Physical and Chemical properties of Medical Lubricant Made from Rice Starch

Sittiporn Punyanitya, M.D.[1], Rungsarit Koonawoot, Ph.D.[2], Anucha Raksanti, Ph.D.[3], Phanlob Chankachang, Ph.D.[4]
[1]Innovative Biomaterials and Medical Device Research Group, Mae Fah Luang University, Chiang Rai 57100, Thailand
[2]Boonyapanit Co., Ltd., 19/44, Singharaj Road, Tumbol Sriphum, Amphur Muang Chiang Mai 50200, Thailand
[3]Multidisciplinary Research Institute, Chiang Mai University, Chiang Mai 50200, Thailand
[4]Faculty of Management Science, Sakon Nakhon Rajabhat University, Sakon Nakhon 41000, Thailand
Received 16 July 2024 • Revised 20 July 2024 • Accepted 31 July 2024 • Published online 1 September 2024

Abstract:

Background: Gel lubricants belong to pharmaceuticals that are included in the cost of diagnostics. This material is pharmaceutical product in gel form that has been synthesized for medical or veterinary use. It is a lubricant for various body parts for surgery, physical examination, or as a reduced friction agent between the body and medical equipment. Normally, this product must be imported from foreign contries billions baht per year.

Objective: This research aims to produce medical lubricant gel from rice starch, a Thai agricultural raw material that helps reduce the problem of importation from abroad.

Materials and Method: The main raw material is pure rice starch, pharmaceutical grade added in different amounts of 37%, 54%, 63%, 70%, and 80% by weight mixed with additives. These additives are sodium hydroxide, carboxyl-methyl cellulose, sucrose, glycerin, and methylparaben. The method of combining the solution with the solution determines the physicochemical characteristics of commercial lubricant gel, compared with the gel samples of this research by using the SEM-EDS technique, pH analysis, and the FTIR technique.

Results: The results showed that the acidity and alkalinity of the two commercial gels compared to the sample gel. The pH is in the range between can be used according to ISO 13485: 2003 in the same range, pH 6-7. The morphology of the commercial gel found that the lubricant gel from the rice starch was uniformly distributed in the structure of the gel. The viscosity of the commercial lubricant gel is 2,991 ± 60.92 cP. This value is near the viscosity of gel 80 wt% of rice starch was 2,936 ± 18.52 cP. The chemical composition of the commercial gels consists of the carbon and oxygen function groups. However, the FTIR technique found amounts of synthetic substances such as sulfur, chloride, nitrogen, and zinc, which may irritate to skin. Meanwhile, the rice gel of this research found that there are carbon compounds, oxygen, and sodium, which are more than 95% organic compounds, and therefore 100% safe.

Corresponding author: Sittiporn Punyanitya, M.D.
School of Medicine, Mae Fah Luang University, Chiang Rai 57100, Thailand
E-mail: punyanitya.s@gmail.com
GMSMJ 2024; 4 (3): 125- 131

Conclusion: The study of lubricating gel made from rice starch by finding the physical, chemical, and biological properties. This project found that rice lubricant gel contains 80% of rice starch by weight. It is the best ingredient which has the same safety and lubrication performance as a commercial gel. Therefore, lubricant gel from rice starch can replace the gel ordered from abroad.

Keywords: Rice starch, Medical lubricant, Gelatinized, Water soluble, Viscosity.

Introduction

Medical lubricants are substances that physicians or health care practitioners are licensed to use to lubricate and reduce any discomfort to patients during medical and surgical procedures. Examples of lubricant gel that are compatible with surgery consist of K-Y jelly, surgilube, lignocaine gel, and medicinal castor oil.[1] These products are usually water-based gels due to the ease of production, such as scalability mechanical properties, fluidity, and biological properties when used together with general condoms, biological compatibility, user acceptance, and safety in a semi-solid form.[2-6] For other lubricants used in drug delivery systems that are generally available, there are disadvantages, such as products that contain oil. Not compatible with condoms.[7] Silicone products tend to be more expensive than traditional lubricants and the product may contain synthetic substances such as sulfur, zinc, and chloride, therefore may cause skin irritation and be difficult to clean. Starch is one of the world's food sources and remain important to the food industry. There is a variety of modified flour research, such as being able to turn into a gel that is stable by chemical modification. Modified starch was able to increase the shear resistance, resistant to acids and alkalis, and high temperature. Aside from physical modifications, the powder can also be mixed with various additives and plasticizers.[8] In 2023, Thailand was third after Vietnam, and India the world of rice exporter. Thailand produces 6.92 million tons of rice exported.[9] However, rice accounts for only 19.2% of the total export value. Therefore, more research is needed on rice to add value to rice flour. Medical lubricants can be produced with rice starch.[10] The objective of this research is to study the physical and chemical properties of medical lubricants from RS compared with commercial gel for a clinical trial in the future.

Materials and Method

Sample preparation

The preparation of rice starch (RS) gel was based on our earlier work.[10] Glycerol solution (Sigma-Aldrich, 99.5% USP, Germany) 10 ml was blended in 3 ml of distilled water and added to 0.5 g of sucrose (Sigma-Aldrich, 99.5% USP, Germany) to the solution and then heated to 80°C and the mixture was stirred for 15 min. Then, 0.02 g of sodium hydroxide (Fluka, 98%, analytical grade, German) was dissolved in 20 ml of distilled water, heated to 90°C (the optimal gelatinization of RS between 85 and 95°C), and then the RS powder was added 37, 54, 63, 70, 80 wt% and added 0.3 g of carboxyl methylcellulose (Sigma-Aldrich, 99.5% USP, Germany). The mixture was stirred for 20 min until homogeneous. Once both solutions were prepared, the mixture was blended in homogeneous paste at room temperature for 30 min in a beaker on a hotplate and stirrer until the RS gel was produced. Then, neutralization of the RS gel with pH = 7. The RS gel was mixed with 0.02 g of methylparaben (Sigma-Aldrich, reagent grade, 95%, Germany), and then the gel was stirred for 10 min until mixed well. The prepared RS gels were taken in a dried oven at 55°C for 24 hours.

Characterization

SEM-EDS

SEM (JSM-6335F, JEOL, Tokyo, Japan) Energy dispersive spectroscopy (EDS) was used to analyze the morphology of commercial and rice starch gels.

Viscosity

Viscosity properties of the samples were studied, using a suspension viscometer (DV-III+, Brookfield), needle No. 29, temperature 31-35°C, and speed +20 rpm up to 9 points. Viscosity model was measured by the following eqation: $\sigma = \sigma_0 + \eta_B \gamma^{\bullet}$, where σ is shear stress, σ_0 is the yield stress, η_B is the plastic viscosity of the samples, and $\gamma^{\bullet}$ is shear rate. All measurements were repeated five times and the mean value was taken.

pH Values

The determination of pH values of the samples was carried out using a waterproof pH spear tester (Oakton pH Spear Waterproof Pocket Tester EW-35634-40-Pro, Singapore). Measured ranges were from -1 to 15, with a resolution of 0.01 and accuracy was +0.01. Measurement of temperatures ranged from 0 to 50°C.

FTIR analysis

The FTIR spectra of composite samples were analyzed using a Nicolet 6700 FTIR spectrometer (Thermo Fisher Scientific Inc., Warsaw, Poland) instrument in attenuated total reflectance (ATR) mode. The samples were mixed with KBr powder at a ratio of 1:150 (w/w). Spectra were scanned from 4000 to 500 cm^{-1} with 32 sample/background scans at a resolution of 4 cm^{-1}, 8 sample gain, and 0.6329 optical velocity and a 100 aperture.

Statistical analysis

All quantitative data were analyzed with origin 8.0 (Origin Lab Corporation, USA) and presented as the mean ± standard deviation. Statistical comparisons were carried out using analysis of variance (ANOVA, Origin 8.0). A value of $p < 0.05$ was considered to be statistically significant.

Results and Discussion

The morphology of the surface of various compositions RS gel was compared with commercial gel. Figure 1 shows that the surface of commercial gel is smooth and does not see any particles that are dispersed between gel structures which is different from RS gel. It showed that commercial gel may have more gel flow ability than RS gel because the SEM image showed the strength of the gel (Observed from the surface of no cracks) with regular between the surfaces of the gel as shown in Figure 1. Meanwhile, RS gel was less strong, due to observing the widely cracking between gel surface and the 5-6 micron rice powder particles are even distributed within the gel structure were shown in Figure 2-6. It is assumed that the RS powder will be effective in increasing the viscosity control overall flow ability and increase gel stability.

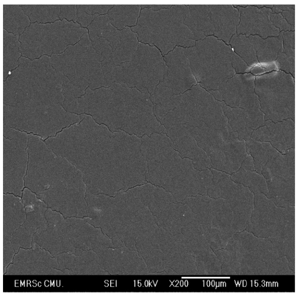


Figure 1 Commercial gel

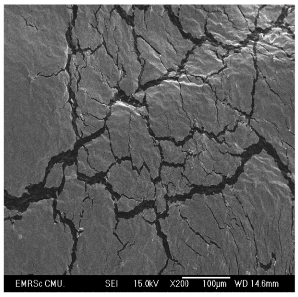


Figure 2 37% RS

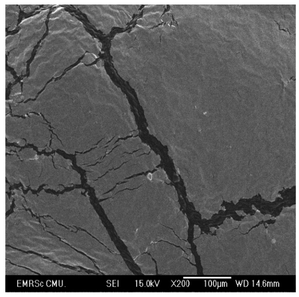


Figure 3 54% RS

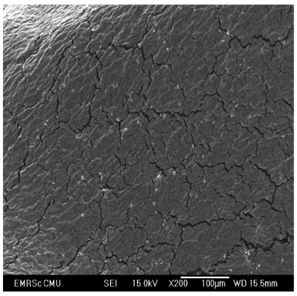


Figure 4 63% RS

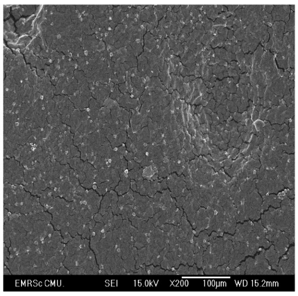


Figure 5 70% RS

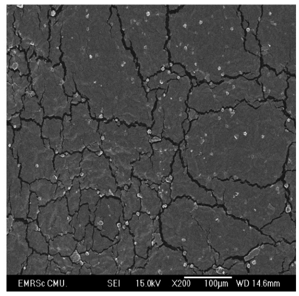
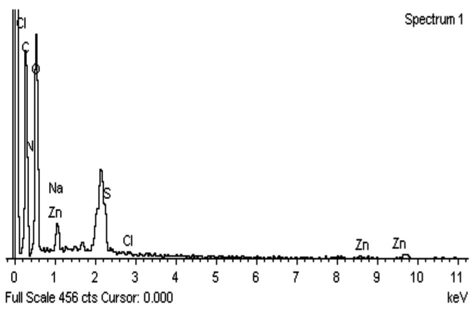


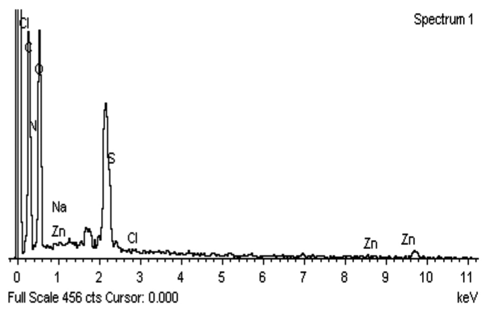
Figure 6 80% RS

Figure 7 shows the chemical composition of commercial gel with the EDS technique found that commercial gel contains carbon atoms 46.48%, oxygen 47.95%, nitrogen 2.62%, sodium 1.81%, sulfur 0.94%, zinc 0.10% and chloride 0.10%, respectively. RS gel (80% RS) found 56.64% carbon atoms, 51.36% oxygen, and 0.17% sodium, which indicated that commercial gel and RS gel had the main ingredient substance of hydrocarbons. There is a high amount of carbon and oxygen. However, RS gel did not find toxic substances in the group of synthetic substances such as sulfur, zinc, chloride, and nitrogen, which are these substances may irritate. Thus, RS gel is safer and more environmentally friendly (Figure 7 and 8).



Element	Weight%	Atomic%
C K	43.44	46.48
N K	2.61	2.62
O K	48.13	47.95
Na K	2.96	1.81
S K	2.14	0.94
Cl K	0.24	0.10
Zn K	0.48	0.10
Totals	100.00	

Figure 7 Commercial gel



Element	Weight%	Atomic%
C K	48.01	56.64
N K	-6.49	-6.43
O K	62.62	51.36
Na K	0.27	0.17
S K	-3.50	-1.51
Cl K	-0.17	-0.07
Zn K	-0.74	-0.16
Totals	100.00	

Figure 8 80% RS

Table 1 shows a comparison of pH values and viscosity values of commercial gel and RS gel. The measurement of pH commercial gel and RS gel found that the pH values both were in the same range between 7.02-7.09. These ranges indicated that its neutral values can be used without irritating human skin. For RS gel, it was found that 37wt% to 80wt% of RS powder had the rheology property as a Bingham plastic. This was due to the maximum shear stress being different because all formulas must use the maximum shear stress equal to the yield stress to flow which was behavior similar to commercial lubricants, and from the data on the viscosity of all gels, 80wt% RS powder. The viscosity nearly value to commercial gel is 2,936 ±18.52 cP (Table 1).

Table 1 pH and viscosity values of commercial gel and different RS gel

Type	pH	Viscosity [cP]
Commercial gel	7.06 ± 0.06	2,991 ± 60.92
37% RS	7.06 ± 0.06	342.77 ± 3.87
54% RS	7.02 ± 0.02	972.80 ± 7.88
63% RS	7.09 ± 0.07	1,865 ± 14.42
70% RS	7.05 ± 0.10	1,059.67 ± 9.61
80% RS	7.06 ± 0.06	2,936 ± 18.52

Figure 9 and Table 2 illustrate that the spectra of commercial gel are OH-group at position 3280 cm^{-1}, which is the elongation mode of water and glycerol. As well as RS gel adds on 37 wt% to 80 wt% RS powder at positions 3265, 3266, 3267, 3279, and 3278 cm^{-1}, respectively. The commercial gel found the functional groups of nitrogen position at 1644 cm^{-1} and ethylene glycol at 1456 cm^{-1} and the sucrose group at 1353 cm^{-1} and the sulfur group at 506 cm^{-1} and ethanol, which shows that there are groups of compounds that may cause tissue toxicity. Apart from this, RS gel had an OH group of water and glycerol in a high quantity. The compound is found in the carbonyl group and carboxylic groups at positions 1652, 1653, 1650, 1595, and 1652 cm^{-1}, respectively. These substances were obtained from carboxyl methylcellulose and some organic acids to neutralize the acid-base values and found the sucrose group at 1152 cm^{-1} and the carbohydrate group -CH2OH at 1026 to 1029 cm^{-1}.[11]

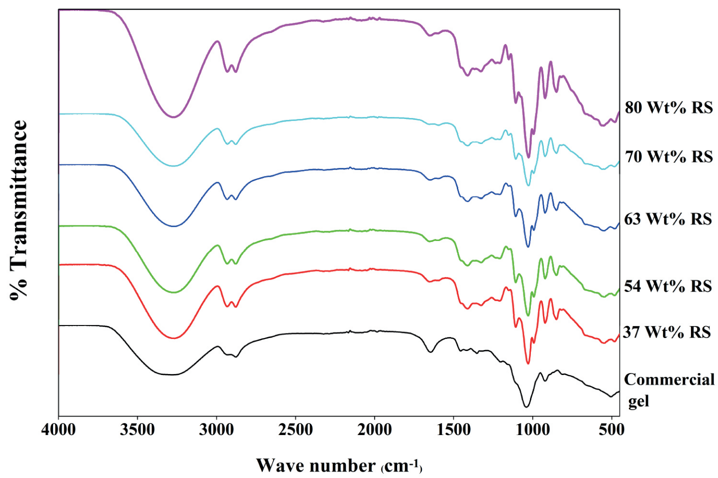


Figure 9 FTIR spectra of commercial gel and different RS gel

Table 2 Interpertation of IR spectra of commercial gel and different RS gel

Wave number (cm-1)						Functional groups /assignment
Commercial gel	37% RS	54% RS	63% RS	70% RS	80% RS	
3280	3265	3266	3267	3279	3278	Stretching O-H symmetric, OH water
-	2931	2932	2933	2931	2931	CH_2 antisymmetric stretch
2878	2878	2879	2879	2879	2879	CH_2 symmetric stretch
-	1652	1653	1650	1595	1652	carboxyl group
1644	-	-	-	-	-	Amide II: (protein N-H stretching)
1456	-	-	-	-	-	(CH_2 bending) of ethylene glycol
-	1412	1413	1412	1412	1412	(CH_2 bending) of glycerol
1353	-	-	-	-	-	CH_2 wagging of sucrose
-	1209	1209	1209	1209	1209	C-C-C, C-O-C stretch of glycerol
-	-	-	-	1152	1152	C-C-C, C-O-C stretch of sucrose
-	1107	1108	1108	1107	1107	C-O stretch of glycerol
1041	-	-	-	-	-	CO-O-CO stretching
-	1029	1029	1029	1027	1026	Vibrational frequency of $-CH_2OH$ groups of carbohydrates (including glucose, fructose, glycogen, etc.)
-	992	993	993	994	994	C-OH stretch of glycerol
922	921	922	922	922	922	C-OH stretch of glycerol
	850	850	850	850	850	Aromatic C-H out-of-plane bend
-	547	548	549	561	551	Out-of-plane C=O bending
506	-	-	-	-	-	(S-S stretch)

Summary

Medical lubricants made from rice starch showed morphology, chemical composition, pH, viscosity, and functional groups compared with commercial lubricants. The optimization condition of RS gel of 80 wt% rice starch showed the appropriate condition of physical cross-linking used for substitute medical lubricants from foreign due to physical and chemical properties close to commercial. RS gel is safe, water-soluble, and low-cost. This research should be further studied in a clinical trial.

Acknowledgments

This research was supported and financed by Fund Innovative Biomaterials and Medical Device Research Group, Mae Fah Luang University.

References

1. Information on https://en.wikipedia.org/wiki/Surgical_lubricant.
2. Pavelic Z, Skalko-Basnet N, Jalsenjak I. Characterisation and in vitro evaluation of bioadhesive liposome gels for local therapy of vaginitis, Int. J. Pharm. 2005; 301: 140-8.
3. das Neves J, Bahia MF. Gels as vaginal drug delivery systems, Int. J. Pharm. 2006; 318: 1-14.
4. das Neves J. Amaral MH, Bahia MF. Performance of an in vitro mucoadhesion testing method for vaginal semisolids: Influence of different testing conditions and instrumental parameters, Eur. J. Pharm. Biopharm. 2008; 69: 622-32.
5. das Neves J, da Silva MV, Gonçalves MP, Amaral MH, Bahia MF. Rheological properties of vaginal hydrophilic polymer gels. Curr. Drug Deliv. 2009; 6: 83-92.
6. Geibel S. Condoms and condiments: Compatibility and safety of personal lubricants and their use in Africa, J. Int. AIDS Soc. 2013; 16:18531.
7. Voeller B, Coulson AH, Bernstein GS, Nakamura RM. Mineral oil lubricants cause rapid deterioration of latex condoms. Contraception. 1989; 39: 95-102.
8. Waterschoot J, Gomand SV, Willebrords JK, Fierens E, Delcour JA. Pasting properties of blends of potato, rice and maize starches, Food Hydrocoll. 2014; 41: 298-308.
9. Information on https://www.thairice-exporters.or.th/List_%20of_statistic.htm.
10. Punyanitya S, Koonawoot R, Shiasem S, Punyanitya W, Novel Rice Gel for Ultrasound Applications: Physical and Chemical Properties, Key Eng. Mater. 2018; 773: 344-8.
11. Coates J. Interpretation of Infrared-Spectra, A Practical Approach, Infrared Spectroscopy Coates Consulting, Newtown, USA. 2006.