Proceedings of the 2020 Design of Medical Devices Conference
DMD2020
April 6, 7-9, 2020, Minneapolis, MN, USA

DMD2020-9004

POINT-OF-CARE VISCOSITY SURROGATE MEASUREMENT THROUGH UTILIZATION OF SMARTPHONE SENSORS AND CUSTOM 3D PRINTED DESIGN

Awaiz Khan[1]
Virginia Tech Carilion School of Medicine
Roanoke, VA, USA

Edmundo Rubio, MD[2]
Virginia Tech Carilion School of Medicine
Roanoke, VA, USA

Bradley Icard, DO[3]
Cone Health Medical Group
Greensboro, NC, USA

ABSTRACT

This project sought to develop a method to provide a clinically meaningful, surrogate measure for viscosity that will help analyze complex biofluids. Goals for this project included precise measurements that differentiate a wide variety of standard viscosities, table-top level of size, and ease-of-use. The design utilized a custom 3D-printed analog of a cone and plate viscometer with an attachment for a smartphone to provide gyroscopic data. The device is currently in the stages of final validation and will ultimately be tested in a 40-patient clinical trial intended to assess efficacy of mucolytic therapy in mechanically ventilated patients.

Keywords: Viscosity measurement, mucous, biofluids

BACKGROUND

Smartphones are ubiquitous technology with unparalleled potential which are being utilized in countless everyday life and industry applications. Smartphones have several high-accurate sensors such as accelerometers, gyroscopes, cameras, global positioning systems, microphones, and others which allow developers to expand their use. Carilion Clinic - VTCSOM and Virginia Tech's College of Engineering are collaboratively developing an affordable solution to allow measurements of various physical phenomena to facilitate academic and research opportunities, otherwise currently being cost prohibitive. Inspiration for this project began with attempting to characterize the thickness of mucous in order to evaluate the efficacy of mucolytic therapy in the mechanically ventilated patients, for which there is a paucity of evidence [1-2]. Current methods to characterize this include cone and cup viscometry which presents challenges for sample handling at the bedside [3].

Applications of this technology to healthcare are broad, including point-of-care testing of body fluids' viscosity. In particular, this project will lay the foundation to characterize respiratory secretion viscosity using a surrogate measure. This will allow better assessment of current and future mucolytic agents. Initially, we plan to use this technology to evaluate the role of mucolytic therapy in intubated patients with respiratory failure and subsequently in an outpatient clinic.

1.1 DESIGN

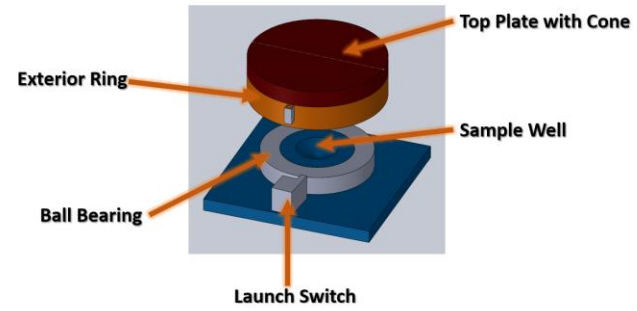
This device was inspired by cone-and-plate viscometry, which utilizes a sample plate in which the sample experiences shear, by which the device is able to measure viscosity. Given our initial target to sample mucous (a heterogeneous complex non-Newtonian fluid) we looked for a reasonable surrogate measure of the relative thickness of this fluid [3]. Time to Decay was found to be an accurate correlate and hence the device measures this [3]. Thus, the device intends to measure a new term, Time to Decay, which serves as a correlate to viscosity. Specific aims for the device included (1) reliability in distinguishing viscosities across a wide range, (2) table top design, and (3) ease-of-use.

The design consists of 5 main elements. All parts were modeled in SolidWorks and were 3D printed. The components include a base plate with a well, a top plate with cone, the exterior ring that is coupled to a radial ball bearing, and a launch switch coupled to a rubber band. The exterior ring is mated to the top

[1] Contact author: awaiz@vt.edu

plate with cone via screws. The device was designed so that samples may be loaded by simply removing the top plate, dispensing the sample, and replacing the top plate such that it is ready for a test run.

(a)



(b)

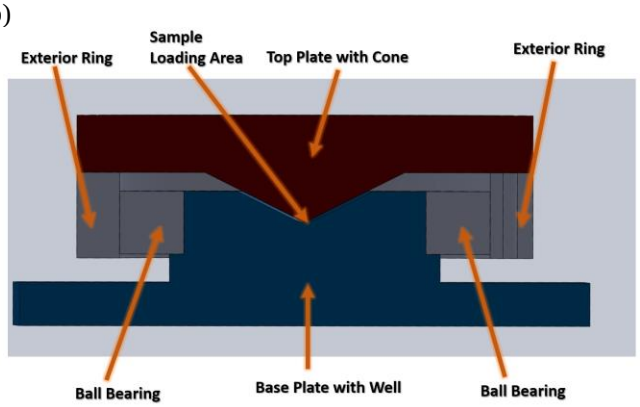


FIGURE 1: Schematic diagram of device design. The inner ring of the ball bearing is fixed against the wall of the sample well while the outer ring is free to spin along with the Exterior Ring (orange) and Top Plate piece. (b) demonstrates the cross section of the device.

(a)

(b)

FIGURE 2: Final assembly with smartphone (a). The top plate is removable (b) and is easily replaceable for sample loading.

A Nexus 5X was utilized for the smartphone that is affixed to the top plate. For a sense of scale, the base plate measures 20 cm x 20 cm and the entire device has a height of 7.5 cm not including the smartphone.

1.2 METHODS

The validation of the device was done by testing a range of standard viscosities that most closely approximate the range of viscosities anticipated with mucous in the clinical setting. A test without any sample in the well was performed to check for consistency of spin. Silicone Oil with viscosities of 100cSt, 3000cSt, 7000cSt, 10,000cSt, and 60,000cSt were used in the evaluation of the performance of the device. These viscosities were chosen as mucous tends to be anywhere from 10^4-10^6 times viscous than water at low shear rates [3]. 5mL of each oil was instilled in the well of the device and the device was spun using the rubber band launch mechanism described. Data was collected from the gyroscope of the smartphone using an app called Sensor Record from the Google Play Store and exported to Microsoft Excel. The Time to Decay value was computed by plotting the rotational velocity vs time graph and identifying the point of impulse and where rotational velocity = 0. The time between these points was computed and compared. This process was repeated for 5 trials. A two tailed t test was done to determine the significance of the differences ascertained by the device with α=0.05.

1.3 RESULTS

In order to validate the device, precision and replicability were essential in order to proceed with testing. First, a dry run without any sample in the well was performed. The results for the Time to Decay value are shown in Table 1 and are followed by the Rotational velocity vs Time graph in Figure 3.

Dry Run	Run 1	Run 2	Run 3	Run 4	Run 5	Mean	SD
Time to Decay (s)	3.2	3.5	3.5	3.3	3.3	3.36	0.13

TABLE 1: Time to Decay for "Dry" run, which consists of no sample in well

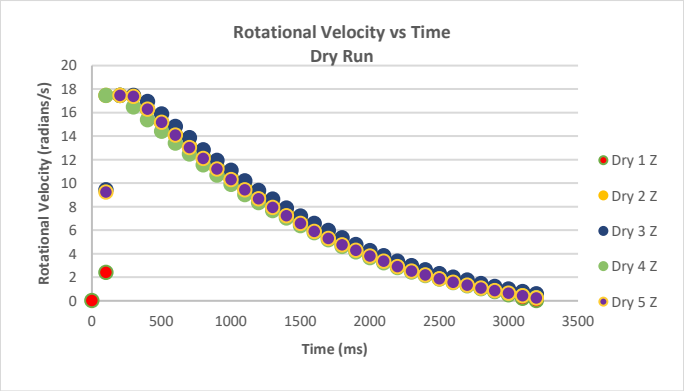


FIGURE 3: Rotational velocity vs Time, demonstrating reliability and decay of rotational velocity with time progressing for "Dry" run

This demonstrated that the device was reliable and consistent in its performance and that the launching mechanism was functioning appropriately. Table 2 (a-e) outlines the results for the Time to Decay function for the selected viscosities.

(a)

100cSt	Run 1	Run 2	Run 3	Run 4	Run 5	Mean	SD
Time to Decay (s)	3.2	3.2	3.39	3.1	2.9	3.1	0.17

(b)

3000cSt	Run 1	Run 2	Run 3	Run 4	Run 5	Mean	SD
Time to Decay (s)	2.6	2.8	2.7	2.6	2.7	2.68	0.084

(c)

7000cSt	Run 1	Run 2	Run 3	Run 4	Run 5	Mean	SD
Time to Decay (s)	2.6	2.6	2.6	2.49	2.6	2.58	0.049

(d)

10,000cSt	Run 1	Run 2	Run 3	Run 4	Run 5	Mean	SD
Time to Decay (s)	2.1	2.3	2	2.3	2.1	2.16	0.13

(e)

60,000cSt	Run 1	Run 2	Run 3	Run 4	Run 5	Mean	SD
Time to Decay (s)	1.4	1.3	1.3	1.4	1.3	1.34	0.054

TABLE 2: Time to Decay for selected viscosities from 100cSt to 60,000 cSt (a-e).

The initial rotational velocity was equal to 17.45 radian/s in each trial for all viscosities tested, which eliminated the need to do an area under the curve analysis to compare across trials. The mean rotational velocity vs mean time is shown in Figure X so as to demonstrate the change in Time to Decay with respect to various viscosities.

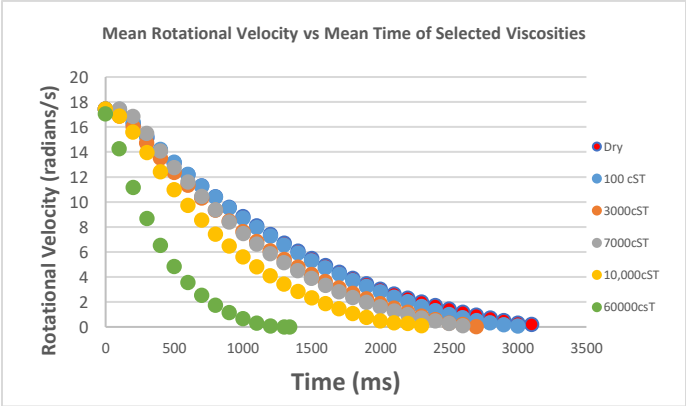


FIGURE 4: Mean Rotational Velocity vs Mean Time of Selected Viscosities

A two tailed t test for significance was done between all trials. Shown are selected comparisons and corresponding P values

	Dry vs 100 cSt	3000 cSt vs 7000 cSt	7000 cSt vs 10,000 cSt	10,000csT vs 60,000cSt
P value (two tailed)	0.044	0.032	0.0051	0.00015

TABLE 3: p values for selected viscosity comparisons. Test utilized was the t-test Paired Two Sample for Means.

1.4 CONCLUSIONS AND FUTURE DIRECTIONS

Based on the results demonstrated, it was found that the device was able to delineate the differences between all tested viscosities with statistical significance. For the purposes of a clinical study, the question that must be answered is to determine if the mucus sample being tested is simply thicker or thinner after a given intervention, which is an important clinical parameter to predict likelihood of mucous lodging into an airway and preventing ventilation/oxygenation [2]. The device is yet to be studied in a clinical setting which will be the next test for this device.

There were several design considerations in the formation of this design. Significant time was taken to determine the

appropriate ball bearing upon which the spinning mechanism is based on. The ball bearing had to have low enough friction such that the magnitude of the friction of the bearing was not orders of magnitude greater than the friction imparted by the viscousness of the fluid itself. The fact that more viscous fluids slowed the rotation such that the time to decay was decreased demonstrates that the friction coefficient of the bearing was low enough to allow for enough sensitivity. Further design considerations included the discovery of a reliable launch mechanism, for which a high-grade rubber band was utilized that provided a consistent impulse for the device. This impulse was found to be of great importance as mucus is a fluid that varies in viscosity with shear rate; thus, if all samples are sheared at the same initial rate, the decay rate can be consistently compared across different samples. Additionally, the conical design of the cone and cup mechanism ensured that the fluid made maximal contact with the cone to impart the greatest amount of friction possible. This design was created such that its output is independent of all other factors except for the friction imparted by the fluid. Limitations of this project include the sensitivity of the device as related to the components used, such as the ball bearing, as well as more viscosities that need to be tested from the 100cSt to the 3000cSt range.

Applications of this new technology to healthcare are broad, outside the intended usage with investigation of mucolytics in the mechanically ventilated patient, including point-of-care testing of body fluids' viscosity. For instance, there is research regarding cervical mucus quality and its role in conception planning [4]. This research may also have implications in the outpatient setting with monitoring of mucus quality in patients with respiratory disease who may require mucolytic medications, for example, in populations with cystic fibrosis or COPD.

With regards to potential results from the clinical trial, this study will elucidate the efficacy of mucolytic agents which are currently being used without basis in evidence. An understanding of the effects of these agents at the bedside will lead to more responsible utilization of mucolytic therapy in patients in the ICU. These patients can have critical complications as a result of mucous plugging and utilization of appropriate therapies may prevent respiratory complications which could be studied in a separate analysis [2]. Some examples of potential outcomes may include number of mechanical ventilator days, length of ICU stay, and need for reintubation.

ACKNOWLEDGEMENTS

The authors would like to acknowledge Nicholas Merrill of Virginia Tech, who was instrumental in the assistance of manufacturing this device.

REFERENCES

[1] Branson RD. Secretion management in the mechanically ventilated patient. *Respiratory Care*. Vol. 52 No. 10 (2007) pp. 1328-1347.

[2] 4. Houtmeyers E, Gosselink R, Gayan-Ramirez G, Decramer M. The effect of drugs on mucus clearance. *Eur Respir J.* Vol 14 (1999) pp. 452-467.

[3] Lai Sk. Micro-and macrorheology of mucus. *Adv Drug Delivery Review.* Vol 61 No. 2 (2009) pp 86-100.

[4] Thijssen A, Meier A, Panis K, Ombelet W. 'Fertility Awareness-Based Methods' and subfertility: a systematic review. *Facts Views Vis Obgyn*. Vol 6 No. 3 (2014) pp. 113-123.

