, which play an important role in the production of sperm and some special hormones, in about 1 minute. Thanks to this device, temperature, volume and consistency parameters of testicles from 50 different patients of different ages were measured in real time with different sensors on the device. The results were analysed with both statistical analysis and machine learning method.
Results: According to the results of this study, it has been revealed that the system designed can help clinicians in testicular examination. In terms of consistency and heat stress, the classification algorithm with the highest accuracy rate according to the 3 different cross validation rates applied is trees and it showed 92.0% accuracy according to validation 5 and 15, but 89.0% according to cross validation 10. In terms of testicle size, Trees and Ensemble with the validation rate of 15 showed the highest accuracy with 89%.
Conclusions: Although the applied methods showed high accuracy, the specificity rate is not optimal due to data limitations. This is because there is not enough data. It is clear that with more data, both the accuracy rates and the level of specificity will be higher.

Üroloji Uzmanı Muayeneleriyle Karşılaştırmalı Olarak Testis Sertliği, Boyutu ve Sıcaklığını Ölçen Yenilikçi Bir Cihaz Tasarımı ve Veri Sınıflandırma Algoritması Analizi

Anahtar Kelimeler
Kısırlık,
Isı Stresi,
Testis Kıvamı,
Makine Öğrenimi

Arka Plan ve Amaç: Kısırlık, dünya genelinde erkeklerde ve kadınlarda yaygın olarak görülebilen bir sağlık sorunudur. Erkek infertilitesinde, problemi çözmek için tedavi yöntemini belirlemek amacıyla birçok test ve inceleme yapılmaktadır. Bunların ilki fiziksel muayenedir, ancak bu muayene ile klinisyen çoğunlukla sayısal veriler elde edemez ve gerekli karşılaştırmaları yapamaz.
Yöntemler: Bu çalışmada, sperm üretimi ve bazı özel hormonların üretiminde önemli bir rol oynayan testislerin fiziksel farklılıklarını yaklaşık 1 dakika içinde ortaya koyacak bir sistem tasarlanması hedeflenmiştir. Bu cihaz sayesinde, farklı yaşlardan 50 farklı hastanın testislerinin sıcaklık, hacim ve tutarlılık parametreleri, cihazdaki farklı sensörlerle gerçek zamanlı olarak ölçülmüştür. Sonuçlar, hem istatistiksel analiz hem de makine öğrenimi yöntemi ile incelenmiştir.
Bulgular: Bu çalışmanın sonuçlarına göre, tasarlanan sistemin, kliniklerde testis muayenesine yardımcı olabileceği ortaya konulmuştur. Tutarlılık ve ısı stresi

açısından, uygulanan 3 farklı çapraz doğrulama oranına göre en yüksek doğruluk oranına sahip sınıflandırma algoritması "decision trees" (karar ağaçları) olup, doğrulama 5 ve 15'e göre %92,0 doğruluk, çapraz doğrulama 10'a göre ise %89,0 doğruluk göstermiştir. Testis boyutu açısından ise, karar ağaçları ve ansambl yöntemleri, doğrulama oranı 15'e göre en yüksek doğruluk oranı ile %89,0 doğruluk göstermiştir.
Sonuç: Uygulanan yöntemler yüksek doğruluk oranları gösterse de veri sınırlamaları nedeniyle özgüllük oranı optimal değildir. Bunun nedeni, örnek sayısının yetersiz olmasıdır. Daha fazla veri ile hem doğruluk oranlarının hem de özgüllük seviyelerinin daha yüksek olacağı düşünülmektedir.

1. Introduction

Most people who reach adulthood want to have children. However, some are unable to achieve pregnancy and seek help from clinics to understand and solve this problem. If pregnancy cannot be provided, although regular sexual intercourse in 12 months, this situation is called infertility and approximately 14% of couples from all around the world are called infertile because of this problem[1].

The cause of infertility can be from male-related, female-related or both. According to previous studies, every 1 couple out of 3, cannot achieve pregnancy because of solely male-related problems[2] and when both male-related problems and female-related factors are considered together, it can be said that the male factor in infertility is 50 percent[3]. The amount and quality of semen related to male infertility and it is affected by many factor, such as varicocele, cancer, cryptorchidism, idiopathic, genetic disorders, infections, toxic substances and drugs, etc[4, 5].

The testis, an organ found only in men, has two functions. The first of these tasks is the production of testosterone, the most well-known androgen hormone, and the other is the production and storage of sperm[6].
The testis is in the scrotum which is a bag of skin and is located relatively outside the body. The reason for this placement of the testis is to decrease the degree of the organ by 2-4 according to body temperature and to protect the producing of sperm from heat stress[7]. The issue of heat stress is really important to the testis because studies have shown that 1°C increase reduces sperm production by 14% [7].

In order to keep the temperature to which the testis is exposed at a certain level, the muscle and vascular structure in the scrotum has been customized. When Creamaster, a striated muscle that surrounds the testis and spermatic cord, senses an increase in temperature, it contracts involuntarily to protect the testicle from heat, and this contraction is called the Creamasteric Reflex[8]. While the Creamaster muscle provides thermoregulation by bringing the scrotum closer to and away from the abdomen, the Dartos muscle, which is also in the scrotum, keeps the temperature at the optimum level by increasing and decreasing the scrotal surface thanks to stimulation of temperature receptors on the scrotum's skin surface[9]. Because, spermatogenesis is a complex process affected easily by heat stress which is harmful for production of androgen, increase apoptosis of germ cells and can be reason of structural degradation of some enzymes which are related with producing testosterone and so on[10, 11].

In many studies, it has been stated that differences in testicular temperature and volume are associated with varicocele, which is a type of ventricular disorder and is associated with heat stress, and testicular cancer[12]. Because, thanks to varicocele, the hydrostatic pressure in the scrotum increases and this situation affects heat of testis At the same time, according to some studies, the tissues cannot reach enough oxygen due to varicocele, this affects the thickness and shape of the tissues[13], and the testicular volume decreases[14].

Another thing that changes the consistency of the testis is a testicular tumour. Huang et al. In a study where they used Tissue Elastography (TE) to diagnose testicular cancer, they noted that malignant cancer tissues were harder than surrounding tissues, and benign tumours were softer[15]. On the other hand, some studies have shown that benign tumours show normal or soft tissue characteristics[16].

Testicular cancer is the most common type of neoplasm in young men(15-44 years old)[16, 17]. It is a painless hard mass that is usually palpated during physical examination[18]. If a man has cryptorchidism or Klinefelter's syndrome at an early age, has testicular tumours in close relatives, has testicles smaller than 12 ml, has atrophic testicles and cannot have children, it indicates that the person is at risk for this disease[18]. Atrophy literally means shrinkage and is related to volume, and according to previous studies, testicular atrophy is one of the causes of poor quality semen, varicocele, tumor and cryptorchidism[19].

There are various types of testicular cancer, and both the disease itself and the treatment methods cause infertility [20]. Many studies have shown that germ cell testicular cancer directly causes infertility[21–23]. On the other hand, if the tumour is not germ cell, factors produced by the tumour itself or as a result of the body's response to defence or deterioration may also have an effect[22].

If the tumour is not germ cell, even in areas close to the area where the tumour is located, a decrease in sperm count and quality is observed[22]. At the same time, radiation, chemotherapy, surgical methods to remove the testicles and lymph nodes in the region also cause infertility[21]. For these reasons, people need additional measures such as sperm freezing for infertility. This is one of the requirements of early diagnosis of the disease.
In healthy males, the testis is egg-shaped, with a length, diameter, and width of 3-5 cm, 3 cm, and 2-4 cm, respectively[24]. While testicular volume is correlated with sperm count, motile sperm count, and sperm density, it is also inversely proportional to age[25][26][5]. Because sperm are produced in seminiferous tubules which make up nearly three quarters of the testis[27]. It is believed that as the number of seminiferous tubules increases, so does spermatogenesis[28]. Therefore many infertile male has smaller volume testes or bigger volume testes than healthy people and measurement of testis volume is a really important part of physical examination[1, 5].

Infertility examination is a complex study and includes many steps such as patient history taking, scrotal imaging, semen analysis and so on. According to Holstein et al.[29], the diagnostic steps of male infertility include detailed examination of testicular size and consistency, semen analysis and hormone levels.

Physical examination of the scrotal contents is an important step for both clinicians and patients. Because it is the first step to prediction reasons of the infertility. However, insufficient palpation accuracy has been reported for the examination of testicular consistency and volume measurement. During physical examination, it is very important to measure the size and consistency of the testis, especially for sub fertile individuals[30].

For testicular volume measurement ultrasonography, orchidometer (prader or punched-out) and callipers are used, but according to many studies comparing these different methods, ultrasonography is the more accurate way to measure[28]. Although the use of orchidometer is the most widely used method for volume measurements, the error rate is quite high[31]. Because if the orchidometer is used to measure volume, this means that some of the degrees not found in the orchidometer can be ignored and the clinician can obtain an estimated value after the measurement. On the other hand, more complex devices such as USG can be used to measure testicular volume, but they are expensive, take more time, and require people who can operate the system.

During the physical examination, there is no other method other than examining the testicular consistency with palpation. Palpation is a method that requires knowledge and experience. Quantitative data cannot be obtained after this method, only an estimated measurement is made, so it is not a suitable method for comparison.
For scrotal examinations other than palpation, scrotal sonography and colour Doppler techniques are used for testicular-related varicocele, tumours, microlithiasis and some abnormalities, and when scrotal examinations of infertile individuals are examined, it has been observed that 38-59 individuals out of 100 have abnormal scrotal features[3].

Seminoma is usually a non-painful stiffness, and the initial clinical evaluation is very important. Testicular sonography can distinguish this increased tissue stiffness from normal testicular tissue as it creates different patterns[32].

Although gray scale ultrasonography is quite useful in most testicular tumour cases, it is a fact that in some cases benign tissues cannot always be differentiated accurately because they appear as tumours on gray scale and colour and/or strong Doppler ultrasonography[16].

As a result of the pressure applied to the tissue, a tension occurs within the tissue and this tension occurs at different levels for soft and hard tissue[33]. Elastsonography, on the other hand, is a new method of ultrasonography and measures hardness by measuring the deterioration in tissue structure caused by a mechanical stress applied to the tissue[33].

Since malignant tissues change the properties of the tissue, US elastsonography has been used for diseases such as prostate, pancreatic, and breast cancer, but there are limited studies for testicular cancer [33]. On the other hand, according to a study, another scrotal examination method was considered as Elastosonography, but it was not considered sufficient to be applied alone without physical examination, without taking the patient's history and without tumour marker studies [33].

Today, many methods are used when measuring testicular temperature. these methods may be based on continuous measurement or on a single measurement. Thermocouples for the skin surface, thermistor needles for intrascrotal temperatures, infrared thermometry, thermography and liquid crystal thermometry are used for temperature measurement[7].

Statistical analysis methods are very important in terms of interpreting and explaining the data obtained by people as a result of their research. However, Machine learning methods can also reveal patterns and relationships among the data obtained that people may not notice. The most used algorithms in the literature for machine learning are[34]: k-Nearest Neighbourhood (KNN), Random Forest (RF), Support Vector Machine (SVM), Decision Tree (DT), Naive Bayes (NB) and Artificial Neural Network (ANN).
To summarize, the infertility diagnosis procedure applied to people with suspected infertility is a very long and costly process that requires a large number of trained people. Therefore, cost-effective, and easy-to-implement systems are needed. In this study, we focused on developing a very inexpensive, fast, sensitive instrument that can be used during physical examination, can take numerical results of three testicular parameters (volume, temperature, and consistency), and can be used on site, compared to applications that require very expensive and complex instrumentation. This developed system was also tested on volunteers with suspected infertility and the results were tried to be classified with appropriate classification methods.

2. Material and Methods

In this study, we aimed to measure three parameters of testis in real time by palpation method and for this purpose, three sensors were used as shown in figure 1.

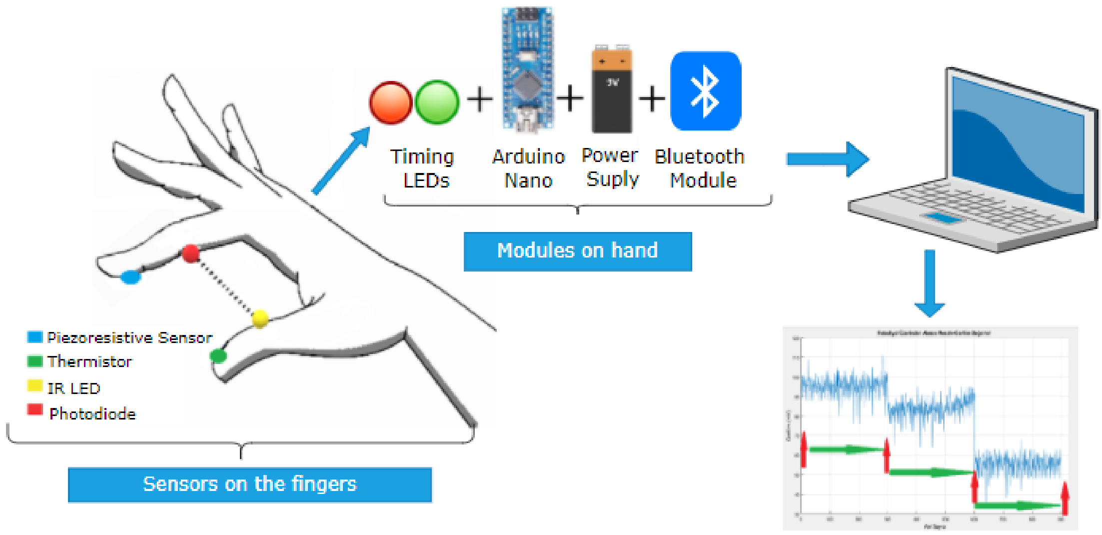

Figure 1. Circuit Diagram

2.1. Material and instrumentation

In this study, thermistor (MF11-50K 503) was used to measure of testicular stress, a piezoresistive sensor (BMP180) was used to measure of the consistency of the testis and a Photodetector (LTR-323DB) and an IR LED (L-7113F3C) were used to measurement of volume. Photodetectors contain both photodiode and transimpedance. Transimpedance is used to convert low current to voltage and achieve high signal-to-noise ratio. near infrared rays are between 780 nm and 1400 nm[30] and the IR led and detector used in this study work at 940nm. All these sensors were placed on finger-sized, long thin perforated pertinax so that they would not be affected by the joints in the fingers.

Data from these three sensors were transferred to the computer via Arduino Nano and Arduino Bluetooth Module (HC-05). Two LEDs (green and red) are used for the clinician to monitor the time. The power requirement of the system was provided by two 9V batteries. The cable between the computer and the device was removed thanks to the bluetooth module and a more comfortable experience for the user was obtained. All these elements were placed on a perforated pertinax and placed on the outer upper part of the hand.

The testis data presented in the study were obtained from real patients with the help of experienced clinicians working at Erciyes University Hospital. The analysis was first performed using SPSS to separate the soft tissue and normal tissue datasets, and then MATLAB to classify all the data.

2.2. Measurement of heat stress

The first sensor is used for the heat stress of the testis and for this purpose the sensor must be able to measure between 31.0°C and 36.0°C, does not need a calibration step for each repeated measurement, and has an accuracy of ±0.1°C[7]. A 50K NTC thermistor was used for this study due to its accuracy, small size, ease of use and suitability for non-invasive studies[35].
Temperature measurement and control aerospace, automotive, medical, laboratory applications, etc. It is a mandatory process and requirement for many fields, and today the most used electronic sensors for this purpose are thermistor, thermocouples and RTD (Resistance temperature detectors)[36, 37].

Regional metabolism and blood perfusion changes affect temperature measurements taken on human skin, and because of this effect, temperature measurement is of great importance in the diagnosis of many diseases such as cancer and diabetes[38].

Thermistors are used quite frequently in the medical field and are especially used for body temperature measurement[39]. For instance, Otahalova et al. have established a system aiming to examine vital data and used thermistor for temperature measurement in their studies[40]. In medical terms, the thermistor is not only used to measure body temperature directly, but also to measure other parameters. For example, in a study by Norman et al., a system that monitors respiratory flow using thermistor was designed in the diagnosis of respiratory disease[41].

Thermistors are a type of resistor made of ceramic and/or polymer. Normally, the resistance value is independent of temperature, and this is important in terms of protecting electronic devices from changing heat stress.
The equation between resistance and temperature is as follows.

$$\Delta R = \Delta T * K \quad (1)$$

ΔR and ΔT denote resistance and temperature changes, respectively. K is the temperature coefficient. According to the equation, it is clear that there is a relationship between temperature and resistance and this relationship depends on the value of K. Ideally for the normal resistor this K value is almost 0 to avoid the temperature effect, but for the thermistor it is completely different.

Since the main purpose of using thermistor is temperature measurement, the K value is not 0 and it is divided into two according to whether this value is negative or positive. If the thermistor is produced as K value < 0, an increase in temperature means a decrease in resistance and it is called NTC (Negative Coefficient Temperature). On the other hand, if the K value is > 0, it is called PTC (Positive Coefficient Temperature) and increasing temperature also increases the resistance.

Although thermistors have many advantages such as fast response, small size, and use over wide temperature ranges, they cannot produce linear results, and to solve this problem, there is an equation that directly converts the nonlinear internal resistance value according to temperature to the thermodynamic temperature[37][42][43]. It is called Steinhart-Hart Equation and showed in equation 2.

$$1/T = A + BlnR + C(lnR)\text{^}3 \quad (2)$$

As shown in Equation 2, A, B, and C are called Stein-Hart coefficients and vary with the thermistor model. T is the temperature as it is known, but it should be noted that it is in Kelvin. R is the resistance in ohms based on the current temperature.

2.3.Measurement of volume

Measuring the three axes of the testis is important in terms of the Lambert Equation ((a x b x c) x (0.71)) used to calculate the testicular volume[31]. In a study, a calipers were used to precisely measure these three axes (the superior-inferior, anterior-posterior, and medial-lateral axes) of the testis[30]. In this study, a simple distance sensor was developed to measure the distance between two fingers (thumb and index finger) using IR led, in on thumb, and photodiode which is on the index, similar to the calliper measurement mentioned.

Infrared rays(IR), which are between visible rays and microwave rays, cannot be detected by the human eye and are divided into three main groups as near, middle and far infrared rays[44, 45]. Since infrared rays have properties such as reflection and scattering, they are suitable for distance measurement for certain ranges[44, 46]. It is becoming more and more important to measure short distances without touching the surface of the measured objects[47]. In general, distance sensors using Infrared technology make measurements by using the properties of the reflected beam. If the reflectance of IR is used to measure of the distance, the user should know that the performance of the sensor depends on the reflectance properties of the object and the system has non-linear character[48]. In other words, the quality of the distance measurement depends on the quality of the reflected light, which is very much related to the scattering, absorption and reflection properties of the object surface[49]. Therefore, the person who wants to measure the distance using the reflection method with the IR sensor should work harder and find additional resources.

As shown in figure 2, the luminous intensity (E) means the number of photons falling on the surface of the object and is inversely proportional to the square of the distance.

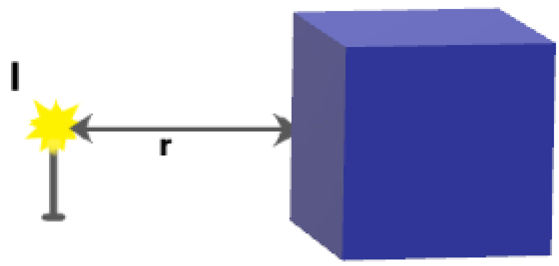

Figure 2. The light source and distance relationship of the illumination intensity on the object

As you move away from the light source, the intensity of light falling on the object decreases, and in this study, this optical law is taken as a reference for distance measurement. Based on this, IR LED was used as the light source in this study and a photodiode was placed instead of the object and the short distance between these two was tried to be measured.

$$E = I/r^2 \quad (3)$$

2.4.Measurement of consistency

The purpose of the third sensor is to measure the consistency of the testis and for this a piezoresistive sensor (BMP180) is used. The piezoresistive sensor was chosen because it has a suitable package for minimal application, does not contain much noise, has a fast response[50] and does not require any calibration process of the BMP180 sensor. The sensor output directly gives the pressure value in pascal. Since the BMP180 is an air pressure sensor, a pressure result according to tissue stiffness was obtained when the normal air pressure was subtracted from the tissue pressure measured in the study.

Pressure measurement is used in many areas such as muscle measurements such as the examination of the heart muscles, measuring the pressure value of the blood, examining the bone structure and skeletal system in the medical field[51].

Systems used to measure pressure today can be piezo-based, and they are divided into three: piezoelectric, piezocapacitive and piezoresistive[52]. Sensors working with piezoresistor logic are used in blood pressure measurements, heart rhythm monitoring and tissue analysis studies due to their advantages such as giving more linear results than other capacitive sensors, not needing too much power, and obtaining good results even at low pressure[52, 53].

Piezoresistive pressure sensors are also used in many areas such as aviation, biomedical applications and automotive, with the advantage of mass production, small size and good performance despite low power consumption[54].

The working principle of piezoresistive sensors is the measurement of the electrical resistance of the material, which changes according to the pressure, together with an external physical force. Against this mechanical stress, the electron and holes structure of the material therefore changes its resistance[55].

The resistance change of a rectangular electrically conductive material is as follows:

$$\frac{\Delta R}{R} = (1 + 2v)\varepsilon + \frac{\Delta \rho}{\rho} \tag{4}$$

In the equation, R, ρ, ν and ε are resistance, resistivity, Poisson's ratio and voltage of the resistor, respectively[55]. Therefore, the pressure sensor has a surface area to be exposed to the impact. This surface can be in different geometric shapes depending on the purpose and the desired sensitivity. Four equal resistance piezoresistors are placed on the surface to form a Wheatstone bridge.

When a mechanical stress is applied to the surface, due to the special configuration of the Wheatstone bridge, the value of two of these equal piezoresistors decreases while the value of the other two increases. The resulting imbalance causes the output voltage to be formed, and the measurement of this voltage is also used in the measurement of mechanical stress. therefore, placing the piezoresistors on the surface is closely related to the pressure of the sensor, and using the Whetstone bridge allows for more precise measurements than bridges with one or two active arms[56].

Pressure sensors are divided into 3 according to the reference state and these are differential pressure, absolute pressure and gauge pressure[57]. The same sensor can be used for all measurements and the important point is here the reference for pressure[57]. Absolute pressure requires a perfect vacuum inside the sensor as a reference and is used in air pressure measuring sensors such as the BMP180. Beccani et al. designed a wireless palpation probe to help detect tumour tissue and stated that the BMP180 sensor can be used in the recommendation part of their study[58]. The pressure sensor used in this study directly gives the pressure value in pascal. However, before use, the current pressure in the environment should be measured by making an empty measurement and subtracted from the tissue pressure.

Expressing and positioning tissue differences with numerical data, especially for tumours, provides guidance for strategically administered drugs that will perform the surgery and be used during the treatment phase. Thus, new ways were sought to perform this procedure and studies were started to use palpation with robotic devices in different diagnostic areas[59]. For example, in one study, a testicular tonometry device was studied to be used in testicular consistency measurements. In the study performed on individuals diagnosed with varicocele by tonometry, it was observed that sperm concentration was consistent with the tonometry data obtained, and sperm morphology of healthy individuals was also compatible with the data obtained[30].

2.5.Getting data

All patients were evaluated in the same clinic and same device. All physical examinations were performed by a single observer (ECA). The mentioned parameters of the testis were measured over the scrotum. The consistency and volume of both testis of the patients and pressure before measurement were measured and recorded. Testicular volumes were determined by using Prader orchidometer. Testicular consistency was obtained using the palpation method.

In order to test whether the difference between testicles can be distinguished with the device, the patients whose testis measurements were made were selected by paying attention to the fact that they were individuals of different ages (range of ages = 6-70) and with different testicular structures.

Table 1. Means and Standard Deviation of Study Variables

Variables	Age		Right Testicular Volume		Left Testicular Volume		Number of Consistency			
							Right		Left	
	M	SD	M	SD	M	SD	Soft	Normal	Soft	Normal
İnfertile	26,6	8,3	17,6	7,18	16,4	7,35	1	14	4	11
Fertile	42,3	13,8	23,5	8,07	23,6	7,23	3	32	3	32

During testicular examinations, temperature, hardness, and 3-axis length measurements of the testicles were tried to be taken. so, a scheduling system was established.

As shown in Figure 3.c. the electronic board has timing LEDs (green and red) to aid control, with these LEDs clinicians can determine when to collect data. The red light first means the clinician has time to move his hand and then the green led turns on so the device starts collecting data and the user cannot move his hand. This process is repeated 3 times for each testicular examination (once for each axis) and takes only 1 minute in total (Figure 3.a and b).

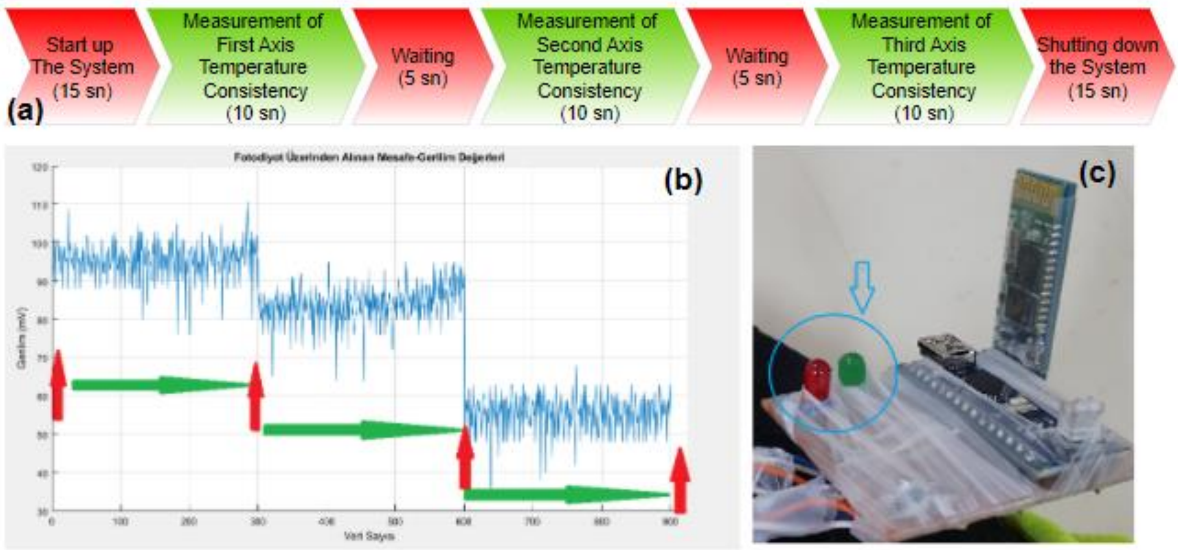

Figure 3. (a) Circuit flow chart (b) Using green, and red led for signal reception (c) Timing led on the board

2.5.Signal Analysis

One of the biggest problems in signal processing is denoising the signal. The collected signals for the study were first freed from noise. Single Spectrum Analysis (SSA) was used for noise elimination. At the same time, using the SSA technique will improve the modelling and forecasting situation[60]. When we look at the previous studies, it is seen that the SSA method is frequently used in this respect. For instance, Pilgrim et al. demonstrated noise elimination by working on a signal containing random noise[61].
SSA, which has attracted great attention recently, is a simple, high-performance time series analysis technique that does not require any special assumptions and is used in signal source separation, financial modelling, many engineering branches and especially in biomedical applications[60, 62].

To briefly mention the SSA, it includes two steps: decomposition and reconfiguration. The N-element signal obtained in the first step is converted to a Hankel matrix and it is called embedding. The column and number of this matrix conform to formula K= N-L+1. K and L are the number of rows and columns of the Hankel matrix, respectively. Then the resulting matrix is divided into three matrices. This division operation is called SVD. SVD is the last action applied in my first step. In the second step, eigentriple grouping and diagonal averaging are applied respectively. As a result of the applied process, a noise-eliminated signal is obtained.

In the study, signals were taken in real time and the final data is obtained by averaging the noise-free signal with the SSA process. This average, which will be statistically analysed or used in classification, is obtained by taking the average of each part divided into three to separate the axes.

2.7.Data analysis using machine learning

In the article, algorithms in Matlab were used while doing machine learning studies. These are KNN, SVM, Trees, Naive Bayes, and Ensemble. There are 5 features applied to machine learning in the study. These are the length of the 3 axes, temperature and consistency data for each testis measured by the device.

Then, it has been tried to be presented by calculating the F score, specificity, precision, and recall values according to the bar graphs showing the accuracy rates of these algorithms and the data obtained from the confusion matrices of these algorithms. The formulas used for these values are as follows:

$$\text{F1 Score} = 2 * (\text{Recall} * \text{Precision}/(\text{Recall} + \text{Precision})) \quad (5)$$

$$\text{Specifity} = \text{True Negative} / (\text{True Negative} + \text{False Positive}) \quad (6)$$

$$\text{Recall} = \text{True Positive} / (\text{True Positive} + \text{False Negative}) \quad (7)$$

$$\text{Precision} = \text{True Positive} / (\text{True Positive} + \text{False Positive}) \quad (8)$$

2.8.Statistical analysis

Statistical applications are used to examine the numerical or verbal data obtained as a result of any study and to find out whether there is a semantic difference between the data. In the proposed model, Mann Whitney U Test was used for consistency data.

When only soft and normal tissue testes were examined in the study, there was only one dependent and one independent variable. If two different groups want to be examined whether they differ from each other, statistically, there are two methods. These are the T test and the Mann Whitney U test. Before starting statistical studies, it is checked whether the data are normally distributed and appropriate test selection is made accordingly[63].

There are two different methods to examine the distribution of data and these methods are to look at the value of kurtosis or skewness of the data and to apply the Kolmogorov-Smirnov and Shapiro-Wilk tests. Skewness is the relationship between the median and the mean of the data, and it is desired that these two values be close to each other, while kurtosis is related to the frequency of the data, and it is desired that the peak of the frequency and the mean value be close to each other[63].

When Kolmogorov-Smirnov and Shapiro-Wilk tests are applied, a significance value of $p < 0.005$ indicates that the data are abnormally distributed. If we look at the skewness and kurtosis values, the fact that these values are between -1 and 1 indicates a near-perfect distribution of the data[64], according to some sources, the obtained values are between -1.5 and +1.5[63] or between -2 and 2. values were considered acceptable in terms of normality of the data[65].

3. Results and Discussion

As mentioned before, the testicular abnormalities are emphasized during the physical examination. In this study, on the detection of these abnormalities, data obtained from volunteers were studied. Scrotal contents were examined with the device by palpation, and this examination includes evaluation of testicular temperature, size, and consistency.

3.1.Consistency

First, we tried to find out whether the piezoresistive sensor can be used to separate soft and normal subjects. Then, Mann Whitney U test was used for this step.

Tablo 3. Mann Whitney U Test results of normal and soft tissue data

Consistency	N	Variance	Median (hPa)	Mean (hPa)	Std. Error of Mean	U	z	P
Normal	89	,372	2,75	2,9770	,06468	209	-3,092	,002
Soft	11	,029	2,53	2,5682	,05104			
Total	100	,350	2,74	2,9320	,05919			

According to table 1, it can be shown that there is a statistical difference between normal tissue and soft tissue data (U = 209, p = .002). It is obvious that the mean of the normal tissue (2,97 hPa) is bigger that the soft tissue data (2,56 hPa).

In this study, we showed that the consistency of a tissue can be measured using a piezoresistive sensor by statistical methods. And according to the results of these data, the piezoresistive sensor shows high pressure when it presses on a hard tissue.

3.2.Volume

The other purpose of the study is to measure the distance between the IR LED and the photodiode. For this reason, 3 measurements were made with 0.5 steps between 0-6 cm and these data were combined in a graph to provide the interpolation equation (Figure 4).

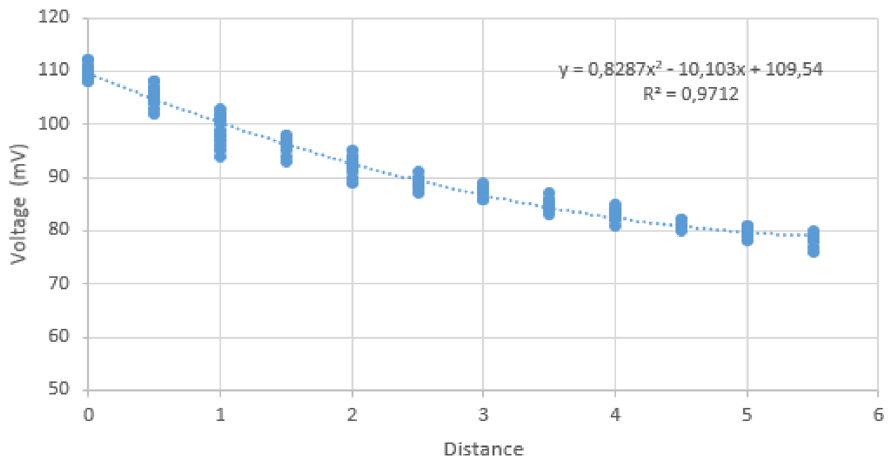

Figure 4. The regression curve obtained according to the measurement results between 0-6 cm

The resulting equation is a polynomial regression and its accuracy rate $R^2 > 0,95$ shows that both the system and the equation are suitable for measuring the distance between two fingers.

It has been concluded that the system used to measure the distance shows high accuracy, that each axis of the testis can be measured precisely, and the volume can be calculated according to the Lambert equation as a result of these measurements.
For this study, as mentioned before, 100 testicles from 50 men were examined and the result of 100 volumes obtained is shown in figure 5 where the three axes converge (black points). According to both figures 4 and 5, the amount of tension obtained decreases as the volume and distance increase.

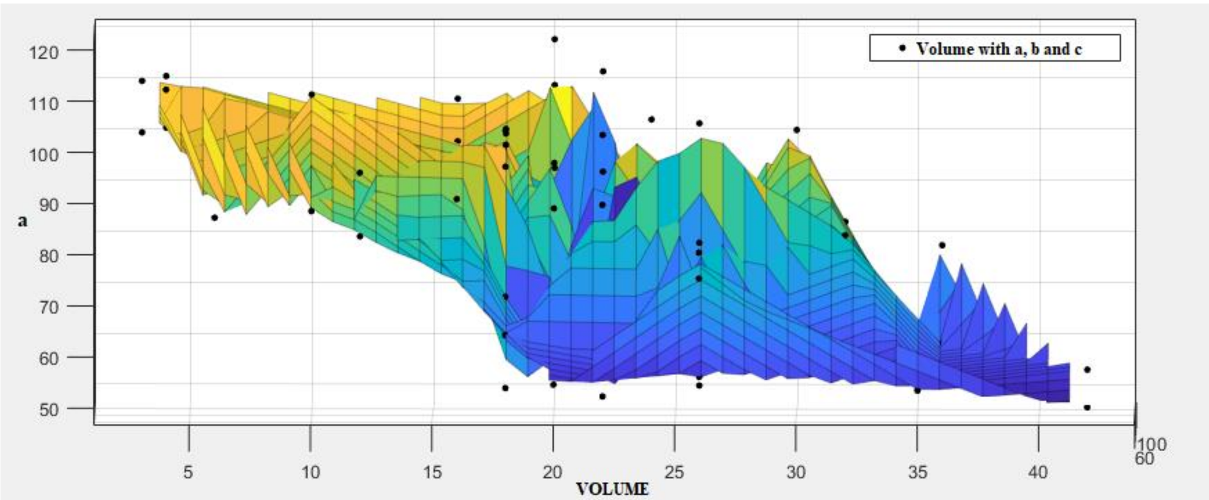

Figure 5. Distribution of 3-axis data from 100 testes by volume of the combination (black dots)

Experimental results have shown that the device can measure all testicular axes. This means that these data can be easily converted into volume values thanks to the Lambert equation.

3.3. Classification results

In this part of the study, accuracy rates were tried to be obtained by using classification algorithms. Algorithms in Matlab were applied to the data and different cross validation rates were applied to all algorithms.

3.3.1. Classification of consistency and heat stress measured with the device and consistency data obtained by palpation

The consistency and heat stress numerical data of the testicles obtained with the help of the device were labelled as soft and hard by palpation method, and the study results for the classification of these two groups are shown in figure 6.

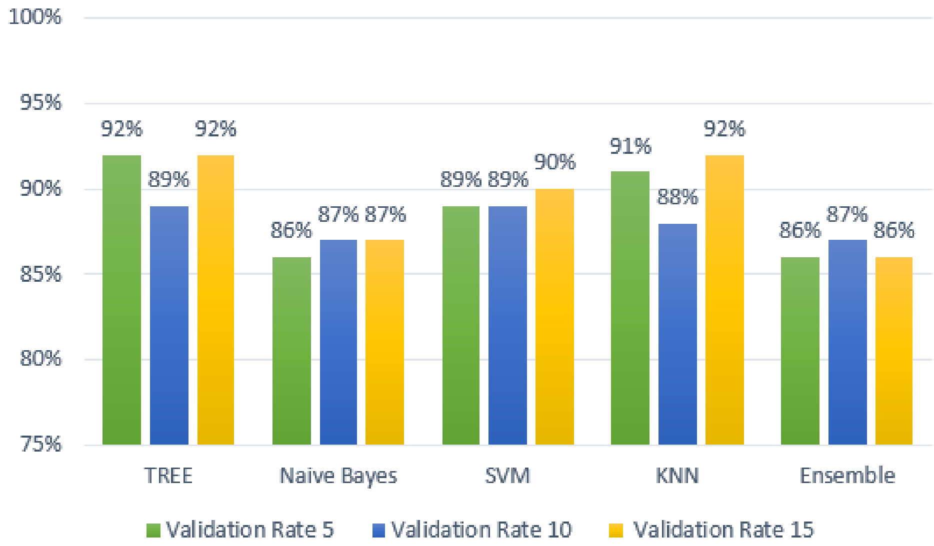

Figure 6. Statistical comparison of experimental results in terms of accuracy for consistency

In the statistical analysis part of the article, it was shown that there was a significant difference between the consistency data (Table 2). Figure 6 contains the results of the classification of the temperature and consistency results measured by the device according to 3 different validation rates for each testicle (total of 100 testicles) labelled according to the consistency information obtained by palpation.

The classification algorithm with the highest accuracy rate according to the 3 different cross validation rates applied is trees and it showed 92.0% accuracy according to validation 5 and 15, but 89.0% according to cross validation 10. The algorithms that show the least accuracy according to each validation rate are naive bayes and ensemble methods (around 87%).

Table 3. Comparison of classification algorithms in terms of consistency and heat stress

Method	Tree			Naive Bayes			SVM			KNN			Ensemble		
Validation Rate	5	10	15	5	10	15	5	10	15	5	10	15	5	10	15
Accuracy (%)	92.0	89.0	92.0	86.0	87.0	87.0	89.0	89.0	90.0	91.0	88.0	92.0	86.0	87.0	86.0
F1 Score	0,94	0,93	0,94	0,91	0,92	0,92	0,93	0,93	0,93	0,94	0,92	0,94	0,92	0,92	0,92
Specificity	0,66	0,50	0,66	0	0,25	0	0,50	0,50	0,55	0,60	0,46	0,71	0,36	0,40	0,57
Recall	0,94	0,93	0,94	0,88	0,89	0,88	0,92	0,93	0,93	0,94	0,94	0,93	0,92	0,92	0,92
Precision	0,96	0,94	0,96	0,96	0,96	0,97	0,95	0,94	0,95	0,95	0,92	0,97	0,92	0,93	0,92

Table 3 shows the F-score, Specificity, Recall and Precision values of the algorithms shown in figure 6, according to their confusion matrix. Among all algorithms and validation rates, trees with 5 cross validation rates have the highest F score of 0.94. The lowest value belongs to Naive Bayes which has 5 cross validation rates with 0.91.

Another important point in the table is specificity, and in general, algorithms cannot be said to have very high specificity. KNN with 15 cross validation rate provides the highest specificity with 0.71. Again, with the worst specificity, Naive Bayes provides 0 at a cross validation rate of 5 to 15.

3.3.2.Classification of the small and normal testicular volume with 3 axes of testis by the device

Since our main aim in this study was to measure testicular volume differences, regardless of whether they were infertile or not, the testes, whose 3-axis distances were measured by the LED and photodetector, were labelled as small and normal, and classification algorithms were applied. While this labelling was done, data with a volume less than 20 mL as a result of orchidometer were labelled as small according to the literature[66]. Other testes were also labelled as normal.

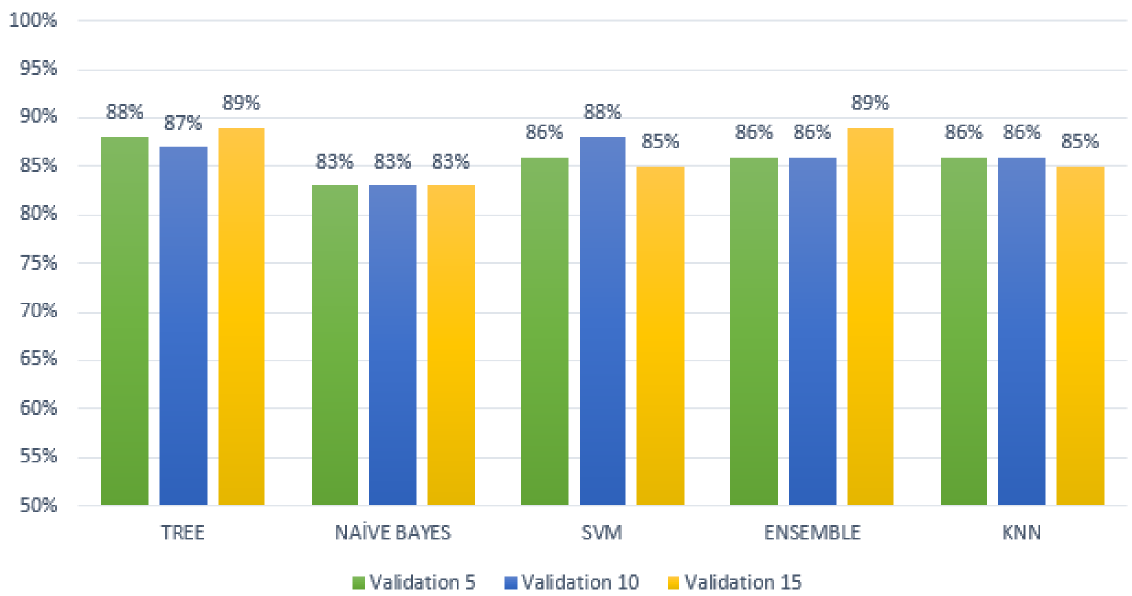

Figure 7. Statistical comparison of experimental results in terms of accuracy for volüme

Figure 7, the algorithms in Matlab were applied to the numerical data in mV of the 3-axis measured with the help of the device for each testis labelled as small or normal according to the volume information obtained by the orchidometer measurement. Again, classification processes were carried out using 3 different cross validation rates.

As seen in Figure 7, the accuracy rates of all algorithms on axis measurement are very close to each other. Compared to the cross validation 5 rate, the highest accuracy rate is 88% in trees. As a result of the study, when the ratio was 10, SVM showed the highest accuracy rate with 88%. Finally, looking at the rate of 15, Trees and Ensemble showed the highest accuracy with 89%.

Table 4. Comparison of classification algorithms in terms of testicle size

Method	**Tree**			**Naive Bayes**			**SVM**			**Ensemble**			**KNN**		
Validation Rate	5	10	15	5	10	15	5	10	15	5	10	15	5	10	15
Accuracy (%)	88.0	87.0	89.0	83.0	83.0	0,83	86.0	88.0	85.0	86.0	86.0	89.0	86.0	86.0	85.0
F1 Score	0,92	0,89	0,92	0,87	0,88	0,88	0,91	0,91	0,90	0,90	0,91	0,92	0,89	0,91	0,90
Specificity	0,83	0,71	0,83	0,52	0,54	0,55	0,85	0,70	0,61	0,66	0,72	0,83	0,70	0,70	0,66
Recall	0,88	0,89	0,89	0,90	0,91	0,88	0,86	0,91	0,90	0,89	0,87	0,89	0,88	0,88	0,87
Precision	0,97	0,91	0,97	0,86	0,87	0,90	0,98	0,93	0,91	0,93	0,96	0,97	0,91	0,95	0,95

Table 4 shows the F-score, Specificity, Recall and Precision values of the algorithms shown in figure 7, according to their confusion matrix. Among all algorithms and validation rates, trees with 5 and 15 cross validation rates have the highest F score of 0.92. The lowest value belongs to Naive Bayes which has 5 cross validation rates with 0.87.

As said before, another important point in the table is specificity. Looking at Table 3, it can be said that the algorithms applied to the data taken for the distance measurement in table 4 generally have higher specificity. Ensemble with 15 cross validation rate and Tree with 5 cross validation rates provide the highest specificity with 0.83. Again, with the worst specificity, Naive Bayes provides 0,52 at a cross validation rate of 5.

4. Conclusion

There are many people all over the world who want to have children but cannot have children due to various problems. These mentioned problems can occur as a result of both male and female factors. Finding the source of infertility is very important both in taking preventive measures and in reaching the necessary treatment without losing time.

Determining the causes of male infertility is a very laborious and long process. The physical examination is the first step of this research, and during this examination, the testicles responsible for sperm production are examined. During the examination, the focus is on testicular consistency and volume. However, during the physical examination, the person performing the examination should be experienced in this regard. Because palpation is unfortunately relative. The physician cannot obtain any numerical data as a result of palpation. The orchidometer used in volume measurement also gives comparative measurements, while some intermediate values are not taken into account. There are more complex systems for measuring both testicular consistency, volume, and testicular temperature. However, these systems also require trained people, are time-consuming and expensive.

In this study, a system that has never been done before is designed. In this system, testicular abnormalities were tried to be revealed by measuring the temperature, volume and consistency of the testis in just one minute at the same time, and the results obtained by the doctor with the palpation method were compared. When the data obtained from the patients were examined, it was seen that there was a significant difference between soft and hard testicular tissue. The distance sensor designed for short distance measurement used in testicular volume examination has also shown that it makes a healthy measurement. However, the system, which was successful in the empty measurement, could not show the same sensitivity when trying to measure the testicular axes. For this reason, the volume calculation could not be made according to the Lambert equation from the measurements taken. The problem affecting this may be that the sensors did not show sufficient sensitivity, or the location of the sensors may be considered to be not suitable for such a measurement. Changing the sensors for the system or making a more suitable positioning will allow the volume calculation to be made according to the equation.
Finally, another issue in the study is the use of machine learning methods. Although the applied methods showed high accuracy, the specificity rate is not optimal due to data limitations. This is because there is not enough data. It is clear that with more data, both the accuracy rates and the level of specificity will be higher.

Conflict of interest statement

Authors declare that they have no conflict of interest.

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