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Title: Development of a simple evaluation instrument for liquid thickness measurement

Short running title: Evaluation instrument for liquid thickness

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Abstract

Simple methods, such as the line spread test (LST), are often used to evaluate thickened liquids in

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clinical settings. Although it is desirable for these simple methods to be rapid, even the LST requires approximately 1 min to complete the evaluation. Herein, we aimed to shorten this time by developing a new simple instrument for evaluating thickened liquids considering the fluid engineering perspective with improved funnel design and evaluation methods. A thickened liquid was prepared with a xanthan gum-based thickening agent and water. Samples with viscosities of approximately 50, 150, 300, and 500 mPa·s were prepared. For evaluation, 30 mL of the sample was injected manually with the outlet closed. The outlet was then opened to allow the liquid to fall as soon as the evaluation began. The time taken for the water surface of the liquid to move 50 mm from the starting point to the target point was measured eight times using a stopwatch, and the average was taken as the evaluation time. The instrument took 2.22–3.29 s, 3.29–9.16 s, and 9.16–23.14 s to classify mildly thick, moderately thick, and extremely thick samples, respectively. This method enabled extremely thick samples to be evaluated in 23 s, which is 27 s less than the time taken by the conventional funnel method. Verification results showed that this developed evaluation instrument for thickened liquids could perform classification according to the criteria of the Japanese Dysphagia Diet 2013. We aim to improve its design for clinical use in the future.

Keywords: thickening liquids; deglutition; deglutition disorders; funnel; evaluation method; line spread test

Introduction

Although providing thickened liquids to patients with dysphagia according to their symptoms is desirable, expensive rotational or cone-plate viscometers are required to accurately evaluate these thickened liquids (Leonard et al., 2014). However, as viscometers are expensive precision instruments and are difficult to install in all hospitals and elderly care facilities, simple methods are often used in clinical settings. For example, Mann and Wong proposed the line spread test (LST) as a simple method for evaluating thickened liquids (Mann & Wong, 1996). Furthermore, Nicosia and Robbins demonstrated the effectiveness of this method (Nicosia & Robbins, 2007). The Japanese Dysphagia Diet 2013 published by the JSDR Dysphagia Diet Committee in 2013 (hereinafter referred to as the Japanese Dysphagia Diet 2013) (Kayashita et al., 2013) included a classification method for meals and a classification method for thickened liquids. Thickened liquids can be classified into three levels, and for each level, the range of viscosity at a shear rate of 50 s^{-1} and the range of LST values are given in addition to a textual description of the liquid's properties. In Japan, the LST has been proposed as a simple evaluation method for thickened liquids, whereas the International Dysphagia Diet Standardisation Initiative (IDDSI) recommends syringe-based evaluation methods (Cichero et al., 2017). In 2017, Watanabe et al. (Watanabe et al., 2017) developed the funnel method as a simple evaluation method. They compared the LST, the funnel method, and a syringe-based method and

reported that the funnel method requires more than 50 s to measure a liquid of 500 mPa·s, and that the syringe-based method tends to leave more liquid with increasing viscosity (Watanabe et al., 2019). Although it is desirable for simple evaluation methods to work quickly, the funnel method and the LST require approximately 1 min to complete the evaluation. Therefore, in this study, we aimed to shorten this evaluation time by developing a new simple evaluation instrument with improved funnel design and evaluation methods. Herein, we developed a simple syringe-type evaluation instrument designed considering the viewpoint of fluid engineering and verified whether the evaluation time (i.e., the time taken for a liquid to pass a certain distance) can be shorter than that required by the conventional funnel method.

Materials and Methods

Samples

To compare the simple evaluation method in samples that exhibited different behaviors of viscosity with shear rate, the third-generation xanthan gum-based Tsururinko® Quickly (Clinico Co., Ltd.) was used as the thickening agent, and the second-generation guar gum-based Hightoromeal® (Food Care Co., Ltd.) and the first-generation starch-based Tromelin® Granules (Sanwa Kagaku Kenkyusho Co., Ltd.) were used for comparison. Water was used as the solvent. The thickening agent was added all at once while stirring the solvent, which had been previously adjusted to a temperature of 20 °C. Stirring

was continued for another minute to prepare a uniform thickened liquid. After stirring, the samples were allowed to stand for 30 min in a thermostatic bath at 20 °C to use for each measurement. The viscosities of the samples were prepared at the concentrations shown in Table 1 using a cone-plate rotational viscometer, Physica MCR301 (Anton Paar), such that the viscosities would be around the boundary of each stage (50, 150, 300, and 500 mPa·s) of the Japanese Dysphagia Diet 2013 for thickened liquids. A rheometer was used to confirm the shear rate of all the samples, which was 50 s^{-1} as defined by the Japanese Dysphagia Diet developed by the Japanese Society of Dysphagia Rehabilitation.

Evaluation of thickened liquids

The apparatus was set up horizontally, and 30 mL of the sample was injected with the outlet closed manually. Then, the outlet was opened to allow the liquid to fall at the same time as the evaluation began. The time taken for the water surface of the liquid to move 50 mm from the starting point to the target point (Fig. 1) was measured eight times using a stopwatch, and the average was used as the measured value. The temperature of the sample was set at 20±1 °C.

Development of simple measuring instrument

The measuring instrument was designed with 3D CAD software (Autodesk's Fusion 360) and molded with a 3D printer (Stratasys Objet260 Connex2) using clear resin as the material. This instrument is

composed of a superstructure and substruction. The superstructure's design has an inner diameter of 20 mm and a total length of 200 mm. The substruction has an outlet diameter of 5 mm and a full size of 50 mm (Fig. 2).

Results

Table 2 shows the evaluation results obtained using the new simple evaluation instrument (hereinafter referred to as "this method") for each stage of the Japanese Dysphagia Diet 2013 for thickened liquids (Kayashita et al., 2013). The xanthan gum-based liquid could be classified in 2.22–3.29 s, 3.29–9.16 s, and 9.16–23.14 s for mildly thick, moderately thick, and extremely thick samples, respectively. In contrast, the starch-based liquid could be classified in 1.71–11 s and 11–42.2 s for mildly thick and moderately thick samples, respectively; however, it was difficult to classify extremely thick samples at the upper limit. The guar gum-based liquid could be classified in 2.57–3.81 s for moderately thick samples and in 3.81–7.03 s for extremely thick samples; meanwhile, there was no significant difference between the lower and upper limits of mildly thick samples. Table 3 compares the evaluation results of existing simple evaluation methods with those of this method. Using this method, the measurement time for evaluating thickening was 23 s, which was 27 s less than that of the conventional funnel method.

Discussion

As many patients with dysphagia experience laryngeal inflow or aspiration with thin liquids in daily clinical practice (Ogoshi, 2011), thickened liquids are often used for these patients. In Japan, the Ministry of Health, Labor and Welfare set the shear rate at approximately 3 s^{-1} in 1994. In 2013, the JSDR Dysphagia Diet Committee changed the shear rate to 50 s^{-1} after the U.S. set the shear rate to 50 s^{-1} based on Wood's research report (Wood, 1968). The Japanese Dysphagia Diet 2013 (Kayashita et al., 2013) indicates three levels of thickened liquids for people with dysphagia: mildly thick, moderately thick, and extremely thick, and recommends the LST as a simple evaluation method for thickened liquids in addition to a precision measuring device. The syringe method (Cichero et al., 2017) reported by the International Dysphagia Diet Standardisation Initiative (IDDSI) and the funnel method (Watanabe et al., 2017) reported by Watanabe et al have been suggested as alternative simple evaluation methods. In 2019, Watanabe et al. compared the LST, the funnel method, and the syringe method and reported that the funnel method and syringe method could evaluate the viscosity of a low-viscosity sample at a shear rate of approximately 50 s^{-1}, whereas a high-viscosity sample was evaluated at a shear rate lower than 50 s^{-1}. As a result, more than 50 s were required for evaluating extremely thick samples using the funnel method. We could not sufficiently evaluate the moderately or extremely thick samples because the syringe method depends on the type of food thickeners (Watanabe et al., 2017). The funnel method evaluates thickened liquids using the principle that a sample flows from top to bottom in a tube owing to gravity (Watanabe et al., 2017). The friction between the decreased sample

and the funnel wall increases when the sample is closer to the tail. As a result, the evaluation time for extremely thick samples increases significantly, making it difficult to perform evaluation using the same funnel. To solve this problem, we modified the evaluation method by improving the distance design to allow a sample to pass through stably, as shown in Fig. 1. The IDDSI flow test is used to classify viscosity based on the residual amount of the sample in the syringe, and most of the thick samples remain in the syringe. In contrast, our device is characterized by the stability of the sample's flow through the set distance even if the sample is extremely thick, and the fluid motion is evaluated using a different approach. Syringe testing is more cost-effective than our device, but it has some demerits. For example, it is a general medical device and is usually not available outside hospitals (Watanabe et al., 2017), and there is no description of sample measurement on the package, because of which healthcare workers may be considered negligent in the event of an accident. In addition, the funnel method requires two types of funnels, and it is not easy to measure the thickness (Watanabe et al., 2017). Our device is not a medical device and can be obtained easily by anyone, and it is unique because all samples can be measured with a single device.

This method enables simple evaluation in a shorter time, e.g., it can evaluate extremely thick samples in 23 s. It was not easy to measure the samples with an outlet diameter of 4 mm because they dropped intermittently. It was also difficult to measure the samples with an outlet diameter of 6 mm because all the liquid fell in a short duration. In contrast, the sample continuously dropped and measurement

could be easily obtained with an outlet diameter of 5 mm. In addition, when mildly thick samples were measured with varying total lengths of the cylinder, the measurement could be obtained in 1.7 s and 1.4 s for the total length of 18 cm and 14 cm, respectively. However, as there was a risk of reduced convenience depending on the user, the total length was finally set to 20 cm. Table 3 lists the viscosity and LST values (Mann & Wong, 1996) of the Japanese Dysphagia Diet 2013 for thickened liquids (Kayashita et al., 2013) and the classification criteria of the funnel method (Watanabe et al., 2017) and this method. There are three main generations of thickening agents: the first generation of starch-based agents released around 1991, the second generation of guar gum-based agents released around 1994, and the third generation of xanthan gum-based agents released around 2000. As this method uses a xanthan gum-based thickening agent as in the LST, it is possible to evaluate samples thickened with solvents whose main component is water.

However, if a nutritional product containing a considerable amount of lipid or protein is used as a solvent, it is not possible to evaluate the viscosity appropriately owing to the differences in the changes in viscosity with shear rate (Watanabe et al., 2017). Moreover, the Japanese Dysphagia Diet 2013 (Kayashita et al., 2013) uses a xanthan gum-based thickening agent as the standard when evaluating thickening liquids, which is not agglomerated by temperature or enzymes such as starch or gelatin, and can be stably thickened (Yamazaki et al., 2013). In addition, xanthan gum-based agents accounted for approximately 80% of the market share of thickened agents in 2020 (Silver Industry News, 2020).

Thus, similar to the LST, this method has the potential to become a simple evaluation method that can be widely used regardless of whether the patient is in an institution or at home. Our device has many advantages. For example, in addition to measuring in a short time, it is readily available to anyone, and all samples can be measured with a single device. Furthermore, it results can be easily reproduced by collecting the dropped samples in a cup. The problem with the LST is that the sample is scattered during and after evaluation, which may be unhygienic in some situations; further, it is difficult to reproduce the evaluation using the same sample when employing the LST. Given that the sample stays in the cup, this method is easy to reproduce and is therefore hygienic. In contrast, as this method uses a syringe with an inner diameter of 20 mm and a total length of 20 cm, it is difficult to clean the syringe efficiently without using a brush, and there may be concerns that the current design will reduce the convenience of this method. The application of gravity-based liquid outflow for viscosity evaluation, such as in the funnel and syringe methods, has been put into practical use in paints such as in the "Ford cup" and in liquid foods, where the use of the "Posthumus funnel" for quality control was attempted (Kutter et al., 2011). In the future, we would aim to further improve the design of our new simple evaluation instrument by shortening its overall length to make it more convenient for clinical use and enable its commercialization.

Conclusion

The verification results of our new simple evaluation instrument designed and created from the perspective of fluid engineering showed that the instrument could classify thickened liquids according to the criteria of the Japanese Dysphagia Diet 2013. In addition, the evaluation time for extremely thick liquids could be reduced by 23 s compared to the funnel method. Additionally, unlike the LST, sample splashing during evaluation could be prevented. In the future, we will further improve the design to increase ease of use and commercialize the device for clinical use.

Conflicts of Interest: The authors have no conflicts of interest to declare.

Author Contributions: All authors contributed to the study conception and design. Material preparation and data collection and analysis were performed by Hirofumi Sei and Kazunori Yasuda. The first draft of the manuscript was written by Hirofumi Sei and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

• Conceptualization: Hirofumi Sei and Kazunori Yasuda; Methodology: Hirofumi Sei and Kazunori Yasuda; Formal analysis and investigation: Hirofumi Sei, Kazunori Yasuda and Rie Asayama; Writing - original draft preparation: Hirofumi Sei; Writing - review and editing: Hirofumi Sei and Kazunori Yasuda; Funding acquisition: Hirofumi Sei and Kazunori Yasuda; Resources: Hirofumi Sei and Kazunori Yasuda; Supervision: Hirofumi Sei, Kazunori Yasuda, Kaori Tanaka and Naohito Hato.

Ethical statement: Our work did not involve live subjects (human or animal).

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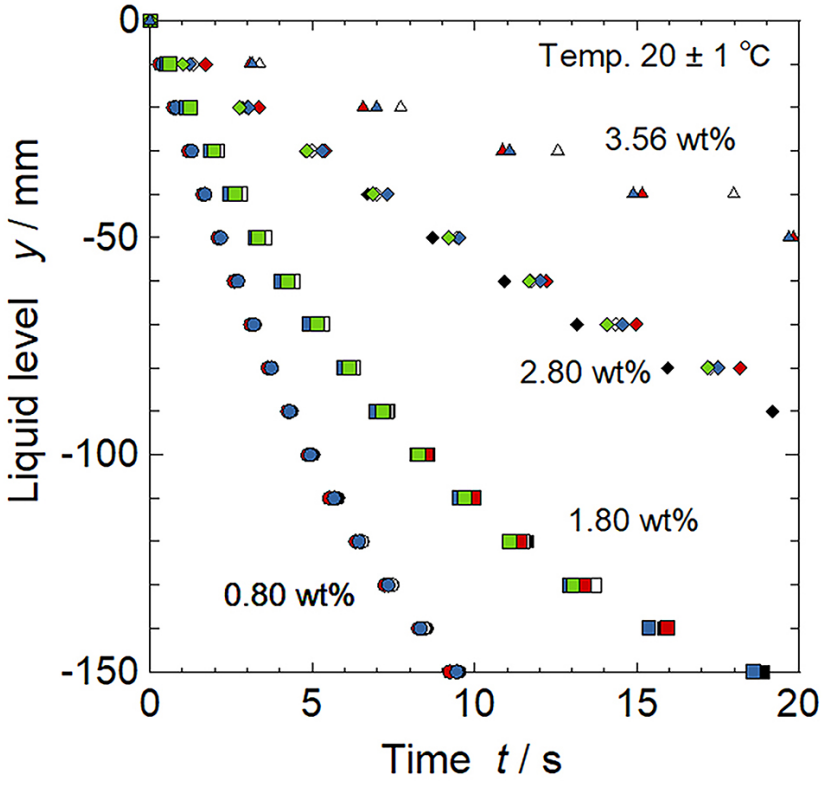
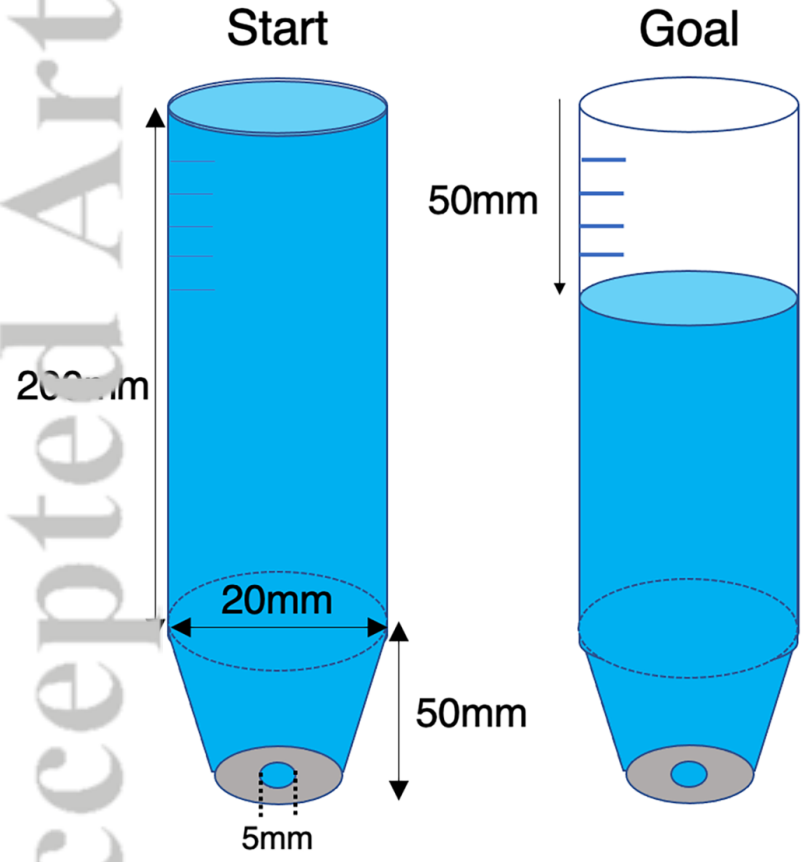
Fig.1 The evaluation results of the new simple evaluation instrument



JTXS_12660_Figure1.png

Fig.2 Evaluation for thickened liquids



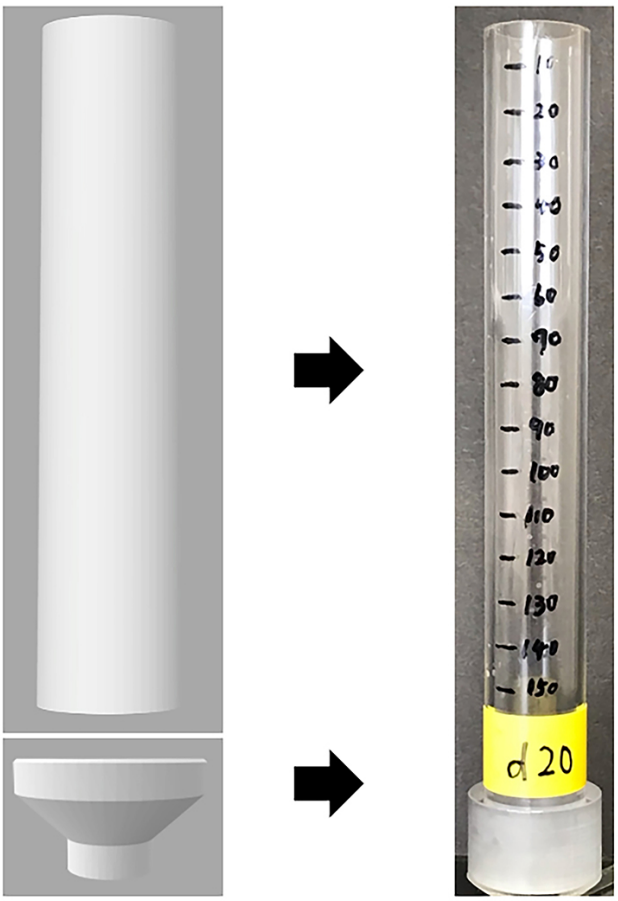
1) Injection 30 ml of the sample.

2) Measurement to move 50 mm from the starting point to the target point using a stopwatch.

3) All samples drop into a cup.

JTXS_12660_Figure2.png

Fig.3 Creation of a simple measuring instrument



JTXS_12660_Figure3.png

Table 1 Additive concentration of thickening agent

Thickening agent	Trade name of thickening agent	Additive concentration (w/w %)	Viscosity at 50 s^{-1} (mPa s)
Starch type	Tromelin Gra	2.7	43
		4.0	172
		4.7	316
		5.2	523
Guar gum type	Hightoromeal	0.75	38
		1.2	151
		1.55	278
		1.9	456
Xanthan gum type	Tsururinko-Quickly	0.8	48
		1.8	153
		2.8	301
		3.56	466

JTXS_12660_Table1.png

Table2 The evaluation results of the new simple evaluation instrument

		Mildly thick	Moderately thick	Extremely thick
Viscosity	(mPa s)	50 – 150	150 – 300	300 – 500
Starch type	(mPa s)	43 – 172	172 – 316	316 – 523
	(sec)	1.71 ± 0.11 – 11 ± 0.52	11 ± 0.52 – 42.2 ± 3.64	42.2 ± 3.64 ≦
Guar gum type	(mPa s)	38 – 151	151 – 278	278 – 456
	(sec)	1.38 ± 0.10 – 2.01 ± 0.07	2.01 ± 0.07 – 3.81 ± 0.06	3.81 ± 0.06 – 7.03 ± 0.14
Xanthan gum type	(mPa s)	48 – 153	153 – 301	301 – 466
	(sec)	2.22 ± 0.14 – 3.29 ± 0.18	3.29 ± 0.18 – 9.16 ± 0.16	9.16 ± 0.16 – 23.14 ± 2.53

JTXS_12660_Table 2.png

Table3 The viscosity of Japanese Dysphagia Diet 2013 (Thickened Liquid) and the classification criteria by the funnel method and this method

	Mildly thick	Moderately thick	Extremely thick
Viscosity (mPa s)	50 – 150	150 – 300	300 – 500
Funnel method (sec)	5 – 10	10 – 50	50 ≧
New simple evaluation instrument (sec)	2.22 – 3.29	3.29 – 9.16	9.16 – 23.14

JTXS_12660_Table3.png