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Design and analysis of the performance of a mechanical system used to reduce of blood clots for long- term patients

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Abstract

A simplified mechanical system was designed that is capable of moving patients' legs(foot+ leg + thigh), which are easily attached to the arms of the system after applying a rotating torque and work to stimulate their blood circulation, which prevents or reduces the appearance of clots in the vessels and deep veins, especially in the area of one of the legs and rarely in both. This study was conducted on several patients, amounting to (176) patients, with ages ranging from 35 to 80 years. They were divided into two age groups: Category (A) for ages over 60 years, numbering (25), and Category (B) for ages under 60 years, number (40). Patients and each group were divided into two groups, a control group and an examination group, after excluding a number of patients amounting to (58) patients because they were taking diluted treatments, which would prevent the results from appearing or would not help in giving accurate results. A number of patients were also excluded, amounting to (53) patients. Because they did not want to continue working on the mechanical system or because they left the hospital based on their wish, (D-dimer test) were performed and measurment temperatures in the the area where clots occur on the patients under study after dividing each age group into two groups, examiner and control, with numbers of 16.and9 patients for the first group and 30 and 10 for the second group, respectively. These results were analyzed after comparing the control and test groups.

Keywords: Mechanical prevention; Venous thrombosis; Deep vein thrombosis; Pulmonary embolism; D-dimer

1. Introduction

The daily movement of a person during his work and movement to perform his daily duties is of high importance for the completion of these tasks and duties, but it is necessary to know that these movements have a great benefit in stimulating blood circulation in the person, so we find patients lying down for long periods when it is impossible for him to perform these movements (movement). Being exposed to many health risks, the most important of which is the appearance of vascular and blood clots, especially in the elderly, which directly threatens their lives, which often appear in one leg and rarely in both, as the usual treatment of these cases is by giving these patients some treatments. Medical blood thinners help break up these clots, which can cause the clots to travel (after they break apart and fragment) through the bloodstream to cause fatal problems in other parts of the body (respiratory system/pulmonary embolism). In many cases, the medical decision is to perform surgical operations. For areas of blood clots in the leg or thigh, which adds additional suffering to patients. Scientist Holger Laval, a member of the German Society of Vascular Medicine, states that starting from the age of 60, the possibility of developing vascular thrombosis in humans clearly increases. Medical estimates also indicate that venous thromboembolism (VTE), which consists of deep vein thrombosis (DVT) and embolism. Pulmonary disease (PE), responsible for 5-10% of all deaths among hospitalized patients [1,2]. In 2008, the US Surgeon General issued a report on Action and Prevention of DVT and Pulmonary Embolism, which highlights the huge numbers of patients with deep vein thrombosis (350,000-600,000) who are die by pulmonary embolism (more

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than 100,000) each year in the United States. American [3]. A simplified mechanical system was designed to help patients who are lying down and unable to walk or move move their legs (foot, leg and thigh areas), which helps the heart stimulate blood circulation by activating the blood pumps (muscles) located in the leg and thus reduces the possibility of developing Clots in the patient's legs, noting that the system is used shortly after patients lie down and for specific periods of time during the day and before swelling or clots appear in the legs. In 1981 [4], researchers (Moser G, Greenbul B, Barroussel R) and others presented a study entitled (Mechanical versus pharmacological prophylaxis of deep vein thrombosis), in which the prevention of postoperative deep vein thrombosis was studied using three different regimens for 227 patients undergoing surgery. The fibrinogen 125I test proved to be more sensitive and accurate. The incidence of deep vein thrombosis and pulmonary embolism was similar in the three groups, and mechanical prophylaxis was as effective as the other two regimens. No side effects were observed when using intermittent compression shoes. In 1983 [5], the researchers (Allan A, Williams JT) and others presented a study entitled (The use of graduated compression stockings in the prevention of deep vein thrombosis after surgery). Its effectiveness was studied in a randomized trial of 200 patients, aged 40 years and over, who underwent surgical operations. In the abdomen (100 for benign diseases, 100 for malignant diseases). The incidence of deep vein thrombosis in patients with malignant disease was 27.9 percent in control limbs and 11.5 percent in instrumented limbs (socks). It was concluded that graduated compression stockings provide a safe and effective method for preventing deep vein thrombosis.

2. The first section is the theoretical framework

2.1. Moments and forces affecting the system's operation

After designing a mechanical system that is easy to work on and meets the needs of the study, taking into account its size to suit the space in which it can be used for patients lying in hospitals, the moments resulting from the effect of the weights of the patients' legs were calculated through the torque equation, which gives the torque resulting from those weights around the special axis of rotation. In the system and according to Figure No. (1) below:

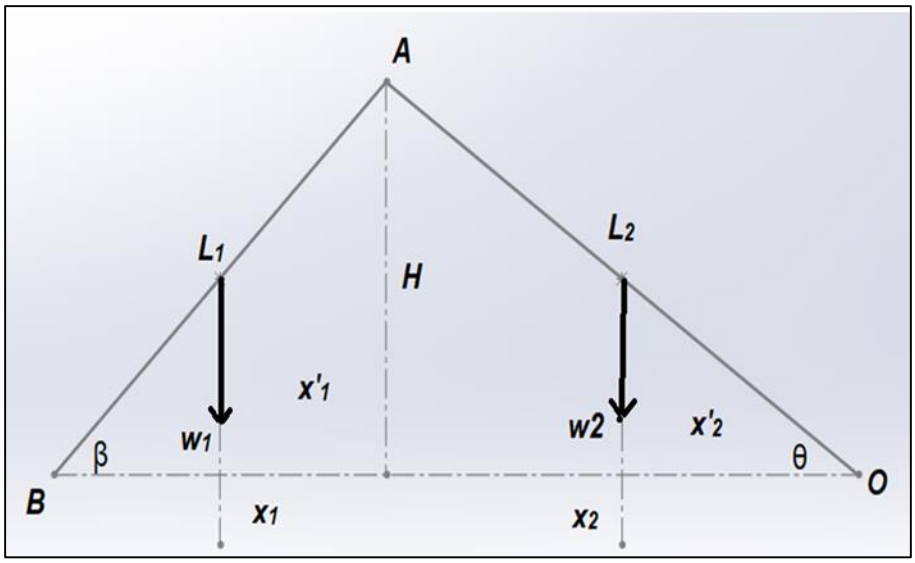

Figure 1 Weights and distances distribution chart for calculating torque

The torque was calculated according to Equation No 1

$$\sum M = M_1 + M_2 \quad \text{.....1}$$

Entering vertical distances according to Equation No 2

$$W_1 \cdot (x'_1 + x_2) + W_2 \cdot x'_2 = M \text{.....} \qquad 2$$

$$x_1^2 = L_1^2 - H^2 \xrightarrow{yields} x_1 = \sqrt{L_1^2 - H^2} = \sqrt{L_1^2 - L_1^2 \cdot sin^2\,\beta} = L_1 \cdot \sqrt{1 - sin^2\,\beta}$$

$$\frac{x'_1}{x_1} = \frac{\frac{L_1}{2}}{L_1} = \frac{1}{2} \xrightarrow{yields} x'_1 = \frac{1}{2} \cdot x_1$$

$$x'_1 = \tfrac{1}{2} \cdot L_1 \cdot \sqrt{1 - sin^2\,\beta} \ldots\ldots\ldots \quad 3$$

$$x_2^2 = L_2^2 - H^2 \xrightarrow{yields} x_2 = \sqrt{L_2^2 - H^2} = \sqrt{L_2^2 - L_2^2 \cdot sin^2\,\theta} = L_2 \cdot \sqrt{1 - sin^2\,\theta}$$

$$x_2 = L_2 \cdot \sqrt{1 - sin^2\,\theta} \qquad \ldots\ldots\ldots \quad 4$$

$$\frac{x'_2}{x_2} = \frac{\frac{L_2}{2}}{L_2} = \frac{1}{2} \xrightarrow{yields} x'_2 = \frac{1}{2} \cdot x_2$$

$$x'_2 = \tfrac{1}{2} \cdot L_2 \cdot \sqrt{1 - sin^2\,\theta} \ldots\ldots \quad 5$$

We substitute (3, 4, and 5) into 2

$$M = W_1 \cdot \left(\frac{1}{2} \cdot L_1 \cdot \sqrt{1 - sin^2\,\beta} + L_2 \cdot \sqrt{1 - sin^2\,\theta}\right) + W_2 \cdot \frac{1}{2} \cdot L_2 \cdot \sqrt{1 - sin^2\,\theta}$$

$$\beta = (0 - 43), \theta = (0 - 24)$$

2.2. Sample calculation

For Right Leg

When β=0, θ=0

$$M_R = 82.4 \cdot \left(\tfrac{1}{2} \cdot 0.45 \cdot \sqrt{1 - sin^2\,0} + 0.56 \cdot \sqrt{1 - sin^2\,0}\right) + 48 \cdot \tfrac{1}{2} \cdot 0.56 \cdot \sqrt{1 - sin^2\,0}$$

M_R=78124 N.mm

Left Leg

When β=43, θ=24

$$M_L = 82.4 \cdot \left(\tfrac{1}{2} \cdot 0.45 \cdot \sqrt{1 - sin^2\,43} + 0.56 \cdot \sqrt{1 - sin^2\,24}\right) + 48 \cdot \tfrac{1}{2} \cdot 0.56 \cdot \sqrt{1 - sin^2\,24}$$

M_L =67992 N.mm

M_{total}=M_L-M_R

=67992-78124

M_{total}= -10132 N.mm

Table 1 The values of the moments that were calculated for both the right and left limbs of a patient with an average weight of 70 kg

M_{total} (N.mm)	Right side				Left side				NO
	M_R(N.mm)	Knee joint angle	θ	β	M_L(N.mm)	Knee joint angle	θ	β	
-10132	78124	180	0	0	67992	163	24	43	1
-8715.92	78046.08	147.1	1.9	4	69330.16	117.7	22.3	40	2
-7287.36	77868.23	169.4	3.6	7	70580.87	122.4	20.6	37	3
-5845.68	77587.6	164.7	5.3	10	71741.92	127.1	18.9	34	4
-4393.51	77204.7	160	7	13	72811.19	131.8	17.2	31	5
-2933.4	76720.21	155.3	8.7	16	73786.81	136.5	15.5	28	6
-1468.03	76135.04	150.6	10.4	19	74667.01	141.2	13.8	25	7
0	75450.23	145.9	12.1	22	75450.23	145.9	12.1	22	8
1468.03	74667.01	141.2	13.8	25	76135.04	150.6	10.4	19	9
2933.4	73786.81	136.5	15.5	28	76720.21	155.3	8.7	16	10
4393.51	72811.19	131.8	17.2	31	77204.7	160	7	13	11
5845.68	71741.92	122.4	18.9	34	77587.6	164.7	5.3	10	12
7287.36	70580.87	122.4	20.6	37	77868.23	169.4	3.6	7	13
8715.92	69330.16	117.7	22.3	40	78046.08	147.1	1.9	4	14
10132	67992	163	24	43	78124	180	0	0	15

3. Mechanism of venous thrombosis

During the past period, many hypotheses have been proposed in order to understand the mechanism behind venous thrombosis, as the scientist Virchow in 1856 AD was the first to make suggestions in this regard, now known as Virchow's triad, as he explains the causes of this thrombotic triad as a result of the medical and health changes that accompany patients and can be called the components of the triad. Which includes [6]:

3.1. Damage to the blood vessel wall

During surgery, the doctor moves soft tissues such as ligaments, muscles, and tendons to reach the area being operated on. In some cases, this can lead to the release of natural substances that promote blood clotting.

3.2. Hypercoagulability

Hypercoagulability is one of the pathological disorders in which we observe blood clotting rapidly and excessively in a patient. This disorder is often an inherited or acquired disorder in which clotting occurs at an excessive rate in healthy people. Blood clots around a substance that does not belong to the veins. During surgery, substances such as fragmented tissue or collagen and fat may be released into the bloodstream, and can cause blood clots. Blood clotting.

3.3. Changes in blood flow

Blood flow slows down during prolonged bed rest and on other occasions when the legs do not move normally (after major injuries), because patients lie for a long time without movement of the leg muscles (calves), which does not help stimulate blood circulation. Which gives a chance for deep vein thrombosis to occur in these patients, which leads to pulmonary obstructive disease or stroke.

4. Venous thromboembolism

Venous thromboembolism (VTE) refers to the formation of blood clots in the veins. It is a health disorder that develops gradually and is often not diagnosed early but can have serious consequences, such as disability and death. However, it is a medical condition that can be prevented if diagnosed accurately and early and includes: [7].

4.1. Deep vein thrombosis

Deep vein thrombosis (DVT or venous thrombosis) is a medical condition that refers to the formation of a blood clot in the veins where clot formation can be caused by infected veins or hypercoagulability (increased clotting affinity). It is usually found in the lower extremities, such as the lower leg, thigh, etc. Deep vein thrombosis can lead to partial or complete blockage of blood flow to other organs of the body, which is more dangerous to human life [8].

4.2. Pulmonary thromboembolism

Also known as pulmonary embolism, this is a medical condition that disrupts (blocks) blood flow in the pulmonary arteries due to an embolus either in the pulmonary artery or its branches. Here, the clot forms elsewhere in the circulation but breaks off and passes through the pulmonary artery or capillaries to cause patients to slowly suffocate and then die [9].

5. Causes of venous thrombosis

There are many reasons why people are more likely to develop a blood clot. Inherited phlebitis refers to a genetic problem affecting 1 in 20 of the population that causes blood to clot more easily than it should. There are other acquired factors that affect the increase in venous thrombosis in people. They can be identified in more than 80% of patients who suffer from venous thrombosis. The factors that lead to venous thrombosis are previous surgery (especially orthopedic and neurosurgery), pregnancy, obesity, Use of certain medications, including birth control pills, immobility, cancer, heart failure, a previous episode of blood clots such as a clot in the leg (deep vein thrombosis) or lung (pulmonary embolism), or kidney problems [10].

5.1. The difference between blood coagulation and thrombosis

Blood clotting is a completely natural process, but its excessive occurrence can cause the formation of venous and arterial blood clots. This means that blood clotting does not cause serious complications except in the event of a blood clot occurring within important arteries in the body, which could threaten the individual's life [11].

Thrombosis is generally classified as either venous thrombosis or arterial thrombosis, depending on where the clot occurs in the body [12,13].

Blood clots in the veins can be classified into [14]:

- Superficial clotting that occurs in a vein located near the skin. It is usually painful, but is not considered dangerous.
- Deep clotting that occurs in one of the deep veins, such as a blood clot in the leg and a blood clot in the hand.

Types of blood clots are heart stroke, brain stroke, lung stroke, and abdominal stroke.

Blood clots can be divided into two main categories, based on their ability to move throughout the body, which are [15]:

- A - Persistent blood clot: which usually remains in place and prevents blood flow through it.
- B - Mobile blood clot: The most dangerous type of blood clot, as its location in the body cannot be controlled. A mobile blood clot usually forms when a fixed blood clot breaks and breaks.

6. Thromboprophylaxis prevention

The main goal of thromboprophylaxis is to reduce mortality and morbidity associated with risk factors for venous thromboembolism. Although overwhelming evidence now indicates that various anticoagulant drug treatments can significantly reduce the risk, additional measures are being used that include the use of methods to stimulate circulation

in patients, such as graduated compression stockings, intermittent pneumatic compression devices, and venous foot pumps. . Although the efficacy of these measures has been extensively evaluated in several clinical studies [16].

In some very rare cases (high-risk cases), and as an alternative to anticoagulant medications, doctors place a filter (the caval filter, formerly called an umbrella) inside one of the large veins between the heart and the area affected by deep vein thrombosis, such as the inferior vena cava. The inferior vena cava is a large vein that returns blood to the heart from the lower part of the body (lower extremities or pelvis). A filter can trap emboli (clots) and prevent them from reaching the lungs, but unlike anticoagulant drugs, filters do not prevent new clots from forming. These filters are used in people who cannot use anticoagulant therapy. [17]

For the purpose of providing an analysis of the results expected from the study, a number of medical tests were measured and performed for the patients, which in turn give indicators of high blood viscosity or the appearance of blood clots, which are [18]:

- D-dimer analysis: It is a blood analysis that is used to help indicate the presence of blood clots or to help diagnose medical conditions associated with blood clotting, as normal levels range from (0-500) nanograms per milliliter, as this analysis is considered one of the The most important tests that quickly detect the presence of blood clots.
- Measuring the temperature rise in the affected areas, which are usually in one of the legs and rarely both.

7. The second section: statistical analysis and discussion

7.1. Preamble

After obtaining the results and clinical examinations of the patients under study, statistical analysis was conducted to extract the value of the improvement after using the mechanical system and the extent of its effect on reducing or preventing clots in patients. This chapter of the analysis provides a comprehensive overview of the frequency and spread of variables within the research. It includes different tests and their respective results, Tabulated data is organized using columns that identify the test number, variable, and test type. Through this structure, the table allows for a detailed examination of how different factors affect test results. As shown below:

For the control and test groups for ages older than 60 years, D-Dimer examination

Table 2 The arithmetic mean, standard deviation, and t-test for the Dimer analysis for ages older than 60 years

Group Statistics							
TEST		**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**	**T**	**P.value**
TEST 1	the device	16	607.3750	163.47920	40.86980		0.884
	without	9	596.8889	172.70238	57.56746	0.149	
TEST 2	the device	16	585.6875	156.30428	39.07607		0.673
	without	9	619.7778	205.59960	68.53320	0.432	
TEST 3	the device	16	560.7500	152.30649	38.07662		0.480
	without	9	624.0000	233.78676	77.92892	0.729	
TEST 4	the device	16	531.7500	156.19112	39.04778		.310
	without	9	633.8889	263.07244	87.69081	1.064	
TEAT 5	the device	16	497.0625	164.15784	41.03946		0.187
	without	9	647.6667	296.10513	98.70171	1.409	
TEST 6	the device	16	476.5625	181.24200	45.31050		0.120
	without	9	674.4444	324.19019	108.06340	1.689	

The group included 25 patients: 16 who used the system (study group) and 9 who did not use the system (control group). The first group underwent laboratory tests after using the system. The results showed: Inspection of the data mentioned in Table (2) and the p-values for tests 1, 2, 3, 4, 5 and 6 shows that there is no statistically significant difference between the tests with the system and those without the system testing, which showed that use of this system had no impact on the results of D-dimer analysis. Statistically significant, the laboratory results (of the study group) showed that the proportion of patients with an analysis rate higher than the normal range of the above study was 12.5%. The laboratory results (control group) and the results recorded in show that the high analysis rate (presence of manifestations) of the same laboratory test mentioned above is 44%. Generally speaking, when the total number is equal to that of 25 In a sample size of patients, the system achieved a positive metric of reducing blood clots in patients by 31.5%. figure (2) and (3) show the distribution of laboratory testing rates and control groups in the above study.

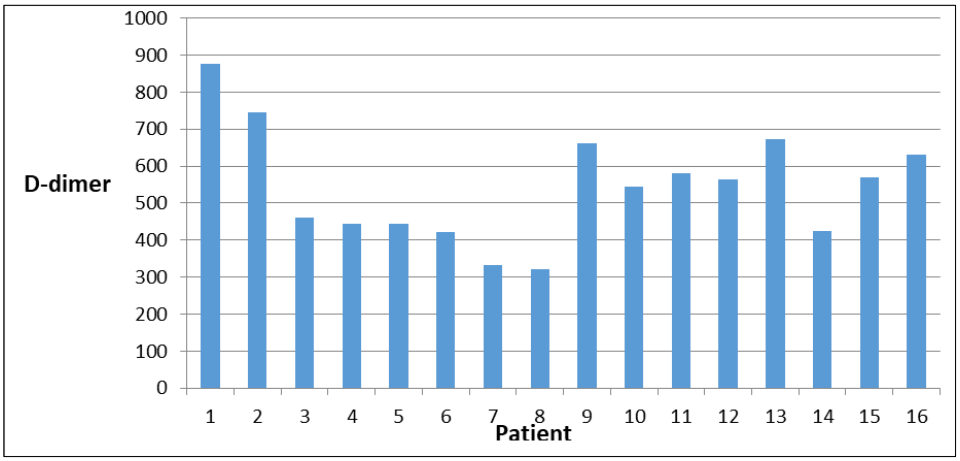

Figure 2 Average D-dimer test results for patients (test group) over 60 years of age

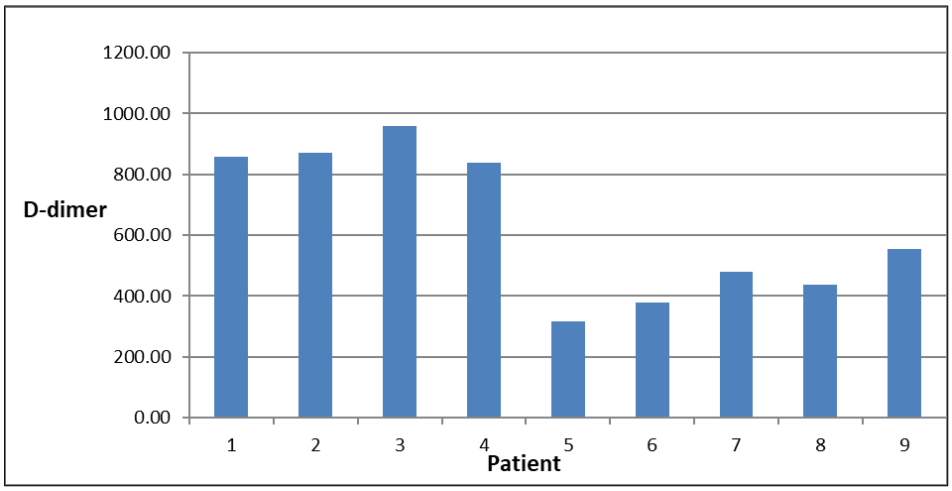

Figure 3 Average D-dimer test results for patients (control group) over 60 years of age

8. D-dimer examination for the control and test groups for ages less than 60 years

The group included 40 patients, 30 of whom used the system (study group) and 10 patients who did not use the system (control group). The first group underwent laboratory testing after using the system using Table (3). Taking the data mentioned and examining the p-values for tests 1, 2, 3, 4, 5 and 6, it was found that there was no statistically significant difference between the tests used in the test. Tests with and without the system showed that use of the system did not affect D-dimer analysis results in a statistically significant way for patients under 60 years of age, while laboratory results (for patients under 60 years of age) Table The results recorded indicate that the high percentage of patients with an analysis rate higher than the normal rate for the above examination is 10%. The laboratory results (control group),

show that they tested at a high rate of 4% in the same laboratory test mentioned above. Summary Assuming a total sample size of 40 patients, this system will achieve positive indicators of reducing blood clots in patients by up to 30%. figure (4) and (5) show the distribution of laboratory detection rates in the study and control groups in the above study.

Table 3 The arithmetic mean, standard deviation, and t-test for Dimer analysis for ages less than 60 years

Group Statistics							
	VAR00001	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**	**T**	**P.value**
TEST 1	the device	30	581.1667	136.60668	24.94085		
	Without	10	546.4000	160.40657	50.72501	0.615	0.549
TEST 2	the device	30	560.7333	124.76127	22.77819		
	Without	10	553.0000	151.02759	47.75912	0.146	0.886
TEST 3	the device	30	536.9667	121.65879	22.21175		
	Without	10	551.4000	162.58755	51.41470	0.258	0.801
TEST 4	the device	30	507.3667	129.35316	23.61655		
	Without	10	550.8000	185.86483	58.77562	0.686	0.506
TEST 5	the device	30	485.3667	140.71480	25.69089		
	Without	10	541.7000	204.33091	64.61511	0.810	0.434
TEST 6	the device	30	464.4333	154.88810	28.27857		
	Without	10	549.0000	237.92389	75.23814	1.052	0.314

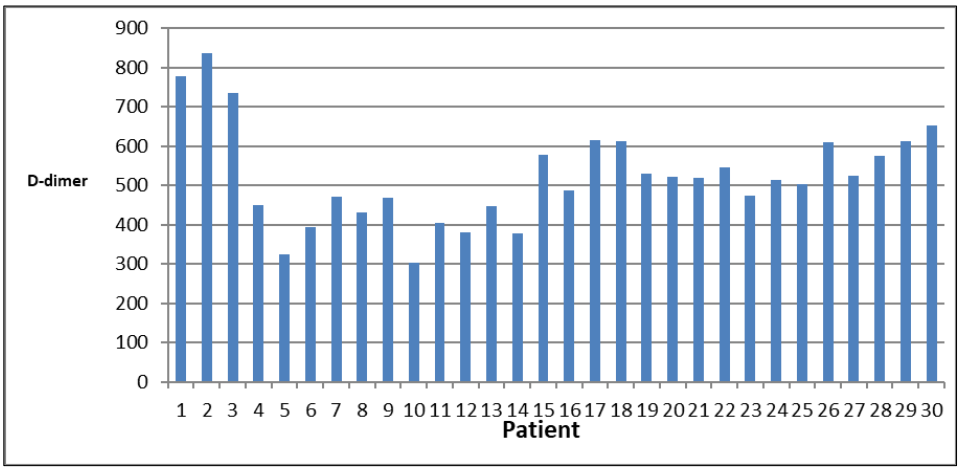

figure 4 Average D-dimer test results for patients(test group) under 60 years of age

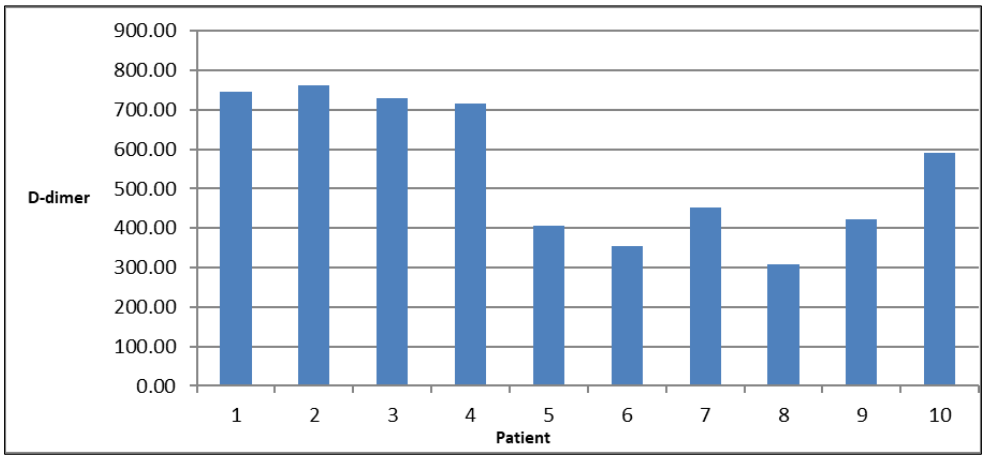

Figure 5 Average D-dimer test results for patients (control group)under 60 years of age

9. Temperature check for ages over 60 years

Table 4 The arithmetic mean, standard deviation, and t-test for temperature screening for ages over 60 years

Group Statistics							
	VAR00001	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**	**T**	**P.value**
TEST 1	the device	16	37.0313	0.39110	0.09777	0.401	0.693
	without	9	36.9667	0.38406	0.12802		
TEST 2	the device	16	36.9688	0.34394	0.08598	-0.766-	0.457
	without	9	37.1000	0.44441	0.14814		
TEST 3	the device	16	36.9313	0.27981	0.06995	-0.955-	0.359
	without	9	37.0889	0.44845	0.14948		
TEST 4	the device	16	36.9187	0.29489	0.07372	0.053	0.959
	without	9	36.9111	0.37565	0.12522		
TEST 5	the device	16	36.8625	0.29861	0.07465	-0.889-	0.393
	without	9	37.0333	0.53151	0.17717		
TEST 6	the device	16	36.8437	0.30104	0.07526	-1.248-	0.240
	without	9	37.1222	0.63004	0.21001		

After classifying patients into numerical groups, as in study number (1) and based on the data shown in Table (4), and examining the p-values for tests 1, 2, 3, 4, 5, and 6, No statistically significant differences were found between examinations with and without the system, indicating that use of the system did not affect the results of the temperature test in a statistically significant way for patients over 60 years of age. The results listed represent 6% of the patients in the study group who experienced high temperatures above normal body temperature. It has been scientifically proven that one of the symptoms of blood clots in the body is that deep veins in certain parts of the human body can cause this High temperature in one or both parts of the body, usually the legs.

As the control group's results show that the proportion of patients with body temperature higher than the normal range is generally 33%. When the total sample size is 25 patients, the system corresponds to the people surveyed in this study and of people reached a positive indicator of about 27%. figure (6) and (7), respectively, show the distribution of laboratory detection rates and control groups in the above study

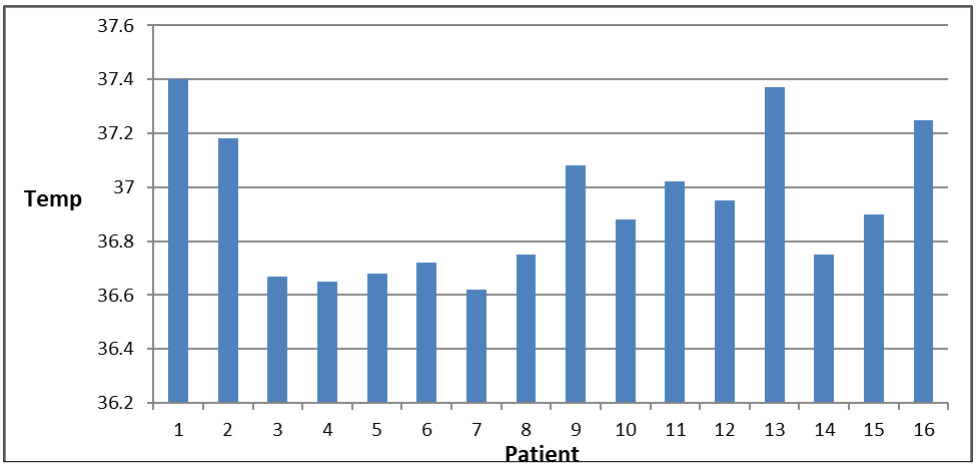

Figure 6 Average Temperature test results for patients (test group) over60 years of age

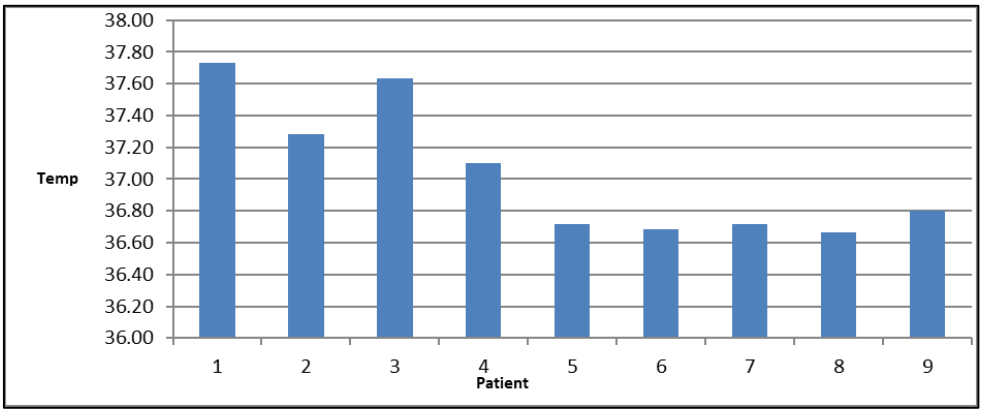

Figure 7 Average temperature test results for patients (control group) over 60 years of age

9.1. Temperature check under 60 years old

Table 5 The arithmetic mean, standard deviation, and t-test for temperature screening for ages less than 60 years

Group Statistics							
	VAR00001	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**	**T**	**P value**
TEST 1	the device	30	36.8700	0.28180	0.05145		
	without	10	36.8300	0.18886	0.05972	0.507	0.617
TEST 2	the device	30	35.7233	6.18322	1.12890		
	without	10	36.7900	0.14491	0.04583	0.944	.0353
TEST 3	the device	30	36.8933	0.16595	0.03030		
	without	10	36.8700	0.14181	0.04485	0.431	0.672
TEST 4	the device	30	36.9067	0.23183	0.04233		
	without	10	36.9300	0.14944	0.04726	0.368	0.716
TEST 5	the device	30	36.8917	0.25464	0.04649		
	without	10	36.9600	0.19551	0.06182	0.883	0.387

TEST 6	the device	30	36.9483	0.34101	0.06226		
	without	10	36.9800	0.37947	0.12000	0.234	0.818

After classifying the patients into numerical groups as in study number (1) and based on the data mentioned in table (5) and checking the p-values of tests 1, 2, 3, 4, 5 and 6, No statistically significant differences were found between studies with and without the system, indicating that use of the system did not affect the results of temperature tests in a statistically significant way for patients under 60 years old, according to the results of the research group recorded the proportion of patients with body temperature higher than the normal range is 3%, because it is scientifically proven that one of the symptoms is due to various parts of the human body (usually the legs, one side or both sides). Legs), and the presence of blood clots in the deep veins in these areas is serious.

The result of the control group. The percentage of patients who develop higher than normal high temperature is generally 10%, assuming the total sample size is 40 patients, which is the research system used in this study Positive indicators improved by about 7%. figure (8) and (89) show the distribution of laboratory testing rates in the study group and control group in the above study.

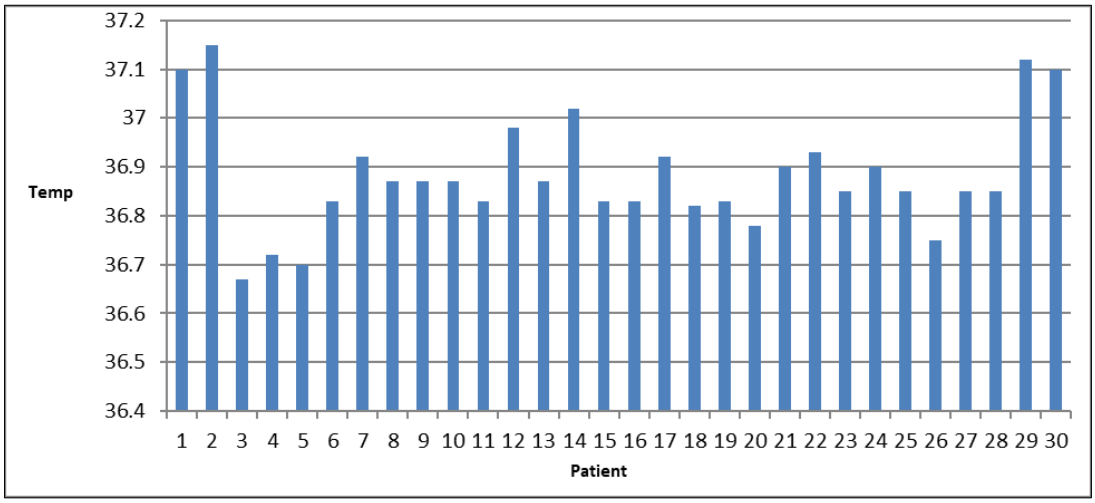

Figure 8 Average Temperature test results for patients (test group) under 60 years of age

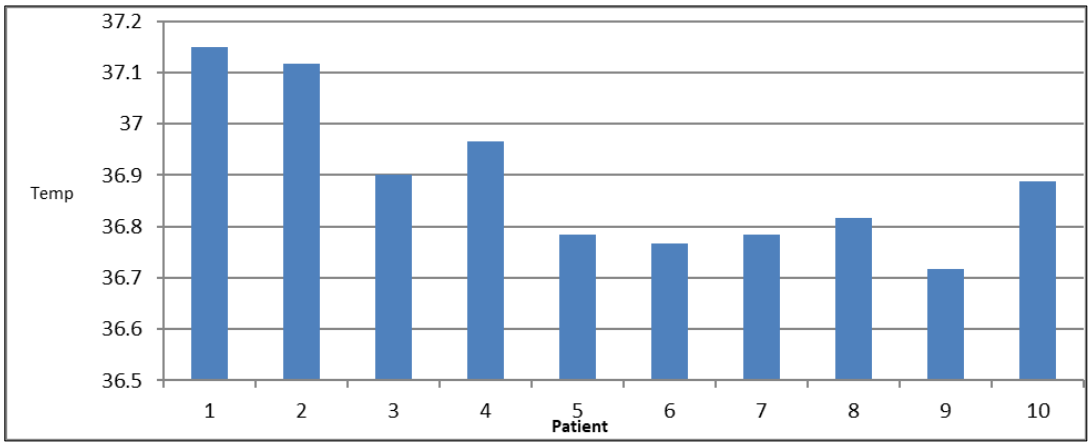

Figure 9 Average temperature test results for patients (control group) under 60 years of age

10. Conclusions

After obtaining the results and clinical examinations of the patients and completing the statistical analysis, the following conclusions can be drawn according to the laboratory and clinical examinations conducted on the patients under study, which were as follows:

- D-dimer examination. The results of this examination showed that the use of the system achieved an improvement rate of 31.5% for the first age group (patients lying in bed for long periods ranging from 7 days or more up to more than 15 days). It also showed a positive indicator for the second age group by a percentage of up to To 30%.
- The results of clinical examinations related to high temperatures in areas likely to suffer from blood clots. The results showed, as recorded later, and after adopting the division of the above groups, that the use of the system achieved a positive indicator of improvement for the test and control groups, which was 27% and 7%, respectively, to confirm the effectiveness of using the system under study in reducing Clots.

Future recommendations

The following can be recommended for future work and continuation of the findings from this study:

- Study the effect of adding pillows to patients' legs with the mechanical system used.
- Study the effect of the vibration factor with the operation of the current system after adding a vibration factor that helps generate a vibrating movement for the patient's legs.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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