Novel Mechanical Approach for Coagulation Monitoring Device in Hemostasis Assessment

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Abstract. Coagulation is an intricate process due to which blood clot formation takes place. It is an intrinsic part of hemostasis thrombus blocks the blood vessels, and as a result, bleeding will stop. During cardiopulmonary bypass surgery, the hemostasis status of a patient is mandatory to monitor continually to shun uncontrolled bleeding or coagulum disorders. Increasing safety for patients undergoing surgical procedures is the primary objective of coagulation monitoring of hemostasis. Coagulation and bleeding abnormalities are among the crucial causes of death in the developed world, so research in this area is necessary. Now for the monitoring of hemostasis status during cardiopulmonary bypass, there is a solution through this proposed model for coagulation monitoring. In ongoing coagulation monitoring by mechanical principle, the clotting time (i.e. PT and aPTT) is mandatory to diagnose the bleeding disorder. The coagulation monitoring device is an automated laboratory instrument based on mechanical principles, used to measure the coagulation time. The prototype requires samples that have been drawn in the cuvette. The system has a stable temperature (i.e. 37˚C) through a temperature sensor, DC fan, and heating coil controlled by a microcontroller through the relay. It is equipped with a DC motor and magnetic ball due to which the blood coagulation is monitored by the rotation of the magnetic ball in the cuvette. The rotation of a magnetic ball is sensed by a sensor (i.e. Hall Effect sensor module), by cause of this, the timer will start, as the viscosity of blood increases the magnetic ball faces the hindrance in rotation and the formation of fibrin take place, as a result, the timer will stop. This device is programmed so that the formation of blood clots is befallen.

Keywords: Coagulation, haemostasis, cardiopulmonary bypass clot detection, prothrombin time, activated prothromboplastin time.

1 INTRODUCTION

Blood has been revered since ancient times. The ability to convert blood components from liquid to solid form is represented by an enzymatic network of activation and inhibition [4]. Blood is regarded as valuable as it's the fundamental requirement for the wellbeing of our physique and requires a constant supply of oxygen, delivered via blood, to reach billions of tissues and cells. A coagulation analyzer uses these factors to determine the clotting time of blood, used to detect clot formation and determine the Prothrombin Time (PT), and Activated Partial Thromboplastin Time (aPTT). The coagulation monitoring device is an automated laboratory instrument based on me chanical principles, used to measure the coagulation time. The prototype requires samples that have been drawn in the cuvette. The system has a stable temperature (i.e. 37˚C) through a temperature sensor, DC fan, and heating coil controlled by a microcontroller through the relay. It is equipped with a DC motor and magnetic ball due to which the blood coagulation is monitored by the rotation of the magnetic ball in the cuvette. The rotation of a magnetic ball is sensed by a sensor (i.e. Hall Effect sensor

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module), cause of this the timer will start, as the viscosity of blood increases the magnetic ball faces the hindrance in rotation and the formation of fibrin takes place, as a result, the timer will stop. It is employed to assess the blood's ability to clot to identify and evaluate bleeding disorders like hemophilia or to keep track of patients who are taking anticoagulants like aspirin or heparin [5][6]. Prothrombin timeand activated partial prothrombin time are by far the most commonly used broadcasttests for coagulastion abnormalities

2 METHODOLOGY

The coagulation analyzer requires samples that have been drawn on the tube containing reagents. The temperature of the system is kept constant i.e. 37 since the normal body temperature is about 37˚C. The device is further cooperative in measuring the blood clotting stage of the patient who is prescribed a specific range of anticoagulants [8] The design of the clot detection system is based on four modules: incubation, mechanical part, sensory part, and output. The heating element, DC fan, and temperature sensor make up the incubation component. The temperature is maintained by a DC fan and heating coil with the help of a relay in the incubation circuit, which primarily serves the cuvette. A DC motor is the foundation of the mechanical component. An electromagnetic field detects the movement of a magnetic ball within a plasma reagent solution when the DC motor starts up. The sensory component is the Hall Effect sensor. It detects the ball's movement. At a point, the ball shows a hindrance when the viscosity of blood increases and eventually stops. As a result, it demonstrates how the ball moved at the appropriate time. This time is related to the speed of fibrin formation.

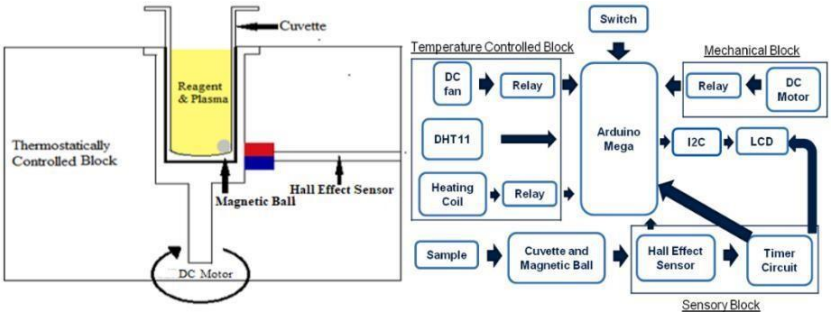

Fig. 1. Working of Coagulation Monitoring Device

The device is operated by the Arduino software. The system has a stable temperature of 37˚C, the temperature is kept constant because of normal body temperature (i.e. 37˚C). The reason behind the stable temperature is that the device will give accurate results. It has a plastic cuvette along with a magnetic ball in it. The sample is added to the cuvette. The cuvette is placed into the well of the coagulation monitoring device. The ball inside the cuvette rotates slowly with the help of a DC motor. When the blood is about to coagulate the fibrinogen threads start forming becoming a hindrance to rotating the magnetic ball properly. Then the proper coagulation occurs the speed of the magnetic ball will gradually decrease and the time at which the magnetic ball ejects, will be detected by the Hall Effect sensor due to which the timer will stop, and the result will be displayed on LCD. This whole process is controlled by a microcontroller (i.e. Arduino Mega 2560).

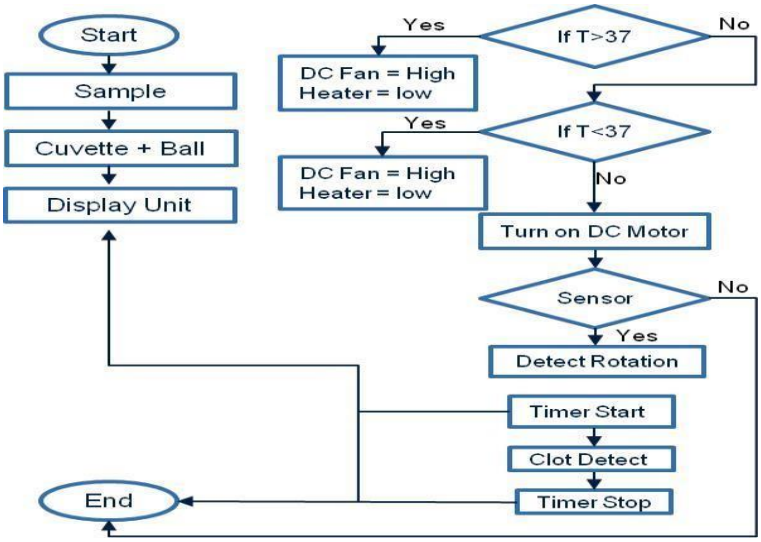

Fig. 2. Device Flow Chart

3 RESEARCH ELABORATIONS

In 1999, the SYSMEX CA 6000 coagulation analyzer, which has a cappiercing apparatus, used in the current investigation and a photooptical thrombus monitoring de vice, was assessed in terms of its technical capabilities for determining the results of common thrombosis tests, as well as for determining the coagulation factor [9]. In 2005, Florence Fischer utters that The Sysmex CA7000 is a completely automatic, multi parameter hemostasis analyzer featuring a cappiercing and a photooptical clotdetecting device. It is intended to carry using immunological and fluorogenic tests in addition to coagulation tests [10]. In 2001, T. Iba, Y. Umemura, H. Wada, and J. H. Levy, Throm bosis and Hemostasis International Society developed the overt disseminated in travascular coagulation (DIC). The role of coagulation issues in the formation of sepsis, however, has been made clearer by recent advances in the disorder [11]. Currently, it is acknowledged that coagulation and inflammation are the two factors that lead to organ dysfunction in septic shock and sepsis. The World Health Organization estimates that there are 48.9 million cases of sepsis worldwide each year, with eleven million deaths being documented [12]. In 2019, Milind Thakur, and Aamer B Ahmed, those patients with active bleeding, thromboelastography (TEG) is frequently utilized to forecast the coagulation state [13]. To collect TEG parameters, a TEG 5000 thromboelastogram device was used. The elevated coagulation condition in the patient group is supported by the link between TEG parameters and common tests including DD, FIB, and platelet function [14]. Their results show that in individuals with acute cerebral infarction, TEG values are sensitive indications of a high coagulation level [15] [16]. In 2020, Regina Ru¨ckerl, and other authors research that the mortality rates from coronary heart disease (CHD) have steadily decreased in Western nations over the past 20–30 years. It is generally known that people with chronic heart failure (CHF) have a higher risk of thromboembolism and stroke [17]. These alterations in blood indicators may raise the risk factor, especially in people with chronic heart failure (CHF), and may worsen arterial thrombotic problems when exposed to a lot of air [18] [19]. The incidence of arterial thromboembolism, according to a

study of the major research, ranged from 0.9 to 5.5 occurrences per 100 patientyears, with the highest studies suggesting an occurrence of 2.0 to 2.4% per 100 patientyear [20].

4 RESULTS

For the proper testing of the device, clinical trials have occurred in the medical laboratory. In which the collection of ten (10) blood samples takes place in the coagulation device. The test occurred in both healthy and unhealthy patients; every unhealthy patient was suffering from different diseases which were affecting their coagulation time. According to the result, the coagulation time of all the samples is not interrelated. The whole blood samples coagulated under the normal coagulation time which is about 815 minutes.

Table 1. Blood Clotting Time

Patient Sample	Age	Clotting Time (min)	Clotting Time (sec)
01	15	1:59	119
02	45	2:30	150
03	48	2:25	145
04	45	3:55	235
05	45	2:10	130
06	50	2:45	165
07	55	3:05	185
08	40	2:00	120
09	60	2:35	155
10	35	2:20	140

5 DISCUSSION

5.1 Comparative Studies

Data Summary for Each Age Group:

Group 1 (15-29 years):

- Patient 01: Age 15, Clotting Time 119seconds

Group 2 (30-44 years):

- Patient 08: Age 40, Clotting Time 120 seconds
- Patient 10: Age 35, Clotting Time 140seconds

Group 3 (45-59 years):

- Patient 02: Age 45, Clotting Time 150 seconds
- Patient 03: Age 48, Clotting Time 145 seconds
- Patient 04: Age 45, Clotting Time 235 seconds
- Patient 05: Age 45, Clotting Time 130 seconds
- Patient 06: Age 50, Clotting Time 165 seconds
- Patient 07: Age 55, Clotting Time 185seconds

Group 4 (60+ years):

- Patient 09: Age 60, Clotting Time 155 seconds

Table 2. Group wise Statistical Data

	Average Clotting Time	**Median Clotting Time**	**Standard Deviation**
Group01 (1529 Years)	119 Seconds	119 Seconds (Only one value)	Not Applicable (Only one value)
Group02 (3044 Years)	130 Seconds	130 Seconds	10 Seconds
Group03 (4559 Years)	168.33 Seconds	157.5 Seconds	31.5 Seconds
Group04 (60+)	155 Seconds	155 Seconds (Only one value)	155 Seconds (only one value)

5.1 Statistical Tests

ANOVA Test: Conducting an ANOVA test across the groups (excluding single data points) would likely show a significant difference in clotting times between age groups, confirming that age affects clotting times.

PostHoc Analysis: Pairwise comparisons would reveal that:

Group 1 (1529 years) has significantly lower clotting times compared to Group 3(4559 years). Group 2 (3044 years) also shows lower clotting times than Group 3, with lesspronounced differences compared to Group 1.

Table 3. Qualitative Feedback from Participants

Comfort	**Usability**	**Satisfaction**
Most participants reported that the clotting time measurement was generally comfortable. The procedure was well tolerated, though some participants in older age groups noted slight discomfort due to the procedure's duration.	The testing procedure was largely seen as straightforward, but participants from older age groups suggested improvements. Recommendations included clearer instructions and a more streamlined process.	Overall satisfaction was high, with participants indicating that they would be willing to repeat the procedure if needed, particularly if the feedback suggestions were addressed.

6 CONCLUSION

In conclusion, the comparative study reveals significant differences in clotting times across age groups, with increased times and variability noted in older participants. These findings underscore the importance of considering agerelated changes in clinical evaluations of coagulation. It has been recapitulating that "A Coagulation Monitoring Device" will be used in many clinical situations like major surgeries. This proposed prototype focuses on the process of mechanical principle which is very helpful for the treatment of clinical situations. This device provides a wholesome solution for managing coagulation disorders by providing a more comprehensive.

Disclosure of Interests. The authors have no competing interests to declare.

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