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Original Article

Calcium carbonate instead of cornstarch as the releasing agent for powder-free surgery gloves

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Abstract

This research investigated the feasibility of replacing cornstarch with calcium carbonate in surgery glove manufacturing. Cornstarch in slurry form is currently used as the releasing agent in order to prevent the gloves from sticking to the formers, to each other, and to the hands of the users. However, some people have a protein allergy and a skin infection can develop from the protein and bacteria contained in cornstarch. Therefore, calcium carbonate could be used as an alternative releasing agent. The quality of gloves prepared from different compositions of calcium carbonate in slurry form were assessed and compared with those of standard gloves prepared from various concentrations of cornstarch. As the amount of calcium carbonate increased, residual powder increased which resulted in high grip forces and stickiness, i.e. unsatisfactory donning. Calcium carbonate (5% w/w) resulted in comparable properties to gloves manufactured from 20% w/w cornstarch which suggested that calcium carbonate has potential application as the releasing agent in slurry form for surgery glove manufacturing.

Keywords: calcium carbonate, cornstarch, surgery glove, releasing agent, donning

1. Introduction

Surgery rubber gloves were first introduced more than a century ago as a protective barrier for surgeons and surgical teams from exposure to blood, body fluids, germs, and diseases (Ellis, 2008; Field, 1997; Truscott, 2002). Since rubber, by nature, is tacky, the problems of gloves sticking to the formers and tearing when removed from the formers arose during the manufacturing process. Furthermore, sticking also occurred when they were packaged in boxes where they also stuck to each other. Moreover, users found it difficult, if not impossible, to don them. To overcome these drawbacks, the spores of *Lycopodium*, which is a clubmoss, was introduced as a dusting powder (lycopodium powder) to facilitate glove donning. Although lycopodium powder was widely accepted to be a good lubricant, unfortunately after several decades it was found that it caused severe granuloma in patients after laparotomy. Talcum powder, which is magnesium silicate, soon replaced lycopodium powder; however, it was later found to be responsible for causing peritoneal cavity granulomas. Then in 1947, Lee and Lehman reported the ability of crosslinked cornstarch with epichlorhydrin to withstand steam sterilization and sweat and since then cornstarch has been used as the releasing agent in glove manufacturing.

Nevertheless, in 1955 two cases of starch powder granulomas were discovered (Sneierson & Woo, 1955). Since then, there have been numerous medical reports associated with surgery cornstarch powder gloves such as granulomas, adhesions, infertility, peritonitis, exaggerated inflammation, and dentist hand dermatitis (Field, 1997; Woods, Morgan, Watkins, & Edlich, 1997). Lee, Collins, and Largen (1952) started an in-depth investigation on cornstarch powder gloves and concluded that cornstarch produced a foreign-body reaction. Subsequently, many investigations on the effects from cornstarch powdered gloves were conducted and these general conclusions were made: (i) diseases or symptoms associated with cornstarch powdered gloves can arise from either direct contact with the gloves in an operating room or

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by the respiratory airborne route, (ii) cornstarch itself acts as a foreign body in human tissue, (iii) cornstarch can be the source of a potential latex protein allergy which is a type I IgE-mediated hypersensitivity which is currently the most serious concern, (iv) there is a slight amount of protein in cornstarch that can cause type IV delayed hypersensitivity (allergy), (v) cornstarch can cause non-allergic irritant contact dermatitis, and (vi) cornstarch is a natural product which can contain bacteria causing skin wound infections (Allmers *et al.,* 1998; Brown, Taenkhum, Buckley, & Hamilton, 2004; Field 1997; Jackson *et al.*, 2000; Quirce *et al.*, 2003; Swanson & Ramalingam, 2002; Yip & Cacioli, 2002).

As the awareness of natural rubber latex (NRL) allergen became an emergent issue, several strategies were carried out to reduce and prevent the problems. Some manufacturers, especially in Malaysia, made an effort to remove the NRL protein to sufficiently low levels by enzymatic deproteinization, low protein lattices, and leaching (Long, 2001; Truscott, 2002; Yip & Cacioli, 2002). Wang, Xue, Liu, Zhou, and Shang (2016) investigated the anti-allergic effect of nine natural compounds on type I and IV allergy in mouse cells and found that arctigenin showed promising potential to be an anti-type I and IV allergic effect after being added into the latex. Synthetic rubber latex is one option which prevents NRL protein allergy despite the fact that NRL provides an extraordinary ability for stretch and tear resistance (Gnaneswaran, Mudhunuri, & Bishu, 2008). In addition, their results also showed that powdered latex gloves are the best in terms of tactility and sweat absorption. Interestingly, with vinyl gloves, it seemed that sweat generation is more if powdered. Drastic NRL aeroallergen load reduction in a hospital was detected when powdered NRL gloves were substituted with synthetic gloves (Allmers *et al.*, 1998). Even though synthetic latex is non-protein, there are reports linking it to dermatitis and urticaria from nitrile and polyvinyl chloride gloves (Long, 2001; Wang *et al.*, 2016). Cost and personal preference are other reasons for surgeons to choose NRL gloves rather than synthetic rubber gloves.

It was recognized that a release agent is necessary for glove removal from the formers as well as for glove donning. However, cornstarch which dominates the glove market as a releasing agent has significant drawbacks in terms of healthcare. As a result, researchers and manufacturers have established two directions in order to achieve powder-free gloves. One is to eliminate the remaining powder on gloves and the other is to look for alternatives to cornstarch. Fraser (1982) compared different approaches of removing starch powder and found that rinsing the powdered gloves with water for 30 s leaves about 10% of the cornstarch on the gloves, whereas brushing the gloves in water for 30 s resulted in only 1% cornstarch remaining. However, there were concerns that scrubbing the gloves with a brush could cause glove perforations which can lead to the risk of contamination during surgery. When povidone-iodine was used to clean the gloves from 30 s to 1 min prior to rinsing, 99.9-100% of the cornstarch was removed. Chlorination was acknowledged to be the most effective method that greatly reduced the remaining powder, surface tack, proteins, and other remaining chemicals and is currently used widely in surgery glove manufacturing (Truscott, 2002). The process involves exposure of the powdered gloves to either chlorine gas or chlorine solutions at the final stage of glove manufacturing. Despite the benefits of glove chlorination, the process produces dark colored gloves with a strong odor, poor durability, and a possible cause of skin irritation (Anacha rungsuk, Polpanich, Jangpatarapongsa, & Tangboriboonrat, 2010; Long, 2001; Woods *et al.*, 1997; Yip & Cacioli, 2002). In addition, the powder cannot be entirely eliminated and small amounts of remaining powder may still trigger an allergic response in a sensitized individual (Field, 1997). Polymer coating is an alternative to powder-free gloves. Many polymer types including polyurethane, polyacrylamide, and poly(methyl methacrylate) (PMMA) have been studied. The process bonds a film of hydrogel polymer to the surface of the glove called "Biogel®". This hydrogel polymer (PMMA) has been used to make contact lenses and has proven to be clinically safe. VanMeter *et al.* (1995) studied the surface texture of the Biogel® gloves and concluded there was no difference in tactile discrimination between smooth and textured gloves; however, textured glove provided a better grip. Results from Pavlovich, Cox, Thacker, and Edlich (1995) demonstrated that there was no difference in dry hand donning force between two types of polymer coated glove, i.e. Biogel® and Encore®, and a powdered glove. With wet hands, the donning forces were nearly two-fold greater than those of dry hands. However, tearing appeared with wet hand donning for Encore® and powdered gloves, whereas Biogel® could stand wet donning perfectly well. Though polymer coated gloves seemed to be the best solution for powder-free gloves, durability and donning capability of the coated gloves depends on the bonding and elasticity of the coating polymer. Moreover, hand flexion, friction, stretching, other activities can cause coating delamination which can potentially enhance NRL protein release. Anacharungsuk *et al.* (2010) attempted to improve PMMA coating on NRL gloves by using sulphur-prevulcanised natural rubber grafted with polyacrylamide. The results showed potentially significant cytotoxic reduction in mouse fibroblast cells. Since rubber grafting and subsequent coating with PMMA was time consuming, Arpornwichanop, Polpanich, Thiramanas, Suteewong, and Tangboriboonrat (2014) developed the PMMA-N,N,N-trimethly chitosan (TMC) polymerisation for NRL coating and found that surface coverage of PMMA-TMC nanoparticles could be improved at increased TMC concentrations. Swanson and Ramalingam (2002) compared gloves using cornstarch, which is crosslinked, and oat starch, which is not crosslinked, as a donning powder and revealed that total allergen uptake per weight of cornstarch was dramatically greater than that of the oat starch.

This research investigated the feasibility of using calcium carbonate as a replacement to cornstarch as the releasing agent in slurry form for powder-free gloves. Calcium carbonate is currently being used in a coagulant solution along with calcium nitrate in glove manufacturing industries to facilitate stripping of gloves from the formers (Yip & Cacioli, 2002; Brown, Taenkhum, Buckley, & Hamilton, 2004). Its weight is less than cornstarch and hence has the potential to reduce the remaining powder if substituted for cornstarch in a slurry solution (Truscott, 2002). Experiments were carried out at a glove manufacturing company which followed their procedures. The study focused on the physical and mechanical properties of the gloves, i.e. flexion, friction, stretching, and donning, which occur during surgical operations and could be affected by the remaining powder and

the results were compared to the manufacturing standards. Due to confidentiality, some information cannot be disclosed. Raw material cost savings were also evaluated as a manufacturing guidance.

2. Materials and Methods

2.1 Coagulant and rubber latex preparation

Materials and chemicals used in the study were provided by a collaborating surgery glove manufacturer whose identity cannot be disclosed. Preparation methods as well as compositions followed their procedures and cannot be revealed in detail. The coagulant was composed mainly of calcium carbonate and calcium nitrate with small amounts of surfactants. The former is dipped into the calcium nitrate which coagulates the rubber latex while the calcium carbonate prevents the latex from sticking to the former. The synthetic rubber latex compound imported from Japan was polyisoprene. Small amounts of other chemicals such as a vulcanising agent, activator, accelerator, and antioxidant were also added.

2.2 Slurry preparation

One of the most important steps for rubber glove manufacturing is slurry dipping. This process provides anti-sticking properties to prevent gloves sticking to the former, with each other, and most importantly with the hands of the users. Calcium carbonate (particle size around 1 μm) was studied in this research as the releasing agent as a replacement of cornstarch (particle size less than 44 μm) at different concentrations (Table 1). Besides the releasing agent, some other chemicals such as a dispersing agent, antimicrobial agent, thickening agent, and lubricating agent were also included in the formulation. This study also investigated the effects of lubricating agents and different types of antimicrobial agents represented by Formula 5 and Formula 6.

2.3 Sample preparation

The sample preparation was carried out at the company. The formers were cleaned and dried at 60 °C. They were then dipped into the coagulant at 55 °C and oven dried at 58 °C. When dry, they were subsequently dipped into rubber latex at 25 °C and left to be dried for 2 min before they were leached with hot water at 60 °C for 3 min. The gloves were vulcanised in an oven at 135 °C for 20 min. Samples were then slurry dipped followed by oven drying before removing the formers. The last step was the chlorination process in which the gloves were dipped into 600 ppm chlorine solution for 10 min to remove the remaining releasing agent and then oven dried at 60 °C for 30 min (Figure 1).

2.4 Residual powder characterization

Residual powder measurement on medical gloves was carried out according to ASTM D6124. An amount of 500 mL of water was put into a 1000 mL Fleaker. Next, 250 mL of water was added into a glove and the glove was put into the

Table 1. Slurry compositions studied in this research.

Compositions	Cornstarch (reference)	Calcium Carbonate					
		Formula 1	Formula 2	Formula 3	Formula 4	Formula 5	Formula 6
Releasing agent	20	5	10	15	20	6	6
Water	77.7	92.7	87.7	82.7	77.7	92.05	93.85
Lubricating agent	1.8	1.8	1.8	1.8	1.8	1.8	-
Antimicrobial agent	0.4	0.4	0.4	0.4	0.4	0.15*	0.15*
Other ingredients	0.1	0.1	0.1	0.1	0.1	-	-

*different type of antimicrobial agent from reference and formula 1-4.

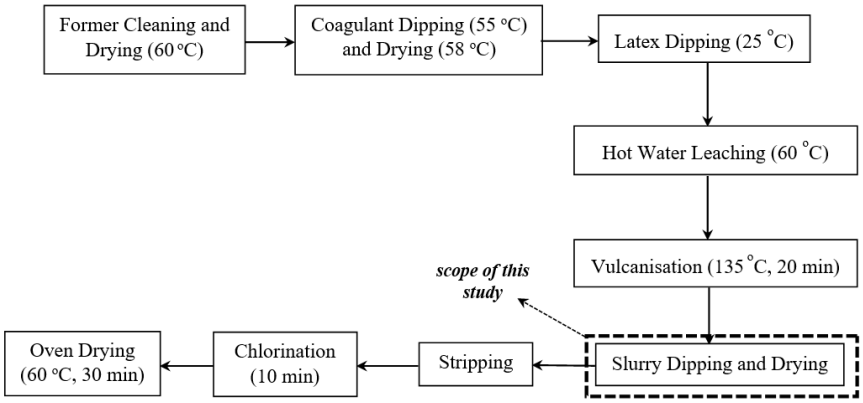

Figure 1. Surgery glove preparation steps.

Fleaker holding the wrist part on the neck of the Fleaker and the lid was subsequently closed. After the Fleaker was shaken at 100 rpm for 30 sec, the water in the Fleaker was then vacuum filtered through filter paper which was initially weighed with a 4-digit analytical balance. A similar test was repeated for another 4 gloves and filtered through the same filter paper. The filter paper was oven dried at 100 ºC for 1 h and subsequently put in a desiccator for 30 min prior to measuring the weight. The residual powder was calculated according to Equation 1. Another two sets of experiments were performed to obtain an average value along with a standard deviation.

$$residual\ powder\ (\frac{mg}{glove}) = \frac{(w_f - w_i)}{5} \times 1000 \quad (1)$$

where w_i and w_f are the initial and final weights of the filter paper, respectively. The standard residual powder of the non-powdered surgery gloves was under 2.0 mg/glove.

2.5 Tensile test

According to ISO 37, three pieces of type II dumbbell were cut from one glove from either the palm or back of the hand side. The sample was subjected to tensile test using an Instron Tensile Machine Model 5564 at a speed of 500 mm/min. Thirteen gloves (39 samples) were tested to obtain an average tensile strength and standard deviation. The standard tensile strength of the non-powdered surgery gloves was greater than 173 kg_f/cm^2.

2.6 Grip test

Prior to the grip test, the gloves were sterilized with gamma rays at 25.0-55.0 Kgy using cobalt radiation to kill microorganisms. The samples were then dried in an oven at 40 ºC for 7 days. The thumb, index finger, and middle finger of the sample gloves were cut and placed on a specially designed fixture of the Instron Model 5564 (Figure 2a). Once a proper load cell was placed on the machine, a reading of the force was attained (Figure 2b). There was no standard for the grip force but the target was a value similar to a reference glove that used 20% w/w cornstarch as a releasing agent.

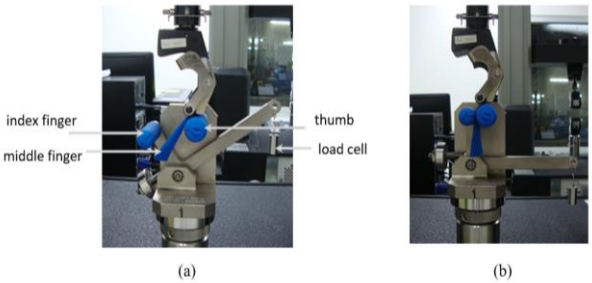

Figure 2. Sample positions before grip test (a) and sample position after grip test (b).

2.7 Donning

Similar to the grip test, the gloves were processed with gamma irradiation using the same method. Both dry-hand and damp-hand donning were tested by the company's highly experienced tester who graded the quality of the gloves into three scoring levels.

3. Results and Discussion

3.1 Residual powder

As a rule of thumb, higher amounts of calcium carbonate added into the slurry result in more residual powder remaining on the gloves (Figure 3). The results indicated that the current concentration of chlorine solution used to wash out the gloves was not capable of reducing the residual powder of the gloves prepared from 20% w/w calcium carbonate to 2 mg/glove even though the particle size of calcium carbonate was significantly lower than starch. This must be due to the fact that dissolubility of calcium carbonate is lower than that of cornstarch. The formulation that was the closest to the standard contained 5% w/w calcium carbonate. Interestingly, despite a slightly higher amount of solid content in Formula 5 compared to that of Formula 1, the amount of residual powder was much higher. This possibly was because dissolution of an antimicrobial agent contained in Formula 5 was worse than Formula 1. When the lubricating agent was not included, the antimicrobial agent contained in Formula 5 could dissolve better which resulted in a lower amount of residual powder as seen in Formula 6.

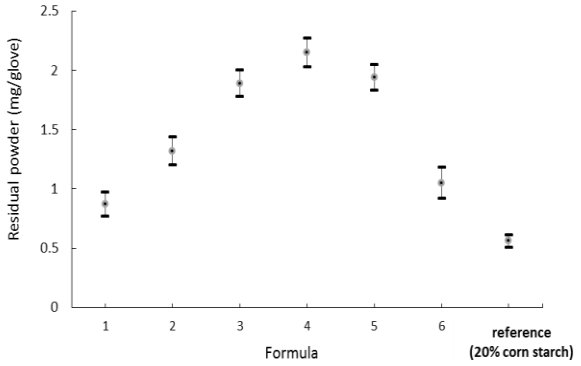

Figure 3. Residual powder of the gloves prepared from different slurry formulations.

3.2 Tensile test

Figure 4 illustrates the tensile strength of the gloves prepared from different slurry formulas (Table 1). It was noted that the calcium carbonate content had only a slight effect on tensile strength. In addition, the average tensile strength of gloves using calcium carbonate as the releasing agent at every concentration was comparable to the reference glove which used 20% w/w cornstarch as the releasing agent. Varying the antimicrobial agent type or excluding the lubricating agent had little effect on the tensile strength. The standard deviations of the results for all the gloves were also similar. This was possibly due to the fact that powders of the releasing agent were only attached to the outside and were not incorporated into the rubber latex. Most importantly, all tensile strength values were well above the standard value of 173 kg_f/cm^2 for surgery gloves.

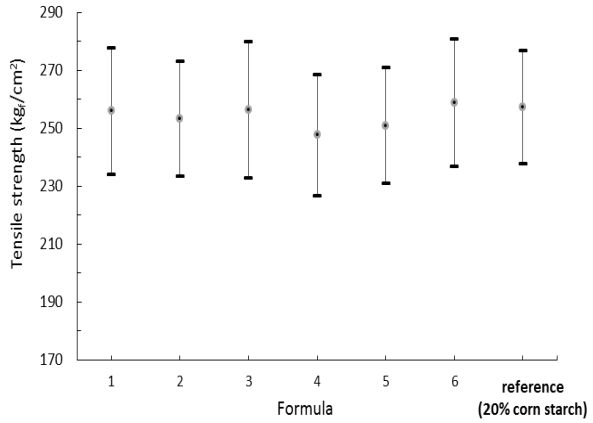

Figure 4. Tensile strength of the gloves prepared from different slurry formulations.

3.3 Grip test

Since the amounts of residual powder of gloves prepared from calcium carbonate were high, they resulted in high grip forces (Figure 5). Surgery gloves with high grip forces can cause difficulties when doctors are trying to put down medical equipment. Since equivalent amounts of residual powder were obtained from the gloves manufactured with 5% w/w calcium carbonate and 20% w/w cornstarch slurry, the grip test results of these two gloves were very close (45-50 g_f). Calcium carbonate (10-20%) produced similar grip forces of around 75-80 g_f. Despite the considerably higher amount of residual powder observed in Formula 5, these gloves produced grip force results close to the gloves formulated with 5% w/w calcium carbonate (Formula 1). In contrast, although the amount of residual powder of Formula 6 was comparable to that of 5% w/w calcium carbonate (Formula 1), its grip force was observed to be the highest. This was due to the fact that Formula 6 did not contain the lubricating agent and hence resulted in tacky gloves. This hypothesis was confirmed from the donning results.

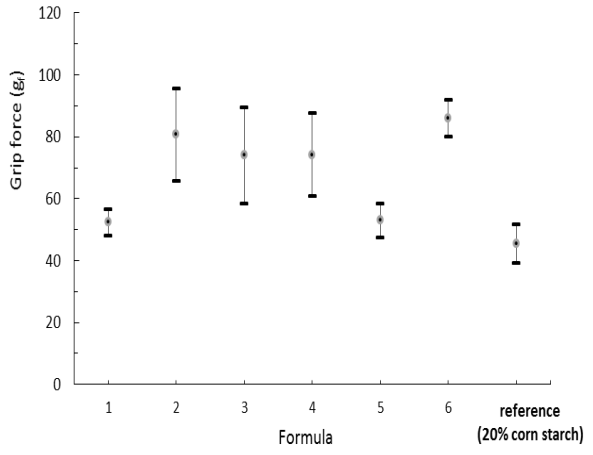

Figure 5. Grip force of the gloves prepared from different slurry formulations.

3.4 Donning

Table 2 summarizes the dry-hand and damp-hand donning of the gloves prepared in this study. As a result of the high amounts of residual powder causing stickiness, especially when the hands are damp or wet, the gloves prepared from 15-20% w/w calcium carbonate did not pass the test. Despite the slightly higher amount of residual powder and higher grip value, 10% w/w calcium carbonate gave satisfactory donning properties. The gloves prepared from the Formula 5 slurry did not pass the damp-hand donning test due to significantly higher amounts of residual powder. Also, dry-hand donning and damp-hand donning of the gloves prepared from Formula 6 were unsatisfactory because there was no lubricating agent in the formula. None of the gloves seemed to be slippery.

Table 2. Dry-hand and damp-hand donning.

Donning	Dry-hand			Damp-hand		
	slippery	standard	sticky	slippery	standard	sticky
Reference (20% cornstarch)		×			×	
Formula 1 (5% $CaCO_3$)		×			×	
Formula 2 (10% $CaCO_3$)		×			×	
Formula 3 (15% $CaCO_3$)		×				×
Formula 4 (20% $CaCO_3$)			×			×
Formula 5		×				×
Formula 6			×			×

4. Conclusions

The study found that calcium carbonate is a promising material in surgery glove manufacturing and is a potential alternative to cornstarch which is currently used as the releasing material. The results showed that a 5% w/w calcium carbonate could produce surgery gloves with similar properties of gloves produced from 20% w/w cornstarch. While the tensile strength seemed to be unaffected by the amount of calcium carbonate and cornstarch, higher calcium carbonate content resulted in higher amounts of residual powder which had a negative effect on the grip and donning of the glove. The study showed that lubricating agents have a great effect on the grip of the gloves which in turn affect the donning properties. A switch to calcium carbonate at 5% w/w as an alternative to cornstarch could achieve gloves with comparable properties as well as a saving of approximately 120,000 USD per year based on the amount of materials used in the company and the current market prices of these materials. Since a smaller amount of calcium carbonate can be used, it is likely that any health problems involving the powder from the surgery gloves should be minimal; nevertheless, studies concerning the long term health issue should be carried out.

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